

# REGIONAL HEALTH INFORMATION EXCHANGE (RHIE)

---

*Stakeholders, Requirements, and Guidelines*

Amir Delfan



---

# REGIONAL HEALTH INFORMATION EXCHANGE (RHIE)

---

THESIS

submitted in partial fulfillment of the  
requirements for the degree of

MASTER OF SCIENCE

in

COMPUTER SCIENCE

by

Amir Delfan  
born in please define birthplace



Web Information Systems  
Department of Software Technology  
Faculty EEMCS, Delft University of Technol-  
ogy  
Delft, the Netherlands  
[www.wis.ewi.tudelft.nl](http://www.wis.ewi.tudelft.nl)



ChipSoft  
TT Melissaweg 23-25, 1033 SP  
Amsterdam, the Netherlands  
[www.chipsoft.nl](http://www.chipsoft.nl)





---

# REGIONAL HEALTH INFORMATION EXCHANGE (RHIE)

---

Author: Amir Delfan  
Student id: 1096109  
Email: amirdelfan@gmail.com

## Abstract

Health Information Exchange (HIE) is a term used to describe the sharing of health information electronically among two or more entities. These entities are mostly organizations, which provide health services to their clients (the patients) and also enable the sharing of electronic health information. The exchange of medical data takes place primarily between different medical departments within the same health organization. This happens most of the time through an Electronic Health Records (EHR) system within the organization, but also across the organizational borders on the regional level (through Regional Health Information Systems, RHIS) or across the country (National EHR).

The previous efforts of the national EHR system in the Netherlands (L-EPD) had a top-down approach, based on the national architecture (i.e. AORTA). The top-down implementation of the national EHR in the Netherlands, as evidenced by the opinion of a number of Dutch experts in the field, has caused several resistance among GPs, medical specialists, patients and several other interest groups. The upcoming stakeholder analysis also reveals severe problems in this regard. Requirements analysis in a bottom-up fashion can be a practical remedy to this problem. Following this perspective, the present research tries to specify some of the viewpoints of the most important stakeholders, including the users of RHIS. It describes the functional and non-functional requirements for the regional health information exchange in the Netherlands. These requirements are based on two different questionnaires, which were designed and further conducted by the author among the primary users (i.e. medical staff) and secondary users (i.e. patients) in 2012. In addition, the interviews with several RHIS experts (representatives of almost 50% of all Dutch hospitals) and an extensive document analysis of an EHR vendor of hospital information systems revealed several constraints and complementary requirements.

---

The primary contribution of this research is the identification and thorough analysis of the most important stakeholders, involved in the field of health information systems, their viewpoints and the existing problems with RHIS. Furthermore, it is one of first attempts to translate these findings into important use-cases, real-case scenarios and a set of business goals, areas of concern and requirements. The outcomes of the research indicate that future works in this field should focus on a bottom-up approach towards gathering more specific information and adapting the general requirements found in this research to particular cases and contexts of use.

Thesis Committee:

Chair:	Prof.dr.ir. G.J. Houben, Faculty EEMCS, TUDelft
University supervisor:	Dr. ir. J.Hidders, Faculty EEMCS, TUDelft
Company supervisor:	Ir. R. Nienhuis, Senior Software Architect, ChipSoft
Committee Member:	Dr. ir M. de Reuver, Faculty TPM, TUDelft

---

# Preface

These days, several news headlines concern the latest developments of the Dutch national health records as well as abundant problems around them. Considering the current shortcomings of the national EHR in the Netherlands, it is very interesting to investigate the current situation of medical data exchange from the inside-out. During the whole study at TU Delft we deal with all kind of practical technical problems, where most of the time in the beginning the research question is not defined or is vaguely described. By coincidence I got in contact with one of the largest IT-suppliers of health information systems in the Netherlands (ChipSoft B.V.). This company is one of the main players in developing complete EHR (Electronic Health Record) systems for the health care. Also here in the beginning the research question was not clear at all. After a couple of meetings together with my coordinators at ChipSoft and my professors at TU Delft we all agreed that we were not only dealing with one single problem, but several parallel problems of the regional health information exchange. The national infrastructure project for the exchange of medical data hasn't been such a success as it was planned to be and several health organizations prefer regional exchange of medical data in the first place. A next discovery was that different stakeholders have different viewpoints, problems and needs from the regional exchange systems. All in all it was a great challenge to discover these problems and translate them into concrete technical issues, from which a list of general functional and non-functional requirements could be defined. It was also a pleasant experience to combine the theory and a practical problem.

I would like to thank the following people who helped me directly and indirectly during this research. For their direct support: I especially would like to thank my supervisor dr. ir. A.J.H. Hidders. Also I would like to thank my Prof. dr. ir. G.J. Houben and other members of the graduation committee for reading and commenting my work. From ChipSoft B.V. I especially would like to thank ir. R.Nienhuis for his support and motivation from the beginning until the end of this research. Also my special thanks to ir. L.Truijens for all his clear view and vital coordination through the whole project. Beside these people I sincerely would like to thank other people who have supported me, starting from my dear mother Mrs. A.Azarnejad and my father Mr. H.Delfan for their great support always in my life. Also not to forget the support from my dear girl friend Ms. P.Nikoo, for her support during the surveys, but also for her patience during this project. I would also like to thank all other dear family member and friends dr.ir.

F.Zand, Mr. B.Tahmooresi and ir. A.H.Talab who motivated me and whom I could share my experiences with in this project.

Next I would like to explain some of the personal experiences and findings through this research: During this research I have been working from the IT-Suppliers office and was able to discuss several technical and non-technical issues with multiple involved people within the company. I was also able to write relatively small parts of code in two different modules EZIS (ChipSoft's EHR system) in the back-end and front-end of the system. It is remarkable to see that the knowledge of different software modules within this system is distributed among different departments and employees. Some people specialized themselves for many years only on a single module within the complete EHR and do not know the functionalities of all other modules. Beside the knowledge differences between different departments there are also sometimes other technical terms that are being used (related to the specific functionality of the system). I have been visiting couple of hospitals during the normal visiting hours and EHR test days. On these days I had the chance to talk with different medical specialists and IT support about their experiences with the exchange of medical data at regional level. Here I discovered that there are remarkable differences among different medical specialist and IT support staff regarding their knowledge about the exchange of medical data. The need for exchange of data is different among several medical specialities.

I believe that working as an IT-Software developer in health-care one often need to consider the needs of the users, their viewpoints for specific health-care situations. This also necessitates a long-term relation between the developers, medical specialists, insurance companies and different governmental and non-governmental organizations. The software solutions are quite complex and consist of several modules developed through the years each with specific and unique reasons. The architecture of the systems depends often on existing legacy solutions and case specific considerations. In my opinion the existing software solutions for health-care in general and the medical data exchange solutions specifically still need a lot of improvement in their functionality and efficiency (this is based on multiple discussions with different users). On one side the expectations of the users, insurance companies, laws, regulations, several interest group's viewpoints and on the other side the technical complexity. This creates a great challenge for the researchers and developers of such systems to develop technical solutions that full-fill the needs of all groups. I must admit that from the beginning I have enjoyed the research on health information system. The idea that there are still many unanswered questions and many issues to improve in the existing software solutions in the health-care motivated me to follow my existing activities in this field for the upcoming years.

Amir Delfan  
Delft, the Netherlands  
February 4, 2013

---

# Executive Summary

## What is the problem?

Medical records can exist in different types and formats. These records can be paper based (PBMR), or stored digitally as Electronic Medical Records (EMRs). Patient's medical data is often distributed in several databases maintained by different health organizations. At times, this data needs to be compiled together in order to provide high quality care to the patients. This means that the data should be available when it is needed or at least be easily transferred between health organizations. The current problems with the exchange of medical data are mainly dependent on the type (one-way, both-ways), purpose (corporation, patient transfer) and level (local, regional, national). This research focuses on the exchange of medical data at regional level, regardless of the type and the purpose of medical data exchange. According to several sources (Chapters 1.2.1-2) and the preferences of the main users (see next paragraph), the development of regional information exchange among health care organizations can be seen as an important step in the development of health information technology. Considering the scope of this research, the next paragraphs will explain the existing problems of PBMRs, EMRs and the shortcomings of the Dutch national EHR (L-EPD), for the exchange of medical data at regional level.

The existing problems with traditional formats like PBMR include: High effort (both for the patient and the health providers), long transport time (in some cases several days or weeks) and the possibility that parts of the medical data can get lost during the transport from one organization to the next. In addition, Re-entering / translating the medical data into the EHR database costs a lot of time and effort. Also, the possibility exists that parts of data can become so disorganized that it can lose its usefulness.

The physical exchange of medical data is not the only way to transfer medical files between organizations. Digital exchange of medical data is very common in health care. The existing problems with this type of exchange include limited possibilities provided by existing systems. Often only plain text messages can be exchanged, which are more or less fixed in format and size. Other problems are unsecured mail communication, direct access by external health providers into the system (which can cause responsibility and security risks), but also high effort to gain access and lack of user-friendliness.

The national EHR system in the Netherlands (L-EPD) had originally the goal to enable both regional and national exchange of medical data. The previous efforts of (L-EPD) had a top-down approach, based on the national architecture (AORTA). Despite the fact that nowadays many health provider organizations are connected to L-EPD, still the number of active members is much smaller than what was expected beforehand. This is mainly caused by the lack of willingness of GPs to make patient's data accessible by putting their data in the L-EPD. Still, the need for the exchange of medical data at regional level exists and less effort has been made to develop regional health information systems from a bottom-up perspective, where the main users are involved during the design phase.

## **Who has the problem?**

The shortcomings of the existing systems cause several problems for the health providers, patients and in general for the health organizations. Beside the mentioned problems, this report also discusses (Chapter 1.2.3-4) several other problems related to double effort, long waiting lists, loss of files and medical errors due to lack of data.

## **Why is it a problem?**

The results in this report (Chapter 5.1.4) show that still a large part of the health providers use traditional services for the exchange of medical data. Developing new systems is a complex task because of the multi-actor character of the problem context (Chapter 1.2.4, 6.1.3). In fact "one" single problem or "one" single solution does not exist and several stakeholders have their own viewpoints and requirements. Also, until now the national EHR did not provide a solution to the problems of many regional health organizations.

## **The practical relevance and scientific relevance of the topic**

Improving RHIS can help health organizations to work in a more efficient and effective way, decrease the waiting lines and the number of medical errors due to the lack of data during the care ([11]). The scientific relevance of this topic is the analysis and application of quantitative and qualitative data for finding out the requirements of the users. Also, the analytic hierarchy process (AHP, which is based on mathematics and partly psychology) is used for resolving the conflicting requirements. Finally, translating the current processes and scenarios of data exchange into several models, is a possible scientific approach to solving that practical problem.

## **The perspective from which we look at the problem**

This research involves both important users (medical specialists and patients), developers and other important stakeholders in a bottom-up perspective. “Bottom-up” here stands for a process of involving the main users, preferences and ideas during the design. Regional Exchange of data can also be seen as an important step toward the exchange of medical data on the national level (see also Chapter 6.1.1, Pluut and Zurmond [35]).

## **The scope of the problem**

The scope of the problem is the exchange of medical data at regional level, regardless of the type and purpose of the exchange. This research tries to provide a basic set of requirements for RHIS in the Netherlands, including requirements from important stakeholders and involving main users (see also Chapter 1.5).

## **The theoretical approach (theory, discipline)**

This research follows the next steps to solve the problem: “Conceptualization”, contains all relevant theoretical and practical information; “Analysis & Specification”, contains analysis of stakeholders, scenarios, elicitation methods, list of requirements; “Verification and validation of requirements”, main conclusions and future work. The verification and validation of requirements is inspired by best practices described in “Guide to the Business Analysis Body of Knowledge (BABOK Guide)”.

## **The context (sample, generalizations) to focus on when measuring**

This research uses survey results (Chapter 5) in a descriptive way, but also by looking into extreme results. It tries to generalize important preferences of different groups of users. In some cases samples are used and further discussed.

## **The process of deriving results**

The process of deriving the results and their analysis implies the following stages: Gathering research data, statistical analysis of quantitative data, analysis and specification and translating preferences of users and other stakeholders into use-cases, models and list of requirements.

## **The conclusions**

The conclusions include important findings about the current state of RHIS in the Netherlands, important problems, scenarios of exchange, exchange standards, important stakeholders and their positions, the preferences of main users, business goals and different approaches of existing technical solutions for the exchange of data. The verification steps show us that some of the requirements can cause conflicts and inconsistencies with each other. Methods like AHP can be used to deal with these conflicts. Finally, during the validation phase we are able to find possible shortcomings or inconsistencies in the existing list of requirements, by applying the evaluation steps. (See also Chapter 10.1 for other important conclusions and Appendix H for the final list of requirements).

Because of the limitations in time and resources the results of the surveys could only be used in a descriptive way. A larger number of responses can increase the reliability of the data, which are more suitable for several Normal tests. Also, in order to improve questionnaires the list needs to be made shorter. This helps to increase the response rate. Moreover, the users need to be questioned only about very specific cases and open questions shall be avoided. The final list of requirements can be used for evaluating the existing solutions or developing prototypes (Chapter 10.2 provides more points of reflection and recommendations for future research).



---

# Contents

<b>Preface</b>	<b>iii</b>
<b>Executive Summary</b>	<b>v</b>
What is the problem? . . . . .	v
Who has the problem? . . . . .	vi
Why is it a problem? . . . . .	vi
The practical relevance and scientific relevance of the topic . . . . .	vii
The perspective from which we look at the problem . . . . .	vii
The scope of the problem . . . . .	vii
The theoretical approach (theory, discipline) . . . . .	vii
The context (sample, generalizations) to focus on when measuring . . . . .	vii
The process of deriving results . . . . .	viii
The conclusions . . . . .	ix
<b>Contents</b>	<b>xi</b>
<b>List of Figures</b>	<b>xv</b>
<b>1 INTRODUCTION</b>	<b>1</b>
1.1 Background . . . . .	2
1.2 Motivation: Scientific and Social Relevance . . . . .	4
1.3 Research objective . . . . .	8
1.4 Research activities . . . . .	8
1.5 Scope of the research . . . . .	10
1.6 Structure of the report . . . . .	12
1.7 Content of this report . . . . .	14
<b>I Conceptualization &amp; Planning</b>	<b>19</b>
<b>2 REGIONAL HEALTH INFORMATION EXCHANGE</b>	<b>21</b>
2.1 RHIS . . . . .	22
2.2 HIE . . . . .	25

<b>3</b>	<b>REQUIREMENTS ELICITATION PLAN</b>	<b>45</b>
3.1	Stakeholders analysis . . . . .	45
3.2	Communication plan . . . . .	59
3.3	Requirements risk assessment . . . . .	61
<b>II</b>	<b>Analysis &amp; Specification</b>	<b>65</b>
<b>4</b>	<b>ELICITATION METHODS</b>	<b>67</b>
4.1	Quantitative method - surveys . . . . .	68
4.2	Qualitative method - interviews . . . . .	75
<b>5</b>	<b>RESULTS ELICITATION</b>	<b>81</b>
5.1	Results survey medical specialists . . . . .	82
5.2	Results survey patients . . . . .	96
5.3	Results of the interviews . . . . .	105
5.4	Results - document analysis . . . . .	108
<b>6</b>	<b>REQUIREMENTS ANALYSIS &amp; SPECIFICATION</b>	<b>111</b>
6.1	Requirements analysis . . . . .	112
6.2	Requirements specification . . . . .	124
<b>III</b>	<b>Verification &amp; Validation</b>	<b>141</b>
<b>7</b>	<b>REQUIREMENTS VERIFICATION</b>	<b>143</b>
7.1	Verification criteria . . . . .	143
7.2	Resolving conflicts . . . . .	153
7.3	Analytic Hierarchy Process (AHP) . . . . .	156
<b>8</b>	<b>SOLUTION ANALYSIS</b>	<b>165</b>
8.1	EHR based exchange . . . . .	166
8.2	Exchange using a message broker . . . . .	167
8.3	OZIS-Regional medical data exchange . . . . .	170
8.4	Health information portals . . . . .	172
8.5	Secure mail . . . . .	173
8.6	AORTA . . . . .	176
<b>9</b>	<b>VALIDATION OF THE REQUIREMENTS</b>	<b>179</b>
9.1	Structured Walk-through . . . . .	181
9.2	Validate consistency by evaluating the solutions . . . . .	182
<b>10</b>	<b>Conclusions and Future Work</b>	<b>189</b>
10.1	Conclusions . . . . .	189
10.2	Reflections and recommendations for future work . . . . .	193
	<b>Bibliography</b>	<b>195</b>
<b>A</b>	<b>Glossary</b>	<b>199</b>

---

<b>B</b>	<b>Categorization Medical Specialists-UMCU</b>	<b>203</b>
<b>C</b>	<b>Communication sources &amp; methods</b>	<b>207</b>
<b>D</b>	<b>Initial list of requirements</b>	<b>209</b>
<b>E</b>	<b>Verified list of requirements</b>	<b>223</b>
<b>F</b>	<b>Analytic Hierarchy Process (AHP)</b>	<b>229</b>
<b>G</b>	<b>Validation steps</b>	<b>235</b>
<b>H</b>	<b>Evaluation solutions</b>	<b>239</b>
<b>I</b>	<b>Results- Evaluation solutions</b>	<b>245</b>
<b>J</b>	<b>Measurement tools</b>	<b>247</b>
<b>K</b>	<b>Descriptives</b>	<b>269</b>
<b>L</b>	<b>Analysis statistical data</b>	<b>287</b>
<b>M</b>	<b>Supplementary</b>	<b>295</b>
	M.1 Appendix - Chapter 2 . . . . .	295
	M.2 Appendix - Chapter 3 . . . . .	301
	M.3 Appendix - Chapter 4 . . . . .	304



---

## List of Figures

1.1	Electronic Health Records, different types . . . . .	3
1.2	Thesis report time-line . . . . .	9
1.3	Focus & Demarcation . . . . .	11
1.4	Research phases & activities . . . . .	13
1.5	Report outline . . . . .	17
2.1	Health service providers of RHIS and distribution of patient's medical data	23
2.2	Different levels of interoperability . . . . .	27
2.3	DICOM media communication model . . . . .	31
2.4	Syntactic Structure of ARCHETYPE . . . . .	33
2.5	Example SNOMED . . . . .	35
2.6	Illustration relationships with SNOMED . . . . .	36
2.7	Scenario 1 - Between different organizations within the same speciality (patient transfer) . . . . .	40
2.8	Scenario 2 - Between different organizations and different specialities (pa- tient transfer) . . . . .	41
2.9	Scenario 3 - Between different organizations and within the same specialty (corporation) . . . . .	41
2.10	Scenario 4 - Between different organizations within the same speciality (corporation) . . . . .	42
3.1	General steps of stakeholders listing . . . . .	46
3.2	Dutch hospital classification . . . . .	47
3.3	Stakeholders classification internal and external . . . . .	49
3.4	Stakeholders interest & power . . . . .	58
3.5	Requirements risk assessment, 3D cube impact, probability and control .	63
5.1	Pie diagram, medical specialities . . . . .	83
5.2	Correlation between data from GPS and Radiology & Labs . . . . .	93
5.3	Distribution mean numbers for allergies and medical devices . . . . .	94
5.4	Distribution mean numbers for several data types . . . . .	95
5.5	Correlations frequency of visit health organizations and see benefits RHIE	99
5.6	Correlations having chronic diseases and see benefits rhie . . . . .	100

5.7	correlation suffering from chronic diseases and agree with, risk spreading private data in public . . . . .	102
6.1	Actor's functionalities . . . . .	125
6.2	Use-case 1: User authentication . . . . .	128
6.3	Use-case 6: Pull medical data messageE . . . . .	132
6.4	Use-case 7: Push patient's data message . . . . .	134
6.5	Use-case 8: Subscribe & undo subscription patient data . . . . .	136
7.1	Verification and validation . . . . .	144
7.2	Relation function two requirements . . . . .	157
7.3	Relation between two requirements, transformed . . . . .	158
7.4	Calculate the eigenvectors . . . . .	159
7.5	Sum of the columns . . . . .	159
7.6	Normalize the sum of rows . . . . .	159
8.1	Multiple clients using the same EHR system to access a Health Information System (HIS) database . . . . .	166
8.2	EHR interface, UZI-card login . . . . .	167
8.3	Exchange of medical data using a message broker . . . . .	168
8.4	Exchange of medical data using EDIFACT . . . . .	170
8.5	Basic OZIS messaging using a regional patient index . . . . .	171
8.6	Sequence diagram, OZIS example communication . . . . .	172
8.7	Sequence diagram, example communication pattern secure email . . . . .	175
8.8	AORTA architecture, using national switch (LSP) . . . . .	176
K.1	Pie diagram, position . . . . .	272
K.2	Mean, frequency exchange medical data within the same region for different medical specialties. . . . .	272
K.3	Mean of difficulty exchange different organizations within the same region . . . . .	273
K.4	Mean numbers, successful attempts for the exchange between different organization within the same region . . . . .	273
K.5	Mean numbers, the time for the exchange of medical data between different organizations within the same region . . . . .	274
K.6	Mean numbers for exchange, RHIE will improve providing care . . . . .	274
K.7	Mean of exchange, RHIE will improve providing care . . . . .	275
K.8	Mean plot, benefits sharing medical data vs risks . . . . .	275
K.9	Push medical data, tools (current situation) . . . . .	276
K.10	Pull medical data, tools (current situation) . . . . .	276
K.11	Means plot, importance exchange of medical data within the same region . . . . .	277
K.12	Means plot importance data from gps . . . . .	277
K.13	Mean numbers important data for exchange . . . . .	278
K.14	Mean numbers barriers RHIS . . . . .	278
K.15	Pie diagram, age . . . . .	279
K.16	Pie diagram, gender . . . . .	279
K.17	Pie diagram, education . . . . .	280
K.18	Pie diagram, number of children . . . . .	280
K.19	Pie diagram, living situation . . . . .	281

K.20	Pie diagram, latest visit emergency . . . . .	281
K.21	Pie diagram, chronic diseases . . . . .	281
K.22	Pie diagram, heard about medical data exchange . . . . .	282
K.23	Pie diagram, frequency visit health organizations . . . . .	282
K.24	Mean numbers, several advantages rhie . . . . .	283
K.25	Mean numbers risks RHIE, according to the patients . . . . .	283
K.26	Frequencies risks paper based exchange of medical data . . . . .	284
K.27	Frequencies benefits rhie outweighs the risks, patients survey . . . . .	284
K.28	Inter-correlations effects, risks and benefits . . . . .	285
K.29	Mean numbers important data rhie, according to the patients . . . . .	285
L.1	Overview correlations between different data sources . . . . .	288
L.2	Kruskal-Wallis test, benefits RHIE and the frequency of visiting health organizations . . . . .	289
L.3	MANN-WHTNEY test, risk of spreading private data in public . . . . .	290
M.1	Regional health providers in the Netherlands . . . . .	296
M.2	Geographic classification of the corporation between health providers at regional level. source: Nictiz . . . . .	297
M.3	Example ARCHETYPE Definition Language (ADL) . . . . .	300
M.4	International Classification WHO, [32] . . . . .	301
M.5	Common organizational chart in the Netherlands . . . . .	302
M.6	Communication methods & sources for elicitation of requirements . . . . .	303
M.7	generalizations different users . . . . .	305
M.8	Use-case 2: User authorization . . . . .	306
M.9	Use-case 3: Selecting patients . . . . .	307
M.10	Use case 4: Selecting organizations . . . . .	308
M.11	Use-case 5: Maintain patient's medical data . . . . .	309
M.12	Use-case: Setting state medical data (EHR database) . . . . .	310
M.13	Use-case: Create request message . . . . .	311
M.14	Use-case: Read new request message . . . . .	312
M.15	Use case 9: Publish & undo publishing patient data . . . . .	313
M.16	Exchange of medical data using a web-portal . . . . .	314
M.17	Sequence diagram, health portal example communication pattern . . . . .	315
M.18	Sequence diagram AORTA [29], example selecting patient's medical data . . . . .	316





# Chapter 1

---

## INTRODUCTION

### Overview

In order to have a basic understanding of the most fundamental knowledge regarding the exchange of medical data, it is important to understand the difference between uncoupled health records (isolated medical data) and shared medical data (connected by the regional or national networks). This chapter provides an overview of some of the most important definitions related to the electronic health records and the exchange of medical data. (section 1.1). In addition, it is important to have a basic understanding of the existing problems regarding the exchange of medical data (section 1.2) and it will be described why the development of regional health information systems can be considered as a complex problem. This leads to the research objective (section 1.3). The research activities will be explained in several sub-steps (section 1.4), followed by the scope (section 1.5). It will be made clear which activities are within the scope of this research and which ones fall outside and belong to further development. In the last part of this chapter (section 1.6), several phases and chapters of this report will be mapped to the earlier described activities.

**At the end of this chapter the reader will have an overview of the following:**

- Important concepts regarding the exchange of medical data,
- Research questions and objectives,
- Research activities,
- The scope of this research,
- Outline of this report, including several phases and chapters.

## 1.1 Background

Before we start with the main topics of this research, which are Regional Health Information Systems (RHIS) and the exchange of medical data at regional level (RHIE), let us explain some of the important definitions that are also used through the rest of this report.

The term **Electronic Health Records (EHR)** has various meanings. In this report we refer to EHR as the electronic version of integrated health information systems that contain different data about patients. According to Yina and Nanchang [49], EHRs represent the integration of different services like demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, and billing information.

**Electronic Medical Records (EMR)**, refers to the medical records stored in digital format. The main effort of developing EMRs is to convert patient records into digital format for archiving by scanning reports, letter and other parts of the record. "A more advanced form of EMR requires the application of processing and analytic methods" Lim et al. [25]. What distinguishes EHR from EMR, is the way in which the data is shared among health participants. EMRs contain several collections of patient's data that are often hard to access in an efficient way. The sharing process is often dependent on the architecture of the system, or in other words how data is distributed among different resources. EHR is in fact an e-health concept for shared medical documentation where medical data objects of "care providers" can be exchanged with other care providers in order to maintain, review and share medical data objects Sebastian et al. [38].

**Personal Health Record (PHR)**, is a health record that is initiated and often can be maintained by the individuals. It includes information provided by several medical specialists and patients. The PHR refers to medical records where a large amount of participation and responsibility of a patient is involved. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual.

**Electronic Case Records (ECR):** Because EHRs are often combined with other systems, this can cause the confusion that EHRs and Electronic Case Records (ECR) are in fact the same. ECRs however comprise a context-oriented selection of medical data for a specific medical used by several care providers. Some of the EHR systems have beside the mentioned basic functionalities as well the ability to keep results of all kind of medical tests, order entry/management, medication and other important data. They can also include the decision support modules to assist the medical specialists with detection of adverse events and identification of disease outbreaks and to provide proactive advice for preventive measures Cotter [10].

Figure 1.1: Electronic Health Records, different types

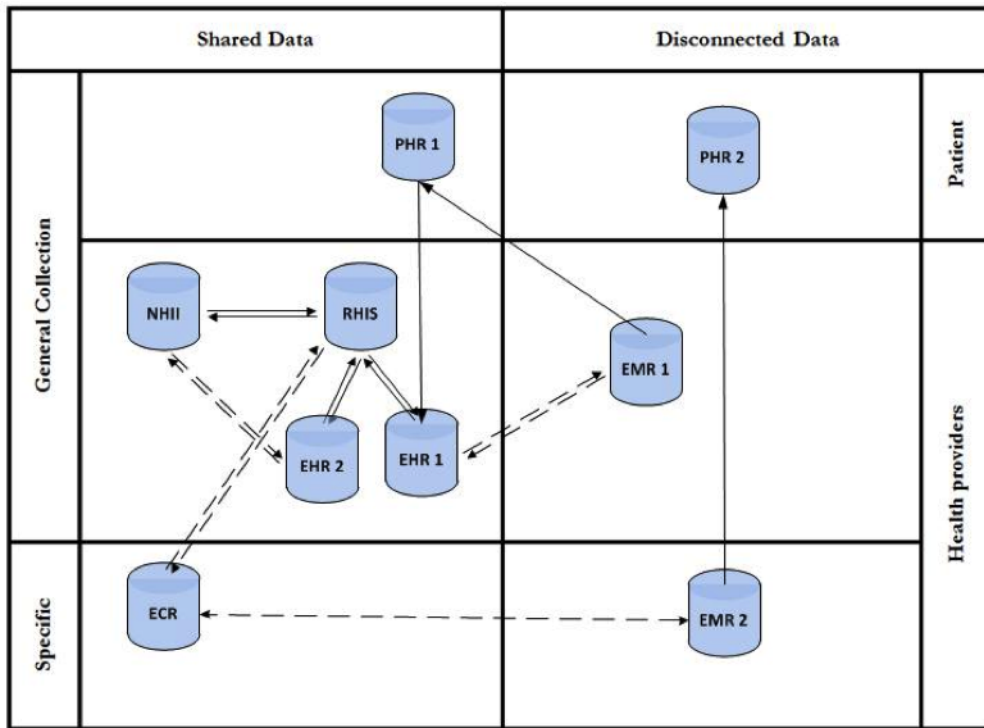


Figure 1.1 illustrates different Health Information Systems including Electronic Health Record (EHR), Personal Health Record (PHR), Electronic Medical Records (EMR), Electronic Case Records (ECR), Regional Health Information Systems (RHIS) and National Health Information Systems (NHI). The regional and national health information systems will be discussed later. For each system, the type of data (general, specific), responsibility for maintaining (patient, health providers) and the type of exchange (shared, disconnected) are shown.

The literature survey prior to this thesis report (Electronic Health Records, Research Project IN5020 October 2012) describes the most important features of the EHRs in more details. It also describes the most important features of the EHR, its impact, adoption, acceptance factors, privacy and security risks, you are strongly recommended to read this literature survey document beforehand.

## 1.2 Motivation: Scientific and Social Relevance

### 1.2.1 Previous efforts on the national EHR (L-EPD)

The national EHR in the Netherlands (Het Landelijk Elektronisch Patiëntendossier, L-EPD) is intended to digitally store and retrieve medical patient data and give access to different parties in healthcare. The patient medical data includes medication lists, allergies and referral letters. In addition, in some cases the possibility exists to grant access to the patients. The development of L-EPD is mainly carried out by different governmental organizations in the Netherlands commissioned by the Ministry of Health, Welfare and Sport with corporation of IT suppliers and insurance companies in the Netherlands.

The electronic health records are not a new concept in the Netherlands. The first electronic health record in the Netherlands was introduced in the academic hospital of Leiden on behalf of the Dutch government in 1972. In the early years this EHR was already capable of registering the medical summaries and diagnosis for several patients and the consulting laboratory test results. In 1978 this database contained more than 350,000 patients with 500,000 diagnoses and 2,000,000 laboratory test results. J.A.v.N.E.J.Groenevelt et al published these numbers in 1978-8 after an evaluation of the so called “Nobin-Zis-Project”. [15]

Considering the long history of the first EHR in the Netherlands, the development of Dutch National EHR (L-EPD) had its ups and downs despite all efforts by different responsible governmental and non-governmental organizations. The expert meeting of the Dutch lower house in 2010 provides a good overview of the most common problems (Expert Meeting - Eerste Kamer der Staten-Generaal [43]). During this meeting most of the long existing uncertainties and problems with the Dutch EHR were discussed by different important actors. Especially the privacy and security aspects of the L-EPD were the hot topics of this meeting. [11]

Furthermore despite the fact that nowadays many health provider organizations are connected to L-EPD, still the number of active members is much smaller than expected beforehand. This is partly caused by the lack of willingness of GPs to make patient’s data accessible by putting their data in the L-EPD. On the other hand the exchange of medical data at regional level, between co-operating health organizations is more common. Many experts emphasize the importance of the exchange of medical data at regional level and believe that it is much more feasible to develop and improve exiting regional exchange networks, before starting on the national exchange of medical data (Pluut and Zuurmond [35]).

### 1.2.2 Regional Information Systems (RHIS)

The main topic of this research are Regional Information Systems (RHIS) and the exchange of medical data at regional level. RHIS can be explained as collaborations between different health providers at a regional level. Often these providers know each other very well and have reached proper agreements (about the exchanged medical data). Examples are the collaboration between general practitioners, pharmacists, laboratories, university medical centres and hospitals. The development of regional information exchange among health care organizations is viewed as an important step

in the development of health information technology. Maenpaa et al. [26]

Beside the users of RHIS many interest groups of the health organizations prefer regional exchange of medical data above the national exchange, mainly because they believe that the introduction of a national EHR will not improve quality of care at all. According to Pluut [36], some of the important reasons for preferring regional systems by these groups above the national EHR are:

- The added value of the information exchange at national level would be limited. The majority of electronic communication between care providers takes place at regional level (approximately 85-95%) . All other cases concern emergency situations where patients are undergoing treatments outside their own region (5-15%). These are mainly patients with complex conditions, who require specialized treatments.
- Another important reason is the amount of participation of care providers and doctors. These groups are more likely to exchange medical data at regional level.
- The willingness of medical specialists to exchange medical data is mainly based on the trust level between different health organizations. It is more likely that health providers at regional level often know each other better and often have the opportunity to select relevant data in a specific situation in a more efficient way (for example, in the case of a medical reference).
- Other reason to choose RHIS above the national EHR is the privacy issue and “impersonal” form of communication in the national EHR.

### 1.2.3 Existing problems: traditional health information systems

The traditional health information systems use distributed medical information or paper based medical records (PBMR) in order to save the patient’s medical records. The medical files are distributed among different providers. When PBMR is used to store and exchange medical data, printed versions of medical data report are sent by post or carried by the patient from one health provider to the next. Sometimes medical images or other documents are saved and exchanged on CDs, DVDs or flash memory cards. These media storages might also include scanned versions of medical data. However physical exchange of medical data (using paper based files or using storage media causes) can cause the following problems:

- The exchange of medical data can take a large effort (both for the patient and the health providers). The medical specialists need to contact colleagues by phone, fax and other services. In other words it costs them a lot of time and energy to acquire medical data.
- In some cases it takes several days or weeks to gain the needed documents.
- The possibility exists that parts of the medical data can get lost during the transport from one organization to the next.

- Re-entering / translating the medical data into own EHR system cost a lot of time and effort. In addition, parts of data can become so disorganized that it can lose its usefulness.

The physical exchange of medical data is not the only way to transfer medical files between organizations. Digital exchange of medical data is also very common in health care. Some of these organizations make use of legacy systems to exchange data that originate from the old days. However the possibilities provided by these systems are often very limited. Often only plain text messages can be exchanged, which are more or less fixed in format and size.

Because of these problems some health organizations chose to provide direct digital access to external parties (for example to specialists in other hospitals) in order to share medical data of the patients. In some other cases the medical data of the patients are sent by email services. Most of the time the users of these services are not fully aware of the involved security risks. For example some organizations send unencrypted email messages in order to exchange medical data. In fact in these situations the patient's medical data is quite vulnerable for attacks from outside. In addition, the authorization rights for accessing the medical data of the patients are not always properly arranged when sending medical messages over to other organizations.

Beside the mentioned direct problems we can also mention inefficient work processes due to double effort or wrong medical treatments caused by loss of medical files. Sometimes health organizations decide to perform certain tests and procedures several times, because of limited access to medical data during the treatment. Double medical efforts can lead to extra costs in healthcare. In some cases the lack of medical data (like important medication and allergies data) can lead to medical errors. Kohn et al. have investigated the number of death due to medical errors (as a result of lack of medical data) in the U.S. These results showed that there are about 98,000 deaths yearly in the US. [23]

According to Bates et al, there is a direct link between medical errors and illegible prescriptions, insufficient information about allergies (decision support) and non-transparent registration of adverse events. D.W. Bates [12]

These and other problems can be partly prevented by better and faster access to the medical information during the treatment. Still a large number of regional health providers are making use of the traditional services (like paper and phone) for the exchange of medical data (See also chapter 5, Exchange services).

#### 1.2.4 Complexity of RHIS

Developing generic architectures for the exchange of digital medical data is a difficult task. A good example is the development of the national EHR in the Netherlands. Many years of consecutive effort to develop a generic architecture for the National EHR, have led to complex and long-term political and several social discussions (beside still rising costs).

One of the main reasons why the development of systems for exchange of medical data is a quite complex activity is its multi-actor nature, where each of the actors has its own viewpoints, problems and requirements. The requirements might in some cases even be contradictory. In fact "one" single problem and "one" single solution does

not exist. Moreover, within “one” health organization different departments might have different needs and viewpoints dependent on their needs and the type of medical speciality.

Developing a system for digital exchange of medical data requires careful investigation of different requirements from important stakeholders (users, patients, investors, but also government organizations) at technical and non-technical level. Both organizational and technical knowledge is needed in order to create a single consistent and coherent list of requirements.

### **1.2.5 Remedy: necessity of a bottom-up approach**

In order to be able to describe the existing problems it is important to know the real needs and viewpoints of the main users of such systems. This can only be achieved by directly involving them. Likewise, is important to investigate different scenarios where there is a need for the exchange between different health providers.

The national developments by NICTIZ (a governmental organization for development of IT in healthcare in The Netherlands) had a “top-down” approach for creating requirements and standard at the national level. These requirements and standards at the national level are not intended for use by the regional health information systems. The development of RHIS need a “bottom-up” approach, that takes mainly the viewpoints of its users and other stakeholders at regional level.

This research tries to gather a basic set of requirements as a starting point that can be used by the designers and developers of RHIS for building generic software solutions for the exchange of medical data. Knowing the differences between the needs of several users can help the developers of RHIS to improve existing solutions and create better custom-made software solutions.

### 1.3 Research objective

During this research we mainly focus on gathering, analysis and specification of:

***“Functional and non-functional requirements of important Dutch stakeholders for the exchange of medical data at regional level.”***

In order to achieve this, it is important to know the real importance of regional health information exchange for different health providers in the Netherlands. What are the current initiatives, risks and challenges? Who are the main actors, what is their role and how do they influence the current and future initiatives? It is important to know the role of different users in active participation of exchanging medical data.

In order to investigate exactly what types of data need to be exchanged, it is good to focus at the most common situations in the care process. We need to specify different important scenarios and use cases of regional medical data exchange.

### 1.4 Research activities

Given the motivation and research questions the research activities can be summarized as follow:

- Literature survey EHR (previous report)
- Gather, analyse, specify, verify and validate a list of most common functional and non-functional requirements for the exchange of medical data, looking at the most active areas of medical data exchange. The users of these requirements are mainly IT-Suppliers (designers and developers of IT solutions for the health-care), IT management of hospitals, policy makers and other interested groups in the health-care.
- Gain knowledge about the main actors, their interests and influence on creating RHIS and exchange of medical data.
- Use different quantitative and qualitative methods like surveys, interviews and other field research, in order to gather most important requirements of the main actors.
- Resolve conflicts between contradictory requirements of explored actors, in order to present a single functional and non-functional requirement list.
- Use different technical and analytical tools to specify the list of requirements, in order to improve the usability for the requirements.
- Study and compare different available technical and non-technical solutions using earlier qualified requirements. This can also be used to validate the usability of the requirements.



Figure 1.2 illustrates important milestones and activities of this project in a time-line.

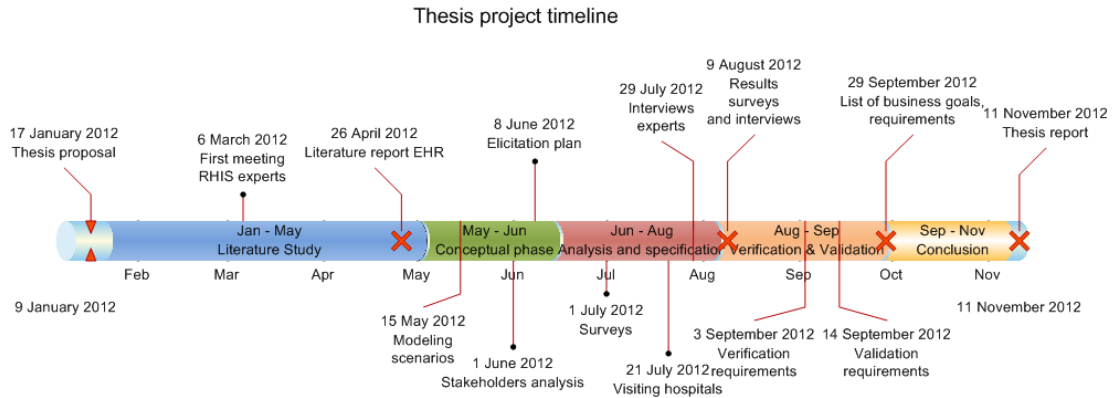


Figure 1.2: Thesis report time-line

Beside the mentioned goals this research tries to clarify some of the complexities around regional health information systems, which are partly caused by lack of persistent field research (notwithstanding all prior efforts) and earlier top-down approach by the policy makers in the Netherlands. It uses a bottom-up approach (by observing the interests, needs and objectives of the main users of RHIS and considering patients viewpoints) we try to compose the basic requirements for the exchange of medical data at regional level. The current state of user's objectives, needs and the actual state of the current solutions in relation with current existing technical and non-technical problems can be used to show these complexities. Often these complexities are caused by the lack of knowledge by different concerned actors. This lack of knowledge can create different "grey areas", which are filled with a lot of assumptions. It would be valuable to know the "real" interest of different medical specialities separately. In fact even a simple task like the exchange of medical data needed for the patient's registration in a new medical centre can imply completely different rules and procedures. Likewise the patient's viewpoint is in many cases misunderstood. This research is meant to clarify some of these "grey areas", providing a basic requirements list originating from the viewpoint of the most important actors and investigate different important current solutions, their capabilities and limitations.

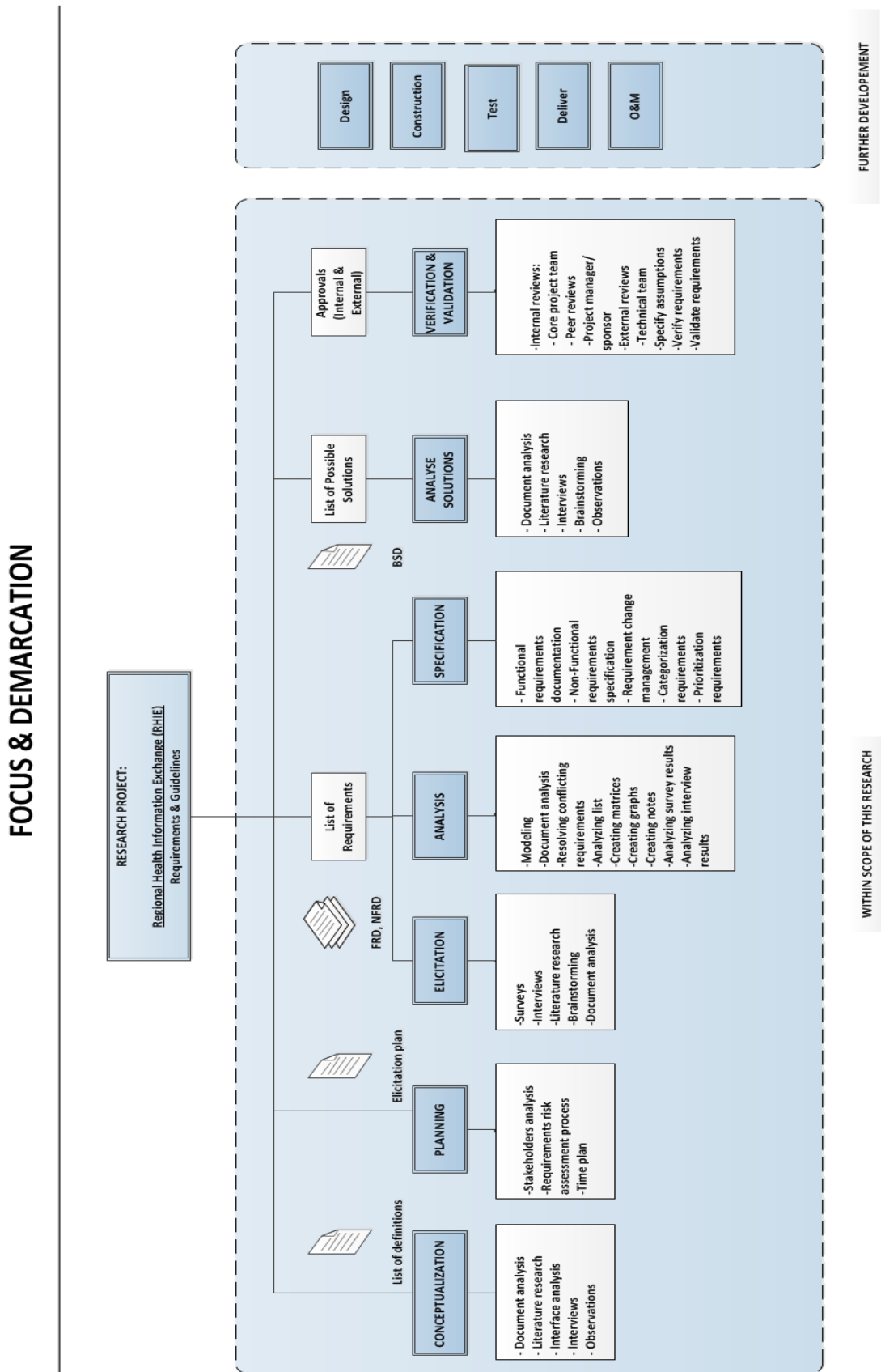
## 1.5 Scope of the research

The first phase of the report we have focused on conceptualization and planning (chapter 1.1 and 1.2). This included also the definition of Regional Health Information (RHIE) and Health Information Exchange (HIE). Furthermore in chapter 2, different scenarios of the exchange of medical data and the requirements gathering plan are explained. The second phase of the research focuses on analysis and specification of requirements (chapters 3-6). The third phase focuses mainly on validation and verification of the list of requirements (chapters 7-9). Summarizing, the results are represented in the next sub-parts :

- Definitions and explanations of some of the most important aspects of RHIS and HIE
- Different scenarios for the exchange of medical data at regional level
- Elicitation plan
- Stakeholders analysis
- Communication plan
- Explaining survey methods, interviews and document analysis
- Results surveys, interviews and document analysis
- Analysis and specification of areas of concern, constraints, business goals and requirements
- Verification & Validation of requirements
- Solution analysis
- Conclusions and guidelines.

Excluded activities in this research are design, construction, test, delivery and operating & management (O& M). Figure 1.3 illustrates the research's demarcation and several outcomes of different research activities.

Figure 1.3: Focus & Demarcation



## 1.6 Structure of the report

The general strategy in this research to gather, analyse, specify, verify and validate requirements is the so-called “modified waterfall” is an improvement upon the initial “waterfall model” (sequential steps), making it possible to process main actor’s feedback.

Because prototyping is outside the scope in this research, it makes it difficult to choose common iterative methods where by delivering different versions of prototypes, the end product can be improved. On the other hand, it is known that the standard sequential methodology limits actor’s involvement where the main focus is on retrieving requirements rather than discovering. Also it is known that often misunderstandings are not realized until the end of the process and that they can cause extensive rework.

For these reasons a modified waterfall method is used, which is more flexible and furthermore special feedback tasks are introduced to make it possible to get feedback from the actors before the specification phase. Also during the validation phase there is time to improve the list of requirements.

In theory the feedback iteration can loop infinitely, however in reality it will stop when an acceptable level is reached in accordance with the project managers. This research is divided into 3 main phases (see also figure 1.4 and 1.5):

1. Conceptualization contains all the relevant theoretical and practical information about regional health information systems and research goals.
2. Analysis & Specification contains analysis of stakeholders, scenarios for exchange of data, elicitation methods for gathering requirements and specification of requirements.
3. Verification and validation of requirements, main conclusions and future work.

## Research phases & activities

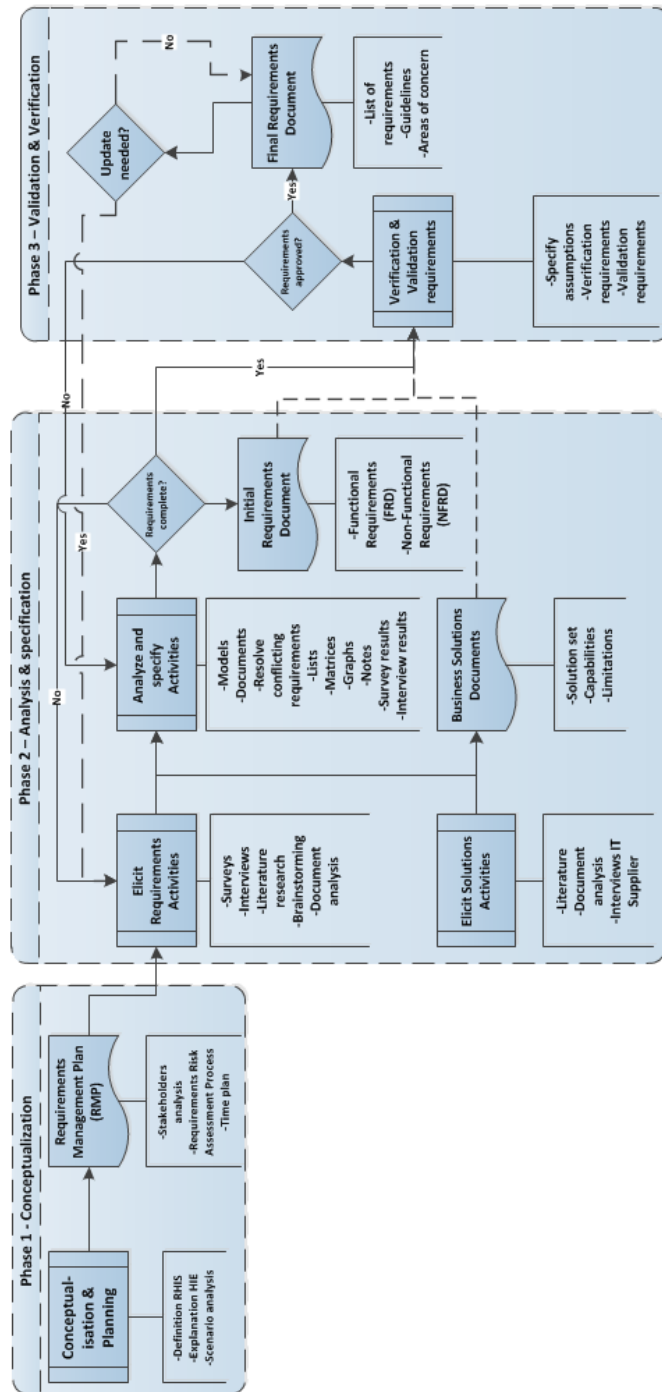


Figure 1.4: Research phases & activities

## 1.7 Content of this report

**Chapter 1** explains important concepts including Electronic Health Records (EHR) and Regional Health Information Systems (RHIS). This chapter also discusses why the previous attempts of the Dutch national EHR (L-EPD) have not been successful and that many interest groups of the health organizations prefer the regional exchange of medical data above the national exchange. Considering the existing problems of the traditional health information systems and the preferences of important users and stakeholders a bottom-up approach is more suitable. RHIS can also be seen as an important building block in developing national exchange networks. At the end of Chapter 1, the research questions, objectives, scope and the methodology are explained.

**Chapter 2** introduces Regional Health Information Systems and their current state in the Netherlands. Further, at a more general level the Health Information Exchange (HIE), where Regional Health Information Exchange (RHIE) is part of, is described. The exchange of medical data mainly takes place between several health organizations, each maintaining different parts of the patient's medical history. During the exchange of medical data interoperability plays an important role. This chapter distinguishes 4 different levels of interoperability. The current problems of RHIS regarding interoperability usually relate to the syntactical level (also called functional information standards).

**Chapter 3** discusses the viewpoints, roles, interests and power levels of several important stakeholders for the exchange of medical data at regional level. These stakeholders can be divided into two main groups (internal and external). One of the main reasons why the development of systems for the exchange of medical data is quite complex is its multi-actor nature, where each of the actors has its own viewpoints, problems and requirements. The requirements can in some cases even be contradictory. The main users of RHIS are the medical specialists (primary users) and the patients (secondary users). This chapter also provides a basic communication plan for each stakeholders group and an overview of important risks and response strategies for each risk.

**Chapter 4** explains the quantitative and qualitative methods for finding the main requirements of the primary users and secondary users (patients). First, the theoretical backgrounds of these methods are discussed. Second, by defining several important hypotheses (gathered with the help of the experts in this field) and other existing data, two different questionnaires (one for medical specialists and other for patients) are created. Also, the tools used for the analysis of data, including online surveys and statistical analysis software, are briefly explained. Third, the planning for qualitative survey methods like interviews with the experts and document analysis are described. At the end some of the important remarks from medical specialists regarding RHIS are summarized and discussed.

**Chapter 5** provides and discusses the results of quantitative and qualitative survey methods. Looking at the extremes of averages and some existing correlations between different groups, the results have been used to verify or reject the existing hypotheses. Using the results of the survey methods we are also able to specify some of the preferences from different groups of specialists, but also the patients. The qualitative methods (like interviews), on the other hand, support the outcomes of the surveys, but also improve the list of requirements. The interviews with several experts provide valuable information regarding the RHIS as well. The results from stakeholders analysis and the elicitation methods are used to define functional and non-functional requirements. Some of these results are used to define the constraints and business goals. The areas of concern or constraints pose restrictions on the acceptable solution options.

**Chapter 6** the results of the quantitative and qualitative survey methods are translated into a list of functional and non-functional requirements. Before specifying the requirements, the business goals are described. These business goals are partly the result of the interviews with the experts, but also the results of document analysis and other literature research. The new list of requirements will mainly help the developers of RHIS to manage transition from the “current situation” to a “desired situation”. In this thesis report we refer to this transition as “the core characteristics of changes”. During the interviews, surveys, document analysis and the stakeholders analysis a number of areas of concern have been identified. These areas of concern are also explained in this chapter. In fact the areas of concern are comparable with constraints regarding the exchange of medical data at regional level.

After defining the business goals and areas of concern, the requirements are specified. In order to define the exact scope of the system for which the requirements are collected, several use-cases are described (**Chapter 6.2.1-3**). These use-cases explain the main functionalities of the system and are also illustrated using several models (UML, BPMN). The following use-cases are explained in this report: User authentication, User authorization, Selecting patients, Selecting organizations, Maintain patient’s medical data, Pull medical data message, Push medical data message and Subscribe & Undo subscription.

**Chapter 6.2.4** discusses several functional requirements. These requirements are also listed in Appendix D. These requirements are divided into several categories such as: access, authentication, control, freedom, orchestration / integration, privacy and security. In **Chapter 6.2.5**, the non-functional requirements are discussed and are also listed in Appendix D. These requirements are divided into several categories such as: authentication (non-functional requirements for the authentication), customization, freedom, orchestration / integration, performance, privacy, security, reliability, standards, user-friendliness and capabilities.

**Chapter 7**, the initial list of requirements is verified through several steps. During the verification phase of the requirements, the initial list of requirements is checked to assure consistency, correctness, lack of ambiguity and testability of the requirements. Also, the internal consistencies among several requirements are checked. The final activity to verify the requirements is solving conflicts between the requirements. In order to find a proper prioritization of the conflicting requirements, the Analytic Hierarchy Process (AHP) is used. The AHP is a structured technique for organizing and analysing complex decisions. AHP is usually used in large-scale, multi party, multi-criteria decision situations. The list of the verified requirements is provided in Appendix E.

**Chapter 8**, several existing technical solutions for the exchange of medical data at regional level are discussed. The reason that these specific solutions have been chosen is that each of them uses a completely different approach for the exchange of medical data. During the validation phase these solutions are partly used to help improve the list of requirements.

**Chapter 9**, the list of verified requirements are validated in several steps. During the validation process, two different approaches are used to find out whether the requirements represent the actual needs of the stakeholders. The first approach is a structured walk-through with the experts. The second approach is an evaluation process of several existing technical solutions, using the list of acquired functional and non-functional requirements. During the evaluation process some shortcomings and inconsistencies in the list of requirements are found and improved. These are often the requirements, which could be met by none of the solutions or otherwise could be met by all of them. In both of these cases, the requirements need to be adapted, in order to improve their quality. The list of the validated requirements is provided in Appendix H.



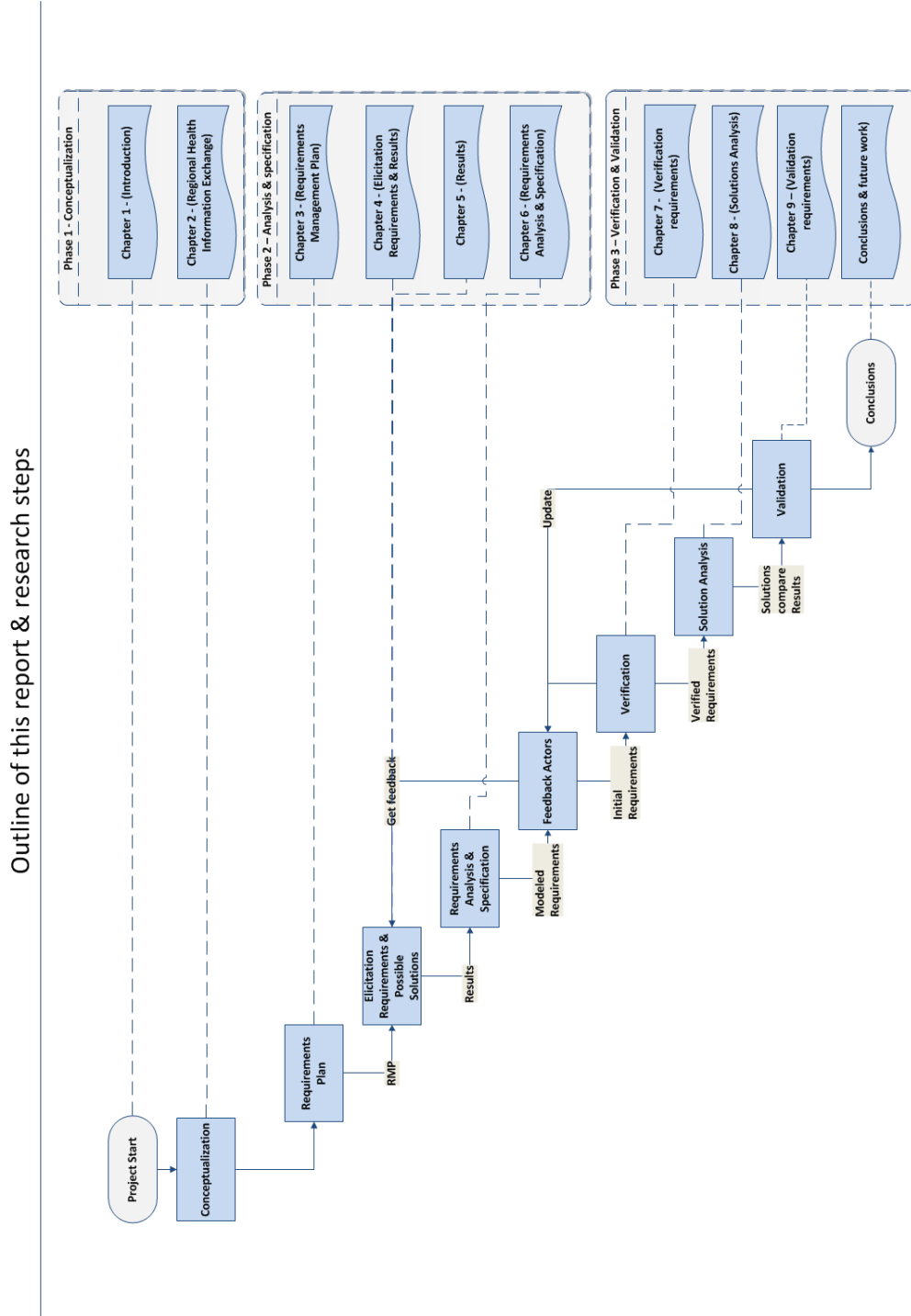


Figure 1.5: Report outline

### **Summary**

This chapter introduced some of the important concepts regarding the electronic health records (EHR). What distinguishes EHR from EMR, is the way in which the data is shared among health participants. EHR is in fact an e-health concept for shared medical documentation where medical data objects of “care providers” can be exchanged with other care providers in order to maintain, review and share medical data objects. Regional information systems (RHIS) can be explained as collaborations between different health providers at a regional level. In other words the exchange of medical data takes place among different health organizations within the regional borders.

Considering the previous efforts and the current shortcoming of the national electronic health records in the Netherlands, regional health information exchange can be seen as on the important building blocks in developing national exchange networks. Also the main users and several health organizations emphasize the need for the exchange of medical data at regional level.

The main objective of this research is to gather, analyze and specify a list of the functional and non-functional requirements of important Dutch stakeholders for the exchange of medical data at regional level. This consists of several steps from elicitation to verification and validation of the requirements. Design, construction, test and delivery of any technical solution fall outside of the scope of this research. However the results of this research might be used as input for further development of such systems.

This report consist mainly of the next three phases:

1. Conceptualization (Chapters 1 and 2)
2. Analysis and specification (Chapters 3, 4, 5 and 6)
3. Verification and validation (Chapters 7, 8 and 9)

**Part I**

**Conceptualization & Planning**



## Chapter 2

---

# REGIONAL HEALTH INFORMATION EXCHANGE

### Overview

Regional health information exchange should be studied in the context where it is applied. First of all this chapter describes the regional health information exchange in general and outlines the context specific situations of Dutch healthcare systems. This is described in section 2.1 of this chapter. In the worst case the patient's medical data are distributed among several health providers, each maintaining their own EHR databases.

In order to understand health information exchange in general, we need to investigate its goals, common standards (section 2.2.2) used and different possible exchange scenarios (2.2.7). The health organizations use several standards to save, maintain and exchange medical data records of the patients. It is important to know the differences and the purpose of each of these standards. In general we can distinguish 4 different layers where interoperability is needed.

#### **At the end of this chapter we will have an overview of:**

- Regional health information systems and providers in the Netherlands
- Current situation where patient's data are distributed among several providers (and the problems caused)
- 4 levels of interoperability
- Different standards used in each level
- Several scenarios for the exchange of medical data

## 2.1 RHIS

As it was also explained earlier Regional information systems (RHIS) can be explained as collaborations between different health providers and related organizations at a regional level. Often these providers know each other very well and a proper agreement (about the exchanged medical data) is reached.

The general goal of RHIS is to provide secure, ubiquitous access to complete health-care information and to improve health care through the quality, completeness, and timeliness of public health data reporting from clinical care settings. Examples are the collaboration between general practitioners, pharmacists, laboratories, university medical centres, hospitals, rehab services and insurance companies, based in the same or neighbouring cities.

### 2.1.1 Regional health providers

The medical care process is very dependent on the type of the health complication of a patient. Usually in the Netherlands the patients are not able to visit medical specialists in the hospitals directly. The patient needs to be checked by a general practitioner before visiting the specialist. The GP has a coordination role in the health process of the patient. The GP is as well able to prescribe medication and perform different relatively basic medical care. Only for medical tasks where special knowledge and/or equipment is needed, the patient is forwarded to a nearby hospital.

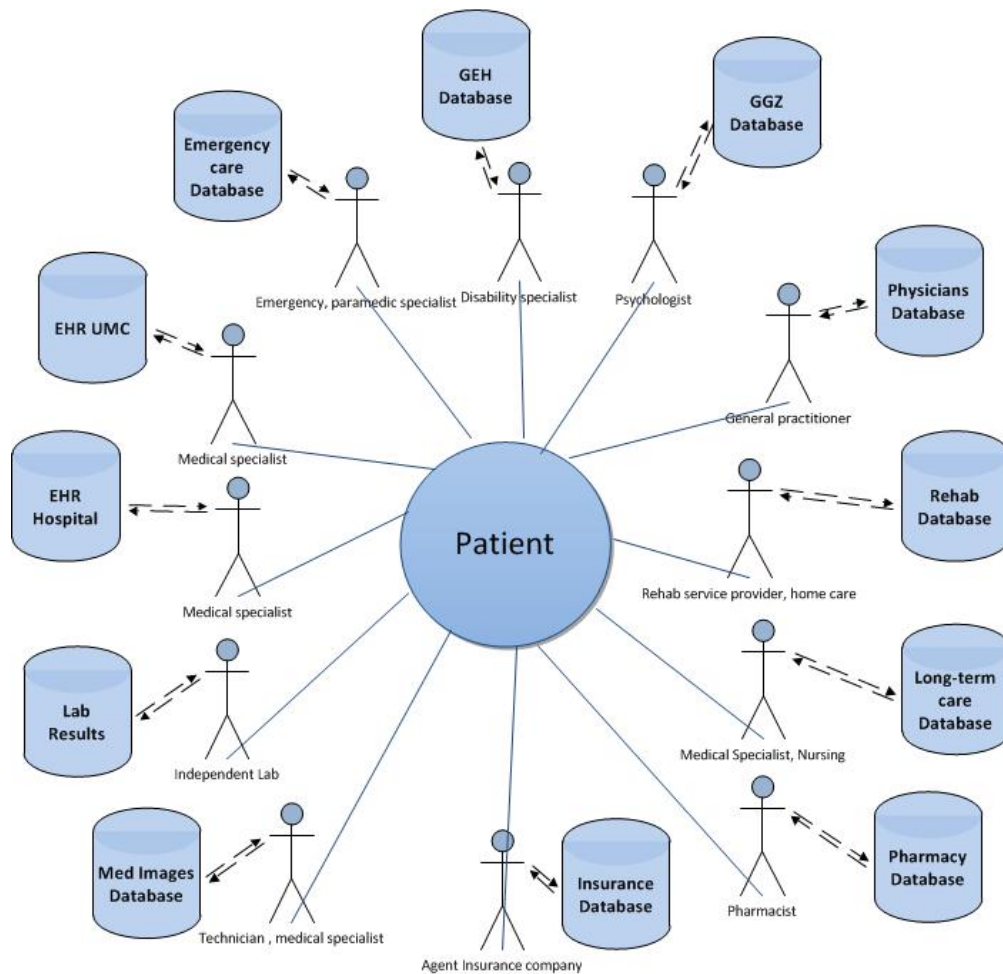
In the Netherlands mainly 3 types of hospitals exist:

- General hospitals (small to middle scale hospitals, existing of several specialities)
- University Medical Centres (large hospitals, existing of almost all medical specialities. Also, cooperating with several medical universities and scientific agencies in order to perform scientific research and provide education to their students.)
- Specialized hospitals (specialized in specific types of medical treatment. Examples are child hospitals or hospitals for the army personal)

Normally a large part of the medical data exchange takes place between different specialists within the same organization. However also different health organizations often need to exchange medical data. Medical information is transferred between several related parties in different formats dependent on the specific case of treatment.

Figure M.1 of appendix M, illustrates the simplified situation of medical care process at the regional level. In reality more parties may be involved, but we will only focus on the most common situations in the health process. Examples of actors that are not mentioned in this picture are insurance companies, governmental organizations and the industry (for example companies which provide implants or assist in medical scientific research). Beside, in some cases the patient directly may contact the hospital, which is not shown here. This situation often arises when patients need to access emergency care of hospitals. In this situation often the medical specialists send patients medical data afterwards to the GPs for further investigations. Having said that,

Figure 2.1: Health service providers of RHIS and distribution of patient's medical data



almost in all cases the GP is the party who is the “closest” to a patient and often has the most complete medical history of this patient.

### 2.1.2 Distributed patient's data

In order to explain in more details which parties are involved in providing health-care and other related services at regional level it is much easier to start with the patient. The medical information is in theory carried by the patient or by different parties who provide directly health services to the patient. Often different health providers maintain their own separate databases. However in some cases these databases can be connected by the same EHR or using a customized data exchange coupling. Occasionally different actors exchange several parts of medical data of the patients, dependent on earlier achieved earlier agreements or specific needs between these organizations. Later in this report we discuss several possible scenarios for the exchange of medical data at regional level. Figure 2.1 illustrates some of the common involved actors and their databases, each containing parts of the medical data belonging to the patient.

According to a research in 2010 by NICTIZ [30] (national experts for development

of IT in health-care in The Netherlands) there are already 24 organizations (figure M.2 of appendix M) in the Netherlands that already exchange electronic medical information at regional level [28]. Some of these organizations even exchange medical data both at regional and national level. These organizations are:

- RSO Haaglanden (Den Haag)
- Stichting EZDA (Amsterdam)
- Stichting Gerrit (Friesland en Groningen)
- IZIT (Twente)
- Stichting RijnMondNet (Rijnmond)
- Sleutelnet (Zuid Holland Noord)
- Stichting Zorgring (Noord Holland Noord)

In all of the regional exchange situations the main goal is to improve the quality and accessibility of care through better electronic information exchange, supported by IT applications.

The development of regional information exchange among health care organizations is often seen as an important step in the development of health information technology. The implementation of electronic records alone is not enough to make use of all the benefits that Information Technology can provide to the health care. Only when the possibility exists to share this information with others health providers, we would be able to make use of most of these benefits. The regional health information infrastructure or strategies provide the capability to move from a traditional paper-based retrospective data collection and review mode of operation, to real-time, interactive electronic data exchange and action response practice.

Also it is important to mention the role of RHIS in further development of health information systems at national level. It is important to have regional information exchange first before we start to build on the national or even international level. This is also the reason why a major part of the policy makers often emphasize to further develop at regional level. Having knowledge about the key challenges and shortcoming of RHIS can help us understand the challenges of the bigger national infrastructures in a better way.

According to a research by the National Resource Centre for the health information technology in the US [14], the challenges of HIE include a range of issues related to developing a business case for HIE, including:

- Gaining trust and commitment from the stakeholders
- Quantifying the costs and benefits
- Creating value around HIE



Among other challenges of RHIS we can mention the effort to have an interoperable, regional information systems network that would enable semantic interoperability. A research by Karimaa and Nykanen [21], investigated the Information System (IS) design and development of these systems, with the purpose to improve the effectiveness and efficiency of the regional health care system. “This is done by finding the success and failure factors in the development of RHIS” Karimaa and Nykanen [21].

According to these studies next conclusions can be drawn:

- Modelling is the key issue with information system development
- The socio-technical nature of health information system is often not well understood, this should get more attention
- Design and development of health information systems should not be based on practice only, but on health informatics as a scientific discipline
- Constructive evaluation study following the RHIS life cycle helps to guide further systems development.

Likewise the viewpoints of the main users and the impact of RHIS on the daily work of health providers is an important factor for the success of these systems. Scientific research combined with direct involvement in practical cases help us to build and improve RHIS.

In the next section we will first explain health information exchange in general. Furthermore, we will explain some to the most common types of standards of health information exchange. This will help us to better understanding the exchange of medical data at regional level.

## 2.2 HIE

### 2.2.1 What is health information exchange (HIE)?

The term Health Information Exchange is used to describe the sharing of health information electronically among two or more entities. These entities are mostly organization, which provides health services and also enable the sharing electronically of health information. According to HIMSS [16], “*By facilitating access to and retrieval of clinical data, HIE can promote more efficient, effective, and equitable patient-centered care. Health information exchange (HIE) makes inaccessible medical data available to clinicians, resulting in more complete information.*”

### 2.2.2 Health information exchange standards

In order to understand different technical and non-technical standards for HIE it is important to understand their purpose. The main reason to make use of different standards is to reach an acceptable level of interoperability between different involved parties at different levels. According to Chen and Doumeingts, the European Interoperability Framework (EIF) [7] interoperability is both a prerequisite for and a facilitator of efficient delivery of public services. Interoperability addresses the need for:

- Cooperation among public administrations with the aim to establish public services
- Exchanging information among public administrations to fulfil legal requirements or political commitments
- Sharing and reusing information among public administrations to increase administrative efficiency and cut red tape for citizens and businesses.

**With the goal:**

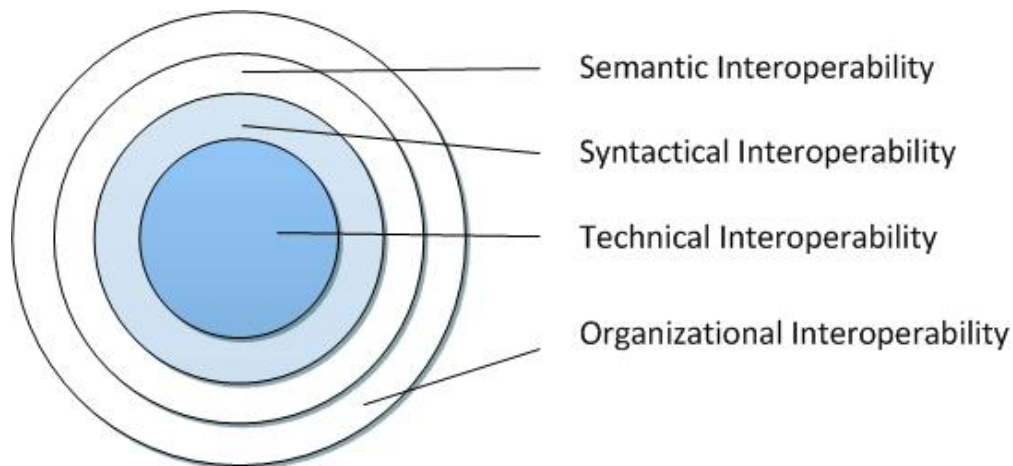
- Improved public service delivery to citizens and businesses by facilitating the one-stop-shop delivery of public services
- Lower costs for public administrations, businesses and citizens due to the efficient delivery of public services.

**According to European journal of ePractice (2009) [1], there exist 4 levels of interoperability:**

1. Technical Interoperability is usually associated with hardware/software components, systems and platforms that enable machine-to-machine communication to take place. This kind of interoperability is often centred on (communication) protocols and the infrastructure needed for those protocols to operate. van der Veer and Wiles [45] (examples are HTTP, SSL, FTP).
2. Syntactical Interoperability is usually associated with data formats. Certainly, the messages transferred by communication protocols need to have a well-defined syntax and encoding, even if it is only in the form of bit-tables. However, many protocols carry data or content, and this can be represented using high-level transfer syntaxes. (examples are EDIFACT, HL7, Continuity of Care Record (CCR) and others).
3. Semantic Interoperability is usually associated with the meaning of content and concerns the human rather than machine interpretation of the content. Thus, interoperability on this level means that there is a common understanding between people of the meaning of the content (information) being exchanged. Examples are , Datasets, SNOMED CT and others.
4. Organizational Interoperability, as the name implies, is the ability of organizations to effectively communicate and transfer (meaningful) data (information) even though they may be using a variety of different information systems over widely different infrastructures, possibly across different geographic regions and cultures (examples are agreements about responsibilities, processes and organization represented by different models).

**Table M.1 of appendix M, shows an overview of these levels with their explanation.**

Figure 2.2: Different levels of interoperability



### 2.2.3 Technical information standards

The technical information standards are the standards that are used in order to obtain technical interoperability between different systems. The technical information standards are often defined by international network protocols. In other words these protocols describe how systems should interact in order to exchange digital data using an internal network or an Internet connection.

**Some of the important international network protocols are [46]:**

- **Routing protocols:** Specifies how routers communicate with each other.
- **HTTP Hyper Text Transfer Protocol:** A request-response protocol in the client-server computing model
- **HTTPS Secure Hyper Text Transfer Protocol:** Communications protocol for secure communication over a computer network
- **SSH Secure Shell:** Secure Shell (SSH) is a network protocol for secure data communication, remote shell services or command execution and other secure network services between two networked computers that it connects via a secure channel over an insecure network.
- **FTP File Transfer Protocol:** Standard network protocol used to transfer files from one host to another host over a TCP-based network.
- **SFTP Secure File Transfer Protocol:** SSH File Transfer Protocol, a network protocol designed to provide secure file transfer and manipulation facilities over SSH.
- **SSL Secure Socket Layer:** A protocol for encrypting information over the Internet.
- **TLS Transfer Layer Security:** A network protocol and successor to Secure Sockets Layer

- **OSI:** Information exchange standards developed jointly by the ISO and the ITU-T
- **SMTP:** Simple Mail Transfer Protocol: Standard for electronic mail (e-mail) transmission across Internet Protocol (IP) networks.

**Prominent members of the Internet Protocols [46] are:**

- **Transmission Control Protocol (TCP):** The Transmission Control Protocol (TCP) is one of the core protocols of the Internet Protocol Suite. TCP is the protocol used by major Internet applications such as the World Wide Web, email, remote administration and file transfer.
- **User Datagram Protocol (UDP):** Standard used by applications, which do not require reliable data stream service, may use the User Datagram Protocol (UDP), which provides a datagram service that emphasizes reduced latency over reliability.
- **Internet Control Message Protocol (ICMP):** Protocol mainly used by the operating systems of networked computers to send error messages indicating
- **Hypertext Transfer Protocol (HTTP):** Application protocol for distributed, collaborative, hypermedia information systems.
- **Post Office Protocol (POP3):** An application-layer Internet standard protocol used by local e-mail clients to retrieve e-mail from a remote server over a TCP/IP connection.
- **File Transfer Protocol (FTP):** See explanation above.
- **Internet Message Access Protocol (IMAP):** Protocol for e-mail retrieval.

#### 2.2.4 Functional information standards (SYNTACTIC)

Functional standards exist for all medical concepts and definitions, which define how the medical data are stored or exchanged. For example the blood pressure, may be described as consisting of a systolic and a diastolic blood pressure. These two values are recorded in millimetres of mercury. Functional information standards are relatively stable and independent of technical choices. In addition functional information standards can be used for both recording and exchange purposes. Here we will explain some of the important syntactical standards:

##### **Continuity Of Care Record (CCR)**

CCR is a standard used for clinical data exchange, developed by the ASTM International organization ASTM [3]. CCR provides a snapshot of treatment and a basic patient medical record. Its primary function is to ease the transition of a patient from one provider to the next. The information included in the record focuses on the diagnosis and reason for referral rather than symptoms and treatment chronology. It may

include information from only a single provider visit or may be more extensive to include data from multiple visits. The amount of information included varies by provider and patient.

Traditionally transferring patients between different health organizations is achieved by written letters. It is logical, therefore, that the way in which the information is organized is very much similar to a letter. An ordinary letter has a recipient, a subject, the actual content of the letter, the signature and if necessary one or more attachments. The CCR standard is organized therefore in three parts: a header, a body and footer. The header contains general data of a patient. Each CCR document contains a unique number (a unique identifier), language specific parts, a version number, date and time the CCR is composed, information about the patient, information about the sender and the recipient of the document. It also contains the reason why it was created. These are mostly included in the header. In the body there are 17 types of information sections. These sections contain the most essential information concerning the treatment and care to the patient. Table M.2 of appendix M provides a list of these sections.

### **2.2.5 Clinical Document Architecture (CDA)**

CDA is an XML-based, electronic standard used for clinical document exchange, developed by Health Level 7 (will be explained further-on). CDA conforms to the HL7 V3 Implementation Technology Specification (ITS), is based on the HL7 Reference Information Model (RIM), and uses HL7 V3 data types. It was known earlier as the Patient Record Architecture (PRA). CDA can be read by the human eye or processed by a machine. This is due to its use of XML language, which also allows the standard to be broken into two different parts. A mandatory free-form portion enables human interpretation of the document. Text, images and even multimedia can be included in the document.

As explained earlier CCR is a standard that uses a defined set of core data. However an important distinction between CCR and CDA is that CCR uses only XML format. It does not support/allow narrative text (free-text) which can sometimes be hindering to physicians, and it is not electronically acceptable by all systems. Also unlike CDA, CCR was intended to remain neutral with technology and so can be transmitted electronically or on paper. Therefore the patient can manually carry the CCR to the referring physician's office. [9]

### **HEALTH LEVEL 7 (HL7)**

The Dutch government has chosen HL7.v3 as the standard for exchange of medical data for its national EHR program (EPD). The HL7 standards include all types of data exchanges in all domains of care and health care sectors. The standard is developed and managed by the international HL7 organization. HL7 NL is the Dutch sector organization (affiliate) of the international HL7 organization, looking after the Dutch interests. As explained earlier HL7 has developed the Clinical Document Architecture (CDA). HL7 besides developed several EHR profiles that enable the constructs for management of electronic health records for different medical usage [17]. Some examples are:

- HL7 EHR Behavioural Health Functional Profile
- HL7 EHR Child Health Functional Profile (CHFP)
- HL7 EHR Clinical Research Functional Profile (CRFP)
- HL7 EHR Pharmacist/Pharmacy Provider Functional Profile
- And many other profiles.

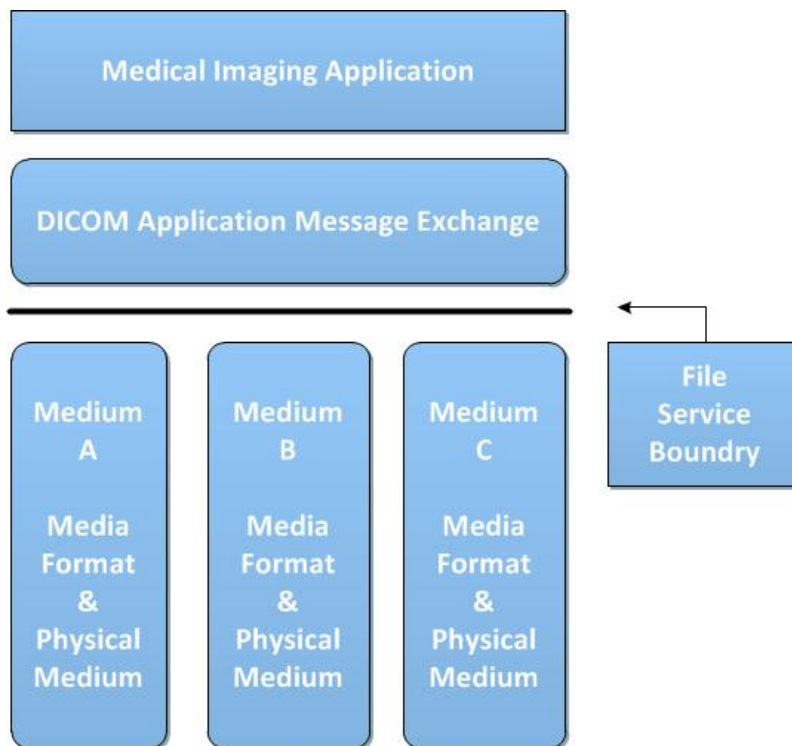
### **Digital Imaging And Communication In Medicine (DICOM)**

DICOM is a standard that describes how medical image information can be stored, shared and printed. This standard defines a file format and a network protocol, an application protocol on top of TCP/IP. The copyright on the standard is owned by the National Electrical Manufacturers Association (NEMA). The DICOM Standard facilitates interoperability of medical imaging equipment by specifying:

- Network communications, a set of protocols to be followed by devices claiming conformance to the Standard.
- The syntax and semantics of commands and associated information that can be exchanged using these protocols.
- Media communication, a set of media storage services to be followed by devices claiming conformance to the Standard, as well as a File Format and a medical directory structure to facilitate access to the images and related information stored on interchange media.
- Information that must be supplied with an implementation for which conformance to the standard is claimed.

Figure 2.3 illustrates different layers of the communication model of DICOM.

Figure 2.3: DICOM media communication model



## EDIFACT

EDIFACT is an international data interchange standard for administration, commerce and transport developed by the United Nations. The EDIFACT standard is also used for healthcare systems and is one of the earliest standards for the exchange of medical data in the Netherlands. Different interpretations exist of how EDIFACT messages can be arranged for each specific usage. NICTIZ the Dutch creator of IT standards for the health sector has published different tutorials for different sectors within the health-care. The EDIFACT standard provides:

- A set of syntax rules to structure data
- Interactive exchange protocol (I-EDI)
- Standard messages which allow multi-country and multi-industry exchange

Still until today EDIFACT is one of the most common standards for the exchange of medical data in the Netherlands. This standard is especially very common for the exchange of medical data between different GPs. In chapter 7 the technical features of EDIFACT are explained in more details.

## Cross Enterprise Document Sharing

Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the share of documents between any healthcare enterprise,

ranging from a private physician office to a clinic to an acute care in-patient facility and personal health record systems. XSDS has a document repository responsible for storing documents. A document registry is responsible for storing information, such that the medical documents can be easily found, selected and retrieved.

### ARCHETYPE

An archetype as defined by openEHR T. Beale [41] is an open-source, formal definition of domain level information. The key feature of the archetype approach is to compute a complete separation of information models (such as object models of software, models of database schema's) from domain models. Archetype has a number of key purposes:

- It allows domain experts such as clinicians to create the definitions which will define the data structuring in their information systems
- Provides runtime validation of data input via GUI or any batch process
- Provides a basis for intelligent querying of data.

Some examples of information, or content that can be modelled using archetypes In the health-care are:

- Observations: weight measurement, blood pressure, microbiology results
- Reports: discharge referral
- Orders: prescription
- Assessments: diagnosis

Archetypes are defined in terms of the following specifications [41]:

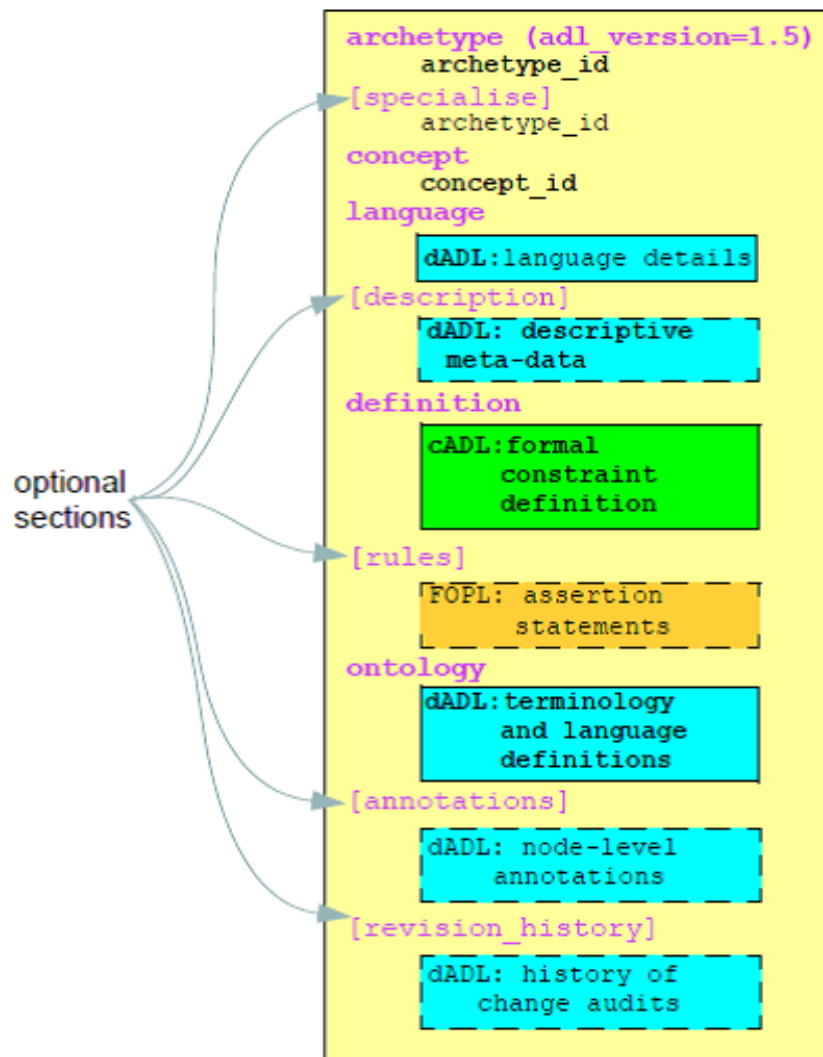
- Archetype Definition Language (ADL) - this specification;
- OpenEHR Archetype Object Model (AOM);
- OpenEHR Archetype Profile (oAP).

The Archetype Definition Language (ADL) syntax is semantically equivalent to the Archetype Object Model (AOM). ADL documents are parsed into in-memory objects (known as a “parse tree”) which are defined by the Archetype Object Model (AOM) class definitions. The AOM can in turn be re-expressed as any number of schemas, including as a W3C XML schema. An archetype can thus be serialized as ADL or in its XML form, and parsed from either form into its object form. The XML-schema (.XSD) is used for parsing ADL into the object form. The AOM is the definitive expression of archetype semantics, and is independent of any particular syntax. The Archetype Definition Language is a formal abstract syntax for archetypes, used to provide a default serial expression of archetypes, and as the explanatory framework for most of the semantics.

**Syntactic Structure of Archetype:** ADL uses three syntaxes, cADL (constraint form of ADL), dADL (data definition form of ADL), and a version of first-order predicate logic (FOPL), to express constraints on data which are instances of an underlying



Figure 2.4: Syntactic Structure of ARCHETYPE



information model. The cADL syntax is used to express the archetype definition, while the dADL syntax is used to express data which appears in the language, description, ontology, and revision history sections of an ADL archetype. This is shown in figure 2.4.

Let us explain the usage of ADL by providing a practical example. Imagine we would like to describe a concept named guitar, which is a stringed instrument, has a neck, body and timber. Each Archetype starts with a version number, in this case: archetype (version=1.5).

Next line is the name of the concept we are trying to explain, followed by the standard language. Furthermore, it is a generic model of the concept INSTRUMENT. The names mentioned down the left-hand side of the definition section (“INSTRUMENT”, “size” etc.) are alternately class and attribute names from an object model. Each block of braces encloses a specification for some particular set of instances that conform to

a specific concept, such as “guitar” or “neck”, defined in terms of constraints on types from a generic class model. The leaf pairs of braces enclose constraints on primitive types such as Integer, String, Boolean and so on. For more explanation see figure M.3 of appendix M.

### **Other syntactic standards**

Externe integratie (EI), concerns frequent electronic communication (not necessary medical data) between health insurers, care agencies and care providers. For example, millions of claims submitted by health insurers. On the website of Vektis an overview of EI-standards are published. Vektis collects and analyses data on costs and quality of health care in the Netherlands. Continua Health Alliance is a non-profit, open industry organization of health-care and technology companies joining together in collaboration to improve the quality of personal health-care. Continua Health Alliance has developed standards for integration profiles for personal health systems. Besides, different ISO-guidelines are used to support exchange of medical data in the Netherlands.

### **2.2.6 Terminology and classification standards (SEMANTIC)**

Different terminology and classification systems are used for the medical applications, depending on their specific purposes. For example the Declaration treatment codes (DBC's) are used for the declaration, the International Classification of Diseases (ICD) codes for the diagnostic statistics, the International Classification of Primary Care (ICPC) for GPs, the G-standard for medicines and Logical Observations Identifiers Names and code LOINC for laboratories. In contrary Systematizes Nomenclature of Medicine (SNOMED CT) can be used for a broad group of healthcare applications.

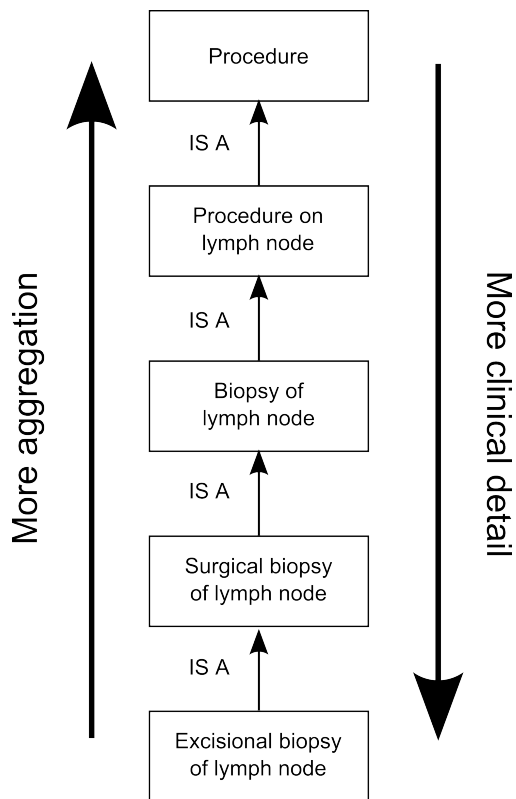
In this part of the chapter we will describe some of the most common terminology and classification standards.

#### **SNOMED CT**

SNOMED CT [39] is an international medical terminology system that includes a standard set of terms with their synonyms. It stands for Systematized Nomenclature of Medicine - Clinical Terms. The terms are used in direct patient care for the recording of complaints, symptoms, conditions, disease processes, interventions, diagnoses, outcomes and decision-making. It is a structured collection of medical terms that are used internationally for recording clinical information and are coded ready for processing by computers. SNOMED CT provides for consistent information interchange and is fundamental to an interoperable electronic health record. The availability of free automatic coding tools and services, which can return a ranked list of SNOMED CT descriptors to encode any clinical report, can help healthcare professionals to navigate the terminology.

SNOMED CT can be characterized as a multilingual thesaurus with an ontological foundation. SNOMED CT concepts are representational units that categorize all the things that characterize health care processes and need to be recorded therein. A “concept” has a clinical meaning identified by a unique numeric identifier (ConceptId) that never changes. A unique human-readable Fully Specified Name (FSN) represents the concepts. The concepts are formally defined in terms of their relationships with

Figure 2.5: Example SNOMED



other concepts. These logical definitions give explicit meaning, which a computer can process, and query on. Every concept likewise has a set of terms that name the concept in a human-readable way. The meaning represented by a Concept can be general (for example “procedure”), specific (for example “excisional biopsy of lymph node”) or somewhere in between (for example “biopsy of lymph node”).

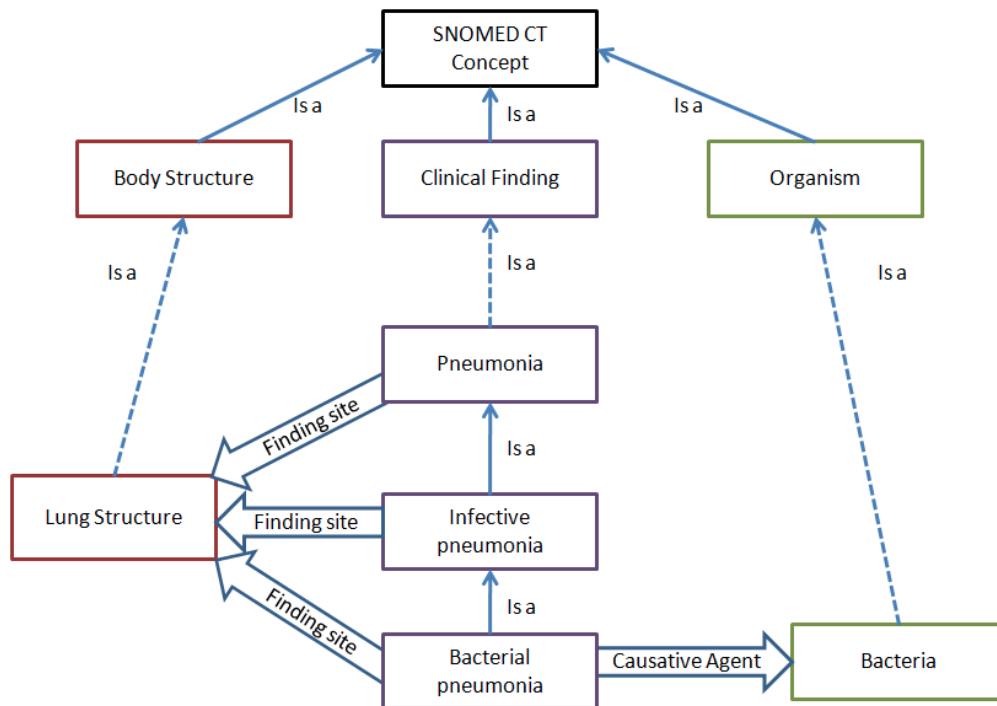
Specific Concepts:

- Have finer granularity (more granular);
- Represent clinical detail.

General Concepts:

- Have coarser granularity (less granular);
- Represent less clinical detail;
- Aggregate similar Concepts.

Figure 2.6: Illustration relationships with SNOMED



### Relationships link concepts in SNOMED CT

There are four types of relationships that can be assigned to concepts in SNOMED CT:

- Defining
- Qualifying
- Historical
- Additional

An attribute relationship is an association between two concepts that specifies a defining characteristic of one of the concepts (the source of the Relationship). Each Attribute Relationship has a name (the type of Relationship) and a value (the destination of the Relationship).

Figure 2.6 illustrates in an example the standard and attribute relationships | is a | Relationships relate a concept to more general concepts of the same type. In contrast, attribute relationships (such as | Finding site | and | Causative agent |) relate a concept to relevant values in other branches of the subtype hierarchy.

Beside the basic components of SNOMED CT explained, this standard also uses different attributes, hierarchies and structures (like tables, subsets etc.) to describe different Clinical terms.

## Datasets

When a care provider wants to capture or exchange digital information, it is important that this data is unambiguous, and it is well defined how this information is recorded or exchanged. Datasets are developed for this particular reason. A dataset contains definitions of the data, which needs to be recorded or exchanged. These definitions are non-technical by nature and are determined by the users of ICT systems, but also by care providers and patients. A dataset is usually developed and maintained by a working group consisting of (representatives of) medical specialists, patients and an information analyst. In a dataset, non-technical definitions of data are recorded or exchanged by the health professionals or patients for some data, such as the sex of a person or a diagnosis code. This value should be chosen from a list of fixed values. Such a list is called a value set.

## Other standards developed by the World Health Organization (WHO) Organization [32]

**The International Classification of Diseases (ICD)** is a classification, terminology or vocabulary introduced by the World Health Organization. ICD is the standard diagnostic tool for epidemiology, health management and clinical purposes. It is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition ICD is used to enable the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes.

**The International Classification of Functioning, Disability and Health (ICF).** Where ICD is a reference classification to capture information on mortality and morbidity, ICF is developed to capture information on various domains of human functioning and disability.

**The International Classification of Diseases for Oncology (ICD-O)** published by WHO in 2000, is intended for use in cancer registries, and in pathology and other departments specializing in cancer (1). ICD-O is a classification with coding systems for both topography and morphology.

**The International Classification of Health Interventions (ICHI).** WHO has also been exploring to the possibility of replacing the former International Classification of Procedures in Medicine by the new ICHI standard. This process will take place over several stages of consultation, field-testing and approval by the WHO governing bodies.

**International Classification of Primary Care (ICPC) [32]** ICPC classifies patient data and clinical activity in the domains of General/Family Practice and primary care, taking into account the frequency distribution of problems seen in these domains. In Netherlands this is the most common classification used by the GPs. It allows classification of the patient's reason for encounter (RFE), the problems/diagnosis managed, interventions, and the ordering of these data in an episode of care structure. There

are different derived classification from ICD, as for instance ICD-O-3 (classification of diseases for Oncology), ICD-10 (mental and behaviour disorder), ICD-DA (dentistry and Stomatology) and ICD-CY (children and youth). Figure below shows the classifications of WHO that cover the main parameters of the health system, such as death, disease, functioning, disability, health and health interventions. (Figure M.4 of appendix M)

### 2.2.7 Scenario analysis, health information exchange

In order to distinguish different types of exchange of medical information, we can look at the possible situation where exchange might take place. The most common type of exchanging data between health providers is within the same specialisms at the same hospital. This can happen when a medical specialist and a colleague (at the same department) both store and access medical data of a patient. The reason for this can simply be a transfer (for further treatment) or corporation between different specialists. It might as well happen that a patient is transferred to another speciality for further treatment or corporation. When different specialists are involved we call this Multi-disciplinary corporation. Corporation in treatment and consultancy can happen when different specialists of the same speciality but from different hospitals need to cooperate. Table 2.1 illustrates these situations:

Table 2.1: Different scenarios medical data exchange

	Transfer patient		Corporation	
	Within same speciality	Between different specialities	Within same speciality	Between different specialities
<b>Within same organization</b>	Medical Check	Transfer treatment	Collegial corporation	Multi-disciplinary consultation
<b>Between different organizations</b>	Transfer treatment	Transfer treatment	Corporation in treatment and consultation	Multi-disciplinary consultation

Often the health providers in the same hospital make use of the same EHR system. Indeed authorization is needed to provide access to specific parts of the EHR. Beside the digital exchange of medical data between different departments often medical maps are transferred physically (written or printed) from one room to the next.

However in this research we are mostly interested in the exchange of medical data across the borders of the health-organization. Still until today a large part of exchange of medical data is performed by traditional ways (written letters, phone, fax). Also, it is interesting to remark that most of the times the initiation for the request of medical data from other providers is done by use of traditional ways, even though the response is in digital format. In chapter 7 we explain some of the current solutions used to exchange medical data.

In the next pages we will explain 4 different scenarios, by providing different practical examples in different sectors.. These scenarios are:

- Scenario 1 - Between different organizations within the same speciality (case-example: transfer patient between diabetes specialisms)
- Scenario 2 - Between different organizations and different specialities (case-example: transfer patient from paramedic to GP)
- Scenario 3 - Between different organizations within the same speciality (case-example: corporation between crisis centre, GP and the GGZ psychologist)
- Scenario 4 - Between different organization and different speciality (case example: multidisciplinary diabetes specialism and ophthalmologist).

### **Scenario 1 - Between different organizations within the same speciality (patient transfer)**

The first scenario concerns the exchange of medical data between different health organization. Both specialist are within the same medical speciality, but located in different organizations. Let us explain this scenario by providing one of the many use cases that exist for this scenario. Assume that a patient has visited a specialist for diabetes treatment and for some reason the specialist decides to transfer the patient to another co-specialist. This can relate to a more specific treatment, that is needed from a second co-specialist. Another reason can for instance concern the availability of a specialist who sits in for a colleague in charge. The figure below shows the generic information exchange between the health providers. The terms “Main doctor” refers to the specialist who has the initial responsibility of treatment for the patient related to diabetes illness. The term “Secondary doctor” refers to the co-specialist who takes over the treatment. Lets assume that the exchange of information is performed in about 6 steps:

1. Main doctor informs the secondary specialist of diagnosis of diabetes.
2. Both parties inform each other about the desired planned or implemented contacts.
3. Co-specialist asks the basic information (for instance by phone) and gets back the data.
4. Co-specialist asks and gets back the targets values.
5. Co-specialist asks and receives the risk profile.
6. Co-specialist asks and receives the medication list.

This is illustrated in figure 2.7. Also in the left and right side of this diagram, the specific data elements are provided for each step.

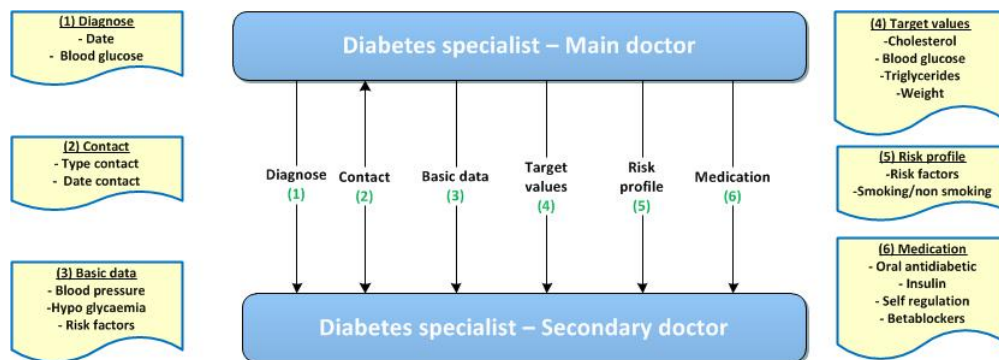


Figure 2.7: Scenario 1 - Between different organizations within the same speciality (patient transfer)

### Scenario 2 - Between different organizations and different specialities (patient transfer)

Within the second scenario different specialists from several organizations are involved. This scenario in fact describes a situation where a patient, bystanders and ambulance staffs report a request for an emergency help. The patient needs to be transferred with an ambulance to the emergency department. The control room and ambulance send the relevant information beforehand to the emergency room. Once arrived as well the ambulance intervention data is over-handed to the emergency department. These data can contain medical measurement, diagnoses, medication and treatment information. The patient is transferred to the emergency department. Once the patient is ready to go home, a report of emergency help is send to the patient's GP. The patient is transferred then to the GP for further medication and treatment. Figure 2.8 describes this scenario in more details. Also, the data elements in each step are illustrated (left and right side of the picture).

### Scenario 3 - Between different organizations and within the same speciality(corporation)

This scenario concerns a situation when a general practitioner (GP) and a front and back-office of a mental health treatment organization are involved. The GPs in the Netherlands are usually the first contact for the patients with mental problems. GPs have a broad knowledge, inclusive mental health and are capable in assisting or collaborating with other psychologists. That is why the GP is also seen here as a mental health provider. It is also possible that patients directly contact crisis centre of GGZ (the Dutch mental health provider organization). In both cases the crisis centre is investigating the patient in order to decide whether this person needs further mental treatment. The crisis centre sends together with the intake confirmation a message back about the diagnoses. The rest of the communication takes place between the GP (here as a mental health specialist) and the psychologist at GGZ. This is illustrated in figure 2.9. Beside the information that needs to be exchanged also in this case several physical transfer messages (written letters) are send over from one organization to the next.



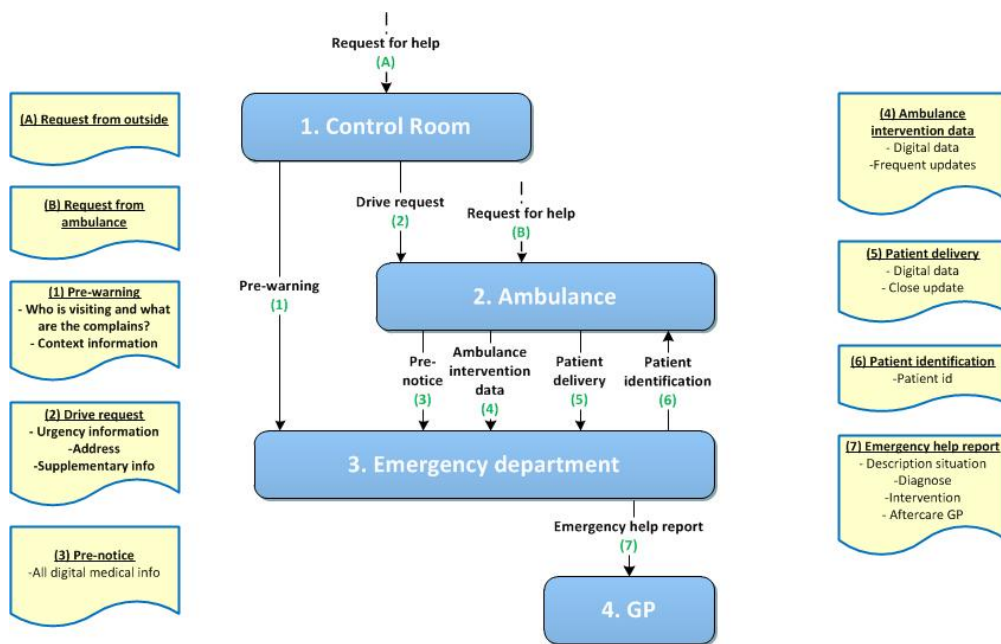


Figure 2.8: Scenario 2 - Between different organizations and different specialities (patient transfer)

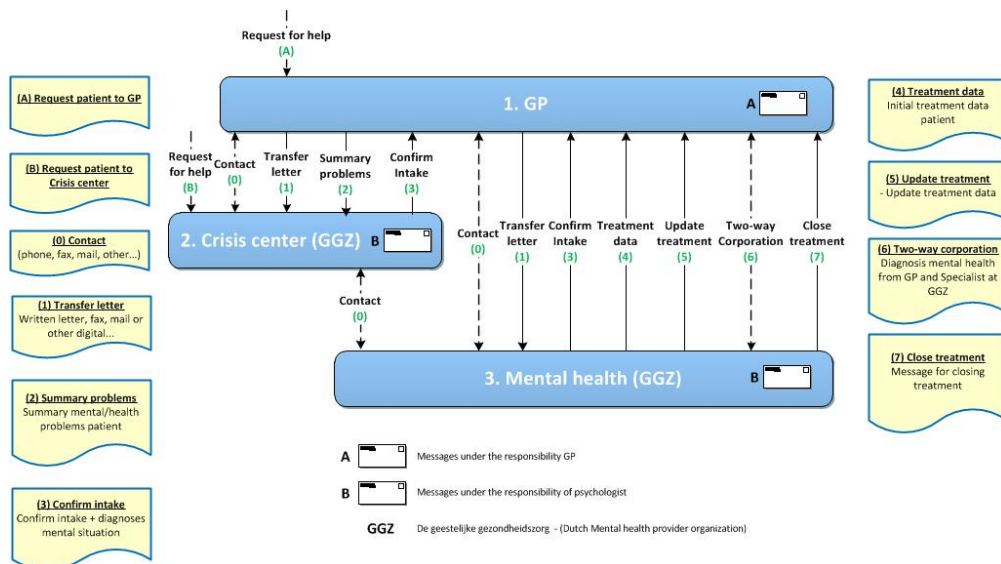


Figure 2.9: Scenario 3 - Between different organizations and within the same specialty (corporation)

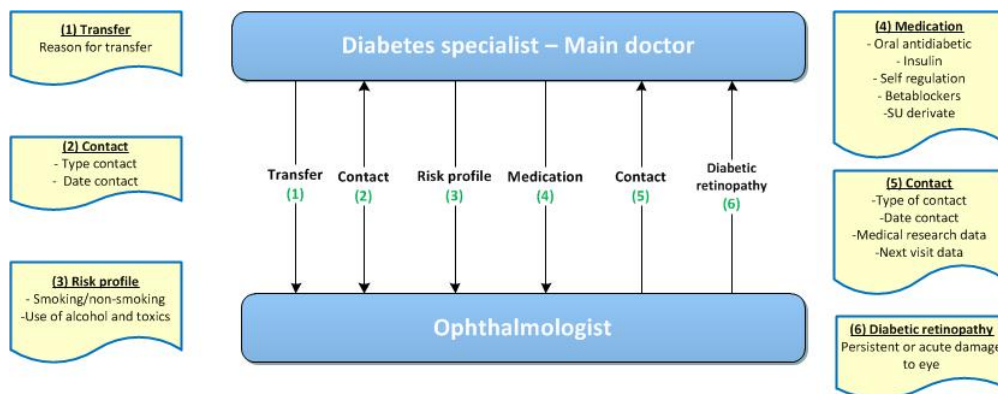


Figure 2.10: Scenario 4 - Between different organizations within the same speciality (corporation)

#### Scenario 4 - Between different organizations within the same speciality (corporation)

This scenario includes the corporation of a diabetes specialist and an ophthalmologist (speciality concerning problems with eye and view of patient). It often happens that diabetes patients who are an advanced stage of diabetes, suffer from persistent or acute complications with their eye. A multi-disciplinary team of specialists is involved in the treatment of this group of patients. The diabetes specialist sends a request for transfer of the patient to the ophthalmologist for further treatment. The diabetes specialist needs to send all the relevant data to the corporation doctor. The results of tests and treatment are returned back by the ophthalmologist. This is illustrated in figure 2.10.

Beside the mentioned scenarios many other cases are possible between different specialisms; for transfer, corporation and consulting purposes. It is clear that in all these cases the first health provider sends a transfer request, then delivers all relevant medical data, which are important for further treatment. Also, in all cases the receiving health provider sends back a confirmation (in some cases using phone or an email). The results of the treatment are returned to the health provider that requested, and used in further treatments. In some case the relevant medical data are returned by the initiator (first health provider). In other cases the receiving party requests the needed information. In none of the described situations the receiving party has already access to the patient's data from the beginning. However this can sometimes occur in the practice when certain levels of agreement is reached between the two parties. The medical data of the patients can be "pushed" to the receiving health providers.

## Summary

This chapter explained the current situation of regional health information exchange in the Netherlands. The providers of health information data are in general hospitals, but also GPs, smaller clinics and labs play an important role. The GPs mainly play an important role in coordination and management of the patient's data. In general three different types of hospitals can be distinguished: general hospitals, university medical centres and specialized hospitals. At this moment there are already several regional corporations in the Netherlands for the exchange of medical data. Regional information systems (RHIS) can be explained as collaborations between different health providers and related organizations at a regional level. Health Information Exchange (HIE) is a term used to describe the sharing of health information electronically among two or more entities. Some of the challenges of RHIS are gaining trust and commitment from the stakeholders, their costs and benefits, value around HIE and the interoperability problems. Four different levels of interoperability can be distinguished:

1. Technical Interoperability (technical and data transport standards)
2. Syntactical Interoperability (associated with data formats)
3. Semantic Interoperability (associated with the meaning of content and concerns the human rather than machine interpretation)
4. Organizational Interoperability (agreements about responsibilities, processes and organization represented by different models).

The current problems of RHIS regarding interoperability usually relate to the syntactical level (also called functional information standards). Most common functional standards used in the Netherlands are EDIFACT (used by GPs) and HL7 (used by the hospitals and others). An important problem here is that it is not always possible to translate data from one standard to another, without losing some content and the important structure of data.

This chapter also explained several important data exchange scenarios. An important scenario, which we will focus on in this research, is the exchange between different types of specialists, each located in different health organizations. In section 2.2.7 several other examples are provided to explain some of the most common scenarios for the exchange of medical data.



## Chapter 3

---

# REQUIREMENTS ELICITATION PLAN

### Overview

Gathering important requirements for the development of RHIS needs a proper analysis of different stakeholders, their interest and influence. Beside this, a communication plan can help us to anticipate on effective elicitation of requirements. We can also take into account the possible risks, to be prepared as much as possible for the unexpected situations.

**At the end of this chapter the reader will have an overview of:**

- Important stakeholders, their viewpoints, roles and power level
- Primary and secondary users of RHIS
- Classification of the stakeholders
- Communication plan for each stakeholder group
- Overview of important risks and response strategy for each risk

### 3.1 Stakeholders analysis

One of the most important parts of creating a requirements plan is to make an overview of the involved stakeholders, their viewpoints and interests. It is also important to plan the contact with these stakeholders beforehand, in order to collect their viewpoints, where after a plan is made to contact these stakeholders, in order to collect their viewpoints. We describe several important stakeholders of RHIE in this chapter, providing their viewpoints and final a communication strategy.

#### 3.1.1 Analysis steps

Different approaches exist for the specification of stakeholders. It is common to investigate the viewpoints, roles and power levels of all important stakeholders. Figure 3.1 illustrates some of the important questions, that can be used to specify the main stakeholders of RHIE.

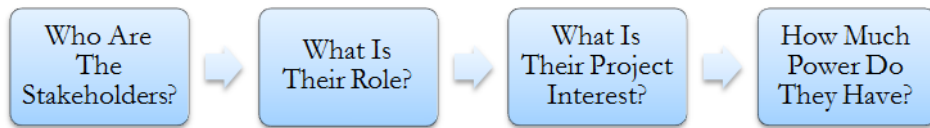


Figure 3.1: General steps of stakeholders listing

### 3.1.2 Who are the important stakeholders?

In order to explain the stakeholders of RHIS in a better way, we can first divide them in 2 different groups: the internal and external stakeholders. Sometimes there is a distinction made between an actor and a stakeholder. Often an “Actor” is referred to a person or a group of persons which is directly involved in the project and may have a big influence on the developments. On the other hand, “Stakeholder” are persons or group of people who are not directly involved, but have some interest in the project. In this report we will use them interchangeably, because we analyse each stakeholder or actor separately. The stakeholders can be divided into internal (directly involved and influenced) and external (indirectly involved or have power on decisions made). Before describing the internal and external stakeholders we will describe the most common structure of the hospitals in the Netherlands. This will help us to understand the position of the main users of RHIE.

### 3.1.3 Organizational structure of the hospitals in the Netherlands

The internal actors are all within the same health organization. In order to be able to create a good overview of the internal actors, the organizational structure of a hospital can be quite helpful.

In the Netherlands and most European countries there exist often three different kinds of hospitals:

**General hospitals:** In “General Hospitals” the most common specialisms are gathered, and thus are visited by patients with different types of problems.

**Specialized hospitals:** The specialized hospitals are only limited to a certain type of patients and specialists. Among the specialized hospitals we can mention:

- Children’s Hospital
- Rehabilitation
- Hospital focused on oncology
- Hospital focusing on orthopaedics
- Hospitals special for army.

**UMCs (University Medical Centres):** In UMCs almost all medical specialities are available. A university hospital also has a training department and an academic position. Figure 3.2 illustrates the common organizational structure which represents more or less all three types of hospitals.



Figure 3.2: Dutch hospital classification

Furthermore the hospitals are relatively large and complex organizations. The complexity normally depends on the size of a hospital, often indicated by number of beds and the number of different specialities. The medical specialists are grouped into different polyclinics (departments) of a hospital. Each department can have a separate clinical care or make use of the general clinical care facilities. Research and treatment and clinical care are the heart of each hospital, but not the only important parts. Beside treatment and clinical services a hospital has different supporting departments, which play an important role in handling financial, and administration requests (also for the patients). The management of hospitals are represented by a group of people (not necessary with a medical background) who are directly responsible for managing different departments of a hospital, which are under the supervision of the first responsible person of each department. In treatment and clinical departments these people are specialists who are head responsible for the departments. The supervisory board, medical council, patient advisory council and employees council have a supervisory and advisory role. Figure M.5 of appendix M, represent a basic organization of a hospital in the Netherlands.

### 3.1.4 Stakeholders classification

#### Internal actors

Internal actors are persons or groups of persons (with a specific role and responsibility) who are directly influenced by RHIS. These are the main users: medical specialists, nurses, medical assistance, admission support, and laboratory staff. Because hospital executives and IT-support play also a direct role and are operated from inside of health provider organizations we also include these groups into the internal actors.

#### External actors

External actors are all groups of people that are outside of the health organization. These groups include several interest group of the medical specialists and patients. Practically in our case we consider almost all groups that operate or are located outside the organizations border, as external stakeholders. The IT supplier of health information systems is also an external stakeholder that is often intensively involved in design and development of RHIS. The IT supplier has often a close relation with the internal IT department of a hospital. Figure 3.3 illustrates internal/external classification of the stakeholders. For simplification it is chosen to put some of the individual actors in one single group. For instance medical staff contains different specialists, nurses from the treatment and clinical care departments.

Most of the hospitals in the Netherlands have their own internal laboratory. This is because of the urgency for the results, during the treatment. The medical staff will often need the results on the same day. However for the smaller health organization this is not always the case and they might use an external party for laboratory purposes. Also, it is remarkable that we have now two different groups of medical staff: Internal medical staff and the external ones. In fact the external medical staffs are doctors and specialists of a partner health organizations. All other interest groups are included in the external group of stakeholders. Obviously during the elicitation stage we need to make a clear distinction between the internal and external medical staff in order to acquire the right requirements for each group.



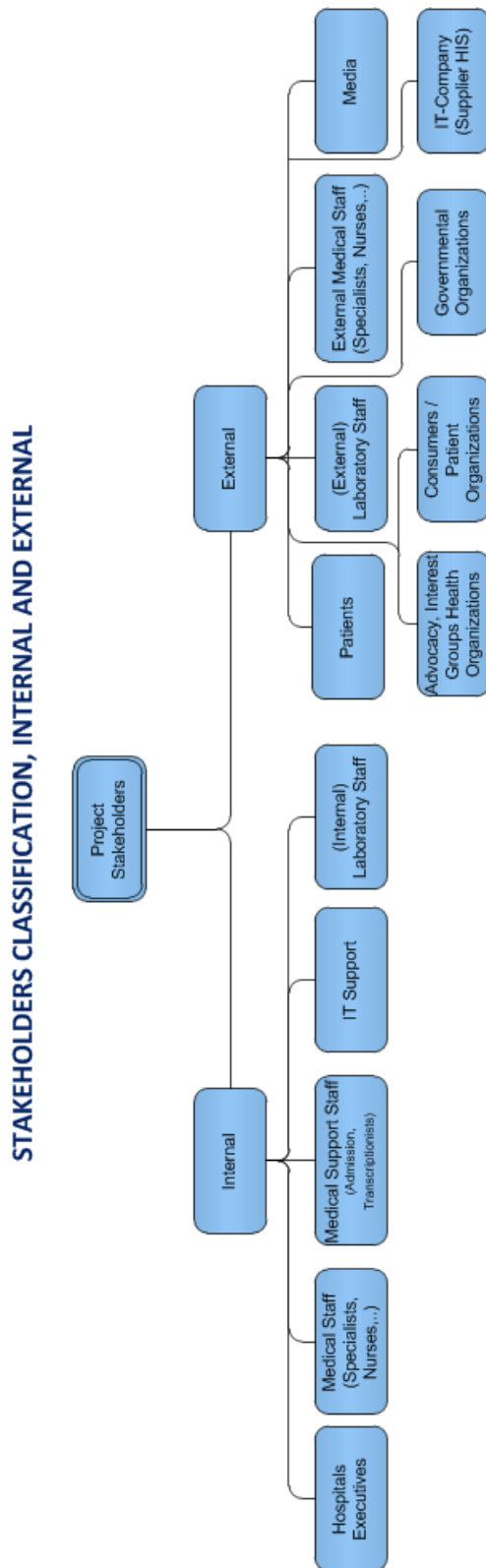


Figure 3.3: Stakeholders classification internal and external

### 3.1.5 List of the important stakeholders

In this chapter the role of different stakeholders are explained in more details.

#### Internal actors

**HOSPITAL EXECUTIVES (CODE: S-HE)** Hospital executives are most concerned about the quality of care, efficiency of work process and total costs of a health provider organization. By the introduction of a new system they would like to decrease the time, needed to gain medical data from corporation organizations, but at the same time the quality of health should be improved. The input of these groups is mainly important during the implementation phases of a new system. An approval from this group is needed to purchase and use a particular system in the health organization. An overview of sub-actors within the hospital executive actor group is as follow:

- Hospital Directors
- Board of Directors
- Supervisory Board
- Managers Clinics
- Coordinators Clinics.

**HOSPITAL IT MANAGEMENT (S-HIT)** Almost all medium and large health provider organization have an own IT-department. This department takes care of installation and maintenance of the hardware and software packages. They also cooperate and communicate closely with the hospital director and the board of directors. Beside these, the hospital IT manager and other people working in this department occasionally have meetings with all external software suppliers. During the elicitation of requirement for development of RHIS this department can share their experiences about technical possibilities within the organization. Also, because the employees working in this department have daily contact with other hospital personal, their experience in existing problems can be of high importance.

**HOSPITAL COUNCILS (CODE: S-HC)** The Patient Advisory Council represents the common requirements of the people who receive medical care in hospital. The board advises solicited and unsolicited the management on patient's interests. This group might be helpful in getting common requirements of the patients, because they represent the patients in general. The impacts of implementation of RHIS can be different, from positive in patients comfort and increase of the quality of care, but RHIS might also cause new privacy and security risks. The medical specialists are united in the medical staff whose aim is to improve the mutual cooperation and quality of care. The employees council has the power to inform and influence individual medical specialists by making appointments, gatherings and others. This group will not be directly involved, but has indirect influence.

The hospital council group mainly exist of next sub-actors:

- Patient Advisory Council
- Medical Council
- Employees Council

**PRIMARY USERS (CODE: S-PU)** The hospital's medical specialists are responsible for the diagnosis of diseases and treatment of the patients. They are the main users of the system, so it is important to ask their viewpoint, requirements and advices. Knowing their important requirements very well will reduce the risks and help increase their wiliness to corporate with the development of the new services. If the development of the RHIS succeeds it will decrease the time and effort needed to exchange medical data between health providers, decrease workload and take away unneeded handling. Due to unsuccessful implementation, the situation may remain the same or even get worse, because the system functions differ from what its users expect from it. The primary users of RHIS can be grouped as follow:

- Medical specialists
- Nurse practitioners, public health nurses and many other nursing professionals.
- Medical scientists

Some examples of the medical specialities are provided in table 3.1. This categorization is collected from the website of the University Medical Centre Utrecht [44]. University Medical Centre Utrecht is one of the largest University Medical Centre in the Netherlands with a large diversity of medical departments. The specialisms can be categorized mainly in the next five groups:

1. Diagnostic Specialists
2. Interdisciplinary
3. Internal Medicine
4. Other Major Specialities
5. Surgery.

*Appendix B provides a more detailed categorization of medical specialists.*

Table 3.1: OVERVIEW OF SOME OF THE IMPORTANT MEDICAL SPECIALTIES

<b>Medical Speciality</b>			
Anaesthesiology	Medical Genetics	Orthopaedics	Radiotherapy
Cardiology	MKA	Otolaryngologist	Rehabilitation
Dental Surgery	Neurology	Paediatrics	Special Dentistry
Dentistry	Neurosurgery	Pharmacy	Surgery
Family medicine	Nursing	Physical therapy	Urology
Gynaecology	Obstetrics	Plastic Surgery	Vascular Medicine
Intensive Care	Occupational therapy	Psychiatry	Vascular Medicine
KNO	Ophthalmology	Psychiatry	Other
Lung Medicine	Oral Surgery	Radiology	

**SECONDARY USERS (CODE: S-SU)** Beside the medical specialists, patients are important users of RHIS and can be seen as the secondary users of these systems. In some cases the patients have direct access into their own medical data. The patients are becoming more aware of their own health-care and in some cases participate to gather and provide medical data. For instance measuring the blood pressure at home and fill in this data into the system using several web-based applications (web-portals). The patients are also able to make appointments through the system in various ways. For instance by filling in a reference number, which they received from their general practitioner. In other words in some cases the patients are able to access several systems (such as portals) to view and edit information. Beside these reasons, the patients are also the citizens and might be used in surveys in order to get a better understanding of the general cultural norms and acceptance of new developed systems. The privacy and security of patient's medical data is one of the hot topics in the Netherlands and is often seen as one of the main obstacles for development of the national EHR. Also, at regional level the privacy and security of patient's medical data play an important role in the success or failure of such systems.

Regarding the position of the patients in general we can also see the patients as clients of insurance companies and the health organizations. The admission fees of medical treatments are paid by the insurance companies, which makes the insurance companies in some way the direct clients of the health providers. The patients are the clients of insurance companies, which make them the clients of clients of health provider organizations. The insurance costs in the Netherlands are paid directly by the patients, however in some cases a part of the insurance costs are paid back to the patients by the Dutch government, depending on their income. The prices for health treatment and medication are standardized by the agreements between insurance companies, health providers and the Dutch government.

## External actors

In this section we will explain the role of different external stakeholders in more details.

**ADVOCACY, INTEREST OR LOBBY GROUPS HEALTH PROVIDER ORGANISATIONS AND PHARMACISTS (CODE: S-I)** This group of actors mainly represent the medical specialists, dentists, surgeons, laboratory and pharmacy specialists. Normally the actors in this group are not involved in each individual software project, but actively engage themselves in the projects that can affect the positions of the medical specialists. For instance where specialists are asked to exchange sensitive medical information of their patients. This has to do with promises that doctors have made which relate to ethical issues. Other reason for the specialists being sensitive has to do with commercial consequences and the way they perform treatment tasks. We will explain some of the important organizations that can be included in this group of actors:

**Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG)** [22], represents the interests of more than 53,000 physicians and medical students. The development of RHIS might satisfy this stakeholder in its objective of the development of regional exchange of data. According to this stakeholder the recognition of regional systems is seen as a crucial point in the entire EHR development. KNMG publishes regularly the current and future developments of RHIS. In the past it had a big resistance against national EHR, but in general it supports the developments of regional exchange services.

**De Landelijke Huisartsen Vereniging (LHV):** [24], is representing physician's interest and ensuring the preconditions for the introduction of the national electronic patient record . This organization supports the regional development of RHIS, and prioritizes the developments of regional EHR above the national EHR (L-EPD).

**NHG (Nederlands Huisartsen Genootschap):** defines guidelines for the co-operation between GPs and other workers in primary care [27]. NHG explains the core values of general practice-family medicine (GPs) and provides patient's information. The NHG thinks that it has a role in achieving a cultural shift among doctors when it comes to support for including patient access. If patient access is implemented this will satisfy them. The reason why NHG is pleased with regional sharing of data, is because RHIS helps the development of national EHR and improves quality of care. NHG generally has a better image than the KNMG and LHV. The NHG does not see itself as an interest group, which is more the role of the LHV. When it comes to the EHR it shares the opinion of LHV (who is against the national EHR). The only exception is the subject of patient access , where NHG is against providing access to the patients..

**De Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP)** [42], The Royal Dutch Pharmacists Association is the umbrella organisation for both professional pharmacists and the pharmacy in general, and it promotes both the interests of its members and the interests of the pharmaceutical sector in general. Also, this actor supports the regional exchange of medical data. KNMP thinks

that even at the regional level, we should make a distinction between different types of medical data, which might be allowed to exchange. According to KNMP the GPs have a larger need for the electronic exchange of digital lab results and referral letters. These forms of information may get higher priority. If this happens there would be perhaps more support for (cross-region) exchange of electronic medical data. When it comes to the exchange between hospitals the medication list would be more preferred.

**Vrije Huisarts**, the Free Physicians is an organisation existing of a group of GPs, which is against Dutch EHR. They are also against any kind of medium and large-scale exchange of medical information [18]. However their exact viewpoint about regional exchange of data is not yet clear. In general this group of doctors think that the exchange of medical data between health provider organizations limits the job freedom (the freedom to perform their profession) of GPs. Also, they point out that the development of systems for the exchange of medical data may create new security and privacy risks for personal information of the patients. This group has made its voice clear by attracting a lot of media attention.

**Comité Wake-Up** is formed by a number of troubled practice GPs who have a lot of criticism about the way it is handled with the preconditions of the physician's position during the design of the national EHR system [48]. This group blocked in the past the process of data exchange with the main objections related to the privacy and medical confidentiality. This organization has about 800 members who feel that the interests of GPs should weigh a bit harder. Comité Wake-Up is one of the main partners of Vrije Huisarts.

#### **Consumers & patient organizations (CODE: S-C)**

**Nederlandse Consumenten Patienten Federatie (NPCF)**, Dutch Patients Consumers Federation) is a federation of the patients and consumers organizations that support everyone who needs care [31]. The NPCF represent the interests of all patients, and anyone who pay health insurance in the Netherlands. The NPCF believe that the patients should have optimal choices. For instance the patient should have the right information to decide which doctor to visit or in which hospital to be treated. Also according to this interest organization each patient should be asked about his/her opinion for exchange of medical data in regional systems. The patient should be able to say yes or no for the participation in digital exchange of medical data between different health providers.

**Chronische Zieken en Gehandicapten Raad (CG-Raad)**, Chronic Sick and Disabled Council. The CG Council believes that the Electronic Patient Record can mean a lot for the chronically ill and can contribute to good health care in the Netherlands [6]. Especially for the patients who regularly use health care it is important that the course of their disease and treatment is well known. However they emphasize the risks of privacy and security dangers.

**Consumentenbond, Dutch consumer's organization** The Consumer's Association [8] is more critical of the exchange of medial data than the NPCF. This association characterizes its position as "Yes" only if it should also include extra requirements, that

can guaranty the protection of patient's data. The main concerns of the consumers are the preconditions in terms of privacy, security and liability. The developing parties should guarantee these. The union endorses especially the effort to reduce the risk of medical errors.

#### **Governmental organizations (CODE: S-G)**

**College Bescherming Persoonsgegevens (CBP)** is the governmental organization for protection of personal data and privacy [5]. It has a coordinating and enforcement role to protect privacy of the citizens, according to the privacy laws. One of the main privacy laws related to exchange of medical data is the law that obligates all organizations to ask permission from each patient before exchanging their personal medical data. This should be a formal written statement by the patient. CBP has agreed on using BSN (citizen number in the Netherlands), in the healthcare on the national level. If the same procedures are followed this will be the same for exchange of data at regional level. CBP claims that direct access by insurers is in violation of the intent and the legitimacy for the of the EHR exchange systems. Therefore the insurance companies should not have access to the medical data of the patients. For more details regarding law and regulations, please see chapter 6 (Requirements Analysis & Specification - Areas of concern).

**Ministerie van Volksgezondheid, Welzijn en Sport (VWS)**, Ministry of Health, Welfare and Sport has been one of the main forces of the development of the national EHR. The development of regional health information systems can further improve the development on the national level. The problems of development of the national EHR has created a negative image for the VWS [47].

**NICTIZ**, the National IT Institute for Healthcare in the Netherlands - is the national coordination point and knowledge centre for IT and innovation in the healthcare sector [30]. The problems of development of National EPD has caused negative image for the NICTIZ. This organization encourages the health providers to improve regional systems and provides them all needed knowledge and technical assistance. NICTIZ has published many different publications about the exchange of medical data, created the national EHR architecture (AORTA) [29] and worked on standardization of different data levels. These standards are widely used by the IT suppliers and health provider organizations.

#### **Health insurance companies (CODE: S-IN)**

The insurance companies are the largest clients of hospitals. They usually have access to a lot of resources (money, influence) and have a high interest in medical data exchange. The exact role of insurance companies in the beginning is not so clear, but in practice sometimes it happens that they put a particular hospital on the blacklist because of existing conflicts. It could be interesting to gather requirements regarding integrated services from this group. This is because they are mostly interested in decreasing the health costs and the so called chain services are one of the tools. However what is commonly known is that insurance companies would like to exchange medical

treatment data in order to control the costs that are related with the medical treatments. It is interesting to mention that there exists fear among the patients that the insurance companies can get access to privacy sensitive data of the citizens. Different groups are watching the movements of insurance companies on this issue. However the insurance companies power cannot be neglected mainly because of their huge resources which remain their strongest tool.

#### **IT Company (CODE: S-IT)**

Suppliers of health information systems have also an important role in development of RHIS solutions. From the technical perspective they can provide functional requirements. From a non-technical perspective the support & consulting department can provide valuable non-functional and additional requirements. Beside these, the IT companies are one of the main actors, which take often the first initiatives in development of new technology.

#### **3.1.6 Stakeholders interests v.s. influence & power**

It is important to investigate the interests, viewpoints and the power of different mentioned stakeholders in RHIS. The knowledge can help us to collect most important requirements of medical data exchange at regional level. These stakeholders are whether interested parties (financial, organizational) or the users of these systems. As explained in the previous section, each stakeholder might have its own viewpoints on RHIE. The requirements supported by them might in some cases even be conflicting. By looking at the interest & power level of different actors we can decide which of the requirements need to be adapted, eliminated or added. Simply spoken the requirements of highly interested and powerful actors are considered more important. The results of this section are used in chapter 7 (requirements verification, resolving conflicts).

To illustrate the general interest and influence of the stakeholders of RHIS we mainly try to answer next questions:

- What are actor's expectations?
- Do the expectations align with the stated objectives?
- How does the actor benefit from the project implementation?
- In which extent are the stakeholders impacted by the project execution or implementation?



We need to find a measure for each interest and power level of several stakeholders. In general the interest level of actors consist of next factors:

- Expectation/Objective Alignment (whether the development of RHIS aligns with the expectations or objectives?)
- Benefit (does this actor directly benefit directly it?)
- Impact (what impact does it have for the position of this actor?)

Having this in mind we can estimate the interest and power level for each actor. We can choose from “very low”, “low”, “medium” and “high”. These estimation relate to the interest and position of different actors on the exchange of medical data on the regional level. The estimations shown in this list differ from the viewpoints of different stakeholders during the developments of the national EHR in the Netherlands. As explained earlier, the main resistance during the developments of the national EHR came from the GPs and patients. On the regional level almost all organizations are mainly participating voluntary. Moreover, the systems are not top-down implemented. Also in general the primary users have very high interest because it can directly influence their daily work. The secondary users on the other hand use less frequently the system and are mainly effected by the privacy and security aspects. In general individual users have less power and their viewpoints are mainly represented by all other interest groups. (Table 3.2)

Table 3.2: Stakeholders interest and power level

Items	Code	Stakeholder	Interest Level	Power Level
1	S-HE	HOSPITAL EXECUTIVES	High	Very High
2	S-HIT	HOSPITAL IT MANAGEMENT	High	Low
3	S-HC	HOSPITAL COUNCILS	High	High
4	S-PU	PRIMARY USERS	Very High	Low
5	S-SU	SECONDARY USERS	High	Low
6	S-I	ADVOCACY, INTEREST OR LOBBY GROUPS HEALTH PROVIDER ORGANISATIONS AND PHARMACISTS	Low	Low
7	S-C	CONSUMERS/ PATIENTS ORGANIZATIONS	Medium	Low
8	S-G	GOVERNMENTAL ORGANIZATION	Low	High
9	S-IN	HEALTH INSURANCE COMPANIES	Low	High
10	S-IT	IT COMPANY	High	Low

Knowing the interest and power levels of the stakeholders we need to cope with each of the stakeholders separately, in order to prioritize their viewpoints (chapter 7). Scatter-plot of figure 3.4 shows the level of interest and power level of stakeholders.

The most common way to analyse the results is to categorize them in four different groups:

- Low Interest - Low Power: Common Strategy: Monitor casually lowest priority group
- Low Interest - High Power: Common Strategy: Keep informed and use for opinion dissemination - important group
- High Interest - Low Power: Common Strategy: Empower if interests aligned with project - Keep satisfied- important group
- High Interest - High Power: Common Strategy: Manage stakeholders - most critical group

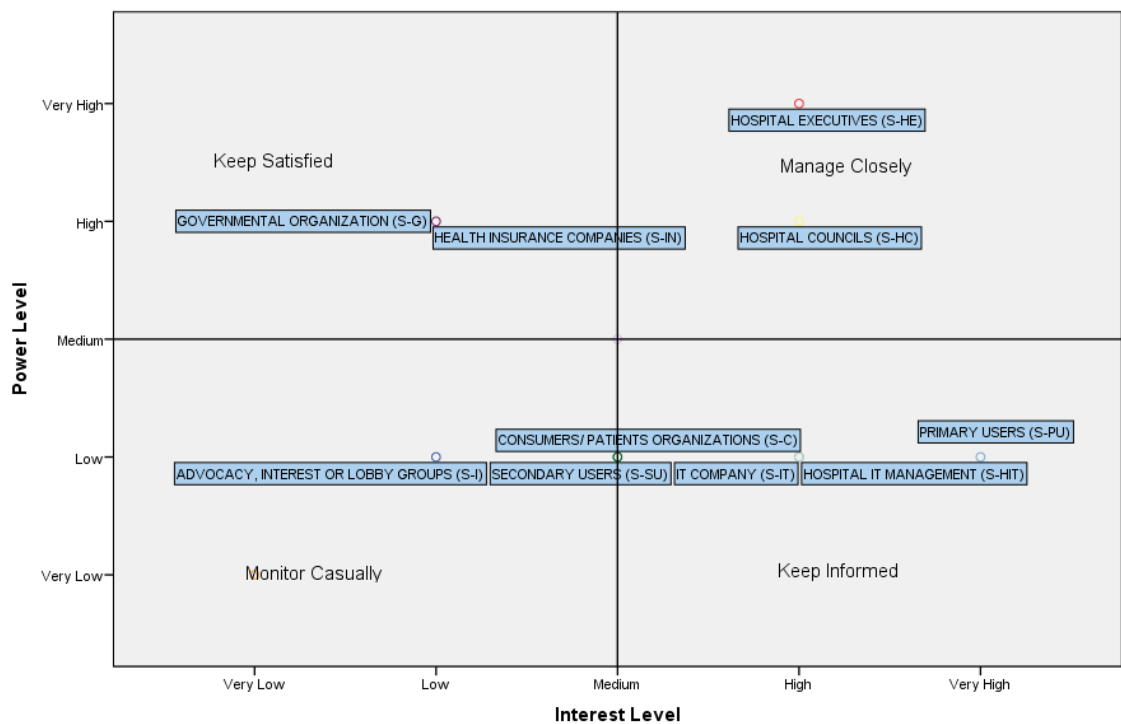


Figure 3.4: Stakeholders interest & power

As scatter-plot of figure 3.4 illustrates, the hospital executives and coordinators of clinics are included in the group that need to be managed closely. However these groups are not able to provide us the concrete functional and non-functional requirements. This is because they are not necessary aware of the details of the work process as for instance medical specialists are aware of. The group that needs to be informed and monitored will include the primary users (medical specialists and nurses). The actors in the scatter-plot which are more on the right side/below (low-medium power, but high interest) are the group of actors who need to be investigated for gathering requirement for the development of the new system. This group includes as already

mentioned the primary users of RHIS. These results are used in chapter 7 (resolving conflicts) method, for the Analytic Hierarchy Process.

## 3.2 Communication plan

Knowing the position of the users and other important stakeholders we are able to plan the requirements gathering activities. This chapter describes the methods, sources and tools that can be used to collect functional and non-functional requirements of important stakeholders for the regional health information exchange.

The group of primary users (medical specialists, nurses and other employees) are the most important group regarding the functional and non-functional requirements. The contact with this group of people is usually very difficult. Often the medical specialist are too busy for interviews. The survey of medical specialists needs to be as compact as possible (both on-line and printed versions). Approximately about 200 specialists need to be approached. This is in accordance with the earlier experiences of several experts in this area. For the patients (which are considered as secondary users) it is chosen to ask their opinion in a statistical survey over a population of about 150 participants. Bigger statistical surveys might of course provide more reliable data. Unfortunately this can not be achieved in this research because of the limitation in time and needed resources.

For gathering requirements of the interest groups it is chosen to mainly investigate published documents. In addition to these, textual statements and in some cases email conversation can be helpful. These methods are chosen because they normally require less time than surveys and interviews. The same technique is used for governmental organizations where literature and published documents can provide lot of valuable information. Also, it is important to note that finding the right contact person who is responsible for the right subject is quite hard in big scale health organizations. Using provided information on the website or earlier publications from the archive can be helpful. Health Insurance companies are one of the important stakeholders in development of new systems. Their power is often underestimated and sometimes feared, because of the risks that the private information would be “misused” by the insurance companies. In reality insurance companies in some cases can use their financial power to force hospitals to take particular (in their profit) steps. That is also the reason that this stakeholder is included in the group, which needs to be managed closely. Communication toward this group is also via interviews (through consultants) and by reading several information on their websites.

And the last important group, which also needs proper effort, is the supplier of Health Information Systems (HIS). For communication with this group we have chosen to interview with experts from different departments of the company, other suppliers can be investigated by visiting their websites, catalogs or relevant seminars. These all is done to actively acquire functional and non-functional requirements. Also, these group of people can be helpful for finding and describing the set of possible technical solutions.

In the rest of this section we provide an overview of the communication methods and sources used in this research for the elicitation of the requirements.

### 3.2.1 Communication methods

The methods used in this research for gathering requirements are:

- Survey/questionnaire of the primary users (medical specialists, nurses, hospital employees)
- Survey/questionnaire of the secondary users (patients)
- Interviews consultants different Dutch health organizations, representative in about 50% of all Dutch hospitals.
- Document analysis requests of the health organizations, a database of the previous 3 years of an important IT Supplier.

### 3.2.2 Other sources of data

Among some of other sources used for gathering requirements or constrains are:

- Brainstorms important stakeholders viewpoints.
- Analysis of some of the important technical solutions (solutions analysis).
- Literature survey, including papers, books, websites, magazines and news articles
- Interface analysis existing software solutions.
- Modelling and textual statements.

*The table of Appendix C provides a detailed overview of different methods and sources used for several stakeholder.*

### 3.2.3 Tools

Next tools were used to contact different groups of people:

- Direct face-to face contact (users, administrators and software developers)
- Web and printed versions of the surveys for primary and secondary users.
- Several presentations and meetings among HIS specialists.
- Email, phone.

Figure M.6 of appendix M illustrates several methods and sources for elicitation of requirements.

### 3.3 Requirements risk assessment

In this section we describe the important risks related to the development regional medical data exchange systems. We also describe a couple of common respond strategies in order to respond to these risks.

In general two main areas of risk can be distinguished:

1. Risks associated with requirement gathering process
2. Risks associated with the product being developed.

In this report we mainly focus on risks, which are created during requirements gathering processes. The mentioned risks can and will influence the eventual development of RHIS. But because of the limitation of time and scope we focus on the risks during the elicitation of the requirements.

Some of the requirements gathering risks to consider are:

- **R-001, Stakeholders not knowing what they want:** This is often a question of not being able to clearly express what the users want, partly caused by lack of technical knowledge.
- **R-002, Researcher not understanding the business:** Traditionally most business analysts come from a technical background. The complexity of different needs in hospitals and minor understanding of medical terms might cause to incorrect requirements.
- **R-003, Lack of important skill on existing software solutions and tools.**
- **R-004, Important stakeholders not willing to dedicate enough time for requirements process:** Most stakeholders actually have a regular job to do. It is often hard to find time to meet.
- **R-005, Stakeholders defining solutions, not requirements:** People often see something similar to what they want. Instead of describing what they need, they describe what they perceive as the best solution.
- **R-006, It is not really clear how many iterations are needed in order to reach an accepted quality level:** This might cause that more or less iterations are performed than actually needed.
- **R-007, Unnecessary documentation and extensive rework:** One of the common known disadvantages of classical methodologies like waterfall is the amount of unnecessary documentation in some case. It is quite hard to know when to stop with documentation and organization.
- **R-008, lack of time:** It is possible that because of the scarce time of important stakeholders the necessary feedback is not provided and as consequence misunderstandings exist until last steps. This can lead to a low quality set of requirements.

- **R-009, missing requirements:** During verification some important requirements are eliminated, this leads to exclude some of the important product specifications.
- **R-010, change in time:** The list of requirements of stakeholders changes from the time of initial interview to the delivery of requirements document or product delivery.

### 3.3.1 Dealing with risks

In this part some of the important strategies are described in order to deal with the earlier mentioned risks. In all cases we can use four common strategies to respond to these risks:

1. Avoid: Don't do the risky behaviour. If the risk is associated with this action, if possible try to avoid this it.
2. Mitigate: Take some action to minimize the risk.
3. Transfer: Find someone to absorb all or part of the risk. Could involve outsourcing, insurance, and penalties in contracts.
4. Accept: Maybe there is nothing that can be done, or the price of action is higher than the price of doing nothing

Based on common strategies, these are the possible responds to the mentioned risks.

- R-001, Accept, this situation because changing stakeholders behaviour is not realistic within the available time.
- R-002, Migrate, extra study and involvement by researcher to reduce risk.
- R-003, Migrate, extra study and involvement by researcher to reduce risk.
- R-004, Accept, it really depends on the person willing to participate fully.
- R-005, Accept, this situation because changing stakeholders behaviour is not realistic within available time.
- R-006, Transfer, ask project managers for help.
- R-007, Avoid, unnecessary documentation if possible.
- R-008, Accept, because changing stakeholders behaviour is not realistic within the available time.
- R-009, Avoid, by better communication with stakeholders and the project team.
- R-010, Avoid, make good use of iteration phases.

Based on these assumptions and strategies we can create the next table, where you can find for each risk the impact, probability and control level (table 3.3). Three different levels are indicated in this table. “L” stands for “Low”, “M” stands for “Middle” and “H” stands for “High”. These levels are based on intuition supported by the reasoning provided above.

Table 3.3: Overview of impact, probability and control level

Risk	Impact	Probability	Control
<b>R-001</b>	M-H	M-H	L-M
<b>R-002</b>	M-H	M-H	M-H
<b>R-003</b>	M-H	M-H	M-H
<b>R-004</b>	M-H	M-H	L-M
<b>R-005</b>	L-M	M-H	L-M
<b>R-006</b>	M-H	L-M	M-H

Figure 3.5 illustrates the position of each risk, describing the level of control for each mentioned risk, in a so called “3D Cube Risk Assessment” model. From this picture we can conclude that R-001, 004 and 010, are the most unmanageable risks from all. On the other side, R-002 and R-003 have to do with the lack of knowledge of researcher and are quite manageable, but with large impact and probability. The risks, which are less controllable, we should in general accept or avoided. The ones with high control can be migrated, transferred or sometimes avoided. Different risks mentioned above are illustrated by the red coloured text in the 3D cube of figure 3.5.

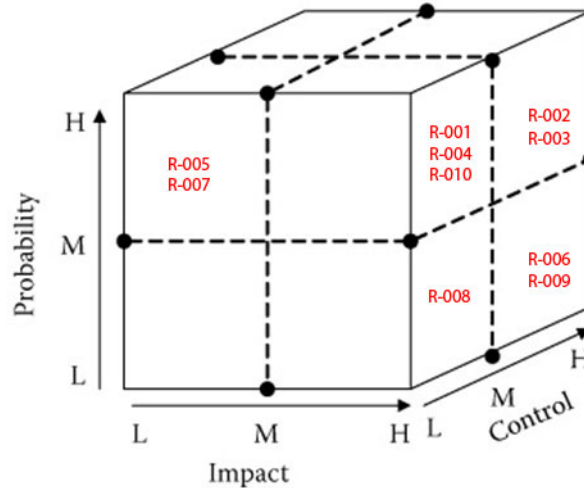


Figure 3.5: Requirements risk assessment, 3D cube impact, probability and control

### Summary

This chapter explained the viewpoints, roles, interests and power levels of several important stakeholders for the exchange of medical data at regional level. These stakeholders can be divided among two main groups (internal and external). The internal actors are persons or groups of persons who are directly influenced by the RHIS and are within the borders of the health-organization. The external stakeholders contain all persons or groups who are operating from outside the borders of the organization. These include for instance all kind of interest or lobby groups.

The main users of the exchange systems are the medical specialists, but also other employees within the health organizations (medical assistants, information clerks...). The secondary users of RHIS are the patients, who are in some cases able to access and maintain their own personal health data.

Some of the described stakeholders are supporting RHIS, while others are completely against any kind of medical exchange. The consumers and patient's organizations are mostly concerned about the privacy and security of the patient's data. The governmental organizations support in general the exchange of medical data and have already invested in the national infrastructure. They also see the development of RHIS as an important step in further development of a national infrastructure for sharing medical data. The insurance companies would also like to access medical data of the patients in order to have a better understanding of the costs made by the patients. The IT companies (vendors of health information systems) are involved in design and development of the regional health exchange software solutions.

By studying the level of interest and power of several stakeholders we can define strategies for communication and the requirements elicitation activities. Some of the strategies that can be used are as follow:

- Monitor casually (interest groups, secondary users, consumers and patients groups)
- Keep informed (primary users, hospital IT management, IT company)
- Keep satisfied (governmental organizations and insurance companies)
- Manage closely (hospital executives and council)

Several communication methods like interviews, surveys, document analysis and direct communication can be used to gather important requirements from these stakeholders. Some of the strategies that can be applied to the mentioned risks (see section 3.3) are: the avoid, mitigate, transfer and accept strategy. For each mentioned risk it is described which of the risk strategies is most applicable.



**Part II**

**Analysis & Specification**



## Chapter 4

---

# ELICITATION METHODS

### Overview

In this chapter we will explain the quantitative and qualitative methods for finding the main requirements of the primary users (medical specialists) and secondary users (patients). Before we do that let us explain the importance of measuring user's viewpoints in general during the elicitation phase. As was explained earlier the medical specialists, GPS, laboratory staff and other medical employees are the main target group when looking for the functional and non-functional requirements. These group of users are usually maintaining and exchange medical data more than any other of the stakeholders. The patients belong to the secondary group of users, who also are able to maintain and exchange medical data, but less frequently than the medical specialists.

In this research both quantitative research (surveys) and qualitative research methods (interviews) are applied, for the elicitation of the requirements. In this chapter it is explained how these methods are applied. The results of these methods are explained in the next chapter (Results). During the quantitative research different variables are measured. In order to support the findings during the quantitative research the same variables and other information is gathered by interviewing different specialists in this field (interview consultants IT supplier Health Information Systems).

According to Bryman and Bell [4] there are three main reasons for the measurement of the relevant variables during the research :

1. Measurement allows us to illustrate the differences between different users in terms of characteristics of the system. This is very useful, since we can often distinguish between medical specialist in terms of extreme categories. Finer distinctions however are much more difficult to recognize. For instance, we can detect clear variations in levels of acceptance and the needs for RHIS.
2. When a wide and random population is chosen, the measurement is a consistent tool for making such distinctions. This consistency relates to two things: our ability to be consistent over time and our ability to be consistent with other researchers. In other words, a measure should be something that is influenced neither by the timing of its administration nor by the person who administers it. Obviously, saying that timing does not influence the measure it is not meant to indicate that measurement results do not change at all: they are in fact bound to be influenced by the process of social change. What it means is that the measure

should generate consistent results, rather than those that occur as a result of natural changes. Because of the limitation of time and resources during this research we have tried to focus only on the main groups of users, within a short period of time. Due to this we need to take into account the reliability of our results.

3. Measurement provides the basis for more precise estimation of the degree of relationships between concepts (for example, through correlation analysis). Thus, if we measure both “acceptance of RHIS” and the things to which it might be related, such as the medical speciality, we will be able to produce more precise estimations of how closely they are related.

The interviews are used to support the findings of the surveys, but also to gain other vital information about the requirements of the existing problem owners (Health organizations). For the same reason document analysis of recent enquiries of problem owners can be used to get more specific knowledge regarding the previous problems and solutions. The rest of this chapter explains the mentioned methods and their relevance in more details.

**At the end of this chapter the following questions have been answered:**

- How quantitative methods (such as the surveys) can be used to gather important requirements.
- How qualitative methods (such as interviews, document analysis) can be used to gather important requirements.

This chapter will also provide an overview of the most important statements that need to be tested during the elicitation phase. These statements are in fact hypotheses which need to be clarified and can lead eventually to important conclusions regarding the user’s viewpoints.

## **4.1 Quantitative method - surveys**

In this research two different surveys are used for gathering the requirements of the medical specialist (primary users) and the patients (secondary users). In this part we will explain the quantitative research approach in more details by providing the theoretical explanation, but also the pragmatic approach used in this research. According to Bryman and Bell [4] “Quantitative research can be construed as a research strategy that emphasizes quantification in the collection and analysis of data”, that entails:

- A deductive approach to the relationship between theory and research, in which the accent is placed on the testing of theories;
- Has incorporated the practices and norms of the natural scientific model and of positivism in particular; and embodies a view of social reality as an external, objective reality.

“In very broad terms quantitative research method entails the collection of numerical data and as exhibiting a view of the relationship between theory and research as deductive, a predilection for a natural science approach (and of positivism in particular), and as having an objectivity conception of social reality.” [4]

In the previous chapter we have provided an introduction of theory (conceptualization RHIS), which led to couple of hypotheses that will be explained in more details. These hypotheses can be measured quantitatively, but also rigorously analysed and evaluated according to established research procedures. The data about the medical specialists and patients are collected for two main reasons:

1. To better understand the phenomena of RHIS in a specific group.
2. To make inferences about a broader group beyond those being studied.

Quantitative techniques are particularly strong at studying groups of people and making generalizations from the sample being studied to broader groups beyond that sample. Contrary the qualitative methods are particularly strong at attaining deep and detailed understandings about a specific group or sample, but at the expense of generalization. Each approach has its unique strengths and weaknesses; each is valuable depending on the purpose of the research.

#### 4.1.1 Existing hypotheses:

One of the practical reasons for measuring different variables during the quantitative research is to try to get a better understanding of what the users of RHIS think are most important. Also we try to find out what the current state of RHIS are before trying to suggest improvements. The information we are trying to find out is formulated as a list of hypotheses that we try to prove right or wrong. These statements can help us to come up later with the important requirements for the RHIS. These hypotheses are mainly composed together with some experts in this field and discussed beforehand with several medical specialists. This list represents important missing information, which plays an important role in specifying the requirements.

##### **Important hypotheses:**

Table 4.1 lists important hypotheses related to medical specialists (primary users of RHIS.) These hypotheses are mainly used to create questionnaires and further specify the requirements of the main users.

##### **Important hypotheses, related to the patients:**

Table 4.2 contains important hypotheses related to the secondary users of RHIS (the patients). As explained earlier, this list is mainly composed together with some experts in this field and discussed beforehand with several patients. It is used to create the questionnaire for the patients. The results are used to specify important requirements of the secondary users of RHIS.

Table 4.1: List of important hypotheses, related to medical treatment and medication:

Code	Description
<b>H-S-01:</b>	RHIS is already active in many health provider organizations.
<b>H-S-02:</b>	The exchange of medical data by some medical specialities is more frequent than others, depending on the type of speciality.
<b>H-S-03:</b>	At this moment it is quite hard to exchange medical data between different health providers.
<b>H-S-04:</b>	There are different needs for the exchange of medical data within the same organization, within the same group of speciality or between different organizations.
<b>H-S-05:</b>	There are significant differences between groups of specialists when it comes to the security and privacy.
<b>H-S-06:</b>	Most of the health organizations use traditional tools like phone, fax and written letters to exchange medical data.
<b>H-S-07:</b>	The exchange of medical data within the same region is more important than outside the region.
<b>H-S-08:</b>	The exchange of medical data between different organizations on regional level is different for each speciality.
<b>H-S-09:</b>	The exchange of medical data on regional level can improve the quality of care provided by different specialists.
<b>H-S-10:</b>	The efficiency of work will be improved due to medical data exchange
<b>H-S-11:</b>	Medical exchange at regional level will decrease the number of double medical effort.
<b>H-S-12:</b>	Exchange of medical data can reduce the numbers of medical errors and the total costs in the health care.
<b>H-S-13:</b>	Digital exchange of medical data can create security and privacy risks.
<b>H-S-14:</b>	The benefits of exchange of medical data at regional level outweighs the risks.
<b>H-S-15:</b>	There are different needs for the exchange of medical data within the same organization, within the same group of speciality or between different organizations.
<b>H-S-16:</b>	There are remarkable differences between groups of specialists when it comes to security and privacy.
<b>H-S-17:</b>	Most of the users are not enough informed about their rights and obligation in RHIS.
<b>H-S-18:</b>	The time that is needed to exchange medical data in some cases can add up to couple of hours.
<b>H-S-19:</b>	The difficulty to exchange medical data is dependent on the medical speciality.
<b>H-S-20:</b>	Some data sources of medical data are more popular than others.
<b>H-S-21:</b>	There are differences between preferences of medical specialists for each data source.
<b>H-S-22:</b>	RHIS should make it possible to exchange data related to: Medical tools, Appointments, Medication list, Allergies, Lab results, Radiology results, Transfer notes, Demographic data of patients, Contacts, Medical reports, DBC's, Intoxications.
<b>H-S-23:</b>	Privacy and security are the main barriers of RHIS.

Table 4.2: List of important hypotheses, related to medical treatment and medication:

Code	Description
<b>H-P-01:</b>	The patients that visit the health providers more frequently (or who need more frequent care), are supporting RHIS more than the patients who need less health care.
<b>H-P-02:</b>	The patients are aware of the fact that RHIS will improve the communication between different health providers.
<b>H-P-03:</b>	The patients think that RHIS can improve the accessibility to patient's medical data.
<b>H-P-04:</b>	The patients are aware of all other possibilities and advantages of RHIS.
<b>H-P-05:</b>	The patients are worried about the security and privacy risks of RHIS.
<b>H-P-06:</b>	The patients are also worried about the security and privacy risks involved with traditional services.
<b>H-P-07:</b>	According to the patients the advantages of RHIS outweigh its risks.
<b>H-P-08:</b>	There exists a correlation between the benefits and risks.
<b>H-P-09:</b>	Patients who suffer from chronic diseases are less worried that their private medical data are made public.
<b>H-P-10:</b>	The patients would like to have the possibility to look back which entities had access to their personal health data.
<b>H-P-11:</b>	Patients think it is important to be clearly informed about all the ways their health information may be used or shared.
<b>H-P-12:</b>	Patients must be able to decide whether the medical data can be shared with other parties (e.g. family, friends, employers, insurance companies, scientific research ...)
<b>H-P-13:</b>	Patients must be able to decide whether or not to share the medical data with other health care providers within the region.
<b>H-P-14:</b>	Patients must be capable to decide for each type of data whether or not share the medical data can be shared (for instance the referral letters yes, but not the medication list)
<b>H-P-15:</b>	Patients must be able to decide whether the medical data can be shared with some specific medical specialist
<b>H-P-16:</b>	Patients must be able to decide whether the medical data can be shared with some specific institution .
<b>H-P-17:</b>	Patients must be able to decide whether the medical data should be exchanged in electronic or printed format.

### 4.1.2 Quality consideration

In this section we describe the measures, that are important in order to guaranty the quality of the surveys.

#### Asking the right questions

In order to compose the right questions first from the mentioned hypotheses, these questions are first categorized in logical steps. For instance the first part contains more and less the general questions about RHIS, which relates to the current state of the RHIS in the Netherlands. The second part of the survey contains advantages and disadvantages of the exchange of medical data and the third part different data types that are the most important for the exchange.

It is also important to check the correctness of these questions. The first version of the questionnaire is checked and developed in accordance to the available experts (R&D and Implementation and Support ChipSoft B.V. Amsterdam). Different terminologies and the levels of abstraction are checked and corrected by the available expert.

We have also tried to avoid any technical terms as much as possible, because in general the participants are non-technical and too much technical terms might have negative effects on the results. Another measure that was taken to improve the quality is to provide a wide range of possibilities for the participants in each question. Within each question the participant has the choice to fill in or chose the “others” field, which enables him/her to choose for a non-standard answer. In this way it is tried not to limit the participants to the information that is provided to them. In some cases extra text field is added where the participants can fill in extra information.

The multiple-choice questions which contain similar answers (having still small differences) are distributed in a random way, in order to avoid that the participants chose their answers without paying too much attention.

And last, it is chosen to create two different surveys: one for the specialists and other for the patients, because a large part of the questions needed a quite different approach due to many specific questions (for the patients and specialists).

#### Determining the right participants

During the selection of the participants for the surveys it was tried to use random people from all kinds of backgrounds, education, sexual orientation (men and women) and ages. This is because we need to represent as much as possible a diverse population of the people. On the other hand for the questionnaire of medical specialists the most important issue is to get a good picture of all different medical specialities. This is because we would like to find as much as possible different types of problems and differences between the needs of the participants. We have done this by randomly selecting different specialists at special test days organized by ChipSoft (IT-supplier). These test days were particularly meant for testing new releases of the existing software solution at different hospitals in 2012, when large number of users of the EHR system were present.



Beside the diversity of medical specialism it is important to ask in particular the opinions of the participants who are most frequently involved in the exchange of medical data. It would not be interesting to ask different unrelated employees in the health-care who never deal with the problems related to the exchange of data. In other words the target group should be the first and second responsible medical specialists, doctors and medical assistances. Also, the information from the consultants can be an important because the consultants are very much involved in resolving complex exchange problems. However we need to be able to separate these groups from each other. These mentioned groups of people frequently add, edit and exchange medical data with other health provider organizations.

### Sample sizes

The actual number of participants for the surveys is very much dependent on the willingness of the group of people we are trying to approach. In general it is known that the medical specialists are quite difficult to approach. This is because of their limited time to participate, but also in general the lack of willingness to be involved in non-medical issues. In other words we need to deal with the limited numbers of participants for the specialists survey (about 50-70). These numbers are however enough in order to be used for non-parametric analyses of the data. Regarding the limited time and resources it is also chosen to gather almost the same number of reactions for the patients survey.

In contrast to the numbers of reactions for the first survey we expect to have higher numbers of reactions from the patients, because this group can be accessed more easily. Non-parametric, or distribution free tests are less reliable, because the assumptions underlying their use are fewer and weaker than those associated with parametric tests. On the other hand there are also some advantages of analysing the data with non-parametric tests:

1. If the sample size is very small, there may be no alternative to using a non-parametric statistical test unless the nature of the population distribution is known exactly.
2. Non-parametric tests typically make fewer assumptions about the data and may be more relevant to a particular situation. In addition, the hypothesis tested by the non-parametric test may be more appropriate for the research investigation.
3. Non-parametric tests are available to analyse data, which are inherently in ranks, as well as data whose seemingly numerical scores have the strength of ranks. That is, the researcher may only be able to say of his or her subjects that one has more or less of the characteristic than another, without being able to say how much more or less.
4. Non-parametric methods are available to treat data which are simply classificatory or categorical, i.e., are measured in a nominal scale.
5. There are suitable non-parametric statistical tests for treating samples made up of observations from several different populations. Parametric tests often cannot

handle such data without requiring us to make seemingly unrealistic assumptions or requiring cumbersome computations.

6. Non-parametric statistical tests are typically much easier to learn and to apply than are parametric tests. In addition, their interpretation often is more direct than the interpretation of parametric tests.

**Some of the disadvantages of non-parametric tests:**

1. Non-parametric tests are less powerful than parametric ones. Parametric tests make use of information consistent with interval scale measurement, whereas parametric tests typically make use of ordinal information only.
2. Parametric tests are much more flexible, and allow you to test a greater range of hypotheses. For example, factorial ANOVA designs allow you to test for interactions between variables in a way that is not possible with non-parametric alternatives.
3. Because of the mentioned the results of parametric test are in many cases more acceptable.

**Selecting the right variables and measures**

One of the important parts of a quantitative research is to define the variables and measure. “Variables are the phenomena that varies depending on the conditions affecting it.” Swanson and Holton [40]

Normally we can distinguish two types of variables: dependent and independent. A dependent variable is the variable that is the object of the study or the studied outcome. Examples might include level of control by the patient. An independent variable is a measure that is related somehow to a dependent variable. For example, the ability of patient to choose to whom medical data can be send (independent variable) is widely believed to influence the level of control (dependent variable). In other words that the ability to choose whether data can be send (independent variable) is widely believed to influence the level of control by patients (dependent variable).

Both independent and dependent variables can be measured by categorical, continuous, or ordinal data. Categorical, or nominal, data come from measures that have no inherent numeric value to them; they are simply categories such as, department, medical speciality, position and so forth. For some questions the participants need to choose the degree of how much they agree with a statement. For instance 1 stands for disagree and 5 for completely agree. All other numbers illustrate something between.

The variables used in the survey of medical specialists and patients are listed in Appendix J.01 and J.02. The questionnaires can be found in Appendix J.03.

**4.1.3 Analysis tools**

Different tools can be used for the analysis of the gathered data. A software package like Survey Monkey is one of those tools that enable the users to create relatively easy on-line surveys. The interfaces are quite simple to realize and the layout is quite

professional. The disadvantage is however that it is a commercial service. There is a limit of the number of reactions allowed and exporting data is not included in the free trial. Another alternative which it is used in this research for gathering the results is the survey / on-line service provided by Google (forms). This application is free to use and also exporting data is possible. In order to analyse the results of the survey a more sophisticated statistics program SPSS is used to generate all kind of plots, statistical tests and correlations between the variables.

## 4.2 Qualitative method - interviews

According to Bryman and Bell [4] “Qualitative research can be construed as a research strategy that usually emphasizes words rather than quantification in the collection and analysis of data and that predominantly emphasizes an inductive approach to the relationship between theory and research, in which the emphasis is placed on the generation of theories” [4].

As a matter of fact the quantitative research methods like the surveys cannot be enough to describe the current problems of existing systems facilitating regional exchange of medical data. It is also important to consider the viewpoints of different actors who are involved in a qualitative way. The actual list of requirements always remains dependent on the specific case that we are trying to describe. The requirements of each organization is very much dependent on the actual needs and existing problems of a specific organization. Often we also have to deal with organization specific constraints that are for instance dependent on factors like level of education of employees, region where the problems plays and size of the organizations. For this reason it is important to interview some of the health organizations.

However because of the limitation of time and resources, but also because we are not trying to solve each specific case and are interested in the most common requirements we have decided to follow a more manageable method. Instead of interviewing all different specialists at different health organizations we have asked the opinion of different consultants of the IT supplier ChipSoft who are represented in about 50% of all hospitals in the Netherlands. These consultants visit frequently different health organizations around the country, asking for their current problems and providing advice for improvements. The interviews with these consultants can provide us valuable information regarding the existing problems and requirements of the organizations that they are representing.

### 4.2.1 Non-official interviews medical specialists during the test days

During the test days at health organizations new releases of the EHR system are being tested by the IT-supplier in co-operation with the medical specialists. Different medical specialists, medical assistances and medical technicians are evaluating the new release. These evaluation meetings are organized in different meeting rooms at the hospital or at the software supplier ChipSoft B.V. Some departments that exist of smaller groups of employees are also able to participate the tests in their own clinics in the hospital. During these test days some of the medical specialists are asked to also fill in the questionnaire. At the same time several discussions are made with different health

providers regarding their experiences with the exchange of medical data at regional level.

#### **4.2.2 Interviews with the consultants**

The supplier of IT systems for the health sectors ChipSoft B.V. provides a custom made EHR system to almost 50% of all hospitals in the Netherlands. Different account managers normally perform the relation with the existing clients. All kinds of problems related to couplings and interoperability of different systems working on several health provider organizations is brought to the attention of these consultants. During the interviews with these consultant we have asked them next questions:

1. Are any of your clients suffering from the problems related to the exchange of medical data at regional level?
2. What is the average size of the hospitals, which are suffering from these problems?
3. Is there a specific medical speciality that can be pointed as the focus problem area?
4. What is in your opinion the reason that it has not been solved earlier?
5. Do you think that existing solutions like OZIS and EDIFACT can help these organizations? Which ones can't be helped and what is the reason?
6. Can you mention one or more requirements, which are applicable to all these different situations?
7. Can you mention some examples of the data that need to be exchanged between different organizations?
8. Can you mention one or more organizations which you think are interested in an interview to point out the most important requirements for their specific case? At the end the consultants are asked to provide any other specific information regarding their experiences with existing problems related to exchange of medical data at regional level.

### 4.2.3 Document analysis- Health providers problems

During this step of the qualitative research a list of problems, inquiries (request for information), requirements of different health provider organizations in the Netherlands were analysed. These were the requests or communication documents, which were sent to the IT-suppliers in the previous three years (2010,2011,2012). In order to find the related documents to exchange of medical data the list was filtered for the documents in past three years using next keywords:

- Exchange
- Coupling
- Regional, regional exchange
- External
- GP coupling
- Transmuraal

Also the list was filtered for documents related to “Transmuraal” services. “Transmuraal” is the term that is used for interfaces between the primary and secondary care, but is also frequently used as a “exchange” or “external” message. These documents were scanned looking for describing problems, requirements and functionalities required.

### 4.2.4 Remarks from medical specialists

During the survey among others next issues have been indicated by the specialists in the comments fields (a place in the questionnaire, where the specialists are allowed to add their comments). The specialists were asked to mention other additional issues, including difficulties they experience in obtaining clinical information from other providers (outside of their health organization).

Next issues are mentioned:

- The exchange of data are often controlled by the polyclinic staff. In some cases the communication with this group is not as optimal as it should be..
- The result of exchange and the time that is needed is very dependent on the person that you are communication with. If the communication with this person is optimal the exchange goes much faster, otherwise it cost me and others a lot of effort and time.
- Different EHR systems are indicated as one of the barriers. This is due to the lack of standards or technical solutions
- The difficulty of exchange depends on the size of the organization. The exchange with larger organization (larger hospitals and clinics) is more difficult. “It takes in some cases between 2-4 month before we can get the necessary medical report, what is too bad”.

- The communication using phone takes too much time (low efficiency and high effort needed) and is often very difficult.

The specialists were asked to mention other data-sources which they mostly rely on for the treatment of their patients. Some of the extra data-sources that were mentioned:

- University medical centres (UMCs)
- Dentists
- Industry: Companies that provide customized implants for the patients
- Other hospitals outside the region
- Physiotherapists

Next types of data were mentioned by the specialists (extra useful needed to provide care):

- OK (operation room) reports
- Discharge letters
- X-Ray data
- Microbiology data
- Pathology reports
- Appointments list
- Older archived reports (often not easily accessible)
- MMI results
- Nuclear Medicine Reports
- All components from the CCR standard
- Pre-operative reports
- Nurse transfer in cooperative care (Ketenzorg)
- Audiometry (hearing tests)
- Medical images

### Summary

The quantitative methods that are used in this research include two separate surveys among the primary (medical specialists) and secondary users (patients). The results of these surveys can help us to:

1. Better understand the phenomena of RHIS in a specific group.
2. Make inferences about a broader group beyond those being studied.

The hypotheses explained in this chapter are used to clarify some of the uncertainties and questions regarding the exchange of medical data at regional level. These results help to find out the actual needs of the main users. It is also important to know which medical specialities are belonging to the group that need to exchange medical data most frequently, but also which data types are considered as most important for the exchange. The questions in the patients survey relate also to the control level of the patients for sharing their medical data with other organizations. Several outcomes of the patients and specialists surveys can be compared with each other. The similarities or difference between these results can be used to explain the needs of its users.

The qualitative methods (like interviews) on the other hand will support the outcomes of the surveys, but will also add missing data to the list of requirements. The interviews with several experts who have frequent contact with different health organizations, can provide valuable information regarding RHIS and will improve the requirements.

A document analysis into the database of an important EHR vendor in the Netherlands (in years 2010, 2011, 20112) , searching for all requests of the health organization regarding the exchange of medical data, can also be used to find other practical requirements.

Beside the surveys and interviews also several other results are used to implement the list of functional and non-functional requirements. Among these methods are:

- Remarks from medical specialist
- Non-official interviews during the test days
- Literature survey





## Chapter 5

---

# RESULTS ELICITATION

### Overview

In this chapter we will explain the results of quantitative and qualitative research methods, which are used to gather the requirements of the primary users (medical specialists) and secondary users (patients). As explained earlier, the following two surveys have been used to gather important requirements of the users:

1. Survey medical specialists (in order to gather the requirements of the primary users)
2. Survey patients (in order to gather the requirements of the secondary users)

We have also used qualitative methods. These were:

1. Interviews consultants HIS software supplier, who are represented in approximately 50% of the hospitals in the Netherlands
2. Document analyses, requests from health organization to HIS software supplier in past three years (2010, 2011, 2012).
3. Literature survey in order to gather all other stakeholders (see stakeholders analysis).

The results of the surveys are gathered using on-line forms (Google forms). These data are imported as CSV files into the statistical program SPSS for further analysis.

### **This chapter provides the most important results of:**

- Survey among the medical specialists in several Dutch health organizations.
- Survey among the patients
- Interviews with the IT-consultants
- Document analysis

## 5.1 Results survey medical specialists

The survey / questionnaire of the specialists contained about 20 different questions, focusing at the target group of medical specialists and all other related employees of several health organizations. By related employees, we mean all employees who are directly involved in the development and use of RHIS. The questions in the survey were mainly related to the frequency of exchange within or outside the organization, importance of medical exchange, barriers and risks. The medical specialists were also asked to indicate, which types of medical data are important, for the exchange between different organizations within the same region. At the end, approximately 200 different specialists were approached. However, only a part of the approached specialists were willing to fill in the questionnaire that was send to them. A more successful approach was visiting different health organizations and gathering reactions by giving them the printed version of the survey. This was during the test days of the EHR software, where different medical specialists were participating (which is obligated by their organization). Other reactions were filled by the medical specialists of different medical universities, or by some small-scaled local health organizations. In total, we received 63 reactions with more than 19 different medical specialities from 18 organizations.

Table 5.1 provides an overview of several medical specialities that have been participating in this survey. The numbers of respondents within these groups are represented in table K.1. From this table it is clear that some of the groups contain less than 3 respondents. This means that not all groups are suitable for statistical analysis and can only be used as descriptive references. To be able to run statistical tests the data is re-categorized into three main specialisms; i.e. Surgical, Non-Surgical, and Supplementary (see Table K.2 of Appendix K). The first group (Surgical) includes Oral, Plastic, and general Surgery. Supplementary specialisms are ICT, Nursing, Other, Pharmacy, and Radiology. All other specialisms belong to the third category of Non-Surgical. This pie diagram of figure 5.1 illustrates different medical specialists and their representative quantities (percentages). As it is illustrated, dentists and nursing are the largest represented groups among the specialists (see also the pie diagram Appendix K, ,figure K.1 for the quantities for each position type). Also, about 20% of all participants did not mention their medical specialism. These were mainly among the printed versions, because this was an obligated field in the on-line version.

Table 5.1: Medical specialities

Medical speciality	
Ophthalmology	Oral Surgery
Anaesthesiology	Paediatrics
Cardiology	Pharmacy
Dentistry	Plastic Surgery
Family medicine	Psychiatry
KNO	Radiology
Lung Medicine	Special Dentistry
MKA	Surgery
Neurology	Urology
Nursing	Other

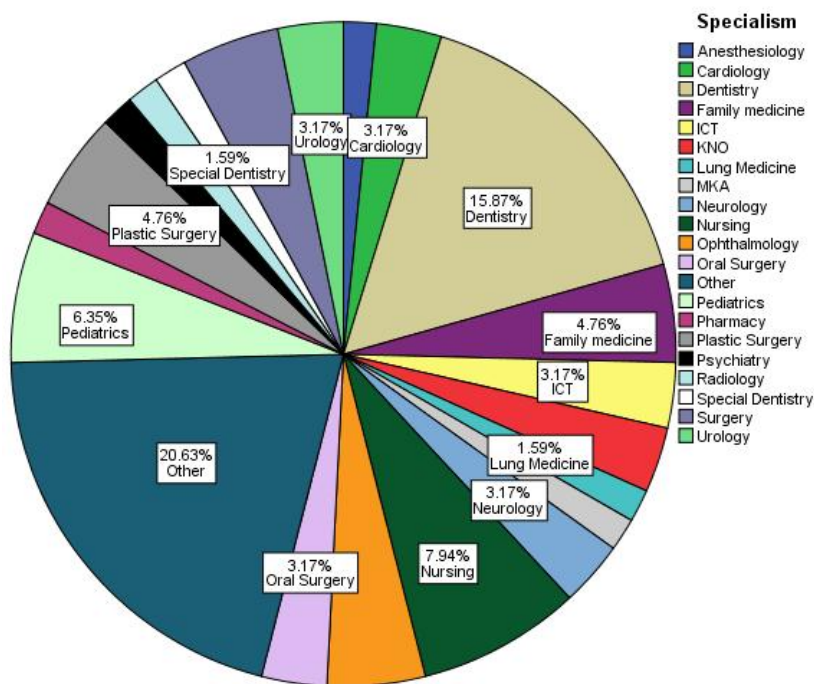


Figure 5.1: Pie diagram, medical specialities

### 5.1.1 Frequency medical exchange

In order to describe the current frequency of the exchange of medical data at different levels we have compared the means of different frequencies of exchange in different situations. After applying a normality test (to check whether the data set is well-modelled by a normal distribution or not) in SPSS, we conclude that the data has no normal distribution. In other words, we cannot assume that the data is normal distributed. For this reason, in the rest of this chapter we only apply non-normal tests and assumptions. Considering the frequency of the medical exchange, the participants could choose between 1 (less than once a month) and 3 (daily use). The total mean for the exchange of medical data within the same organizations scored highest of all (with 2.62), followed by the exchange within the own profession (with 2.19) and the exchange outside own profession (1.87). This last one could include both internal and external exchange. The current exchange of medical data at regional level had a mean of 1.67 and lowest mean number was for the exchange outside of own region (with 1.22). In other words, the current exchange of medical data takes place mostly within the same organization and same professions. Also, from the results it is clear that the regional exchange is higher than the exchange outside the region. However, looking at the standard deviations these numbers are relatively (relative to the mean numbers) high and we also need to take this into consideration.

Table 5.2: Frequency medical exchange.

Variable	Mean	Std. Deviation
<b>Frequency exchange within same organization (current)</b>	2.62	.705
<b>Frequency exchange within own profession (current)</b>	2.19	.840
<b>Frequency exchange outside own profession (current)</b>	1.87	.852
<b>Frequency exchange within same region (current)</b>	1.67	.823
<b>Frequency exchange outside region (current)</b>	1.22	.490

Comparing the outcomes from different specialities on the exchange between different organizations within the same region, we found MKA (Oral diseases, jaw and facial surgery) having highest frequency, what means on daily exchange. Followed by Neurology, Ophthalmology and surgery with a mean between 2 and 2.5, what means couple of times in a week/month. The rest of the specialities indicate to exchange medical data between different organizations in the same region less than couple of times a month. Figure K.2 of Appendix K illustrates different means for the exchange of medical data at regional level for each medical speciality. The horizontal line illustrates the total mean for frequency of exchange at regional level.

Having these results, the hypotheses explained in chapter 4 will can be tested:

**Hypothesis H-S-01:** RHIS is already active in many health provider organizations. This is somehow true, however at the same time most of the exchange takes place within the organization especially between the same medical specialities. Inter-organizational exchange at regional and inter-regional level is less frequent at this moment.

**Hypothesis H-S-02:** The exchange of medical data by some of the medical specialities is more frequent than others, depending on the type of speciality: This is true, differences between mean numbers for the exchange by different medical specialities were found (see also figure K.2).

### 5.1.2 Level of difficulty exchange

In order to understand the current difficulty (how much effort needed) for the exchange of medical data between different organizations within the same region, the specialists were asked to choose between 1 (very easy) and 5 (very difficult). They also could choose 3 for when they were not sure. At the end the average result was 2.81 what shows that most of the participants could not exactly tell the difference. This could also mean that this question was not clear enough to make a right judgement. Looking further into the details, among specialities that suffered mostly from difficulty during the exchange (mean  $\geq 3$ ) were:

- Anaesthesiology
- Cardiology
- Dentistry
- Ophthalmology
- Neurology
- Psychiatry
- Surgery

An overview of the mean numbers for the levels of difficulty are illustrated in figure K.3 of appendix K. The mean number for each medical speciality is indicated in the graph. The horizontal line illustrates the total mean for all specialities. In order to explain the difficulty of exchange for each medical speciality we can also look at the mean numbers of successful attempts for the exchange of medical data and the time it takes for each speciality to exchange data. For instance Anaesthesiology for which the difficulty is relatively high, the number of successful attempts has a mean number equal to 1. On the other side the mean for the estimated time of exchange is 4 which is close to the average mean, so this does not count so high. In other words the high level of difficulty for this specialism matches the low level of successful attempts, but not the exchange time, which is quite normal. The same pattern we see for psychiatry (figure K.4 of appendix K illustrates this). The mean numbers for the exchange time are illustrated in figure K.5 of appendix K.

To explain the relation between the variables “difficulty of exchange”, “success” and “estimated time to exchange data”, we have performed a so called reliability test (confidence level 0.95) with “Cronbach’s alpha” using SPSS program. Although we can not assume that the data is normally distributed (by using the normality test), we are still able to use this test to find out about the relation between different variables. Cronbach’s alpha is a measure of internal consistency, that is how closely related sets

of items are as a group. A “high” value of alpha is often used (along with substantive arguments and possibly other statistical measures) as evidence that the items measure an underlying (or latent) construct. In case a value close to 1 or -1 indicates that the variables are closely related and a value close to zero indicates that these variables are unrelated. In addition, to measure the internal consistency, you wish to provide an evidence that the scale in question is unidimensional, additional analyses need to be performed. Exploratory factor analysis is one of these methods that can be used to check dimensionality. Technically speaking, Cronbach’s alpha is not a statistical test - it is a coefficient of reliability (or consistency).

If we check Cronbach’s alpha for the two variables the difficulty and successful exchange we find 0.837 what means that unsuccessful attempts result in higher difficulty of exchange. The results of the Cronbach’s alpha reliability are provided in table 5.3

Table 5.3: Reliability results, Cronbach’s alpha, mean successful attempts for exchange & difficulty of exchange

<b>Reliability Statistics</b>	
<b>Cronbach’s Alpha</b>	<b>N of Items</b>
.837	2

If we check the same to find out the relation between variables the difficulty of exchange and the time it takes to exchange medical data, we find a number close to 0, what means that statistically these two variables cannot be considered related (table 5.4).

Table 5.4: Reliability results, Cronbach’s alpha, mean time of exchange & difficulty of exchange

<b>Reliability Statistics</b>	
<b>Cronbach’s Alpha</b>	<b>N of Items</b>
.151	2

Considering these results we can judge some of the earlier explained hypothesis:

**Hypothesis H-S-03:** At this moment it is quite hard to exchange medical data between different health providers. We cannot accept this, but we can also not reject it, mainly by looking at the average mean and the distribution. Most of the people could not make clear whether the difficulty is high or low. It is quite possible that other factors play an important role, which are not included in this research. (see section 5.1.2 level of difficulty).

At the same time we can also use these results to test next hypothesis:

**Hypothesis H-S-18:** The time that is needed to exchange medical data in some cases can add up to couple of days. This is true, according to the mean numbers found and 95% confidence level. In some cases as indicated earlier in this section the time even can add up to couple of days (examples: Radiology and Special Dentistry).

**Hypothesis H-S-19:** The difficulty to exchange medical data is very dependent on the medical speciality. This is true, we have also show that the difficulty of exchange depends on the number of successful attempts for the exchange of medical data and that the time does not related with this variable. All three variables: difficulty to exchange, time to exchange and the number of successful attempts depend very much on the situation and the medical speciality. In other words some medical specialities suffer more than others from the current problems of RHIE. We need to consider each case separately.

### 5.1.3 The potential for medical exchange

By analysing the reactions of different participants about the advantages we can estimate the potential for exchange of medical data at regional level. The participants were asked to choose between 1 (totally disagree) and 5 (totally agree). For a neutral answer, if the participants were not sure a number 3 could be chosen. Most of the participants reacted positively and almost all agree or completely agree with the benefits. Table 5.5 contains variables that are used to find the most important advantages of exchange (in order of their importance):

Table 5.5: Frequency medical exchange.

Variable	Mean	Std. Deviation
Exchange will improve the way I provide care	4.21	0.65
The efficiency of work process will benefit from exchange	4.16	0.74
The quality of care in general will be improved	4.11	0.72
Reducing of double medical effort	4.05	0.83
My department will benefit from exchange	3.95	0.73
My patients will benefit from this	3.94	0.80
My organization will benefit from exchange	3.92	0.76
Reducing of medical errors	3.60	0.81
Reducing costs of health care	3.38	0.81

There are differences between different specialities regarding the effect of exchange of medical data on the way care is provided by them and the quality of care. It is interesting to note that GPs, Ophthalmologists and Special Dentistry are quite neutral when it comes to the effects of exchange on providing health care. Anaesthesiology, MKA and Surgery for instance had a remarkable high mean numbers. This can be related to the amount of medical information that is needed during the pre-operative screening. However for instance the mean number of Special Dentistry is relatively low, or in other words these specialists do not consider the exchange of medical data as a factor for improvement in the care process. Figure K.6 of appendix K illustrates different mean numbers for each medical speciality. The horizontal line describes the total mean number.

**Hypothesis H-S-09:** The exchange of medical data on regional level can improve the quality of care provided by different specialists. In general this is true if we look at the averages for the effects on specific care, department and organization. Also, with an average of 3.94 the participants think that the exchange can have positive effects

for the patients. However again the results varies for each category of specialists. For instance for the Ophthalmologists, Paediatrics and Special Dentistry the exchange of medical data has no direct positive effect regarding the quality of care provided by them. For all other mentioned specialities it can improve the quality of care provided by them.

**Hypothesis H-S-10:** The efficiency of work will be improved due to medical data exchange: According to the average answers of 4.16 (agree on improvement) it will be an improvement.

**Hypothesis H-S-11:** Medical exchange at regional level will decrease the number of double medical effort: This is true; however for some this is more important than others. Especially this is important for Dentistry, MKA, Neurology, Psychiatry and Urology. This might relate to the medical data that is needed from earlier inspections, in order to prevent double tests. On the other side for Pharmacy for instance this situation is very rare. However the results for Cardiology and Lung Medicine cannot directly be described (figure K.7 appendix K).

**Hypothesis H-S-12:** Exchange of medical data can reduce the numbers of medical errors and the total costs in the health care. Most of the participants think that the exchange of medical data on regional level has less or no effect on reducing the numbers of medical errors (Mean = 3.60) and reducing the total costs (3.38). In other words the participants could not directly relate the exchange of medical data at regional level with reduce of medical errors and costs.

**Hypothesis H-S-13:** Digital exchange of medical data can create security and privacy risks: Considering the disadvantages we can look at the descriptive analyses of the frequencies for the next variables:

- It will create extra security risks
- It will create privacy risks for the patients
- The benefits of sharing medical data outweigh the risks.

About 35% of participants agree or totally agree that exchange of medical data can create privacy risks (table 5.6). 51% of the participants think that digital exchange will also create new security risks (table 5.7). In other words higher percentages were found for the security risks.

Table 5.6: Frequencies disadvantage, privacy risk

ID	Frequency	Percent	Valid Percent	Cumulative Percent
2	11	17,5	17,5	17,5
3	30	47,6	47,6	65,1
4	18	28,6	28,6	93,7
5	4	6,3	6,3	100
<b>Total</b>	<b>63</b>	<b>100</b>	<b>100</b>	

Considering the mean numbers of the disadvantages privacy and security risks, we can conclude that the security risk (Mean = 3.44, Std. Deviation = 1.01) are consid-



Table 5.7: Frequencies disadvantage, Security risk

ID	Frequency	Percent	Valid Percent	Cumulative Percent
1	2	3,2	3,2	3,2
2	9	14,3	14,3	17,5
3	20	31,7	31,7	49,2
4	23	36,5	36,5	85,7
5	9	14,3	14,3	100
<b>Total</b>	<b>63</b>	<b>100</b>	<b>100</b>	

ered relatively more important than privacy risks (Mean = 3.24, Std. Deviation = 0.81).

**Hypothesis H-S-14:** The benefits of exchange of medical data at regional level outweigh the risks: More than 65% of the participants (Mean 3.75, Std. Deviation = 0.86) think that the advantages of exchange of medical data outweigh the risks.

Table 5.8: Frequencies, the benefits vs risks RHIE

ID	Frequency	Percent	Valid Percent	Cumulative Percent
1	1	1,6	1,6	1,6
2	3	4,8	4,8	6,3
3	18	28,6	28,6	34,9
4	30	47,6	47,6	82,5
5	11	17,5	17,5	100
<b>Total</b>	<b>63</b>	<b>100</b>	<b>100</b>	

An overview of different Mean numbers for several questioned specialist are illustrated in the figure K.8 of appendix K. Considering the mean plot, Anaesthesiology, MKA, and Psychiatry see more than others the benefits of RHIE.

**Hypothesis H-S-15:** There are different needs for exchange of medical data within the same organization, within the same group of speciality or between different organizations. This is true and depends on the way specialists provide care (see also figure K.8).

**Hypothesis H-S-16:** There are remarkable differences between groups of specialists when it comes to security and privacy.

To be able to run statistical tests the data is re-categorized into three main specialisms; i.e. Surgical, Non-Surgical, and Supplementary. The first group (Surgical) includes Oral, Plastic, and general Surgery. Supplementary specialisms are ICT, Nursing, Other, Pharmacy, and Radiology. All other specialisms belong to the third category of Non-Surgical (Table K.2 appendix K).

The difference between these groups for security and privacy is not significantly important when you choose 95% as the confidential interval and using one-way ANOVA test (assuming we have normal data). The dependent variable list in this case is security and privacy risk and the factor on which it should be tested is the specialism. First,

a test of homogeneity of variances for variables Barrier-Security and Barrier-Privacy is performed (Table L.1 appendix L) This shows that only for security the Levene's Test is significant (the value under "Sig." is less than .05). However, the outcome of the ANOVA test shows that the significance is 0.6 and 0.7 that are above 0.05. In other words there are statistically no significant differences between groups. This means that you can be 95% sure that on average all specialities concern these two risks at same level. The null hypothesis is rejected. However this result is based on the assumption that the categories of data have homogeneous variances, which is the case of Privacy but not for the security. All in all, this hypothesis is rejected.

#### 5.1.4 Exchange services

During the survey the medical specialists were asked how they send the medical data of patients to other organizations within their own region. We call this part the "push data strategy". Figure K.9 and table K.3 of appendix K, illustrate the numbers for each type of exchange. It is clear that at this moment a large part of the exchange is performed using traditional tools like written/printed letters; phone and fax. Email is also one of the tools which is actively used for sending medical data to other organization. The same situation plays an important role for requesting and getting medical data from other organizations "Pull". Also, here traditional services are used in most of the cases. This is shown in figure K.10 and table K.4 of appendix K. We are now ready to test the previous mentioned hypothesis:

**Hypothesis H-S-17:** Most of the health provider's organizations use traditional tools like phone, fax and written letters to exchange medical data. This is true.

#### 5.1.5 Scenarios data exchange

As explained earlier in chapter 2 we are mostly interested in 4 different types of scenarios for organizational and inter-organizational exchange of medical data. These scenarios were:

- Scenario 1, Between different organizations within the same speciality
- Scenario 2, Between different organizations and different specialities
- Scenario 3, Between different organizations within the same speciality
- Scenario 4, Between different organization and different speciality.

the opinion of the medical specialists, about the state of these different scenarios the participants were asked to choose a level of importance (between 1 for not important at all and 5 very important). The total mean of all respondents for these variables were measured. The results are provided in table 5.9. As it is indicated in this table the exchange within the organization is the most important type of exchange. The exchange of medical data outside the region scored the lowest.

**Hypothesis H-S-07:** The exchange of medical data within the same region is more important than outside the region. This is true, we have seen that the exchange within the same region has a higher mean (3.63 against 2.92). What means that on average the participants find that the regional exchange is more important than exchange with

Table 5.9: Mean numbers and std. deviations importance, different exchange scenarios

Variable	Mean	Std. Deviation
<b>Importance exchange within the organization</b>	4,75	0,47
<b>Importance exchange within own care group</b>	4,41	0,79
<b>Importance exchange outside own care group</b>	3,63	1,11
<b>Importance exchange within the same region</b>	3,63	1,20
<b>Importance exchange outside own region</b>	2,92	1,36

other organizations outside the region.

**Hypothesis H-S-08:** The exchange of medical data between different organizations on regional level is different for each speciality. Yes, there are differences between different specialities. The highest numbers are from Family Medicine, MKA and Psychiatry. This is illustrated in figure K.11 of appendix K (the horizontal line is the total mean number for all medical specialities).

### 5.1.6 IMPORTANT DATA SOURCES

During the test the participants were questioned to vote for different data sources by choosing between 1 (not-important) to 5 (very important). To compare the outcomes for these variables, the total mean of each result can be calculated. The results are shown in table 5.10:

Table 5.10: Mean numbers and Std. deviations, Important data sources

Variable	Mean	Std. Deviation
<b>Importance data from nursing houses</b>	2,48	1,43
<b>Importance data from clinics outside own organizations</b>	3,05	1,47
<b>Importance data from other regional hospitals</b>	3,83	1,27
<b>Importance data from Radiology and Laboratory</b>	3,84	1,31
<b>Importance data from GPs</b>	4,13	1,08

The Mean plot of the importance of medical data from GPS (the most important data-source) shows us that for instance Special Dentistry is not at all interested in the data from the GPS. However Anaesthesiology, MKA, Nursing and Radiology considered this data very important (see also figure K.12 of appendix K).

An overview of specialities which voted between 3 and 5 on different sources:

- Data source nursing houses: Cardiology, Nursing, Ophthalmology, Pharmacy, Radiology, and Urology
- Data source external clinics: Anaesthesiology, Cardiology, Lung Medicine, Neurology, Plastic Surgery, Psychiatry, MKA, Nursing, Ophthalmology, Radiology, and Urology
- Data source regional hospitals: All, except Oral Surgery and Special Dentistry

- Data source Radiology and Laboratory: All, except Anaesthesiology, Ophthalmology and Special Dentistry.
- Data source GPs: All except Special Dentistry

Mentioning these results we find out that each of data source is preferred by a group of specialities, which all share the same characteristics. In other words we presume that the preferences of specialists for different data sources are somehow correlated. We can use the Pearson's correlation for this reason, which can be used to find a correlation between at least two continuous variables. The value for a Pearson's can fall between 0.00 (no correlation) and 1.00 (perfect correlation). Other factors such as group size will determine if the correlation is significant. Figure L.1 shows the correlation between different mentioned variables. It can be read that significant correlation exist between:

Table 5.11: Possible correlations between different variables

Variable 1	Variable 2
Data source nursing houses	Data source external clinics
Data source nursing houses	Data source regional hospitals
Data source external clinics	Data source regional hospitals
Data source external clinics	Data source Radiology and Laboratory
Data source external clinics	Data source GPs
Data source external clinics	External Pharmacy
Data source regional hospitals	Data source Radiology and Laboratory
Data source regional hospitals	Data source GPs
Data source regional hospitals	External Pharmacy
Data source Radiology and Laboratory	Data source GPs
Data source Radiology and Laboratory	External Pharmacy
Data source GPs	External Pharmacy

To illustrate these correlations visually let us consider the correlation between a pair consisting of high correlation. The scatter-plot of figure 5.2 shows how different data are distributed for data source GPs versus Radiology and Laboratory. An interpolation line connects the data values. From this scatter-plot we can see that if the importance for medical data from GPs grows also the importance for data from Radiology and Laboratory considered higher.

Having this information, we are able to answer the earlier mentioned hypotheses:

**Hypothesis H-S-20:** Some data sources of medical data are more popular than others. This is true; the medical data from GPs is the most preferred by the medical specialists.

**Hypothesis H-S-21:** There are differences between preferences of medical specialists for each data source. True, each speciality prefers some data sources than others. However the preferences for data sources are for some cases correlated.

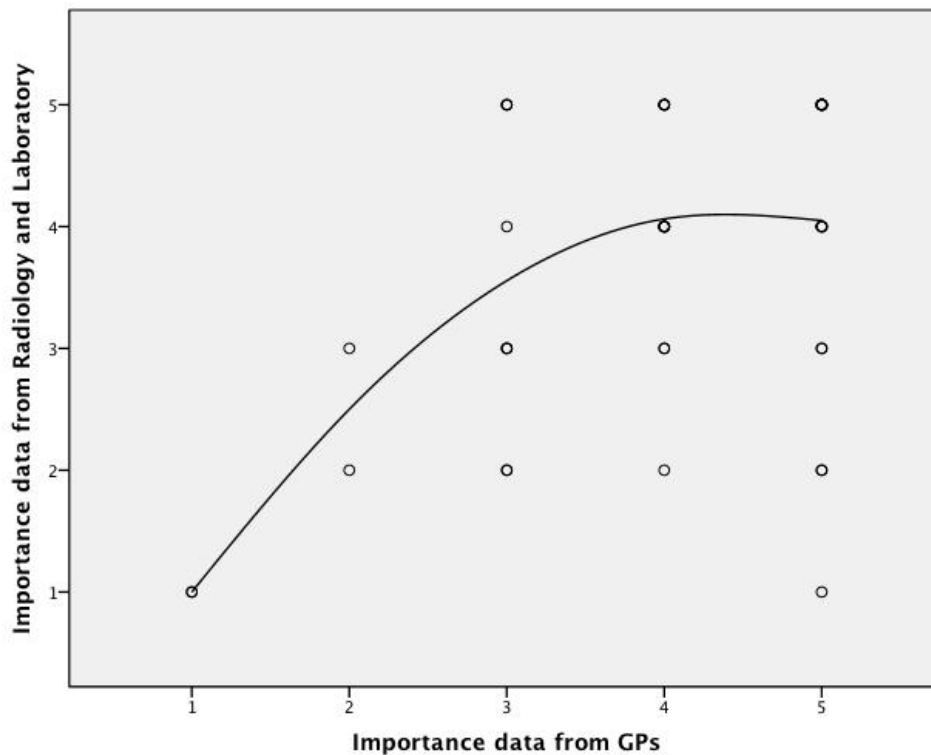


Figure 5.2: Correlation between data from GPS and Radiology & Labs

### 5.1.7 Important data for exchange

Medical data can be divided into different types, each used for other reasons. In the survey the participants are asked what types of data they consider most important for the exchange on the regional level. The results are shown in figure 5.17. In order to find the important data we use this time the median of all mean numbers (horizontal line), that provides us a more robust number than the total mean. All results above the median we consider as important data. These are Medication list, allergies, lab-results and radiology reports. All results close to the median we consider as the data which could be useful. All other data far below the line we consider as not relevant data for exchange (figure K.13 of appendix K).

However we need also to be aware that there are different needs for several types of data among the medical specialities. For instance if we see the details for Special Dentistry and compare the needs for allergies and medical devices, we find remarkable results. The mean number for importance of Special Dentistry for allergies was 1 (not important) and for the medical devices the mean was 5 (very important). This is shown in figure 5.3. The results for all medical data types are shown in figure 5.4. It is also interesting to note that the data types like allergies, medication lists, lab and radiology results, can be considered for almost all specialities as important data. These data types can be indicated as generic data, which are preferred by almost all medical specialists.

All other types of data are more gradually distributed. In other words other data than the generic data described above, need to be considered separately looking at each medical specialism.

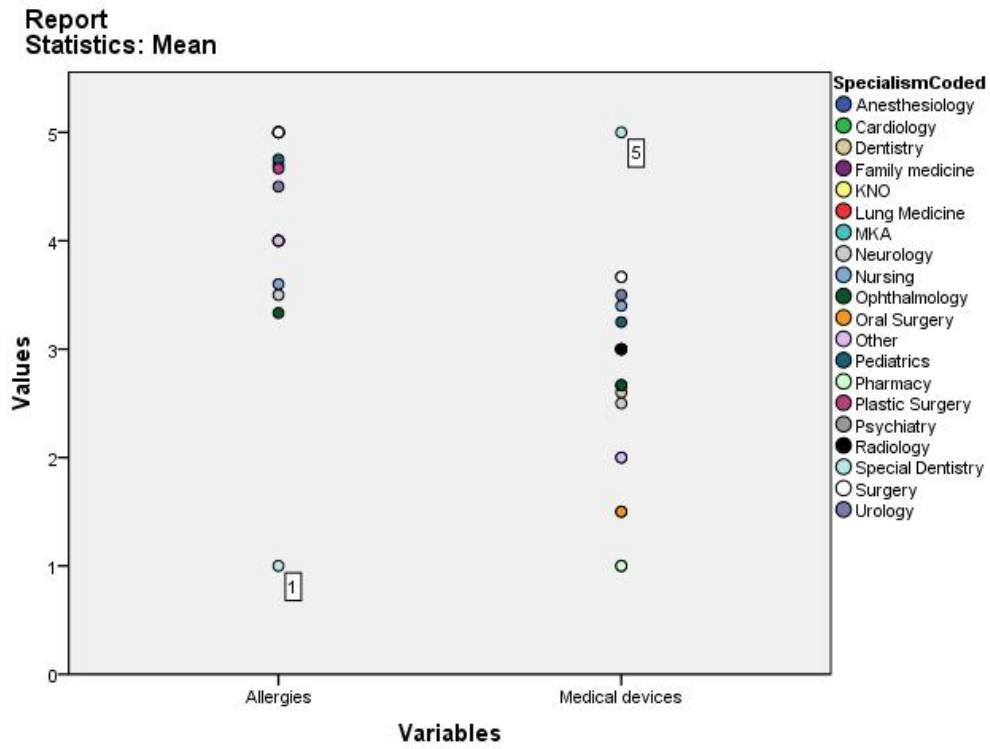


Figure 5.3: Distribution mean numbers for allergies and medical devices

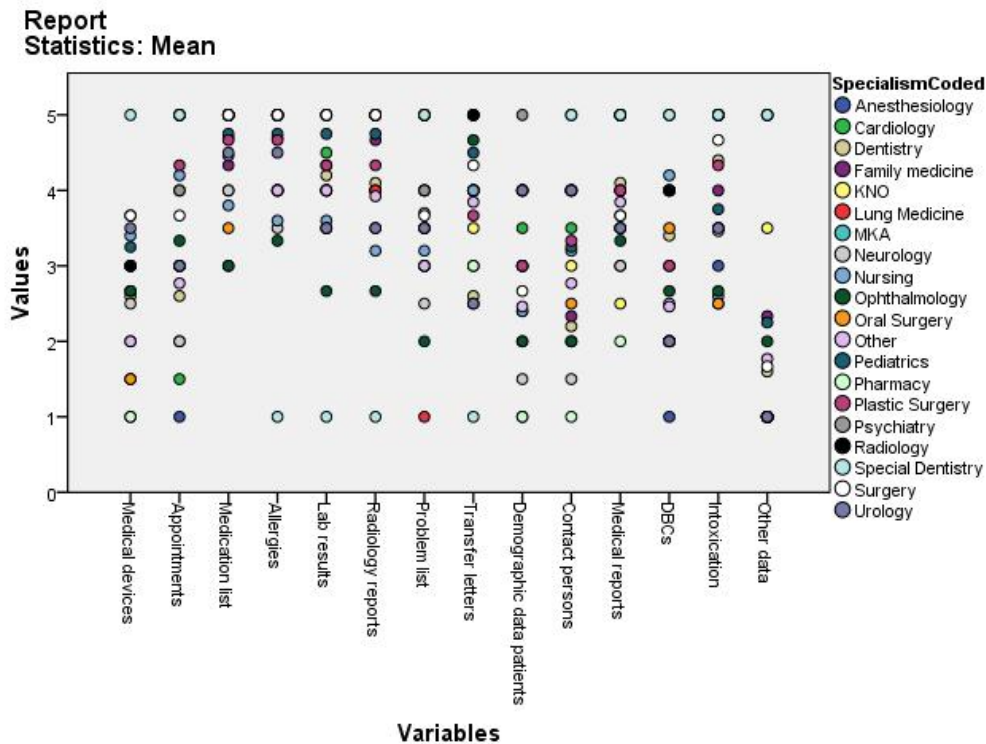


Figure 5.4: Distribution mean numbers for several data types

### 5.1.8 MAIN BARRIERS

In order to get an idea of the importance of different barriers for the development of RHIS we asked the participants about the most common barriers. Of course there might be more barriers for the development of RHIS related to the specific organization and regional plans, but because of the limitation of the time we only focus now on the most common barriers (like security, privacy...). Some of the barriers listed here were also very important during the development of the national EHR in the Netherlands. Especially the security and privacy issues were the most important ones. During the survey we have asked the participant to choose only the barriers they consider as the most important ones. In other words if a barrier is of high importance they could choose 1, otherwise the value is 0. The overview of mean numbers for different barriers are illustrated in figure 5.20. The horizontal line illustrates the median (which is more robust than the mean number). We consider all barriers that are above the line as important barriers, the barriers close to the line as moderate barriers and all others (below the line) as non-relevant (figure K.14 of appendix K).

**Hypothesis H-S-23:** Privacy and security are the main barriers of RHIS. This is true, about 81% of participants think that privacy is one the most important barriers. Also, 78% of them think that security risk is an important threat. The barrier “Different standards between the organizations” is more and less gradually distributed into two

similar groups. About 42% think that this is indeed an important barrier, 58% on the other side think that this is not the issue at all. All other barriers are closer to 0 and in other words not so important.

## 5.2 Results survey patients

In this part of the chapter the results of the patients survey are explained in more details. Also, some of the earlier explained hypotheses will be checked by testing the relations between different variables and outcomes of this questionnaire. In total 77 patients (of about 150) have filled in the questionnaire. The results described in this section related to the general (demographic) data of the patients, the advantages, risks, important data for the exchange and the control possibilities of the patients.

### 5.2.1 General information about the patients

In this section we will explain some of the results of demographic information about the patients who have filled in the questionnaire. It is tried to ask different groups of people that normally represent the estimated population. The pie charts below show the distribution of the demographic information of the patients for the age, gender, education and their living situation.

**The age of patients** The age of the patients is grouped into 4 categories. As the pie chart of figure K.15 (appendix K) shows, most of the patients asked in this survey are between 18 and 30 years, but also other groups are represented. A small group of young people (< 18 years) from the high school are also asked to answer the questions regarding the regional exchange of their medical data. All participants filled in the on-line version of the questionnaire that was send to them by email.

**Gender** About 60% of the questioned people were men and 40% women. There is no special reason for the difference and the results are random. In larger populations of course this number may differ. (figure K.16 appendix K)

**Education** Almost half of the participants had a university degree or was following one. The rest of them had a graduate diploma (Hogeschool in Dutch) or was still on college. The participant who were still on the high school (< 18 years) formed about 8% of the total population. These group of people are following a higher level of education (VWO). In general we can assume that almost all participants are relatively high educated. (figure K.17 appendix K)

**Have 1 or more Children** About 78% of the participants had no children and only 22 % had 1 or more children. (figure K.18 appendix K)

**Living situation** The living situation is divided into two main groups: The single living and non-singles (Cohabiting). About 57% of the participants are living together (with a partner or with a parent) and 43% are living alone. (figure K.19 appendix K)

**Latest visit emergency health-care department** It is important to know which of the participants have recently visited an emergency department, because in such



situations the data regarding the medical background of the patients is crucial during the treatment. The participants could choose between 1 (never), 2 (years before), 3 (months before), 4 (weeks before) and 5 (couple of days before). About 41% of the participants had never visited an emergency department before, 39% of the participants had a visit couple of years before, 16% couple of months before, 3% couple of weeks before and 1.5% couple of days before. Visiting an emergency department does not necessary means that the person self was getting a treatment. It can also happen that this person was together with others (for instance family members) who needed their company. Also, in such situations the participants can answer that they had visited the emergency department and were counted positively in the results. (figure K.20 appendix K)

**Chronic diseases** About 88% of the participants did not have a chronic disease and about 12% suffered from chronic disease. Chronic diseases are diseases that need longer treatment and in some cases cannot be cured at all during the lifetime of the patient. Examples are diabetes, aids, asthma and hart diseases. In these situations the patient needs to visit the health provider regularly. (figure K.21 appendix K)

**Heard about medical data exchange** The participants could choose between yes (1) and no (0). 85% of all participants were aware of the exchange of medical data between health providers. Only 15% of patients were not well informed about this matter. (figure K.22 appendix K)

**Frequency visit health organizations** The participants had to choose between 1 (never), 2 (every year), 3 (every month), 4 (every week) and 5 (every day). 20% of the patients had never visited a health provider, 60% once a year, 10% every month, 4% every week and 4% every day. If we consider monthly visit and higher as “frequent visit”, in total 18% of the patients are visiting a health provider frequently. If we compare this with 12% of the patients who are suffering from chronic diseases this percentage can partly be explained. The other part (6%) are probably the patients who visit a health organization frequently for other reasons (work in a health organization or for other reasons). (figure K.23 appendix K)

### 5.2.2 Advantages

In order to know the opinions of patients about the advantages of medical data exchange we have asked the patients in which degree they are aware of the advantages of RHIS. The results were as next (in decreasing order of importance):

Table 5.12: Mean numbers and Std. deviations, Important data sources

Variable	Mean	Std. Deviation
Better communication between different health providers	4.43	0.67
The necessary medical data will be available during the treatment	4.35	0.60
Easier first registration of the patients	4.04	0.93
It will improve the efficiency of the work process	4.04	0.75
It will reduce double medical effort	4.03	0.79
Easier to get repeated prescriptions	3.81	0.98
It will help prevent that the medical records of patients get lost	3.73	0.91
It will improve the quality of care in general	3.65	0.80
It will reduce the number of medical errors	3.31	0.95
It will reduce the total costs in the health-care	3.31	0.99

Figure K.24 (appendix K) illustrates the mean numbers of different the advantages of RHIE in a mean graph. The horizontal line describes the median of all mean numbers. We consider all advantages of same importance (except the last three, which are considered as less important). As you can see in the list provided above, better communication (95% agree or completely agree), availability of data during treatment (93% agree or completely agree), easier first registration (78% agree or completely agree) and improve of efficiency of work (78% agree or completely agree) are on the top in this list. If we compare some of these results with the answers of the specialists we see that a mean number of 4.04 of the patients for the advantage of improvement of efficiency of work process is almost the same as the average given by the specialists (4.06). The patients agreed or completely agreed (about 82%) that the medical data exchange will improve the efficiency of work process of the health providers. This was comparable with results of the medical specialists (about 79%). Also, the averages of the double medical effort were quite similar (4.03 of the patients against 4.04 by the specialists). We see the same pattern also for the number of medical errors and reduce of costs (exactly in the same order).

In other words we can conclude that the specialists and patients have large similarities regarding their viewpoints on the advantages of medical data exchange. However a mean number of 4.18 and std. deviation of 0.96 was provided by the patients for whether they think the benefits of medical data exchange outweighs its risks. This number is lower for the medical specialists (3.67, see previous section). This means that the patients are more positive about RHIS, considering the advantages and its risks.

At this moment we are able to test some of the hypotheses which are described earlier:

**Hypothesis H-P-01:** The patients that visit health providers more often (or who need more frequent care), are supporting RHIS more than the patients who need less health care. To answer this question we can test whether there are significant differences on the benefit level based on the frequency of visit at the health organizations. We use the k-independent non-parametric test because we cannot assume that the data is normal distributed. Furthermore the Kruskal-Wallis test and the exact tests are used to find out the significance of the results. As you can see in the test statistics table below (figure L.2 appendix L), the significance is below 0.05. Based on 95% confidence level, this means that there are significantly important difference between the groups. When comparing the means of the results whether “the patients see the benefit of RHIS” and the “frequency of visit” we discover that it is not true that a larger frequency of visiting health organizations leads to higher results of seeing the benefits. However patients who are suffering from chronic diseases show a more clear increase in seeing the benefits of RHIS (figure 5.5 and 5.6).

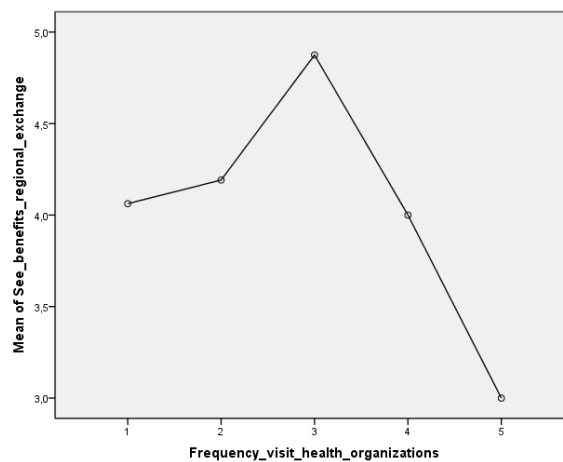


Figure 5.5: Correlations frequency of visit health organizations and see benefits RHIE

**Hypothesis H-P-02:** The patients are aware of the fact that RHIS will improve the communication between different health providers. Yes, this is true. About 95% agreed or completely agreed with this statement.

**Hypothesis H-P-03:** The patients think that RHIS can improve the accessibility to patient’s medical data. Yes, about 93% of the patients agreed or completely agreed that the exchange of medical data at regional level will help to improve the availability of medical data during the treatment.

**Hypothesis H-P-04:** The patients are aware of all other possibilities and advantages of RHIS. No, The average of the participants of this survey answered neutral or positive on the advantages of RHIS. None of the asked advantages scored with an

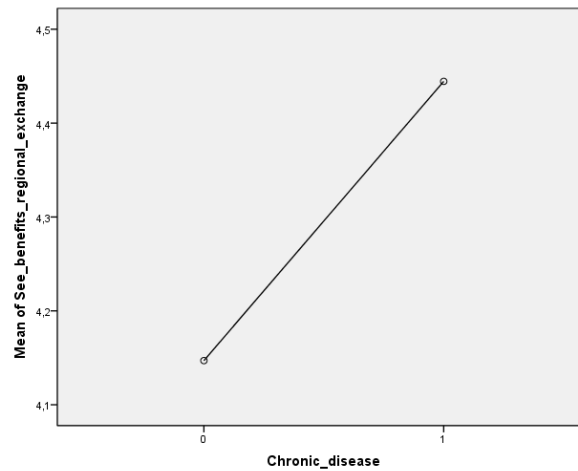


Figure 5.6: Correlations having chronic diseases and see benefits rhie

average of lower than 3 (what stands for a neutral answer).

### 5.2.3 Risks

In this survey we have also investigated the risks of RHIS by asking the patients how much they agree on importance of different risks. Below is an overview of the results (in order of importance):

Table 5.13: Mean numbers and Std. deviations, Important data sources

Variable	Mean	Std.Deviation
I worry that my private data will come in the hands of “third parties”	3.84	0.96
I worry that my private data are made public because of low security of the systems	3.74	1.14
The benefits of RHIS outweigh the risks	3.61	0.96
RHIS will cause extra security for my medical records	3.68	1.00
RHIS will cause privacy risks	3.45	1.10
I am also concerned about the security of “paper” medical records	3.43	1.06
Too much security would be able make it unnecessarily difficult	3.27	1.12

These results are also illustrated in the figure K.25 of appendix K. The horizontal line illustrates the median of all mean numbers. The patient were also asked whether they agree that too much security would make it unnecessarily difficult for the care-givers to access the appropriate medical records. The patients answered with an mean of 3.27. In other words they were quite neutral to this questions (50% of participants agreed). However as explained earlier we had also found an average of 3.61 for the statement whether the benefits of RHIS outweigh the risks. This is about 50% of all patients; the other 50% are quite worried about the risks.

**Hypothesis H-P-05:** The patients are worried about the security and privacy risks of RHIS. This is true, however the results on averages for all risks are between 3 (neutral) and 4 (agree). To be more exact only 25% of the patients agreed or totally agreed that they are worried that their private data will become in the hands of the “third parties”. About 32% agree or totally agreed that their private data can be made public because of the low security measures of the current systems. In other words larger number of people were not completely sure about the consequences or did not worry at all. If we compare this with the outcomes of the specialists survey we see that the specialists are more worried about the security and privacy than the patients.

**Hypothesis H-P-06:** The patients are also worried about the security and privacy risks involved with the traditional services. We see that about 50% of all participants were neutral or disagreed with the risks of the traditional services like printed transfer of medical documents. The other 50% agreed or totally agreed that they are also worried about the traditional services. So the results are quite equally distributed in two different groups (see also figure K.26 of appendix K).

**Hypothesis H-P-07:** According to the patients the advantages of RHIS outweigh its risks. Yes, about 57% of the participants agree or totally agree with this statement. Only 13% disagree or totally disagree. The rest of the people (about 30%) are neutral (see also figure K.27 of appendix K).

**Hypothesis H-P-08:** There exists a correlation between the benefits and risks. Investigating the correlations between benefits, risks and disadvantages (see correlation table of figure K.28 of appendix K), the conclusions are as next:

- If the patients see the benefits of regional data exchange they also agree that the benefits of sharing outweigh the risks.
- Most of the patients who worry about their private medical data see also less benefits of RHIS.
- The patients that believe too much security can lead to negative contra-effects, are at the same time more aware of the benefits of RHIS.
- The patients, who think that the benefits outweigh the risks, see its benefits as well. At the same time the same group also disagrees more with the statement that third parties might access private data of the patients, but also think that too much security can have negative effects.

**Hypothesis H-P-09:** Patients who suffer from chronic diseases are less worried about their private medical data. We see a difference between the patients suffering from chronic diseases and how worried patients are regarding access to the private data. There is a clear decrease of this worry when the patient is suffering from chronic diseases. Often these kind of patients are mostly suffering from the problems created due to the lack of possibilities for the exchange of medical data. We have also used a non-parametric 2-independent samples test (making use of Mann-Whitney) for checking the significance of the difference between the means. The found significance 0.034 and 1.017 which are below 0.05, mean that we can be 95% sure that there is a significant difference (or in other words these two variables are related). See also the results of the tests in figure L.3 of appendix L (MANN-WHTNEY test) and 5.7.

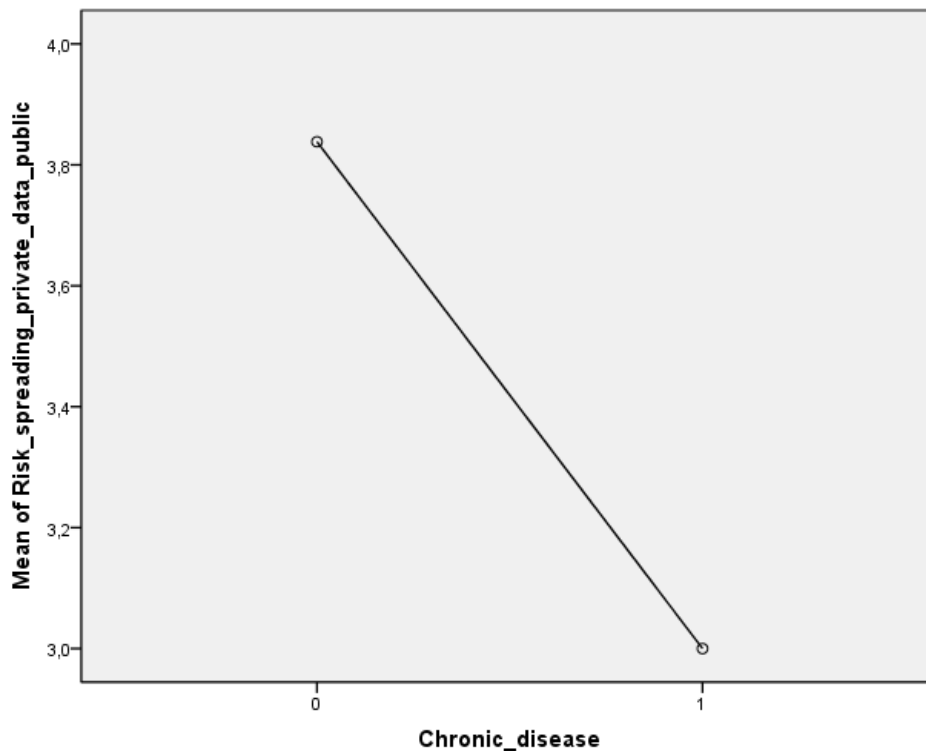


Figure 5.7: correlation suffering from chronic diseases and agree with, risk spreading private data in public

### 5.2.4 Important data for exchange

The same list of the important data for exchange as we have shown earlier in the medical specialists survey is now also shown for the patients. The patients are asked what types of data they think are most important for the exchange between several organizations on the regional level. The results in order of decreasing mean numbers are as next (1 stands for not useful and 5 for most useful):

Table 5.14: Mean numbers and Std. deviations, Important data sources

Variable	Mean	Std.Deviation
Allergies	4.55	0.55
Medication list	4.38	0.62
Lab results	4.30	0.77
Radiology reports	3.30	0.72
Medical reports	4.03	0.88
DBC's	4.03	0.87
Medical devices, scale	4.00	0.88
Intoxication	3.95	0.98
Problem list, scale	3.95	0.85
Transfer letters	3.83	0.88
Appointments, scale	3.78	0.95
Contact persons	3.69	0.93
Demographic data patients	3.60	1.07
Other data	3.42	0.90

These results are also shown in the line diagram of figure K.29 appendix K. The horizontal line illustrates the median of the mean numbers. We consider all medical data that scored above this line as important types of data for exchange (according to the patients). Again similar to the answers of the specialists the medication list and allergies are top data for exchange. However in general the patients reacted more positively on the importance of different medical data reflected into higher mean numbers for several variables.

### 5.2.5 Control level patients

Regarding the possibility to provide control to the patients to access their own medical data, next statements have been investigated. The results are provided in the list below (in order of importance):

1. Patients should be able to look back which entities had access to their personal health data (Mean = 4.62, Std. Deviation = 0.62). This is about 95%.
2. The patients think it is important to be clearly informed about how their health information may be used or shared (Mean = 4.61, Std. Deviation = 0.61). This is about 96% of the participants agreed or totally agreed with this statement.
3. Patient must be able to decide whether the medical data can be shared with other parties (e.g. family, friends, employers, insurance companies, scientific research

- ...) (Mean = 4.55, Std. Deviation = 0.66). About 93% of all participants agreed or totally agreed.
4. Patient must be able to decide whether or not share the medical data with other health care providers within the region (Mean = 4.31, Std. Deviation = 0.79). 89% of all participants agreed or totally agreed with this statement.
  5. Patient must be capable to decide per data type whether or not share the medical data (for instance the referral letters yes, but not the medication list), (Mean=3.92, Std. Deviation = 1.09). About 80% of all participants agree or totally agree with this statement.
  6. Patient must be able to decide whether the medical data can be shared with some specific medical specialist (Mean = 3.86, Std. Deviation = 1.07). About 73% of all participants agreed or totally agreed with this statement.
  7. Patient must be able to decide whether the medical data can be shared with other specific health organizations (Mean = 3.84, Std. Deviation = 1.08). About 70% of all participants agreed or totally agreed with this statement.
  8. Patient must be able to decide whether the medical data should be exchanged using an electronic or a printed version (Mean = 3.08, Std. Deviation = 1.37). Only 42% of all participants agreed or totally agreed with this statement.

Clearly most of the patients would like to have more control and access to their private medical data and decide with whom the data can be shared. However smaller part of the patients think it is important to be able to choose between printed or digital versions of the exchange.



### 5.3 Results of the interviews

In this section we will explain some important outcomes of the interviews with the consultants of the IT supplier, who is represented in almost 50% of all hospitals in the Netherlands. During the interviews the consultants were asked about the existing problems regarding the exchange of medical data at regional level. They were also asked about the reasons why they think these problems haven't been solved earlier. The consultants are asked to report one or more main requirements for RHIS.

*Are any of your clients suffering from the problems related to the exchange of medical data at regional level?*

Most of the consultants believe that there are several problems at this moment related to the exchange of medical data at regional level. Some of these clients have already asked for a possible solution in order to solve these problems. However there are different types of situations and health organizations, according to the consultants. These are some of the possible scenarios mentioned by the experts:

- Partnerships across different hospitals (in Dutch Maatschappen): Different health organizations that work together on specific areas of care. In some situations the medical specialists are working in different organizations and need to access the medical data of the patients in different hospitals. Also the patients need to visit these different organizations for several medical tests and treatments. One of the examples of such corporation is between the Westfriesgasthuis (WFG) hospital which is located in Hoorn, Enkhuizen, Heerhugowaard and the Zaans Medisch Centrum (ZMC) located in Zaandam.
- Integrated care (in Dutch ketenzorg): Different types of organizations are working closely together in order to provide different types of "chained" care. We "chained care" we mean the types of care, which is provided separately in the past, but because of several organizational reasons these organizations decided to work closely together. Improving the efficiency of work, better communications, specialization and reducing costs are some of the main reasons for the exchange of data. Some examples are the corporation between the hospitals and after-care (nursing houses, home care). Due to the aging problem especially in the north and southern parts of the Netherlands this type of corporation is becoming very popular.
- Specialized health provider organizations: In some situation different organizations of the same specialism need to exchange vital medical data of the patients. Normally this includes smaller scaled health provider organizations like revalidation centres or individual clinics.
- Cross-regional exchange: Some organizations, which are located in different locations in the same or outside the region need to exchange medical data between each other. One of the examples is the Kempenhaeghe expert centres for epileptology, sleep medicine and neurology. Other examples are the centres specialized in treatment of other chronic diseases like diabetes. In some cases one or more of these centres are connected through a regional network like OZIS

with other hospitals in the same region. In other cases however these centres are working individual and are not connected to others.

**Other existing problems:**

Some of the other existing problems relate to the lack of possibilities for efficient, fast and reliable exchange of medical data. Beside these shortcomings the current situation can cause different security problems. According to one of the interviewed experts a large part of the exchange today is performed using email services. This expert explains that “today a large part of sensitive medical data is sent by email messages. At the same time it is widely known that this type of communication might also cause security damages”. According to this consultant, “we all know that using email is not safe, but we do it because it is at this moment the easiest way.”

Another consultant explains that it is at this moment quite difficult to send or acquire data between different health provider organizations. “Sending a transfer letter between the GP and the hospitals is not the problem, but that exchanging all other data is far more difficult”, explains the consultant. Different barriers play an important role, including the permission level settings and the interest to provide internal medical data to the outside world.

***What is the average size of the hospitals, which are suffering from these problems?***

The health provider organizations can have different sizes from relatively small regional clinics +/- 20 employees, to large hospitals with more than 1200 beds. However the types of the problems and needs for the exchange of data is also related to the size of these organization.

***Is there a specific medical speciality that can be pointed as the focus problem area?***

The account managers mention different specialisms, but in general in most cases the medical specialities related to the chronic diseases can be pointed out as the “red zones”. These specialisms need to exchange medical data more often, because of the frequently visit by the patients and the complexity of these diseases. Another examples are heart and vascular diseases and diabetes.

***What is in your opinion the reason that it has not been solved earlier?***

There are several reasons according to the consultants, which have made these problems hard to solve. “One of these reasons is the high initiation costs to join the regional networks. Especially the smaller health provider organizations are suffering from this problem. Economically it is not attractive enough to join regional networks, because of the high initiating costs”.

Other mentioned problems are related to the lack of standards for the exchange of medical data. “This problem is seen as one of the important barriers to create exchange networks”. Health provider organizations make use of different systems each having another interpretations of medical data. In some cases it can even be dangerous to take over different variables from different external systems. For example the variable smoking cigarettes which can have a value “yes or no” can have different meanings in several EHR systems. In one system this might mean that a person is smoking

regularly and that this person is a frequent smoker and in the other system this might be interpreted as a person who has ever smoked a cigarette. Taking over the same variables from one medical record to another can have negative effects on the medical judgements of health providers. Many other inconsistencies and interpretations might exist in these systems. A clear and consistent representation standard is needed to translate medical data variables from one system to another. NICTIZ [30] the governmental organization has tried to create different standards from the top level at the national level in the Netherlands. However different consultants think that NICTIZ has not enough put enough attention into the real need of different medical specialities. In other words the made standards are too much “top-down” implemented and in many cases these standards cannot be used by these organizations.

Other problems are referred to the lack of initiative by these organizations. “It is not clear who has to take the initiative and the responsibility to create and adapt the standards, but also start developing these systems” explains one of the consultants. Often especially larger hospitals like the university medical centres are very conservative in providing outsiders information about their existing technical solutions and problems.

Another reason why until now some of these problems could not be solved is due to the lack of knowledge about the existing solutions and the possibilities. In some cases the problem owners are not enough informed about the technical details of several problems and solutions.

***Do you think that existing solutions like OZIS and Edifact can help these organizations? Which ones can't be helped and what is the reason?***

“In practice Edifact does not provide enough possibilities to exchange all types of medical data. This is because of the limitations of Edifact in providing an easy customizable transfer files. It is relatively hard to adapt the existing schemas for the transfer of medical data. Also, it does not provide the possibility to exchange all kind of medical attached documents”, explains one of the consultants.

One of the drawbacks of OZIS is the high initiation cost, which makes it quite unattractive for smaller scaled organizations. Also, it does not provide enough support for different types of medical data and is incapable to exchange data cross regional. In other cases a more specific solution is needed between different cooperating organizations.

***Can you mention one or more requirements, which are applicable to all these different situations?***

- In all cases the consultants agree that high security is one of the important requirements. The developed system must guaranty the privacy of patients and should be in line with all national regulations.
- Most of the consultants also mention that in most cases the medical specialists prefer to access the complete medical record of a patient. In other words it should be able to provide access to specific or all parts of medical records if needed. However emphasis should be on the possibility to exchange medication, allergies and a short medical history.

- It should be possible to take over specific parts of the medical records from other organizations. This is because in some cases the specialist can decide to take over the medical data. For instance if this data might cause medical mistakes, the specialists should be able to reject the data.
- Another requirement mentioned by the consultant is the exchange time (in other words it should be possible to exchange medical data within a relatively short time).
- It should make use of uniform open source standards.
- Patient should have access to their own data and must be able to control the exchange of medical data. The patient should also be the owner of the medical data.
- Authorization and authentication should be arranged properly.
- The development costs should be relatively low.

*Can you mention some examples of the data that almost in all these cases need to be exchanged between different organizations?*

Almost all consultants emphasize the importance to exchange of the medication list, allergies and the recent medical history. Others think that it should be possible to exchange specific parts or in some cases the complete medical records.

## 5.4 Results - document analysis

As explained earlier during this step a database of the supplier of EHR systems (Chip-Soft B.V.) is analysed, for the past three years (2010, 2011, 2012). Only the requests related with cross-organizational regional exchange of medical data were investigated. Some of the general requirements related to the RHIS found in these documents are summarized in appendix L.05. Please refer to this appendix for more details.

### Summary

This chapter explained the results of the surveys among important users, the interviews with the experts and finally the results of the document analysis. The results (raw data) are imported into a statistical program called SPSS, for further analysis. After performing a normality test and the fact that the data was not normal distributed, in some parts non-parametric tests were applied to check the significance of difference between different results.

**Some of the interesting results from the medical specialists survey are as follows:**

- The exchange of medical data occurs mostly within the organizational borders and least on the national level.
- Regional exchange of medical data by some of the medical specialities is more frequent than others, depending on the type of speciality

- The difficulty of the exchange of medical data is experienced differently by each group of medical speciality. The difficulty level has a higher correlation with the number of successful attempts than with the total exchange time.
- Medical specialists agree on the advantages of RHIS regarding improving quality of care, efficiency and reducing double efforts. They however disagree that RHIS will decrease the number of medical errors.
- Security followed by privacy is seen as the most important barrier of RHIS. About 35% of participants agree or totally agree that exchange of medical data can create privacy risks (table 5.5). 51% of the participants think that digital exchange will also create new security risks
- The benefits of exchange of medical data at regional level outweigh the risks: More than 65% of the participants (mean 3.67) think that the advantages of exchange of medical data outweigh the risks.
- There are different needs for exchange of medical data within the same organization, within the same group of speciality or between different organizations.
- Still a large part of exchange goes through traditional services like phone, fax, email etc.
- Some data sources of medical data are more popular than others. For instance the medical data from GPs is the most preferred by the medical specialists.
- There are differences between preferences of medical specialists for each data source. Each speciality prefers different data sources. However the preferences for data sources are for some cases correlated.
- Medication data, allergies and lab-results can be considered as generic data (important for almost all specialisms). For all other types of data we need to study each medical speciality separately.

**Some of the interesting results from the patients survey are as follow:**

- About 41% of the participants had never visited an emergency department before, 39% of the participants had a visit couple of years before, 16% couple of months before, 3% couple of weeks before and 1.5% couple of days before.
- The patients see better communication between health providers and the availability of medical data during the treatment as the most important advantages of RHIS.
- Frequency of “visiting health organizations” and “suffering from chronic diseases” are correlated with frequencies of “see benefits of RHIE”.
- The patients are also worried about the security and privacy risks, but less worried than the medical specialists.
- According to the patients the advantages of RHIS outweigh its risks. About 57% of the participants agree or totally agree with this statement.

- Patients who suffer from chronic diseases are less worried about their private medical data.
- Medication data, allergies and lab-results can be considered as generic data. This is comparable with the answers of the medical specialists.
- Most of the patients would like to have more control and access to their private medical data and decide with whom the data can be shared. However smaller part of the patients think it is important to be able to choose between printed or digital versions of the exchange.. Only 42% of all participants agreed or totally agreed with this last statement.

**Some of the interesting results from the interviews with the IT-consultants are as follow:**

From the interviews we can conclude that in general regional exchange of medical data can be divided into partnerships across different hospitals, integrated care, specialized health organizations and cross-regional exchange. Other important conclusions are regarding the size of the health organizations which can differ from small size to large hospitals with approximately 1200 beds. According to the experts medical specialists who are dealing with chronic diseases (like diabetes and hart diseases) are considered as the important users of RHIS. This is because they often need to exchange medical data. The current technical solutions do not provide enough possibilities to solve the existing problems. For instance EDIFACT because of its limited support for complex data, OZIS for its high initiation cost (especially important for smaller organizations) and email communication because of the high security risks that are involved with it. The consultants also emphasize the importance of universal standards, high security, proper authentication and authorization, as some of the important requirements.

**Some of the interesting results from the document analysis are as follow:**

The clients of the IT-supplier prefer almost in all documents the universal or open standards. The requirements that are related to the vendor, emphasize the reliability of the vendor (experience, previous projects), long term contracts and 24 hours support by the supplier. Also, some of the requirements were regarding the consistency of code and the coupling possibilities for the existing software solutions. It is important that new software solutions can easily be connected to the existing legacy systems.

## Chapter 6

---

# REQUIREMENTS ANALYSIS & SPECIFICATION

### Overview

In this chapter the business goals, areas of concern, the list of constraints and the requirements are explained in more details.

The results of the previous chapters such as the results from stakeholders analysis and the elicitation methods are used as input in this chapter. Some of these results are used to create requirements, while others are used to gather the constraints or even support the business goals.

#### **At the end of this chapter you will have an overview of the following:**

- Important business goals for developing regional medical data exchange systems.
- Core characteristics of changes (desired situation)
- Area's of concern (constraints)
- Explanation why RHIS can also be considered as a multi-actor problem.
- User roles and functionalities
- Several important use-cases (to explain some of the common functionalities)
- List of functional requirements
- List of non-functional requirements

## 6.1 Requirements analysis

### 6.1.1 Business goals

Regional health information systems (RHIS) are seen as one of the important building blocks in creating collaborative networks of health organizations. During the interviews we have discovered that there is still a high need for the exchange of medical data among different health organizations. These corporations can often be categorized in next situations:

- Partnerships across different hospitals (in Dutch Maatschappen),
- Integrated care (in Dutch Ketenzorg),
- Specialized health provider organizations,
- Cross-regional exchange (distributed organizations over different locations).

There are different reasons for coupling separated health organization into a network of corporative units. In the ext paragraphs we will explain some of the important reasons for the exchange of medical data at regional level:

**Assistance in the care as a corporative tool.** At this moment it often happens that a patients who is transferred from one health organization to the next for further treatment needs to contact these organizations separately. This means extra effort for the patients, but also for the organizations that are involved. Also because of the lack of coordination and collaboration between these organization, it often happens that the patients need to wait for a long time before a treatment can start. Sharing appointments data can help to plan much more efficiently, by these organizations. In other cases (for instance partnerships or integrated care) by proper corporation between different health organizations the scarce tools, facilities and the specialists can be shared in much more efficient way. Making medical data of patients available on different corporation health organization makes it possible for the patients to freely move between different locations. In other words the patients can get treatment in a more dynamic way. At the same time this helps the health organizations to be more efficient and flexible for providing health services to their patients.

**Easier access to medical data during treatment:** Medical data like medication, allergies and recent medical history are important for providing health care services to the patients. This can be more important for some departments like the emergency department where it is crucial to have fast and easy access to the medical data of the patients. The access to the medical data of the patients suffering from chronic diseases is also an important one. In earlier chapter (5, patients survey) we have seen remarkable proofs for high potential of medical exchange in case of patients with chronic diseases.

**Case specific improvements:** for instance the prediction of some specific diseases due to better share of knowledge among different organizations. The prediction of pancreatic cancer diseases is one of these examples. There are also other examples related



to chronic diseases like heart diseases and diabetes.

**Improving the efficiency of work:** At this moment in almost all health organizations the patients need to be registered separately. In many cases the patient needs to provide a copy of the medical history that needs to be re-typed or scanned into the system. In some cases it is hard to find the proper information because of different standards used or the format in which the data is saved. In other words it takes a lot of time and effort to translated these data into the system. Beside these often different health providers need first to request the medical data of the patients from other external health providers. As we have seen in the results of the specialists survey until now in many cases this is still done using the traditional services like phone, fax and written letters. This costs a lot of effort and in some cases (depending on the speciality) it can take many days, weeks or months before the requested medical data are received. The exchange of medical data at regional level can help to improve these situations.

**Reduce of double medical effort:** In many cases it happens that lab tests or other treatment need to be redone, simply because the medical results are not available at the time of treatment. This brings extra costs for the organizations and eventually for the patients. At this moment, the most common type of the exchange of medical data is within the same organization or within the same care group (see specialists survey). This is partly because the health providers can make use of the same EHR system within the organization. However if it is easier to exchange medical data between different health organizations within the same region, the health providers are more willing to share their data for the relevant cases (providing care to the same patients).

**Reduce of the medical errors:** At this moment the patients are often rechecked for allergies and need to fill in several questions regarding their recent medication, unless the patient is able to provide them this information beforehand. This is not always possible, for instance during an emergency visit or when visiting a GPs post in the weekend. Most of the times the patients are asked to later visit their own GP during the usual working hours for an extra check, simply because these specialists are missing vital information about the medical history of the patients or because of the missing test results. The availability of the relevant medical data at the right place can prevent medical errors due to availability of vital information and make the specialist's effort less.

**Saving costs due to gained efficiency:** As explained earlier we can prevent unnecessary double effort, when having access to the medical data of the patients from other cooperating organizations. Less effort by employees might eventually lead to less needed resources (manpower and other medical facilities) and thus decrease costs.

**Improve security:** As indicated by the consultants (see chapter 5) at this moment many organizations these days make use of insecure email communication to exchange medical data of the patients. In theory this might never happen, but in practice according to the consultants this is one the most used communication methods (see also results specialists survey). Hackers, spoofer and other unseen evil-doers are lurking behind almost every router on the Internet scanning email communication. Email

communication is not as secure as often is thought, because it is possible to read them on the electronic route from a sender to a receiver. Patient-identifiable information are not always encrypted in these cases and very sensitive for any harm. Making use of more secure technology instead of the current used ones, can help improve these existing situations for saved exchange of medical data.

### **Health service orchestration**

In general considering the four common cases for corporation between health organizations explained above improving the current problems are part of a much “bigger process”. In fact this bigger process is the orchestration of health services. Usually the orchestration of services consist of three growth stages:

1. Message integration: bilateral information exchange,
2. Process integration: exchange of status, control and management information,
3. Process orchestration: closely collaborating by sharing resources and expertise and understanding each other processes. Beside these the process orchestration is about (shared) control of the cross-organizational processes.

### **Bottom-up development**

The improvement of existing RHIS and development of new successful networks of corporative health organizations needs a bottom-up approach instead of a top-down one as it was applied during the developments of the national EHR. In the old situation (national EHR), NICTIZ [30] has created different standards for the exchange of medical data. At the same time many regional organizations criticized this approach, because it had less attention to all the specific cases in the practice. For example not all organizations needed to exchange the medication list of the patients. Several organizations needed to exchange different data types as it was prescribed by AORTA [29]. Also the standards did not always comply with the ones used at regional level, resulting into different problems for these organizations. Another example is the willingness of GPs to share the medical data of their patients with other health providers in the country. This created a situation where minimum amount of medical data is shared via the national switch (LSP), despite the fact that large numbers of organizations are connected with this service. A bottom-up approach that takes into account the case specific problems, can be more successful in development of such systems.

### **Empowered Patients**

As we have already discussed in chapter 3 (stakeholders analysis) the patients are included in the group of stakeholders with relatively low power. However providing the patients more power in controlling their own health records can help us to reduce some of the complexities related to the privacy issues. Beside this the Dutch law obligates the health provider organizations to officially ask the patients for their permission regarding the exchange of the medical data (see areas of concern privacy). By empowering the patients we can shift some of the responsibilities toward the patients. Also, the patients in general are very positive regarding their role in which they have

more responsibility over their own medical records (we have seen this in the results of the patients survey). By providing more responsibility to the patients at the same we accomplish more satisfaction among the patients and improved the quality of health service by a shift from “passive” into more “participative” patients who are more involved in their own health care process. Also different interest groups of the patients and the specialists are supporting this idea (see stakeholder analysis, interviews consultants, chapter 3 and chapter 5).

### **6.1.2 Core characteristics of changes**

In table 6.1 we summarize some of the project (development of RHIS) goals by explaining the old and new situation (desired):

Table 6.1: Core characteristics of changes

<b>Old situation</b>	<b>Desired situation</b>
Isolated regional health organization	Cooperating network of regional health organizations
Lack of tools for collaboration between the organizations	The new tools help the health organization in planning and efficient use of available medical resources
Relatively difficult to access medical data of the patients during the treatment	It is easier to send and request medical data to other health organizations
A copy of the medical data of the patients is transferred between health organizations which needs to be scanned or manually translated into the new system.	Automatic transfer of medical data guaranteeing the consistency of data. The efficiency of exchanging medical data has improved.
The patient needs a new registration when visiting a new health organization. This means extra effort for the patients and the staff.	A new registration is not needed, if the patient is already registered in a partner organization in the same area.
Double medical tests are needed because of the lack of access to existing results to previous tests.	If medical results are available, these data can be reused and extra repeated tests won't be needed any more.
Medical errors due to lack of access to the existing medication lists, allergies, intoxication and other recent medical history.	The availability of previous medical records can help the health providers to provide better diagnoses and treatment. (We cannot conclude that the quality of care is improved, more research is needed, see also survey specialists, chapter 5).
Extra costs due to extra effort (translation medical data, re-enter data, new registrations and medical tests )	Costs can be saved making sufficient use of tools available for exchange of medical data.
Making use of unsafe email communication and other traditional services	The use of unsafe email communication is avoided, translating current services into more secure communication methods.
Separated health care services (the patients transferred from one health organization to other for further treatment)	Orchestrated health services (integrated processes and process orchestration)
Top-down development (for instance LSP and the national EHR)	Bottom-up development (considering the specific needs of regional health organization)
Patients are asked for permission to exchange data (by signing a confirmation letter), no or small responsibility for exchange	Patients are in charge. The patients keeps track of their own health records and can control the exchange of their medical data.

### 6.1.3 Areas of concern

During the interviews, surveys, document analysis and the stakeholders analysis a number of areas of concern have been identified. In this chapter we will explain some of the important areas of concern. In fact the areas of concern are comparable with the constraints regarding the exchange of medical data at regional level. Constraints pose restrictions on the acceptable solution options. Technical and business constraints pose restrictions on the design of a system or the process by which a system is developed. They do not affect the external behavior of the system, but they must be fulfilled to meet technical, business, or contractual obligations. In general we can divide constraints into two different types:

1. Business constraints (examples costs, law and regulation, organizational, support)
2. Technical constraints (for instance standards, preferred technical solutions)

**Design constraints typically originate from one of the next three sources:**

- Restriction of design options (e.g., use a specific authentication system and not making use of insecure communication)
- Conditions imposed on the development process (often based on existing infrastructure and the business environment)
- Regulations and imposed standards

#### **Organizational**

During the development of RHIE the health organizations mainly contact the “reliable” vendors for consultancy and further development of these system. It is important that the vendor has a great experience in building such systems. In the Netherlands there are couple of market leaders for the development of complete EHR systems. The rest of the vendors are focusing mainly on specialized software or segments within this market. The supplier needs to be a trustworthy partner. Also the type of contract provided by the vendor is very important. In general the health organizations are looking for long-term relations. It is important that the contract is valid for a minimum period of 10 years. What is even more important is the support if the contract ends or when a supplier for some particular reason stops with further development of the system. It is important that the maintenance of the system can be continued, because these organizations are very dependent on the existing software solutions.

#### **Support**

One of the important considerations for acceptance of new systems in the health care is the 24 hours availability of the support from the supplier. The health organizations are in almost all cases very dependent on the IT support systems for their basic daily tasks. It is important that these systems are working day and night, without any interruption. However these systems need to be maintained (for instance due to unexpected errors in the system). In all cases the support of the vendor is very important in handling

such unexpected situations, in order to solve problems as quickly as possible. Also the existence of user's platforms for support is very important. The users can ask others regarding their existing problems with the system and can help each other with the issues regarding the use of the system.

### **Law and regulation**

During the interviews and document analysis we explained several references to different law and regulations regarding the exchange of medical data. In all the system's functionalities must comply with the existing law and regulations. These law and regulation are mainly about security of the system and privacy of patients and its users. We will describe of these in the next sections into more details.

### **Security**

Security is one of the main areas of concern for the exchange of medical data. This has also been indicated by the primary and secondary users as one of the main barriers for the development of RHIS. Today a large amount of the health organizations are connected using the Internet. While technology is supporting these organizations to provide better services to the patients, it is also affecting the ways medical data are accessed over networks. This introduces new risks along with compliance and legal issues that need to be considered and addressed. This concerns not only individual health organizations, but also the entire partnership of health organizations. Protecting sensitive data of the patients has taken on a whole new meaning with the rise of communication over the public networks. Health organizations are turning to Virtual Private Networks (VPNs) on the Internet as the transport backbone to establish secure links with partners, regional polyclinics and remote users; to decrease the costs of communication and enhancing the level of security.

Some of the risks that consistently plague the communication between different health organizations at regional level include next:

- Application level vulnerabilities that allow exploits to pass through firewalls and intrusion detection systems undetected
- Inadequate security controls for authenticating third parties
- Unencrypted data residing on web servers and databases without proper authentication / data protections.

Security data and transactions are important in order to provide high quality service and reliable regional exchange of data. This required carefully managing of the computing infrastructure as well as security devices, according to corporative security policies. To do this health organizations require a scalable management system that manages:

- Authentication systems like public key infrastructures or making use of UZI-card
- Authorization and access control systems

- Configuration of all security resources such as firewalls, remote access servers and so on, in order to compliance with security policies
- Monitoring of all computing resources, such as EHR system, network devices and applications, for changes in configuration that increase security risks
- Audit and archiving systems that record the recent and past activities of the users that accessed the medical files of patients (also indicated by the patients as an important feature).

As the number of different organizations, departments, users and roles increases, the health organizations will need proper tools to support them to quickly deploy their RHIS applications. Some of these tools include:

- Software module that easily help the administrators to set authorization and access rights to different data and functions in the system.
- Software deployment capabilities that automatically identify and solve distribution and configuration problems.
- Software modules that automatically manage software reliability after deployment
- Software management systems that rapidly expand to cover new software technologies.

### **Privacy**

Beside security, privacy is seen as one of the main barriers for the development of RHIS. During the design and development of the new system privacy concerns need enough attention. Most of the time the discussion of privacy is related with ethical concerns. Both patients and the specialists worry about the risks of getting access of sensitive medical data by third parties (insurance companies or other public organizations). The results of the patients and specialists surveys in this research also illustrate these concerns.

The new system should also comply with all Dutch and European privacy laws and regulations. The European data protection law can originally be found in the directive 95/46/EC of the European council on the protection of individuals regarding the processing of personal data and on the free movement of data [34]. From this directive in 24 October 1995 another directive has been adopted. Also, the directive 2002/58/EC (privacy directive) concerns the processing of personal data and the protection of privacy in the electronic communication sector. The council of Europe Convention for the protection of individuals directive 95/46/EC states: "Personal data shall mean any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identifies, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to this physical, psychological, mental, economic, cultural or social identity." Parliament and of the Council

**Beside the European regulations we can mention some of the important regulations in the Netherlands which are specifically applied in the health care:**

**Wet geneeskundige behandelingsovereenkomst (WGBO):** This law regulates the relationship between a patient and a therapist (doctors, nurses, special educators, psychologists, midwives, physiotherapists, speech therapists, special education, etc.). When a patient invokes the help of a caregiver, medical treatment creates a contract between them. This law implies:

- The right to information by the counsellor
- Consent for medical treatment
- The right to inspect the medical file by the health provider
- The right to a second opinion
- Representation of patients who are not able to decide
- Right of privacy

**The duties of the patient:** The patient needs to inform the care provider good, honest and fully of the health problems. With this accurate and complete data, the health provide can provide faster and better diagnosis and treatment.

**The patient's right to get information:** As a patient you have the right to be informed in understandable language, about your illness, treatment, consequences and risks of that treatment and possible alternative treatments.

**The patient's right not to get information:** The right not to get the medical information if the patient asks for this, unless serious harm can result to the patient or to others, then the patient gets still that information from the care provider.

**The patient's right to inspect his/her medical file:** Each patient has a medical record that contains all information relevant to the treatment. Because this file contains information about the body and health of the patients, it can be obviously accessed by the patient (on request), with the exception that the data not directly relates to the personal information of the patient. Besides the patients also the clinicians should have access to the health records of the patient. Others should not have access to these files unless the patient gives necessary permissions. The patient is allowed to copy the personal health records, for which the patients can be charged for a reasonable amount. The patient is also allowed to ask the care provider to edit or change the health records if this is containing mistakes.

**The patient's right for protection of his or her privacy** The caregiver should protect and preserve the privacy of the patients. Everything must be kept confidential. The medical file is only made available to the caregiver and those involved in treatment. The caregiver may not provide any information to other third parties (including immediate family), unless the patient has given explicit permission or if the



law obliges the caregiver, or if the information concerns the purpose of scientific research (only under strict conditions). The secrecy originates from the patient's right to confidentiality of personal data. This right is implicitly mentioned in article 10 of this law. The death of a patient does not mean that privacy no longer needs to be protected. Even after death, third parties have no right to inspect the file, unless the caregiver is sure that the patient had no objections.

**The duties of care providers to keep a medical file:** A counsellor has a duty to keep a separate file for each patient. A file is the data set that tracks the care of a patient. The information included in the file varies per treatment and the medical profession. This is assessed by the provider, but also depends on laws or regulations. The file must contain at least the basic information recorded. This includes the findings of a physical and psychiatric examination, the diagnosis, the established treatment, the progress of treatment, anaesthesia and surgical procedure reports, vital signs and laboratory results, referral and discharge letters, x-rays, nursing reports, notes of discussions and findings of former workers or experts consulted.

**Retention of the medical records:** The general retention of medical records is 15 years. After the retention period the file should be destroyed. However there are some exceptions:

- The medical information may be kept longer if there is a good reason for this. Also, the GP is allowed to keep the medical data for more than 15 years in the context of continuity of care.
- For the case of an involuntary psychiatric patient is a statutory retention period of 5 years after termination of compulsory admission.
- The patient can request that certain medical records shall be preserved longer than 15 years.
- If the care provider anonymities the patient's data, they can exceed 15 years.
- Interests of others, when it comes to genetic disorders the data can be kept longer in the interest of the patient's children.

**The right of the caregiver to refuse a request of a patient:** For various health professions apply professional standards. The caregiver has the right to refuse a not unreasonable desire of the patient.

**Patient consent is required:** Each study and for each treatment the care provider requires the consent of the patient. The patient ultimately decides whether or not treated, by the caregiver. The patient has the right to refuse a treatment or investigation and given permission to withdraw.

**Wet bescherming persoonsgegevens (WBP):** The data protection act by The Data Protection Authority (CBP): This law states, what can and cannot be done with patient's personal data. For example, the patients have the right to see their own data, and possibly correct them. The health organizations must also be able to explain why

they capture certain data. These organizations may only capture necessary data. More information may be committed with the consent of the citizens themselves. The CBP enforces the statutory provisions.

**The law to use Social Security number (BSN) in the care:** This law regulates the use of the Social Security number as a national patient identification number. This law was already adapted in the national EHR in the Netherlands.

**Law on EPD:** This law is an adaptation of the BSN-law and goes one step further. It regulates among others the use of the Social Service Number (BSN) in the care.

### **Standards**

From interviews with the consultants, document analysis and stakeholders analyses we can conclude that in all cases the used standards should comply with the existing standards used by different regional health organizations. Beside this the system shall make use of universal standards that are known to all different parties. Open standards like (HL7 or DICOM) are good examples of such standards. However it should be possible to choose other standards. For instance in some situation these organization already make use of the same EHR system (from the same vendor). It is much more easier to make use of the existing standards. In other words it should be possible to exchange medical data according to the existing standards of the organization and the agreements for each specific case by reaching agreements between the involved organizations.

### **Costs**

As already mentioned in the results of different interviews with consultants and the earlier stakeholders analysis the initial costs of RHIS is one of the main barriers. This is especially the case for smaller scaled health provider organizations, for which it is not worth to invest in sophisticated high cost solutions (results interviews consultants). The hospital executives judge new technological investments in matters such as return on investment. In other words the commercial and organizational advantages of new systems should outweigh the initial costs. Also, maintenance costs are important, in order to keep the total costs of the health organizations as low as possible. For these reasons the costs of the new system should be decreased as much as possible. Especially the initiation costs play an important role in acceptance of the new system. Other issue regarding the costs is the transparency of all costs provided by the developers of such systems. A clear overview of the initiation and maintenance costs shall be provided by the IT-company before the development (see general requirements, document analysis).

### **Typical multi-actor problem**

Further investigation of the current situation, stakeholders and the past developments of RHIS show that the development of such system can be also considered as a typical multi-actor problem. Multi-actor problems can be characterized as problems having:

- Large number of different stakeholders. In other words the design environment is a network of actors, thus:
  - Not one problem definition
  - No objective measurement possible
  - No consensus on criteria, objectives, preferences
- Dynamics of and in the network: variables influencing the situation can change or the parameters can change, for instance because of new laws and regulations.
- Different sub systems: different regional systems, each with different goals
- Different standards: depending on application and time when it was introduced. Older standards like EDIFACT are originating from the old times, while now days HL7 is getting more support.
- Public responsibility: many developments depend on the national laws and regulations. Public responsibility is needed because in many cases the services are used by a large group of citizens.
- Accountability: It is hard to define who is really accountable for the development of new systems. Lack of accountability is seen as one of the important barriers for the development of RHIS (interview consultants)

**Other typical characteristics of multi-actor systems are:**

- Often large scale systems
- Technologically complex systems
- Often including actors as components
- Designing these systems involves many stakeholders
- Spanning over years (decades)

**System complexity**

The system complexity of RHIS can be described using different factors depending on the specific situations, but we can mention next general factors:

**Related to the system components:**

- The number of parts
- The type of parts, e.g. human actors.

**Related to the relations between the system components:**

- The number of relations
- Connectivity, e.g. interdependence

- Asymmetry, differentiation
- Dynamics
- Non-linearity
- Randomness

## 6.2 Requirements specification

From the results of the quantitative methods (surveys specialists and patients) and qualitative methods (like interviews, document analysis and stakeholders analysis), a list of functional and non-functional requirements are gathered. These requirements are some of the common requirement for enabling the exchange of medical data at regional level. This does not mean they do represent all requirements for all specific cases of health data exchange. These requirements do not imply all requirements and viewpoint that can be found. However as explained earlier in chapter 5, we do have discovered several differences between the medical specialities (results survey specialists and the results of the patients survey). In this chapter we first start with explaining the users and the common functionalities (by UML diagrams) of the exchange systems. Further some of the important procedures for the exchange of medical data are explained in the uses cases (by BPMN diagrams); where after we will further discuss functional and non-functional requirements into more details. The initial requirements are included in Appendix D.

### 6.2.1 Users

Before we start with the use cases it is first important to make some generalizations of different user groups. This makes it easier to discuss different functionalities in the next sections. The users are illustrated in the figure M.7 of appendix M, that shows generalization and categorization of the main user groups. There are 3 main groups of users: Health providers (primary users), Patients (secondary users) and Administrators or maintainers of the system. With health providers we mean both medical specialists and employees within health organizations.

### 6.2.2 Functionalities

The general system functionalities for the exchange of medical data can be divided into three different categories:

1. Exchange functionalities (push, pull, subscribe, publish and taking over medical data)
2. Authorization functionalities (authorization patients, specialists, organizations and other parties)
3. Maintenance functionalities (Maintain patient's data and system maintenance).

Also other combinations are possible. However we mainly focus here on the functionalities that are related with the exchange of medical data between organizations. Other functionalities are very much dependent on the type of the chosen solution and specific architectural choices. (Figure 6.1)

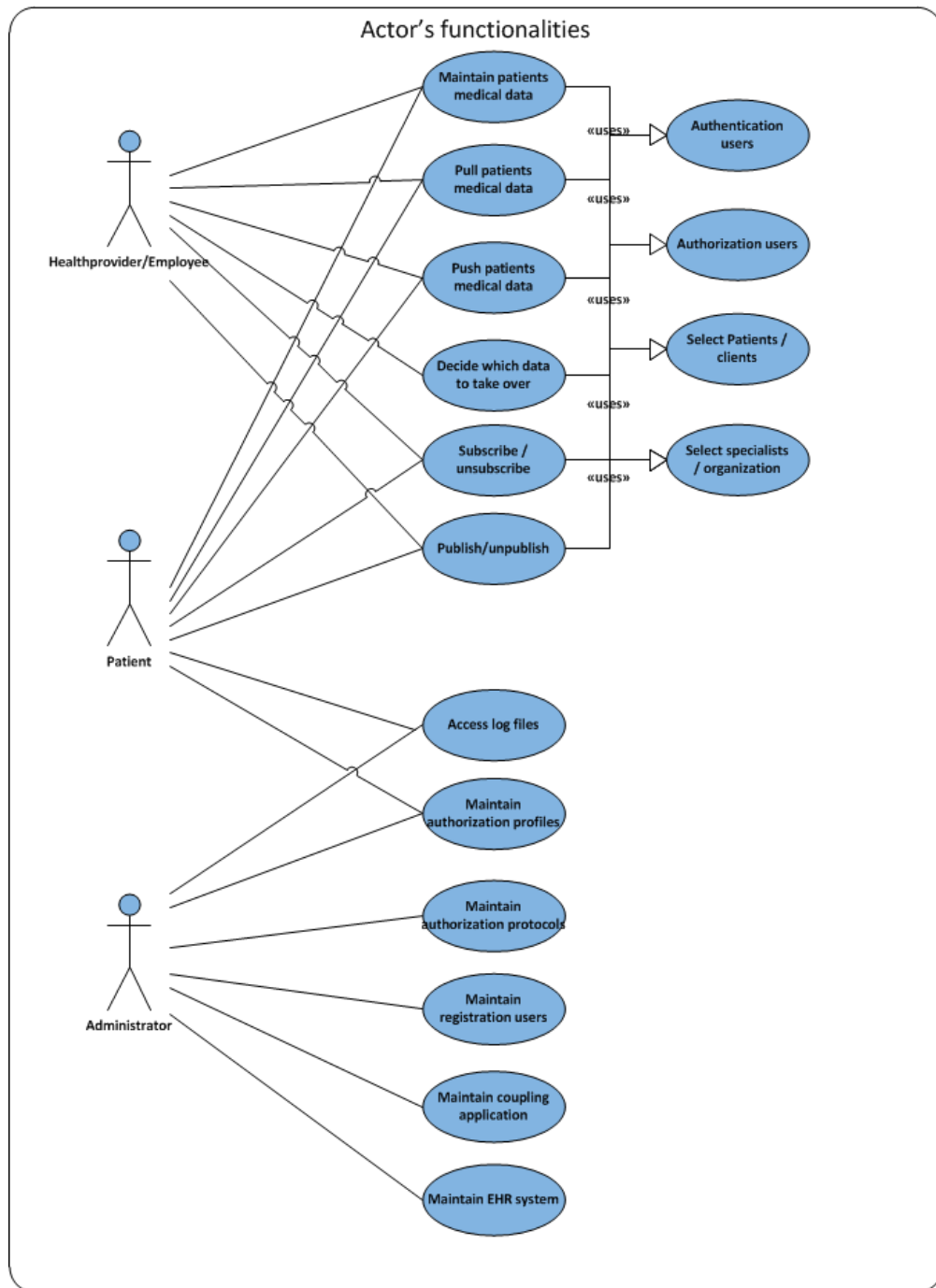


Figure 6.1: Actor's functionalities

**Explanation actor's functionalities:** In general the medical specialists/employees are responsible for the exchange of medical data. However also the patients have access to these data or in some cases they are allowed to add information to their medical records. This is frequently used in home-care situations, where patients need to measure constantly all kind of parameters of their body. Patients are also able to fill in extra information about their medication, allergies and other additional data.

The exchange of data is divided into four different types:

1. Pull data (requesting medical data/results from other health providers)
2. Push data (sending medical data/results to other health providers)
3. Subscribe to patient's data (getting updates of patient's medical data)
4. Publish patient's data (publishing updates of patient's medical data)

The medical specialists are able to accept or reject specific parts of the medical data. Also, this functionality is a design choice and already described in the results of the specialists survey and/or the interview. More details and reasoning will be provided later-on in the section about the functional requirements. Furthermore the primary and secondary users can also make use of advanced functionalities like transfer of patients, making appointments and registration of the patients.

The patients are also able to access and maintain their own medical records. They might also be enabled to look back into the log files in order to see who had accessed their medical data in the past (conclusions from the results of the patients survey). If by design choice the authorization functionality is provided to the patient, the patients will be able to control which specialists or the health organization are allowed to access their medical data. In other words if the patients decides not to exchange medical data with other specialists the authorization settings will be adapted such that specific specialists will not access the medical data.

The administrator is allowed to configure and maintain all kind of system specific parts. Maintaining and implementing authorization rules, users registrations, back-up and all other EHR maintenance tasks are part of the responsibilities of the administrators. Other supporting functionalities like authentication, authorization, selecting patients, selecting organization and setting authorization settings are in fact supporting functionalities. In other words these are the functionalities that can be used by one or more of the previously explained functionalities.

### 6.2.3 Use-cases

In this section we will discuss some of the important use-cases for the exchange of medical data. We first start with some basic scenarios commonly needed for any health information system in general (like authentication, authorization, ...). Later-on in this section we will also discuss some of the more advanced use-cases of the RHIS.

#### Use-case 1: User authentication

The authentication of the users is one of the most important functionalities of the system. Usually it is common to use user's credentials and a proven reliable tool for

authentication of users in the health-care. The tool frequently used in the Netherlands (also prescribed by the Dutch law) is the UZI-card combined with a card reader. There exist three types of UZI-cards:

1. UZI-health-care card (UZI-Zorgverlener)
2. UZI-Identified employee card (UZI-Medewerkers op naam)
3. UZI-Unidentified employee card (UZI-Medewerkers niet op naam)

The UZI card reader can be connected to a PC or a Mac using a special software delivered by the vendor of the card. Beside authentication of the users, the UZI card can also be used for creating digital signature and encrypting/decrypting medical data of the patients. For the authentication of patients DigiD can be used. The DigiD is very common for identification of citizens for using public services (tax office, education). Also, in the health-care this technology is commonly used to verify the identity of the users. The process of authentication of users is illustrated in the figure 6.2.

For the authentication of the user the user's credentials and a secure authentication tool (UZI-card) are used. However not always both the user's credentials and the authentication card are needed. For authentication of users it is important to make a distinction between a health providers and a patient. The health providers or employees use UZI-card to login into the system. The patients on the other side make use of DigiD for authentication. (XOR gateway ,figure 6.3) This is simply because at this moment not all patients in the Netherlands have a health-card similar to the UZI-card of the health providers, for authentication. In some other countries (for instance Belgium) the patients have already a health card that can be used for authentication of the users.

The authentication process for the health providers needs both a valid UZI-card (checked by the reader) and the user credentials. Also, the BSN (citizens number) of the user can be checked (by looking into a national database (for instance SBV-Z)). Sometimes it is only possible to login into the system using an UZI-card (Smart card login). The patients on the other side login with their DigiD user-name and password, the BSN(citizens identification numbers) is checked by looking into a national database and finally the user needs to fill in a token that automatically is send to user's mobile phone (which is earlier registered).

### **Use-case 2: User authorization**

During the authorization of the users in fact the user's identification data are matched with an existing authorization profile (one user can have several roles and thus multiple profiles). The protocol contains all kind of rules, which are collected by the designers of the system and maintained by the administrator of the system. It is also possible to allow the patients to maintain their own authorization profile that defines which parties are allowed to access their personal medical data. However this is a design choice and is not obligated. Later on in this chapter (functional requirements) we will explain that the patients in fact would like to control which parties are allowed to access patient's private medical data.

The medical specialists on the other side can decide to share some parts of the medical record with other specialists. In fact this functionality is not part of authorization, but part of the publishing possibilities. This functionality will be described later

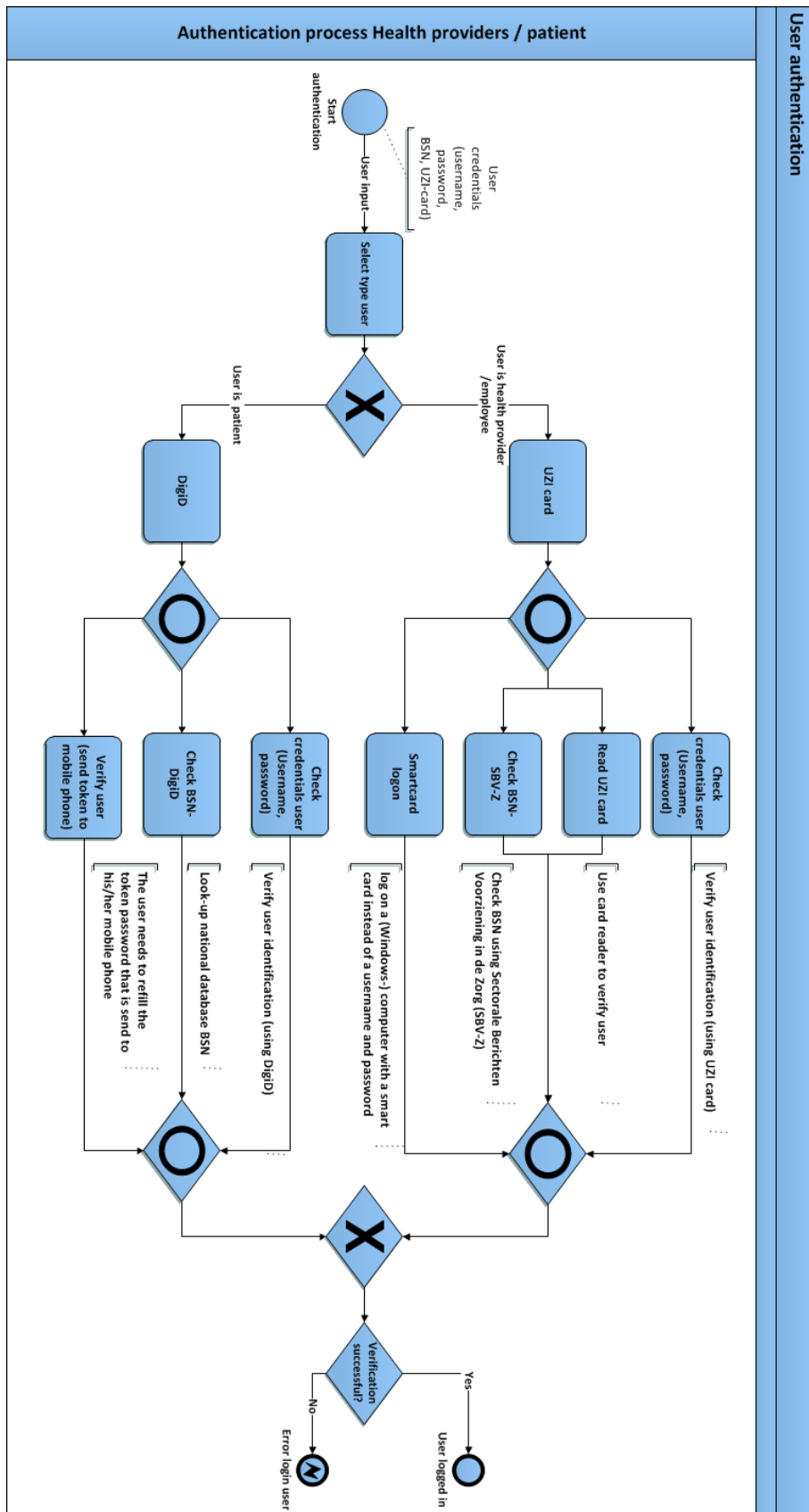


Figure 6.2: Use-case 1: User authentication



on in more details. It is important that a user is authenticated before the authorization profile is retrieved. In other words in all use cases (see also next pages), the user needs to be logged in before retrieving the user's authorization profiles.

As explained above, one user can have multiple authorization profiles, depending on the tasks that this person can perform. This is also why in some case more than one profile (a collection of profiles) can be send back. Whether the user is able to perform a specific task is checked later in the process. In other words during the authorization process we just collect all settings and later on it is checked for each particular functionality whether the user is authorized to perform this task or not. (Figure M.8 of Appendix M)

### **Use-case 3: Selecting patients**

Selecting (medical data) of a patient is also one of the basis functionalities of the system and is also needed by several other functionalities. Normally selecting the right patient data is seen as one of the core functionalities of almost all EHR systems. All other functionalities are built upon or use this functionality. As described before all users need to be authenticated and have the correct authorization profiles to access medical data of the patients. First of all it is important to check the identification of the patient. The precise order of how this should be done depends very much on the final design choices of the system, but in all cases we need to check whether we are dealing with the right patient. This is also important for the safety of the patient to get the right treatment and prevent medical errors as much as possible. (Figure M.9 of appendix M)

First of all as explained earlier the authentication of the patient depends on the type of login by the user. In the case that the user is an employee at the health organization, who is trying to access the patient's medical data, we can consider next two situations:

1. The patient is physically present (patient is visiting this specific health provider)
2. The patient is physically not present (patient's data is requested by other organization).

In the first case the employee at the health organization can ask the patient for his/her legal identification documents and the BSN number (citizen number, can also be found on the id card). Further the name, birth-date, and a picture of the patient are verified with what can be found in the system. Also, the BSN of the patient can be looked up in a national database containing all numbers. If the patient does not exist yet in the EHR database only the BSN and the picture are checked. This patient then needs to be registered in the next steps.

In the second situation only the BSN number of the patient needs to be checked. This is because the patient is already checked by the first organization. If needed it is also possible to send a copy of patient's identification document. In order to protect patient's data from unauthorized requests (digital request pretending to be valid patient), it is important to encrypt data and use secure communication (will be explained in next use cases). And last it is important to have an acceptable level of trust between the two organizations. In other words in both cases it is important to know that your cooperating partner is trust worthy.

However if the user is a patient, this user is already checked using the DigiD verification. This means that we can be almost sure that we are dealing with the right person (unless DigiD is hacked, what is a bigger problem because all other public services will also be insecure). When the identification of the patient is valid the requested medical files of the patient can be retrieved. This cannot be allowed unless the user is authenticated and authorized earlier in the process. In other words the authorization rights are checked earlier in the process and the data can now be retrieved. If however the medical file of the patient is missing, the patient needs to be registered first. At the end the patient's digital medical file is returned.

#### **Use case 4: Selecting organizations**

In order to exchange medical data between health organizations, the system should also be able to allow electronic exchange of data. Also, the authorization profile of an organization is needed. Finding a health organization is a search task, which returns one, or more health organizations (depending on which ones are saved earlier) from the index using a selection criteria (for instance name, id, address etc). Next from this list of organizations only one is selected (manually or automatically). The organization index exists of all different organizations saved in at a central place (similar to the national register of AORTA [29]) or simply a list maintained by the organization. The health provider's information needs to be verified (name, address, contact information) and improved if needed. Also, if requested the changes in the data and the requests attempts can be saved into the log. (Figure M.10 of appendix M).

#### **Use-case 5: Maintain patient's medical data**

As described earlier in the beginning of this chapter maintaining the medical data of the patients is part of the core functionalities of the system. Typical operations on patient's data include: create, view, modify and delete. Because patient's medical documents should never be changed, means that a new version of the outdated patient needs to be created and added to the file. Also, patient's medical documents should not be removed except after the expiry of the retention or by the request of the patient. In the latter case, it is desirable that the deletion can be undone if the patient is asking for this. When errors are discovered in the medical data, these data cannot be removed simply, but should be revoked by declaring it invalid.

Because of this limitation, we will explain next two relevant scenarios:

1. Adding patient's medical data (add new version) to the records,
2. Declaring a document invalid.

Figure M.11 of appendix M, illustrates adding new medical data into the patient's medical records. First of all the user needs to be authenticated and only when authorized be able to add any new information.

After authentication and checking of the rights, the medical file of the patient can be retrieved. Unless this does not exist then a new registration process is requested. Having the right medical record a new data file can be created. This includes copying exiting records, creating a new version and adding information to this record. The

changes need to be signed electronically (required by the law). This is done by making use of a UZI-card (for health providers or employees) and DigiD (for the patients). The UZI card and DigiD can also be used for all other purposes than creating digital signatures. This tasks will further be explained in next pages. When a new file is created, this contains the new medical information that needs to be saved into the EHR database. The changes are also logged for later use (only if needed). Declaring the state of the medical data (invalidating data) almost the same procedure can be followed, except when the relevant version of the file needs to be set invalid. (Figure M.12 of appendix M)

#### **Use-case 6: Pull medical data message**

Pulling patient's data is a scenario where an electronic message (or document) is requested from an external health organization. This message can be compared to a posted letter or an email, which can include all kind of medical information about the patient. It is an one-time request from another organization. It describes a digital request for the exchange of medical data. The requesting party receives the result of its request within a limited time and in the best scenario a valid message is send back.

This use-case is a little more complex than the use-cases described previously. In fact there are different ways to check the authorization, sending request messages and handle the return messages. "Health organization 2" first needs to trust that the provided BSN number is a correct number. This is because the patient is physically not available at the front desk of this organization. However the identification of the patients is performed earlier by the "Health organization 1". In other words in order to make it possible to retrieve medical data it is important that both organizations already have created a certain level of trust between each other.

This is illustrated in figure 6.3. At the start the user needs to be authenticated and the necessary authorization profiles are retrieved (details use-case 1,2). If the user has the necessary rights the right patient is selected (details use-case 3). If the necessary information of the patient is found a request message is build and this message is encrypted (using a secure encryption process). This is important for securing communication between different organizations. Also, an electronic signature is retrieved, in order to make the request message traceable. Next this activity is logged into the system. When a request message is received in "Health organization 2", this message is decrypted first (see also use-case read new request). Thereafter the request is checked on having the necessary rights. If the requested party has enough authorization rights the medical data is collected from the EHR system of the second organization. The message is encrypted and is send back to requesting party. The message does not need to be signed again, because there are no changes made in the file. However this depends on the final design choices of the system.

If however things go wrong different error messages can be thrown depending on the events (incorrect information, non-existing data or not having enough rights). We call the retrieval of the medical data successful if it does return a valid medical file and no time-out event has been indicated. We need to set a time limit in order to prevent infinite loops. Figure 6.3 illustrate the pull scenario:

Creating new requests is illustrated in figure M.13 of appendix M. The same process can be used for multiple use cases, where only the context of request is different.

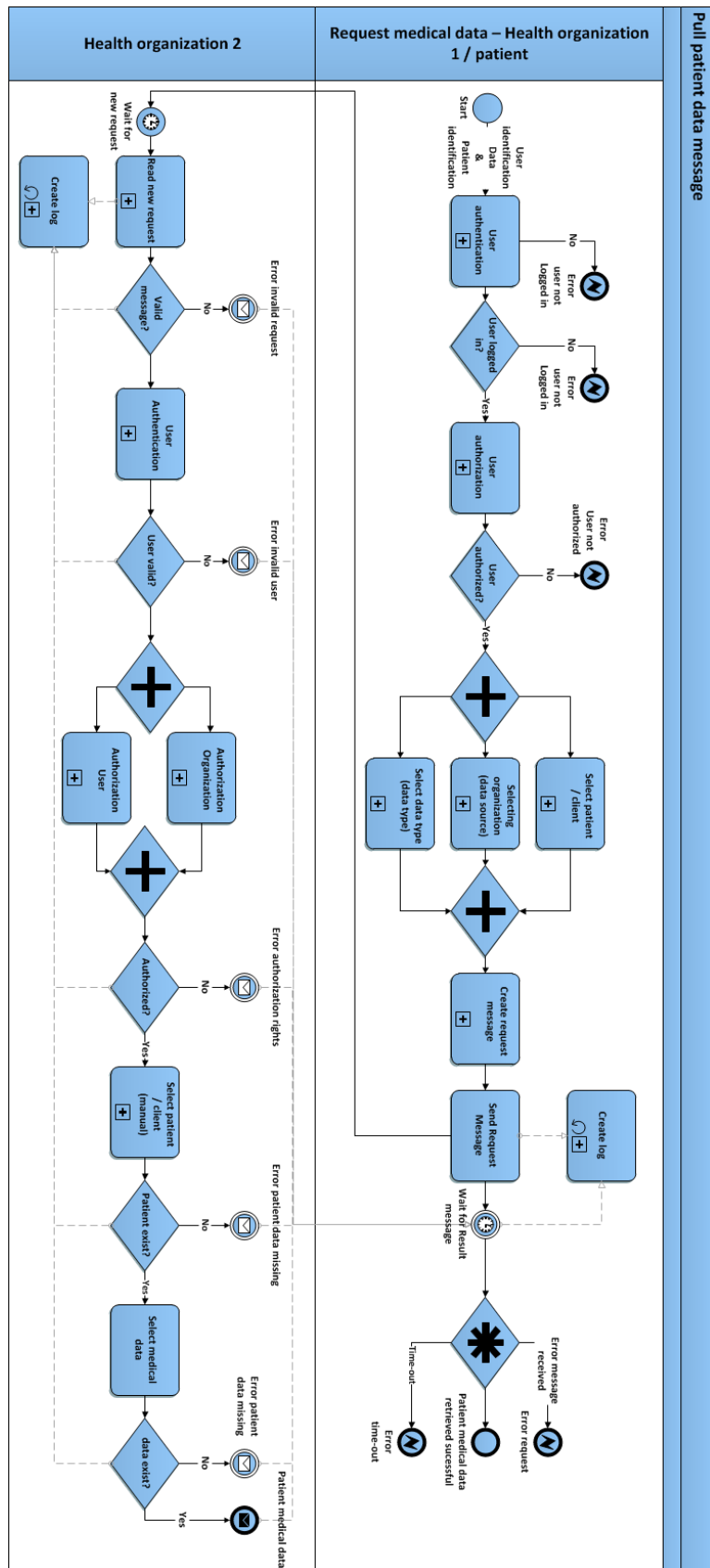


Figure 6.3: Use-case 6: Pull medical data messageE

Read new request message (figure M.14 of appendix M) is a use-case where a new request is received and needs to be decrypted. Also, the validity of the message is checked (based on agreements or used standards). From a received message different data fields can be retrieved. These fields are in fact request parameters that can explain the type, needed data, patient's information and all other needed information. These parameters can also be used to return a medical data automatically or manually by for instance showing them on a GUI to the user. Beside the header and the message content that contain all relevant medical data a message can also contain several files attached.

#### **Use-case 7: Push medical data message**

Push patient data message is similar to the previous use case, except that in this situation the health organization or the patient is sending a message without having received a request from another organization. This is comparable with a posted letter or an email from one organization to another. The message can for instance contain transfer information, but also all other medical documents. Before sending the medical file, this data needs to be retrieved from the EHR database (of the first organization). Then the organization is selected to which this message needs to be sent. In AORTA (Dutch national EHR architecture) [29], the organization is looked up from a central index of the national switch "Landelijke Schakelpunt". Here we do this by looking into a list of organizations maintained by the health organization. Furthermore an official encrypted message needs to be created including an electronic signature. Also it is checked whether the patient has allowed other users to transfer his/her medical data. If the patient allows this, the message is send to the second organization, where it is first decrypted. Because officially the receiving party is not aware of receiving a message, this message can be declined, if the receiver rejects to take over the data. However if the receiving party accepts this message an approval message is send back to the sender. The message is then saved into the EHR system of the second health organization (figure 6.4).

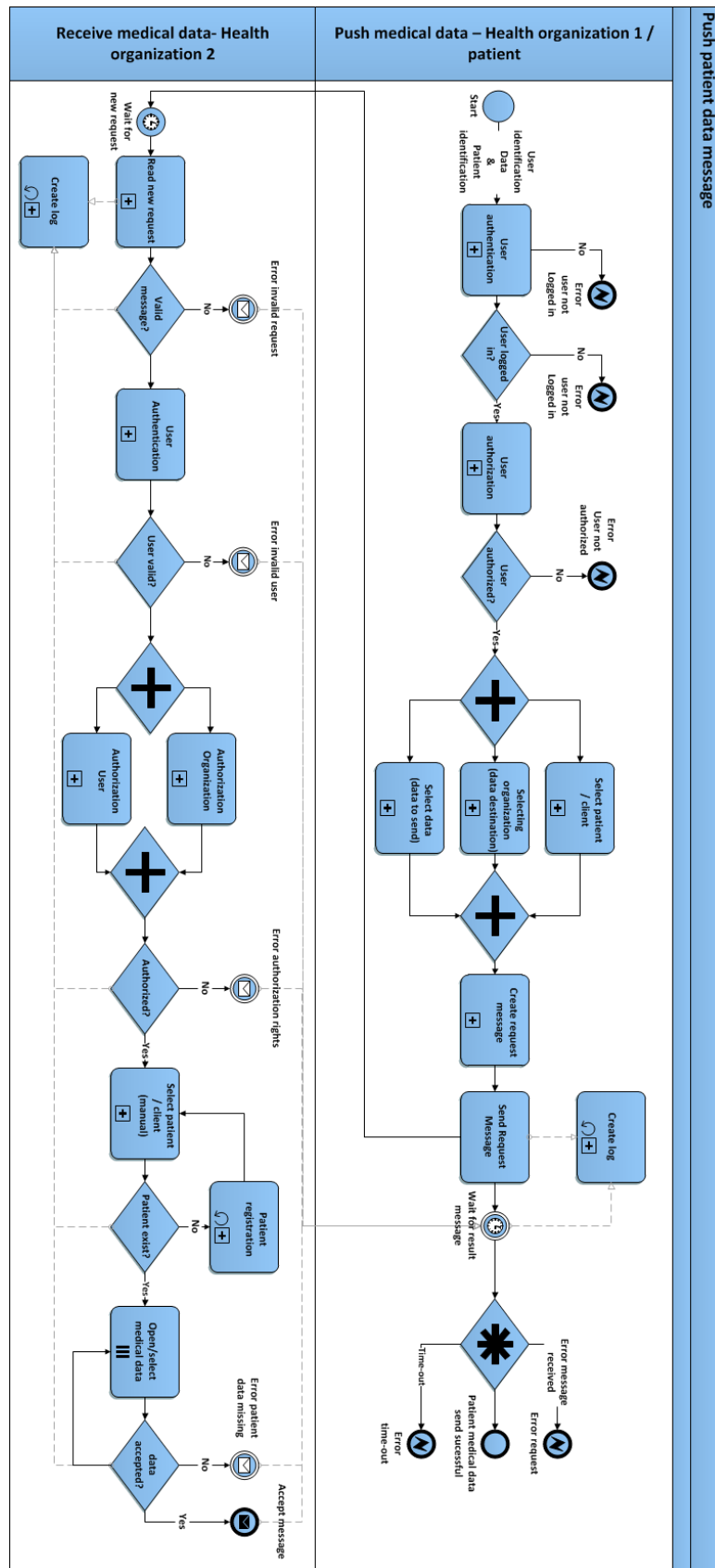


Figure 6.4: Use-case 7: Push patient’s data message

**Use-case 8: Subscribe & undo subscription**

When a user (specialist organization 1 / patient) is interested in patient's data that is not yet available, it might be useful to be notified when these results are becoming available. The user can specify whether he will be kept informed once this data is available. The user must (after he has received a notification of the subscription) be able to retrieve the data by simply clicking on the desired patient in his own EHR system. The details of how this can be achieved are out of the scope of this research and should be specified during the design phase. A care provider may also choose to undo subscription of the past requests (for instance if treatment of a patient is finished). Instead of a subscription request the care provider can now send a un-subscription request. The data will not be available any more for the future changes (unless a new subscription is requested). Subscription of data is very dependent on the agreements between different parties. Also, all kind of local rules and regulations can be obtained if needed. However the overall idea of subscription is the ability to receive continues updates from the sending organization, until this is not any-more preferred. Also, all kind of different authorization rights can be consulted. These need to be set before the process can be continued. Authorization rights can originate from the top management, but also from medical specialists and the patients (figure 6.5).

**Use case 9: Publish & undo publishing**

When a user decides to publish parts of the medical file, this data can be made available for other caregivers. This health provider may decide to share the medical files with other health providers. When some parts of the medical file of the patient are removed, they are obviously no longer available for retrieval. The medical specialist is not the only person who can decide to share the data. Actually it depends on the authorization profiles of the health care providers. If the patient is in control, he/she can influence this profile. In other words whether his/her own health provider is able to share the data with other health providers. Only if all authorizations are guaranteed, the medical data of the patient can be published to other health providers. On the other hand the receiving party can still decide whether to subscribe to this data or not. At the end of this process a confirmation message is send back, to indicate the state of the subscription. (Figure M.15 of appendix M)

**6.2.4 Functional requirements**

Functional requirements describe the capabilities a system can have in terms of behaviors or operations, triggering a specific system action or response. Functional requirements provide a firm foundation for the system architecture of the medical data exchange systems. In this section we will describe some of the important functional requirements for an exchange application, which makes it possible to exchange medical data between different users.

As explained before we focus in this report mainly on the most common functionalities of RHIS systems. It is important to note that most of these requirements can be seen as generic requirements for the exchange of medical data, without making use of any centralized index of patients neither health organizations. However at the same

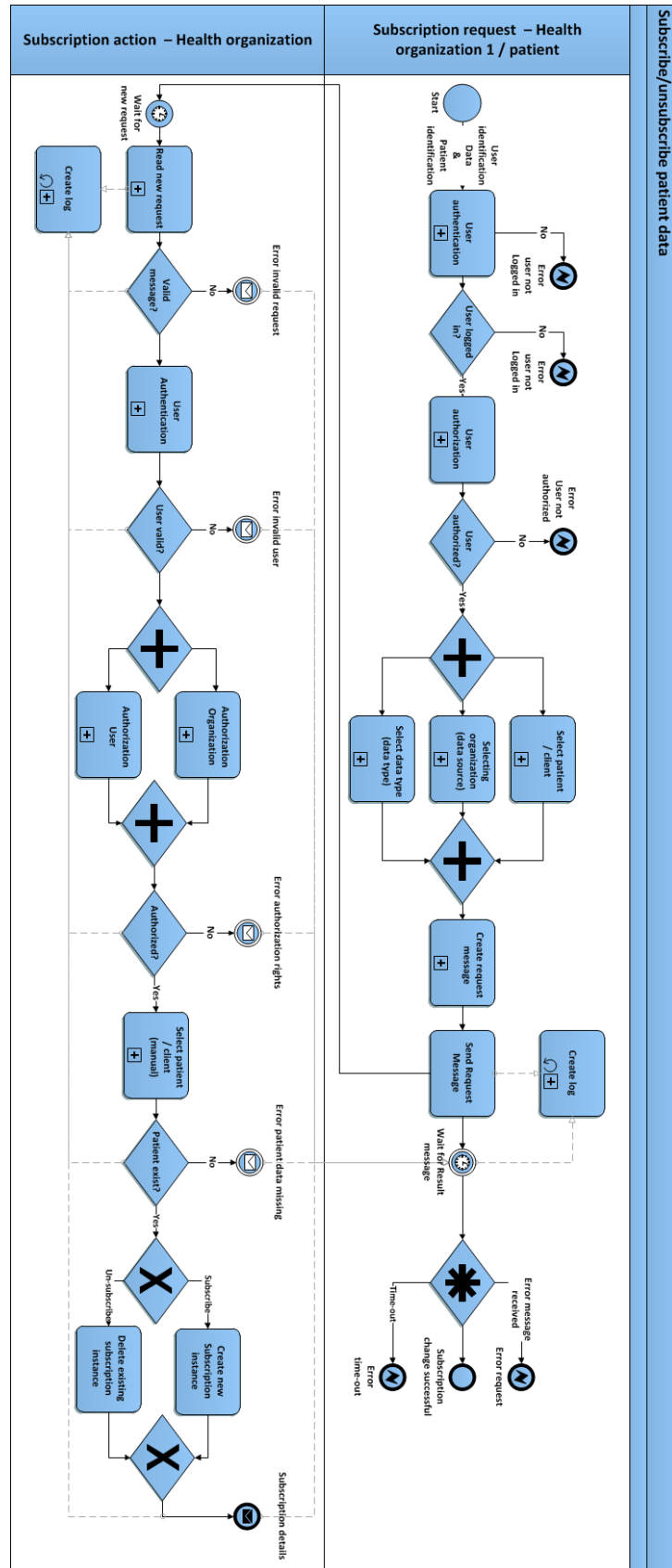


Figure 6.5: Use-case 8: Subscribe & undo subscription patient data



time we are not trying to create a generic architecture, like the national exchange architecture AORTA [29]. Still large numbers of requirements can be included in this list that, are independent of the design or architectural choices. The functional requirements explained in this chapter relate mainly to the use-cases described earlier in this chapter and include:

- The specifications of the system's functionality (what the system does)
- The actions the system must take (check, calculate, record, retrieve).

These requirements are gathered during the quantitative and qualitative research methods (see chapter 5 for more details).

**In general we can divide the functional requirements into next categories:**

**Access functionalities:**

- Access (functionalities enabling or disabling access of users and others)
- Specialists access (functionalities for setting authorization and other settings by the specialists)
- Patient access (functionalities for enabling patients access to data)
- Remote access (functionalities making remote access possible)

**Authentication functionalities:**

- Authentication (functionalities and actions)
- Authorization (functionalities to set and check authorizations)

**Control functionalities:**

- Data sources (functionalities enabling or disabling different data sources)
- Data types (functionalities for selecting different data types)
- Patient control (functionalities for setting authorization and other settings by the patient)

**Freedom functionalities:**

- Freedom of participation (functionalities for accepting or rejecting the exchange of medical data)
- Freedom of choice (functionalities for accepting or rejecting digital exchange of data)

**Orchestration / Integration:** functionalities for integration with existing solutions.

**Privacy and security:** functionalities which can influence the privacy of patients and security of the RHIS.

**Other functionalities:**

- Cooperative tasks (corporative functionalities using exchange of medical data)
- Advanced possibilities (functionalities using exchange of medical data)
- Coupling possibilities (functionalities coupling different organizations)

*Table of Appendix D shows a list of functional requirements for the exchange of medical data at regional level. Every requirement has an unique id-number (No.), actor name (from whom this requirement originates), the specification of the requirement (short description), category, source and a detailed explanation.*

### 6.2.5 Non-functional requirements

Non-functional requirements are often called qualities of a system. They specifies criteria that can be used to judge the operation of a system, rather than specific behaviors. The non-functional requirements that are gathered during the quantitative and qualitative research methods (see chapter 5 for more details). In general we can divide the non-functional requirements into the next ten categories:

1. Authentication requirements (non-functional requirement for authentication of users)
2. Customization (customization of the system solutions)
3. Freedom requirements:
  - Freedom of participation (non-functional requirements for accepting or rejecting the exchange of medical data)
  - Freedom of choice (non-functional requirements for accepting or rejecting digital exchange of data)
4. Orchestration, Integration (non-functional requirements for integration with existing solutions)
5. Performance (performance of the system)

6. Privacy and security (non-functional requirements regarding the privacy and security)
7. Reliability (reliability of the system)
8. Standards (non-functional requirement regarding the standards used)
9. User-friendliness (user-friendliness of the system)
10. Capabilities (non-functional requirements for improve of existing tasks)

***Table Appendix D - shows also a list of important non-functional requirements for the exchange of medical data at regional level. Every requirement has an unique id-number (No.), actor (from whom this requirement originates), the specification of the requirement (short description), category, source and a detailed explanation.***

### Summary

The main goals of RHIS is to provide secure and accessible medical data exchange between several cooperating health organizations. These data can be used by the medical specialists during the treatment. RHIS make it possible to have easier access to medical data during the treatment. Also, in some cases easy access to important medical data of the patients can improve the quality of care. At the same time having access to important medical data can reduce the number of double medical effort, when important medical data is available. This can also lead to less effort by the employees, and might reduce the total costs. In general considering the common cases for the corporation between health organizations, RHIS is part of a bigger process called “Health service orchestration.”

Regional health information systems which are widely supported need close participation and engagement of their users during design and development of such systems. This requires a so called “Bottom-up approach” where the viewpoints of different users are included from the beginning. Also, the role of the patients has changed from “passive” into more “participative”, where the patients are now also part of their own health care.

The areas of concern or constraints pose restrictions on the acceptable solution options. In this chapter we have explained several constraints. These constraints mainly relate to the organization, support, law, regulations, security, privacy, standards and costs. The development of RHIS can be considered as a typical multi-actor problem, because it includes large number of different stakeholders each having their own problems, where there is also little or no consensus on criteria, objectives and preference. Also the technical complexity and the diversity of the standards used make this a complex problem.

The users of RHIS include mainly the health providers, employees in the health-care, patients, but also the administrators of the system. Each of these users have different roles and responsibilities. Also, the functionalities enabled in the system can be different for each one of the users. The system’s functionalities can be divided into mainly three different categories: Exchange, authorization and maintenance functionalities. The exchange functionalities include pull, push, subscribe and publishing of

the medical data. Different use-cases explain the main functionalities of the system (which this research focuses on) in more details . These use-case are:

1. User authentication
2. User authorization
3. Selecting patients
4. Selecting organizations
5. Maintain patient's medical data
6. Pull medical data message
7. Push medical data message
8. Subscribe & undo subscription
9. Publish & undo publishing

Functional requirements describe the capabilities a system can have in terms of behaviours or operations, triggering a specific system action or response. In the end several functional requirements were found. These requirements are divided into several categories such as: access, authentication, control, freedom, orchestration / integration, privacy and security.

Non-functional requirements are often called qualities of a system. They specifies criteria that can be used to judge the operation of a system, rather than specific behaviors. These requirements are divided into several categories such as: authentication (non-functional requirements for the authentication), customization, freedom, orchestration / integration, performance, privacy, security, reliability, standards, user-friendliness and capabilities.

**Part III**

**Verification & Validation**



## Chapter 7

---

# REQUIREMENTS VERIFICATION

### Overview

In chapter 6 the initial list of requirements were presented and divided into different categories. This list still contains several inconsistencies, partly because the requirements originate from different sources. Some of the presented requirements are duplicated or contain unclear definitions. This list of “raw” requirements needs to be evaluated and in some cases if needed combined into more consistent new requirements. The list of functional and non-functional requirements should ensure that the intended behaviour of the product is achieved. It is also important to consider the business goals and areas of concern explained earlier. Figure 7.1 illustrates the order of verification and validation steps of the requirements. From the results of the elicitation phase and considering the areas of concern and the business goals, the initial list of requirements is created. This list needs to be checked on consistency, correctness, ambiguity, testability and other criteria.

This chapter explains in several steps the verification of the requirements. A set of criteria advised by the International Institute of Business Analytics (IIBA) [20] is used for the verification of the requirements. The IIBA [20] is the independent non-profit professional association for the growing field of business analysis. These criteria are presented in the Guide to the Business Analysis Body of Knowledge (BABOK Guide) [19] and contain a description of generally accepted practices in the field of business analysis. The content included in the BABOK [19] has been verified through reviews by practitioners, surveys of the business analysis community and consultations with recognized experts in the field. In the next sections we will describe for each of the criteria the steps needed to improve the initial list of requirements presented in the previous chapter (also presented in Appendix D).

### 7.1 Verification criteria

First of all let us apply three verification criteria, also mentioned in the BABOK Guide [19] that do not need any further actions, because they are already met in the previous chapters (Requirements Analysis & Specification). These criteria relate to how good

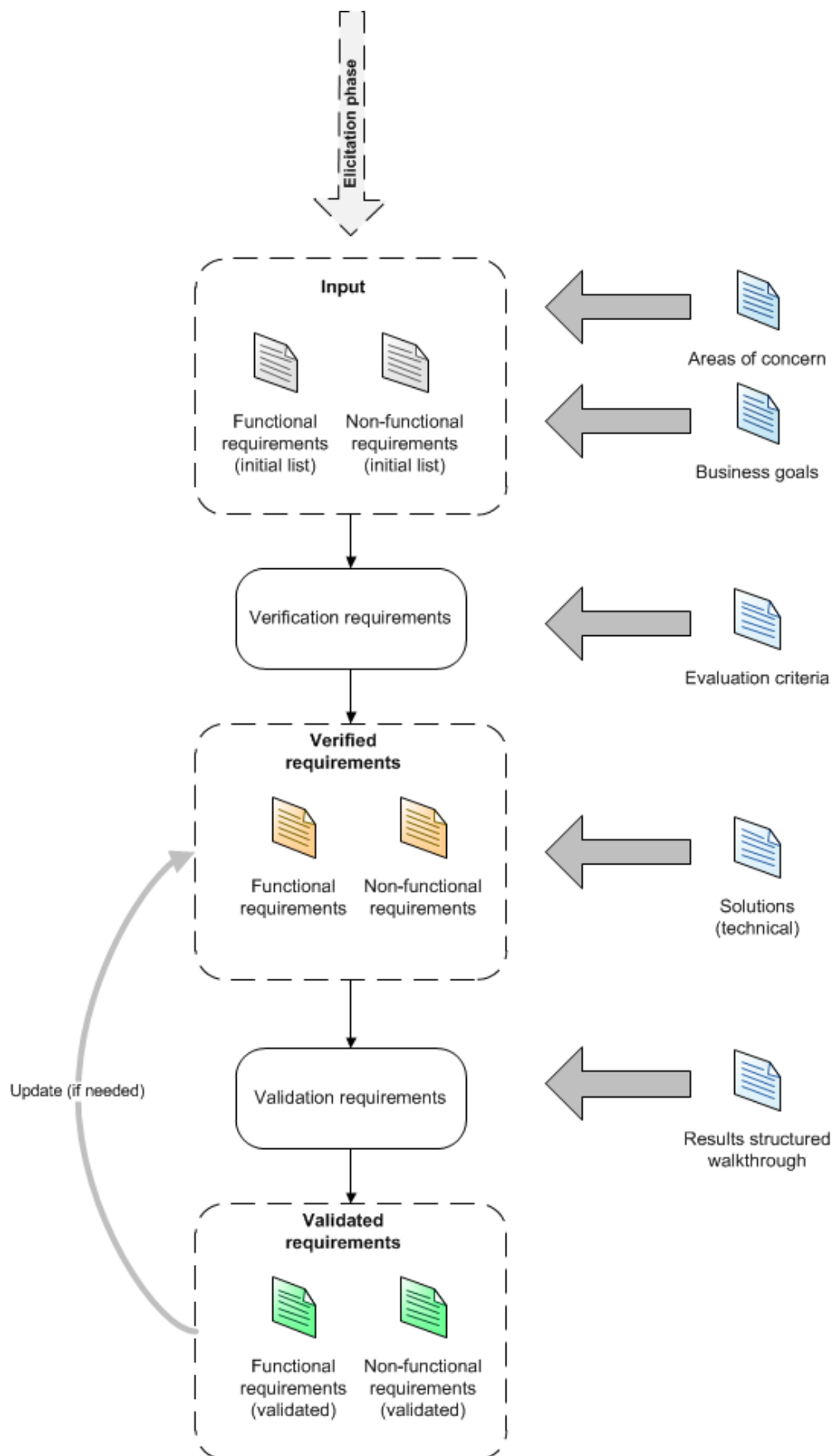


Figure 7.1: Verification and validation



the requirements are organized, whether they are modifiable and traceable.

### 7.1.1 Organized

Requirements need to be categorized and easy to locate. As explained in chapter 6, each requirement has an id-number (No.) and is distributed among different categories. The id-number is a unique string starting with character “R” what stands for requirement, followed by “F” or “NF” what stand for functional and non-functional and ends with a number (the unique number of requirement). The categories relate to the classification of the requirements.

### 7.1.2 Modifiable

Related requirements must be grouped together in order to be easy modifiable. This characteristic is exhibited by a logical structuring of the requirements. This criteria is also already achieved. In next steps some of the requirements need to be modified to meet the specific criteria. Some of the requirements form together new requirements that contain an improved specification.

### 7.1.3 Traceable

The origin (source) of the requirement must be known and the requirement can be referenced or located throughout the system. Traceable backwards: Each requirement can be traced back to specific customer, user, or stakeholder input, such as a use case, a business rule, or some other origin (indicated in table column “Source”). Traceable forward: Each requirement should have a unique identifier that assists in identifying the requirement, maintaining its change history, and tracing the requirement through the system components (indicated in the table column “State”).

**In next pages we explain the steps for verification of different requirements for which extra action are needed:**

### 7.1.4 Requirements dependencies

As explained earlier the requirements originate from different stakeholders and sources. In some cases it can happen that more than one stakeholder or source share the same requirement. In other words the same requirement can originate from multiple parties. One example is security, which can be important for all users (because of the risk that exist for losing their personal information), but also the administrators of the system (responsible for security). In some situations similar requirements may occur, only described in different words. In order to prevent repetition of requirements and improve consistency we need to investigate dependencies and relations between different requirements. Almost in all cases the redundant requirements can be eliminated. Depending on the requirement in some cases it is better to introduce new requirements that in fact also include the old requirements. In this way we can reduce the numbers of requirements, but also improve the consistency of the requirements.

It is important to note that in none of the cases it is possible to find duplicate requirements that can occur in both functional and non-functional list. This is because

the functional requirements refer to the actions of the system and non-functional requirement to all issues that are not directly related to the action in the system. However if this happens we can almost be sure that the requirement has a wrong type and that this requirement should be checked.

The column “Dependency / relation” in the table of Appendix D, contains the id numbers of all requirements that are somehow very closely related or that can be combined into another requirements.

**During this step next adaptations were made to the list of functional requirements:**

- Introduced requirement R-F-81: combining the requirements R-F-03, R-F-04, R-F-06, R-F-23,R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73. All these requirements prescribe the usage of HL7 standard for the exchange of data or coupling to other existing systems.
- Combined requirement R-F-77: the requirement R-F-07 and R-F-30 can be eliminated, because in fact these requirements are the specific cases of integration with an existing EHR.
- Eliminating requirements R-F-16, R-F-17 and introduced R-F-81. These requirements are about the possibility to provide/block authorization access to health organization or specialists. However a new requirement is needed to include both specialists and organizations.
- Eliminated R-F-21, this requirement is already specified by R-F-15 in a much better and more generic way.
- Eliminated R-F-27, R-F-28, R-F-29 and introduced R-F-82. These requirements are all about the coupling with GPs using EDIFACT standard.
- R-F-32 and R-F-38 are both about the possibility to exchange medical data of patients with chronic diseases. One of them can be eliminated.
- R-F-34, R-F-37, R-F-39, R-F-68 eliminated, these requirement can all be summarized in R-F-83 (it must be possible to exchange important medical data).
- Combined R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48; into R-F-84 (introduced requirement). The system must be able to exchange medical data, regardless the type of the organization. The possibility must exist to exchange medical data with different types of health organization and if needed non-health organizations.
- Duplications requirements R-F-54 and R-F-55. Requirement with id R-F-54 can be eliminated.

**The changes in the list of non-functional requirements are as next:**

- Duplicated requirements R-N-02, R-N-05, eliminate R-N-05
- Duplicated requirements R-N-11, R-N-01, eliminate R-N-11

- Duplicated requirements R-N-12, R-N-22, eliminate R-N-22
- Multi-defined requirement R-N-15, R-N-16, R-N-18, eliminate R-N-15 and R-N-16.

### 7.1.5 Necessary

The requirement is essential to meet the business goals and objectives. If the system can meet prioritized and real needs without it, the requirement is not necessary. The requirement should be traceable to a goal stated in the project, or the constraints. Requirement R-F-76 “Any kind of large-scale exchange of the medical information won’t be possible”, is contradictory with the goals stated in the project. This requirements limit the start of any comparable exchange project. This is different for R-F-74, R-F-75 and R-F-76, because the type of exchange is argued. Action: Eliminate R-F-76, no need for new requirement.

### 7.1.6 Unambiguous

Individual requirements must never be unclear. A requirement must not allow for multiple divergent valid interpretations of the requirement. We will explain some of the requirements that need to be adapted to meet these criteria.

#### **Adaptations for functional requirements:**

- R-F-08, it must be possible to exchange transfer data of a patients: It is not clear what is exactly meant by transfer data. The reason that this requirement is introduced in the first place is because the users would like to exchange medical data digitally when a patient is transferred from one health organization to another. Let us assume that the data that needs to be transferred includes important medical data, a text message (reason for transfer) and some medical documents. In order to meet this criteria, next actions can be taken:
  - Eliminate R-F-08 - according to the criteria this requirement is invalid
  - Exchange of medical data is already contained in R-F-83.
  - Attaching medical documents is already contained in R-F-05, but this possibility is only provided to the patient, what is not correct as well. This functionality should be available for all users. In other words eliminate R-F-05.
  - Introduce new requirement R-F-85, what makes it possible to add the reason for the exchange (text), when transferring patients.
  - Introduce new requirement R-F-86, The user must be able to attach a medical file to the exchange message.
- R-F-22, the specialist must be able to make on-line appointments on behalf of the patients. This requirement misses the correct specification. It shall be clear that the specialist will be able to make an appointment in a partner health organization on behalf of the patient. In other words, the exchange of data can be used to make an appointment for the patient in other health organizations. Next actions can be take:

- Eliminate R-F-22
- Introduce new requirement R-F-87, The specialist must be able to make on-line appointments on behalf of the patients in other partner health organizations (making use of the exchange services).
- R-F-24, unclear requirement. Using terms as Sioux (what is in fact an image storage systems) is unclear. Beside this requirement is too specific and does not cover all other cases (in general the image storage systems). Actions needed:
  - Eliminate R-F-24
  - Introduce new requirement R-F-88, The system could have a custom a coupling to other image storage systems.
- R-F-36, unclear requirement. This requirement is already covered much better by R-F-49 and R-F-50, action: Eliminate R-F-36
- R-F-59, the requirement “The patient must be able to accept/ reject the participation of digital exchange of medical data” is already contained in R-N-12. This requirement is a non-functional requirement because it does not directly relate to the exchange actions/ functionality of the system. Action: Eliminate R-F-59.
- R-F-61, the requirement “The patients should be clearly informed about how their health information may be used or shared”, is not directly related to the exchange actions or functionality of the system. Action:
  - Eliminate R-F-61
  - Introduce R-N-23 (new non-functional requirement) with the same specification.
- R-F-65, this requirement is unclear, because the actual goal is missing. Actions:
  - Eliminate R-F-65
  - Introduce R-F-89; the system should encrypt query string parameters in order to provide secure communication.
- R-F-78, the requirement authorization and authentication must be arranged properly is too wide in specification. This requirement shall be met using existing requirements on authentication and authorization. Action: Eliminate R-F-78, this requirement is already met by R-F-10 to R-F-21, R-F-80, R-F-81.

**Adaptations for non-functional requirements:**

- R-N-04, the requirement “The system should be dynamic and innovative” is unclear, because it is not described what it is meant with dynamic and innovative in particular. Action:
  - Eliminate R-N-04. By dynamic we mean that changes in the system can be easily realizable. This requirement is already specified by R-N-07.
  - Introduce R-N-24: The system should make use of latest web engineering technologies.

### 7.1.7 Correct

Defects in requirements will lead to defects in the resulting solution. These criteria cannot be checked in this phase. It is partly tested during the validation. A future prototype of the system can be used to test these criteria much better.

### 7.1.8 Feasible

All requirements can be implementable within the existing scope, infrastructure, with the existing budget, time-line and resources available (or the project must develop the capability to implement the requirement). **Next changes were made:**

- The requirement R-F-01 “It must still be possible to exchange data within the same organization and own care group” is outside the scope. In fact this is already realized by the existing EHR systems and is not part of the functionality of the system. Action: Eliminate R-F-01, new requirement not needed.
- The requirement R-F-57 “The patient could be able to make on-line appointments, after the GP or a specialist send an approval.” is outside the scope. This is functionality is included in some advanced solutions (for example advanced functionality health portal). Action: Eliminate R-F-57, new requirement not needed.
- The requirement R-F-58 “The patient should be able to accept or reject the existing appointments made by medical specialist.” is outside the scope. This is functionality is included in some advanced solutions (for example advanced functionality health portal). Action: Eliminate R-F-58, new requirement not needed.
- The requirement R-F-87 “The specialist could be able to make on-line appointments on behalf of the patients in other partner health organizations.” is outside the scope. This is functionality is included in some advanced solutions (for example advanced functionality health portal). Action: Eliminate R-F-87, new requirement not needed.

### 7.1.9 Design-independent

The specification does not imply a specific architecture. Requirements are stated in a way that allows all possible designs. This characteristic is also referred to as solution-independent. **Next changes were made:**

- R-F-10 “The UZI card and verification of the Citizen Service Number (BSN) should be used for the authorization.” This requirement can lead to problems, because it limits the solutions range. The users of HIS in the Netherlands commonly use UZI pas and the verification of BSN. Because of this, R-F-10 cannot be eliminated. We can still change the “should” in “could” to provide the possibility not to use these solutions.
- R-F-12 “The system should make use of a central reference index to keep record of all available patients.” This requirement can lead to problems, because it

limits the solutions range. Action: Eliminate R-F-12, because it is a design-dependent requirement

- R-F-56 “The system could provide an appointment code, which can be used to make an appointments by the phone.” This requirement can lead to problems, because it limits the solutions range. Action Eliminate R-F-56, because it is a design-dependent requirement

### 7.1.10 Testable

There must be a way to prove that a requirement has been fulfilled. Each requirement should be testable that is, it must be possible to design a test that can be used to determine if a solution has met the requirement or some other means of determining whether to accept a solution that meets the requirement.

**In order to meet these criteria next actions need to be made:**

- Requirement R-F-75 “The exchange of medical data at regional level should only be possible for specialities that benefit from it” cannot easily be tested. From the results of the surveys we discovered that there are different needs for exchange among several medical specialities. This means that the specialists should decide in each situation whether they would like to exchange medical data. The requirements R-F-49 and R-F-50 provide the possibility to accept or reject for certain or all parts of the data. Action to be taken: Eliminate R-F-75, this requirement is already specified by R-F-49 and R-F-50.
- Requirement R-N-01 “It should be possible to exchange data within a relatively short time.”, it is not clear what is meant with relatively short time. This requirement cannot be tested and because of this not valid. Action: Eliminate R-N-01 and use R-N-20 (“It must be possible to exchange medical data within couple of minutes”). The requirement R-N-20 contains the same specification and is also testable. We can test R-N-20 by for instance checking the number of minutes needed for exchange is equal or less than accepted number of minutes.
- Requirement R-N-02 “The digital exchange of medical data should improve the efficiency of work process” is also hardly testable. However we can divide this requirement into other requirements, which can be testable. Assuming that the efficiency can be measured by the number of task and the time needed to exchange medical data we can take next actions:
  - Eliminate R-N-02
  - Requirement R-N-20 can be used for checking the amount of needed time.
  - Introduce R-N-25, “It should be possible to exchange data within only couple of steps.” This can be tested by checking the number of needed steps is equal or less than the accepted number of steps.
- R-N-03 “Regional exchange of medical data should improve the quality of care” is hardly testable. However we can divide this requirement into other requirements, which can be testable. We assuming that the quality of care can be measured by reduce of number of medical errors and double medical effort. Again

because reduce of the number of medical errors over a short period will be almost impossible, we only focus at double medical effort. Assuming that the availability of medical data will make it unnecessary to perform the same test over again, next actions need to be taken:

- Eliminate R-N-03
- The availability of medical data is met by requirement R-F-66 “It must be possible to access medical data received from other health providers during the medical treatment”.
- R-N-06 “The system should improve the communication between different health providers.” This requirement cannot be tested. This is a business goal and not a requirement. Action: Eliminate R-N-06
- R-N-07 “Changes in the package should be easily realizable and maintenance friendly.” This requirement in fact contains two different requirements. One concerning changes effort in the package and other maintenance effort. Both of these requirements are quite hard to be tested. Let us assume that Service oriented architecture (SOA) can improve maintenance friendliness of the system and relatively decrease changes in the system. This is because SOA is based on loosely coupled units of functionality, distributed among different modules in the system. Based on these assumptions we can take next actions to create a new testable requirement.
  - Eliminate R-N-07
  - Introduce new requirement R-N-26 “The system should have a Service oriented Architecture (SOA) consisting of several loosely coupled modules.”
- R-N-14 “The system must guaranty secure exchange of medical data”, is not testable. Let us assume that good security can be defined by: proper authentication, authorization, secures email, application level security and a reliable network. Please consider:
  - R-F-13 specifies “The users must need to be authenticated before entering the system.”
  - R-F-18 specifies, “Unauthorized persons (specialists or others) won’t be able to access medical data of the patients.”
  - R-F-89 specifies: “The system should encrypt query string parameters in order to provide secure communication.”

**Next requirements need to be introduced:**

- R-F-90 “All exchanged messages must be encrypted before sending.”
- R-F-91 “The system must decrypt messages by receive, unless the user is not authorized.”
- R-N-27 “All security resources such as firewalls, remote access servers and so on must be configured properly, in order to compliance with security policies.”

- R-N-28 “All computing resources, such as EHR system, network devices and applications should be monitored for changes in configuration that increase security risks.”
- R-F-92 “Audit or archiving systems should make log files that record the activities of users who access medical files of the patients.”
- R-N-19 “It should be easy to access medical data” is not testable. Assuming that easy access to medical data is defined by the number of tasks needed to acquire data and the time needed, we can take next actions: o
  - Eliminate R-N-19
  - Requirement R-N-20 specifies “It must be possible to exchange medical data within couple of minutes.”
  - Requirement R-N-25 specifies, “It should be possible to exchange data within only couple of steps.”

#### 7.1.11 Prioritized

We need to prioritize requirements to determine which are essential, desirable, or optional. A priority is assigned to each requirement or feature to indicate how essential it is to a particular system release. The most important factor when prioritizing is business value. According to the BABOK [19] Guide we can use the MoSCoW method for privatization of the requirements. MoSCoW [19] is a prioritization technique used in business analysis and software development on the delivery of the requirements.

- **M-MUST:** Describes a requirement that must be satisfied in the final solution, otherwise the solution will not be accepted.
- **S-SHOULD:** Represents a high-priority item that should be included in the solution if possible. This is often a critical requirement but might also be satisfied in other ways if strictly necessary.
- **C-COULD:** Describes a requirement, which is considered as desirable but not necessary. This will be included if time and resources permit.
- **W-WON’T:** Represents a requirement that stakeholders have agreed will not be implemented in a given release, but may be considered for the future.

All requirements represented in the table of Appendix-D contain one of the Moscow words described above. Also, the “Priority” column in the table indicates how important a requirement is. The prioritization of the requirements is in general based on how important certain features or functionalities are. They also represent the viewpoints of the actors from which they originate. The prioritization in some cases represents how important a certain requirement is for a specific actor, as it was found during the surveys and the interviews.



### **7.1.12 Consistent**

Ensure that individual requirements do not contradict each other or describe the same requirement using different wordings (also checked by finding and resolving dependencies earlier). In addition, the level of details supplied for each requirement in a set or model should be the same. Checking and resolving contradictions will be explained in the next section (resolving conflicts 7.1.13).

## **7.2 Resolving conflicts**

As explained earlier each stakeholder has its own viewpoints and goals regarding the functionalities and the characteristics of the system. It is possible that some of the requirements create conflicts, because they contradict each other or cannot be met at the same time. In order to create a consistent list of requirements we need to solve these conflicts. We have already explained the MoSCoW [19] method for prioritization. However at the same time we also need to take into account the requirement's source (actor's power and power, see chapter 3). The requirements originating from important stakeholders should get higher priority.

### **7.2.1 Existing conflicts between requirements**

Table 7.1 shows a list of requirements that contain one or more conflicts.

Table 7.1: Requirements conflicts

ID	Actor	Actor ID	Specification	Conflict	Priority
R-F-02	Hospital executives	S-HE	Cross regional exchange should be possible in exceptional cases.	R-F-74	Should
R-F-11	Primary users	S-PU	Single-Sign-On (SSO) could be possible, so that the health provider only needs to login once.	R-F-13, R-F-15, R-F-18, R-F-19	Could
R-F-13	Primary users, Secondary users	S-PU, S-SU	The users must need to be authenticated before entering the system.	R-F-11	Must
R-F-15	Primary users, Secondary users	S-PU, S-SU	The users must only get to see the specific functionalities of the system depending on their authorization level.	R-F-11	Must
R-F-18	Consumers, Patients organizations	S-C	Unauthorized persons (specialists or others) won't be able to access medical data of the patients.	R-F-11	Won't
R-F-19	Advocacy, interest or lobby groups, health provider organizations and pharmacists, Consumers, Patients organizations	S-I, S-C	Only the specialists in charge must have authorized access to private medical data of the patient	R-F-11	Must
R-F-49	Primary users	S-PU	The specialists must be able to choose which data they prefer to share.	R-F-50, R-F-51	Must
R-F-50	Primary users	S-PU	The specialists must be able to choose which data they prefer to take over.	R-F-49, R-F-51	Must

Table 7.1: Requirements conflicts

ID	Actor	Actor ID	Specification	Conflict	Priority
R-F-51	Consumers, Patients organizations	S-SC	Patient must be able to provide access for each specific part of the medical data.	R-F-49 R-F-50	Must
R-F-53	Hospital executives	S-HE	It must still be possible to use traditional services like phone and written letters if necessary.	R-N-24	Must
R-F-62	Secondary users	S-SU	Patients must be able to provide access to other parties.	R-F-19	Must
R-F-67	Insurance Companies	S-IN	It must be possible to get access to medical treatment data by the insurance companies.	R-F-18, R-F-19, R-N-12	Must
R-F-69	Governmental organization	S-G	The system could have a link to public pharmacies in accordance with the Health / NICTIZ guidelines.	Constraints standards	Could
R-F-74	Advocacy, interest or lobby groups, health provider organizations and pharmacists	S-I	The exchange of medical data won't be possible outside the region.	R-F-02	Won't
R-F-81	Secondary users	S-SU	The patients should be able to maintain the authorization profiles.	R-F-49, R-F-50	Should
R-N-12	Consumers/ Patients organizations	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	R-F-67	Must
R-N-24	Hospital executives	S-HE	The system should make use of latest web engineering technologies.	R-F-53	Should

In the next section a more sophisticated method than the MoSCoW method [19] will be used in order to prioritize the requirements in a much safer way, considering the internal relations between the requirements.

### 7.3 Analytic Hierarchy Process (AHP)

The analytic hierarchy process (AHP) is a structured technique for organizing and analyzing complex decisions, based on mathematics and psychology. AHP was first developed and explained by T. Saaty [37] in 1980. In this chapter we use Analytic Hierarchy Process (AHP) to find the scaled prioritization of requirements. The technique itself is not adapted to distribute prioritization with multiple stakeholders [2]; hence it has to be modified in one way or another (which we will explain in the next pages).

In AHP the candidate requirements are compared pair-wise, and to which extent one of the requirements is more important than the other requirement. Saaty [37] states that the intensity of importance should be according to the table 7.2.

The reason why we just cannot only use the MoSCoW and importance of stakeholders for solving the conflicts between requirements is because the requirements are also interrelated. In other words one requirement can have multiple conflict relations with other requirements and those requirements can also conflict each other. Let us explain a simple example to explain this: Assume that requirement A, B and C each conflict. Let's assume A is more important than B and B is more important than C. ( $C < B < A$ ). It should be logical to say that from this concludes that also A is more important than C ( $C < A$ ). But in some cases it can happen that in some case C can be more important than A ( $A < C$ ). This is because these requirements might also have conflict relations with other requirements in the list. It is wiser to calculate the importance of each requirement also with other requirements (for instance requirements D, E, F....) that might conflict both requirements A and C.

Table 7.2: Scale according to Saaty [37] for pair-wise comparisons in AHP

How important *	Description
1	Equal importance
3	Moderate difference in importance
5	Essential difference in importance
7	Major difference in importance
9	Extreme difference in importance
2,4,6,8	Intermediate values between

\* If requirement  $i$  has one of the above numbers assigned to it when compared with requirement  $j$ , then  $j$  has the reciprocal value when compared with  $i$ . Shortly Next steps are taken:

1. Comparing every pair of requirements, this is the “engine” of AHP.
  - Comparing every pair using numerical values of MoSCoW [19]
  - Comparing every pair using numerical values of Stakeholders importance.
  - Sum of differences

2. Deriving a priority vector of relative weights for these requirements, i.e. the principal eigenvector.
3. Calculate the by-product from 2, i.e. the inconsistency measure.

**We will explain these steps in more details:**

First we take the requirements that should be prioritized (the total amount of requirement is  $n$ ), and put them into a matrix, where the rows have the index of  $i$  and columns have the index of  $j$ . The matrix is called  $W$  and the elements in the matrix are called  $w$ .

**Comparing every pair using numerical values of MoSCoW.**

As explained earlier each requirement has a priority value (by MoSCoW [19]). These values need to be translated into numerical scale:

- Must (value=4)
- Should (value=3)
- Could (value=2)
- Won't (value=1)

We can put this in a matrix used for further calculations (Appendix F-table 1). Next we need to compare different values of requirements. The requirement that is placed in row  $i$  and column  $j$  gets the index  $ij$ . Therefore the element  $w_{ij}$  has the row index =  $i$  and column index =  $j$ .

Table 7.3: Example matrix AHP

	Req 1	Req 2	...	Req n
Req. 1	1	w12	w1j	w1n
Req. 2	w21	1	w2j	w2n
...	wi1	wi2	1	win
Req. n	wn1	wn2	wnj	1

Each matrix element consists of the comparison between two requirements ( $i$  and  $j$ ), which gives us the following relationship:

$$w_{ij} = \frac{w_i}{w_j}. \quad (1)$$

Figure 7.2: Relation function two requirements

An important notice is that the person that does the prioritization does not put any value on  $w_i$  and  $w_j$ , instead he or she decides the value for  $w_{ij}$  which is the ratio between  $w_i$  and  $w_j$ . That leads us to another important relationship, which is that for every index of  $i, j, k$  has the following relationship:

$$w_{ij} = w_{ji}^{-1}, w_{ij} = w_{ik} w_{kj} \quad (2)$$

Figure 7.3: Relation between two requirements, transformed

With the information from formula (1) and (2) and the matrix table above we can see that some pair-wise comparisons are doing twice. In other words we do not need to do  $n^2$  comparison. Instead we only need to do half the comparison, since the formula (2) say that  $w_{ij} = 1/w_{ji}$ . So it is really easy to apply this formula (2) to the comparisons that are not necessary. This leaves us to the diagonal, with the comparison with requirement  $w_i$  and  $w_i$  they will always be equal (i.e. The reciprocal value 1).

**Table 2 of Appendix F illustrate the values (differences between MoSCoW values.)**

**Comparing every pair using numerical values of stake-holder's influence** As explained in chapter 3 (stake-holder's Interest v.s. Influence & Power) we can compare different stakeholder on their interest and power level. This allows us to find an indication to compare how importance of each stakeholder. We need now to give a numerical value to each stakeholder that can be used in the matrix:

- High interest - High power (value = 4)
- Low interest - High power (value = 3)
- High interest - Low power (value = 2)
- Low interest - Low power (value = 1)

All requirements have now a numerical value based on the actor who defined the requirement. For example if a requirement has been indicated by actor  $x$  and this actor is defined earlier as "low interest - high power" it gets a 3. *See table 3 of Appendix F.*

Now we can calculate pair-wise differences of stakeholders for each requirement as we did in the previous step (*table 4 of Appendix F*).

**Sum up differences** Assuming that the value of difference between the requirements is the total value of differences of stakeholders and values provided by the MoSCoW we can create a new matrix. (*See table 5 of Appendix F*).

Some finishing steps to find the combined scale matrix from the summed up table of differences are:

- Change every difference "0" into "1", the reason for this is because in fact difference 0 means that the two compared requirement have equal importance.
- Negative values mean that in fact this requirement is of less important. Using formula (1) and (2) can know that for opposite importance  $x$ , we need to divide

1 to this value (1/x). In other words if we have negative values we just multiply by -1 and divide 1 to this value.

- All positive values can remain.

Please consider that the left and right side of the diagonal should be opposite (1/x). This makes sense because if requirement x is 2 times important as requirement y, then y is half less important as requirement x. **The result is illustrated in table 6 of Appendix F.**

**Calculate the eigenvectors** The next step according to Saaty [37] is to calculate the eigenvector v. The elements of the eigenvector correspond to the priorities of the requirements. If W is a consistent matrix, i.e. formula (2) holds for all the indices of i, j, k, then W is of rank one and  $\lambda_{max} = n$ . If the relationship  $\lambda_{max} = n$  is true, W is a positive reciprocal matrix.

$$Wv = \lambda v \tag{3}$$

Figure 7.4: Calculate the eigenvectors

The formula (3) is the mathematical definition on the relationship between the eigenvalue and the eigenvector. This is nothing that is specific for AHP, but is valid for all matrices. This means that v must be the eigenvector of W that correspond to the maximum eigenvalue  $\lambda$ . What this mean in reality is that you take every prioritization in you matrix and calculate the sum of the j columns.

$$w_{11} + w_{21} + w_{i1} + \dots + w_{(n-1)1} + w_{n1} = z \tag{4}$$

Figure 7.5: Sum of the columns

Then you divide each element in the column with the sum, z, you calculated with formula (4). The next step is to add up the element in row i. The final step is to divide each row sum with the amount of requirements n. So the next step is to calculating the sum of each column. For the first column we get for instance 10, the next column we get the sum = 31 and in the final column we get the sum = 10. Now it is time to divide each element with the corresponding sum of its column and calculate the row sums. (See result table 7).

The final step is to normalize the sum of the rows (i.e. divide each row sum with the number of requirements, which is in our case 17. (The result is shown in the last column of table 7).

$$\frac{1}{17} * \begin{pmatrix} 1.59 \\ 0.56 \\ 1.08 \\ \dots \end{pmatrix} = \begin{pmatrix} 0.09 \\ 0.03 \\ 0.06 \\ \dots \end{pmatrix}$$

Figure 7.6: Normalize the sum of rows

The last column with all the values (i.e. 0.09; 0.03; 0.06 etc) represents the normalized eigenvector of the comparison matrix. Based on the elements in the normalized eigenvector, also known as the priority vector, we can find the list of prioritized requirements (more details about the calculations can be found in Appendix F). The next section will use the presented prioritization to solve the existing conflicts between the requirements.

- Requirement R-F-02, degree of importance is 9%
- Requirement R-F-11, degree of importance is 3%
- Requirement R-F-13, degree of importance is 6%
- Requirement R-F-15, degree of importance is 6%
- Requirement R-F-18, degree of importance is 1%
- Requirement R-F-19, degree of importance is 4%
- Requirement R-F-49, degree of importance is 9%
- Requirement R-F-50, degree of importance is 9%
- Requirement R-F-51, degree of importance is 4%
- Requirement R-F-53, degree of importance is 13%
- Requirement R-F-62, degree of importance is 4%
- Requirement R-F-67, degree of importance is 4%
- Requirement R-F-69, degree of importance is 4%
- Requirement R-F-74, degree of importance is 1%
- Requirement R-F-81, degree of importance is 3%
- Requirement R-N-12, degree of importance is 5%
- Requirement R-N-24, degree of importance is 10%



### 7.3.1 Using AHP results to solve existing conflicts

In this section the solutions to the existing conflicts will be described using the results of Analytic Hierarchy Process:

- R-F-02 “Cross regional exchange should be possible in exceptional cases”, contradict R-F-74 “The exchange of medical data won’t be possible outside the region.” Eliminate R-F-74 considering the priority list of AHP.
- R-F-11 “Single-Sign-On (SSO) could be possible, so that the health provider only needs to login once” conflicts R-F-13, R-F-15, R-F-18, R-F-19. According to the AHP the degree of importance of R-F-11 is less than R-F-13, R-F-15, R-F-19. Eliminate R-F-11 (what mean Single-Sign-On (SSO) won’t be possible).
- R-F-49 “The specialists must be able to choose which data they prefer to share” conflicts with: R-F-51. “Patient must be able to provide access for each specific part of the medical data.” The degree of the importance of R-F-49 (9%), is higher than R-F-51(4%). This means that R-F-51 can be eliminated.
- R-F-50 “The specialists must be able to choose which data they prefer to take over” conflicts also with R-F-51 that is already eliminated. No action has to be taken.
- R-F-53 “It must still be possible to use traditional services like phone and written letters if necessary.” conflicts with R-N-24 “The system should make use of latest web engineering technologies.” In fact if we adapt R-F-53 we do not have to eliminate any of these requirements. Technically is possible to make use of existing traditional services beside new technologies. Both requirements can stay. In this case it was not necessary to use the AHP.
- R-F-62 “Patients must be able to provide access to other parties” conflicts R-F-19. The degree of importance is the same for both, but because R-F-19 is already eliminated R-F-62 can remain.
- R-F-67 “It must be possible to get access to medical treatment data by the insurance companies” conflicts R-F-18, R-F-19, R-N-12. The R-F-67 has lower degree of importance than R-N-12 and same degree as R-F-19. We eliminate R-F-67.
- R-F-69 “The system could have a link to public pharmacies in accordance with the NICTIZ [30] guidelines” conflicts with open standard constrains. We decide to remove R-F-69, because we decide not to implement requirements that contradict the project constraints. Also, here using AHP is not necessary.

The changes can be added to the list of requirements. *See Appendix (E)*

### Summary

This chapter introduced some criteria that could be used for the verification of the requirements, in order to improve the consistency, correctness, ambiguity and testability of the requirements. These criteria were originating from the Guide to the Business Analysis Body of Knowledge (BABOK Guide) [19]. First, the initial list of requirements is tested with the next criteria:

- Organized (whether the requirements are categorized and easy to locate)
- Modifiable (related requirements must be grouped together in order to be easy modifiable)
- Traceable (the source of the requirement must be known and the requirement can be referenced or located throughout the system)

However because of the categorization in several groups and providing an unique id's for each requirement, the initial list already meets these criteria and no actions were needed. Following this procedure, the requirements are also checked on internal dependencies. In some situations similar requirements may occur, only described in different words. In order to prevent repetition of requirements and improve consistency, we have investigated dependencies and the relations between different requirements.

Furthermore the requirements are also checked using the next criteria:

- Necessary (whether a requirement is essential and meets the business goals and objectives)
- Modifiable (related requirements must be grouped together in order to be easy modifiable)
- Unambiguous (a requirement must not allow for multiple divergent valid interpretations of the requirement)
- Correct (spelling and grammatical corrections)
- Feasible (whether the requirements can be implementable within the existing scope, infrastructure, with the existing budget, time-line and resources available)
- Design-independent (the specification must not imply a specific architecture)
- Testable (each requirement should be testable that is, it must be possible to design a test that can be used to determine if a solution has met the requirement)
- Prioritized (in order to determine which requirements are essential, desirable, or optional)
- Consistent (ensure that individual requirements do not contradict each other or describe the same requirement using different wordings)

The final activity to verify the requirements was resolving conflicts between the requirements. It happens that among some of the requirement conflicts exist, because these contradict each other or because they cannot be met at the same time. In order to create a consistent list of requirements we need to resolve these conflicts first. One of the common techniques for prioritization of requirements is applying the MoSCoW method, which is also advised in the BABOK Guide [19]. However each requirement can also have multiple conflict relations with other requirements and those requirements can also conflict each other. In other words, the MoSCoW method considers only pair-wise prioritization. A better method is applying Analytic Hierarchy Process (AHP) what is originating from a decision-making framework used for large-scale, multi party, multi-criteria decision analysis and first introduced by L.Saaty [37]. In contrast with the MoSCoW method, AHP calculates pair-wise comparison for all requirements in the list by providing a scale of 1-9 to each pair. This scale is a measure for the difference between each of the requirements. In general the AHP method compares every pair of requirements, derives a priority vector of relative weights for these requirements and calculates the by-product, i.e. the inconsistency measure. At the end the results of the AHP prioritization method can be used to resolve the existing conflicts between the requirements.



## Chapter 8

---

# SOLUTION ANALYSIS

### Overview

This chapter describes several existing technical solutions for the exchange of medical data at regional level. The reason that these specific solutions have been chosen, is that each of them use a completely different approach for the exchange of medical data. In this chapter for each solution, its goals and the communication approach is described. For some of the solutions also the communication pattern is explained.

**At the end of this chapter we will have an overview of the next solutions:**

- S1-EHR based exchange
- S2-Exchange using a message broker
- S3-OZIS-Regional medical data exchange
- S4-Health information portals
- S5-Secure mail
- S6-AORTA

## 8.1 EHR based exchange

The most basic and at the same time frequent type of digital medical data exchange occurs within the same organization, through the same EHR system across different departments. In these situations the user is able to access medical data from a database of Health Information System (HIS, or in Dutch ZIS). Each user connects to the system using a client where an EHR application is installed. Based on the authorization profile and the rights provided to the user, the user is able to access and use specific functionalities of the EHR. The access rights are configured by the administrator of the system. Some of the most common functionalities that these users apply are adding new patients, reading medical data and editing the medical file of the patients. Because all EHR clients are using the same database, the medical data can easily be accessed by different authorized users (within the same organization). (Figure 8.1)

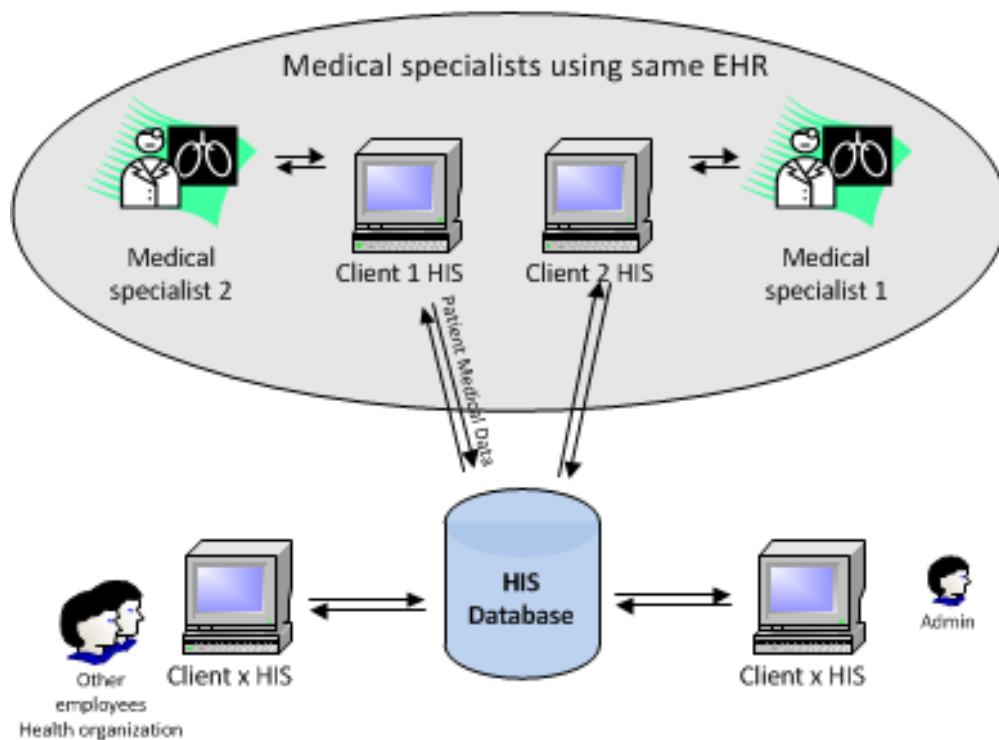


Figure 8.1: Multiple clients using the same EHR system to access a Health Information System (HIS) database

In some cases the user needs to use a valid UZI-card for the authentication. This might be important for some specific functionalities, for which the user might perform sensitive tasks that need extra security. Figure 8.2 illustrates an example of an EHR interface (EZIS CS) requesting for UZI-card login.

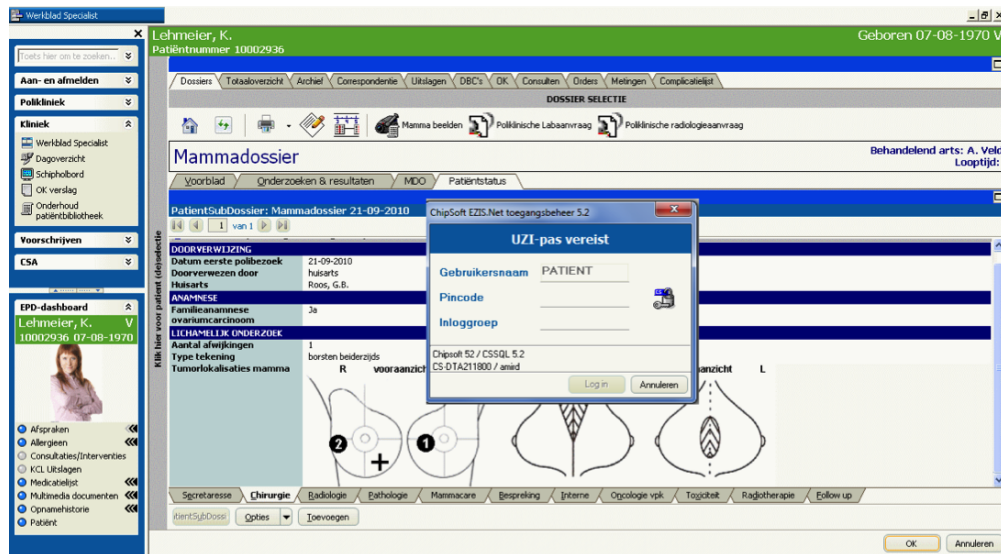


Figure 8.2: EHR interface, UZI-card login

## 8.2 Exchange using a message broker

A possible type of the exchange of digital medical data is between different EHR systems located in multiple health organizations. The standards used in each system are often different and the exchanged message need to be translated to a uniform standard (for instance EDIFACT format) before sending. Several customized message brokers are used for this reason. Message broker is an intermediary program, which translates the language of a system from one standard and sends it over by way of a telecommunications medium. It is possible to use the same type of message broker and exchange servers for both sides, but this is not always the case and different message brokers can be used. Often it is common to run the exchange server couple times a day (for instance at the end of the day). The message broker reads then all messages (for instance discharge letters of the patients) from the EHR database and send them to another partner organizations. This is done by a scheduled script, which collects and translates all data according to the standards (EDIFACT, HL7 etc. see chapter 2.2.2 for more details). The translated message is transferred through the Internet to a router of the next organization (Health organization 2, in figure 8.3). The message needs first to pass through a firewall, where-after the message is forwarded through the Demilitarized Zone (DMZ) to the right communication server. Next this message is translated back to the standards used in health organization 2. (This is shown in figure 8.3)

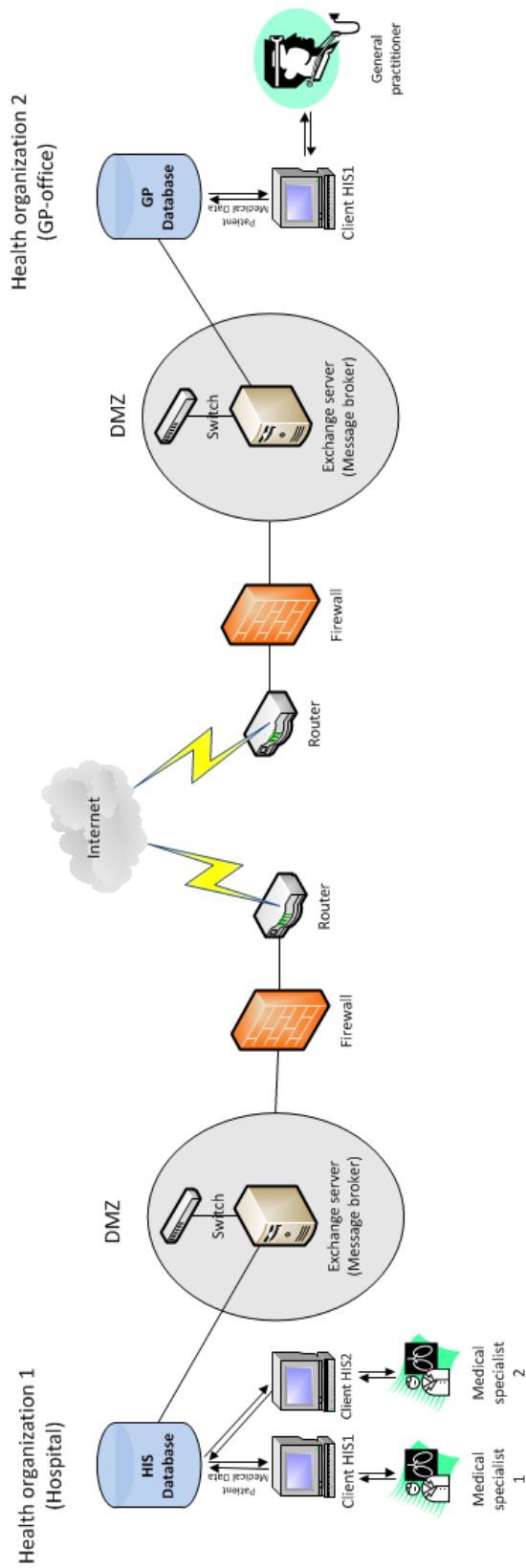


Figure 8.3: Exchange of medical data using a message broker



### 8.2.1 Communication pattern: message broker

Let us explain different requests that are sent to the message broker in more details, by providing a practical example. Assuming that two different health organizations decided to exchange medical data using EDIFACT (see chapter 2.2.2 for more details) standard. The Edifact organizations are often initiated by (a group of) hospitals. In some cases the insurance company is the initiator (example is the RHIS GEMS in Schiedam, Vlaardingen, Maassluis & Delftland ). [28] Beside the hospitals especially GP organizations and laboratories are co-founders of EDIFACT data exchange systems. The type of communication realized with EDIFACT, is in almost all cases a one-way communication (a so called “push” communication). EDIFACT standards originate from the old days, when the size of messages in electronic communication was the most important factor. For this reason the messages are quite small in size, but very hard to read and understand by its users. It also does not facilitate a “two-way” communication, simply because it is not build for this purpose.

Figure 8.4 illustrates a simple example using the EDIFACT standard and a message broker. In this situation a general practitioner (GP) wants to send a patient to a hospital for further investigations or treatment. The GP does this by sending the hospital a written letter (one copy for the patient, who needs this in order to make an appointment). The GP can also call, fax or send an email to the hospital. In other words the first initiation by the GP is not necessary electronically. In some cases the GP can make an appointment for the patient by logging into a health portal (see for more details next pages) or some other tool provided by the hospital.

It is however unusual that EDIFACT will be used to start the first initiation (request for an appointment). The return message however can be an EDIFACT message. Also, changes relating to the current situation of the patient are updated, by occasionally sending out EDIFACT messages. In figure 6, a situation is shown where a patient is transferred to another department in the same hospital and a new update message is sent to the GP. Because in general there exist different interpretations of the EDIFACT messages, these need often to be translated into another version of EDIFACT that is known by the GP’s information system. The translation is normally performed by a separate external message broker application. This message broker application has a depository of the translation keys (different definitions of EDIFACT by GP information systems), messaging and communication handlers. Another internal application takes care of creation and sending EDIFACT messages to the message broker. Normally this is done periodically (for instance at the end of the day). This communication module checks the database of the EHR system and creates and sends back the necessary messages to the message broker. The records gathered from the EHR database needs to be translated into EDIFACT messages before sending.

All send messages by the message broker are saved into a separate folder on the GP’s side, where another application translates the data into more readable format used in the GP’s system.

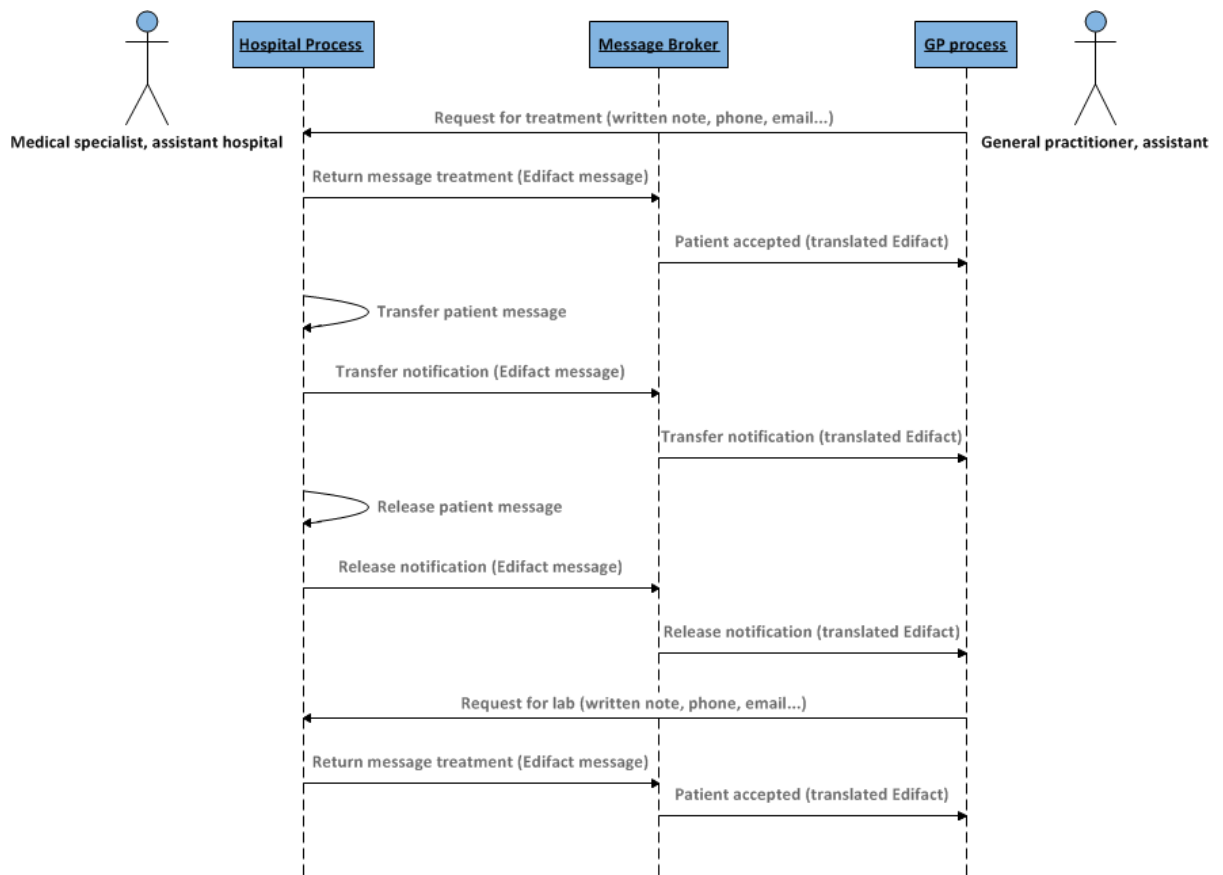


Figure 8.4: Exchange of medical data using EDIFACT

### 8.3 OZIS-Regional medical data exchange

A third type of regional health information exchange takes place by making use of the facilities developed by OZIS [33]. The OZIS Foundation is a partnership of providers of information systems, which aim at the implementation of standards and the exchange of data at regional level. [33]

**OZIS standards mainly focus at four areas:**

- Exchange services for pharmacies
- Exchange services for GPs
- Exchange services for integrated care.

The OZIS [33] standards are designed for local and regional applications of data exchange between pharmacies and physicians that have a certain close corporation. Usually, this contains co-operating local or region health information organizations. OZIS networks make use of a Regional Switch Point (Central Patient Index) using a patient's reference index and a health-care portal. Pharmacists have traditionally been organized separately in so-called "self-OZIS rings" (approximately 90% of the pharmacies in the Netherlands has joined a OZIS-ring). The participant (medical special-

ist) first needs to send a request (including all needed authorization and authentication data) to the central index. If the actor has all needed rights a list of the patients is returned back. Next the participant sends a new request to obtain patient's medical file and as the final step, the participant sends back the medical report. (this is illustrated in figure 8.5)

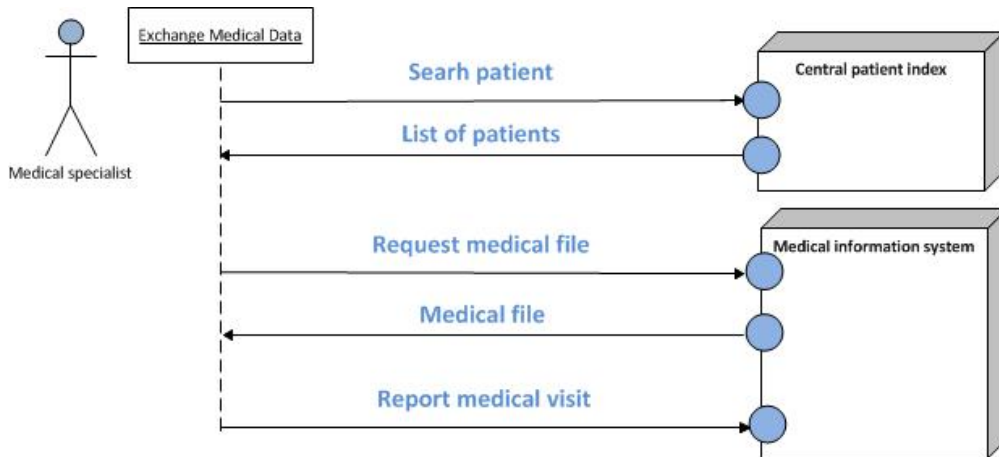


Figure 8.5: Basic OZIS messaging using a regional patient index

Using OZIS [33] medical information messages can be transmitted in a structured way from one information system (IS) to the next. OZIS organizations make use of the same standards for the exchange of medical data. This is in contrary with the previous explained solution (exchange using a message broker), where different standards are possible. In theory by using the same standards we expect the loss of data should be minimal. However in practice this is still also very dependent on the EHR system used in each organization. Certain structures in the medical record may or may not be present in the EHR systems. If data is transferred from a more complex structured database to another (less structured), the information that is transported needs to be converted into a “free text” information. In fact there is no loss of information, but in a technical sense the structure of information has been lost.

### 8.3.1 Communication pattern: OZIS

As explained earlier the communication between different health organizations in the OZIS cases always start by a search into the Central Patient Index (CPI). Next a direct request from one health organization to another takes place, following by a possible result. Let us explain this pattern into more details by providing the steps needed in a practical example (co-operation between a hospital and a pharmacy):

- First the hospital selects the patient's medical file from its own EHR database (see chapter 6 - use cases) and searches into the CIP using some of the important search parameters (like: patient's number, name, birth date, gender, zip code, insurer and, or policy number). If this patient is found in the CPI database, a “local” patient's number within the pharmacy database is returned back.

- Now the hospital is sending a new request to the pharmacy asking for the medication history of the patient. A unique process identifier is assigned to this request, which will be used during the rest of the process.
- In the next step the requested medication history will be returned to the hospital.
- Finally, after delivery of the drug to the patient (at the hospital) the updated pharmacy information is returned back by means of a message with the dismissal data. (figure 8.6)

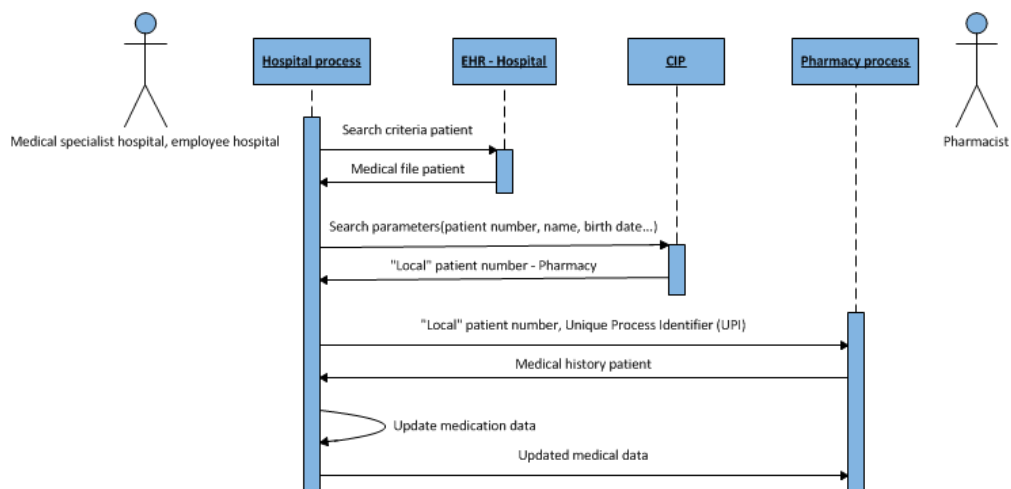


Figure 8.6: Sequence diagram, OZIS example communication

## 8.4 Health information portals

In some regions the health providers, exchange medical data using a patients portal (or health portal). These web-applications make selected parts of the medical file accessible for other users outside of the borders of a health organization. Also, it is common to provide access to the patients. Health portals are in fact dynamic web pages that are presenting data retrieved from the web-server, which has at the same time access to the EHR database. In order to see a page the user needs to be logged in. This is done by providing the users with a unique user-name and a password. Also, it is possible to make use of the more secure authentication techniques like verification of the BSN by DigiD or making use of UZI-cards by the specialists. Health portals are well known for their various possibilities for the exchange of medical data. A health information portal can also be used as a communication tool between different users in the system (medical specialist and/or patients). Also, it provides different possibilities for patient's participating in the health care. Patients are now able to share their personal health data with the medical specialists. One of the biggest disadvantages of web-based applications are the security risks that are involved with it. The data that are transferred across Internet need to be encrypted to prevent for instance "man in the middle" attacks. Also, the risk of getting direct access from the DMZ to the database is

considered as one of the threads. There is also a chance that an application or user can make direct connection with the database or access the data that is transferred between the web-server and the database. Strict configuration and monitoring applications are needed to reduce these types of threads. (Figure M.16 of appendix M)

#### 8.4.1 Communication pattern: Health information portal

Concerning the communication pattern of health information portals, there are several sequences possible. Figure M.17 of appendix M, illustrates a situation where only one of the organizations is sharing the medical data from its own EHR database with others. However it is also possible that more than one co-operating parties at the same time make use of web-services to exchange their data with other organizations. The external users need to login into a different web-portal to access medical data. In other words the communication pattern really depends on the available services and achieved agreements between different parties.

To provide an example of how this might work, let us describe a simple situation with only one web-server and different users exist. The web-server at “Health organization 1” is able to collect specific parts of the medical data from the HIS/EHR database. In other words some data that are filled in by the medical specialists into the database (using an internal EHR system), are made available to other external users through the web applications. Let us assume that the users from other locations (right side of figure 8.8) are already logged in by providing their user credentials in the web-browser.

The communication pattern described in figure 8.8 is only one of the possible communication sequences of the health portals. As describes earlier the medical specialists in health organization 1 are also able to fill in medical data of the patient using the EHR system. This does not necessary happens at the time of request, but is could happen earlier. A user can also add medical data or files using the health portal. Again this user should be authenticated and the authorization rights are checked by the web-server. If these are all fine, a request is send to another page that can add these data to the database.

Beside the explained situation all other scenarios are also possible, but the important issue, that we would like to note is that all communication goes through the web-server that has access to the database. At the same time the medical specialists are also able to add or update data through the usual EHR system within their organization.

### 8.5 Secure mail

Email is nowadays one of the most common communication methods. Also, care providers have widely access to an e-mail account. The common email services do not sufficiently secure the medical content that is send together with the messages. In most cases the users are the weakest security point of the system, which is also the case with email communication. Not all users are aware of the encryption possibilities and some users bring in several security threads by for instance opening links or files that can contain spam or viruses. This can in some cases even lead to the loss of private medical data and spreading this data in public.

Also most generic email interfaces are not build to send and display data message in EDIFACT or HL7 standards. Common email services represent EDIFACT messages as plain text (which is very hard to read and understand). The HL7 messages are in fact comparable with XML messages and may be blocked by some of the providers. With introducing the more secure e-mail solutions custom made for the exchange of medical data we can overcome some of these problems. One of the existing solutions for the secure-mail in the Netherlands is Zorgmail. According to the developers of the Zorgmail 90% of all electronic messages in care are sent through this system. Annually, there are about 50 million messages sent over by 9,000 participants. [13]

Secure email in the health-care is intended for communication between:

- Specialists, from various institutions
- Specialist, first line health-care
- caregivers, firs line health-care.

Some examples are: Electronic communication between doctor and prescription pharmacy, electronic transfer of specialists letters, electronic exchange mutations, dismissal and transfer messages, electronic exchange and laboratory results. The authentication takes place with a certificate in combination with user-name and password and / or the UZI system certificate (depending on the situation). Also, it is possible to translate different messages from one standard to another. Some examples are mappings from HL7 or XML to EDIFACT and EDIFACT to email or XML and EDIFACT to fax.

### 8.5.1 Communication pattern: Secure mail

The communication pattern of secure mail for the health-care can be described as next: First the user needs to fill in the credentials into the page of secure mail provider. The secure email page can now be opened, by selecting a link to this page (select link, button or tab). When a user opens a email message, it can see among other information, the receiver of the message, title and some text. Depending on the number of co-operating organizations several contact persons exist within the contact book. Similar to a common email a message contains a subject, content, receiver and if needed an attachment (medical file as image, PDF, Word, EDIFACT, HL7 etc.). The user is also able to fill in an email-address, which is “not” included in the secure network list of addresses. In this case the user gets a message that the application cannot guaranty secure communication. In other words the secure communication is only possible if both parties make use of the same secure-email application. The user also can see the received message by looking into the email in-box as all other usual email services. Figure 8.7 illustrates one of the possible scenarios for sending an encrypted email message using the secure mail application. The communication goes through a web-server that handles the request from the web-browser of the user. This message is encrypted and send back to an exchange server. In this case the web-server applies some of tasks of an ordinary email-server (email application). The same server also takes care of publishing web-pages and sending encrypted email messages to another servers, where these messages are saved. In practice it can happen that several tasks are distributed among multiple servers. (see also figure 8.7)

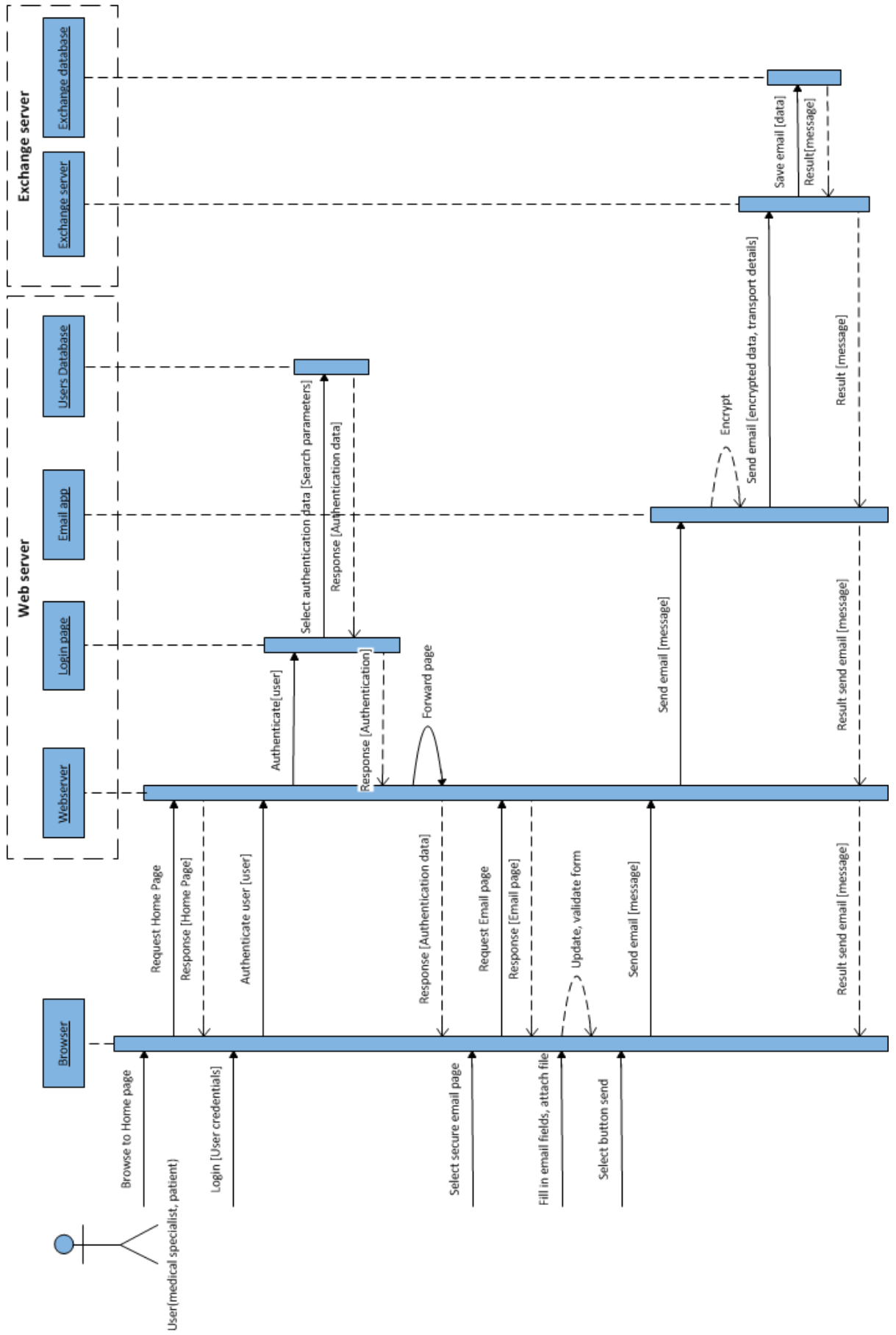


Figure 8.7: Sequence diagram, example communication pattern secure email

## 8.6 AORTA

AORTA is the architecture of the national infrastructure for the exchange of medical data between different health providers at the national level [29]. Among the first users of this system were health providers, but later plans should also provide access to the patients and health insurance companies. AORTA includes the following applications:

- Electronic medication record (EMD)
- Exchange medical data of patient between GPs (WDH)
- Exchange medical data between emergency units (SHE)
- Electronic pathology records (PAD)

The most important part of AORTA is its health-care information broker (ZIM), which is operated on the national switch (LSP). The health provider system (XIS) should connect through the national switch in order to make use of the exchange possibilities. To uniquely identify patients, health-care providers and health-care systems this system uses the UZI-register (Unique Health-care Identification) and the SBV-Z (Post Sector Provision in Care BSN). The connection is enabled via a data communications networks (DCN) and operated by the health provider services (ZSP). Figure 8.8 illustrates how the health provider system (XIS) is connected through ZSPs to the national switch (LSP).

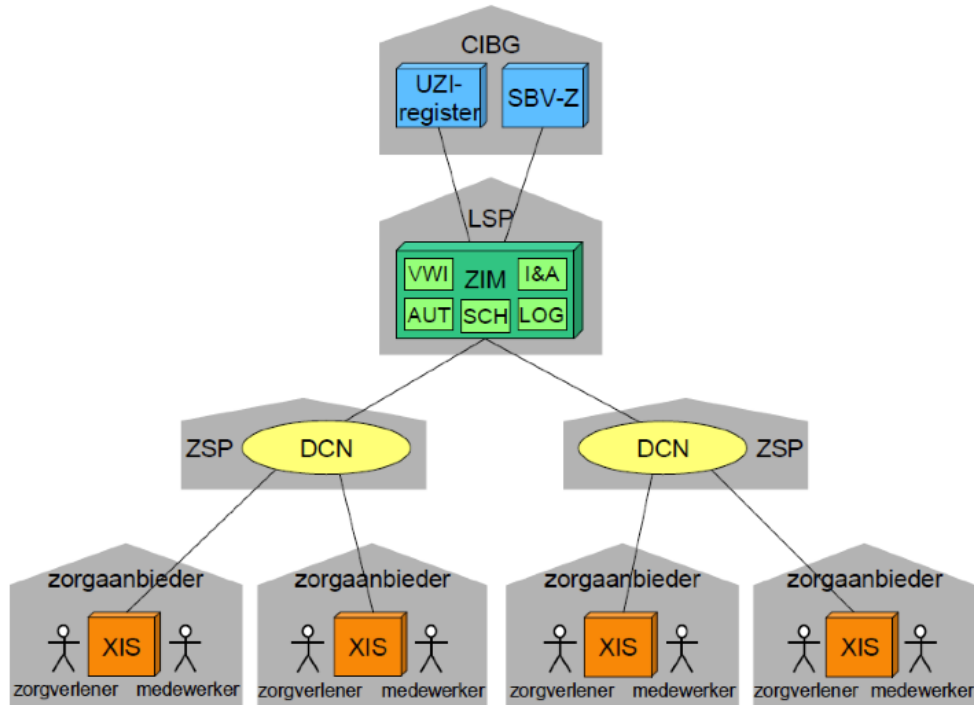


Figure 8.8: AORTA architecture, using national switch (LSP)



### 8.6.1 Communication pattern: AORTA

As described earlier the communication in AORTA [29] is based on the national switch (LSP). All communication goes first through this point. In fact the LSP acts as a bridge between several services (like authentication, authorization and selecting data services). Figure M.18 of appendix M, illustrates selecting patient's medical data, which is one of the possible scenarios of data exchange using the national infrastructure. The LSP is used to find the reference index of the source for the searched medical data. This reference index contains in fact the identification data of the health organization that has the medical data of a specific patient. There are also all other scenarios like pushing data, publishing and subscribing to data possible, which will not be explained here because of the limitation of time and the scope of this report.

#### Summary

The most basic and at the same time frequent type of digital medical data exchange occurs within the same organization, through the same EHR system across different departments. In these situations the user is able to access medical data from a database of Health Information System (HIS, or in Dutch ZIS). Each user connects to the system using a client where an EHR application is installed. Based on the authorization profile and the rights provided to the user, the user is able to access and use specific functionalities of the EHR.

A second type of data communications between health organizations is making use of message brokers. A message broker is an intermediary program, which translates the language of a system from one standard and sends it over by using a telecommunications medium. Often it is common to run the exchange server couple times a day (for instance at the end of the day). The message broker reads then all messages (for instance discharge letters of the patients) from the EHR database and will send them to another partner organizations. This is done by a scheduled script, which collects and translates all data according to the standards (EDIFACT, HL7) etc. The message first needs to pass through a firewall, where-after the message is forwarded through the Demilitarized Zone (DMZ) to the right communication server.

A third type of regional health information exchange takes place by making use of the facilities developed by OZIS. The OZIS Foundation is a partnership of providers of information systems, which aim at the implementation of standards and the exchange of data at regional level [33]. OZIS networks make use of a Regional Switch Point (Central Patient Index) using a patient's reference index and a health-care portal. OZIS organizations make use of the same standards for the exchange of medical data. This is in contrary with the previous explained solution (exchange using a message broker), where different standards are possible. In theory by using the same standards we expect the loss of data should be minimal. However, in practice this is still also very dependent on the EHR system used in each organization. If data is transferred from a more complex structured database to another (less structured), the information that is transported needs to be converted into a "free text" information. In fact, there is no loss of information, but in a technical sense the structure of information has been lost.

A fourth type of regional health information exchange takes place by making use of the health portals. In some regions the health providers, exchange medical data using

a patients portal (or health portal). These web-applications make selected parts of the medical file accessible for other users outside of the borders of a health organization. Health portals are in fact dynamic web pages that are presenting data retrieved from the web-server, which at the same time has access to the EHR database. A health information portal can also be used as a communication tool between different users in the system (medical specialist and/or patients). Also, it provides different possibilities for patient's participating in the health care.

The fifth solutions explained in this chapter is the Secure mail application customized for the health-care. Email is nowadays one of the most common communication methods. Also, care providers have widely access to an e-mail account. Most generic email interfaces are not build to send and display data message in EDIFACT or HL7 standards. Common email services represent EDIFACT messages as plain text (which is very hard to read and understand). The HL7 messages are in fact comparable with XML messages and may be blocked by some of the providers. With introducing the more secure e-mail solutions, custom made for the exchange of medical data, we can overcome some of these problems. The users can send via a special web-page secure mails to each other. The exchange of the messages is arranged by a custom made mail server. Also, all type of medical documents can be exchanged between different health organizations.

The sixth solution explained in this chapter is AORTA. AORTA is the architecture of the national infrastructure (also called L-EPD) for the exchange of medical data between different health providers at the national level [29]. The most important part of AORTA is its health-care information broker (ZIM), which is operated on the national switch (LSP). The health provider system (XIS) should connect though the national switch in order to make use of the exchange possibilities. To uniquely identify patients, health-care providers and health-care systems this system uses the UZI-register (Unique Health-care Identification) and the SBV-Z (Post Sector Provision in Care BSN). The connection is enabled via a data communication network (DCN) and operated by the health provider services (ZSP).

## Chapter 9

---

# VALIDATION OF THE REQUIREMENTS

### Overview

The list of verified requirements need also to be validated. During the validation we try to find out whether the requirements represent the actual needs of the stakeholders. In this research, a structured walk-through (further explained in next chapters) with the experts is used to test the validity of the requirements. Beside, the list of requirements can be used to evaluate some of the existing solutions explained in the previous chapter. By applying an evaluation process we will be able to find possible shortcomings or inconsistencies in the existing list of requirements. In practice, the validation is an ongoing process. The list of requirements can be updated and improved. This is because during each meeting with the experts new points for improvement can be indicated. Because of the limitation of time and resources during this research only one iteration phase is performed (in accordance with the experts on this field within the IT providers organization).

During the verification phase of the requirements (chapter 7) we mainly focused on the consistency of the requirements among each other. The requirements were also tested on correctness, feasibility, relevance, testability and other important criteria. The consistency of the requirements has been improved by resolving existing contradictions and conflicts between each of the requirement (chapter 7.2). In contrast to the verification, validation is the process of evaluating requirement documents, models, and attributes to determine whether they satisfy the business needs. In many software projects a prototype is developed at the end and the results are evaluated together with the stakeholders. However, in this research prototyping is out of scope. This is because we do not try to develop a software solution, but a list of requirements that need to be usable by its users (IT-software developers). The list of requirements will be used by the Software developers to design new RHIS and to improve existing exchange systems.

Also, it is important that these requirements can be used to evaluate existing software solutions. That is why it has been chosen to use them for the evaluation of couple of important existing solutions. Beside this, also a technique named “structured walk-through” is used to evaluate the list of requirements with some experts of regional health information systems. The structured walk-through is a technique advised by the International Institute of Business Analysis (IIBA) [20] in the BABOK guide [19] and used very often in software projects.

**This chapter explains the two requirements validation steps:**

1. Structured walk-through (evaluation together with experts)
2. Validate usability of requirements (using existing solutions)

## 9.1 Structured Walk-through

Structured walk-through is performed to communicate, verify and validate requirements with experts of health information systems. Walk-through may also be referred to as a requirements review. This is partly true, but it follows a more formal process and uses check-lists and other tools.

The structured walk-through methods requires next prerequisites: List of constraints, functional and non-functional requirements: The list of requirements is already gathered, specified and verified in previous chapters. The review may cover only one requirement document, several related documents, or an entire requirements package. A list of appropriate reviewers: Reviewers are project stakeholders, project team, or other resources with specific expertise in the type of requirement being reviewed. The available reviewers at ChipSoft Netherlands are:

- Experts health information systems (evaluating constraints and the requirements)
- Consultant health information systems (evaluating constraints and the requirements)
- Technical developers (evaluating functional requirements and use cases).

The external reviews include:

- External project managers (TU Delft)
- Patients (evaluating patient's requirements)

A meeting vehicle: A review may be held in a presentation room with all participants present or it may be held using a technical facility allowing participants in remote locations to participate (i.e. collaboration tool, video-conference, Internet meeting software). Also, it is important that the participants are fully aware of the scope and goals of this project. To all members it is explained what is requested from them and which issues need to be reviewed.

### **Tasks during the session:**

- Introduction of parties attending presentation
- Statement of purpose of the reviewed deliverable
- Project background (if required for external parties)
- Agreement of actions or changes required
- Formal walk-through or review of deliverable (evaluation requirements)
- Review of deliverable status (e.g. signed-off, not signed off, etc.)

The main goal is to achieve one of the next agreements:

- There are quality improvements that can be made to the requirements document
- The requirements document is acceptable in its current form

- Additional reviewers are required to comment on or approve the requirements document

At the end of the session the notes (of all stakeholders) are evaluated and considered for the next revision.

### **9.1.1 Results structured walk-through**

During the presentations at the IT-company (vendor of health information systems), minor changes / improvements have been made in the list of the requirements. As explained earlier, during the validation we try to find out whether the requirements represent the actually needs of the stakeholders. In general the experts were pleased with the current list of requirements. In general the experts agreed with the presented list of requirements and think that this list represents the needs of several important stakeholders. However, the experts were not sure whether the requirements of the IT vendors (during the development) should be included or not? The IT experts were also pleased with the requirements that can be used to evaluate their current software solutions, because in the past a concrete list of requirements did not exist. They were also satisfied with the methodological approach for gathering, analysing and specification of the requirements. Also several presentations have been given at TU-Delft during the 2-weeks meetings. The comments during these meetings are regularly updated. Small groups of patients (3-5 persons) are asked for their opinions specially about the requirements that related to the patients. Almost all asked persons agreed with the participative role of the patients in exchanging medical data.

## **9.2 Validate consistency by evaluating the solutions**

During this step the list of verified functional and non-functional requirements (chapter 7) are used to evaluate different solutions (chapter 8). As explained earlier, by applying the requirements we will be able to find possible shortcomings or inconsistencies in the existing list of requirements. Using the list of the functional and non-functional requirements for evaluating the existing software solutions is one of the purposes of making this list, beside its use during the development of new software. During the evaluation, it is checked whether this list can help us to find important differences between several existing solutions. In other words, this validation step checks the usability of the list of requirements for the evaluating of different solution. An evaluation can also help us to check the list of requirements on completeness. Any missing requirement can be added to the list of requirements after the evaluation has taken place.

**Appendix G - provides an overview of the validation process by applying different requirement to next 6 solutions:**

1. S1-EHR based exchange
2. S2-Exchange using a message broker
3. S3-OZIS Regional exchange
4. S4-Health information portals

5. S5-Secure mail (Zorgmail)

6. S6-8.6 AORTA

These solutions are explicitly chosen because of their different approaches for exchange of medical data.

### **9.2.1 Results validating the consistency**

During the evaluation of different solutions couple of issues were found for the next requirements:

- R-F-09: None of the solutions could meet this requirement. All systems needed to register the patient before any exchange could take place. In other words it almost never happens that the data of some patient is exchanged without before having this patient registered. This requirement is not valid and needs to be removed.
- R-F-10: This requirement contains two different things, using the UZI-card and the verification of social citizens numbers (BSN, verification). There are however solutions that only use one of these techniques without implementing the other. In order to improve the consistency this requirement needs to be eliminated. Actions:
  - Eliminate R-F-10 “The UZI card and verification of the Citizen Service Number (BSN) could be used for the authorization.”
  - Add new requirement R-F-93 “The UZI card could be used for the authorization.”
  - Add new requirement R-F-94 “The verification of the Citizen Service Number (BSN) could be used for the authorization.”
- R-F-32: “It should be possible to exchange medical data of the patients suffering from chronic diseases.” If we compare different solutions we also find out that it is possible to exchange medical data within the same EHR. The importance of this requirement is the possibility to exchange medical data within the integrated care, inclusive treatment of chronic diseases. In fact all solution meet this requirement completely. This requirement can not be valid. Action: Adapt R-F-32: “It should be possible to exchange medical data between different health organization within integrated care.”
- R-F-53: “It must still be possible to use traditional services like phone and written letters if necessary.” All solutions meet this requirement. It is always possible to use other traditional services beside the provided solutions. This requirement is always met, regardless which solution we chose. Action: Eliminate R-F-53
- R-N-27 “All security resources such as firewalls, remote access servers and so on must be configured properly, in order to compliance with security policies” It

is very hard for all solutions to decide whether they meet this requirement or not. In fact it is very much dependent on the situation. This requirement is part of the administrator tasks and is not very much related to the data exchange systems. This requirement is invalid and also outside of the scope. Action: Eliminate R-N-27

- R-N-28 “All computing resources, such as EHR system, network devices and applications should be monitored for changes in configuration that increase security risks.” Same as R-N-27. Action: Eliminate R-N-28.



### 9.2.2 Remarks evaluation solutions

The requirements are used to evaluate several solutions for the exchange of medical data at regional level. We have looked at the level of accomplishment for each requirement in different solutions. In order to be able to measure the level of accomplishment a factor (number between 0 and 1) is used. If the requirement is 100% guaranteed by the solution, the factor of accomplishment is equal to 1, otherwise if this requirement is not fulfilled this factor is equal to 0, otherwise if the requirement is partly fulfilled then this factor is equal to 0.5. It is also important to look at the priority factor of the requirement (importance of a requirement). The priority (nominal value) is found according to the next mapping:

- Won't = 1
- Could = 2
- Should = 3
- Must = 4

The level of accomplishment of the requirements for each solution is equal to: Level of accomplishment = (Priority nominal value) \* (Factor accomplishment requirement)

*Appendix H, illustrates the evaluation considering the found requirements for solutions 1 to 6 (see chapter 8 for detailed explanation of the solutions).*

At the end by summing up all numbers, provides us an estimation of the quality of several solutions, considering different functional and non-functional requirements.

#### **The evaluation results were as next:**

The Health information portal in the end scored highest, followed by the secure mail and the EHR exchange. In general it seems that the Health portal and Secure mail are relatively independent from the existing systems and solutions and this is also their main power. Because of this the efforts to integrate them with the existing infrastructure is relatively minimal. Also, the accessibility of such systems scored high, because these services can be accessed relatively easy by its users from anywhere using an Internet connection. It is also much easier to provide patients access to their health information using the health portal through the web. This is for other solutions not really easy to realize.

Table of *Appendix I*, provides an overview of the sum of levels of accomplishment for different categories. For the advanced possibilities in exchange of medical data, such as attaching medical files and being able to exchange all types of data format S1 (EHR based), S4 (Health portal) and S5 (Secure mail) scored highest. On the authentication requirements category S6 (AORTA) had the most secure authentication. However on authorization and privacy requirements, S6 (AORTA) scored not so high, because in fact all medical specialists in the country are connected to this network and have access to the data. This increases the risks for the privacy of important private data of the patients. The capabilities category included the possibility to make use of

the latest web engineering techniques or if it is possible to exchange data in couple of steps. S4 (Health portal) scored also highest on this requirements category. The coupling possibilities to the existing systems (like external medication link to pharmacists and EDIFACT messages), scored highest by the OZIS and Health portal. The details of the results of the evaluation for several solutions can be found in the table of Appendix I.

## **Summary**

This chapter presented two different methods for the verification of the requirements. These methods were:

1. Structured walk-through (evaluation together with experts)
2. Validate usability of requirements (using existing solutions)

Through several presentations at an important IT-supplier of health information systems the results were shown to several experts and consultants. In general these people were satisfied with the current state of the requirements and think that these requirements are worthy enough to be applied in the practice. Also, several presentations have been given at TU-Delft during the 2-weeks meetings. The comments during these meetings are regularly updated. Beside these also small groups of patients (3-5 persons) were asked on their opinion. Almost all patients were pleased with the participative role of the patients in exchanging medical data.

During the validation phase, through the evaluation of the existing solutions, several requirements needed improvement. These were often the requirement where none of the solutions could meet, or that all different solutions could meet. In both of these cases the requirements needed to be adapted, to improve the validity of the requirements. Without applying these requirements to these technical solutions the validation was not possible.

After the evaluation of the six solutions, the health information portal scored highest, followed by the secure mail and the EHR exchange. In general it seems that the Health portal and Secure mail are relatively independent from the existing systems and solutions and this is also their main power. Because of this the efforts to integrate them with the existing infrastructure is relatively minimal. Also, the accessibility of such systems scored high, because these services can be accessed relatively easy by its users from anywhere using an Internet connection. It is also much easier to provide patients access to their health information using the health portal through the web. This is for the other solutions not really easy to realize.



## Chapter 10

---

# Conclusions and Future Work

### 10.1 Conclusions

Considering the research objectives described in Chapter 1, the main goal of this research has been the identification and specification of the requirements of Dutch stakeholders, from which the most important are the users of RHIS. Beside the mentioned goal this research also tried to describe the current state of RHIS in the Netherlands and clarify some of its complexity factors.

The findings in Chapter 2 show us that the organizations, which are involved in the exchange of medical data at regional level, are mainly regional health providers. These providers are often hospitals, but also smaller clinics including GPs. The hospitals can be divided into three main groups: General hospitals, university medical centres (UMC's) and specialized hospitals. Often the patient's medical data is distributed in several databases maintained each by different health organizations. Occasionally, collection of these data is needed to provide high quality care to the patients. This means that the data should be available where it is needed or otherwise transferred between health organizations. The transfer of patient's medical data creates several complexities related to the privacy and security of personal patient's data.

Previous research (discussed in Chapter 2.1) showed that challenges of Health Information Exchange (HIE) are often related to the trust and commitment from the stakeholders, the costs and benefits and its overall value. Other research indicate that proper modelling and design is very important for the successfulness of RHIS (Kari-maa and Nykanen [21]). The socio-technical nature of health information systems is often not well understood and should receive more attention. According to these investigators, the design and development of health information systems should not only be based on practice, but also be based on health informatics as a scientific discipline. Constructive evaluation study following the RHIS life cycle helps to guide further systems development.

Different scenarios for the exchange of medical data at the regional level involve patient transfer and corporation between several health providers. These scenarios can be categorized by defining whether the exchange takes place within or outside the organizational borders. Furthermore, we can distinguish the exchange of data between the same or different medical specialities. This research distinguished 4 different important scenarios, several standards and different interoperability levels (see Chapter 2.2 for more details).

According to Chapter 3, the stakeholders of RHIS can be divided into two different groups: the internal and external stakeholders. Some of the described stakeholders are supporting RHIS, while others are completely against any kind of medical exchange. The consumers and patients organizations are mostly concerned about the privacy and security of patients' data. The governmental organizations generally support the exchange of medical data and have already invested in the national infrastructure. They also see the development of RHIS as an important step in further development of a national infrastructure for sharing medical data. Despite the concerns of privacy and security, the insurance companies like to access medical data of the patients in order to have a better understanding of the costs made by them. The IT companies (vendors of health information systems) are involved in design and development of the regional health exchange software solutions. The medical specialists (primary users of RHIS) and the patients (secondary users of RHIS) belong to the group of stakeholders with the highest interest in RHIS. The viewpoints of this group of stakeholders can directly be used for specifying the functional and non-functional requirements. Beside this, the viewpoints of other stakeholders (governmental organization, IT developers, patient's and specialists' interest groups) are used to add complementary requirements and constraints.

Chapter 5 presented the results of quantitative and qualitative research among the users of RHIS and experts. Previously, in Chapter 4 the survey methods have been explained in details. The results of the survey among the medical specialists (represented in Chapter 5.1) revealed that regional exchange is already active in several health organizations. However, the exchange of medical data occurs mostly within the organizational borders and less at the national level. The medical specialists generally recognize the benefits of RHIS regarding improving quality of care, efficiency and reducing double efforts. They, however, disagree that RHIS will decrease the number of medical errors. According to the medical specialists the difficulty level (for the exchange of data) is more related to the number of successful attempts than to the total exchange duration. Also, according to this group of users the system should guarantee the safety of patient data and privacy of the patients. This research also indicates that still a large part of exchange goes through traditional services like phone, fax, email etc. As a result, new solutions should also be able to integrate easily with the existing technologies.

Regarding the importance of data-sources for different medical specialities, results very much depend on the type of medical speciality. Each speciality prefers different data sources. However the preferences for data sources are for some cases correlated. The same is with the need for important types of medical data. However, Medication

data, allergies and lab-results can be considered as generic data (important for almost all specialisms). Accordingly, any new system should be able to exchange at least these types of medical data.

From the results of the patients survey (represented in Chapter 5.2) we can conclude that the security and privacy issues are also very important for the patients. Any new system should be able to guarantee the safety of patient's data. However, comparing the results, we see that the patients are less worried about security and privacy than the medical specialists. In addition, according to the patients, medication data, allergies and lab-results can be considered as generic data. This is compatible with the opinion of the medical specialists. Most of the patients would like to have more control and access to their private medical data and decide with whom the data can be shared. However, smaller part of the patients think it is important to be able to choose between printed or digital versions of the exchange in the first place.

Considering the results of the interviews with the experts in this field (represented in Chapter 5.3), any RHIS solution should be able to exchange "more" complex data (i.e. more than just plain text and other media files). The consultants also emphasize the importance of universal standards, high security, proper authentication, authorization and low costs as some of the important requirements. The results of the document analysis (represented in Chapter 5.4) also emphasized the importance of universal or open standards for these systems. Moreover, the reliability of the vendor (experience and previous projects), long-term contracts and 24 hours support by the supplier, the consistency of code and the coupling possibilities for the existing software solutions were considered to be vital.

Outlined in Chapter 6, the business goals for developing RHIS relate to assistance in the care as a corporative tool, access to medical data, case specific improvements, the efficiency of work, double medical efforts, medical errors, costs, security, health service orchestration, bottom-up development and empowering the patients. The business and technical constrains of RHIS are mostly organizational, support related, law and regulations, security, privacy, standardization and financial.

In addition, the findings of Chapter 6 suggest that the exchange functionalities used in RHIS are very similar to the basic functionalities of the national EHR architecture (AORTA [29]) in the Netherlands. These functionalities include pull, push, subscribe and publish the medical data. Important use-cases are user authentication, user authorization, selecting patients, selecting organizations, maintaining patient's medical data, pull, push, subscribe and undo subscription. Finally, an initial list of functional and non-functional requirements can be created, which can be found in Appendix D.

The verification steps in Chapter 7 showed that some of the requirements caused conflicts and inconsistencies with each other. The initial list of the requirements (Appendix D) needed several adaptations and improvements during the verification phase. Several techniques for the verification of requirements are used. Also, in order to solve conflicts between several requirements and to create a non-conflicting list of requirements the Analytic Hierarchy Process (AHP) method is used. The AHP is a structured

technique for organizing and analysing complex decisions. Using AHP, we were able to compare the candidate requirements pair-wise and check to which extent each of the requirements is more important than others, considering the internal relations between all requirements. The applied methods proved to be useful and insightful in this context. As a result of the verification, a list of verified requirements is provided in Appendix E.

The technical solutions discussed in Chapter 8, each use a different approach to exchange medical data between health providers. The most basic and at the same time frequent type of digital medical data exchange occurs within the same organization, through the same EHR system across different departments. This type of exchange can be specified as data exchange within the same organizational borders. A second type of data communication between health organizations is making use of message brokers. This type of exchange can be specified as data exchange outside the organizational borders, where each organization still uses its own health information system. A third type of regional health information exchange takes place by making use of the facilities developed by OZIS, which is a separate communication network facilitated by regional health organizations. OZIS networks make use of a Regional Switch Point (Central Patient Index) using a patient's reference index and a health-care portal. A fourth type of regional health information exchange takes place by making use of the health portals. These portals make selected parts of the medical file accessible for other users outside of the borders of a health organization.

Finally, during the validation phase (represented in Chapter 9) the list of requirements is validated and further improved. The main conclusions imply the reactions of experts in this field and the applicability of the requirements after the evaluation of several existing solutions.

The structured walk-through was used to find out the feeling of the experts with the new list of requirements. In general the participants were pleased with the list of requirements. According to this group of people this list represents a large part of the needs of several important stakeholders. However, the experts were not sure whether the requirements of the IT vendors (during the development) should be included or not. They were also pleased with the list of requirements that can now be used to evaluate their current software solutions, because in the past a concrete list of requirements did not exist.

By applying an evaluation process we were able to find possible shortcomings or inconsistencies in the existing list of requirements. The final list of requirements is further extended and can be found in Appendix H. After the validation phase, the initial list of requirements was improved where needed. Evaluating six different existing technical solutions for the implementation of RHIS provided significant insights into important differences among them. The Health Information Portal at the end scored highest, followed by the Secure Mail and the EHR exchange. In general Health Portal and Secure Mail are relatively independent from the existing systems and solutions (meaning high integration and technical possibilities) and this is also their main advantage.



## 10.2 Reflections and recommendations for future work

During this research, two different questionnaires were made (surveys of the medical specialists and patients). The main goals of these surveys was to collect the most important requirements from the main users of regional health information systems. Despite all the efforts, the total number of responses was lower than expected. According to some critics, this was partly because the questionnaire was too long and time consuming. Furthermore, some of the questions contained difficult definitions and terms that were hard to understand by some of the participants. Future researchers should bear in mind these issues when conducting their research in the field. A larger number of responses can increase the reliability of the data.

Considering the stakeholders interest and power level (Chapter 3.1), the values “Low” and “High” are approximations, based on what could be found in the available sources. Only with extensive field research and perhaps in some cases by contacting the representatives of these stakeholders can the actual values be determined.

The Analytic Hierarchy Process (AHP) provides an alternative estimation approach for prioritization of the requirements in parallel to the original MoSCoW method. In fact two different factors are used to calculate the pair-wise differences:

1. Comparing every pair using numerical values of MoSCoW
2. Comparing every pair using numerical values of Stakeholders importance

Both factors (MoSCoW values and Stakeholders importance) are based on estimations. One has to take into account that mistakes in estimation of these factors can also affect the results. What is also relevant in the case of this research, is that we have only included all requirements that have one or more conflicts with each other, due to the time limitation. In other words the requirements that did not cause any conflict were not included in the calculations for prioritization by the AHP. Hence, one has to take into consideration that the outcomes of the AHP are only valid among requirements that do have a conflict relation with other requirements. However because AHP normalizes the values and calculates pair-wise differences for all requirements and translates them all into numerical values, based on the linear scale, we can consider AHP as a consistent method of prioritization.

The results of the evaluation of several solutions by the list of requirements (Chapter 9.2.2) should not be used as a reference to show which of the solutions “wins” against others. First of all the results in Appendix I, are the outcomes *before* the validation of the requirements. In the final list some of the requirements may be dropped or improved after the validation phase. A second reason is that, due to the time limitation, this list of requirements does not necessarily include “all” requirements, because it has only focused on specific stakeholders and areas of concern. The list of the requirements can nevertheless be used as an evaluation tool for comparing several technical

solutions for each category of systems. In other words one should check the outcomes only per requirements category and the sum of all rows only represents the sum for “included” categories in the research. This limits the generalizability of the research findings.

A better future approach for the surveys among the primary and secondary groups of users might include some of the results in this research. It is much better to ask the opinion of the users only for very specific questions. After all, in order to improve user satisfaction it might be wise to recheck some of the important requirements with the actual users before implementing them. This would increase the level of confidence in the attained results.

The list of requirements provided in this research can also be used to evaluate case-specific solutions. Different shortcomings in the existing solutions can be improved, for instance by looking at other solutions which scored better on the same category, or by creating prototypes that might improve some of the missing features. I believe this is a promising venue for future research.

---

## Bibliography

- [1] Three dimensions of organizational interoperability. *European journal of ePractice*, 2009. ISSN 1367-5788. doi: 10.1016/j.arcontrol.2003.09.001. URL <http://www.dlorg.eu/uploads/External%20Publications/6.1.pdf>.
- [2] Viggo Ah. *An experimental comparison of five prioritization methods- Investigating ease of use, accuracy and scalability*. School of Engineering Blekinge Institute of Technology Sweden, 2005.
- [3] ASTM. Standard specification for continuity of care record (ccr)@ONLINE, jul 2012. URL <http://www.astm.org/Standards/E2369.htm>.
- [4] Alan Bryman and Emma Bell. *Business Research Strategies , Business Research Methods*. Oxford University Press, 2003.
- [5] CBP. College bescherming persoonsgegevens (cbp)@ONLINE, jun 2012. URL <http://www.cbpweb.nl/Pages/home.aspx>.
- [6] CG-Raad. Chronische ziekten en gehandicapten raad (cg-raad)@ONLINE, jun 2012. URL <http://www.cg-raad.nl/>.
- [7] David Chen and Guy Doumeingts. European initiatives to develop interoperability of enterprise applications basic concepts, framework and roadmap. *Annual Reviews in Control*, 27(2):153 – 162, 2003. ISSN 1367-5788. doi: 10.1016/j.arcontrol.2003.09.001. URL <http://www.sciencedirect.com/science/article/pii/S1367578803000257>.
- [8] Consumentenbond. Consumentenbond, dutch consumer's organization)@ONLINE, jun 2012. URL <http://www.consumentenbond.nl/>.
- [9] CorepointHealth. The continuity of care document, changing the landscape of healthcare information exchange. *White paper*, 2012. URL <http://www.corepointhealth.com>.
- [10] C.M. Cotter. Making the case for a clinical information system: the chief information officer view. *Journal of critical care*, 22(1):56–65, 2007.
- [11] A. Delfan. Electronic health records, literature survey. TU-Delft - Master Project IN5020, October 2012.

- [12] N. Laird D.W. Bates, D.J. Cullen. Incidence of adverse drug events and potential adverse drug events. *JAMA*, (374):29–34, 1995.
- [13] Enovation. Zorgmail, dutch secure-mail solution of the healthcare, numbers of transactions@ONLINE, aug 2012. URL <http://www.zorgmail.nl/index.php/zorg-profs>.
- [14] The Agency for Healthcare Research and US Quality National Resource Center for Health Information Technology. Establishing a business case for health information exchange (hie), findings from the state and regional demonstrations in health information technology regional meeting. URL <http://healthit.ahrq.gov>.
- [15] E.J. Groenevelt, J.A. van Nieuwkoop, C.G. Wouters, and A.D. de Jonge. Nobin-zis-project. *Centrale Dienst Informatie Verwerking Academisch Ziekenhuis Leiden*, 1978-8.
- [16] HIE Steering Committee HIMSS. Overview of health information exchange. HIMSS, 2009.
- [17] HL7. Health level seven international (hl7) - standards@ONLINE, aug 2012. URL <http://www.hl7.org/>.
- [18] Vrije Huisarts. Vrije huisarts@ONLINE, aug 2012. URL <http://devrijehuisarts.org/>.
- [19] IIBA. *A Guide to the Business Analysis Body of Knowledge (BABOK Guide), Version 2.0 by The International Institute of Business Analysis (IIBA)*. Berrett-Koehler, 2010.
- [20] IIBA. International institute of business analytics (iiba)@ONLINE, aug 2012. URL <http://www.iiba.org>.
- [21] Karimaa and P. Nykanen. Success and failure factors in the regional health information system design process. *Methods Inf Med - Schattauer GmbH*, 1-2006, 2006.
- [22] KNMG. Koninklijke nederlandse maatschappij tot bevordering der geneeskunst (knmg)@ONLINE, march 2012. URL <http://knmg.artsennet.nl/home.htm>.
- [23] L.T. Kohn, J.M. Corrigan, and M.S. Donaldson. Het landelijke epd als blackbox besluitvorming en opties in kaart. *WRR-Webpublicaties*, 2010.
- [24] LHV. De landelijke huisartsen vereniging (lhv)@ONLINE, march 2012. URL <http://lhv.artsennet.nl/home.htm>.
- [25] Eugene Lim, Fulham Michael, and Dagan Feng David. Electronic medical records. *Technological Fundamentals*, 2008.

- [26] T. Maenpaa, T. Suominenand, P. Asikainen, M. Maass, and I.Rostila. The outcomes of regional healthcare information systems in health care: a review of the research literature. *International journal of medical informatics*, 78(11):757–71, 2009.
- [27] NHG. Nederlands huisartsen genootschap(nhg)@ONLINE, aug 2012. URL <http://nhg.artsennet.nl/home.htm>.
- [28] Nictiz. Regionale samenwerkingsorganisaties voor zorg en ict. pages 29–34, 2010.
- [29] NICTIZ. Architectuur aorta, version 6.10.0.0@ONLINE, jun 2012. URL <http://www.nictiz.nl/page/Infrastructuur>.
- [30] NICTIZ. The national it institute for healthcare in the netherlands (nictiz)@ONLINE, jun 2012. URL <http://www.nictiz.nl/>.
- [31] NPCF. Nederlandse consumenten patienten federatie (npcf)@ONLINE, jun 2012. URL <http://www.npcf.nl/>.
- [32] World Health Organization. Classifications@ONLINE, aug 2012. URL <http://www.who.int/classifications/icd/en/>.
- [33] OZIS. De stichting ozis@ONLINE, aug 2012. URL <http://www.ozis.nl>.
- [34] Directive The European Parliament and of the Council. Directive 95/46/ec @ONLINE, oct 1995. URL <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>.
- [35] B. Pluut and A. Zuurmond. Changing perspectives on informatics? a comparison of three national electronic health records. *HEALTHINF*, 2009.
- [36] Bettine Pluut. Het landelijke epd als blackbox besluitvorming en opties in kaart. *WRR-Webpublicaties*, 2010.
- [37] T. Saaty. The analytic hierarchy process: Planning, priority setting, resource, allocation. *McGraw-Hill*, 1980.
- [38] Duennebeil Sebastian, Sunyaev Ali, Leimeister Jan Marco, and Krcmar Helmut. Strategies for development and adoption of err in german ambulatory care. *Pervasive Health*, 8887, 2010.
- [39] SNOMED. Snomed ct user guide january 2012 international release (us english). *International Health Terminology Standards Development Organisation*, 2002-2012.
- [40] R. Swanson and F. Holton. *The Basics of Quantitative Research , Research in Organizations: Foundations and Methods of Inquiry*. Berrett-Koehler, 2005.
- [41] S. Heard T. Beale. The openehr archetype model. *International Health Terminology Standards Development Organisation, The openEHR Archetype Model, ADL 1.5*, 2012.

- [42] De Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie. Knmp@ONLINE, aug 2012. URL <http://knmp.nl>.
- [43] Sdu Uitgevers. Expert meeting - eerste kamer der staten-generaal. *Sdu Uitgevers*, 2009-2010.
- [44] UMCU. Different specialities university medical center of utrecht@ONLINE, jun 2012. URL <http://www.umcutrecht.nl/zorg/patienten/specialismen/>.
- [45] H. van der Veer and A. Wiles.
- [46] Various. Overview communication protocols @ONLINE, jul 2012. URL [http://en.wikipedia.org/wiki/Communications\\_protocol](http://en.wikipedia.org/wiki/Communications_protocol).
- [47] VWS. Ministerie van volksgezondheid, welzijn en sport; dutch ministry of health, welfare and sport(vws)@ONLINE, jun 2012. URL <http://www.rijksoverheid.nl/ministeries/vws/>.
- [48] Comite Wake-Up. Comite wake-up@ONLINE, jun 2012. URL <http://comite-wake-up.org/>.
- [49] Wan Yina and R Nanchang. Application of ehr in health care. *IEEE, Second International Conference on MultiMedia and Information Technology*, 978-0-7695-4008-5/10:60–63, 2010.

# Appendix A

## Glossary

In this appendix we give an overview of frequently used terms and abbreviations.

Table A.1: Definitions

Reference	Description
<b>ADL</b>	Archetype Definition Language
<b>AOM</b>	Open EHR Archetype Object Model
<b>BSN</b>	Burgerservicenummer (Social Citizen's Number)
<b>cADL</b>	Constraint form of ADL
<b>CCD</b>	Continuity of Care Document
<b>CCR</b>	Continuity of Care Record
<b>CPR</b>	Cardiopulmonary resuscitation (an emergency procedure which is performed in an effort to manually preserve intact brain function)
<b>dADL</b>	Data definition form of ADL
<b>DBC's</b>	Declaration treatment codes
<b>DICOM)</b>	Digital Imaging And Communication in Medicine
<b>Edifact</b>	United Nations Electronic Data Interchange For Administration, Commerce and Transport
<b>EHR</b>	Electronic Health Records
<b>EMR</b>	Electronic Medical Records
<b>FRD</b>	Functional Requirement Document
<b>GP</b>	General Practitioner
<b>HIE</b>	Health Information Exchange
<b>HIT</b>	Health Information Technology
<b>HL7vx</b>	HL7 Version x Standard
<b>ICD</b>	International Classification of Diseases
<b>ICPC</b>	International Classification of Primary Care
<b>I-EDI</b>	Interactive exchange protocol
<b>IOP</b>	Interoperability
<b>ISO</b>	International Organization for Standardization
<b>L-EPD</b>	Het Landelijk Elektronisch Patiëntendossier, (The national Electronic Health Records, in the Netherlands)
<b>LOINC</b>	Logical Observations Identifiers Names and code

Table A.1: Definitions

Reference	Description
<b>NFRD</b>	Non-Functional Requirement Document
<b>NHII</b>	National Health Information Infrastructure
<b>NICTIZ</b>	National experts for development of ICT infrastructures in health-care in the Netherlands
<b>OAP</b>	Open EHR Archetype Profile
<b>OSI</b>	Open Systems Interconnection
<b>OZIS</b>	Open Zorg Informatie Systeem (the co-operation of regional health organizations in the Netherlands)
<b>PHR</b>	Personal Health Record
<b>PMBR</b>	Paper Based Medical Records
<b>RHIE</b>	Regional Health Information Exchange
<b>RHIO</b>	Regional Health Information Organizations
<b>RHIS</b>	Regional Health Information Systems
<b>RIM</b>	Reference Information Model
<b>SNOMED CT</b>	Systematized Nomenclature of Medicine
<b>UZI</b>	Unieke Zorgverleners Identificatiepas (Unique Healthcare identification card)
<b>W3C</b>	World Wide Web Consortium
<b>WBP</b>	Wet Bescherming Persoonsgegevens (Data Protection Act)
<b>WGBO</b>	Wet op de geneeskundige behandelingsovereenkomst (Law on Medical Treatment Agreement)
<b>WHO</b>	World Health Organization
<b>XSD</b>	XML Schema Definition Language
<b>ICF</b>	International Classification of Functioning, Disability and Health
<b>ICD-O</b>	International Classification of Diseases for Oncology
<b>ICHI</b>	International Classification of Health Interventions
<b>ICPC</b>	International Classification of Primary Care
<b>ICD-O-3</b>	classification of diseases for Oncology
<b>GGZ</b>	Geestelijke gezondheidszorg en verslavingszorg in Nederland (Mental health and addiction care in the Netherlands)
<b>KNMG</b>	Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (Royal Dutch Society for the Advancement of Medicine)
<b>LHV</b>	De Landelijke Huisartsen Vereniging (The National Association of General Practitioners)
<b>NHG</b>	Nederlands Huisartsen Genootschap (Dutch College of General Practitioners)
<b>KNMP</b>	De Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (The Royal Dutch Pharmacists Association)
<b>NPCF</b>	Nederlandse Consumenten Patiënten Federatie (Dutch Patients Consumers Federation)
<b>CG-Raad</b>	Chronische Zieken en Gehandicapten Raad (Chronic Sick and Disabled Council)



Table A.1: Definitions

<b>Reference</b>	<b>Description</b>
<b>CBP</b>	College Bescherming Persoonsgegevens (Governmental organization for protection of personal data and)
<b>VWS</b>	Ministerie van Volksgezondheid, Welzijn en Sport (Ministry of Health, Welfare and Sport)
<b>EPD</b>	Elektronische patiënten dossier (Electronic Medical Record)
<b>AORTA</b>	The national EHR exchange architecture
<b>WGBO</b>	Wet geneeskundige behandelingsovereenkomst (Medical Treatment Agreement Act)
<b>WBP</b>	De Wet bescherming persoonsgegevens (Data protection act by CBP)
<b>WMO</b>	Wet maatschappelijke ondersteuning (the social support act)
<b>WVG</b>	Wet voorzieningen gehandicapten (the welfare, the disabled act)
<b>DICOM</b>	Document Capture Distribution
<b>DigiD</b>	Personal digital signature
<b>DMZ</b>	Demilitarized Zone
<b>EMD</b>	Electronic medication record
<b>SHE</b>	Exchange medical data between emergency units
<b>PAD</b>	Electronic pathology records
<b>LSP</b>	Landelijke Schakelpunt (National switch)
<b>ZIM</b>	Hospital information broker
<b>XIS</b>	The health provider system
<b>DCN</b>	Data communications networks
<b>ZSP</b>	Ziekenhuis service provider (Health provider services)
<b>IIBA</b>	International Institute of Business Analysis
<b>BABOK</b>	Business Analysis Body of Knowledge



## **Appendix B**

---

# **Categorization Medical Specialists-UMCU**

This appendix provides an overview of several medical specialists found at one of the University Medical Centres in the Netherlands.

## Appendix B - Categorization Medical Specialists - UMCU

Category	English term	Dutch term	Description	Relevant Policlinics
Diagnostic specialties	Clinical chemistry	Klinische Chemie	Clinical chemistry is the discipline concerned with medical laboratory tests of blood and other body fluids (urine, feces, spinal fluid).	- Laboratory
Diagnostic specialties	Clinical Neurophysiology	Klinische Neurofysiologie	The Clinical Neurophysiology of the Cluster Neurology and Neurosurgery provides medical diagnostics lack of interference in the functioning of: the central nervous system, peripheral nervous system and muscles	Neurology and Neurosurgery
Diagnostic specialties	medical microbiology	Medische microbiologie	Medical Microbiology is concerned with the laboratory diagnosis and treatment and prevention of infectious diseases.	Laboratory
Diagnostic specialties	Nuclear Medicine	Nucleaire Geneeskunde	Nuclear Medicine literally means "nuclear medicine" medicine using radioactive substances.	-
Diagnostic specialties	Pathology	Patholoog	Works mainly at the request of other medical specialists. Examines cells, tissues, fluids, swabs or other body material. Examines patients who are deceased.	Laboratory
Diagnostic specialties	Radiology	Radiologie	is concerned with imaging of the human body, e.g. by x-rays, x-ray computed tomography, ultrasonography, and nuclear magnetic resonance tomography.	Radiology
Interdisciplinary fields	Pain Management	Pijnbehandeling	The Pain Management specialization focuses on examining and treating patients with acute pain, chronic pain and pain due to cancer.	Pain Management
Interdisciplinary fields	Dietetics	Diëtetiek	nutrition	Dietetics
Internal Medicine	Endocrinology	Endocrinologie	The endocrinology specialty is part of the division "internal medicine" and is engaged in the function of hormones in the body.	Endocrinology Internal Medicine
Internal Medicine	Gastroenterology and Hepatology	Maag-, Darm- en Leverziekten	focuses on the diagnosis and treatment of disorders of the gastrointestinal tract (esophagus, stomach, small intestine and colon), liver, biliary tract and pancreas.	Gastrointestinal and liver diseases Endoscopy Department
Internal Medicine	Geriatrics	Geriatric	Geriatrics is a medical specialty that focuses on diseases associated with aging or strongly influenced by aging.	Geriatrics
Internal Medicine	Hematology	Hematologie	Hematology is the specialty that deals with diagnosis and treatment of diseases of bone marrow, lymph nodes and blood.	Hematology, Laboratory
Internal Medicine	Infectiology	Infectieziekten	The specialty of Infectious Diseases focuses on the diagnosis and treatment of infectious diseases and immune disorders.	Infectiology
Internal Medicine	Internists	Interne geneeskunde	The specialty of internal medicine deals with the entire internal medicine and is an extension of the care that all patients receive from their GP.	Diabetologie Endocrinology Internal Medicine
Internal Medicine	Nephrology	Nefrologie	Nephrology is the medical specialty for diagnosis and treatment of patients with kidney disease.	Nephrology
Internal Medicine	Oncology	Medische Oncologie	Oncology is the specialty that deals with all forms of cancer. This department is responsible in particular for the treatment of cancer patients with chemotherapy and other new specific drugs	medical Oncology
Internal Medicine	Pulmonology	Longziekten	Pulmonology is the specialty that deals with the diagnosis and treatment of lung diseases.	Pulmonology
Internal Medicine	Rheumatology and Clinical Immunology	Reumatologie en Klinische Immunologie	joint and / or complaints of the immune system (also called immune).	Rheumatology
Internal Medicine	Cardiology	Cardiologie	The specialty Cardiology focuses on the diagnosis and treatment of cardiovascular diseases. (hart deceases)	Cardiology Cardiac Rehabilitation

## Appendix B - Categorization Medical Specialists - UMCU

Category	English term	Dutch term	Description	Relevant Policlinics
Other major specialties	Allergology	Allergologie	Allergology is a medical specialty that deals with diagnosis and treatment of allergies.	Allergology Dermatology
Other major specialties	Anaesthesiology	Anesthesiologie	The medical department of Anaesthesiology can be found at all locations of the Division of Perioperative Care and Emergency Department.	Pre-operative screening
Other major specialties	Dermatology	Dermatologie	Dermatology is a medical specialty that focuses on the diagnosis and treatment of skin diseases and sexually transmitted diseases	Allergology Dermatology STD clinic
Other major specialties	Gynecology	Gynaecologie	In the specialty of gynecology is focused at the reproductive organs of the female.	Gynecology Fertility Obstetrics Early pregnancy
Other major specialties	Medical Genetics	Medische Genetica	Is this disease hereditary? What genetic factors play a role in birth defects? With these questions, the medical genetics is involved	Genetic counseling
Other major specialties	Neurology	Neurologie	Neurology is the medical specialty that deals with the diagnosis and treatment of disorders of the nervous system (brains, spinal cord and peripheral nerves) and muscles	Neurology and Neurosurgery
Other major specialties	Obstetrics	Verloskunde	The clinic Obstetrics focuses on the care of the mother and the unborn child	Obstetrics
Other major specialties	Occupational therapy	Ergotherapie	Occupational therapy focuses on the daily actions. By physical or mental complaints in your daily life sorts of practical problems experienced	Rehabilitation Sports Medicine
Other major specialties	Ophthalmology	Oogheelkunde	The Ophthalmology Department provides ophthalmic patient care	Ophthalmology
Other major specialties	Physical therapy	Fysiotherapie	Physical therapy focuses on functional movement.	Sports Medicine Rehabilitation
Other major specialties	Radiotherapy	Radiotherapie	Radiotherapy is a medical treatment with radiation. Treatment is usually for cancer.	Radiotherapy
Other major specialties	Rehabilitation	Revalidatiegeneeskunde	Rehabilitation is concerned with the (expected) consequences of an illness or accident.	Rehabilitation Sports Medicine
Other major specialties	Psychiatry	Psychiatrie	Psychiatry is the medical specialty that deals with issues that adults can have in behavior and perception.	Acute and Consultative Psychiatry Psychotic disorders mood disorders
Surgery	Cardio-thoracic surgery	Cardio-thoracale chirurgie	The specialist cardio-thoracic surgery is involved in the surgical treatment of heart and lung diseases.	Cardiac Rehabilitation
Surgery	Dental Surgery	Kaakchirurgie	The specialty of Oral Diseases, Jaw and Facial Surgery, Dental Surgery, is the head and neck area.	Oral and Maxillofacial Surgery
Surgery	Intensive Care	Intensive Care	<ul style="list-style-type: none"> <li>• after heart surgery</li> <li>• after (vascular) surgical operation or</li> <li>• after a neurosurgical operation.</li> </ul>	Intensive Care
Surgery	Neurosurgery	Neurochirurgie	The specialty of Neurosurgery focuses on surgical treatment of disorders: central nervous system, the bony shell (the skull and vertebrae), the peripheral nervous system	Neurology and Neurosurgery
Surgery	Orthopaedics	Orthopaedie	The medical specialty of Orthopaedics deals with disorders of the support and movement system. These are the joint bones, joints, muscles, tendons and ligaments.	Pre-operative screening Orthopaedics
Surgery	Otolaryngologist	KNO	Ear, nose and ear specialist (otolaryngologist) is engaged in the treatment of diseases of throat, nose and ears.	Ear, Nose and throat (ENT)
Surgery	Plastic surgery	Plastische chirurgie	Plastic surgery is the medical specialty that deals with the restoration of form and function of the anatomy.	Plastic surgery
Surgery	Urology	Urologie	Urology is the specialty that deals with the treatment of diseases of the kidney, urinary tract and male genitals.	Urology

**Appendix B - Categorization Medical Specialists - UMCU**

Category	English term	Dutch term	Description	Relevant Policlinics
Surgery	Vascular Medicine	Vasculaire Geneeskunde	Vascular Medicine, the part within the specialty of Internal Medicine, which deals with diagnosis, prevention and treatment of disorders of blood vessels.	Vascular Medicine, Internal Medicine
Surgery	Vascular Medicine	Vasculaire Geneeskunde	Vascular Medicine, the part within the specialty of Internal Medicine, which deals with diagnosis, prevention and treatment of disorders of blood vessels.	Vascular Medicine
Surgery	Vascular surgery	Vaatchirurgie	The medical specialty vascular surgery is mainly concerned with diseases of the arteries in the neck, chest, abdomen and legs.	Vascular surgery / vascular center

## Appendix C

---

# Communication sources & methods

This appendix provides a detailed overview of different communication methods and sources used for several stakeholder.





## **Appendix D**

---

# **Initial list of requirements**

This appendix provides a detailed overview of the initial functional and non-functional requirements.

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-01			Primary users	S-PU	It must still be possible to exchange data within the same organization and own care group.		Orchestration / Integration, Freedom of participation	Functional	Eliminated	-	-	Must	Survey specialists	<b>Eliminated: this requirement is outside the scope.</b> In fact this is already realized by the existing EHR systems and is not part of the functionality of the system. Still the communication within the same organization and own care group is the most important scenario. Scenario data exchange, survey specialists.
R-F-02			Hospital executives	S-HE	Cross regional exchange should be possible in exceptional cases.	Whether exchange is between same organization distributed in different regions.	Orchestration / Integration, Freedom of participation	Functional	Original	R-F-74	-	Should	Survey specialists, Interview consultants	One example of such exceptional cases is when a specific organization has several cross regional locations. See for more details results of the interviews with the consultants
R-F-03	R-F-80		Hospital IT management	S-HIT	The system could make use of HL-7 PORX clinical message delivery		Advanced possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling OZIS medication data
R-F-04	R-F-80		Hospital IT management	S-HIT	The system could make use of HL-7 PORX REC message to send the prescribed medication to the medication gateway		Advanced possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling OZIS medication data
R-F-05	R-F-86		Hospital IT management	S-HIT	The patient could be able to attach a file to add his or her records, which is automatically part of the patient's PHR.		Advanced possibilities	Functional	Eliminated	-	-	Could	Document analysis	Coupling in order to exchange medical images
R-F-06	R-F-80		Hospital IT management	S-HIT	The system could have a HL-7 ADT query link serving the exchange of patient information.F29		Advanced possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling to image storage systems. It should be possible to link with image storage systems like Sioux medical systems.
R-F-07	R-F-77		Hospital IT management	S-HIT	A unidirectional link should be made which ensures that the appointments made in the EHR are also visible to a user in MS Exchange.		Advanced possibilities	Functional	Eliminated	-	R-F-07, R-F-30, R-F-77	Should	Document analysis	Coupling for the appointments, A link is realized based on the Routing Service a link is created between the user of the EHR and the MS Exchange user. The link runs as a Windows service application, which periodically updates the Microsoft Exchange calendars. The interval at which this is done is adjustable in minutes.
R-F-08	R-F-85, R-F-86		Primary users	S-PU	It must be possible to exchange transfer data of a patients.		Advanced possibilities	Functional	Eliminated	-	-	Must	Document analysis	Functionalities, included in regional Health Care Portal
R-F-09			Consumers/ Patients organizations	S-C	The registration of new patients won't be needed, if the patient is already registered by a partner health organization.	New registration needed/not needed	Advanced possibilities	Functional	Original	-	-	Won't	Survey patients	Survey patients, advantages

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-10		R-F-78	Hospital IT management	S-HIT	The UZI card and verification of the Citizen Service Number (BSN) could be used for the authorization.	Authorization uses UZI and/or BSN verification	Authentication	Functional	Adapted	-		Could	Document analysis	Coupling for UZI-card and Citizen Service Number (BSN). <b>Adapted priority from "should" to "could" to meet criteria "design independent"</b>
R-F-11		R-F-78	Primary users	S-PU	Single-Sign-On (SSO) could be possible, so that the health provider only needs to login once.	SSO is possible/impossible	Authentication	Functional	Eliminated	R-F-13, R-F-15, R-F-18, R-F-19	-	Could	Document analysis	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts)</b> Functionalities, included in regional Health Care Portal, Only enables on request of the client
R-F-12			Hospital IT management	S-HIT	The system should make use of a central reference index to keep record of all available patients		Authentication	Functional	Eliminated	-	-	Should	Document analysis	Functionalities, included in regional Health Care Portal. This is only appropriate when there is actually a central reference index which is maintained in the region. In the central reference index lists all names and addresses of the patients in the region are saved. The central reference index is fed by the affiliated institutions. This link facilitates the patient data (new and modified) from the hospital transmitted to the central reference index. <b>Eliminated to meet criteria "design independent"</b>
R-F-13		R-F-78	Primary users, Secondary users	S-PU, S-SU	The users must authenticate before entering the system.	User can access the system without authentication.	Authentication	Functional	Original	R-F-11		Must	Document analysis	General requirements
R-F-14	R-F-18		Consumers/ Patients organizations	S-C	An unauthorized medical specialist won't be able to access the medical documents of the patient.		Authorization, Privacy	Functional	Eliminated	R-F-11	R-F-14, R-F-18, R-F-20	Won't	Document analysis	Functionalities included in regional Health Care Portal
R-F-15		R-F-21, R-F-78	Primary users, Secondary users	S-PU, S-SU	The users must only get to see the specific functionalities of the system depending on their authorization level.	User can/cannot access functionality for which it is not authorized.	Authorization, Privacy	Functional	Combined	R-F-11	R-F-15, R-F-21	Must	Survey specialists, patients survey, interviews	General requirements, contains also R-F-21
R-F-16	R-F-81		Consumers/ Patients organizations	S-C	Only the medical specialists who are allowed by the patient must be allowed to access medical data of the patient.		Authorization, Privacy	Functional	Eliminated	R-F-11	R-F-16, R-F-17	Must	Survey patients	Most of the patients indicate that they would like to control which medical specialists are allowed to access medical data of the patients
R-F-17	R-F-81		Consumers/ Patients organizations	S-C	Only the organizations that are allowed by the patient should have access to the medical data of the patient.		Authorization, Privacy	Functional	Eliminated	R-F-70	R-F-16, R-F-17	Should	Survey patients	Most of the patients indicate that they would like to control which organizations are allowed to access medical data of the patients
R-F-18		R-F-14, R-F-20, R-F-78	Consumers/ Patients organizations	S-C	Unauthorized persons(specialists or others) won't be able to access medical data of the patients.	User can/cannot access medical data for which it is not authorized.	Authorization, Privacy	Functional	Combined	R-F-11	R-F-14, R-F-18, R-F-20	Won't	Survey specialists (barriers), Document analysis	Contains also R-F-14 & R-F-20

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-19		R-F-78	Advocacy, interest or lobby groups, health provider organizations and pharmacists, Consumers / Patients organizations	S-I, S-C	Only the specialists in charge must have authorized access to private medical data of the patient	Specialist not in charge can/cannot access medical data of the patient.	Authorization, Privacy	Functional	Eliminated	R-F-11		Must	Survey specialists, patients	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts).</b> Risks survey patients
R-F-20	R-F-18	R-F-78	Consumers/ Patients organizations	S-C	Third parties won't be able to access medical data of the patients		Authorization, Privacy	Functional	Eliminated	R-F-70	R-F-14, R-F-18, R-F-20	Won't	Survey patients	Examples of third parties are insurance companies and governmental organizations. Important risk according to the patients
R-F-21	R-F-15	R-F-78	Primary users, Secondary users	S-PU	An authorized medical specialist must be able to make an appointments for the patient.		Authorization	Functional	Eliminated	R-F-20; R-F-17; R-F-18	R-F-15, R-F-21	Must	Document analysis	Functionalities, included in regional Health Care Portal
R-F-22	R-F-87		Primary users	S-PU	The specialist could be able to make online appointments on behalf of the patients.		Cooperative task	Functional	Eliminated	-		Could	Document analysis	Functionalities, included in regional Health Care Portal
R-F-23	R-F-80		Hospital IT management	S-HIT	The system could have a standard HL7 SIU appointments link serving the transfer of the appointment information from the CS-EZIS Sioux. The data is shown on the work list of Sioux.		Coupling possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling to image storage systems. It should be possible to link with image storage systems like Sioux medical systems.
R-F-24	R-F-88		Hospital IT management	S-HIT	The system could have a custom coupling ORU for exchange reporting data to Sioux. Apart from any free text messages, within this link also a reference (link) to the recorded images is available.		Coupling possibilities	Functional	Eliminated	-		Could	Document analysis	Coupling to image storage systems. It should be possible to link with image storage systems like Sioux medical systems.
R-F-25	R-F-80		Hospital IT management	S-HIT	The system could have a HL-7 QRY custom link which developed from the nursing records. With this coupling a number of values of Spacelabs can be retrieved.		Coupling possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling with SpaceLabs Healthcare systems
R-F-26	R-F-80		Primary users	S-PU	The system could contain a HL-7 link to SIU appointments link to Fit4Care must be realized.		Coupling possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling for the appointments, A standard HL-7 SIU link between the EHR and the system for transmur diabetes care Fit4Care for sending messages from the appointment module. The coupling is based on the CS-Specifications.
R-F-27	R-F-82		Primary users	S-PU	The system should contain a link which makes it possible to receive EDIFACT-MEDSPE messages from and to the GPs.		Coupling possibilities	Functional	Eliminated	-	R-F-27, R-F-28, R-F-29	Should	Document analysis	Coupling EDIFACT-MEDSPE
R-F-28	R-F-82		Primary users	S-PU	The system should contain a link in EDIFACT format for sending text results of the pathology laboratory as in the EHR received to the GPs.		Coupling possibilities	Functional	Eliminated	-	R-F-27, R-F-28, R-F-29	Should	Document analysis	Coupling EDIFACT-MEDSPE

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-29	R-F-82		Primary users	S-PU	The system should contain a link in EDIFACT format for sending laboratory results as in the CS-EZIS received to the GPs.		Coupling possibilities	Functional	Eliminated	-	R-F-27, R-F-28, R-F-29	Should	Document analysis	Coupling EDIFACT-MEDSPE
R-F-30	R-F-77		Primary users	S-PU	The system should contain a link between different organization who make all use of the same CS-EZIS (EHR system of ChipSoft). For example a link between the mental health care (GGZ) department which uses a customized CS-EZIS system and CS-EZIS of a cooperating hospital.		Coupling possibilities	Functional	Eliminated	-	R-F-07, R-F-30, R-F-77	Should	Document analysis	Coupling between CS-EZIS systems
R-F-31	R-F-80		Hospital IT management	S-HIT	The system could make use of the HL7 ADT coupling for the exchange between the EHR and the Regional Portal		Coupling possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Functionalities, included in regional Health Care Portal
R-F-32		R-F-38	Advocacy, interest or lobby groups, health provider organizations and pharmacists	S-I	It should be possible to exchange medical data of the patients suffering from chronic diseases.	Medical data needed for treatment of chronic diseases available/not available.	Data types	Functional	Combined	-	R-F-32, R-F-38	Should	Stakeholders analyses, literature	Especially for patients who regularly use health care it is important that the course of their disease and treatment is well known. Chronische Zieken en Gehandicapten Raad, see stakeholders analysis, Includes also R-F-38
R-F-33			Hospital IT management	S-HIT	It could be possible to exchange medical images.	Users can/cannot add medical images to the exchange message.	Data types	Functional	Original	-	-	Could	Document analysis	Coupling in order to exchange medical images
R-F-34	R-F-83		Primary users	S-PU	It must be possible to exchange the medication list of the patient.		Data types	Functional	Eliminated	-	R-F-34, R-F-37, R-F-39, R-F-68	Must	Document analysis	Functionalities included in regional Health Care Portal
R-F-35			Primary users	S-PU	The system must be able to exchange archived medical data.	Users can/cannot access archived medical data.	Data types	Functional	Original	-		Must	Survey specialists	This is especially important because older archived files are difficultly to access. Indicated by several specialists in the field comments.
R-F-36	R-F-49, R-F-50		Primary users	S-PU	The specialists must be able to choose which data they prefer to exchange.		Data types	Functional	Eliminated			Must	Survey specialists	Examples of mentioned data during the survey: OK reports, discharge letters, telegrams, X-ray pictures, microbiology, pathology reports, operation reports, appointments list, PA results, MMI results, reports Nuel medicine, all components of the CCR standard, pre-operative reports, nurse transfer (in chain), audiometry (hearing tests)
R-F-37	R-F-83		Primary users, Secondary users	S-PU, S-SU	It must be possible to exchange important data (medication list, allergies, lab and radiology reports).		Data types	Functional	Eliminated	-	R-F-34, R-F-37, R-F-39, R-F-68	Must	Survey specialists, patients survey	Important data for exchange, survey specialists and patients

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-38	R-F-32		IT company	S-TT	The system should be able to exchange the medical data of patients with chronic diseases.		Data types	Functional	Eliminated	-	R-F-32, R-F-38	Should	Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-F-39	R-F-83		IT company	S-TT	It should be possible to exchange exchange medication, allergies and a short medical history		Data types	Functional	Eliminated	-	R-F-34, R-F-37, R-F-39, R-F-68	Should	Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-F-40	R-F-84		Primary users	S-PU	It should be possible to exchange medical data between industry and health providers.		Data sources	Functional	Eliminated		R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Should	Survey specialists	This is especially important with companies that developed implants for the patients. Indicated by different surgeons during the survey.
R-F-41	R-F-84		Primary users	S-PU	It should be able to exchange medical data between dentists.		Data sources, Freedom of participation	Functional	Eliminated		R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Should	Survey specialists	The dentists implicitly indicated the need for exchange of medical data within their own specialty. The reason for this need to be investigated further.
R-F-42	R-F-84		Primary users	S-PU	It must be possible to exchange medical data between nursing houses and medical departments inside the hospital.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Important data sources, survey specialists. including Cardiology, Nursing, Pharmacy, Radiology, and Urology
R-F-43	R-F-84		Primary users	S-PU	It must be possible to exchange medical data between Physiotherapy clinics and hospitals		Data sources, Freedom of participation	Functional	Eliminated		R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Implicitly indicated by several specialists
R-F-44	R-F-84		Primary users	S-PU	It must be possible to exchange medical data between external clinics and medical departments inside the hospital.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Important data sources, survey specialists. including Anesthesiology, MKA, Nursing, Ophthalmology, Radiology, and Urology
R-F-45	R-F-84		Primary users	S-PU	It must be possible to exchange medical data between other regional hospitals and medical departments inside the hospital.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Important data sources, survey specialists- including Anesthesiology, Lung Medicine, Ophthalmology, Pharmacy, Radiology, Surgery, and Urology
R-F-46	R-F-84		Primary users	S-PU	It must be possible to acquire medical data from Radiology and Laboratory to medical departments inside the hospital.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Important data sources, survey specialists, including Cardiology, Dentistry, Family Medicine, Lung Medicine, Neurology, Nursing, Pediatrics, Pharmacy, Plastic Surgery, Radiology, Surgery and Urology
R-F-47	R-F-84		Primary users	S-PU	It must be possible to acquire medical data from GPs to medical departments inside the hospital.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	Important data sources, survey specialists. Anesthesiology, Cardiology, Dentistry, Lung Medicine, MKA, Nursing, Ophthalmology, Pediatrics, Pharmacy, Plastic Surgery, Radiology, Surgery and Urology
R-F-48	R-F-84		Primary users	S-PU	It must be possible to exchange medical data from GPs to all other organizations.		Data sources, Freedom of participation	Functional	Eliminated	-	R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Must	Survey specialists	The GPs are mostly interested in Radiology, Laboratory and data from regional hospitals. Important data sources, survey specialists

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-49		R-F-36, R-F-75	Primary users	S-PU	The specialists must be able to choose which data they prefer to share.	Primary users can/cannot choose relevant data type to share.	Freedom of choice	Functional	Combined	R-F-19, R-F-81	-	Must	Survey specialists	See results potential for medical exchange of specialists survey. There are different needs for exchange of medical data within the same organization, within the same group of specialty or between different organizations.
R-F-50		R-F-36, R-F-75	Primary users	S-PU	The specialists must be able to choose which data they prefer to take over.	Secondary users can/cannot choose relevant data type to take over or reject.	Freedom of choice	Functional	Combined	R-F-19, R-F-81	-	Must	Interview consultants	This is because in some cases the specialist can decide not to take over the medical data. For instance if this data might cause medical mistakes.
R-F-51			Consumers/ Patients organizations	S-SC	Patient must be able to provide access for each specific part of the medical data.	Whether secondary users are able to maintain authorization for each specific part of data.	Freedom of choice	Functional	Original	-	-	Must	Stakeholders analysis	( for instance the referral letters yes, but not the medication list) Survey patients, level of control
R-F-52			Hospital Councils	S-SH	It must be possible to request specific parts of the medical records from the other organization.	User is able to select from a list of datatypes if this is available, otherwise fill in a text message for request.	Freedom of choice	Functional	Original	-	-	Must	Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-F-53			Hospital executives	S-HE	It must still be possible to use traditional services like phone and written letters if necessary.	User is still able/unable to use traditional services beside new system.	Orchestration / Integration	Functional	Adapted	R-N-24	-	Must	Survey specialists, patients survey	The existing systems should work beside new services.
R-F-54	R-F-55		Secondary users	S-SU, S-TT	The patient must have access to his/her medical records		Patient access	Functional	Eliminated		R-F-54, R-F-55	Must	Survey patients	The results of the patients survey show that a very large group of patients like to control their own medical records. Also the consultants emphasize the importance of this functionality for the patients.
R-F-55		R-F-54	Secondary users	S-SU, S-TT	The patient must be able to maintain his/her medical records	The patient can view and/or edit own medical records.	Patient access	Functional	Combined	-	R-F-54, R-F-55	Must	Survey patients	The results of the patients survey show that a very large group of patients like to control their own medical records. Also the consultants emphasize the importance of this functionality for the patients.
R-F-56			Secondary users	S-SU	The system could provide an appointment code, which can be used to make an appointments by the phone.		Patient access	Functional	Eliminated	-	-	Could	Document analysis	<b>Eliminate R-F-56, because it is a design-dependent requirement.</b> Functionalities, included in regional Health Care Portal
R-F-57			Secondary users	S-SU	The patient could be able to make online appointments, after the GP or a specialist send an approval.		Patient access	Functional	Eliminated			Could	Document analysis	Functionalities, included in regional Health Care Portal
R-F-58			Primary users, Secondary users	S-PU	The patient should be able to accept or reject the existing appointments made by medical specialist.		Patient access	Functional	Eliminated	-	-	Should	Document analysis	Functionalities, included in regional Health Care Portal
R-F-59	R-N-12		Advocacy, interest or lobby groups, health provider organizations and pharmacists	S-I	The patient must be able to accept/ reject the participation of digital exchange of medical data.		Patient control	Functional	Eliminated	-		Must	Stakeholders analyses, literature	Nederlandse Consumenten Patiënten Federatie (NPCF), see stakeholders analysis

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-60			Secondary users	S-SU	Patients must be able to look back which entities had access to their personal health data.	The patient can/cannot access log files.	Patient control	Functional	Original	-	-	Must	Survey patients	Survey patients, level of control
R-F-61	R-N-23		Secondary users	S-SU	The patients should be clearly informed about how their health information may be used or shared.		Patient control	Functional	Eliminated	-	-	Should	Survey patients	Survey patients, level of control
R-F-62			Secondary users	S-SU	Patients must be able to provide access to other parties.	The patient is able/unable to choose different parties in the list. Authorization profile is adapted.	Patient control	Functional	Original	R-F-19	-	Must	Survey patients	Only to their own data! Survey patients, level of control. Examples of other parties include: family, friends, employers, insurance companies, scientific research ...
R-F-63			Hospital IT management	S-HIT	Application must be accessible from different location(s).	The user is able/unable to connect to the system regardless the location.	Remote Access	Functional	Original	-	-	Must	Document analysis	General requirements
R-F-64			IT company	S-IT	It must be possible to have remote access to the system.	The user can/cannot connect remotely to the system.	Remote Access	Functional	Original	-	-	Must	Document analysis	General requirements. By this requirement we mean that the user should not necessary access the system from inside the organization, but also the possibility to access data from outside.
R-F-65	R-F-89		Secondary users	S-SU	The system should use the Secure Query string API (SQAPI). This system makes use of the authenticated data and the BSN-number of the patients using a HTTP-query string.		Security	Functional	Eliminated	-	-	Should	Document analysis	Functionalities, included in regional Health Care Portal
R-F-66		R-N-03	Primary users	S-PU	It must be possible to consult medical data received from other health providers during the medical treatment.	The user is able/unable to consult transmural medical data during treatment.	Specialists access	Functional	Original	-	-	Must	Survey specialists	Only when authorized
R-F-67			Insurance Companies	S-IN	It must be possible to get access to medical treatment data by the insurance companies.	The insurance company can access the history of medical treatment data, by logging into the system.	Access, Privacy	Functional	Eliminated	R-F-18, R-F-19, R-N-12	-	Must	Stakeholders analyses, literature	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts).</b> In order to have control on the costs that are related with medical treatments. Insurance companies, see stakeholders analysis
R-F-68	R-F-83		Secondary users	S-SU	It should be possible to access medical results (tests, diagnoses) of patients from other cooperating health organizations.		Data types	Functional	Eliminated	-	R-F-34, R-F-37, R-F-39, R-F-68	Should	Survey specialists	see results potential for medical exchange, double effort, specialists survey



## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-69			Governmental organization	S-G	The system could have a link to public pharmacies in accordance with the Health / NICTIZ guidelines.	The system uses/does not use Health / NICTIZ guidelines as standard.	Coupling possibilities, Standards	Functional	Eliminated	Constraints standards	-	Could	Document analysis	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts).</b> Coupling OZIS medication data achieved with medication links.
R-F-70			Hospital IT management	S-HIT	The system should have a link for the creation of transmural medication records with an external medication gateway	The link exist/does not exist.	Coupling possibilities	Functional	Original	-		Should	Document analysis	Coupling OZIS medication data, (e.g. OZIS or Microbais).
R-F-71	R-F-80		Secondary users	S-SU	The system could have a HL-7 VVI coupling for receiving the home medication system in the EHR medication module.		Coupling possibilities	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling OZIS medication data
R-F-72	R-F-80		Secondary users	S-SU	The system could use a valid Unique Healthcare Identification card (UZI card), for the exchange of medication information and electronically sign of recipes.		Authentication	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	The UZI card should be provided to the caregiver on condition. Coupling OZIS medication data
R-F-73	R-F-80		Secondary users	S-SU	The system could have a HL-7 MPI query link for verification of the patient gateway to the medication		Standards	Functional	Eliminated	-	R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Could	Document analysis	Coupling OZIS medication data
R-F-74			Advocacy, interest or lobby groups, health provider organizations and pharmacists	S-I	The exchange of medical data won't be possible outside the region.	The user/organization outside the region is not able to login into the system.	Freedom of participation	Functional	Eliminated	R-F-02	-	Won't	Stakeholders analyses, literature	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts).</b> This is supported by different interest groups. These groups support regional exchange, but are again cross regional exchange. Koninklijke Nederlandse Maatschappij tot bevordering der Geneeskunst (KNMG), De Landelijke Huisartsen Vereniging (LHV), NHG (Nederlands Huisartsen Genootschap)
R-F-75	R-F-49, R-F-50		Secondary users	S-SU	The exchange of medical data at regional level should only be possible for specialties that benefit from it.	-	Freedom of participation	Functional	Eliminated	R-F-70	-		Stakeholders analyses, literature	<b>Eliminated to met the criteria "Testable".</b> An example is that the GPs have a larger need for the electronic exchange of digital lab results and referral letters. De Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP).
R-F-76			Secondary users	S-SU	Any kind of large-scale exchange of the medical information won't be possible.		Freedom of participation	Functional	Eliminated	All	-		Stakeholders analyses, literature	Vrije Huisarts and Comite Wake-Up, see stakeholders analysis
R-F-77		R-F-07, R-F-30	Hospital IT management	S-HIT	The system must be integrated with existing EHR systems.	The user can select parts of the data from the EHR system.	Orchestration / Integration	Functional	Combined	-	R-F-07, R-F-30, R-F-77	Must	Document analysis	General requirements, contains also R-F-07 AND R-F-30

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-78	R-F-10 to R-F-21, R-F-80, R-F-81		Secondary users	S-SU	Authorization and authentication must be arranged properly.		Security	Functional	Eliminated	-			Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-F-79			Secondary users	S-SU	It should be possible to add text messages to the exchange requests.	The user can/cannot add text message.	Advanced possibilities	Functional	Eliminated	-	-	Must	Survey specialists	This is especially important for specialisms like: Anesthesiology (S-PU-001-D2), Nursing (S-PU-s), Surgery (S-PU-001-S) and Ophthalmology (S-PU-001-D9)
R-F-80		R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Hospital IT management	S-HIT	The system could use HL7 standard for the exchange of medical data and coupling with the existing systems.	HL7 standard is used/not used.	Standards	Functional	Introduced	-	-	Could	Document analysis	New requirement, combination R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73
R-F-81		R-F-16, R-F-17	Secondary users	S-SU	The patients should be able to maintain the authorization profiles.	Secondary users are able/ are not able to view and edit authorization profile for their own medical file.	Authorization, Privacy	Functional	Eliminated	R-F-49, R-F-50	-	Should	Survey patients	<b>Eliminated to resolve conflicts - see Chapter 7 (resolving conflicts).</b> The patients should be able to provide/block authorization access to health organization or specialists. Introduced from R-F-16 & R-F-17
R-F-82		R-F-27, R-F-28, R-F-29	Secondary users	S-SU	The system should have a link to EDIFACT.	EDIFACT messages can/cannot be viewed and edited.	Coupling possibilities	Functional	Introduced	-	-	Should	Document analysis	Coupling with GPs, contains R-F-27, R-F-28, R-F-29
R-F-83		R-F-34, R-F-37, R-F-39, R-F-68	Secondary users	S-SU	It must be possible to exchange important medical data.	Important medical data such as medication list, allergies, lab and radiology reports can/cannot be exchanged.	Data types	Functional	Introduced	-	-	Must	Survey specialists, patients survey, document analysis, Interview consultants	Important medical data are: medication list, allergies, lab and radiology reports. Contains also R-F-34, R-F-37, R-F-39, R-F-68
R-F-84		R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Secondary users	S-SU	It must be possible to exchange medical data, regardless the type of the organization.	Whether the system can/cannot be accessed from different (important) health organizations.	Data sources, Freedom of participation	Functional	Introduced	-	-	Must	Survey specialists	The possibility must exist to exchange medical data with different types of health organization and if needed non-health organizations, contains also R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48
R-F-85		R-F-08, R-F-79	Secondary users	S-SU	It must be possible to add text to the transfer exchange message.	The user can/cannot add text message.	Advanced possibilities	Functional	Introduced	-	-	Must	Document analysis	This text message contains reason and other extra information needed for the transfer of the patient from one health organization to another.
R-F-86		R-F-05, R-F-08	Secondary users	S-SU	The user must be able to attach a medical file to the exchange message.	The user can/cannot attach medical files (standard formats .pdf, .xls, .jpg, .png...)	Advanced possibilities	Functional	Introduced	-	-	Must	Document analysis	Improvement of R-F-05 which stated that only the patient is able to attach medical files. It is also needed that specialist have this functionality.

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-87		R-F-22	Secondary users	S-SU	The specialist could be able to make online appointments on behalf of the patients in other partner health organizations.		Cooperative task	Functional	Eliminated			Could	Document analysis	Making use of the data exchange services to make appointment in other partner health organizations.
R-F-88		R-F-24	Hospital IT management	S-HIT	The system could have a custom coupling to other image storage systems.	The medical images from other storage systems can/cannot be accessed by the system.	Coupling possibilities	Functional	Introduced	-		Could	Document analysis	Coupling to image storage systems. It should be possible to link with image storage systems like Sioux medical systems.
R-F-89		R-F-65	Hospital Councils	S-HC	The system should encrypt query string parameters in order to provide secure communication.	Encryption is used/not used.	Security	Functional	Introduced	-		Should	Document analysis	Functionalities to improve secure communication
R-F-90		R-F-14	Primary users, Secondary users	S-PU, S-SU	All exchanged messages must be encrypted before sending.	Message is encrypted/not encrypted, man in the middle attack for testing	Security	Functional	Introduced	-		Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-F-91		R-F-14	Primary users, Secondary users	S-PU, S-SU	The system must decrypt messages by receive, unless the user is not authorized	Message is encrypted/not encrypted. If user has not enough authorization rights the message should not be decrypted.	Security	Functional	Introduced	-		Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-F-92		R-F-14	Primary users, Secondary users	S-PU, S-SU	Audit / archiving systems should make log files that record the activities of users who access medical files of the patients	Log records are created / not created.	Security	Functional	Introduced	-		Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-N-01	R-N-20	R-N-11	Secondary users	S-SU	It should be possible to exchange data within a relatively short time.	-	Performance	Non-funtional	Eliminated	-	-	Should	Stakeholders analyses, interview consultants	<b>Eliminated to met criteria "Testable", the requirement R-N-20 contains the same specification and is also testable.</b> The digital exchange of medical data should decrease the total time required for exchange of medical data.
R-N-02	R-N-25	R-N-05	Secondary users	S-SU	The digital exchange of medical data should improve the efficiency of work process	-	Capability	Non-funtional	Eliminated	-	R-N-02, R-N-05	Should	Stakeholders analyses, interview consultants, Survey specialists	This requirement is needed to convince this actor. See also results potential for medical exchange specialists survey

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-N-03	R-F-66		Secondary users	S-SU	Regional exchange of medical data should improve the quality of care, by reducing medical errors and double medical effort	-	Capability	Non-functional	Eliminated	-	-	Should	Stakeholders analyses, interview consultants	This requirement is needed to convince this actor
R-N-04	R-N-07, R-N-24		Secondary users	S-SU	The system should be dynamic and innovative.		Capability	Non-functional	Eliminated	-	-	Should	Document analysis	General requirements
R-N-05	R-N-02		Secondary users	S-SU	The exchange of medical data Should improve efficiency of the work process.		Capability	Non-functional	Eliminated	-	R-N-02, R-N-05	Should	Survey specialists	See results potential for medical exchange specialists survey
R-N-06			Secondary users	S-SU	The system should improve the communication between different health providers.	-	Capability	Non-functional	Eliminated	-	-	Should	Survey patients	Survey patients, advantages
R-N-07	R-N-26		Secondary users	S-SU	Changes in the package should be easily realizable and maintenance friendly.	-	Customization	Non-functional	Eliminated	-		Should	Document analysis	<b>Eliminated and introduced new requirement to met criteria "Testable"</b> General requirements
R-N-08			Hospital IT management	S-HIT	Changes and authorization instructions should be available.	Instructions available/not available	Customization	Non-functional	Original	-	-	Should	Document analysis	General requirements
R-N-09			Hospital IT management	S-HIT	The program code should be clear and easy to understand.	Code comments available/not available	Customization	Non-functional	Original	-		Should	Document analysis	General requirements
R-N-10			Hospital executives	S-HE	It must be easy to integrate the system with the existing software solutions.	Number of hours needed for configuration	Orchestration / Integration	Non-functional	Original	-	-	Must	Document analysis	It should cost as less as possible effort to integrate the system with existing EHR and all other software (like OK, agenda, disinfection, disinfection, sterilization, weighing machines, laser engraver)
R-N-11	R-N-01		Secondary users	S-SU	It should be possible to exchange medical data within in a relatively short time.	-	Performance	Non-functional	Eliminated	-		Should	Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-N-12		R-N-22, R-F-59	Consumers/ Patients organizations	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	Official form for questioning patients exist/does not exist	Privacy, Law and regulation, Freedom of choice	Non-functional	Combined	R-F-67	R-N-12, R-N-22, R-F-59	Must	Survey specialist, patients and literature	Privacy law and regulation, barriers,
R-N-13			Primary users, Secondary users, Hospital IT management	S-PU, S-SU, S-HIT	The system must be stable.	Average number of hours system is available, without going offline.	Reliability	Non-functional	Original	-	-	Must	Document analysis	General requirements
R-N-14	R-F-13, R-F-18, R-F-89, R-F-90, R-F-91, R-F-92, R-N-27, R-N-28		Primary users, Secondary users	S-PU, S-SU	The system must guaranty secure exchange of medical data.	-	Security	Non-functional	Eliminated	-	-	Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups

## Appendix D - Requirements Regional Exchange of Medical Data - Dutch Health organizations

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-N-19	R-N-20, R-N-25		Secondary users	S-SU	It should be easy to access medical data.	-	User friendliness	Non-functional	Eliminated	-	-	Should	Survey patients	<b>Eliminated to met criteria "Testable"</b> Only when authorized
R-N-20		R-N-19	Secondary users	S-SU	It must be possible to exchange medical data within couple of minutes.	Number of minutes needed for exchange <= accepted number of minutes	Performance	Non-functional	Original	-		Must	Survey specialists	This is especially important for specialisms like: Family medicine(S-PU-x), KNO(S-PU-x), Radiology S-PU-001-D6, Special Dentistry (S-PU-x)
R-N-21			Hospital IT management	S-HIT	Back-up possibility should be provided.	Automatic back-up included/not included	Reliability	Non-functional	Original	-	-	Should	Document analysis	General requirements
R-N-22	R-N-12		Secondary users	S-SU	The patients must be asked for permission before exchanging their medical data. This should be a formal written statement by the patient.		Privacy, Freedom of choice	Non-functional	Eliminated	-	R-N-12, R-N-22	Must	Stakeholders analyses, literature	College Bescherming Persoonsgegevens (CBP), see stakeholders analysis,
R-N-23		R-F-61	Consumers/ Patients organizations	S-C	The patients should be clearly informed about how their health information may be used or shared.	The patient can see in one overview past exchange requests to his/her medical records.	Patient control	Non-functional	Introduced	-		Should	Survey patients, Document analysis	Survey patients, level of control
R-N-24		R-N-04	Hospital executives	S-HIE	The system should make use of latest web engineering technologies.	Whether the system uses Web Information systems to exchange data.	Capability	Non-functional	Introduced	R-F-53		Should	Document analysis	General requirements
R-N-25		R-N-02, R-N-19	Secondary users	S-SU	It should be possible to exchange data within only couple of steps.	Number of needed steps <= accepted number of steps	Capability	Non-functional	Introduced	-	R-N-02, R-N-05	Should	Stakeholders analyses, interview consultants, Survey specialists	This requirement is needed to convince this actor, See also results potential for medical exchange specialists survey
R-N-26		R-N-07	Secondary users	S-SU	The system should have a Service oriented Architecture (SOA) consisting of several loosely coupled modules	SOA is/is not used	Architecture	Non-functional	Eliminated			Should	Document analysis	Introduced requirement. General requirements
R-N-27		R-F-14	Hospital IT management, Consumers/ Patients organizations	S-HIT, S-C	All security resources such as firewalls, remote access servers and so on must be configured properly, in order to compliance with security policies	Remote and inside attacks for testing, creating test cases that try to pass firewalls	Security	Non-functional	Introduced	-		Must	Survey specialists, patients survey, document analysis, Interview consultants	Surveys specialists and patients, this is independent from specialism or patient groups
R-N-28		R-F-14	Hospital IT management, Consumers/ Patients organizations	S-HIT, S-C	All computing resources, such as EHR system, network devices and applications should be monitored for changes in configuration that increase security risks	Create test case for when an application make change in the configuration of security resources.	Security	Non-functional	Introduced	-		Must	Survey specialists, patients survey, document analysis, Interview consultants	Surveys specialists and patients, this is independent from specialism or patient groups



## **Appendix E**

---

# **Verified list of requirements**

This appendix provides a detailed overview of verified list of the functional and non-functional requirements. This list is the result of the verification steps explained in chapter 7 and is used for further validation steps (chapter 9).

## Appendix E - Requirements Regional Exchange of Medical Data - Dutch Health organizations (Verified)

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-02			Hospital executives	S-HE	Cross regional exchange should be possible in exceptional cases.	Whether exchange is between same organization distributed in different regions.	Orchestration / Integration, Freedom of participation	Functional	Original	R-F-74	-	Should	Survey specialists, Interview consultants	One example of such exceptional cases is when a specific organization has several cross regional locations. See for more details results of the interviews with the consultants
R-F-09			Consumers/ Patients organizations	S-C	The registration of new patients won't be needed, if the patient is already registered by a partner health organization.	New registration needed/not needed	Advanced possibilities	Functional	Original	-	-	Won't	Survey patients	Survey patients, advantages
R-F-10		R-F-78	Hospital IT management	S-HIT	The UZI card and verification of the Citizen Service Number (BSN) could be used for the authorization.	Authorization uses UZI and/or BSN verification	Authentication	Functional	Adapted	-	-	Could	Document analysis	Coupling for UZI-card and Citizen Service Number (BSN). <b>Adapted priority from "should" to "could" to meet criteria "design independent"</b>
R-F-13		R-F-78	Primary users, Secondary users	S-PU, S-SU	The users must authenticate before entering the system.	User can access the system without authentication.	Authentication	Functional	Original	R-F-11	-	Must	Document analysis	General requirements
R-F-15		R-F-21, R-F-78	Primary users, Secondary users	S-PU, S-SU	The users must only get to see the specific functionalities of the system depending on their authorization level.	User can/cannot access functionality for which it is not authorized.	Authorization, Privacy	Functional	Combined	R-F-11	R-F-15, R-F-21	Must	Survey specialists, patients survey, interviews	General requirements, contains also R-F-21
R-F-18		R-F-14, R-F-20, R-F-78	Consumers/ Patients organizations	S-C	Unauthorized persons(specialists or others) won't be able to access medical data of the patients.	User can/cannot access medical data for which it is not authorized.	Authorization, Privacy	Functional	Combined	R-F-11	R-F-14, R-F-18, R-F-20	Won't	Survey specialists (barriers), Document analysis	Contains also R-F-14 & R-F-20
R-F-32		R-F-38	Advocacy, interest or lobby groups, health provider organizations and pharmacists	S-I	It should be possible to exchange medical data of the patients suffering from chronic diseases.	Medical data needed for treatment of chronic diseases available/not available.	Data types	Functional	Combined	-	R-F-32, R-F-38	Should	Stakeholders analyses, literature	Especially for patients who regularly use health care it is important that the course of their disease and treatment is well known. Chronische Ziekten en Gehandicapten Raad, see stakeholders analysis, Includes also R-F-38
R-F-33			Hospital IT management	S-HIT	It could be possible to exchange medical images.	Users can/cannot add medical images to the exchange message.	Data types	Functional	Original	-	-	Could	Document analysis	Coupling in order to exchange medical images
R-F-35			Primary users	S-PU	The system must be able to exchange archived medical data.	Users can/cannot access archived medical data.	Data types	Functional	Original	-	-	Must	Survey specialists	This is especially important because older archived files are difficultly to access. Indicated by several specialists in the field comments.
R-F-49		R-F-36, R-F-75	Primary users	S-PU	The specialists must be able to choose which data they prefer to share.	Primary users can/cannot choose relevant data type to share.	Freedom of choice	Functional	Combined	R-F-51	-	Must	Survey specialists	See results potential for medical exchange of specialists survey. There are different needs for exchange of medical data within the same organization, within the same group of specialty or between different organizations.
R-F-50		R-F-36, R-F-75	Primary users	S-PU	The specialists must be able to choose which data they prefer to take over.	Secondary users can/cannot choose relevant data type to take over or reject.	Freedom of choice	Functional	Combined	R-F-51	-	Must	Interview consultants	This is because in some cases the specialist can decide not to take over the medical data. For instance if this data might cause medical mistakes.



## Appendix E - Requirements Regional Exchange of Medical Data - Dutch Health organizations (Verified)

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-51			Consumers/ Patients organizations	S-C	Patient must be able to provide access for each specific part of the medical data.	Whether secondary users are able to maintain authorization for each specific part of data.	Freedom of choice	Functional	Original	R-F-49 R-F-50	-	Must	Stakeholders analysis	( for instance the referral letters yes, but not the medication list) Survey patients, level of control
R-F-52			Hospital Councils	S-SH	It must be possible to request specific parts of the medical records from the other organization.	User is able to select from a list of datatypes if this is available, otherwise fill in a text message for request.	Freedom of choice	Functional	Original	-	-	Must	Interview consultants	Interviews consultant (represented in about 50% of hospitals in the Netherlands)
R-F-53			Hospital executives	S-HE	It must still be possible to use traditional services like phone and written letters if necessary.	User is still able/unable to use traditional services beside new system.	Orchestration / Integration	Functional	Adapted	R-N-24	-	Must	Survey specialists, patients survey	The existing systems should work beside new services.
R-F-55		R-F-54	Secondary users	S-SU, S-TT	The patient must be able to maintain his/her medical records	The patient can view and/or edit own medical records.	Patient access	Functional	Combined	-	R-F-54, R-F-55	Must	Survey patients	The results of the patients survey show that a very large group of patients like to control their own medical records. Also the consultants emphasize the importance of this Functionality for the patients.
R-F-60			Secondary users	S-SU	Patients must be able to look back which entities had access to their personal health data.	The patient can/cannot access log files.	Patient control	Functional	Original	-	-	Must	Survey patients	Survey patients, level of control
R-F-62			Secondary users	S-SU	Patients must be able to provide access to other parties.	The patient is able/unable to choose different parties in the list. Authorization profile is adapted.	Patient control	Functional	Original	R-F-19	-	Must	Survey patients	Only to their own data! Survey patients, level of control. Examples of other parties include: family, friends, employers, insurance companies, scientific research ...
R-F-63			Hospital IT management	S-HIT	Application must be accessible from different location(s).	The user is able/unable to connect to the system regardless the location.	Remote Access	Functional	Original	-	-	Must	Document analysis	General requirements
R-F-64			IT company	S-TT	It must be possible to have remote access to the system.	The user can/cannot connect remotely to the system.	Remote Access	Functional	Original	-	-	Must	Document analysis	General requirements. By this requirement we mean that the user should not necessary access the system from inside the organization, but also the possibility to access data from outside.
R-F-66		R-N-03	Primary users	S-PU	It must be possible to consult medical data received from other health providers during the medical treatment.	The user is able/unable to consult transmural medical data during treatment.	Specialists access	Functional	Original	-	-	Must	Survey specialists	Only when authorized
R-F-70			Hospital IT management	S-HIT	The system should have a link for the creation of transmural medication records with an external medication gateway	The link exist/does not exist.	Coupling possibilities	Functional	Original	-	-	Should	Document analysis	Coupling OZIS medication data, (e.g. OZIS or Microbais).

## Appendix E - Requirements Regional Exchange of Medical Data - Dutch Health organizations (Verified)

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-77		R-F-07, R-F-30	Hospital IT management	S-HIT	The system must be integrated with existing EHR systems.	The user can select parts of the data from the EHR system.	Orchestration / Integration	Functional	Combined	-	R-F-07, R-F-30, R-F-77	Must	Document analysis	General requirements, contains also R-F-07 AND R-F-30
R-F-80		R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73	Hospital IT management	S-HIT	The system could use HL7 standard for the exchange of medical data and coupling with the existing systems.	HL7 standard is used/not used.	Standards	Functional	Introduced	-	-	Could	Document analysis	New requirement, combination R-F-03, R-F-04, R-F-06, R-F-23, R-F-25, R-F-26, R-F-31, R-F-71, R-F-72, R-F-73
R-F-82		R-F-27, R-F-28, R-F-29	Secondary users	S-SU	The system should have a link to EDIFACT.	EDIFACT messages can/cannot be viewed and edited.	Coupling possibilities	Functional	Introduced	-	-	Should	Document analysis	Coupling with GPs, contains R-F-27, R-F-28, R-F-29
R-F-83		R-F-34, R-F-37, R-F-39, R-F-68	Secondary users	S-SU	It must be possible to exchange important medical data.	Important medical data such as medication list, allergies, lab and radiology reports can/cannot be exchanged.	Data types	Functional	Introduced	-	-	Must	Survey specialists, patients survey, document analysis, Interview consultants	Important medical data are: medication list, allergies, lab and radiology reports. Contains also R-F-34, R-F-37, R-F-39, R-F-68
R-F-84		R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48	Secondary users	S-SU	It must be possible to exchange medical data, regardless the type of the organization.	Whether the system can/cannot be accessed from different (important) health organizations.	Data sources, Freedom of participation	Functional	Introduced	-	-	Must	Survey specialists	The possibility must exist to exchange medical data with different types of health organization and if needed non-health organizations, contains also R-F-40, R-F-41, R-F-42, R-F-43, R-F-44, R-F-45, R-F-46, R-F-47, R-F-48
R-F-85		R-F-08, R-F-79	Secondary users	S-SU	It must be possible to add text to the transfer exchange message.	The user can/cannot add text message.	Advanced possibilities	Functional	Introduced	-	-	Must	Document analysis	This text message contains reason and other extra information needed for the transfer of the patient from one health organization to another.
R-F-86		R-F-05, R-F-08	Secondary users	S-SU	The user must be able to attach a medical file to the exchange message.	The user can/cannot attach medical files (standard formats .pdf, .xls, .jpg, .png...)	Advanced possibilities	Functional	Introduced	-	-	Must	Document analysis	Improvement of R-F-05 which stated that only the patient is able to attach medical files. It is also needed that specialist have this functionality.
R-F-88		R-F-24	Hospital IT management	S-HIT	The system could have a custom coupling to other image storage systems.	The medical images from other storage systems can/cannot be accessed by the system.	Coupling possibilities	Functional	Introduced	-	-	Could	Document analysis	Coupling to image storage systems. It should be possible to link with image storage systems like Sioux medical systems.

## Appendix E - Requirements Regional Exchange of Medical Data - Dutch Health organizations (Verified)

Requirement ID	New ID	Contains	Actor	Actor code	Specification	Test	Category	Type	State	In conflict with	Dependency/relation	Priority	Source	Explanation
R-F-89		R-F-65	Hospital Councils	S-HC	The system should encrypt query string parameters in order to provide secure communication.	Encryption is used/not used.	Security	Functional	Introduced	-	-	Should	Document analysis	Functionalities to improve secure communication
R-F-90		R-F-14	Primary users, Secondary users	S-PU, S-SU	All exchanged messages must be encrypted before sending.	Message is encrypted/not encrypted, man in the middle attack for testing	Security	Functional	Introduced	-	-	Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-F-91		R-F-14	Primary users, Secondary users	S-PU, S-SU	The system must decrypt messages by receive, unless the user is not authorized	Message is encrypted/not encrypted. If user has not enough authorization rights the message should not be decrypted.	Security	Functional	Introduced	-	-	Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-F-92		R-F-14	Primary users, Secondary users	S-PU, S-SU	Audit / archiving systems should make log files that record the activities of users who access medical files of the patients	Log records are created / not created.	Security	Functional	Introduced	-	-	Must	Survey specialists, patients survey	Surveys specialists and patients, this is independent from specialism or patient groups
R-N-08			Hospital IT management	S-HIT	Changes and authorization instructions should be available.	Instructions available/not available	Customization	Non-funtional	Original	-	-	Should	Document analysis	General requirements
R-N-09			Hospital IT management	S-HIT	The program code should be clear and easy to understand.	Code comments available/not available	Customization	Non-funtional	Original	-	-	Should	Document analysis	General requirements
R-N-10			Hospital executives	S-HE	It must be easy to integrate the system with the existing software solutions.	Number of hours needed for configuration	Orchestration / Integration	Non-funtional	Original	-	-	Must	Document analysis	It should cost as less as possible effort to integrate the system with existing EHR and all other software (like OK, agenda, disinfection, disinfection, sterilization, weighing machines, laser engraver)
R-N-12		R-N-22, R-F-59	Consumers/ Patients organizations	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	Official form for questioning patients exist/does not exist	Privacy, Law and regulation, Freedom of choice	Non-funtional	Combined	R-F-67	R-N-12, R-N-22, R-F-59	Must	Survey specialist, patients and literature	Privacy law and regulation, barriers,
R-N-13			Primary users, Secondary users, Hospital IT management	S-PU, S-SU, S-HIT	The system must be stable.	Average number of hours system is available, without going offline.	Reliability	Non-funtional	Original	-	-	Must	Document analysis	General requirements
R-N-20		R-N-19	Secondary users	S-SU	It must be possible to exchange medical data within couple of minutes.	Number of minutes needed for exchange <= accepted number of minutes	Performance	Non-funtional	Original	-	-	Must	Survey specialists	This is especially important for specialisms like: Family medicine(S-PU-x), KNO(S-PU-x), Radiology S-PU-001-D6, Special Dentistry (S-PU-x)



## **Appendix F**

---

# **Analytic Hierarchy Process (AHP)**

This appendix illustrates the detailed overview of different steps of the Analytic Hierarchy Process (AHP). The first result is shown in table 1 and the end-result can be found in table 7.

**Appendix F- Analytic Hierarchy Process (AHP)**

**Table 7**

**Difference sum - (stakeholders importance + MoSCoW) - Scale / SUM**

	R-F-02	R-F-11	R-F-13	R-F-15	R-F-18	R-F-19	R-F-49	R-F-50	R-F-51	R-F-53	R-F-62	R-F-67	R-F-69	R-F-74	R-F-81	R-N-12	R-N-24	Sum	Normalized sum (Sum/n)
R-F-02	0,07	0,11	0,07	0,07	0,09	0,10	0,10	0,10	0,10	0,11	0,10	0,10	0,10	0,09	0,11	0,10	0,10	1,59	0,09
R-F-11	0,02	0,03	0,03	0,03	0,03	0,04	0,03	0,03	0,04	0,03	0,04	0,04	0,04	0,03	0,03	0,04	0,03	0,56	0,03
R-F-13	0,07	0,07	0,06	0,06	0,07	0,05	0,08	0,08	0,05	0,06	0,05	0,05	0,05	0,07	0,07	0,05	0,08	1,08	0,06
R-F-15	0,07	0,07	0,06	0,06	0,07	0,05	0,08	0,08	0,05	0,06	0,05	0,05	0,05	0,07	0,07	0,05	0,08	1,08	0,06
R-F-18	0,01	0,01	0,01	0,01	0,02	0,01	0,02	0,02	0,01	0,02	0,01	0,01	0,01	0,02	0,01	0,01	0,02	0,25	0,01
R-F-19	0,03	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,75	0,04
R-F-49	0,07	0,11	0,07	0,07	0,09	0,10	0,10	0,10	0,10	0,11	0,10	0,10	0,10	0,09	0,11	0,10	0,10	1,59	0,09
R-F-50	0,07	0,11	0,07	0,07	0,09	0,10	0,10	0,10	0,10	0,11	0,10	0,10	0,10	0,09	0,11	0,10	0,10	1,59	0,09
R-F-51	0,03	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,75	0,04
R-F-53	0,08	0,14	0,15	0,15	0,10	0,15	0,11	0,11	0,15	0,13	0,15	0,15	0,15	0,10	0,14	0,15	0,11	2,19	0,13
R-F-62	0,03	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,75	0,04
R-F-67	0,03	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,75	0,04
R-F-69	0,03	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,75	0,04
R-F-74	0,01	0,01	0,01	0,01	0,02	0,01	0,02	0,02	0,01	0,02	0,01	0,01	0,01	0,02	0,01	0,01	0,02	0,25	0,01
R-F-81	0,02	0,03	0,03	0,03	0,03	0,04	0,03	0,03	0,04	0,03	0,04	0,04	0,04	0,03	0,03	0,04	0,03	0,56	0,03
R-N-12	0,08	0,04	0,06	0,06	0,05	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,04	0,05	0,04	0,04	0,04	0,80	0,05
R-N-24	0,25	0,11	0,07	0,07	0,09	0,10	0,10	0,10	0,10	0,11	0,10	0,10	0,10	0,09	0,11	0,10	0,10	1,76	0,10
<b>Sum</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>		<b>1,00</b>

**Table 6**

**Difference sum - (stakeholders importance + MoSCoW) - Scale**

	R-F-02	R-F-11	R-F-13	R-F-15	R-F-18	R-F-19	R-F-49	R-F-50	R-F-51	R-F-53	R-F-62	R-F-67	R-F-69	R-F-74	R-F-81	R-N-12	R-N-24
R-F-02	1	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	1	1	2 1/4	8/9	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	1
R-F-11	2/7	1	4/9	4/9	2 1/4	8/9	2/7	2/7	8/9	2/9	8/9	8/9	8/9	2 1/4	1	8/9	2/7
R-F-13	8/9	2 1/4	1	1	4 1/2	1 1/8	8/9	8/9	1 1/8	4/9	1 1/8	1 1/8	1 1/8	4 1/2	2 1/4	1 1/8	8/9
R-F-15	8/9	2 1/4	1	1	4 1/2	1 1/8	8/9	8/9	1 1/8	4/9	1 1/8	1 1/8	1 1/8	4 1/2	2 1/4	1 1/8	8/9
R-F-18	1/6	4/9	2/9	2/9	1	2/7	1/6	1/6	2/7	1/7	2/7	2/7	2/7	1	4/9	2/7	1/6
R-F-19	4/9	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-F-49	1	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	1	1	2 1/4	8/9	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	1
R-F-50	1	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	1	1	2 1/4	8/9	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	1
R-F-51	4/9	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-F-53	1 1/8	4 1/2	2 1/4	2 1/4	6 3/4	3 3/8	1 1/8	1 1/8	3 3/8	1	3 3/8	3 3/8	3 3/8	6 3/4	4 1/2	3 3/8	1 1/8
R-F-62	4/9	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-F-67	4/9	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-F-69	4/9	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-F-74	1/6	4/9	2/9	2/9	1	2/7	1/6	1/6	2/7	1/7	2/7	2/7	2/7	1	4/9	2/7	1/6
R-F-81	2/7	1	4/9	4/9	2 1/4	8/9	2/7	2/7	8/9	2/9	8/9	8/9	8/9	2 1/4	1	8/9	2/7
R-N-12	1 1/8	1 1/8	8/9	8/9	3 3/8	1	4/9	4/9	1	2/7	1	1	1	3 3/8	1 1/8	1	4/9
R-N-24	3 3/8	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	1	1	2 1/4	8/9	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	1
<b>Sum</b>	<b>13 4/7</b>	<b>32 1/7</b>	<b>15 3/7</b>	<b>15 3/7</b>	<b>65</b>	<b>23</b>	<b>10 1/2</b>	<b>10 1/2</b>	<b>23</b>	<b>8</b>	<b>23</b>	<b>23</b>	<b>23</b>	<b>65</b>	<b>32 1/7</b>	<b>23</b>	<b>10 1/2</b>

**Appendix F - Analytic Hierarchy Process (AHP)**

**Table 5**

**Difference sum - (stakeholders importance + MoSCoW)**

	R-F-02	R-F-11	R-F-13	R-F-15	R-F-18	R-F-19	R-F-49	R-F-50	R-F-51	R-F-53	R-F-62	R-F-67	R-F-69	R-F-74	R-F-81	R-N-12	R-N-24
R-F-02	0	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	0	0	2 1/4	-1 1/8	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	0
R-F-11	-3 3/8	0	-2 1/4	-2 1/4	2 1/4	-1 1/8	-3 3/8	-3 3/8	-1 1/8	-4 1/2	-1 1/8	-1 1/8	-1 1/8	2 1/4	0	-1 1/8	-3 3/8
R-F-13	-1 1/8	2 1/4	0	0	4 1/2	1 1/8	-1 1/8	-1 1/8	1 1/8	-2 1/4	1 1/8	1 1/8	1 1/8	4 1/2	2 1/4	1 1/8	-1 1/8
R-F-15	-1 1/8	2 1/4	0	0	4 1/2	1 1/8	-1 1/8	-1 1/8	1 1/8	-2 1/4	1 1/8	1 1/8	1 1/8	4 1/2	2 1/4	1 1/8	-1 1/8
R-F-18	-5 5/8	-2 1/4	-4 1/2	-4 1/2	0	-3 3/8	-5 5/8	-5 5/8	-3 3/8	-6 3/4	-3 3/8	-3 3/8	-3 3/8	0	-2 1/4	-3 3/8	-5 5/8
R-F-19	-2 1/4	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-F-49	0	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	0	0	2 1/4	-1 1/8	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	0
R-F-50	0	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	0	0	2 1/4	-1 1/8	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	0
R-F-51	-2 1/4	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-F-53	1 1/8	4 1/2	2 1/4	2 1/4	6 3/4	3 3/8	1 1/8	1 1/8	3 3/8	0	3 3/8	3 3/8	3 3/8	6 3/4	4 1/2	3 3/8	1 1/8
R-F-62	-2 1/4	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-F-67	-2 1/4	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-F-69	-2 1/4	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-F-74	-5 5/8	-2 1/4	-4 1/2	-4 1/2	0	-3 3/8	-5 5/8	-5 5/8	-3 3/8	-6 3/4	-3 3/8	-3 3/8	-3 3/8	0	-2 1/4	-3 3/8	-5 5/8
R-F-81	-3 3/8	0	-2 1/4	-2 1/4	2 1/4	-1 1/8	-3 3/8	-3 3/8	-1 1/8	-4 1/2	-1 1/8	-1 1/8	-1 1/8	2 1/4	0	-1 1/8	-3 3/8
R-N-12	1 1/8	1 1/8	-1 1/8	-1 1/8	3 3/8	0	-2 1/4	-2 1/4	0	-3 3/8	0	0	0	3 3/8	1 1/8	0	-2 1/4
R-N-24	3 3/8	3 3/8	1 1/8	1 1/8	5 5/8	2 1/4	0	0	2 1/4	-1 1/8	2 1/4	2 1/4	2 1/4	5 5/8	3 3/8	2 1/4	0

**Table 4**

**Stakeholder's Importance difference**

	R-F-02	R-F-11	R-F-13	R-F-15	R-F-18	R-F-19	R-F-49	R-F-50	R-F-51	R-F-53	R-F-62	R-F-67	R-F-69	R-F-74	R-F-81	R-N-12	R-N-24
R-F-02	0	2	2	2	3	3	1	1	3	0	3	3	1	3	3	3	0
R-F-11	-2	0	0	0	1	1	-1	-1	1	-2	1	1	-1	1	1	1	-2
R-F-13	-2	0	0	0	1	1	-1	-1	1	-2	1	1	-1	1	1	1	-2
R-F-15	-2	0	0	0	1	1	-1	-1	1	-2	1	1	-1	1	1	1	-2
R-F-18	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-19	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-49	-1	1	1	1	2	2	0	0	2	-1	2	2	0	2	2	2	-1
R-F-50	-1	1	1	1	2	2	0	0	2	-1	2	2	0	2	2	2	-1
R-F-51	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-53	0	2	2	2	3	3	1	1	3	0	3	3	1	3	3	3	0
R-F-62	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-67	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-69	-1	1	1	1	2	2	0	0	2	-1	2	2	0	2	2	2	-1
R-F-74	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-F-81	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-N-12	-3	-1	-1	-1	0	0	-2	-2	0	-3	0	0	-2	0	0	0	-3
R-N-24	0	2	2	2	3	3	1	1	3	0	3	3	1	3	3	3	0

**Appendix F - Analytic Hierarchy Process (AHP)**

**Table 3**

ID	Stakeholder ID	Stakeholder's Importance - Numerical
R-F-02	S-HE	4
R-F-11	S-PU	2
R-F-13	S-PU, S-SU	2
R-F-15	S-PU, S-SU	2
R-F-18	S-C	1
R-F-19	S-I, S-C	1
R-F-49	S-PU	3
R-F-50	S-PU	3
R-F-51	S-C	1
R-F-53	S-HE	4
R-F-62	S-SU	1
R-F-67	S-IN	1
R-F-69	S-G	3
R-F-74	S-I	1
R-F-81	S-SU	1
R-N-12	S-C	1
R-N-24	S-HE	4

**Table 2**

MoSCoW difference																	
	R-F-02	R-F-11	R-F-13	R-F-15	R-F-18	R-F-19	R-F-49	R-F-50	R-F-51	R-F-53	R-F-62	R-F-67	R-F-69	R-F-74	R-F-81	R-N-12	R-N-24
R-F-02	0	1	-1	-1	2	-1	-1	-1	-1	-1	-1	-1	1	2	0	-1	0
R-F-11	-1	0	-2	-2	1	-2	-2	-2	-2	-2	-2	-2	0	1	-1	-2	-1
R-F-13	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-15	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-18	-2	-1	-3	-3	0	-3	-3	-3	-3	-3	-3	-3	-1	0	-2	-3	-2
R-F-19	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-49	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-50	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-51	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-53	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-62	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-67	1	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-F-69	-1	0	-2	-2	1	-2	-2	-2	-2	-2	-2	-2	0	1	-1	-2	-1
R-F-74	-2	-1	-3	-3	0	-3	-3	-3	-3	-3	-3	-3	-1	0	-2	-3	-2
R-F-81	0	1	-1	-1	2	-1	-1	-1	-1	-1	-1	-1	1	2	0	-1	0
R-N-12	4	2	0	0	3	0	0	0	0	0	0	0	2	3	1	0	1
R-N-24	3	1	-1	-1	2	-1	-1	-1	-1	-1	-1	-1	1	2	0	-1	0



**Appendix F - Analytic Hierarchy Process (AHP)**

Table 1		
ID	Priority	MoSCoW - Numerical
R-F-02	Should	3
R-F-11	Could	2
R-F-13	Must	4
R-F-15	Must	4
R-F-18	Won't	1
R-F-19	Must	4
R-F-49	Must	4
R-F-50	Must	4
R-F-51	Must	4
R-F-53	Must	4
R-F-62	Must	4
R-F-67	Must	4
R-F-69	Could	2
R-F-74	Won't	1
R-F-81	Should	3
R-N-12	Must	4
R-N-24	Should	3



## Appendix G

---

### Validation steps

This appendix provides a list of requirements that is used for the validation steps. Several technical solutions are tested by these requirements and the level of accomplishment (between 0 and 5) is shown for each solutions. Also, the reasoning behind these levels is provided for each pair. The results gathered from this step are used for further evaluation (Appendix H ) of the solutions and improvement of the list of requirements.

**Appendix G-RESULTS VALIDATION REQUIREMENTS**

Requirement specification							S1-EHR based exchange		S2-Exchange using a message broker		S3-OZIS Regional exchange		S4-Health information portals		S5-Secure mail (Zorgmail)		S6-8.6 AORTA	
Requirement ID	Actor code	Specification	Category	Type	Priority	Priority nominal value	level of accomplishment S-1	Explanation S-1	level of accomplishment S-2	Explanation S-2	level of accomplishment S-3	Explanation S-3	level of accomplishment S-4	Explanation S-4	level of accomplishment S-5	Explanation S-5	level of accomplishment S-6	Explanation S-6
R-F-02	S-HE	Cross regional exchange should be possible in exceptional cases.	Orchestration / Integration, Freedom of participation	Functional	Should	3	0	Only exchange within the same organization is possible	1	The are no limitations in location, the communication is through internet	0	OZIS only operates between regional health information systems.	1	The are no limitations in location, the service can be accessed via a web-browser from any place.	1	The are no limitations in location, the service can be accessed via a web-browser from any place.	1	No limitation
R-F-09	S-C	The registration of new patients won't be needed, if the patient is already registered by a partner health organization.	Advanced possibilities	Functional	Won't	1	0	Registration is needed	0	Registration is needed	0	Registration is needed	0	Registration is needed	0	Registration is needed	0	Registration is needed
R-F-10	S-HT	The UZI card and verification of the Citizen Service Number (BSN) could be used for the authorization.	Authentication	Functional	Could	2	0,5	Not guaranteed, but in some situations used	0	Most of the time the exchange is performed by means an automatic script. The authentication does not guarantee use of UZI and BSN verification and is dependent on the EHR system in which it is used.	0	OZIS makes only use of username and a password for authentication.	0,5	It depends on the implementation, in some web portals only username and password is used	0	Users only need a username and password to login	1	Possible
R-F-13	S-PU, S-SU	The users must authenticate before entering the system.	Authentication	Functional	Must	4	1	Included	1	Users still need to authenticate to login to the EHR system	1	Users still need to authenticate to login to the EHR system	1	Users still need to authenticate to login to the EHR system	1	Users still need to authenticate to login to the EHR system	1	Users still need to authenticate to login to the EHR system
R-F-15	S-PU, S-SU	The users must only get to see the specific functionalities of the system depending on their authorization level.	Authorization, Privacy	Functional	Must	4	1	Included	0	Is not guaranteed	0	There is no access control at the level individual user, but at system level.	1	This is possible, in fact the patient has other functionalities than medical specialists.	0	If mail functionalities are enabled for each user	0	Is not guaranteed
R-F-18	S-C	Unauthorized persons(specialists or others) won't be able to access medical data of the patients.	Authorization, Privacy	Functional	Won't	1	1	Authorization profile and rights are always included	0,5	Partly met, still it is possible to set authorization rules in the EHR system of both side, but it is not possible to check for each part whether user is authorized or not?	0	There is no access control at the level individual user, but at system level.	1	For each user there exists an user authorization profile.	0,5	The user needs to be authorized in own system to be able sending emails. However the receiver is not checked again for authorization rights for accessing specific data.	1	It is possible to check generic and specific authorization profiles.
R-F-32	S-I	It should be possible to exchange medical data of the patients suffering from chronic diseases.	Data types	Functional	Should	3	1	Is possible	1	Is possible	1	Is possible	1	Is possible	1	Is possible	1	Is possible
R-F-33	S-HT	It could be possible to exchange medical images.	Data types	Functional	Could	2	1	Exchanging medical images is possible.	0,5	It depends on the possibilities of the message broker. For instance, if the message broker is intended to exchange Edifact messages this is not possible.	0	OZIS has a transmittal message, but this is limited to text messages.	1	Exchanging medical images is possible.	1	Exchanging medical images is possible.	0	The exchange standard of AORTA is based on HL7 and this does not support exchange of digital images.
R-F-35	S-PU	The system must be able to exchange archived medical data.	Data types	Functional	Must	4	0,5	Depends on the implementation.	0,5	Depends on the implementation.	0	Not possible	0,5	Depends on the implementation.	1	It is possible to send different formats of files.	0	Not possible
R-F-49	S-PU	The specialists must be able to choose which data they prefer to share.	Freedom of choice	Functional	Must	4	0	A user can only select specific parts of data during retrieval	0	Not possible	0	A user can only select specific parts of data during retrieval	1	It is possible only to share specific parts of data.	1	It is possible only to send specific parts of data.	1	It is possible only to share specific parts of data. (publish functionality AORTA)
R-F-50	S-PU	The specialists must be able to choose which data they prefer to take over.	Freedom of choice	Functional	Must	4	1	Is possible	0	Only a selection can be made from the possible received data. Specific medical data can only be requested by traditional services like phone, fax...	1	Is possible	1	Is possible	0,5	The specialist depends on the data that is sent to him / her	1	Is possible
R-F-52	SSH	It must be possible to request specific parts of the medical records from the other organization.	Freedom of choice	Functional	Must	4	0	Not possible, exchange only possible within the same organization	0	Only a selection can be made from the possible received data. Specific medical data can only be requested by traditional services like phone, fax...	1	Is possible, co-operative organizations have access to all data from each other, made public to them.	0,5	Depends on the implementation.	1	This is possible by sending the other organization an email and request for the specific data.	0,5	It is possible to request specific parts of the patient's medical data, but this data is only limited to medication and allergies.
R-F-53	S-HE	It must still be possible to use traditional services like phone and written letters if necessary.	Orchestration / Integration	Functional	Must	4	1	Is possible	1	Is possible	1	Is possible	1	Is possible	1	Is possible	1	Is possible
R-F-55	S-SU, S-IT	The patient must be able to maintain his/her medical records	Patient access	Functional	Must	4	0	Not possible, patient has no access to the EHR	0	Not possible, patient has no access to any data.	0	Not possible	1	The patient can view, add or edit medical data	0	Not possible.	0,5	At this state the patient access to data is not implemented yet. But there are plans to improve this in the future.
R-F-60	S-SU	Patients must be able to look back which entities had access to their personal health data.	Patient control	Functional	Must	4	0	A log is kept from all activities in the system, but patient has no access to the log files.	0	A log is kept from all activities in the system, but patient has no access to the log files.	0	A log is kept from all activities in the system, but patient has no access to the log files.	0,5	Depends on the implementation.	0	Not possible.	0	Not possible.
R-F-62	S-SU	Patients must be able to provide access to other parties.	Patient control	Functional	Must	4	0	Not possible, patient has no access to the EHR	0	Not possible, patient has no access to the EHR	0	Not possible	0,5	Depends on the implementation. It can be implemented.	0	It is only possible to send and receive medical data.	0	Not possible, authorization profiles are not maintained by the patients
R-F-63	S-HT	Application must be accessible from different location(s).	Remote Access	Functional	Must	4	0	Not possible to access medical files outside the organization.	1	Can be accessed from any location through internet.	0,5	Exchange only possible within the region. Cross regional exchange is not possible.	1	Can be accessed from any location through internet.	1	Can be accessed from any location through internet.	0,5	Limited to national border. In other words remote location, outside national borders not accessible.
R-F-64	S-FT	It must be possible to have remote access to the system.	Remote Access	Functional	Must	4	0,5	Remote access is only possible using VPN terminals	1	Can be accessed from any location through internet.	1	Can be accessed from any location through internet.	1	Can be accessed from any location through internet.	1	Can be accessed from any location through internet.	1	Can be accessed from any location through internet.
R-F-66	S-PU	It must be possible to consult medical data received from other health providers during the medical treatment.	Specialist access	Functional	Must	4	1	This is possible.	0	Not possible, the data is not send realtime, but at fixed times.	1	This is possible.	1	This is possible.	1	This is possible.	1	This is possible.
R-F-70	S-HT	The system should have a link for the creating transmittal medication records with an external medication gateway	Coupling possibilities	Functional	Should	3	0	Not possible.	0	Not possible.	1	This is the main functionality of OZIS	0,5	Depends on the implementation. It can be implemented.	0	Not possible.	1	This is possible. Also in the national LSP the medication list will be shared.

Appendix G-RESULTS VALIDATION REQUIREMENTS

Requirement specification							SI-EHR based exchange		S2-Exchange using a message broker		S3-OZIS Regional exchange		S4-Health information portals		S5-Secure mail (Zorgmail)		S6-8.6 AORTA	
Requirement ID	Actor code	Specification	Category	Type	Priority	Priority nominal value	level of accomplishment S-1	Explanation S-1	level of accomplishment S-2	Explanation S-2	level of accomplishment S-3	Explanation S-3	level of accomplishment S-4	Explanation S-4	level of accomplishment S-5	Explanation S-5	level of accomplishment S-6	Explanation S-6
R-F-77	S-HT	The system must be integrated with existing EHR systems.	Orchestration / Integration	Functional	Must	4	1	No effort needed.	0,5	Some effort needed	0	A lot of effort needed.	0,5	Some effort needed	1	No effort needed.	0	A lot of effort needed. The health organizations need to be notified.
R-F-80	S-HT	The system could use HL7 standard for the exchange of medical data and coupling with the existing systems.	Standards	Functional	Could	2	0	Not implemented in most existing EHR systems.	0,5	Depends on the implementation. It can be implemented.	0	OZIS has a transactional message, but this is limited to text messages.	0,5	Depends on the implementation. It can be implemented.	1	HL7v2 and HL7v3 supported	1	HL7v3 supported
R-F-82	S-SU	The system should have a link to EDIFACT.	Coupling possibilities	Functional	Should	3	0,5	Some effort needed	0,5	Depends on the implementation. It can be implemented.	1	EDIFACT supported	0,5	Depends on the implementation. It can be implemented.	1	EDIFACT supported	0	HL7 standard is used.
R-F-83	S-SU	It must be possible to exchange important medical data.	Data types	Functional	Must	4	1	This is possible.	1	This is possible. This includes medication, allergies and transfer letters.	0,5	Not all data can be transferred, OZIS is originally meant for exchange of medication list and GP data.	1	This is possible.	1	This is possible.	0,5	Not all data can be transferred, at this moment only the medication list.
R-F-84	S-SU	It must be possible to exchange medical data, regardless the type of the organization.	Data sources, Freedom of participation	Functional	Must	4	1	This is possible.	1	This is possible.	0,5	OZIS is mainly for exchange between pharmacies, GPs and integrated care.	1	This is possible.	1	This is possible.	1	This is possible.
R-F-85	S-SU	It must be possible to add text to the transfer exchange message.	Advanced possibilities	Functional	Must	4	1	This is possible.	0,5	Depends on the implementation. Still not always user-friendly. Messages are mainly hard to read. Edifact messages.	1	This is possible.	1	This is possible.	1	This is possible.	1	This is possible.
R-F-86	S-SU	The user must be able to attach a medical file to the exchange message.	Advanced possibilities	Functional	Must	4	1	This is possible.	0	Not possible, mainly automated textual messages.	0	Not possible, mainly automated textual messages.	1	This is possible.	1	This is possible.	0	Not possible, mainly automated textual messages.
R-F-88	S-HT	The system could have a custom coupling to other image storage systems.	Coupling possibilities	Functional	Could	2	1	This is possible.	0	Not possible, mainly automated textual messages.	0	Not possible, mainly automated textual messages.	1	This is possible.	0	Still the user needs to select every time the image files as attachment.	0	Not possible.
R-F-89	S-IC	The system should encrypt query string parameters in order to provide secure communication.	Security	Functional	Should	3	0	Not guaranteed.	0,5	Depends on the solution.	0	The information through OZIS network is not encrypted. There is a direct connection between health information systems possible.	1	Data communication over internet is encrypted.	1	Makes use of Secure Sockets Layer (SSL)	0	AORTA communication is encrypted during transport over the network (end-to-end authentication). AORTA has specific network requirements.
R-F-90	S-PU, S-SU	All exchanged messages must be encrypted before sending.	Security	Functional	Must	4	0	Not guaranteed.	1,5	Depends on the solution.	1	The information through OZIS network is not encrypted. There is a direct connection between health information systems possible.	2	Data communication over internet is encrypted.	2	Makes use of Secure Sockets Layer (SSL)	1	AORTA communication is encrypted during transport over the network (end-to-end authentication). AORTA has specific network requirements.
R-F-91	S-PU, S-SU	The system must decrypt messages by receive, unless the user is not authorized.	Security	Functional	Must	4	0	Not guaranteed.	0	Not guaranteed. Authorization profiles not always checked.	0	There is no access control at the level individual user, but at system level.	1	This is possible.	0,5	Authorization by receive not always maintained.	1	This is possible. UZI card is used to decrypt.
R-F-92	S-PU, S-SU	Audit / archiving systems should make log files that record the activities of users who access medical files of the patients	Security	Functional	Must	4	1	This is possible.	0,5	Depends on the solution.	1	On OZIS connected care systems have a local logging. Also within OZIS is central logging available when in a region on a central overview get the OZIS activities.	1	This is possible.	0	Not possible.	1	This is possible.
R-N-08	S-HT	Changes and authorization instructions should be available.	Customization	Non-functional	Should	3	1	This is possible.	0	Most of the time the exchange formats are not easy to change. Often based on signed EDIFACT formats.	0	Not available on local level.	1	This is possible.	0,5	New accounts can be made added easily.	0	Not always clear.
R-N-09	S-HT	The program code should be clear and easy to understand.	Customization	Non-functional	Should	3	0,5	Depends on the solution.	0,5	Depends on the solution.	0	Not clear for the clients.	0	Not clear for the clients.	0	Not clear for the clients.	0	Not clear for the clients.
R-N-10	S-HE	It must be easy to integrate the system with the existing software solutions.	Orchestration / Integration	Non-functional	Must	4	1	No effort needed.	0,5	Some effort needed	0	A lot of effort needed.	0,5	Some effort needed	1	No effort needed.	0	A lot of effort needed. The health organizations need to be notified.
R-N-12	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	Privacy, Law and regulation, Freedom of choice	Non-functional	Must	4	0	No	0	No	1	Guaranteed	0,5	Depends on the situation	0,5	Depends on the situation	1	Guaranteed
R-N-13	S-PU, S-SU, S-HT	The system must be stable.	Reliability	Non-functional	Must	4	1	Guaranteed	1	Guaranteed	1	Guaranteed	1	Guaranteed	1	Guaranteed	0,5	Uncertain about the developments.
R-N-20	S-SU	It must be possible to exchange medical data within couple of minutes.	Performance	Non-functional	Must	4	1	Guaranteed	0	Not guaranteed. Sometimes every 12 hours.	1	Guaranteed	1	Guaranteed	1	Guaranteed	1	Guaranteed
R-N-21	S-HT	Back-up possibility should be provided.	Reliability	Non-functional	Should	3	1	Guaranteed	0,5	Depends on the situation	0	Back-up should be arranged by the health organizations.	0	Back-up should be arranged by the health organizations.	1	Guaranteed	0	Back-up should be arranged by the health organizations.



## **Appendix H**

---

# **Evaluation solutions**

This appendix provides a detailed overview of the evaluation of several solutions. Through Priority nominal value and Factor accomplishment the Level of accomplishment is found. At the end of this appendix the final list (verified and validated) list of the requirements is provided.





Appendix H -Evaluation solutions

Requirement specification							S1-EHR based exchange		S2-Exchange using a message broker		S3-OZIS Regional exchange		S4-Health information portals		S5-Secure mail (Zorgmail)		S6-8.6 AORTA	
Requirement ID	Actor code	Specification	Category	Type	Priority	Priority nominal value	Factor accomplishment S-1	Level of accomplishment S-1	Factor accomplishment S-2	Level of accomplishment S-2	Factor accomplishment S-3	Level of accomplishment S-3	Factor accomplishment S-4	Level of accomplishment S-4	Factor accomplishment S-5	Level of accomplishment S-5	Factor accomplishment S-6	Level of accomplishment S-6
R-F-33	S-HIT	It could be possible to exchange medical images.	Data types	Functional	Could	2	1	2	0,5	1	0	0	1	2	1	2	0	0
R-F-35	S-PU	The system must be able to exchange archived medical data.	Data types	Functional	Must	4	0,5	2	0,5	2	0	0	0,5	2	1	4	0	0
R-F-83	S-SU	It must be possible to exchange important medical data.	Data types	Functional	Must	4	1	4	1	4	0,5	2	1	4	1	4	0,5	2
R-F-49	S-PU	The specialists must be able to choose which data they prefer to share.	Freedom of choice	Functional	Must	4	0	0	0	0	0	0	1	4	1	4	1	4
R-F-50	S-PU	The specialists must be able to choose which data they prefer to take over.	Freedom of choice	Functional	Must	4	1	4	0	0	1	4	1	4	0,5	2	1	4
R-F-52	S-SH	It must be possible to request specific parts of the medical records from the other organization.	Freedom of choice	Functional	Must	4	0	0	0	0	1	4	0,5	2	1	4	0,5	2
R-F-53	S-HE	It must still be possible to use traditional services like phone and written letters if necessary.	Orchestration / Integration	Functional	Must	4	1	4	1	4	1	4	1	4	1	4	1	4
R-F-77	S-HIT	The system must be integrated with existing EHR systems.	Orchestration / Integration	Functional	Must	4	1	4	0,5	2	0	0	0,5	2	1	4	0	0
R-N-10	S-HE	It must be easy to integrate the system with the existing software solutions.	Orchestration / Integration	Non-functional	Must	4	1	4	0,5	2	0	0	0,5	2	1	4	0	0
R-F-02	S-HE	Cross regional exchange should be possible in exceptional cases.	Orchestration / Integration, Freedom of participation	Functional	Should	3	0	0	1	3	0	0	1	3	1	3	1	3
R-F-55	S-SU, S-IT	The patient must be able to maintain his/her medical records	Patient access	Functional	Must	4	0	0	0	0	0	0	1	4	0	0	0,5	2
R-F-60	S-SU	Patients must be able to look back which entities had access to their personal health data.	Patient control	Functional	Must	4	0	0	0	0	0	0	0,5	2	0	0	0	0
R-F-62	S-SU	Patients must be able to provide access to other parties.	Patient control	Functional	Must	4	0	0	0	0	0	0	0,5	2	0	0	0	0
R-N-23	S-C	The patients should be clearly informed about how their health information may be used or shared.	Patient control	Non-functional	Should	3	0	0	0	0	0	0	0,5	1,5	0	0	0	0
R-N-20	S-SU	It must be possible to exchange medical data within couple of minutes.	Performance	Non-functional	Must	4	1	4	0	0	1	4	1	4	1	4	1	4
R-N-12	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	Privacy, Law and regulation, Freedom of choice	Non-functional	Must	4	0	0	0	0	1	4	0,5	2	0,5	2	1	4

Appendix H -Evaluation solutions

Requirement specification							S1-EHR based exchange		S2-Exchange using a message broker		S3-OZIS Regional exchange		S4-Health information portals		S5-Secure mail (Zorgmail)		S6-8.6 AORTA	
Requirement ID	Actor code	Specification	Category	Type	Priority	Priority nominal value	Factor accomplishment S-1	Level of accomplishment S-1	Factor accomplishment S-2	Level of accomplishment S-2	Factor accomplishment S-3	Level of accomplishment S-3	Factor accomplishment S-4	Level of accomplishment S-4	Factor accomplishment S-5	Level of accomplishment S-5	Factor accomplishment S-6	Level of accomplishment S-6
R-N-13	S-PU, S-SU, S-HIT	The system must be stable.	Reliability	Non-functional	Must	4	1	4	1	4	1	4	1	4	1	4	0,5	2
R-N-21	S-HIT	Back-up possibility should be provided.	Reliability	Non-functional	Should	3	1	3	0,5	1,5	0	0	0	0	1	3	0	0
R-F-63	S-HIT	Application must be accessible from different location(s).	Remote Access	Functional	Must	4	0	0	1	4	0,5	2	1	4	1	4	0,5	2
R-F-64	S-IT	It must be possible to have remote access to the system.	Remote Access	Functional	Must	4	0,5	2	1	4	1	4	1	4	1	4	1	4
R-F-89	S-HC	The system should encrypt query string parameters in order to provide secure communication.	Security	Functional	Should	3	0	0	0,5	1,5	0	0	1	3	1	3	0	0
R-F-90	S-PU, S-SU	All exchanged messages must be encrypted before sending.	Security	Functional	Must	4	0	0	1,5	6	1	4	2	8	2	8	1	4
R-F-91	S-PU, S-SU	The system must decrypt messages by receive, unless the user is not authorized	Security	Functional	Must	4	0	0	0	0	0	0	1	4	0,5	2	1	4
R-F-92	S-PU, S-SU	Audit / archiving systems should make log files that record the activities of users who access medical files of the patients	Security	Functional	Must	4	1	4	0,5	2	1	4	1	4	0	0	1	4
R-N-27	S-HIT, S-C	All security resources such as firewalls, remote access servers and so on must be configured properly, in order to compliance with security policies	Security	Non-functional	Must	4	0,5	2	0,5	2	0,5	2	0,5	2	0,5	2	0,5	2
R-N-28	S-HIT, S-C	All computing resources, such as EHR system, network devices and applications should be monitored for changes in configuration that increase security risks	Security	Non-functional	Must	4	0,5	2	0,5	2	0,5	2	0,5	2	0,5	2	0,5	2
R-F-66	S-PU	It must be possible to consult medical data received from other health providers during the medical treatment.	Specialists access	Functional	Must	4	1	4	0	0	1	4	1	4	1	4	1	4
R-F-80	S-HIT	The system could use HL7 standard for the exchange of medical data and coupling with the existing systems.	Standards	Functional	Could	2	0	0	0,5	1	0	0	0,5	1	1	2	1	2

## Appendix H -Final List of Requirements

Requirement ID	Actor code	Specification	Category	Type
R-F-85	S-SU	It must be possible to add text to the transfer exchange message.	Advanced possibilities	Functional
R-F-86	S-SU	The user must be able to attach a medical file to the exchange message.	Advanced possibilities	Functional
R-F-93	S-HIT	The UZI card could be used for the authorization.	Authentication	Functional
R-F-94	S-HIT	The verification of the Citizen Service Number (BSN) could be used for the authorization.	Authentication	Functional
R-F-13	S-PU, S-SU	The users must authenticate before entering the system.	Authentication	Functional
R-F-15	S-PU, S-SU	The users must only get to see the specific functionalities of the system depending on their authorization level.	Authorization, Privacy	Functional
R-F-18	S-C	Unauthorized persons(specialists or others) won't be able to access medical data of the patients.	Authorization, Privacy	Functional
R-N-24	S-HE	The system should make use of latest web engineering technologies.	Capability	Non-functional
R-N-25	S-SU	It should be possible to exchange data within only couple of steps.	Capability	Non-functional
R-F-70	S-HIT	The system should have a link for the creating transmural medication records with an external medication gateway	Coupling possibilities	Functional
R-F-82	S-SU	The system should have a link to EDIFACT.	Coupling possibilities	Functional
R-F-88	S-HIT	The system could have a custom coupling to other image storage systems.	Coupling possibilities	Functional
R-N-08	S-HIT	Changes and authorization instructions should be available.	Customization	Non-functional
R-N-09	S-HIT	The program code should be clear and easy to understand.	Customization	Non-functional
R-F-84	S-SU	It must be possible to exchange medical data, regardless the type of the organization.	Data sources, Freedom of participation	Functional
R-F-32	S-I	It should be possible to exchange medical data between different health organization within integrated care.	Data types	Functional
R-F-33	S-HIT	It could be possible to exchange medical images.	Data types	Functional
R-F-35	S-PU	The system must be able to exchange archived medical data.	Data types	Functional
R-F-83	S-SU	It must be possible to exchange important medical data.	Data types	Functional
R-F-49	S-PU	The specialists must be able to choose which data they prefer to share.	Freedom of choice	Functional
R-F-50	S-PU	The specialists must be able to choose which data they prefer to take over.	Freedom of choice	Functional
R-F-52	S-SH	It must be possible to request specific parts of the medical records from the other organization.	Freedom of choice	Functional
R-F-77	S-HIT	The system must be integrated with existing EHR systems.	Orchestration / Integration	Functional
R-N-10	S-HE	It must be easy to integrate the system with the existing software solutions.	Orchestration / Integration	Non-functional
R-F-02	S-HE	Cross regional exchange should be possible in exceptional cases.	Orchestration / Integration, Freedom of participation	Functional
R-F-55	S-SU, S-IT	The patient must be able to maintain his/her medical records	Patient access	Functional
R-F-60	S-SU	Patients must be able to look back which entities had access to their personal health data.	Patient control	Functional
R-F-62	S-SU	Patients must be able to provide access to other parties.	Patient control	Functional
R-N-23	S-C	The patients should be clearly informed about how their health information may be used or shared.	Patient control	Non-functional
R-N-20	S-SU	It must be possible to exchange medical data within couple of minutes.	Performance	Non-functional
R-N-12	S-C	The patients must officially be asked whether they allow a certain health organizations to exchange their medical data.	Privacy, Law and regulation, Freedom of choice	Non-functional
R-N-13	S-PU, S-SU, S-HIT	The system must be stable.	Reliability	Non-functional
R-N-21	S-HIT	Back-up possibility should be provided.	Reliability	Non-functional
R-F-63	S-HIT	Application must be accessible from different location(s).	Remote Access	Functional
R-F-64	S-IT	It must be possible to have remote access to the system.	Remote Access	Functional
R-F-89	S-HC	The system should encrypt query string parameters in order to provide secure communication.	Security	Functional
R-F-90	S-PU, S-SU	All exchanged messages must be encrypted before sending.	Security	Functional
R-F-91	S-PU, S-SU	The system must decrypt messages by receive, unless the user is not authorized	Security	Functional
R-F-92	S-PU, S-SU	Audit / archiving systems should make log files that record the activities of users who access medical files of the patients	Security	Functional
R-F-66	S-PU	It must be possible to consult medical data received from other health providers during the medical treatment.	Specialists access	Functional
R-F-80	S-HIT	The system could use HL7 standard for the exchange of medical data and coupling with the existing systems.	Standards	Functional



## Appendix I

---

### **Results- Evaluation solutions**

This appendix provides a detailed overview of the results of the evaluation for several solutions. The numbers provided in each cell indicated the total level of accomplishment for each requirements category.

## Appendix I - Evaluation solutions - The results

Requirement category	S1-EHR based exchange	S2-Exchange using a message broker	S3-OZIS Regional exchange	S4-Health information portals	S5-Secure mail (Zorgmail)	S6-8.6 AORTA
Advanced possibilities	8	2	4	8	8	4
Authentication	5	4	4	5	4	6
Authorization, Privacy	5	0,5	0	5	0,5	1
Capabilities	3	0	3	6	4,5	3
Coupling possibilities	3,5	1,5	6	7	3	3
Customization	4,5	1,5	0	3	1,5	0
Data sources, Freedom of participation	4	4	2	4	4	4
Data types	11	10	5	11	13	5
Freedom of choice	4	0	8	10	10	10
Orchestration / Integration	12	11	4	11	15	7
Patient access	0	0	0	4	0	2
Patient control	0	0	0	5,5	0	0
Performance	4	0	4	4	4	4
Privacy, Law and regulation, Freedom of choice	0	0	4	2	2	4
Reliability	7	5,5	4	4	7	2
Remote access	2	5,5	4	7	7	4
Security	8	13,5	12	23	17	16
Specialists access	4	0	4	4	4	4
Standards	0	1	0	1	2	2

SUM	<b>85</b>	<b>60</b>	<b>68</b>	<b>124,5</b>	<b>106,5</b>	<b>81</b>
-----	-----------	-----------	-----------	--------------	--------------	-----------

Legend:	
Level	Color
0	
1-5	
6-10	
11-15	
16-20	
21-25	

## Appendix J

---

# Measurement tools

This appendix provides an overview of all variables used in questionnaires for the main users of RHIS. These variables are discussed mainly with the experts in this field and translated later to the questionnaires. This appendix also contains the two questionnaires (for patients and medical specialists), which are explained in the chapter about elicitation methods. These questionnaires were distributed among the questioned groups in two different versions (online and printed).

### **J.0.1 Variables survey medical specialists**

The variables used in the survey of medical specialists are listed as follow:

### **J.0.2 Variables survey patients**

The variables used in the survey of the patients are listed as follow:

## Regionale uitwisseling van medische gegevens

Geachte heer/mevrouw,

Bij een samenwerking tussen verschillende regionale zorgaanbieders (bijvoorbeeld ziekenhuizen, poliklinieken, huisartsen) of tussen ondersteunende instellingen (zoals laboratoria, apothekers) is er vaak behoefte aan de uitwisseling van medische gegevens. Om een beter beeld te krijgen van de bestaande complicaties hierbij en van de vraag vanuit de zorg naar betere oplossingen, willen wij graag uw mening weten over de verschillende aspecten die komen kijken bij de uitwisseling van medische gegevens op regionaal niveau. Uw mening kan ons helpen bij het verbeteren van de huidige oplossingen en uiteindelijk zorgen voor een efficiënter en effectiever zorgproces. Graag zouden wij uw aandacht willen vragen voor de volgende onderdelen:

Deel 1: Huidige staat van de regionale uitwisseling van medische data

Deel 2: Voordelen en nadelen van de regionale uitwisseling van medische data

Deel 3: Top Data – De voor regionale uitwisseling meest waardevolle gegevens

Het invullen van de enquête duurt circa 15 minuten. Alle informatie die u geeft zal vertrouwelijk worden behandeld. De resultaten van het onderzoek zullen zodanig worden gepresenteerd en gepubliceerd dat deze niet te herleiden zijn tot afzonderlijke personen of zorginstellingen.

Bij voorbaat dank voor uw bijdrage!

### Deel 1: Huidige staat regionaal uitwisseling medische data

Dit deel van het onderzoek bevat een aantal vragen over de huidige stand van zaken op het gebied van regionale uitwisseling van medische gegevens tussen zorgaanbieders'

#### Hoe vaak raadpleegt u elektronische informatie over patiënten die afkomstig is van zorgverleners?

(kruis aan hoe vaak voor iedere type)

	<1 keer p.maand	2-3 keer p.maand	1-6 keer p.maand	1 keer p.dag of vaker
binnen uw eigen zorginstelling / praktijk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
binnen uw eigen beroepsgroep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
buiten uw eigen beroepsgroep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
binnen uw eigen regio? (bijv. in een zorggroep)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
buiten uw eigen regio?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Ik vind het belangrijk om op elektronische wijze informatie over patiënten te delen met zorgverleners...**  
(kruis aan hoe belangrijk voor iedere type)

	niet belangrijk	enigszins belangrijk	belangrijk	heel erg belangrijk	n.v.t.
<b>binnen uw eigen zorginstelling / praktijk?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>binnen uw eigen beroepsgroep?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>buiten uw eigen beroepsgroep?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>binnen uw eigen regio? (bijv. in een zorggroep)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>buiten uw eigen regio?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Op welke wijze stuurt u op dit moment medische gegevens van uw patiënten / cliënten naar andere  
zorginstellingen binnen uw eigen regio?**

(u kunt meerdere opties aanvinken)

- Telefonisch
- Fax
- Email
- Via een (geprinte of handgeschreven) brief
- Gebruikmakend van hetzelfde EPD of zorginformatie systeem (directe inzage via een gedeeld systeem)
- Portaal - inzage in het informatiesysteem via een webpagina
- Via een andere elektronische systeem
- Anders
- Ik weet het niet

**Op welke wijze vraagt u op dit moment medische gegevens van uw patiënten / cliënten van andere  
zorginstellingen binnen uw eigen regio?**

(u kunt meerdere opties aanvinken)

- Telefonisch
- Fax
- Email
- Via een (geprinte of handgeschreven) brief
- Gebruikmakend van hetzelfde EPD of zorginformatie systeem (directe inzage via een gedeeld systeem)
- Portaal - inzage in het informatiesysteem via een webpagina
- Via een andere elektronische systeem
- Anders
- Ik weet het niet

**Wat zijn volgens u op dit moment de belangrijkste knelpunten voor uitwisseling van medische gegevens op regionaal niveau?**

(u kunt meerdere opties aanvinken)

- Veiligheidsaspecten - veiligheid van elektronische informatiesystemen en van de uitwisseling van elektronische informatie
- Privacyaspecten - bezorgdheid over privacy van patiënten
- Overdaad aan informatie - moeilijkheid om de informatie te vinden die essentieel is voor het bieden van de goede zorg
- Verschillende standaarden - van medische data verkregen van andere zorgverleners (bijv. om in eigen systeem opnemen van data)
- Stabiliteit en werking van onderliggende software
- De hoeveelheid tijd - die nodig is om medische gegevens van patiënten te ontvangen van andere zorgverleners
- Beschikbaarheid van medische data - tijdens de behandeling
- Gebrek aan interactie - Ik weet niet wanneer nieuwe gegevens binnen zijn
- Gebrek aan duidelijke informatie - over mijn rechten en plichten
- Gebrek aan duidelijke informatie - over wanneer zorgverleners aansprakelijk zijn van eventuele fouten in de gedeelde informatie
- Anders

**Hoe moeilijk is het op dit moment om relevante klinische informatie te verkrijgen van andere zorgverleners binnen uw regio?**

(kies een van de opties)

- Erg moeilijk
- Moeilijk
- Eenvoudig
- Zeer eenvoudig
- Geen idee

**In hoeveel procent van de gevallen probeert u klinische informatie van aanbieders buiten uw zorginstelling te verkrijgen?**

(kies schatting percentage)

- |                                    |                                  |
|------------------------------------|----------------------------------|
| <input type="checkbox"/> 0-10 %    | <input type="checkbox"/> 51-75%  |
| <input type="checkbox"/> 11-26%    | <input type="checkbox"/> 76-90%  |
| <input type="checkbox"/> 26-50%    | <input type="checkbox"/> 91-100% |
| <input type="checkbox"/> Geen idee |                                  |

**Welk percentage van uw pogingen om klinische informatie te verkrijgen van andere zorgverleners (buiten uw eigen zorginstellingen) waren succesvol?**

(kies schatting percentage)

- |                                    |                                  |
|------------------------------------|----------------------------------|
| <input type="checkbox"/> 0-10 %    | <input type="checkbox"/> 51-75%  |
| <input type="checkbox"/> 11-26%    | <input type="checkbox"/> 76-90%  |
| <input type="checkbox"/> 26-50%    | <input type="checkbox"/> 91-100% |
| <input type="checkbox"/> Geen idee |                                  |

**Wat is naar uw schatting het aantal minuten die momenteel nodig zijn om klinische informatie te verkrijgen van andere zorginstellingen?**

(kies gemiddelde aantal minuten)

- |  |  |
|--|--|
| <input type="checkbox"/> Minder dan 1 minuut | <input type="checkbox"/> 30 - 60 minuten |
| <input type="checkbox"/> 1 - 5 minuten       | <input type="checkbox"/> Enkele uren     |
| <input type="checkbox"/> 5 - 10 minuten      | <input type="checkbox"/> Enkele dagen    |
| <input type="checkbox"/> 10 - 20 minuten     | <input type="checkbox"/> Enkele maanden  |
| <input type="checkbox"/> 20 - 30 minuten     | <input type="checkbox"/> Langer          |

**Vermeld a.u.b. eventueel andere aanvullende opmerkingen, o.a. moeilijkheden die u hebt ervaren bij het verkrijgen van klinische informatie van andere zorgverleners (buiten uw eigen zorginstellingen).** (Optioneel)

## Deel 2: Voordelen / Nadelen

Dit deel van de enquête bevat vragen over de kosten en baten van snelle toegang tot klinische informatie van instellingen buiten uw ziekenhuis. U krijgt ook de mogelijkheid om aan te geven van welke soorten zorgaanbieders gegevens voor u het meest nuttig zijn.

**Stel voor dat het mogelijk is om de klinische informatie van andere ziekenhuizen snel en gemakkelijk beschikbaar te kunnen maken op het punt van zorg binnen uw afdeling, tot welke situaties kan dit volgens u leiden?**

(Geef aan in welke mate u het eens of oneens bent met de volgende stellingen, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	Helemaal mee eens	Mee eens	Neutraal	Oneens	Helemaal mee oneens
Het zal ten goede komen aan de manier waarop ik zorg verleen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Het zal ten goede komen van mijn afdeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Het zal ten goede komen van mijn zorginstelling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Het zal bijdragen aan de kwaliteit van het zorg in het algemeen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verhoogt de efficiëntie van het werkproces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Afname of sterk verminderen van het aantal dubbele onderzoeken (door bijvoorbeeld de resultaten van eerdere testen door andere zorginstellingen beschikbaar te maken)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Afname of sterk verminderen van het aantal medische fouten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Afname of sterk verminderen van de kosten voor gezondheidszorg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Het zal in het voordeel zijn van de patiënten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Het zal zorgen voor extra veiligheidsrisico's	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
De privacy van patiënten komt dan in gevaar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
De voordelen van uitwisseling van medische data wegen op tegen de risico's	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Gegevens van welke soorten aanbieders zijn het meest nuttig voor u?**

(Gelieve rangschikken met "1" voor minst nuttig en 5 voor meest nuttig, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	1	2	3	4	5
Verpleeghuizen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Klinieken Buiten uw ziekenhuizen netwerk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Andere regionale ziekenhuizen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiologie en Laboratorium Diensten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Huisartsen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Externe Apothekers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Andere	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Als u op de vorige vraag "Andere" hebt gekozen, gelieve aan te geven om welke soort aanbieder het gaat: (Optioneel, alleen als u bij vorige vraag andere hebt gekozen of een extra instelling wilt aangeven)

**Deel 3: Top Data – De voor regionale uitwisseling meest waardevolle gegevens**

In dit deel van de enquête krijgt u de mogelijkheid om aan te geven welke specifieke data-elementen van andere aanbieders u het meest bruikbaar vindt.

**Hoe waardevol zijn de volgende data-elementen voor uitwisseling van medische data op regionaal niveau?**

(Gelieve rangschikken met "1" voor minst waardevol en 5 voor meest waardevol, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	1	2	3	4	5
Medische hulpmiddelen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Afspraken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medicatie lijsten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Allergieën	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lab resultaten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiologie rapporten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Probleem lijsten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verwijsbrieven	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Demografische gegevens van patiënten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Contact personen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medische verslagen (anamneses, rapportages, behandel plannen)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diagnose behandel combinatie (DBC) en zorgactiviteiten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intoxicatie (alcoholvergiftiging, gebruik van drugs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Andere	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Noem a.u.b. andere types van klinische informatie die indien beschikbaar van andere ziekenhuizen, het nuttigst zouden zijn voor uw klinische praktijk.** (Voorbeelden zijn: pathologie rapporten, medische microbiologie, operatie verslagen, afspraken overzicht ...)

### **Slot - Algemene vragen**

U kunt ervoor kiezen om uw gegevens achter laten als u op de hoogte wil blijven van de resultaten van deze enquête en/of andere gerelateerde ontwikkelingen. Wij danken u voor uw bijdrage!

Naam zorginstelling :

Specialisme (Werkzaam bij) :

Functie:

Naam (Optioneel):

Tel-overdag (Optioneel):

Mobiel (Optioneel):

Email (Optioneel):

Hartelijke dank voor uw bijdrage!

# Regionale Uitwisseling van Medische Gegevens - Enquête Patiënten

Geachte heer/mevrouw,

Bij een samenwerking tussen verschillende regionale zorgaanbieders (bijvoorbeeld ziekenhuizen, poliklinieken, huisartsen) of tussen ondersteunende instellingen (zoals laboratoria, apothekers) is er vaak behoefte aan de uitwisseling van medische gegevens.

Om een beter beeld te krijgen van de bestaande complicaties en de standpunten van de patiënten, willen wij graag uw mening weten over de verschillende aspecten die komen kijken bij de uitwisseling van medische gegevens op regionaal niveau. Uw mening kan ons helpen bij het verbeteren van de huidige oplossingen en uiteindelijk zorgen voor een efficiënter en effectiever zorgproces.

Graag zouden wij uw aandacht willen vragen voor de volgende onderdelen:

Deel 1: Algemene vragen

Deel 2: Voordelen - Regionale uitwisseling van medische gegevens

Deel 3: Nadelen / gevaren - Regionale Uitwisseling van medische gegevens

Deel 4: Mate van invloed - Regionale Uitwisseling van medische gegevens

Het invullen van de enquête duurt circa 15 minuten. Alle informatie die u geeft zal vertrouwelijk worden behandeld. De resultaten van het onderzoek zullen zodanig worden gepresenteerd en gepubliceerd dat deze niet te herleiden zijn tot afzonderlijke personen of zorginstellingen.

Bij voorbaat dank voor uw bijdrage!

## Regionale Uitwisseling van Medische Gegevens - Enquête Patiënten

\* Required

### Algemene vragen

(1/4)

Leeftijd: \*

<18

Geslacht \*

Man

Wanneer heeft u voor het laatst een spoedeisende hulp bezocht? \*

Enkele dagen geleden

Hoe vaak bezoekt u een zorginstelling? \*

Dagelijks

Heeft u last van een chronische ziekte? \*

(Kies a.u.b. één van de twee mogelijke antwoorden)

- Ja  
 Nee

Heeft u al eerder iets gehoord over uitwisseling van de medische gegevens? \*

(Kies a.u.b. één van de twee mogelijke antwoorden)

- Ja  
 Nee

Wat is uw woonsituatie? \*

(Kies a.u.b. één van de twee mogelijke antwoorden)

- Alleenstaand  
 Samenwonend



**Wat is uw woonsituatie? \***

(Kies a.u.b. één van de twee mogelijke antwoorden)


- Alleenstaand
- Samenwonend

**Heeft u 1 of meerdere kinderen? \***

(Kies a.u.b. één van de twee mogelijke antwoorden)

- Ja
- Nee

**Educatie: \***

Middelbare school of minder 

## Regionale Uitwisseling van Medische Gegevens - Enquête Patiënten

\* Required

### Voordelen - Regionale uitwisseling van medische gegevens (2/4)

**Stel voor dat het mogelijk is om de elektronische medische informatie te kunnen delen tussen zorginstellingen binnen uw regio (bijvoorbeeld tussen uw huisarts en uw ziekenhuis). Tot welke situaties kan dit volgens u leiden? \***

(Geef aan in welke mate u het eens of oneens bent met de volgende stellingen, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	Helemaal mee eens	Mee eens	Neutraal	Oneens	Helemaal mee oneens
Het zal zorgen voor een betere communicatie tussen de verschillende zorgverleners.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Registratie bij een nieuwe zorginstelling zal een stuk eenvoudiger worden.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Het aanvragen van herhaalrecepten voor de medicatie zal een stuk eenvoudiger worden.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Het zal er voor zorgen dat de medische documenten (bijv. lab resultaten of medische resultaten van andere zorgverlener) beschikbaar zijn op het punt van zorg.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Het zal helpen voorkomen dat het medische dossier van patiënten zoek raakt.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Verhoogt de efficiëntie van het werkproces in de zorg.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Afname of sterk verminderen van het aantal dubbele onderzoeken (door bijvoorbeeld de resultaten van eerdere testen door andere zorginstellingen beschikbaar te maken)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Afname of sterk  
verminderen van het  
aantal medische  
fouten.

Afname of sterk  
verminderen van de  
kosten voor de  
gezondheidszorg.

Het zal bijdragen aan  
de kwaliteit van het  
zorg in het algemeen.

Als patiënt zie ik  
voordelen in  
uitwisselen van  
medische gegevens  
op regionaal niveau.

**In welke mate bent u er mee eens dat de volgende data uitgewisseld mag worden tussen de verschillende zorginstellingen op regionaal niveau? \***

(Gelieve kiezen, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	Helemaal mee eens	Mee eens	Neutraal	Oneens	Helemaal mee oneens
Medische hulpmiddelen (medisch hulpmiddel is een instrument, toestel of apparaat voor onder andere diagnose, preventie, bewaking, behandeling of verlichting van ziekten)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Afspraken	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medicatie lijsten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Allergieën	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lab resultaten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Radiologie rapporten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Probleem lijsten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Verwijsbrieven	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demografische gegevens van patiënten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contact personen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medische verslagen (anamneses, rapportages, behandel plannen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diagnose behandel combinatie (DBC) en zorgactiviteiten	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intoxicatie (alcoholvergiftiging, gebruik van drugs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Andere	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Noem a.u.b. andere types van klinische informatie die u het nuttigst vindt.**

(Voorbeelden zijn: pathologie rapporten, medische microbiologie, operatie verslagen ...)

**Nadelen / Gevaren - Regionale Uitwisseling van medische gegevens**  
(3/4)

**Wat zijn volgens u de gevaren van uitwisselen van medische gegevens op regionaal niveau? \***

(Geef aan in welke mate u het eens of oneens bent met de volgende stellingen, dit doet u door een kruisje in het desbetreffende hokje te zetten)

	Helemaal mee eens	Mee eens	Neutraal	Oneens	Helemaal mee oneens
Het zal zorgen voor extra veiligheidsrisico's voor mijn medische gegevens.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ik maak me zorgen dat mijn privé gegevens door lage beveiliging van de systemen in de zorg openbaar worden gemaakt	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mijn privacy als patiënt komt dan in gevaar.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ik maak me zorgen dat mijn privé gegevens in de handen komen van "derde partijen" (ongeautoriseerde hulpverleners, zorgverzekering en andere geïnteresseerden).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ik ben ook bezorgd over de beveiliging van "papieren" medische dossier (bijv. dat de receptionisten of ongeautoriseerde zorgverleners mijn privé gegevens kunnen inzien).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Te veel beveiliging zou er voor kunnen zorgen dat het onnodig moeilijk wordt voor de zorgverleners om toegang te kunnen hebben tot de juiste medische gegevens.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
De voordelen van uitwisseling van medische data wegen op tegen de risico's.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Mate van invloed - Regionale Uitwisseling van medische gegevens

(4/4)

Deze vraag gaat over de mate waarin patiënten kunnen bepalen of medische gegevens met verschillende zorgverleners en andere relevante partijen gedeeld mogen worden. \*

	Helemaal mee eens	Mee eens	Neutraal	Oneens	Helemaal mee oneens
Patiënt moet in staat zijn te kunnen beslissen of de medische gegevens wel of niet gedeeld mogen worden met andere zorgverleners binnen de regio.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patiënt moet in staat zijn per onderdeel (of medische data/type) te kunnen beslissen of de medische gegevens wel of niet gedeeld mogen worden (bijv. verwijsbrieven wel, maar medicatielijst niet).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patiënt moet in staat zijn te kunnen beslissen of de medische gegevens via een elektronisch system of dan wel een geprinte versie opgestuurd worden.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patiënt moet in staat zijn te kunnen beslissen of de medische gegevens naar een specifieke instelling gestuurd mogen worden (bijv. van eigen ziekenhuis naar een externe laboratorium of andersom, andere combinaties zijn ook mogelijk).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>Patiënt moet in staat zijn te kunnen beslissen of de medische gegevens naar een specifieke zorgverlener gestuurd mogen worden (bijvoorbeeld van eigen huisarts naar een specialist, andere combinaties zijn ook mogelijk).</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Patiënt moet in staat zijn te kunnen beslissen of de medische gegevens gedeeld kunnen worden met andere partijen (bijv. familie, vrienden, werkgever, zorgverzekeraars, wetenschappelijke onderzoek, ...)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Ik vind het belangrijk om duidelijk te worden geïnformeerd over alle manieren waarop mijn gezondheid gegevens kunnen worden gebruikt of gedeeld.</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Patiënten moeten terug kunnen kijken welke entiteiten toegang hadden tot hun persoonlijke gezondheidsgegevens.</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Table J.1: Variables related to frequency of the exchange of medical data

Variable	Scale
Frequency exchange within the same organization	numeric value: 1-3
Frequency exchange within own profession	numeric value: 1-3
Frequency exchange outside own profession	numeric value: 1-3
Frequency exchange within same region	numeric value: 1-3
Frequency exchange outside region	numeric value: 1-3

Table J.2: Variables related to difficulty and success of data exchange

Variable	Scale
Difficulty exchange different organizations same region	numeric value: 1-5
Percentage cases exchange different organization	numeric value: 1-5
Percentage successful exchange	numeric value: 1-5
Estimation time exchange different organizations	numeric value: 1-5

Table J.3: Variables related to importance of data sources

Variable	Scale
Importance data from nursing houses	numeric value: 1-5
Importance data from clinics outside own organizations	numeric value: 1-5
Importance data from other regional hospitals	numeric value: 1-5
Importance data from Radiology and Laboratory	numeric value: 1-5
Importance data from GPs	numeric value: 1-5
Importance data from external pharmacy	numeric value: 1-5
Importance data from other organizations	numeric value: 1-5



Table J.4: Variables related to advantages & disadvantages

Variable	Scale
Exchange will improve the way I provide care	numeric value: 1-5
My department will benefit from exchange	numeric value: 1-5
My organization will benefit from exchange	numeric value: 1-5
The quality of care in general will be improved from exchange	numeric value: 1-5
The efficiency of work process will benefit from exchange	numeric value: 1-5
Reduce of double medical effort	numeric value: 1-5
Reduce of medical errors	numeric value: 1-5
Reduce costs of health My patients will benefit	numeric value: 1-5
It will create extra security risks	numeric value: 1-5
It will create privacy risks for the patients	numeric value: 1-5
The benefits of sharing medical data outweigh the risks	numeric value: 1-5

Table J.5: Variables related to usefulness data

Variable	Scale
Medical devices	numeric value: 1-5
Appointments	numeric value: 1-5
Medication list	numeric value: 1-5
Allergies	numeric value: 1-5
Lab results	numeric value: 1-5
Radiology reports	numeric value: 1-5
Problem list	numeric value: 1-5
Transfer letters	numeric value: 1-5
Demographic data patients	numeric value: 1-5
Contact persons Medical reports DBCs	numeric value: 1-5
Intoxication	numeric value: 1-5
Other data	numeric value: 1-5

Table J.6: Variables related to usefulness exchange data

Variable	Scale
Importance exchange within the organization	numeric value: 1-5
Importance exchange within own care group	numeric value: 1-5
Importance exchange outside own care group	numeric value: 1-5
Importance exchange within the same region	numeric value: 1-5
Importance exchange outside own region	numeric value: 1-5

Table J.7: Variables related to types of tools of exchange

Variable	Scale
Push-Phone	binary: 1/0
Push-Fax	binary: 1/0
Push-Email	binary: 1/0
Push-Printed	binary: 1/0
Push-Same EPD	binary: 1/0
Push-Portal	binary: 1/0
Push-Other	binary: 1/0
Electronic system	binary: 1/0
Push-Other	binary: 1/0
Pull-Phone	binary: 1/0
Pull-Fax	binary: 1/0
Pull-Email	binary: 1/0
Pull-Printed	binary: 1/0
Pull-Same EPD	binary: 1/0
Pull-Portal	binary: 1/0
Pull-Other electronic system	binary: 1/0
Pull-Other	binary: 1/0

Table J.8: Variables related to barriers

Variable	Scale
Barrier-Security	binary: 1/0
Barrier-Privacy	binary: 1/0
Barrier-Info Overload	binary: 1/0
Barrier-Diff standards	binary: 1/0
Barrier-Software	binary: 1/0
Barrier-Duration	binary: 1/0
Barrier-availability data	binary: 1/0
Barrier-Lack Interaction	binary: 1/0
Barrier-Lack info rights & obligations	binary: 1/0
Barrier-Lack info responsibility	binary: 1/0
Barriers-Other	binary: 1/0

Table J.9: Variables related to background specialities and organization

Variable	Scale
Health organization	string
Specialism	string
Position	string

Table J.10: Demographic information

Variable	Scale
Age	string
Gender	string
Education	string
Have children	string
Living situation	string

Table J.11: Health state and frequency of visit health providers

Variable	Scale
Frequency visit health organizations	numeric value: 1-5
Recent visit emergency	numeric value: 1-5
Chronic disease	numeric value: 1-5
Heard about exchange of medical data	numeric value: 1-5

Table J.12: Variables related to advantages &amp; disadvantages:

Variable	Scale
Advantage better communication between different health provider	numeric value: 1-5
Advantage easier first registration	numeric value: 1-5
Advantage easier repeated prescriptions	numeric value: 1-5
Advantage availability medical data during health-care	numeric value: 1-5
Advantage prevent losing medical records	numeric value: 1-5
Advantage efficiency work process	numeric value: 1-5
Advantage reduce double efforts	numeric value: 1-5
Advantage reduce medical errors	numeric value: 1-5
Advantage reduce costs	numeric value: 1-5
Advantage improve quality care	numeric value: 1-5
See benefits regional exchange	numeric value: 1-5

Table J.13: Variables related to usefulness data

Variable	Scale
Data medical devices	numeric value: 1-5
Data appointments	numeric value: 1-5
Data medication lists	numeric value: 1-5
Data allergies	numeric value: 1-5
Data lab results	numeric value: 1-5
Data Radiology reports	numeric value: 1-5
Data problem lists	numeric value: 1-5
Data transfer letters	numeric value: 1-5
Data demographic data patients	numeric value: 1-5
Data contact persons	numeric value: 1-5
Data medical reports	numeric value: 1-5
Data DBC	numeric value: 1-5
Data intoxication	numeric value: 1-5
Data other	numeric value: 1-5

Table J.14: Variables related to barriers &amp; risks

Variable	Scale
Risks security	numeric value: 1-5
Risk spreading private data public	numeric value: 1-5
Risks privacy	numeric value: 1-5
Risk private data third parties	numeric value: 1-5
Risks paper version	numeric value: 1-5
Contra effect too much security	numeric value: 1-5
The benefits of sharing medical data outweigh the risks	numeric value: 1-5

Table J.15: Variables related to level of influence &amp; control of patients

Variable	Scale
Control decide sharing data between health providers	numeric value: 1-5
Control decide which part shared	numeric value: 1-5
Control decide digital or printed	numeric value: 1-5
Control decide sharing which organizations	numeric value: 1-5
Control decide sharing which specialist	numeric value: 1-5
Control access to others	numeric value: 1-5
Information how medical data used	numeric value: 1-5
Information who has access	numeric value: 1-5

## **Appendix K**

---

### **Descriptives**

This appendix contains several descriptive data that are used to support claims indicated in the chapter 5 (elicitation results). These data mainly include diagrams, charts and tables created by SPSS during the analysis of the gathered data.

### K.0.3 Tables

Table K.1: The numbers and percentages of the respondents from health organizations grouped by their specialism.

<b>Specialism</b>	<b>Frequency</b>	<b>Percent</b>
Anesthesiology	1	1.6
Cardiology	2	3.2
Dentistry	10	15.9
Family medicine	3	4.8
ICT	2	3.2
KNO	2	3.2
Lung Medicine	1	1.6
MKA	1	1.6
Neurology	2	3.2
Nursing	5	7.9
Ophthalmology	3	4.8
Oral Surgery	2	3.2
Other	13	20.6
Pediatrics	4	6.3
Pharmacy	1	1.6
Plastic Surgery	3	4.8
Psychiatry	1	1.6
Radiology	1	1.6
Special Dentistry	1	1.6
Surgery	3	4.8
Urology	2	3.2
Total	63	100

Table K.2: Categorization of the specialisms

<b>Category</b>	<b>Frequency</b>	<b>Percent</b>	<b>Valid Percent</b>	<b>Cumulative Percent</b>
Surgical	8	12.7	12.7	12.7
Non-Surgical	33	52.4	52.4	65.1
Supplementary	22	34.9	34.9	100
Total	63	100	100	100

Table K.3: Frequencies & percentages push medical data

<b>Push-Strategy</b>	<b>Numbers</b>	<b>Percentage</b>
<b>Phone</b>	32	51%
<b>Fax</b>	34	54%
<b>Email</b>	34	54%
<b>Printed or Written letter</b>	54	86%
<b>Using the same EHR</b>	11	17%
<b>Portal</b>	9	14%
<b>Using other electronic system</b>	9	14%
<b>Other</b>	4	6%
<b>I don't know</b>	1	2%

Table K.4: Frequencies & percentages pull medical data

<b>Pull-Strategy</b>	<b>Numbers</b>	<b>Percentage</b>
<b>Phone</b>	43	68%
<b>Fax</b>	33	52%
<b>Email</b>	39	62%
<b>Printed / Written letter</b>	41	65%
<b>Using the same EHR</b>	9	14%
<b>Portal</b>	9	14%
<b>Using other electronic system</b>	7	11%
<b>Other</b>	5	8%
<b>I don't know</b>	1	2%

#### **K.0.4 Figures**

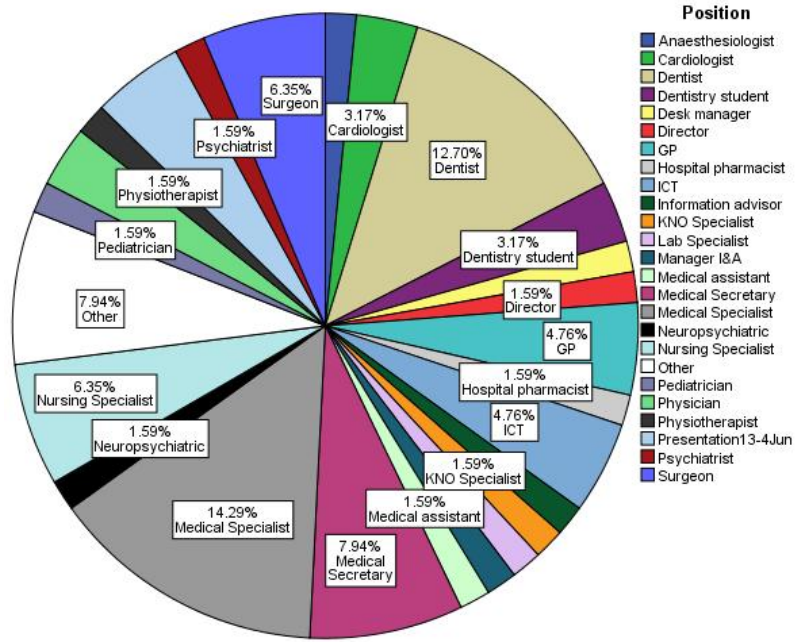


Figure K.1: Pie diagram, position

Report  
 Statistics: Mean  
 Frequency exchange within same region (current)

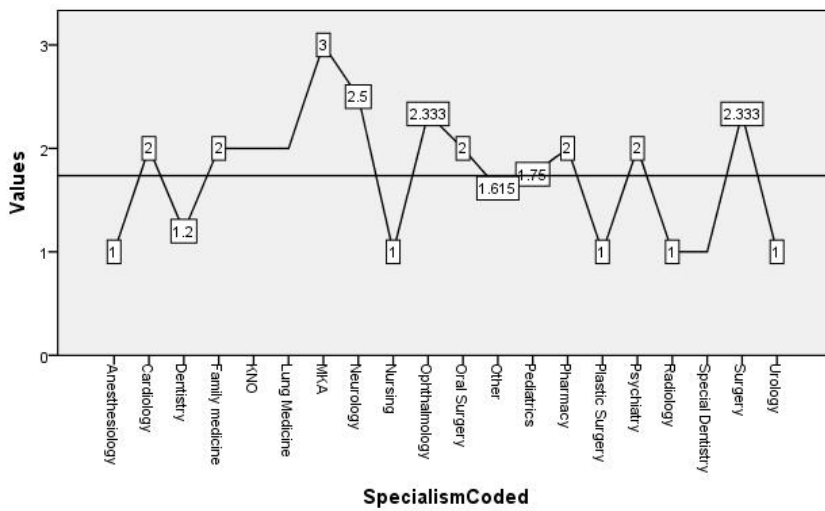


Figure K.2: Mean, frequency exchange medical data within the same region for different medical specialities.



Report  
 Statistics: Mean  
 Difficulty exchange different organizations same region (current)

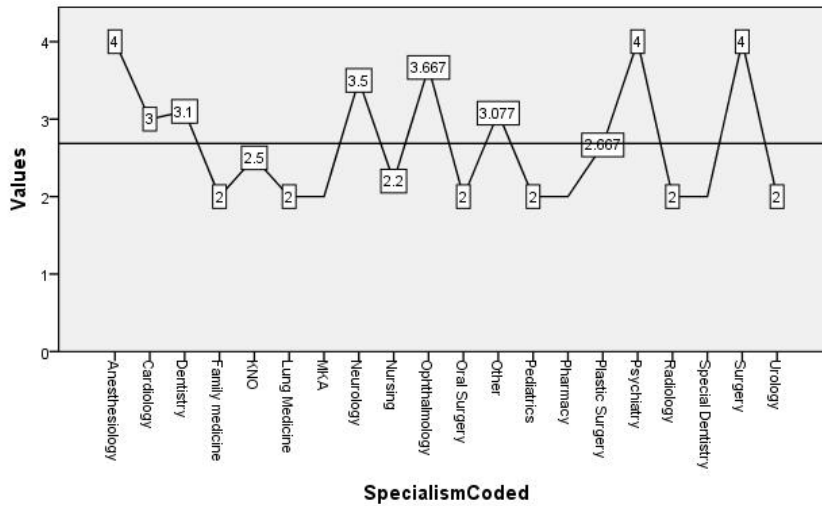


Figure K.3: Mean of difficulty exchange different organizations within the same region

Report  
 Statistics: Mean  
 Percentage successful exchange (current)

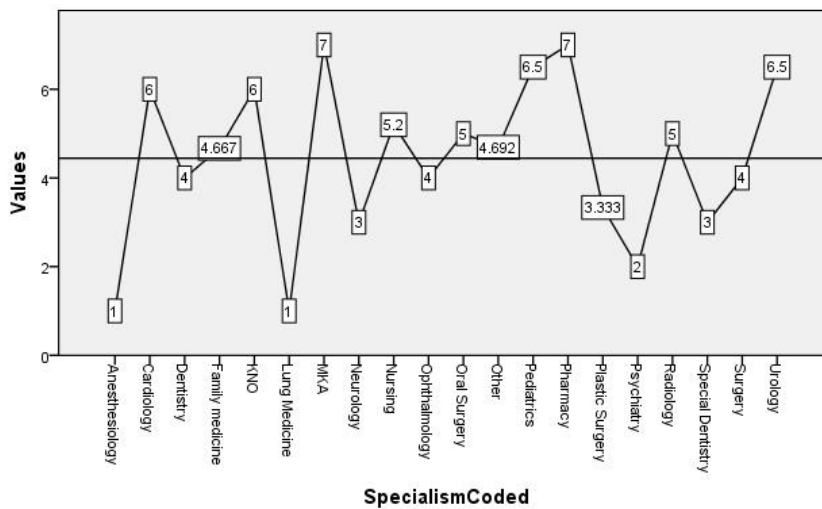


Figure K.4: Mean numbers, successful attempts for the exchange between different organization within the same region

Report  
 Statistics: Mean  
 Estimation time exchange different organizations (current)

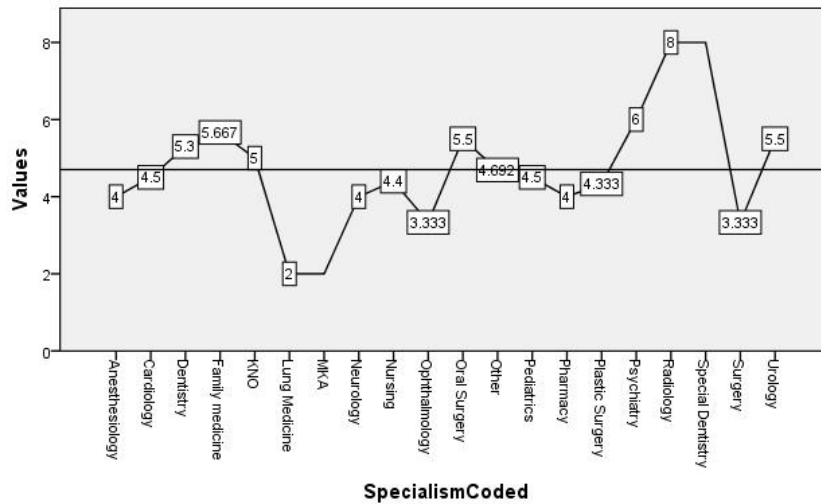


Figure K.5: Mean numbers, the time for the exchange of medical data between different organizations within the same region

Report  
 Statistics: Mean  
 Exchange will improve the way I provide care

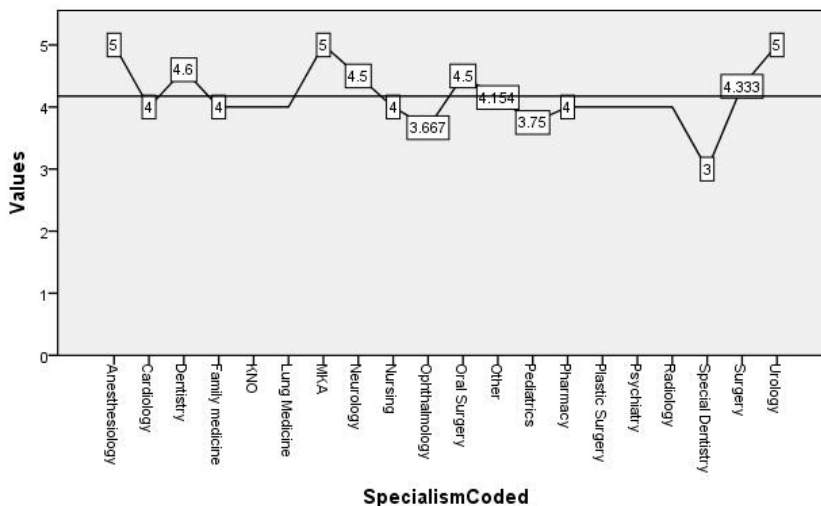


Figure K.6: Mean numbers for exchange, RHIE will improve providing care

Report  
 Statistics: Mean  
 Reduce of double medical effort

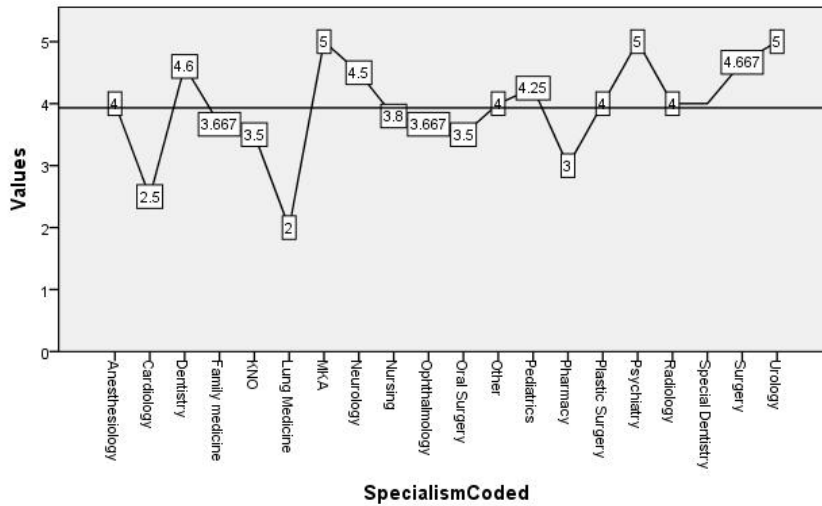


Figure K.7: Mean of exchange, RHIE will improve providing care

Report  
 Statistics: Mean  
 The benefits of sharing medical data outweigh the risks

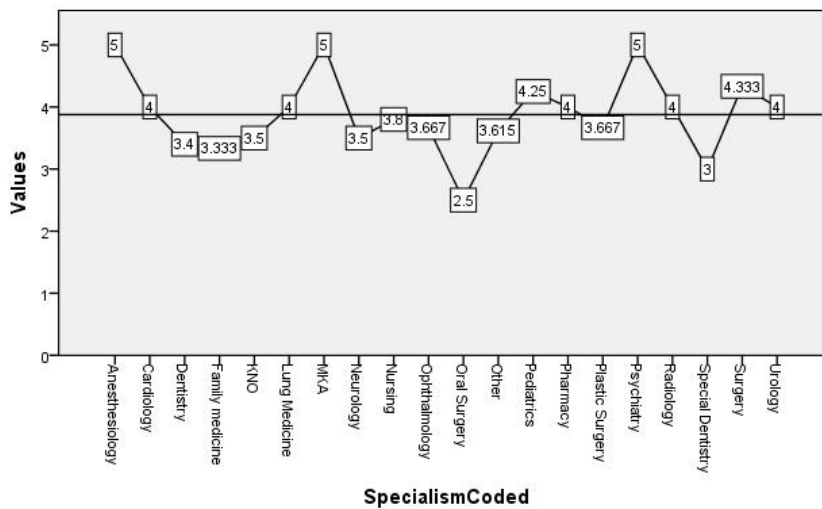


Figure K.8: Mean plot, benefits sharing medical data vs risks

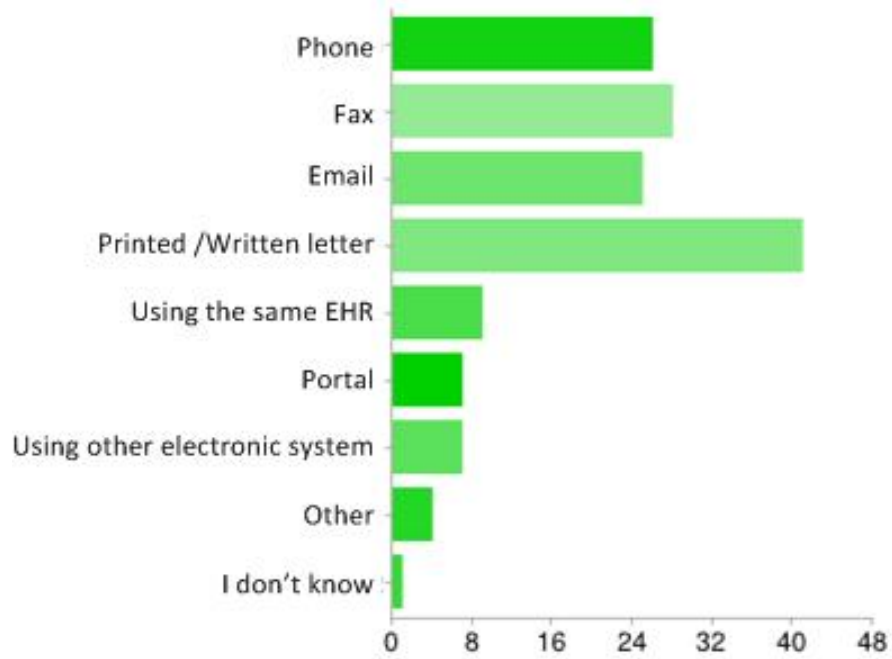


Figure K.9: Push medical data, tools (current situation)

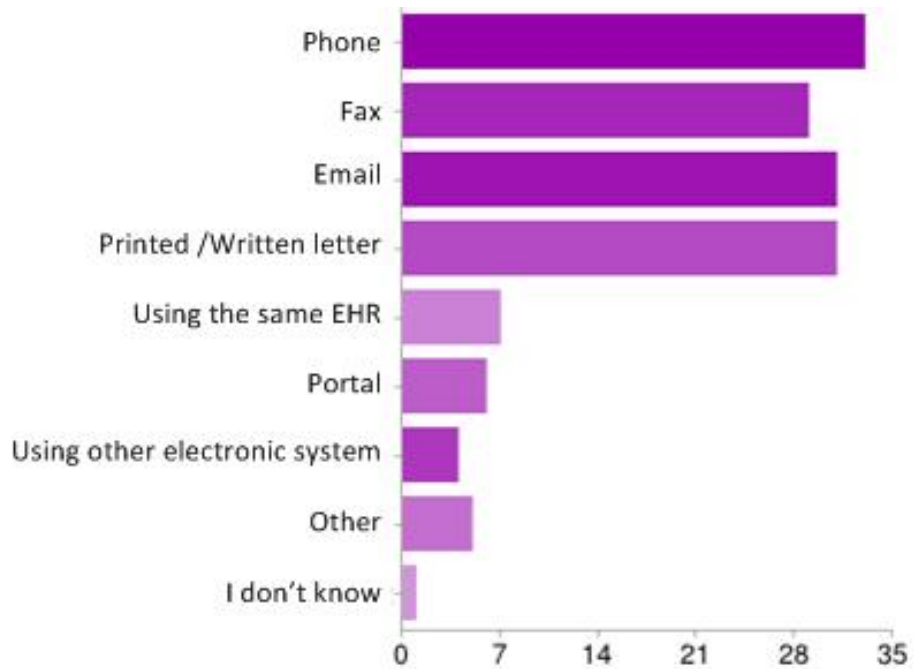


Figure K.10: Pull medical data, tools (current situation)

Report  
 Statistics: Mean  
 Importance exchange within the same region

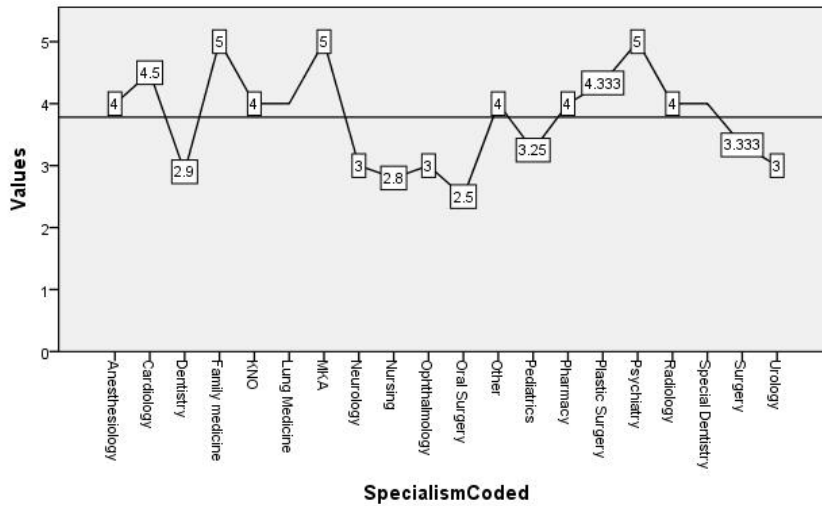


Figure K.11: Means plot, importance exchange of medical data within the same region

Report  
 Statistics: Mean  
 Importance data from GPs

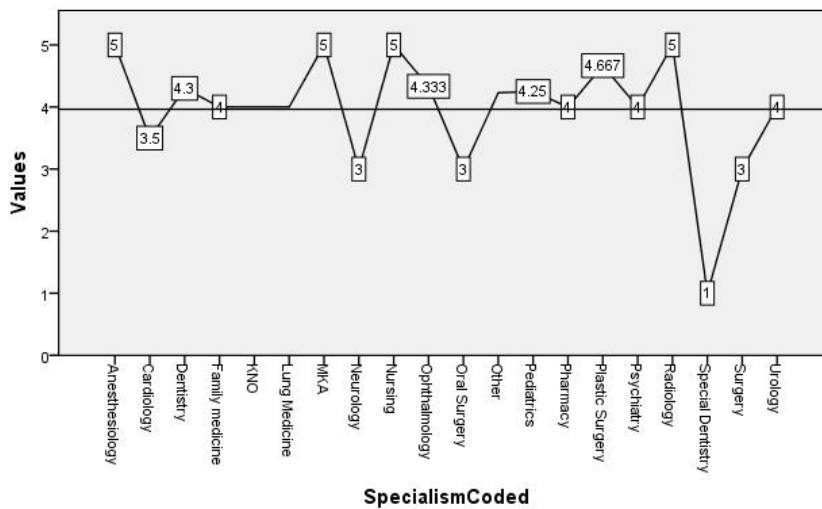


Figure K.12: Means plot importance data from gps

Report Statistics: Mean

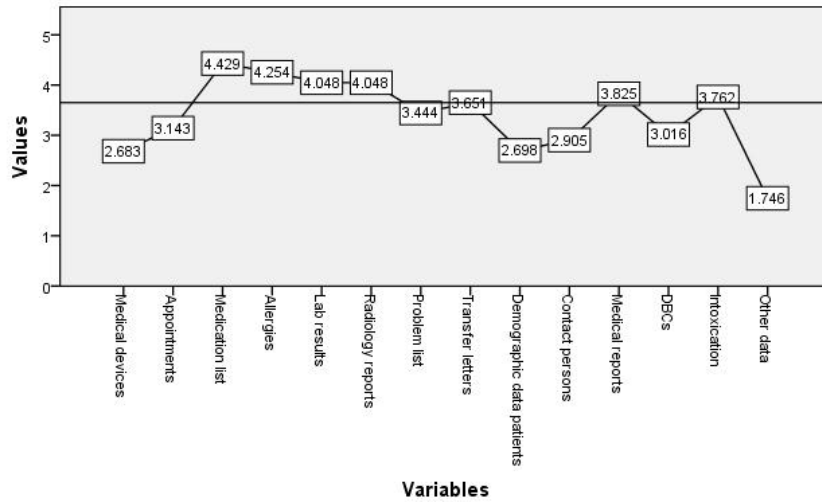


Figure K.13: Mean numbers important data for exchange

Report Statistics: Mean

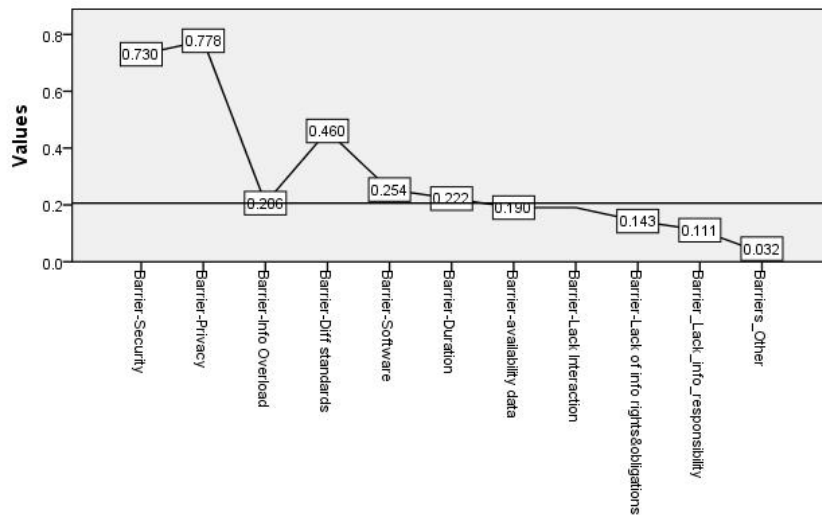


Figure K.14: Mean numbers barriers RHIS

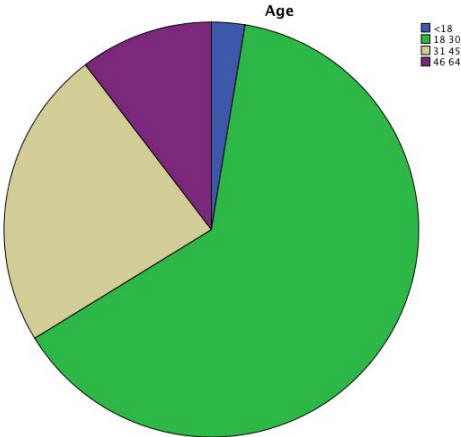


Figure K.15: Pie diagram, age

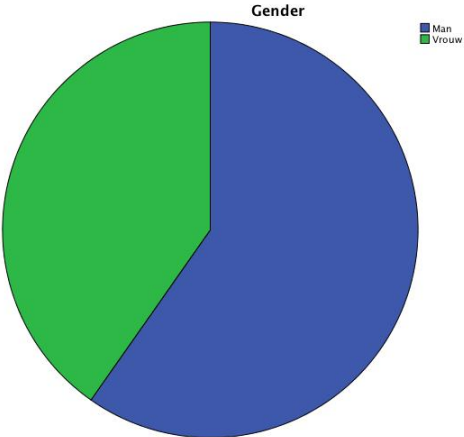


Figure K.16: Pie diagram, gender

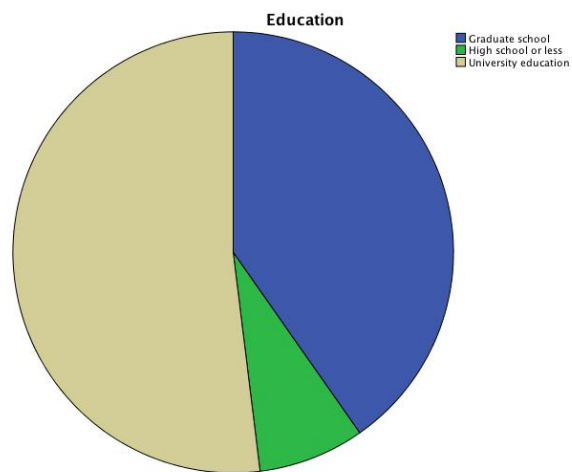


Figure K.17: Pie diagram, education

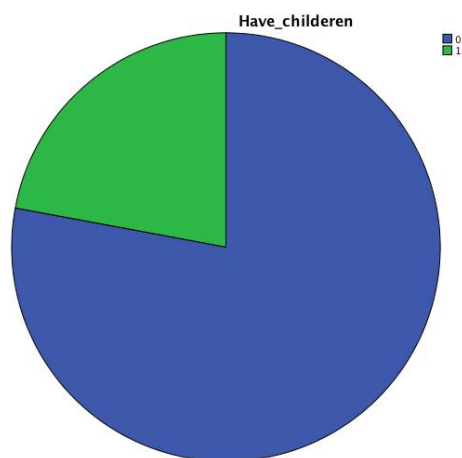


Figure K.18: Pie diagram, number of children



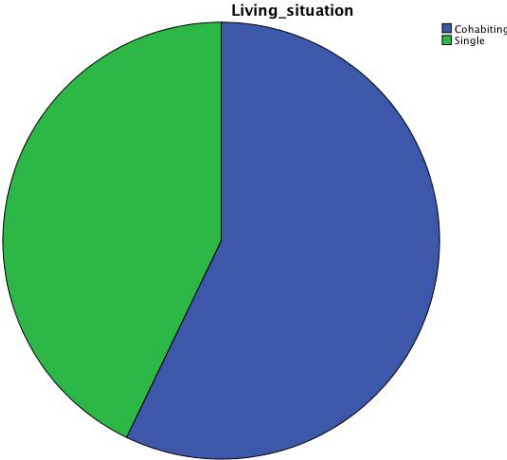


Figure K.19: Pie diagram, living situation

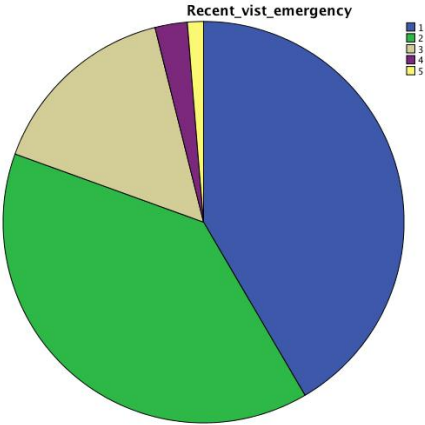


Figure K.20: Pie diagram, latest visit emergency

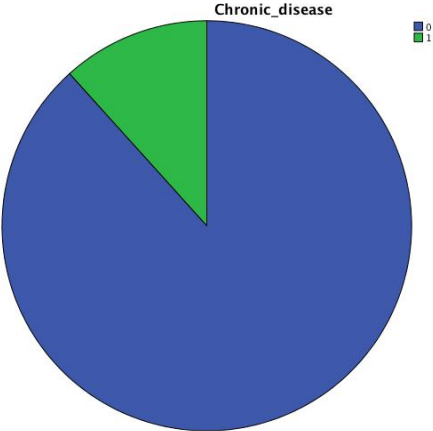


Figure K.21: Pie diagram, chronic diseases

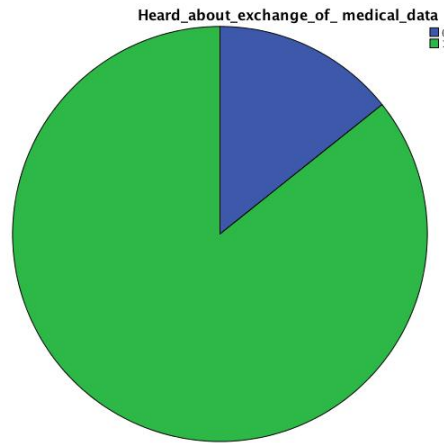


Figure K.22: Pie diagram, heard about medical data exchange

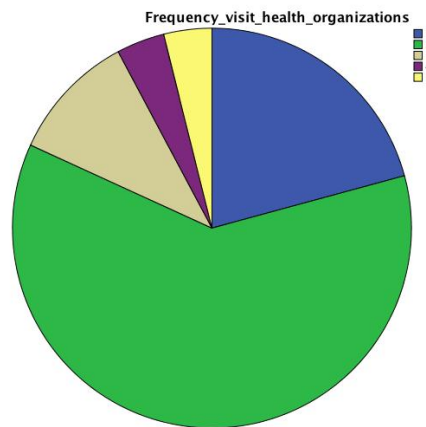


Figure K.23: Pie diagram, frequency visit health organizations

Report  
Statistics: Mean

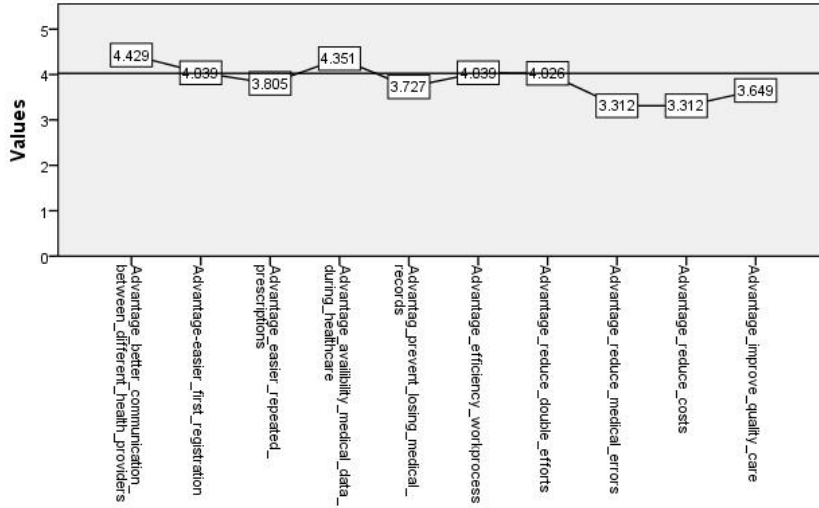


Figure K.24: Mean numbers, several advantages rhie

Report  
Statistics: Mean

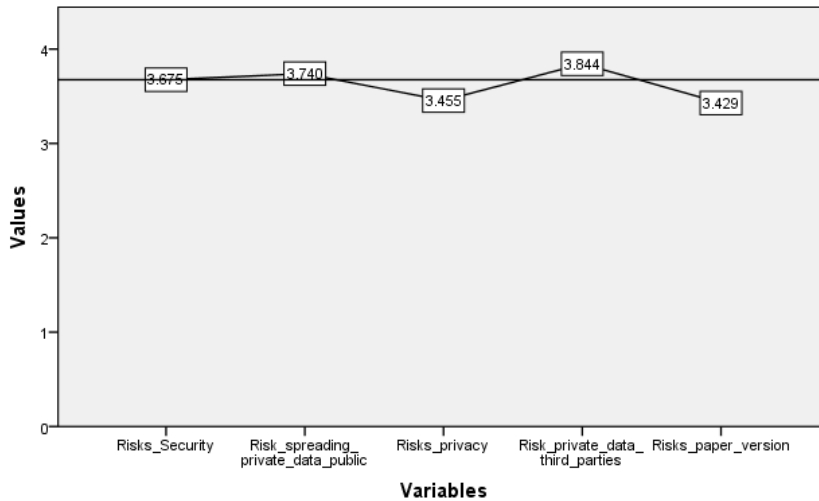


Figure K.25: Mean numbers risks RHIE, according to the patients

**Risks\_paper\_version**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	3	3,9	3,9	3,9
	2	12	15,6	15,6	19,5
	3	24	31,2	31,2	50,6
	4	25	32,5	32,5	83,1
	5	13	16,9	16,9	100,0
	Total	77	100,0	100,0	

Figure K.26: Frequencies risks paper based exchange of medical data

**The\_benefits\_of\_sharing\_medical\_data\_outweigh\_the\_risks**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	1	1,3	1,3	1,3
	2	9	11,7	11,7	13,0
	3	23	29,9	29,9	42,9
	4	30	39,0	39,0	81,8
	5	14	18,2	18,2	100,0
	Total	77	100,0	100,0	

Figure K.27: Frequencies benefits rnie outweighs the risks, patients survey

**Correlations**

		See_benefits_regional_exchange	Risk_private_data_third_parties	Contra_effect_too_much_security	The_benefits_of_sharing_medical_data_outweigh_the_risks
See_benefits_regional_exchange	Pearson Correlation	1	-.196	.096	.262*
	Sig. (2-tailed)		.088	.406	.022
	N	77	77	77	77
Risk_private_data_third_parties	Pearson Correlation	-.196	1	-.095	-.423**
	Sig. (2-tailed)	.088		.413	.000
	N	77	77	77	77
Contra_effect_too_much_security	Pearson Correlation	.096	-.095	1	.271*
	Sig. (2-tailed)	.406	.413		.017
	N	77	77	77	77
The_benefits_of_sharing_medical_data_outweigh_the_risks	Pearson Correlation	.262*	-.423**	.271*	1
	Sig. (2-tailed)	.022	.000	.017	
	N	77	77	77	77

\*. Correlation is significant at the 0.05 level (2-tailed).  
 \*\*. Correlation is significant at the 0.01 level (2-tailed).

Figure K.28: Inter-correlations effects, risks and benefits

**Report Statistics: Mean**

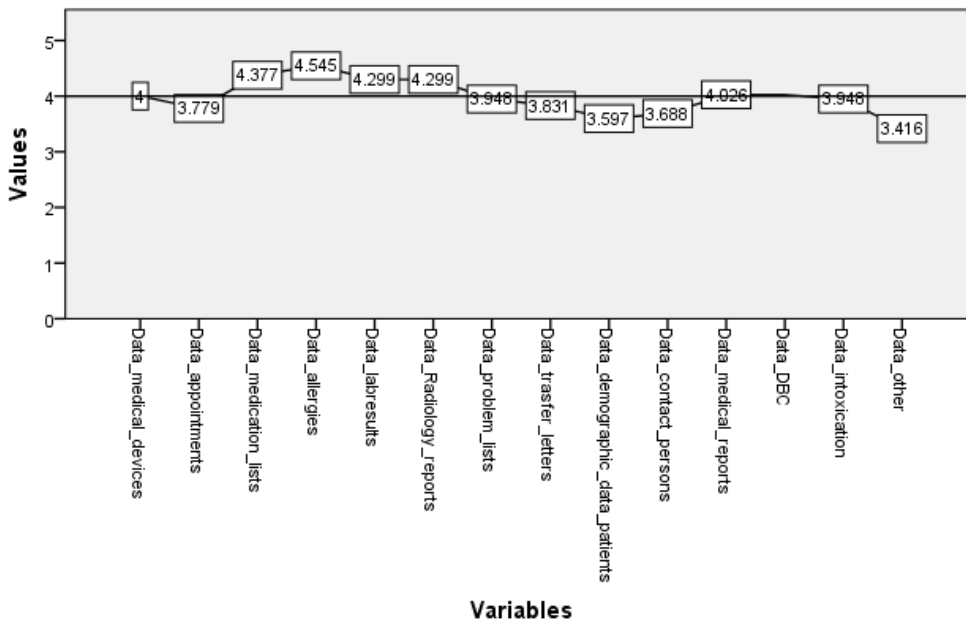


Figure K.29: Mean numbers important data rhiie, according to the patients



## Appendix L

---

# Analysis statistical data

This appendix contains several analytical data that are used to support claims indicated in the chapter 5 (elicitation results). These data mainly include the results of the statistical tests during the analysis of the gathered data.

### L.0.5 Tables

Table L.1: Test of Homogeneity of variances for variables Barrier-Security and Barrier-Privacy

Variable	Levene Statistic	df1	df2	Sig.
Barrier-Security	3.368	2	60	0.041
Barrier-Privacy	1.285	2	60	0.284

L.0.6 Figures

**Correlations**

		Importance data from nursing houses	Importance data from clinics outside own organizations	Importance data from other regional hospitals	Importance data from Radiology and Laboratory	Importance data from GPs	Importance data from external pharmacy	Importance data from other organizations
Importance data from nursing houses	Pearson Correlation	1	,507**	,319*	,075	,230	,226	-,191
	Sig. (2-tailed)		,000	,011	,558	,070	,075	,134
	N	63	63	63	63	63	63	63
Importance data from clinics outside own organizations	Pearson Correlation	,507**	1	,647**	,338**	,369**	,410**	-,205
	Sig. (2-tailed)	,000		,000	,007	,003	,001	,107
	N	63	63	63	63	63	63	63
Importance data from other regional hospitals	Pearson Correlation	,319*	,647**	1	,581**	,517**	,671**	-,007
	Sig. (2-tailed)	,011	,000		,000	,000	,000	,955
	N	63	63	63	63	63	63	63
Importance data from Radiology and Laboratory	Pearson Correlation	,075	,338**	,581**	1	,468**	,575**	-,024
	Sig. (2-tailed)	,558	,007	,000		,000	,000	,850
	N	63	63	63	63	63	63	63
Importance data from GPs	Pearson Correlation	,230	,369**	,517**	,468**	1	,502**	-,032
	Sig. (2-tailed)	,070	,003	,000	,000		,000	,802
	N	63	63	63	63	63	63	63
Importance data from external pharmacy	Pearson Correlation	,226	,410**	,671**	,575**	,502**	1	-,072
	Sig. (2-tailed)	,075	,001	,000	,000	,000		,576
	N	63	63	63	63	63	63	63
Importance data from other organizations	Pearson Correlation	-,191	-,205	-,007	-,024	-,032	-,072	1
	Sig. (2-tailed)	,134	,107	,955	,850	,802	,576	
	N	63	63	63	63	63	63	63

\*\* Correlation is significant at the 0.01 level (2-tailed).  
\* Correlation is significant at the 0.05 level (2-tailed).

Figure L.1: Overview correlations between different data sources



**Descriptive Statistics**

	N	Mean	Std. Deviation	Minimum	Maximum
See_benefits_regional_exchange	77	4,18	,756	1	5
Frequency_visit_health_organizations	77	2,09	,906	1	5

**Kruskal-Wallis Test**

**Ranks**

	Frequency_visit_healt...	N	Mean Rank
See_benefits_regional_exchange	1	16	33,22
	2	47	39,06
	3	8	60,25
	4	3	30,50
	5	3	20,67
Total		77	

**Test Statistics<sup>a,b</sup>**

	See_benefits_regional_exchange
Chi-Square	13,442
df	4
Asymp. Sig.	,009
Exact Sig.	,000
Point Probability	,000

a. Kruskal Wallis Test  
 b. Grouping Variable:  
 Frequency\_visit\_health\_organizations

Figure L.2: Kruskal-Wallis test, benefits RHIE and the frequency of visiting health organizations

### Mann-Whitney Test

Ranks

	Chronic_disease	N	Mean Rank	Sum of Ranks
Risk_spreading_private_data_public	0	68	40,89	2780,50
	1	9	24,72	222,50
	Total	77		

Test Statistics<sup>a</sup>

	Risk_spreading_private_data_public
Mann-Whitney U	177,500
Wilcoxon W	222,500
Z	-2,116
Asymp. Sig. (2-tailed)	,034
Exact Sig. (2-tailed)	,034
Exact Sig. (1-tailed)	,017
Point Probability	,000

a. Grouping Variable:  
Chronic\_disease

Figure L.3: MANN-WHTNEY test, risk of spreading private data in public

### **L.0.7 General requirements document analysis**

The next pages contain some of the general requirements related to the RHIS found during the document analysis:

- Application should work from all different location (s).
- The supplier who develops this system need to be reliable.
- The system should also be able to connect to all different existing systems (Operation room software OK, Polis).
- It should make use of the open source standards like (HL7, XML or DICOM)
- For each subsystem or modality we should be able to determine what the possibilities are.
- The system should be accessible to common standard Microsoft products.
- It should be possible to connect with the existing hospital EHR systems. (hospital information system coupling)
- Compatibility with the existing network infrastructure.
- Changes in the package should be easily realizable, maintenance friendly.
- Changes instructions and authorization should be available.
- Integration with the current database should be realized.
- The possibility to support HL7, multiple protocols for communication with other systems. For instance HL7, XML or DICOM.
- The system should be stable.
- The system should be dynamic and innovative.
- User-friendly and easy user interface.
- Easy coding infrastructure.
- Must comply with the Dutch law and regulations.
- Transparent initiation and maintenance costs.
- Long term contracts.
- 24 hour support from the supplier.
- Training of the employees should be included.
- Back-up possibility.
- Users platform.
- Remote access to the system possibilities.

**Other specific requirements regarding the coupling with existing hospital systems were:**

- Patient Data
- Waiting lists
- Transactions (CTG codes)
- Link with recording and billing
- Output for personnel planning
- Link to a calendar
- Link to instruments module
- Link to operation room planning
- Link to disinfection, sterilization, weighing machines, laser engraver
- Links with washers, autoclaves, metering, scales

**Coupling OZIS medication data:**

- Link to public pharmacies in accordance with the Health / NICTIZ guidelines achieved with some medication links.
- For the creation of exchange medication records, links are required with an external medication gateway (e.g. OZIS or Microbais).
- HL7 MPI query link for verification of the patient gateway to the medication
- HL7 VWI coupling for receiving the home medication system in the EHR medication module.
- HL7 PORX clinical message delivery
- HL7 PORX REC message to send the prescribed medication to the medication gateway
- Use a valid Unique Healthcare Identification card (UZI card) by the caregiver on a condition, for the exchange of medication information and electronically sign of recipes.

**Coupling for UZI card and Citizen Service Number (BSN)**

- Links are also needed to use the UZI card and verification of the Citizen Service Number (BSN).

**Coupling in order to exchange medical images:**

- Regional image exchange between different organizations should be possible.

- The possibility to exchange medical images between the health providers and the patient. The patient is also able to attach a file to add his or her records, which is automatically part of the patient PHR.

#### **Coupling to image storage systems:**

- It should be possible to link with image storage systems like Sioux medical systems.
- Standard HL7 ADT query link serving the exchange of patient information.
- Standard HL7 SIU appointments link serving the transfer of the appointment information from the CS-ECIS Sioux. The data is shown on the work list of Sioux.
- Custom coupling ORU for exchange reporting data to Sioux. Apart from any free text messages, within this link also a reference (link) to the recorded images is available.
- Implementation of the support module Multimedia for the preview Sioux images in the EHR.

#### **Coupling with SpaceLabs Healthcare systems:**

- An HL7 QRY custom link which developed from the nursing records. With this coupling a number of values of Spacelabs can be retrieved.

#### **Coupling for the appointments**

- A unidirectional link which ensures that the appointments made in the EHR are made visible to a user in MS Exchange. A link is realized based on the Routing Service a link is created between the user of the EHR and the MS Exchange user. The link runs as a Windows service application, which periodically updates the Microsoft Exchange calendars. The interval at which this is done is adjustable in minutes.
- HL7 link to SIU appointments link to Fit4Care. A standard HL7 SIU link between the EHR and the system for exchange diabetes care Fit4Care for sending messages from the appointment module. The coupling is based on the CS-Specifications.

#### **Coupling EDIFACT-MEDSPE**

- A link which makes it possible to receive EDIFACT-MEDSPE messages from and to the GPs.
- A link in EDIFACT format for sending text results of the pathology laboratory as in the EHR received to the GPs.
- A link in EDIFACT format for sending laboratory results as in the CS-EZIS received to the GPs.

#### **Coupling between CS-EZIS systems**

- A link between different organizations, that makes use of the same CS-EZIS (EHR system of ChipSoft). For example a link between the mental health care (GGZ) department which uses a customized CS-EZIS system and CS-EZIS of a cooperating hospital.

It is assumed that at least the following features are made available for the outpatient care via the Health Care Portal:

- Access to the medication list of the patient.
- Access to the available medical documents of the patient (transfer letters and other documents which are available in the EHR system).
- The possibility to make appointments. The patient gets an appointment code, which can be used to make also appointments via de phone.
- The possibility to transfer a patient to the hospital.
- Single-Sign-On (SSO) is possible, so that the health provider only needs to login once.
- It is possible to synchronize the patients data between the portal and the EHR system of the hospital.
- The coupling uses the Secure Query string API (SQAPI): This system makes use of the authenticated data and the BSN-number of the patients using a HTTP-query string.
- The system makes use of the HL7 ADT coupling for the exchange between the EHR and the Regional Portal.
- This is only appropriate when there is actually a central reference index which is maintained in the region. In the central reference index lists all names and addresses of the patients in the region are saved. The central reference index is fed by the affiliated institutions. This link facilitates the patient data (new and modified) from the hospital transmitted to the central reference index.

# Appendix M

---

## Supplementary

### M.1 Appendix - Chapter 2

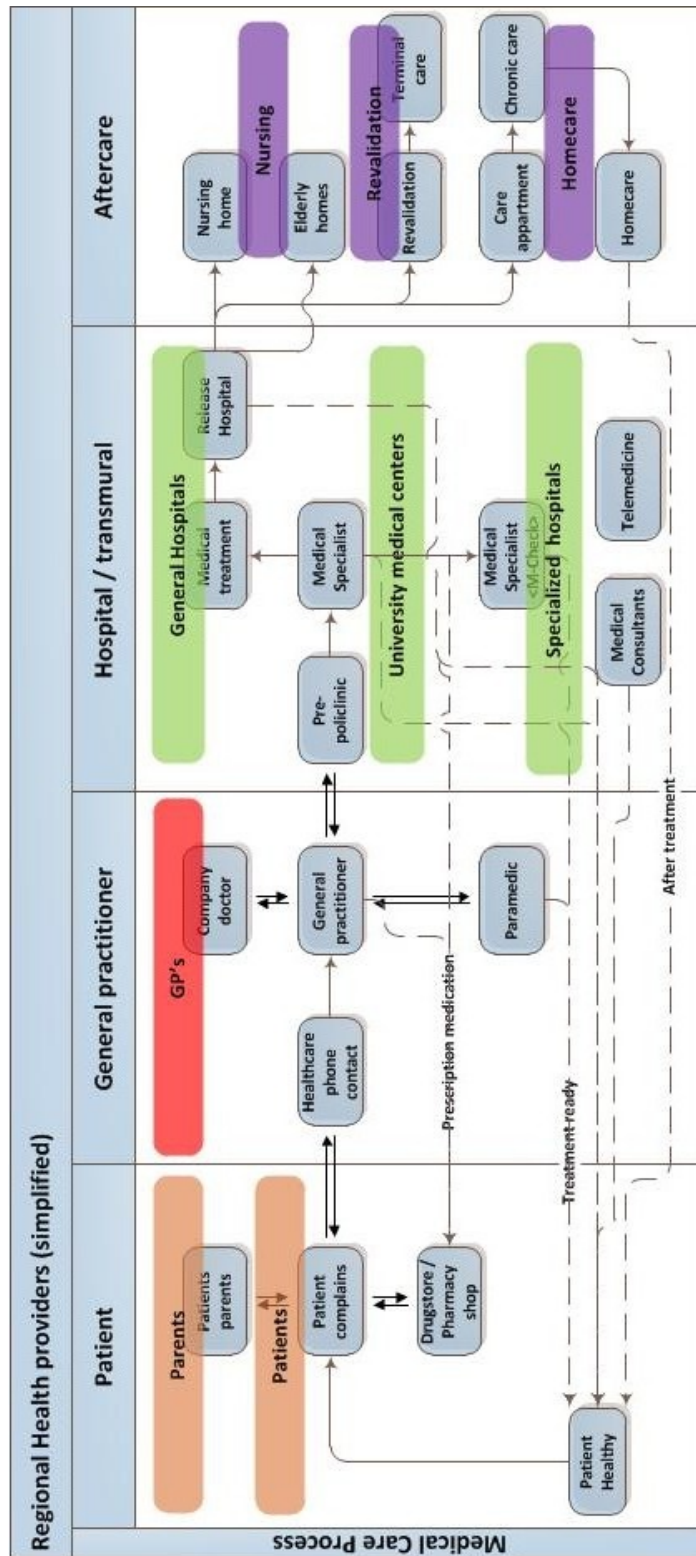
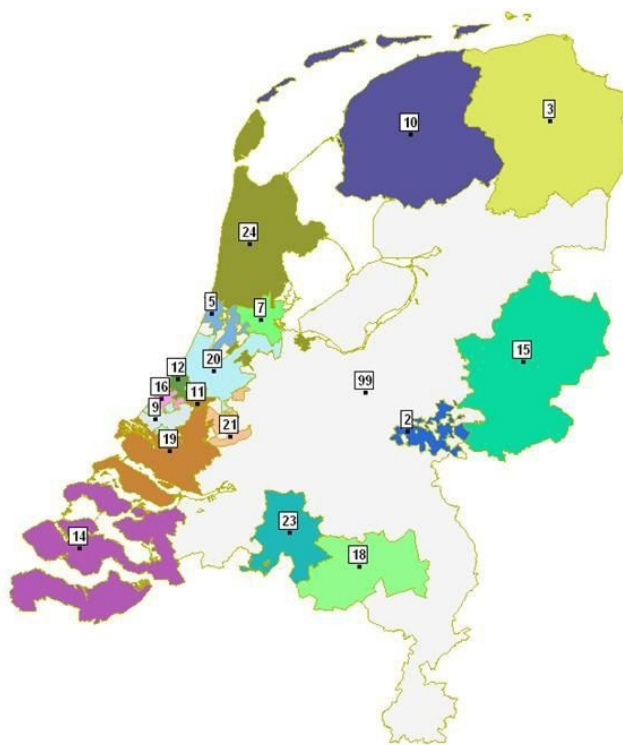


Figure M.1: Regional health providers in the Netherlands



Figure M.2: Geographic classification of the corporation between health providers at regional level. source: Nictiz



Geographic classification of the corporation between health providers at regional level for exchange of medical data, May 2010. The numbers correspond with the text in the table.

2	Anhem
3	LabNoord, CareRing
5	SDSK
7	EZDA
9	GEMS
10	GERRIT
11	Zoetermeer SGZ
12	Haagnet
14	Zeeland IZ-Zeeland
15	IZIT
16	RSO Haaglanden
18	Rheco
19	Rijnmondnet
20	Sleutelnet
21	SPITZ Midden-Holland
23	Zorgnetwerk Midden-Brabant
24	Zorgring
99	Unknown

Table M.1: Four levels of interoperability

Layer of IOP	Aim	Objects	Solutions	State of Knowledge
<b>Technical IOP</b>	Technically secure data transfer	Signals	Protocols of data transfer	Partly developed
<b>Syntactic IOP</b>	Processing of received data	Data	Standardized data exchange formats, e.g. XML	Fully developed
<b>Semantic IOP</b>	Processing and interpretation of received data	Information	Common directories, data keys, ontologies	Theoretically developed, but practical implementation problems
<b>Organizational IOP</b>	Automatic linkage of processes among different systems	Processes(work-flow)	Architectural models, standardized elements (e.g. SOA with WSDL, BPMML)	Conceptual clarity still lacking, vague concepts with large scope of interpretation

Table M.2: Types of information sections CCR:

Section	Description
<b>Payers:</b>	Here, the information is included about the insurer or other bodies that pay for the care and treatment.
<b>Advance Directives:</b>	This part contains the desires of the patient, such as organ donations.
<b>Support:</b>	An addition to the personal information about people who helped this patient. In other words family, acquaintances, friends, but also caregivers.
<b>Functional Status:</b>	A description of dysfunctions. For example movement restrictions, mental condition.
<b>Problems:</b>	Here is a summary of current and the past problems, diagnoses, symptoms, etc.
<b>Family History:</b>	Possible or relevant genetic health problems, common health problems in the family
<b>Social History:</b>	Supplementary personal information related to patients profession, social conditions, and lifestyle, ethnicity, religion etc.
<b>Alerts:</b>	It contains allergies, bad reaction to medication and other warnings that are relevant for the current situation but also in the past.
<b>Medications:</b>	An overview of the current medication and possibly a complete medical history.
<b>Medical Equipment:</b>	All medical devices of the patient from walking to implant.
<b>Immunizations:</b>	Vaccinations, current and possibly the entire history.
<b>Vital Signs:</b>	Current and historical information about things like blood pressure, respiration, weight, height measurements, etc.
<b>Results:</b>	The latest results of laboratory diagnosis and therapies.
<b>Procedures:</b>	All events such as medical procedures, surgery, diagnosis, or therapy.
<b>Encounters:</b>	Summary of consultations, both clinical admissions as outpatient.
<b>Plan of Care:</b>	A summary of on-going research, clinical appointments and outstanding orders.
<b>Healthcare Providers:</b>	All involved in institutions, physicians, health professionals and particularly GPs.

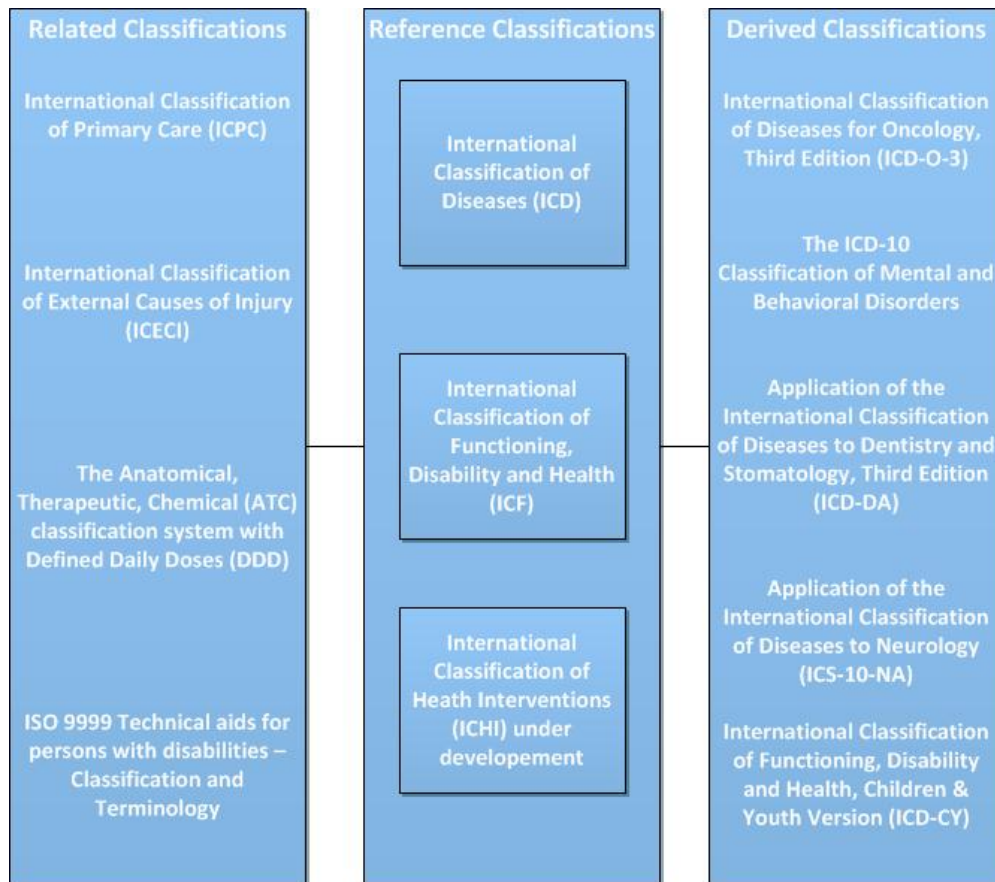
Figure M.3: Example ARCHETYPE Definition Language (ADL)

```

    adl-test-instrument.guitar.draft
concept
  [at0000] -- guitar
language
  original_language = <[iso_639-1::en]>
definition
  INSTRUMENT[at0000] matches {
    size matches {|60..120|}           -- size in cm
    date_of_manufacture matches {yyyy-mm-??} -- year & month ok
    parts cardinality matches {0..*} matches {
      PART[at0001] matches {           -- neck
        material matches {[local::at0003, -- timber
                           at0004]} -- timber or nickel alloy
      }
      PART[at0002] matches {           -- body
        material matches {[local::at0003} -- timber
      }
    }
  }
ontology
  term_definitions = <
    ["en"] = <
      items = <
        ["at0000"] = <
          text = <"guitar">;
          description = <"stringed instrument">
        >
        ["at0001"] = <
          text = <"neck">;
          description = <"neck of guitar">
        >
        ["at0002"] = <
          text = <"body">;
          description = <"body of guitar">
        >
        ["at0003"] = <
          text = <"timber">;
          description = <"straight, seasoned timber">
        >
        ["at0004"] = <
          text = <"nickel alloy">;
          description = <"frets">
        >
      >
    >
  >

```

Figure M.4: International Classification WHO, [32]



**M.2 Appendix - Chapter 3**

**COMMON ORGANISATIONAL STRUCTURE HOSPITALS IN THE NETHERLANDS**

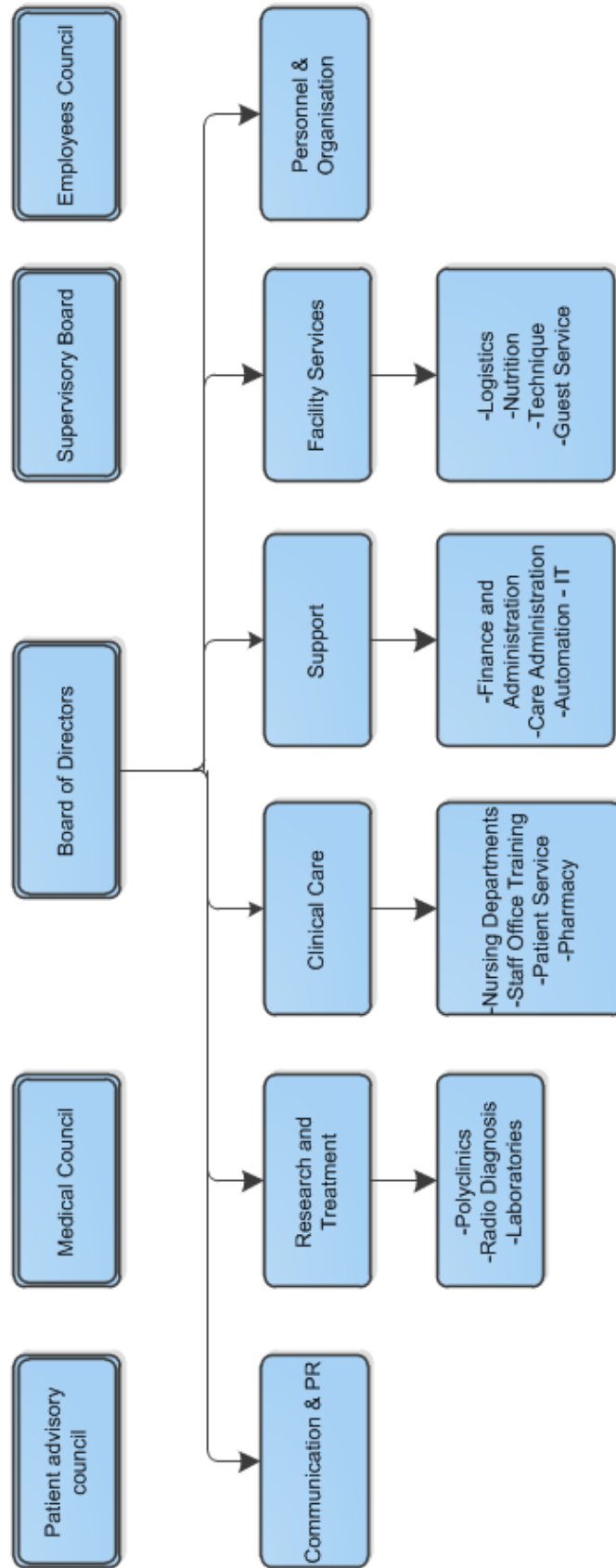


Figure M.5: Common organizational chart in the Netherlands

### Communication methods for Elicitation requirements



Figure M.6: Communication methods & sources for elicitation of requirements

## **M.3 Appendix - Chapter 4**



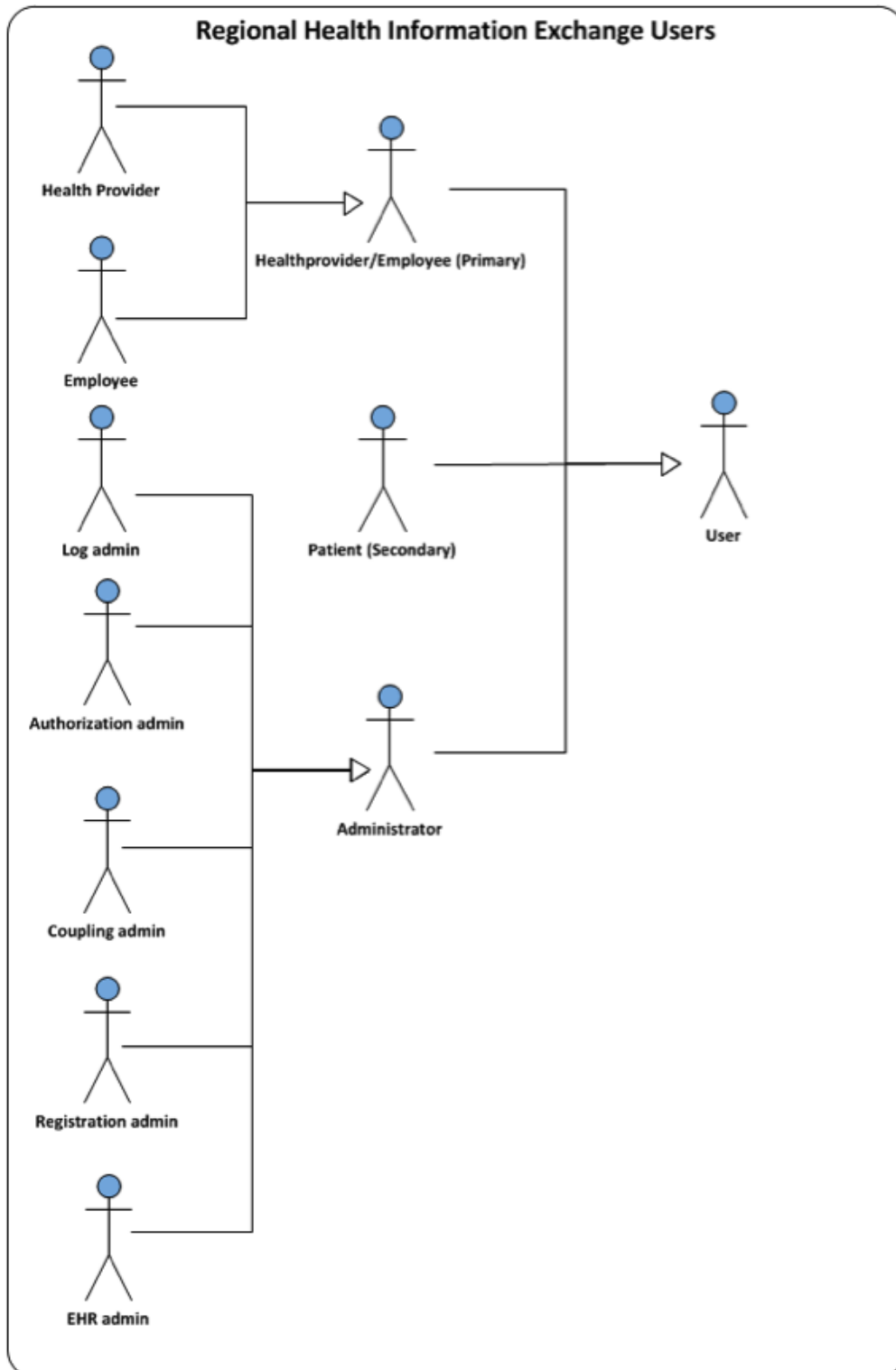


Figure M.7: generalizations different users

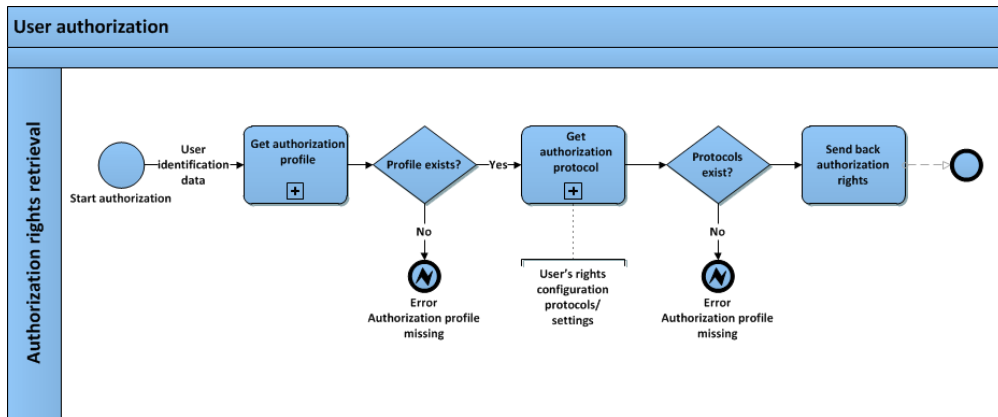


Figure M.8: Use-case 2: User authorization

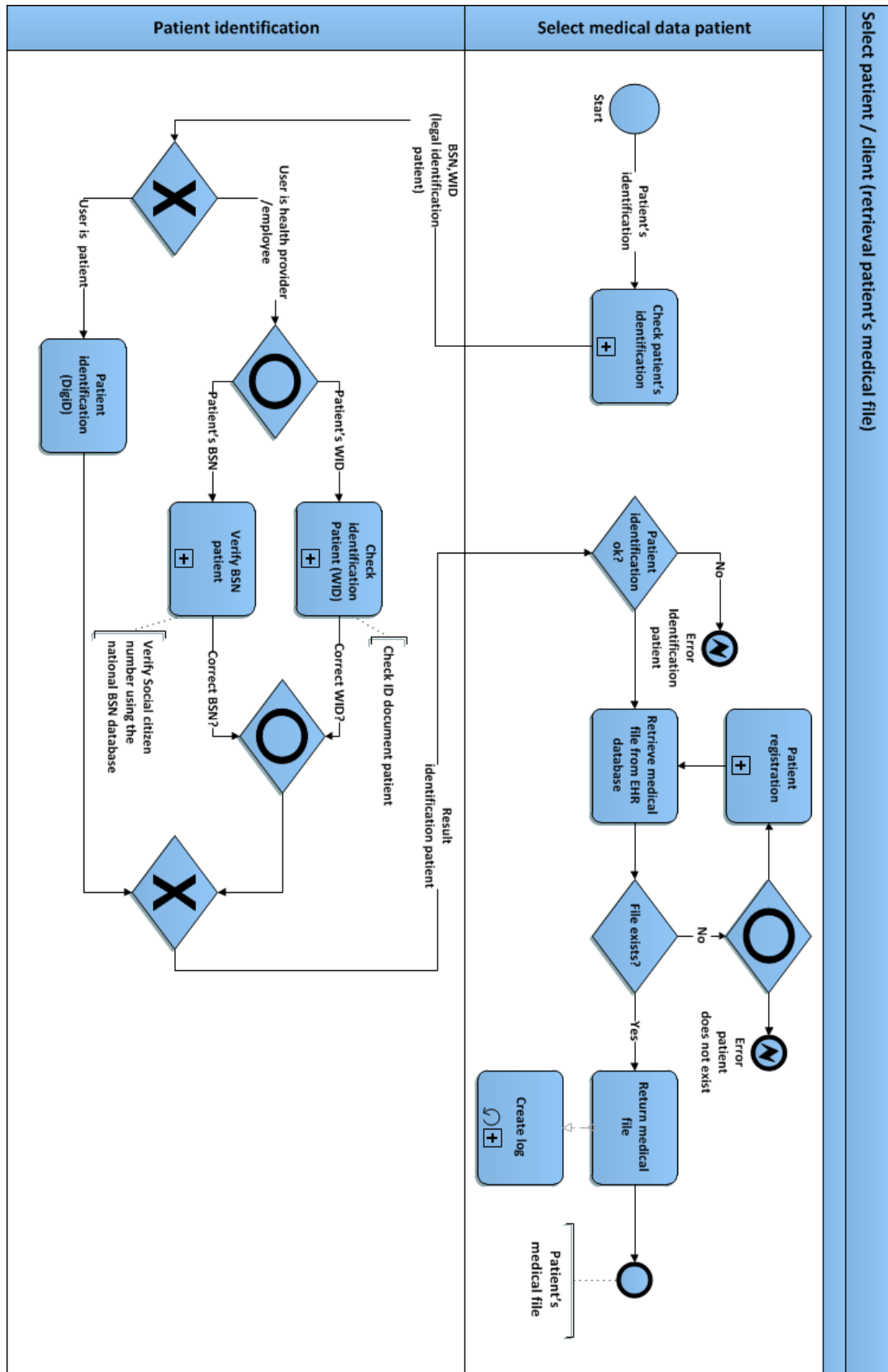


Figure M.9: Use-case 3: Selecting patients

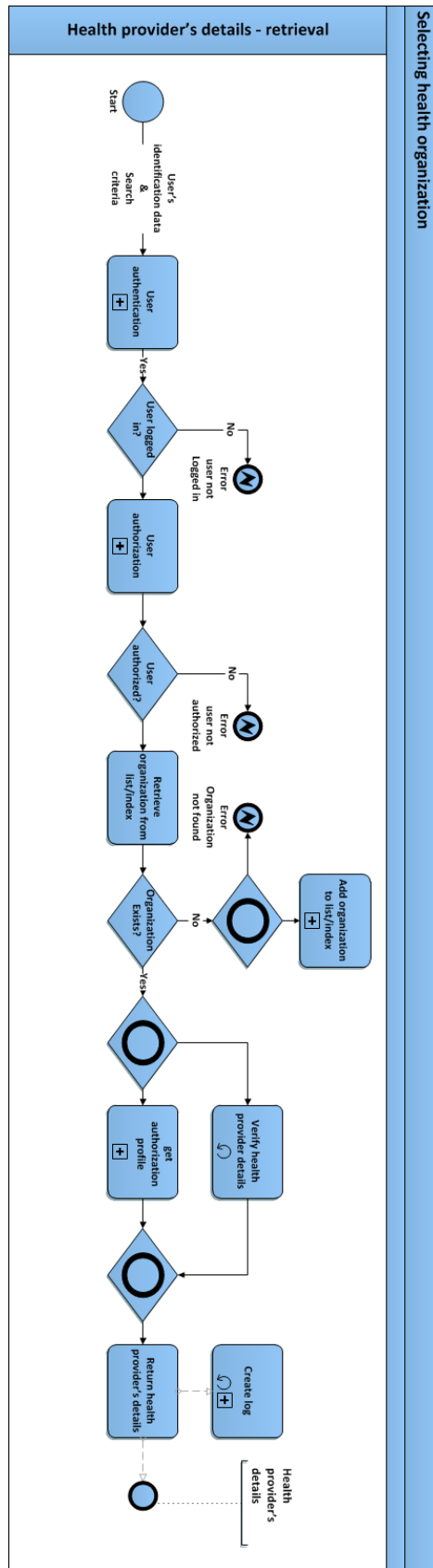


Figure M.10: Use case 4: Selecting organizations

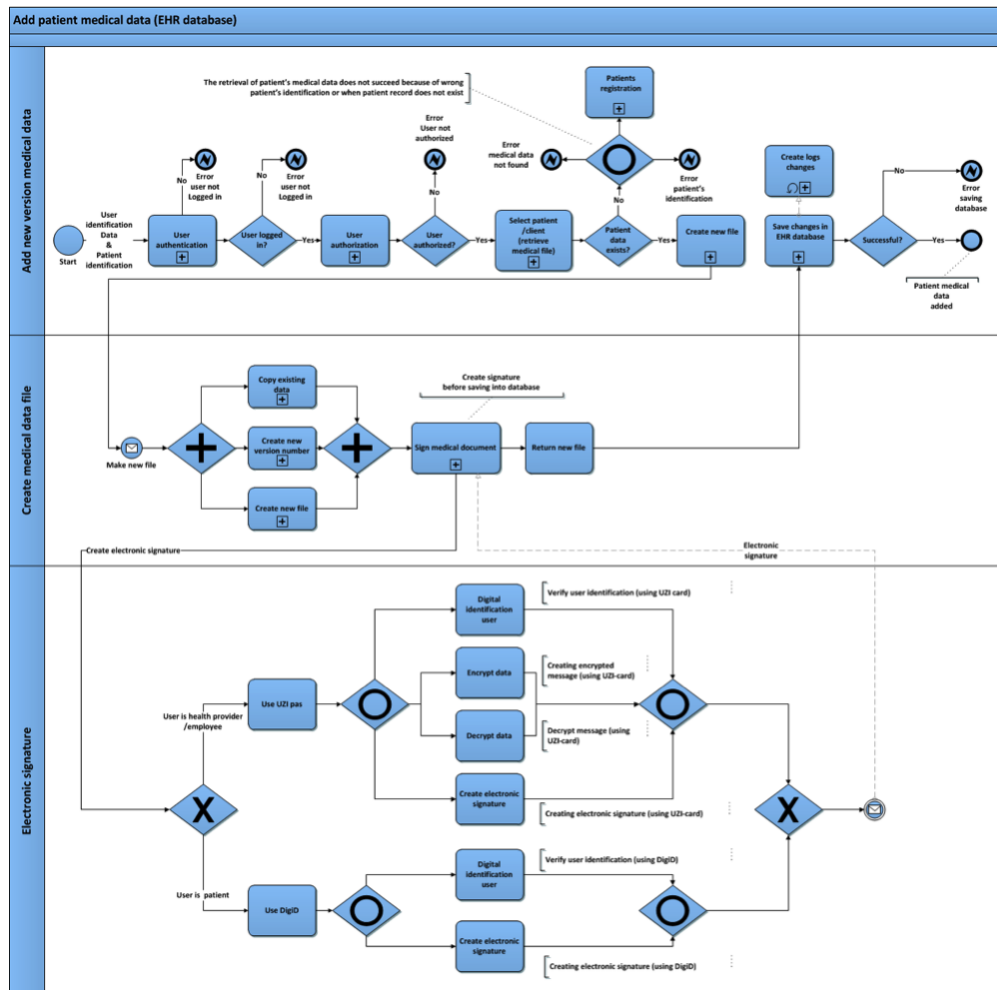


Figure M.11: Use-case 5: Maintain patient’s medical data

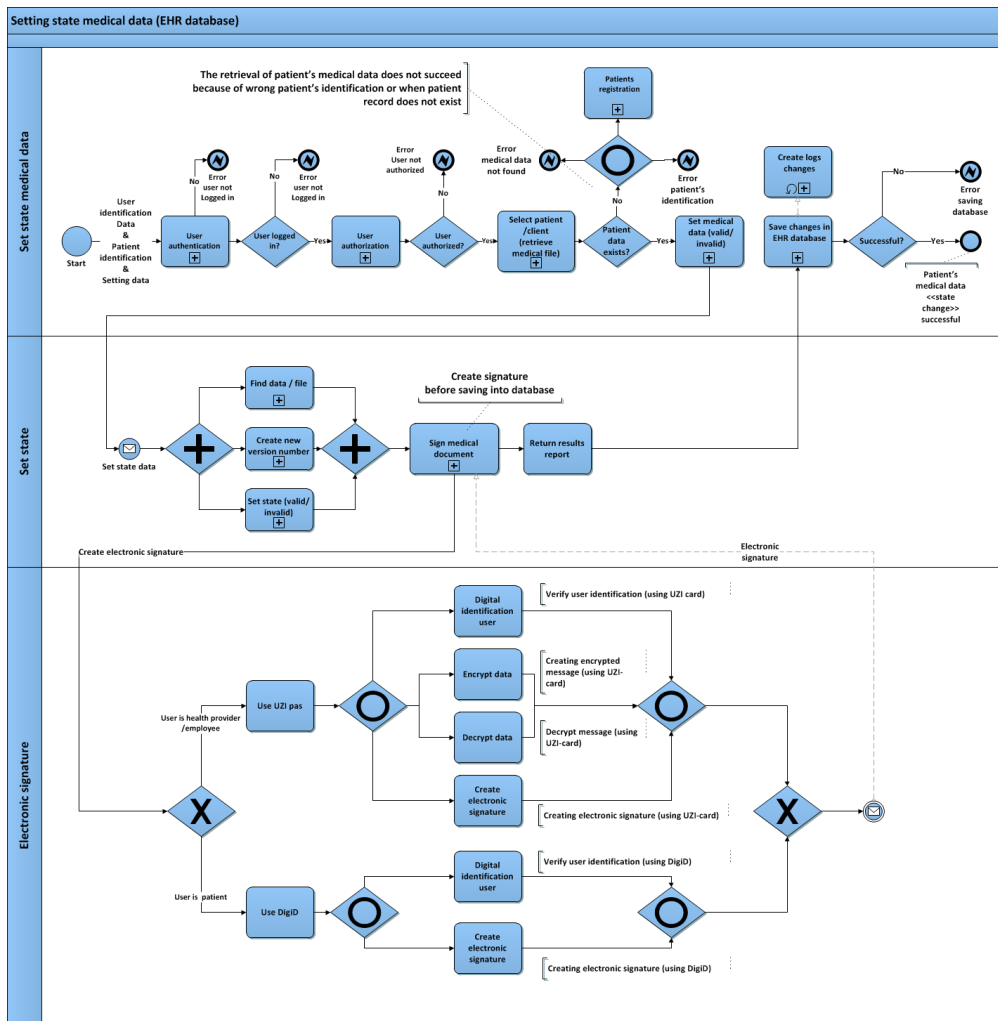


Figure M.12: Use-case: Setting state medical data (EHR database)

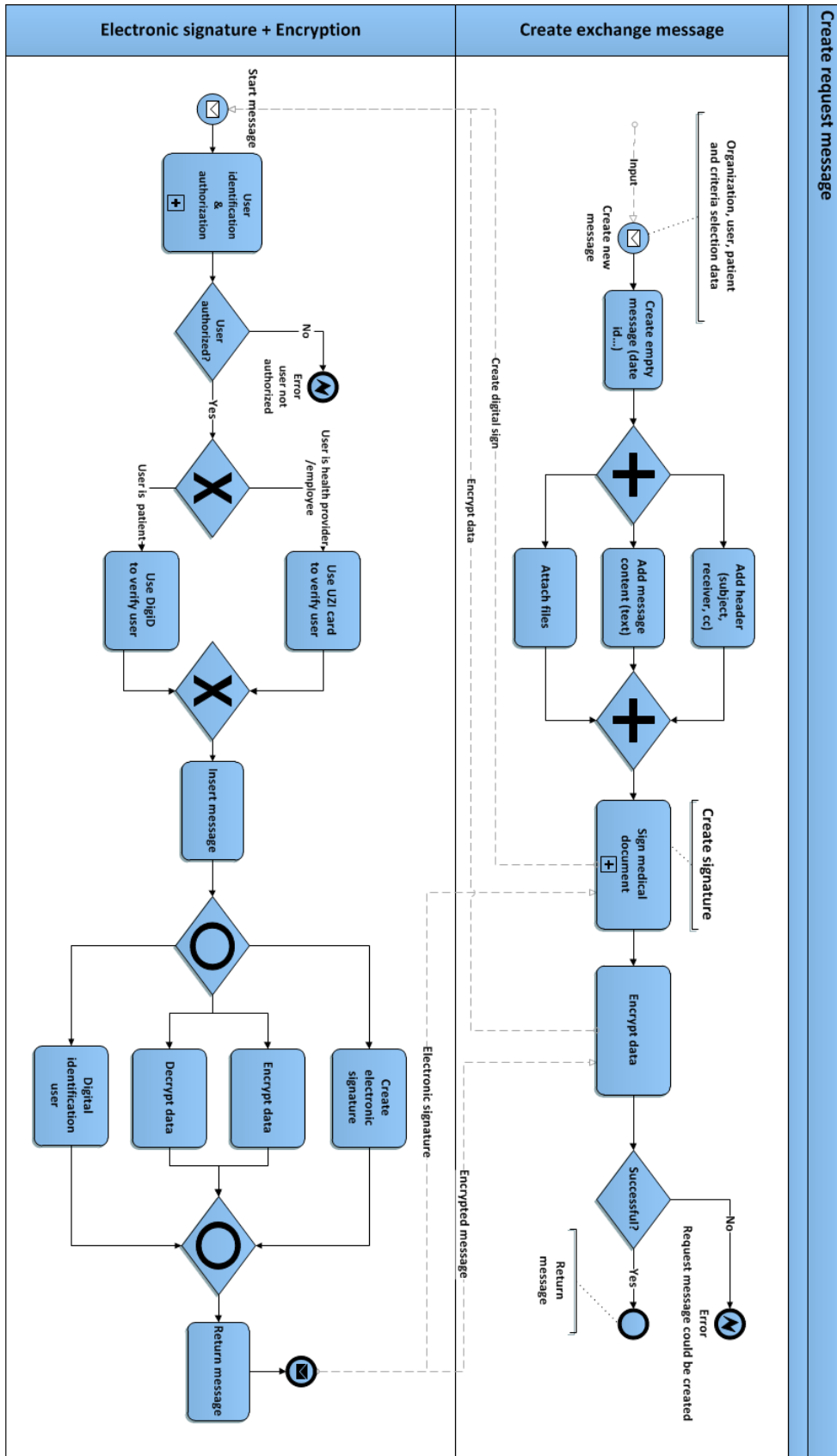


Figure M.13: Use-case: Create request message

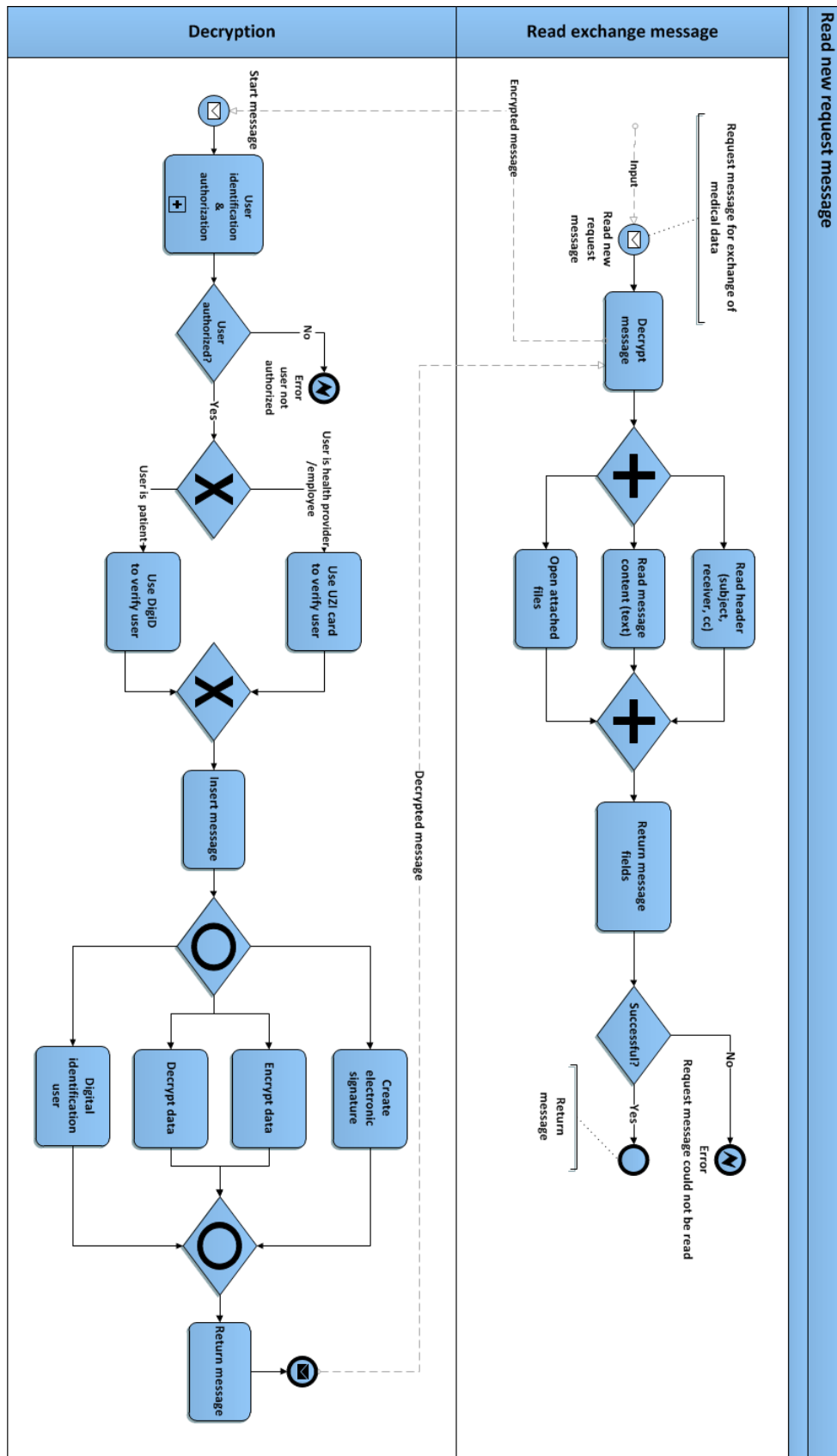


Figure M.14: Use-case: Read new request message



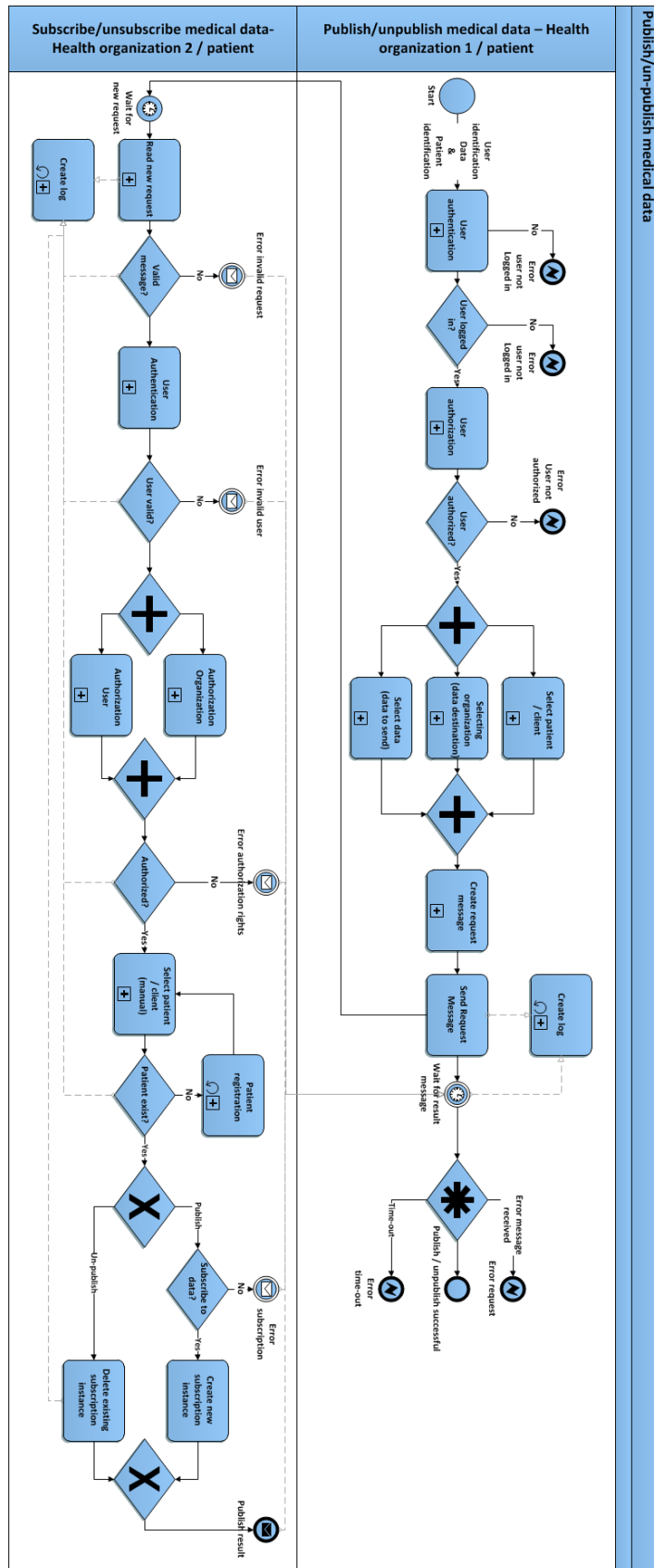


Figure M.15: Use case 9: Publish & undo publishing patient data

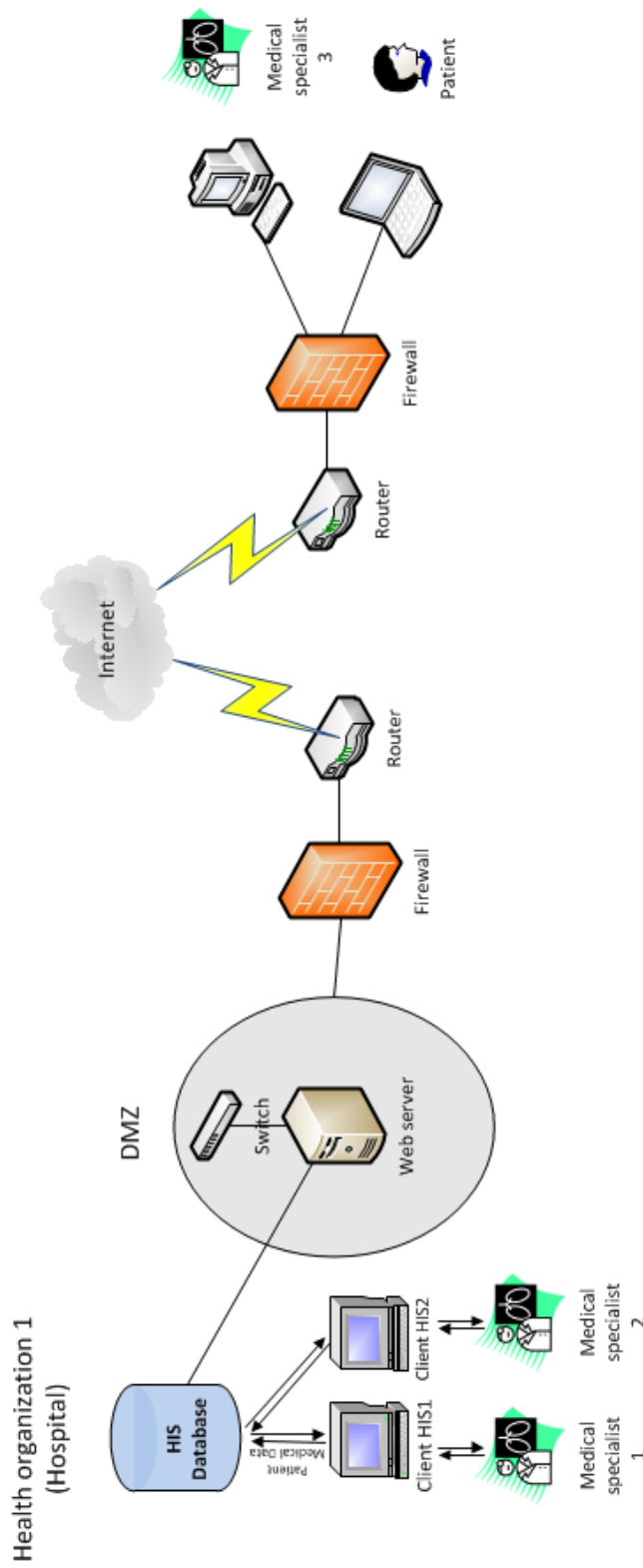


Figure M.16: Exchange of medical data using a web-portal

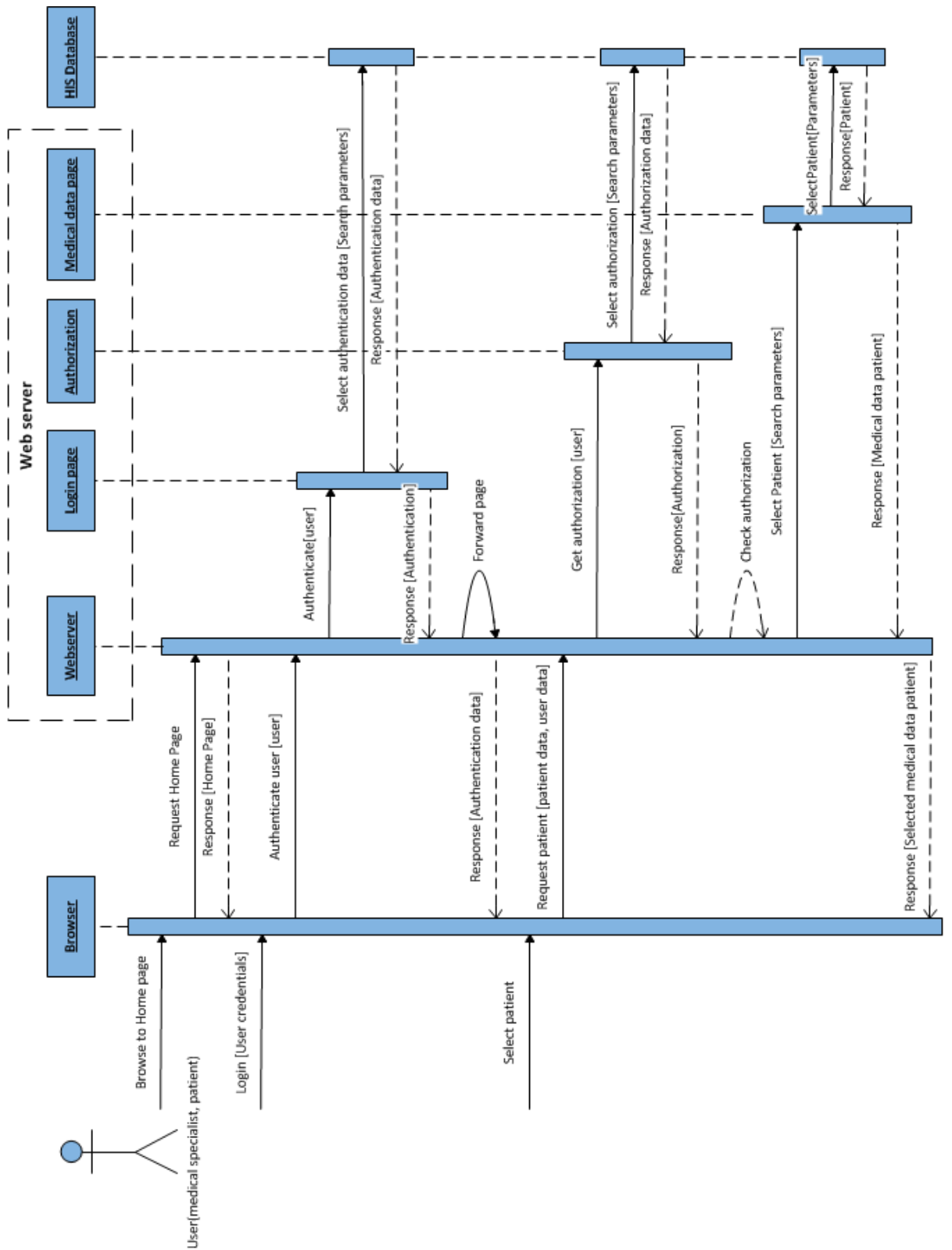


Figure M.17: Sequence diagram, health portal example communication pattern

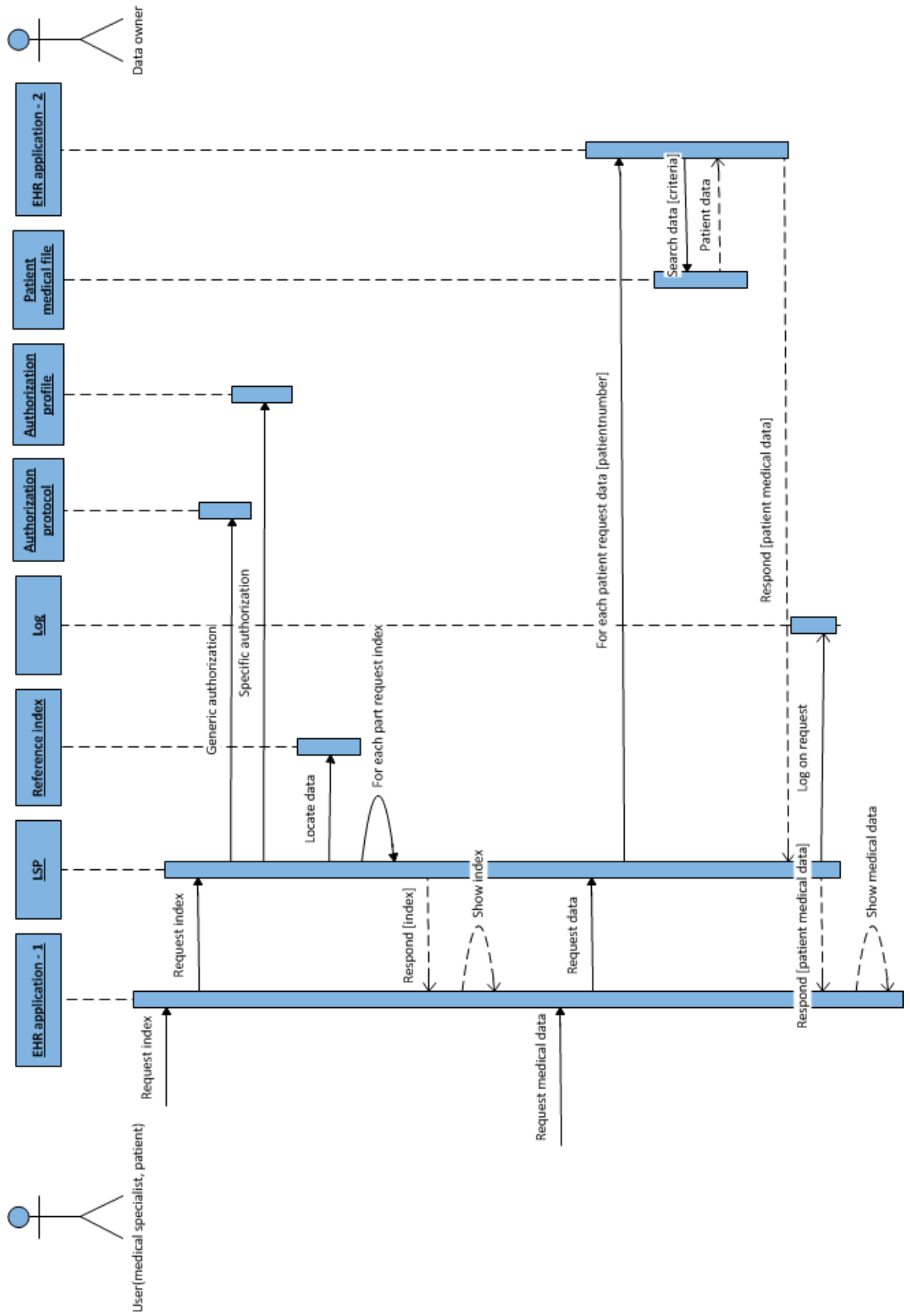


Figure M.18: Sequence diagram AORTA [29], example selecting patient's medical data