

## MASTER

Reusability of clinical rules within a cross-organizational setting  
identifying and ranking current issues and standardizing clinical terms

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Eindhoven, October 2014

**Reusability of clinical rules  
within a cross-organizational  
setting:**

Identifying and ranking current issues and  
standardizing clinical terms

by  
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# Abstract

This study investigates the reuse of clinical rules within a cross-organizational setting. The Santeon hospital group has launched the CRS (Clinical Rules in Santeon) project, in which clinical rules are shared with the involved hospitals. These hospitals all have their own information systems and organizational setting, which hinders the ease of reuse of clinical rules. Awareness of issues in organizational and technological aspects was present. However, it was unclear what the issues exactly were, how important they were and what could be done to solve these. A framework-based analysis of the CRS project has been done and a problem list has been created, which was subsequently ranked on perceived importance. This led to valuable insights into issues that occur during a cross-organizational project like the CRS project. Furthermore, one of the technical issues that was encountered was selected and a solution direction was given. This solution direction involved the standardization of clinical terms that originally were defined on a local level. This could ultimately lead to general CRs that require no local customization and thus enhanced reusability, but more research is required to achieve this.



# Management Summary

The health care sector faces increasing difficulties due to an aging population, growing competition in the market and a more aware patient. Therefore, the sector is forced to reduce costs, but at the same time increase its efficiency and quality [Sun13]. In an effort to do so, six clinical hospitals spread across the Netherlands have joined forces under the name Santeon [San14]. Two of the hospitals involved are the Catharina Hospital Eindhoven (CZE) and the Canisius-Wilhelmina Hospital Nijmegen (CWZ). One of their innovations is the development and use of Clinical Rules (CR) with a Clinical Decision Support System (CDSS). A special pilot project has been set up for this called the Clinical Rules in Santeon (CRS) project. Many different CDSSs exist [Wik14a] and the CDSS in use for the CRS project is called Gaston. Sharing of these clinical rules developed in Gaston could provide large reductions in costs in terms of time spend on development. However, all these hospitals have their own information systems in use and therefore the required mapping of patient information, queried from the electronic health records, to the rules can not be copied. This is one of the many reasons that clinical rules developed in one hospital can not be simply copied to another one. This MSc thesis project has identified and ranked the main issues in organizational and technological aspects when it comes to this reuse of clinical rules and provided a solution direction.

This MSc thesis project is a case study into the CRS project. In order to describe the current situation, a framework-based analysis has been done, covering business, network, process and technology perspectives. For this case study, several interviews were held, local manuals were consulted and personal experience with the CDSS was gained. During the interviews, certain problems concerning the current CRS project arose. All problems that were encountered were collected in a list and this list was fed back to the interviewees for them to judge the importance of each problem. A list ranked on perceived importance of the problems was thereafter created:

1. Deficient communication between IT and domain specialists
2. Lack of a clear project manager
3. Unclear responsibilities
4. Manual editing of alert codes
5. Unseperated server environments
6. Agreements are not always honored
7. Heavy dependency on a single person

8. Linking the CDSS to different HISs
9. Improper introduction of project in IT department
10. Unsupervised access
11. Insufficient knowledge of the CDSS
12. Programming of CRs falls behind on content development
13. Difference in recorded medical data
14. Low awareness of relevance
15. Current version of Gaston only supports 65.000 elements
16. Out of date data infrastructure at CWZ
17. Missing workflow documentation
18. Load of the CDSS on the HIS
19. Instruction of end-user of CR is time consuming
20. Planning of monthly phone meeting with project partners

The final stage of the project concerned the design of a possible solution to one of the encountered problems in the form of an adjustment to the architecture surrounding the CDSS. The problem that was selected for this purpose was on the subject of standardization of clinical data. The expert opinion of dr. William T.F. Goossen on this subject was consulted and based on this and additional literature a conceptual design proposal has been made. The use of a terminology standard such as SNOMED CT is seen as a possibility to reduce the amount of local (and hospital specific) support rules required, or in the long run even eliminate the need at all. Furthermore, standardizing the entire rule will result in easier communication concerning the CR, since no local terms (only familiar to local medical specialists) are used. This improved communication will become necessary if and when the CRS project is extended to more and more hospitals. Standardizing clinical terms within the CR and CDSS alone is not enough. The data within the information system of the hospital where the CRs are run needs to be linked to these standards, and thus needs to be translated. For this, a thesaurus, such as a DCM service is required.

The impact of the proposed standardization of clinical terms to the different features of the current situation has been described. This has been done within the same HCBN framework as was done for the current situation.

The insights (such as the identified problems and the impact of standardizing clinical terms) gained in this MSc thesis are case specific in nature. However, the conclusions that have been drawn are not only interesting for the Santeon members. The number of collaborations between Dutch hospitals is growing [KPM13] and collaborating parties engaged in similar projects can benefit from these insights.

# Preface

The report that lies before you is the result of my graduation project which I have done in order to obtain the degree of Master of Science in Operational Management and Logistics at the Eindhoven University of Technology. I have performed this graduation project in close collaboration with the pharmacy of the Catharina Hospital Eindhoven. In this preface I would like to take the opportunity to thank the people that have supported me during this graduation project and the rest of my life as a student.

First off all I would like to thank Pieter Van Gorp, my first supervisor, for all the time and energy he has put into this project and for guiding me through it. He always made time in his schedule to answer my questions or to provide me with feedback. At times of uncertainty on the project direction I could always count on him to provide viable ideas. Additionally, I would like to thank Uzay Kaymak for being my second supervisor and answering my questions even during the holidays.

From the Catharina Hospital Eindhoven, the Canisius Wilhelmina Hospital Nijmegen and Medecs BV, I would like to thank all people involved in the CRS project who took the time to meet me and provide information for my graduation project. Special thanks go to Arthur Wasylewicz, who took the time to introduce me to the CRS project and later on provided valuable feedback continuously. I would also like to thank Rene Grouls for the time he put into my project and his much appreciated professional opinion. Furthermore, my thanks go out to William Goossen, who provided his expert opinion on the standardization of clinical terms.

Last, but certainly not least, I would like to thank all my friends and family, especially my parents and brother, who provided constant support and motivation without which I would not have been able to complete my study, my girlfriend, who always lend a listening ear and my roommates of Delirium Tremens, with whom many memorable moments were shared.

Martijn Hofstede

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# 1. Introduction

The report that lies before you is the result of a Msc master thesis project that has been conducted at the faculty of Industrial Engineering and Innovation Sciences at the Technical University of Eindhoven. The project has been done in collaboration with the pharmacy department of the Catharina Hospital Eindhoven. The supervisors for this thesis are dr. P.M.E. Van Gorp and prof.dr.ir. U. Kaymak from the Eindhoven University of Technology and A.T. Wasylewicz and dr. R.J.E. Grouls from the Catharina Hospital Eindhoven.

By now it is a well known fact that the health care sector faces difficult times in terms of finance. On a global scale, the financial crisis forces governments to rethink their expenditures which has a negative influence on the budgets assigned to the health care sector [Min13]. On top of these budget issues comes the increasing demand for health care due to the aging population. On a more local scale the health care providers also face growing competition in the market and a more aware patient who is weighing his options in terms of finance and quality. This competition and freedom of choice has been made possible among others by the health insurance act the Dutch government established in 2006. This act is based on the principles of a managed competition, in which all Dutch citizens are required to have an health insurance, but are free to chose among insurers. The insurers in their turn became prudent purchasers of care and are able to contract health care providers freely [BS11, SvdV11]. The health care sector is due to all these increasing difficulties forced to reduce costs, but at the same time increase its efficiency and quality [Sun13].

In an effort to do so, six clinical hospitals spread across the Netherlands have joined forces under the name Santeon [San14]. The hospitals involved besides the aforementioned Catharina Hospital Eindhoven (CZE) are; Canisius-Wilhelmina Hospital Nijmegen (CWZ), Medical Spectrum Twente (MST), Martini Hospital Groningen, Onze Lieve Vrouwe Gasthuis Amsterdam and St. Antonius Hospital Utrecht/Nieuwegein. Together they strive for innovation to offer the best medical care to their patients. One of these innovations is the development and use of Clinical Rules (CR) with a Clinical Decision Support System (CDSS). A special pilot project has been set up for this called the Clinical Rules in Santeon (CRS) project. The CRS project plan can be found in Appendix E.

Many different CDSSs exist [Wik14a] and the CDSS in use for the CRS project is called Gaston. Sharing of these clinical rules developed in Gaston could provide large reductions in costs in terms of time spend on development. However, all

these hospitals have their own information systems in use and therefore the required mapping of patient information, queried from the electronic health records, to the rules can not be copied. This is one of the many reasons that clinical rules developed in one hospital can not be simply copied to another one. This research will try to identify the main issues in organizational and technological aspects when it comes to this reuse of clinical rules and provide some solution directions.

## 1.1. Problem Context and Relevance

In this section, the problem context is described by revisiting the subjects clinical guidelines, clinical rules and clinical decision support systems which were handled earlier in [Hof14]. In the last section, the link between these subjects and the relevance of this research is made.

### 1.1.1. Clinical Guidelines

The Institute Of Medicine (IOM) defines a clinical guideline as: "a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [GFL<sup>+</sup>90]. This is the same definition used in [dC03, LB13], which are written by the founder and an employee of Medecs B.V., the company that developed Gaston. Therefore, it has been chosen to work with this definition throughout the report. Clinical guidelines have existed for over 60 years, but at first were only used by nurses and other ancillary personnel. Most physicians made no use of them whatsoever because the guidelines were very general and did not take into account the difference among patients [LB13]. As stated in the introduction however, the required increase in quality of care has led to a more positive view on guidelines. Still a lot of barriers exist in the actual implementation of the developed guidelines into the daily care. According to [LBTvdHH10] a few examples of such barriers are:

1. The guidelines could contain ambiguous text or even inconsistencies.
2. Paper-based guidelines are difficult to use in clinical practice.
3. Physicians consider the use of guidelines as cookbook medicine (unpersonalized).
4. Physicians are not convinced that the use of guidelines would lead to better care.
5. Organizational barriers are present.

These barriers can be broken however. Issue (2) can be helped by a CDSS which provide a computerized guideline implementation. By connecting this CDSS to an Electronic Health Record (EHR), barrier (3) can be tackled [LB13]. The lack

of confidence in the actual effect of medical guidelines, barrier (4), is a complex problem on its own. In [WGH<sup>+</sup>99] it is already described that there are mixed feelings about clinical guidelines between different groups. Guidelines, developed by governments or other groups that have large concerns over ever increasing costs, are seen by specialists as threatening to their autonomy. Vice versa, the guidelines developed by specialists can come across as being self-serving. It can therefore be concluded that the development of guidelines has to be done with great care. To evaluate the actual effects of guidelines already in place, a systematic review, on studies evaluating the effects of evidence-based guidelines on both the process and structure of care and patient outcomes, has been performed by Lugtenberg et al.[LBW09]. The studies that were selected ranged from 1990-2007 and were all based in Dutch hospitals. They concluded that guidelines seemed to have a positive effect on the process and structure of care. Effects on patients outcomes were studied less and also less convincing. Furthermore, it has been suggested that individual recommendations within the guideline are needed for actual improvements in healthcare. This suggestion also supports the coupling of a CDSS to an EHR.

### 1.1.2. Clinical Rules

Where a clinical guideline is a somewhat broader term and includes text based documents which are too cumbersome to actually implement, clinical rules are more specific. The above mentioned definition for clinical guidelines is used in the definition of clinical rules: "Clinical rules are decision rules in a Clinical Decision Support System that are derived from medical guidelines and which take the current clinical state of a patient into account" [Sun13]. This definition captures the desired individualization of clinical guidelines with the help of a patient's information.

### 1.1.3. Clinical Decision Support Systems

Clinical decision support systems are information systems designed to improve clinical decision making. Characteristics of individual patients can be matched to a computerized knowledge base, and software algorithms generate patient specific recommendations [GAM<sup>+</sup>05]. Alternately, the CDSS might not be knowledge based and make recommendations on historic patient data which are mined for patterns via various mining techniques such as neural networks. The latter eliminates the need for manually modeling the rules based on expert input. Many different CDSSs exist and a list of some of them along with their home pages for additional information can be found in [Hof14].

The effectiveness of CDSSs has been studied by [GAM<sup>+</sup>05]. They conclude that many CDSSs improve practitioner performance. However, the effects on patient outcomes remain understudied and, when studied, are inconsistent. This is pretty much in line with [LBW09], who studied the effects of the use of clinical rules (not

necessarily CDSSs). The acceptance of CDSSs is still an issue like it was with clinical rules 50 years ago [Kap01]. [Kap01] suggests that one of the reasons for this might be that system evaluations often omit important issues as user acceptance or change in work. Due to this, less informed decisions are taken about medical applications.

There is still a lot to be done in the field of CDSSs and [SWO<sup>+</sup>08] has used an iterative, consensus-building process to identify a rank-ordered list of the top 10 grand challenges. It is indicated as a limitation that only a small number of informaticians were surveyed, although they all were experts in the field. In any case, this paper, which was cited 211 times already, is a scientific basis we can build upon at this stage. The resulting list is shown below:

1. Improve the human–computer interface.
2. Disseminate best practices in CDS design, development, and implementation.
3. Summarize patient-level information.
4. Prioritize and filter recommendations to the user.
5. Create an architecture for sharing executable CDS modules and services.
6. Combine recommendations for patients with co-morbidities.
7. Prioritize CDS content development and implementation.
8. Create internet-accessible clinical decision support repositories.
9. Use freetext information to drive clinical decision support.
10. Mine large clinical databases to create new CDS.

If these issues are addressed, the authors believe that the substantial potential of CDSSs can be unlocked. Undoubtedly there are many other challenges, but these represent the core. Addressing these will of course take a lot of time and the solutions may vary vastly, but [SWO<sup>+</sup>08] believe that this is the direction future research on CDSSs should take.

#### **1.1.4. Relevance**

This research will be highly related to number 5 on the list of top 10 grand challenges within the field of CDSS: Create an architecture for sharing executable CDS modules and services. Although the research will not actually result in a solution of this challenge (thinking so would be very naive), it does look into the enabling of sharing developed rules in the specific case of the CRS project. Sharing of developed rules will reduce costs in terms of labour. It is estimated by A.T. Wasylewicz, the most heavily involved pharmacist of the CRS project, that it takes about six months to develop a proper clinical rule, in which time one person is committed to that development full time and numerous other people are involved part-time. Investing that amount of time at every single health care provider who wishes to implement a clinical rule is inefficient to say the least.



## 1.2. Problem Scope

Although the Santeon hospital group consists of six hospitals, only three of those currently use the CDSS Gaston. The hospitals that use it are the Catharina Hospital Eindhoven, the Canisius-Wilhelmina Hospital Nijmegen and the Medical Spectrum Twente. Due to time and logistics, this research will focus on the situations in Eindhoven and Nijmegen. Furthermore, although the CDSS Gaston is used within different departments of the Catharina Hospital Eindhoven, the CRS project only involved the hospital pharmacies. The scope for this research has therefore also been limited to the hospital pharmacies.

## 1.3. Project Outline

This research is a case study into the situation of the CRS project concerning the CDSS Gaston. The motivation for conducting a case study is given in sec. 2.2.1. The current organizational structure will be explored, the process of reusing a clinical rule developed in the Catharina Hospital Eindhoven at the Canisius-Wilhelmina Hospital Nijmegen will be mapped out and the aspects that stand in the way of easy reuse will be identified. This study is partly an exploratory study and the first objective is therefore to identify current problems surrounding the reuse of clinical rules that are developed and used within the CDSS Gaston. Once this identification has been done, a redesign proposal regarding the architecture surrounding the CDSS Gaston will be given. This design proposal is the second objective of the research.

The remainder of this report is structured in the following manner. In chapter 2, the research approach of this Msc thesis project is explained. A case study has been done on the CRS project and the framework-based analysis of this is given in chapter 3, while the problem identification is done in chapter 4. A possible improvement to the reusability of CRs is presented in chapter 5, in the form of a discussion on the standardization of clinical terms and an implementation example. A discussion on the results and consequences of the research is held in chapter 6. Finally, chapter 7 presents the conclusions, recommendations, limitations and suggestions for future research.



## 2. Research Approach

In the previous chapter, the problem context, relevance and scope as well as the project outline have already been given. In this chapter the research problem is given and specific research questions are defined. The methodology developed to answer these questions will be dealt with in sec. 2.2.

### 2.1. Problem Description and Research Questions

The hospitals from the Santeon group all have their own information systems in use and therefore the required mapping of patient information, queried from the EHR, to the rules can not be copied. This is one of the many reasons that clinical rules developed in one hospital can not be easily reused in another one. Awareness of issues in organizational and technological aspects when it comes to this reuse of clinical rules is present. It is however unclear at this point what the issues exactly are, how important they are and what can be done to solve these.

The corresponding research questions that this master thesis will answer are:

1. *Which problems can be identified in the organizational setting surrounding the reuse of clinical rules with the CDSS Gaston?*
2. *How can the architecture surrounding the CDSS Gaston be redesigned in order to facilitate easier reuse of clinical rules?*

### 2.2. Research Methods and Design

This Msc. thesis project is a case study into the CRS project. The choice for a case study is more elaborated upon in sec. 2.2.1. Initial background information on the CDSSs, CRs and the CRS project was gained in a literature review [Hof14]. In order to describe the As-Is situation of the CRS project, a framework-based analysis has been done as described in sec. 2.2.2. This analysis is based on information gained from interviews (on which more in sec. 2.2.3), local manuals and personal experience with the CDSS Gaston. The produced descriptions and models of the different aspects of the CRS project were validated as described in sec. 2.2.4. The problems within the CRS project that were encountered during the interviews were listed and ranked on perceived importance as discussed in sec. 2.2.5. The resulting

ranked problem list was then discussed in a focus group session, which is handled in sec. 2.2.6. Finally, a conceptual redesign proposal was made, which is elaborated on in sec. 2.2.7.

### 2.2.1. Motivation for a Case Study

A case study is defined by [Col14] as:

Case study refers to the collection and presentation of detailed information about a particular participant or small group, frequently including the accounts of subjects themselves. A form of qualitative descriptive research, the case study looks intensely at an individual or small participant pool, drawing conclusions only about that participant or group and only in that specific context. Researchers do not focus on the discovery of a universal, generalizable truth, nor do they typically look for cause-effect relationships; instead, emphasis is placed on exploration and description.

This does not mean however that the results of this research can not be used outside the context the research is done in. Lessons learned from this research that are usable for a broader audience are presented in chapter 7.

The reason behind the choice for a case study is based on the strengths of the case study, such as flexibility. Researchers are comparatively free to discover and address issues as they arise in their study [Col14], which is ideal in the present situation, since not much has been written about the subject at hand within this setting. This setting meaning the small market the Dutch health care sector is, compared to the rest of the world, and the close collaboration between hospitals which seems to become more and more frequent [KPM13]. Wright et al. [WBM<sup>+</sup>09] mention that a number of efforts at sharing decision support content have been made, but none of them has so far gained much traction.

### 2.2.2. Framework-based analysis

The current situation of the CRS project is described using an adjusted BOAT (Business, Organization, Architecture and Technology) framework. The BOAT framework is a framework made by prof.dr.ir. P.W.P.J. Grefen [Gre10] and is designed to analyze the different aspects, that make up the acronym, of an e-business scenario. A variant of the BOAT framework that is found to be more practical, based on personal experience with both frameworks in course projects, is thought in the course Healthcare Business Networks on the Technical University Eindhoven by dr. P.M.E Van Gorp. The difference with the original framework mainly lies in a redistribution of topics among perspectives and more specificity on what should be treated

within these perspectives. The adjusted framework also contains four perspectives; Business, Network, Process and Technology.

For this case study, several interviews were conducted (more deeply discussed in sec. 2.2.3), local manuals were consulted and personal experience with the CDSS was gained. The contents of the minutes of the interviews were categorized into the four perspectives and corresponding parts in the interviews were marked. After this, the information from the interviews was ready to be used in order to fill the framework as has been done in chapter 3.

### 2.2.3. Interviews

Interviews were held with people involved in the CRS project from the locations Eindhoven and Nijmegen. Invitations for interviews were sent via A.T. Wasylewicz and dr. R.J.E. Grouls to accomplish maximum corporation. This ultimately resulted in a positive response from, and thus interviews with, 11 people involved in the CRS project. All different parties were represented; pharmacies, IT departments and the manufacturers of the CDSS. There are some guidelines for interviewing provided by [BMF10], which have been taken into account. The interviews have been recorded (for which first permission has been asked) and the minutes of the interview are fed back to the interviewees. All interviews were held on the basis of an in advance drawn up question list, which covered all perspectives of the HCBN framework. This list was generally the same for all interviewees, but was individually altered based on the occupation of the interviewee. The general question list has been appended to this report in Appendix A. The question lists were a guideline during the interviews in order to get all desired information, but the interviews were dynamic and allowed for side tracks. Furthermore, once a certain issue was encountered during an interview and a following interviewee was expected to have some additional insights into this issue, he or she was asked about this.

### 2.2.4. Validation

As described in sec. 2.2.3, the minutes of the interviews were reported back to the interviewees. This was done to ensure that all information was recorded correctly and it also gave the interviewees an opportunity to indicate whether some information was to be treated with confidentiality.

The network, process and architecture models that were produced within the framework-based analysis, were offered to A.T. Wasylewicz for validation. He was chosen for this due to his central role in the CRS project. Furthermore, the architecture model of the CWZ situation was reviewed by an IT specialist from that location.

### **2.2.5. Problem Identification and Poll Based Ranking**

During the interviews, certain problems concerning the current CRS project arose. All problems that were encountered were marked within the minutes and collected in a list. This list originally contained 36 stated issues (literal duplicate mentionings are not taken into this number) and was brought back to a list of 20 problems by grouping certain problems that covered the same area. Once the list was compiled, a ranking of the perceived importance of the problems by the interviewees was sought. Every participant was asked to judge all problems on a scale from 1-10. After the collection of data, the problem list ranked on perceived importance was compiled and is presented in chapter 4.

### **2.2.6. Focus Group Session**

The problem list ranked on perceived importance was discussed within a focus group, consisting of dr. P.M.E. Van Gorp, dr. R.J.E. Grouls and A.T. Wasylewicz. During this meeting, it was discussed which problems were expected, which were surprising and what role the CRS project plan played in the arising of the problems. The results of the meeting can be found in sec. 4.2.2.

### **2.2.7. Conceptual Redesign Proposal**

The final stage of the project concerned the design of a possible solution to one of the encountered problems in the form of an adjustment to the architecture surrounding the CDSS. The problem that was selected for this purpose was on the subject of standardization of clinical data. The reasoning behind this choice is explained in sec. 4.2. The expert opinion of dr. William T.F. Goossen on this subject was consulted and based on this and additional literature a conceptual design proposal has been made. The results of this part of the research can be found in chapter 5.

## 3. Framework-based Analysis

As described in chapter 2, an adjusted BOAT framework is filled with information which was gained during interviews, from own experiences with the CDSS and from manuals available at the hospitals. Before the different aspects can be discussed, the parties involved in the CRS project have to be briefly described, which is done in sec. 3.1. Thereafter, the business, network, process and technology perspectives are described in sec. 3.2, sec. 3.3, sec. 3.4 and sec. 3.5 respectively.

### 3.1. Parties Involved

Different parties can be identified within the CRS project and the way these parties act within this project is described in the different perspectives. The parties that were encountered (and shown in Fig. 3.1) are:

**Boards of Directors (Santeon Hospitals)** The Boards of Directors of the Santeon hospitals are responsible for the whole business of the hospitals and ultimately decide on the future of the project by allocating funding.

**Head of Research (CZE)** The head of research (and thus also head of the project pharmacists) at the CZE pharmacy is responsible for all ongoing research projects of which this CRS project is one.

**Project Pharmacists (CZE)** Project pharmacists of the CZE concern themselves with the execution of different research projects within the pharmacy.

**Hospital Pharmacists (CZE)** The hospital pharmacists of the CZE are mainly busy with the general daily activities of the pharmacy.

**Clinical Pharmacy (CWZ)** At the CWZ, there is no clear distinction between project and hospital pharmacists as there is at the CZE. The pharmacists at the CWZ combine both tasks and thus no distinction was made.

**End Users (CZE and CWZ)** End users are the people that ultimately act on the advice that an alert of a CR gives. Examples of end users are pharmacy assistants or hospital pharmacists themselves.

**Functional Application Manager (CWZ)** A functional application manager manages, as the name suggests, the applications (such as a CDSS) that are used by the pharmacy. The functional application manager is an integral part of the pharmaceutical team.

**IT Departments (CZE and CWZ)** The IT departments at each location provide the support for the general (data) infrastructure.

**CDSS Supplier** The CDSS for this CRS project, Gaston, is developed and supplied by Medecs B.V.

**IS Supplier** Different information systems are in use at the hospitals and the IS suppliers are those companies that developed and supplied them to the hospitals.

## 3.2. Business Perspective

The business aspect of the adjusted BOAT framework describes the goals a party has. Furthermore, it is analyzed whether these goals come with some key performance indicators and how these indicators are measured. Within this perspective it is investigated as well which formal agreements between parties within CRS project exist. These agreements might be available in some form of a service level agreement or be non existent entirely.

Only the business perspective from the directly interviewed parties are given in this section, since it otherwise would be based on speculation. The discussed parties are the project pharmacists of the CZE, the clinical pharmacists of the CWZ, the IT departments and the CDSS supplier. The application manager of the CWZ was interviewed, but could not give any business goals (other than providing the best possible care) and key performance indicators.

The encountered business goals and key performance indicators are given in sec. 3.2.1 and sec. 3.2.3 respectively. An analysis on the differences of the business goals of the CRS project parties, and thus the motivators or demotivators for collaboration, are given in sec. 3.2.2.

### 3.2.1. Business Goals

All parties involved in the CRS project indicated a common business goal: providing the best possible care for the patient. However, this is a very general goal which could have different interpretations in terms of execution and thus this common goal is no guarantee in itself for corporation. Therefore, the individual business goals that were encountered are mentioned in this section as well.

#### Project Pharmacists (CZE)

The CRS project originated from the CZE pharmacy of which the project pharmacists are the executing party when it comes to research projects. The goals of the CRS project are defined in the CRS project plan as:



The goal of this research is the evaluation of the implementation and cost effectiveness of CRs within a CDSS in a Santeon collaboration.

Effective drug usage and enhanced drug safety are contemplated. This could eventually lead to shorter hospital stays, lower morbidity and a reduction in the amount of complications.

The head of the project pharmacists indicated that patient safety is the primary goal, where financial benefits are always a secondary goal within conducted projects, like the CRS project.

### **Clinical Pharmacy (CWZ)**

The clinical pharmacy of the CWZ uses the CRS project to meet certain CR implementation criteria opposed by the Dutch Healthcare Authority, whilst in the mean time gaining some experience with the use of CDSSs. In the long run they expect to be using the integrated CDSS provided by the upcoming HIS supplier of the CWZ; Epic. Cost reduction is always a secondary business goal.

### **IT Departments (CZE and CWZ)**

As indicated, The IT departments at each location provide the support for the general (data) infrastructure. The CRS project makes use of this infrastructure. This however, is a relatively small project compared to the rest of the responsibilities of the IT departments. Priority is given to primary processes like electronic prescription. The goal of the IT departments is to provide a working infrastructure and applications for hospital staff to use.

### **CDSS Supplier**

Supporting pharmacies with their CDSS has become one of their focal points since they discovered a niche in the market. Eventually they would like to offer the developed CRs as standard content of their product. The main goal is patient safety, but market expansion (and thus an increasing turnover) is a business goal as well.

### **3.2.2. Motivators and demotivators**

In the previous section, 6 business goals have been identified which can be summarized by the following list:

1. Patient well-being
2. Cost reduction
- 3 Turnover
4. CDSS experience
5. Conform to external criteria
6. Provide infrastructure

The different parties and which of the 6 business goals they have, are shown in Tab. 3.1. The patient well-being (goal #1) is the most common business goal and was only not explicitly mentioned by the IT departments. This business goal is the biggest motivator for close collaboration within the CRS project. Another motivator is the shared interest of the project pharmacists (CZE) and clinical pharmacy (CWZ) in the reduction of costs (goal #2). The individual goal of the CDSS supplier (goal #3) is a motivator for good support of the CRS project, since a successful project has the potential of bringing in more customers. The IT departments should already be properly motivated since supporting applications like the CDSS is part of their business goal (goal #6). However, the CRS project does not get priority as previously mentioned in sec. 3.2.1. Using the CDSS for conforming to external criteria (goal #5), such as the CWZ clinical pharmacy does, is conflicting with the original CRS project plan (and thus the business goals of the CZE project pharmacists). Using the developed CRs as such is, according to the CRS project plan, premature. The individual goal of the CWZ clinical pharmacy to gain experience with the use of CDSSs (goal #4), could be a demotivator if ultimately they intent to use another CDSS (integrated within the upcoming HIS by Epic).

	1	2	3	4	5	6
Project Pharmacists (CZE)	X	X				
Clinical Pharmacy (CWZ)	X	X		X	X	
IT Departments (CZE & CWZ)						X
CDSS Supplier	X		X			

**Table 3.1.:** Business goals of CRS project parties

### 3.2.3. Key Performance Indicators

A key performance indicator is an indicator which makes it possible to check whether a business goal is met. The encountered key performance indicators are listed below. Only the parties of whom a business goal was stated in sec. 3.2.1 are taken into account.

#### Project Pharmacists CZE

Sometimes the influence of an implemented CR can be measured. An example is the implementation of the opiate-laxative CR, which resulted in a measurable decrease in constipation among patients.

The primary check on the usage of the CRs is to see whether end-users act according to the rules. If substantial deviations are found, they can be acted upon.

Furthermore, regular subjective evaluations take place, for which no performance indicators are used.

#### **Clinical Pharmacy CWZ**

The clinical pharmacy of the CWZ indicated that some external assessment tools act as performance indicators, such as the aforementioned CR implementation criteria of the Dutch Healthcare Authority. This CR implementation criteria entails a demand of 11 predetermined CRs being in use.

#### **IT Departments**

The IT departments at both locations have no key performance indicators in place for the CRS project. This is due to the fact that the CRS project did not enter the department in the usual manner. Instead, the CRS project entered as a simple server request and subsequent requests for change. The CRS project has therefore never been subjected to performance evaluations at the IT departments.

#### **CDSS Supplier**

The CDSS supplier has no key performance indicators in place.

#### **3.2.4. Service Level Agreements**

Specific and official Service Level Agreements on the CRS project are found to be mostly absent. There is a formal research proposal, but the task descriptions and responsibilities that can be found in there are quite general.

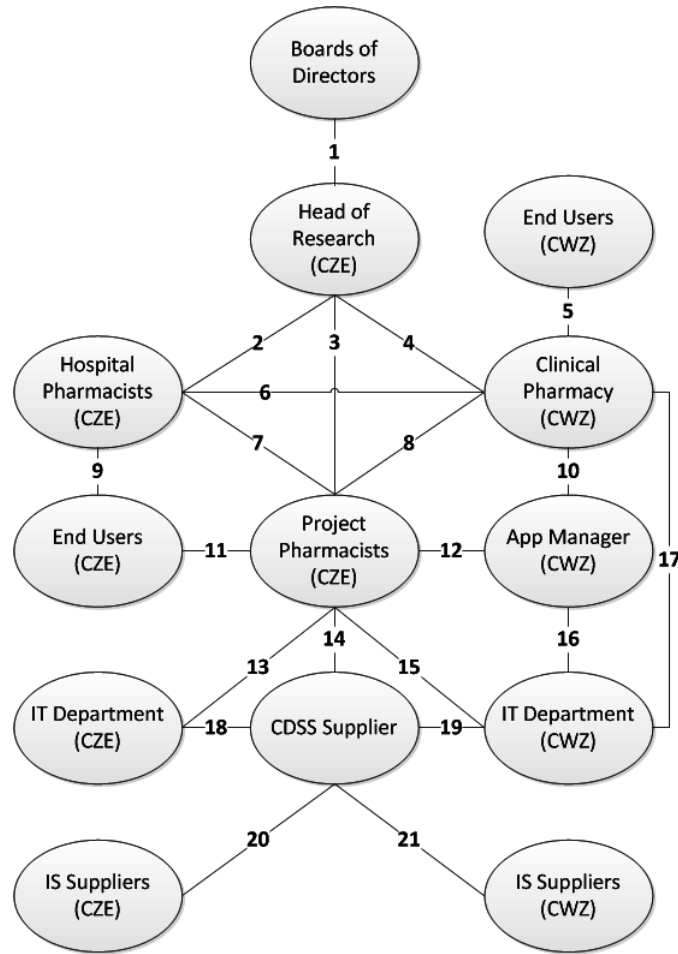
One exception is found between the CDSS supplier and its customers. Legal responsibilities are present within the agreements that are signed upon the purchase of the product.

### **3.3. Network Perspective**

The network perspective, which is given in this section, provides an insight on how the different parties that collaborate on the CRS project are connected.

#### **3.3.1. Network Description**

In Fig. 3.1, each party involved in the CRS project of the CZE and CWZ locations is depicted along with connections which indicate some sort of communication takes place. Each link in the figure has a number and is explained hereafter:



**Figure 3.1.:** Network diagram of the CRS project

- 1** The head of research at the CZE, the official project leader, reports directly to the Boards of Directors of the involved Santeon hospitals. In these meetings, the progress of the CRS project is discussed and difficulties are submitted. In about a year from now, an evaluation will take place of the CRS project, after which the Boards of Directors will decide if the CRS project will be continued.
- 2, 3, 4, 6, 7 & 8** All these connections between the head of research and all pharmacy parties primarily take place in a monthly telephone meeting. Within this meeting the progress of the CRS project, the content of CRs and technical issues regarding the CRs are discussed. More ad-hoc communication between these meetings is always an option.
- 5, 9 & 11** Once a CR is put in place, the end-users like pharmacy assistants need to be instructed on how to handle the alerts given by the CRs. This is done by various members of the pharmacy departments. In Fig. 3.1 the pharmacists at the CZE have been split up, but in this case they act as one group and thus two connections are made. Hospital pharmacists also act as end-users themselves

in the CZE situation. The instruction is given once a CR is introduced of seriously altered during a group meeting. End-users in their turn provide feedback on the CRs by categorizing the given alerts as depicted in Fig. B.6.

- 10** The functional application manager at the CWZ is an integral part of the clinical pharmacy and thus collaborates very ad-hoc with them on the CRS project.
- 12** The project pharmacists of the CZE and functional application manager of the CWZ have mainly worked together in the beginning of the CRS project in order to design the queries necessary for importing data from the IS in use at the CWZ. This collaboration was personal contact and since then if communication is required this happens when needed via telephone.
- 13, 14, 15, 17, 18 & 19** All these connections are about the technical implementation of the CDSS Gaston and feeding it the proper data from the ISs in use at the hospitals. Communications with the IT departments usually concerns sever access or setting up a different server environment. Contacts with the CDSS supplier often involve the actual installation of Gaston to the hospital servers and linking it to the ISs. The pharmacists usually act as mediator or are the requesting (e.g. an extra server environment) party. None of these communications is reported to be structured and they seem to be based on the needs of the moment.
- 20 & 21** Although very sporadic, sometimes the CDSS supplier contacts the IS supplier of the system from the hospital in question directly to connect the CDSS properly.

#### 3.3.2. Network Features

The network depicted in Fig. 3.1 can be further described with some features that it possesses, which provide some additional insights. These features and their description are given here.

**Dedicated-purpose network** It is a dedicated-purpose network, since the network exists specifically and solely for this CRS project.

**Peer-to-peer** All parties involved (with the exception of the boards of directors and arbitrary the project leader) collaborate on the same level. Control is shared and not imposed by one party. They also share the same interest of patient welfare as described in sec. 3.2.1.

**Choreography** This network can be described as a choreography, meaning that the CRS project is coordinated between the involved parties and not controlled by an explicit coordinator. The project pharmacists seem to be most central party and might be seen as an explicit coordinator, but they do not have enough authority over all parties to be actually seen as such. This makes the network flexible, but maybe not so dependable as we will come across in chapter 4.

**Informal** An informal approach is predominant within the network. With the exception of the monthly Santeon meeting, most meetings are ad-hoc. The communication is also mostly done by telephone or e-mail, two informal means of communication.

**Static** The parties within the network do not change during the CRS project and the network exists as long as the project does. the network can therefore be classified as being static.

## 3.4. Process Perspective

In this section, an insight will be provided into the current process of developing and using CRs within the CRS project. Process models have been developed for this purpose using Business Process Model and Notation 2.0 (BPMN). BPMN does as the name suggests, provide a graphical representation for specifying business processes within models and is developed and maintained by the Object Management Group [Obj14]. It is chosen for being a standard at high-level business process design [ZMR08], being easy to understand [CT12] and being used before by [Sun13] so previously built models could be re-used.

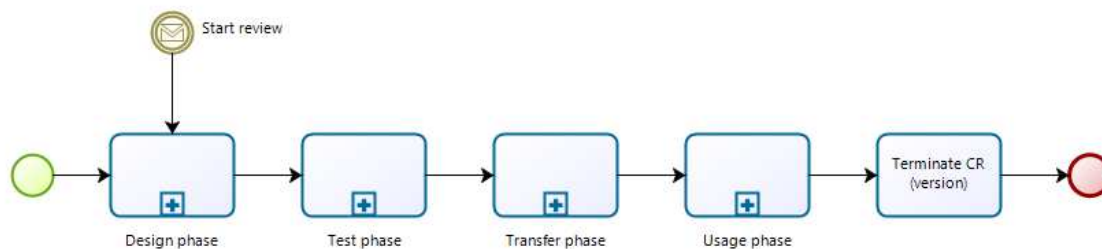
The high level process a CR goes through is shown in Fig.3.2. This model and most of its sub-processes have been adopted from [Sun13]. The situation in the CRS project being discussed here and the situation at the CZE spoken of in [Sun13] (where CRs also are developed at the CZE pharmacy, but subsequently are only used within the CZE pharmacy and are not shared) are very similar. This is not surprising, since the CRS project originated from the CZE. For this reason, only the sub-processes "Design phase" and "Transfer phase" are discussed in this section, since these are the processes that are different from the original model. The whole CR process can still be found in Appendix B.

The built process models are all based on the interviews that were held, as described in sec. 2.2.2 and validated as discussed in sec. 2.2.4.

The high level CR process shown in Fig.3.2 starts with an idea for a new clinical rule, a scheduled periodical review of an existing one or a desired transfer to another hospital. The CR then goes through the design, test, transfer and usage phases until the CR version is terminated. It should be noted that the whole process can be interrupted if it is decided that a certain CR became obsolete.

### 3.4.1. Design Phase

The design phase is a sub-process of the high level CR process and is shown in Fig. 3.3. The design phase is started, as indicated before, with an idea for a new clinical rule, a scheduled periodical review of an existing one or a desired transfer



**Figure 3.2.:** High level CR process

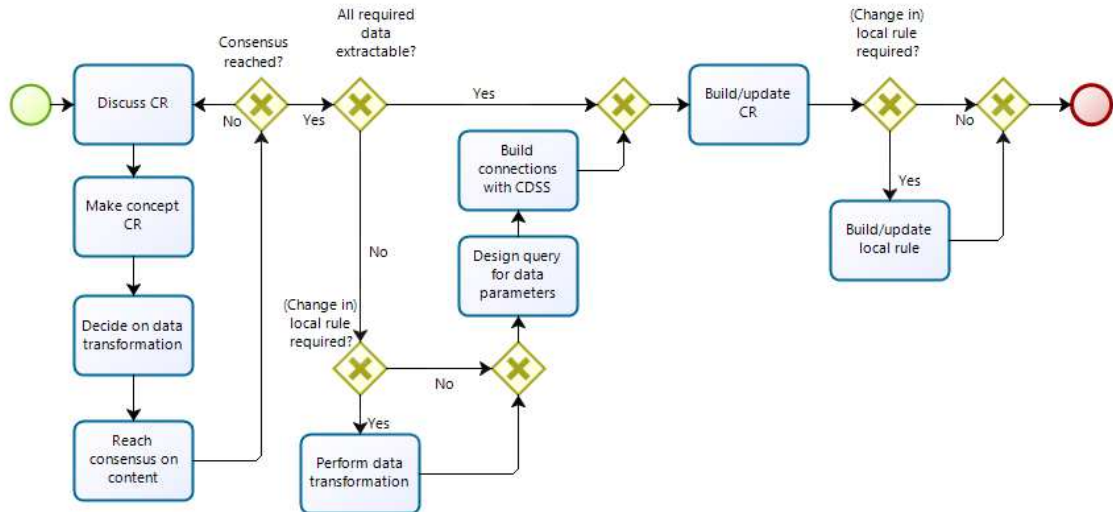
to another hospital. During a periodical review the problems that were encountered with the CR are discussed and the CR is completely checked, justifying usage of the same steps in the process as for a new CR.

Once the process is started, a discussion between the Santeon members is held in order to determine which CRs are selected to be developed for the different hospitals. This is done in the monthly telephone meeting, in which two members of each location (CZE, CWZ and MST) are present. After selection of the CRs, concepts are made on paper by a project pharmacists of the CZE based on already existing CRs of the CZE and additional literature reviews. Its is checked whether there are data transformations needed, based on a comparison of the available data in the HIS and the desired information for the CR. If there are required transformations, a local support rule (which is hospital specific) is required, on which more can be found in sec. 3.5.3. At this stage it is decided how those local support rules should be designed. Subsequently, the concept is discussed within the monthly Santeon meeting and consensus has to be reached on the contents.

If consensus is reached and thus the content of a CR is determined, the technical part can begin, starting with a check on whether all data required for a CR is extractable from the ISs in use at the different hospitals. If it was decided that data transformations are needed, those are done subsequently. If not all required connections to the IS have been made yet, doing so is the next step. Queries to retrieve the data are designed by a project pharmacist and functional application manager. Building the actual connections is done by an employee of the manufacturer of Gaston, Medecs B.V. Once all data is available for the CDSS, the CR and optional local support rules are built by the project pharmacists of the CZE.

### 3.4.2. Transfer Phase

The transfer phase is a sub-process of the high level CR process and is shown in Fig. 3.4. After the CR is tested at the CZE, it is transferred to the CWZ. It starts by zipping the CR, placing it at a site called Lighthouse which is a service (a file



**Figure 3.3.:** CR Process - Design phase

storage server and forum through which support can be sought) from Medecs B.V. and unpacking it at the CWZ server environment.

If the CR is an update from an earlier version, a back/up is first created. The CR is deployed at the CWZ environment with an automated tool. This deployment however, erases the previous general part (the distinction between the general part and the local support is described in sec. 3.5.3) of a CR and installs the update from scratch. Due to a future from Gaston that assigns codes (which are used internal within Gaston to identify elements) randomly to elements, this changes the codes that identify the alerts. This change compromises the traceability of the alert history for a patient, a key feature of the CDSS. Therefore, the codes have to be manually reassigned, which can take up to 4 hours if no errors are made. Next, the local support rule is updated. Updates are not subjected to further testing after this and the CR is brought in to use.

If the CR in question is not an update, but a new build, the local support rule has to be build and manually coupled to the general rule. A technical validation takes place after the deployment. If this validation is satisfactory, the new CR is brought into limited use for further validation (shown in Fig. B.5).

The final step in the transfer phase is to decide whether certain patient groups are excluded from the CR. This decision is made by medical specialists, such as clinical pharmacists, of the hospital in question (in this case the CWZ). If it is decided that certain patients are excluded, this exclusion is implemented and the CR goes through another technical validation. The CR finally continues to the usage phase.



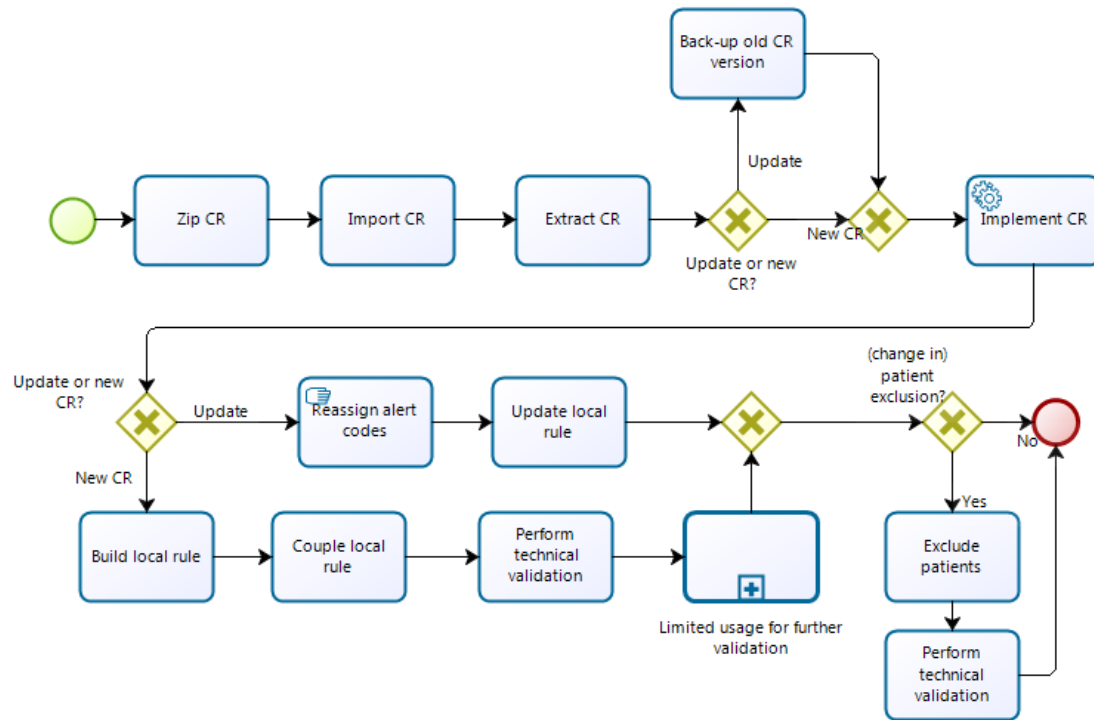


Figure 3.4.: CR Process - Transfer phase

## 3.5. Technology Perspective

For the technological description of this case study, both the CDSS Gaston, with which the clinical rules are developed and run, and the system architecture surrounding this CDSS at both locations (CZE and CWZ) will be discussed.

### 3.5.1. Gaston

Gaston is a CDSS developed by Medecs B.V. [Med]. It is a collection of software modules with which it is possible to design clinical rules and implement these. Gaston provides caregivers with advice and warning based on a patient's records within an information system such as an Electronic Health Record. Gaston uses a decision tree structure that is displayed in the Guideline Interchange Format (GLIF) that contains several decision nodes. Gaston is comprised of three components [Apo12]:

**Gaston Editor** The editor is the environment where the clinical rules are build, changed and tested.

**Gaston Tool (Gaston Manager)** This tool is used to display the alerts and works in a similar manner as an e-mail inbox. It also stores the alerts, due to which the alert history of a patient and the way these alerst were handled is known.

This is considered to be one of the main strong points of the CDSS by the users.

**Gaston DSS** This execution engine is the core of Gaston, it takes the patient records through the clinical rules that were build in the editor and ensures that the results are displayed by the tool.

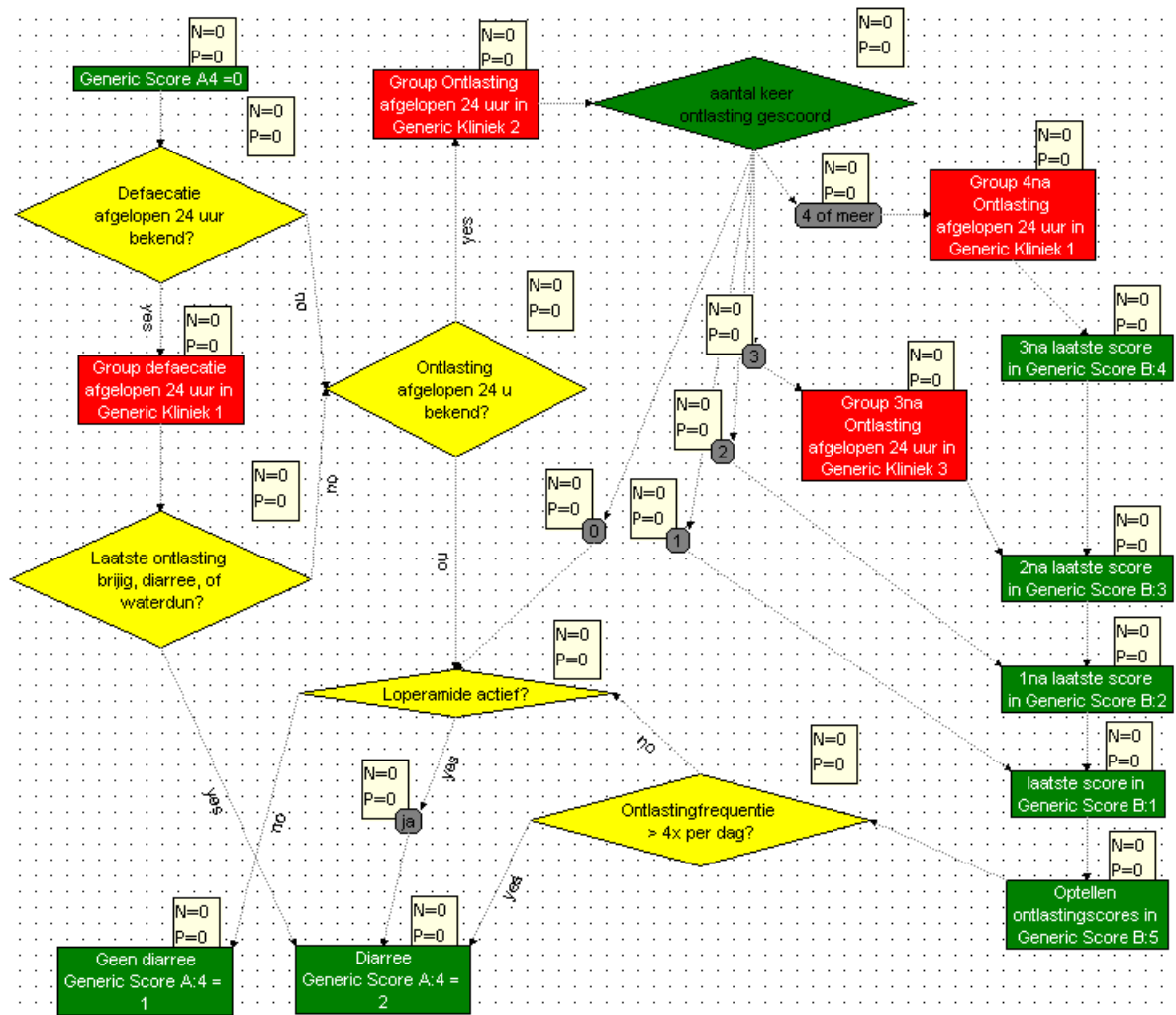
A real life example of a clinical rule modeled in Gaston is shown in Fig. 3.5. This example is the local rule, in use at the CZE, in order to determine whether a patient suffers from diarrhea and is a part of the opiate laxative clinical rule. A quick walk-through of the clinical rule is given below:

The opiate laxative rule uses the Generic Score A4 for diarrhea. When that score is 0 its is unknown whether the patient has diarrhea or not and this is also the starting point of the local rule. At the end of the local rule, either the number 1 or 2 is assigned to the Generic Score A4, meaning having no diarrhea or having diarrhea respectively. The local rule first checks if the sort of defecation the past 24 hours of a patient is known. This decision point is linked to a, down list based, entry done by a nurse in the EHR. If the defecation is known and one of the three possible entries describing diarrhea is found ("brijig", "diarree" or "waterdun"), the Generic Score A4 is set to 2, otherwise the decision tree continues. The next step, if reached, is to check whether the number of times a patient has had defecation the past 24 hours is known. If so, and the score is higher than 4, it is concluded that the patient suffers from diarrhea and the generic Score A4 is set to 2. If the times of defecation is 4 or less, or not known at all, it is checked if the patient receives Loperamide (a known drug against diarrhea), based on ATC and GPK codes. If positive, the generic Score A4 is set on 2 and otherwise on 1. The red and green building blocks within the rule are there to ensure the proper data is retrieved (e.g. only data from the past 24 hours) and are used as calculators.

As shown in Fig. 3.5, different building blocks are used within Gaston with which the clinical rules can be modeled. Fig. 3.6 shows a legend as it is shown in Gaston for these different building blocks. Combining these sorts of elements in a decision tree allows for a great variety of clinical rules to be modeled.

### 3.5.2. Architecture Surrounding the CDSS

Gaston is implemented in several hospitals, general practices and other institutions in the Netherlands and is being used daily. All these institutions use their own information systems to which Gaston has to be linked. for this particular case study, this situation has been schematically depicted in Fig. 3.7 for the CZE and in Fig. 3.8 for the CWZ.

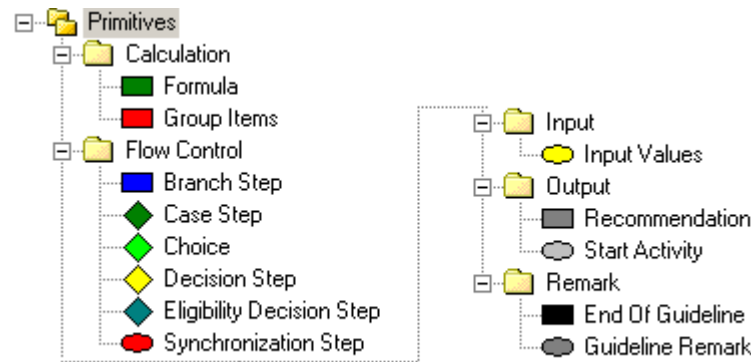


**Figure 3.5.:** Local clinical rule for determination of diarrhea (CZE)

**CZE**

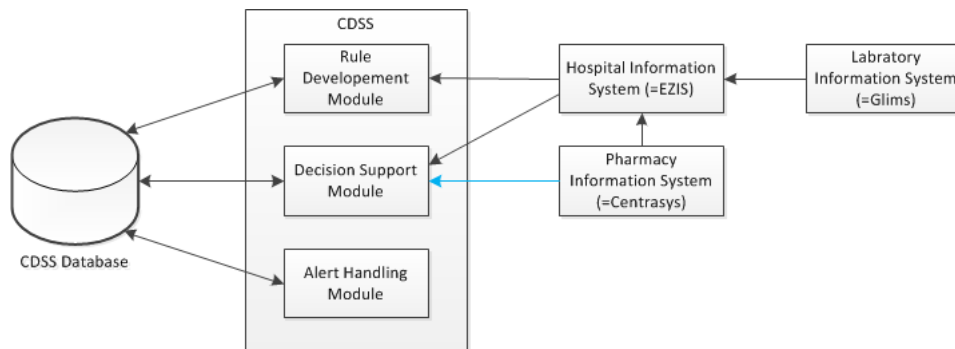
This hospital uses the information system called EZIS (Elektronisch Zorg Informatie Systeem), in which all available data on patients is stored. All information is stored on a SQL server where everything is organized in separate sheets, columns and rows. Each field in EZIS is a separate column on the server and each tab and sub tab in EZIS is a link and collection from different sheets and columns from the server [Apo12]. The connections from the CDSS to the HIS are in the form of queries through which certain data is called upon. In order to be able to make such queries, an Open Database Connectivity (ODBC) connection is required.

As can be seen in Fig. 3.7, The Gaston Editor and DSS are both connected to the Hospital Information System (HIS) EZIS. The CDSS requires these connections to know which information is available for modeling clinical rules (Editor) and to access



**Figure 3.6.:** Legend of Gaston building blocks

the patient information with which the clinical rules are run (DSS). EZIS in its turn gets its information from manual input by medical personnel and by HL7 messages from the pharmacy information system Centrasys and the laboratory information system GLIMS. The blue arrow depicts the situation in which extramural patients, who are only registered in Centrasys, are run through the clinical rules. In that case, Gaston gets its information directly from Centrasys, but the used clinical rules are still the same and thus no connection to the editor is required. The three Gaston components are all connected to a dedicated server, to which Gaston imports the gathered data from EZIS, from which it uses this data to run the clinical rules and to which it writes the results from a run clinical rule. These results can in their turn be read and edited again by the Gaston Tool component.

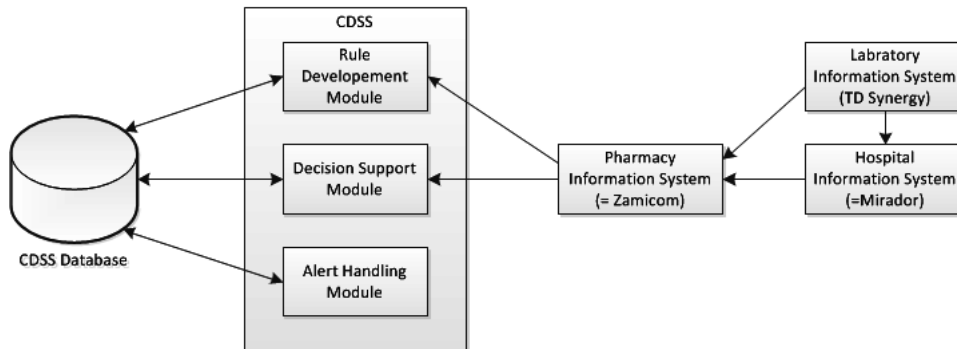


**Figure 3.7.:** Systems linked to the CDSS Gaston at the CZE

## CWZ

The connections between different information systems at the CWZ are shown in Fig. 3.8. The main difference in comparison to the CZE situation is the more centralized role of the pharmacy information system. It acts as the mediator between

all other systems and the CDSS and gets its information from manual input and HL7 messages from the HIS and laboratory information system. The information systems in use are also different from those in use at the CZE. The CWZ uses Mirador, Zamicom and TD Synergy as their HIS and for their pharmacy and laboratory respectively.



**Figure 3.8.:** Systems linked to the CDSS Gaston at the CWZ

#### 3.5.3. Master and Local Support Rules

The concept of a local support rule already came up in the previous process perspective, but is in need of some more elaboration, which will be given with the use of an example. The local clinical rule for determination of diarrhea is shown in Fig. 3.5 and is build for the CZE location. It is a sub process of the general opiate laxative CR and this hierarchical structure is discussed further in sec. 3.5.4. This general CR (which is also referred to as master rule) is a big and complex CR that is build with building block of standardized drug information which is available at every Dutch hospital. to let the CR be more effective however, some additional information about the patient is required, like whether he suffers from diarrhea or not. No national consensus exists on the concept of diarrhea and different hospitals have different workflows on the determination of this. Add the different ISs in use which have different ways of denoting this concept and you get a severe difference in available data at every hospital. To still be able to use such unstandardized information, local support rules are put in place. Eventually you end up with a general CR which is the same for every hospital, which contains some small sub-processes that are specifically build for each location.

#### 3.5.4. Hierarchical Structure of CRs

The CRs that are deployed at the different hospitals (in this case the CZE and CWZ) are put in multiple layers within a hierarchy. This hierarchical structure is schematically shown in Fig. 3.9 and the green rectangles show how the previously

mentioned local diarrhea support rule of Fig. 3.5 is placed within this structure. Four layers are found to be present and they are explained below:

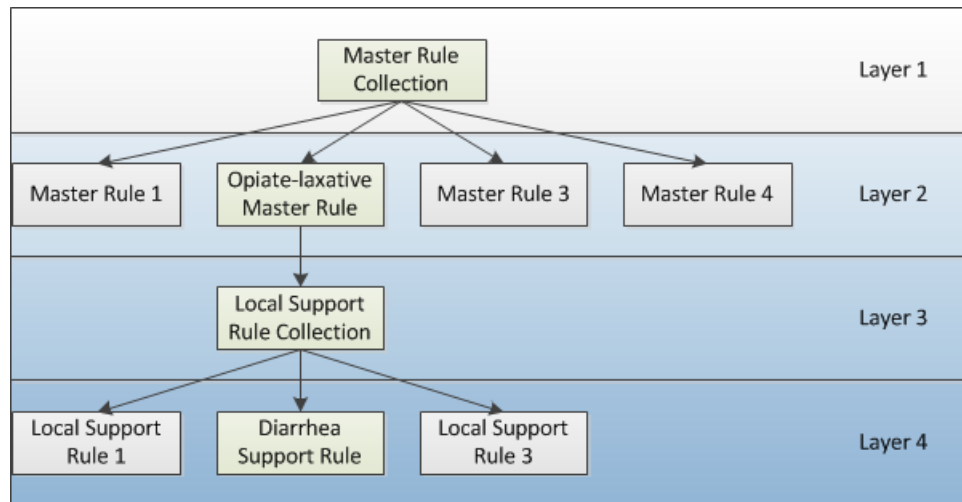
**Layer 1** The top layer contains the starting point of the CRs and all CRs in place are shown in this layer as sub-processes. A screen-shot of this situation at a CZE setting is shown in sec. C.

**Layer 2** When a master rule, a sub-process of layer 1, is opened, one arrives at the second layer. This second layer consists of a master rule like the opiate-laxative CR. A part of this opiate-laxative CR is shown in sec. C.

**Layer 3** Embedded within a master rule, layer 2, is a collection of local support rules. The local support rules are hospital specific and are shown in layer 3 as sub-processes. This layer 3 of the opiate-laxative rule can be found in sec. C.

**Layer 4** The final layer, layer 4, consists of an actual local support rule. An example of such a local support rule is that of Fig. 3.5, where the local support rule for the determination of diarrhea is depicted.

As indicated before, the master rules are general and thus identical for each hospital, but the local support rules that are embedded within these rules are hospital specific.



**Figure 3.9.:** Hierarchical structure of the opiate-laxative CR

## 4. Problem Identification

During the interviews, certain problems concerning the current CRS project arose. All problems that were encountered were marked within the minutes and collected in a list. This list originally contained 36 stated issues (literal duplicate mentionings are not taken into this number) and was brought back to a list of 20 problems by grouping certain problems that covered the same area.

All found issues are listed and described in a publically unavailable version of this report, which is only to be used for internal purposes. A ranking based on the preceived importance of the problems is given in sec.4.1 and a discussion of these problems is held in sec.4.2.

### 4.1. Problem Ranking

The identified problem list of ?? was fed back to the people involved in the CRS project (the same people who were asked for an interview). They were asked to judge the importance of each problem with a number from 1 to 10. With the gathered responses a ranking based on perceived importance of the problems could be created. The results can be found in Tab.4.1. It shows the rank of the problem, the description, the average value awarded and the percentage of respondents that actually assigned a value to the particular problem (they were allowed to leave blanks if the problem was not familiar). Overall, 9 people judged the importance of the problems.

### 4.2. Discussion of the Problems

An analysis of the problem list that was created is held in sec.4.2.1 and a discussion on a focus group session (concerning the ranked problem list) is given in sec.4.2.2.

#### 4.2.1. Analysis

The list as shown in Tab.4.1 can be used in order to improve the CRS project in the future. It shows that the most problems, and also the top ranked ones, are in the organizational setting of the CRS project. Of the 20 problems, between 11

and 13 (rank 11 and 12 are on the edge) can be counted to be within this setting. Problems ranked 4 and 15 are very specific and are already being resolved as this report is being written. Combining the organizational issues, removing the already being solved ones and removing the problems that don't score a passing grade ( $\geq 5.5$ ) a reduced list has been compiled and can be seen in Tab. 4.2.

This reduced list represents the issues that need working on and one is selected to be further discussed in the next chapter. The problems in the organizational setting are very important, but this MSc. thesis will focus on the technical aspect as indicated in chapter 2. Separated server environments are important and are also perceived as such by the respondents, but this is something that just needs to be done and no research can provide additional insights. This leaves problems 3 and 4 from Tab. 4.2 and number 4 (Difference in recorded medical data) is selected due to the interest that was shown in standardizing clinical terms (a possible solution direction to this specific issue) during several interviews.

#### 4.2.2. Focus group session

At September 15, 2014, a meeting was held with the dr. P.M.E. Van Gorp (first supervisor of this MSc project), dr. R.J.E. Grouls (CRS project leader) and A.T. Wasylewicz (key CRS project member) in order to get some feedback on the ranked list of problems as shown in Tab. 4.1. It was indicated by them that some organizational issues were expected, since the CRS project is a pilot study. Some examples are problems ranked 7 and 17. The workflow descriptions are even meant to be deliverables halfway through the project and as indicated they are being written at the time of writing of this MSc thesis. The unclarity of responsibilities and the lack of a clear project manager was countered with the argument that these were defined within the CRS project plan, which can be found in Appendix E. However, when looking into this project plan, the task descriptions are found to be too general. Furthermore, the support of the IT departments is defined in the plan as a precondition, but it is not defined if and how their support is being secured.

During this session, it was also discussed that the CRS project is a pilot project which evaluates the implementation of CRs and their cost effectiveness (as stated in the CRS projectplan which can be found in Appendix E). However, the CWZ clinical pharmacy considered the CRS project as an opportunity to conform to criteria regarding the implementation of CRs (opposed externally) as earlier described in sec. 3.2.1. This misalignment of goals has led to confusion and expectations that were not achieved.

In summary, the identified problems exist, but were to be partially expected due to the nature of the CRS project. They should however be considered if and when the CRS project is being taken to the next level. The framework-based analysis that has been done also gives incentive to give more specificity to project plans in the future. Furthermore, the goals of the involved parties should align.



Rank	Problem description	Avarage grade	Respons
1	Deficient communication between IT and domain specialists	8.3	89%
2	Lack of a clear project manager	7.7	100%
3	Unclear responsibilities	7.6	100%
4	Manual editing of alert codes	7.3	44%
5	Unseperated server environments	7.3	89%
6	Agreements are not always honored	7.2	67%
7	Heavy dependency on a single person	7.1	100%
8	Linking the CDSS to different HISs	7.0	89%
9	Improper introduction of project in IT department	6.4	89%
10	Unsupervised access	6.3	78%
11	Insufficient knowledge of the CDSS	6.3	44%
12	Programming of CRs falls behind on content development	6.0	56%
13	Difference in recorded medical data	5.8	100%
14	Low awareness of relevance	5.8	100%
15	Current version of Gaston only supports 65.000 elements	5.3	44%
16	Out of date data infrastructure at CWZ	5.2	56%
17	Missing workflow documentation	4.5	67%
18	Load of the CDSS on the HIS	4.0	78%
19	Instruction of end-user of CR is time consuming	3.2	67%
20	Planning of monthly phone meeting with project partners	3.0	78%

**Table 4.1.:** Ranking of identified problems within the CRS project, based on perceived importance

Rank	Problem description
1	Problems within the organizational setting
2	Unseperated server environments
3	Linking the CDSS to different HISs
4	Difference in recorded medical data

**Table 4.2.:** Reduced list of identified problems within the CRS project



## 5. Standardizing Clinical Terms

As indicated in the previous chapter, interest was shown by a couple of interviewees into the standardization of clinical terms. More specifically, the implementation of the terminology standard SNOMED CT into the CRs developed in the CRS project. The use of a terminology standard is seen as a possibility to reduce the amount of local support rules required, which were described in sec. 3.5.3, or in the long run even eliminate the need at all. Furthermore, standardizing the entire rule will result in easier communication concerning the CR, since no local terms (only familiar to local medical specialists) are used. According to the CRS project leader, this improved communication will become necessary if and when the CRS project is extended to more and more hospitals.

However, not much was known on the subject by the interviewees and some initial doubts were mentioned straight away. These initial doubts were on the content of SNOMED CT regarding situational information (e.g. intensive care unit and emergency department) and lifestyle concepts (e.g. smoking and diet). The former is already important within current CRs and the latter is a trend the CDSS supplier noticed. An initial search was done and these concepts seemed to be readily available. It was therefore chosen to continue on the subject and provide some initial insight into the matter. An interview was held with an expert in the field, dr. W.T.F. Goossen and a literature review was done to gain the required background knowledge on SNOMED CT. During the interview it became apparent that a good information model could not rely on just one terminology standard like SNOMED CT. Although SNOMED CT is very extensive, other terminologies offer more precision in certain fields, like LOINC does with laboratory results. Special identifiers can be used to differentiate between terminology standards in an information model. The gathered background information is given in this chapter. The identifiers spoken of are discussed in sec. 5.1. Two terminology standards, SNOMED CT and The G-Standaard, are described in sec. 5.2 and sec. 5.3 respectively.

Standardizing clinical terms within the CR and CDSS alone is not enough. The data within the information system of the hospital where the CRs are run needs to be linked to these standards, and thus needs to be translated. The data required for the general rule to run mostly concerns drugs and is already standardized with the help of the G-Standaard. The local support rules however need data which is up to now unstandardized (see sec. 3.5.3) and for this part a thesaurus is needed. This is further discussed in sec. 5.4. During the meeting with dr. W.T.F. Goossen, this subject was discussed as well and it was suggested that Detailed Clinical Models

might provide such a translation.

Once all background information was gained, two local support rules were used as examples to show how such a rule would be standardized. This is done in sec. 5.5. Finally, in sec. 5.6 the benefits of this standardization, the requirements and the challenges that still lie ahead are discussed.

## 5.1. Object Identifiers

When using multiple clinical terminology standards within an information system such as the CDSS Gaston, it is important to know which standards are being used for which data elements or clinical terms. To accomplish this, use can be made of Object Identifiers (OIDs). An OID is a globally unique identifier developed by the International Organization for Standardization (ISO) and the International Telegraph Union Telecommunication Standardization Sector (ITU-T) [Hea14]. It is used for naming any object, concept or "thing" with a globally unambiguous name which requires a persistent name (long life-time) [Ora14]. When an OID has been assigned to an object, it will always describe this object and will never be retracted.

Of course an OID is useless unless it is registered somewhere and can therefore always be linked to the object in question. This registration is decentralized and is done by a registration authority. This authority may assign an OID itself, or delegate it to another registration authority that works under its supervision. This way, a tree-like structure of registration authorities and their OIDs is created. One of these registration authorities is Health Level Seven (HL7) and they have chosen to represent OIDs using a form that consists only of numbers and dots (e.g., "2.16.840.1.113883.6.96" is the OID for SNOMED CT) [Hea14]. The far most left number depicts a root of the "registration authorities and their OIDs"-tree and the far most right number depicts a leaf.

As stated before, the OIDs are necessary in order to identify to which terminology standard a certain code belongs and therefore the OIDs of the clinical standards that are used and discussed in this chapter are listed in Tab. 5.1.

Clinical standard	OID
SNOMED CT	2.16.840.1.113883.6.96
LOINC	2.16.840.1.113883.6.1
WHO ATC	2.16.840.1.113883.6.73
G-Standaard GPK	2.16.840.1.113883.2.4.4.1

**Table 5.1.:** Some terminology standards and their OIDs

## 5.2. SNOMED CT

Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) is an international medical terminology standard that contains an assortment of 295.000 medical, scientifically validated, concepts and their synonyms. Concepts can among others be complaints, symptoms, circumstances, diseases, interventions, diagnoses, results and decisions [Nic12]. All concepts and synonyms are computer processable due to a unique code that is assigned to them, which allows for a structured manner of storing, using and exchanging medical data. SNOMED CT is managed by the International Health Terminology Standards Development Organisation (IHTSDO), an international non-profit organization of which 27 countries are currently member, among which The Netherlands [Int14a].

The main benefits of SNOMED CT, the reasons why this standard can contribute to the case of the CRS project, are listed by [CdK08] as:

- Enabling a consistent way of indexing, storing, retrieving and aggregating clinical data across specialties and sites of care.
- Enabling structuring and computerizing the medical record, thereby reducing the variability in the way data is captured, encoded and used for clinical care of patients and research.
- Enabling automated reasoning, e.g. decision support.

The way in which SNOMED CT provides these benefits is described below. In sec. 5.2.1 the internal structure of SNOMED CT is described, including the logical model on which the core content of the terminology is based and a manner in which to represent clinical phrases which can not be captured by a single concept. In sec. 5.2.2, the manner in which the content can be searched is explained and sec. 5.2.3 addresses the relation of SNOMED CT to other standards.

### 5.2.1. Structure

The content of SNOMED CT is represented with four core components; concepts, descriptions, relationships and reference sets [Int14c].

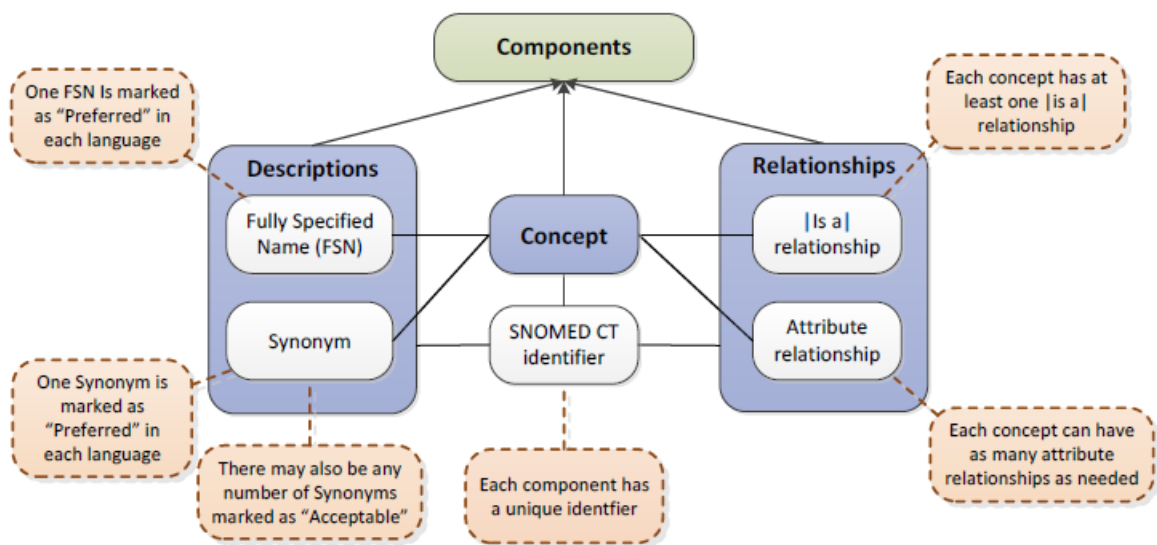
**Concepts** A concept represents a clinical thought and every concept has a unique numerical identifier attached to it. Concepts are placed within an hierarchy, starting from the most general concept to the most detailed. This allows for the use of a single concept with its code if in fact a certain subgroup is meant. SNOMED CT has multiple hierarchies and a concept can exist within more than one hierarchy.

**Descriptions** Descriptions are the synonyms of a unique concept. A concept can have multiple associated synonyms (including translations) and each synonym has a unique code of its own.

**Relationships** Relationships link concepts to each other which are somehow related. The most important relationship is the `|is a|` relationship, which is used extensively in the aforementioned hierarchy.

**Reference sets** Reference sets are used for customization purposes like language preferences and mappings to other coding systems. Every reference set also has its own unique code

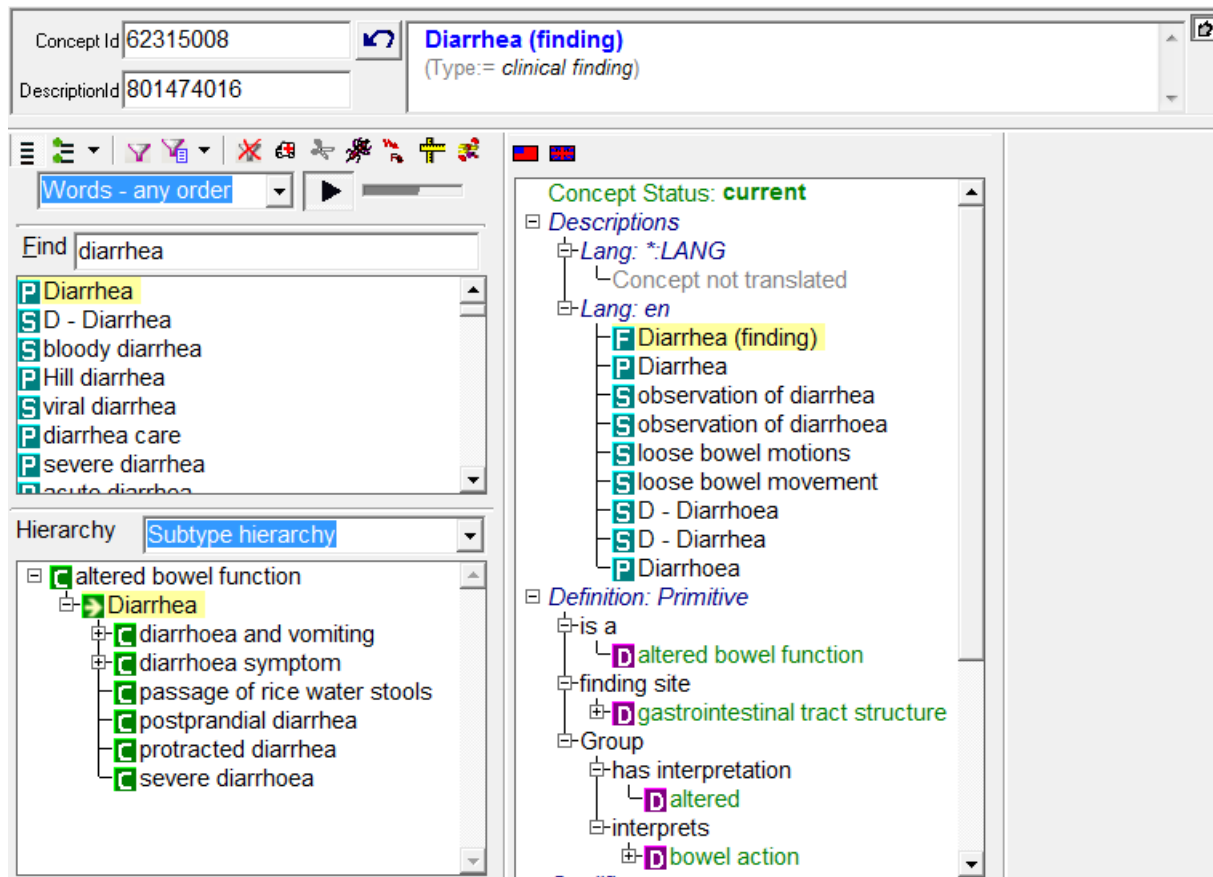
The way that these components are related to each other and represented is defined in the logical model. The logical model shows the fundamental structure of SNOMED CT and is shown in Fig. 5.1.



**Figure 5.1.:** Logical model of SNOMED CT [RHK14]

This logical model is elaborated with an example in Fig. 5.2. It shows how a concept, like diarrhea, is represented within SNOMED CT. The fully specified name is "Diarrhea (finding)", which is shown behind the F in a green block inside the right-bottom frame. The preferred synonym is "Diarrhea" (shown behind the P) and all other acceptable synonyms are shown behind an S in this same right-bottom frame. The concept has the identifier "62315008" and each synonym has its own description ID, which is linked to the concept ID. The bottom-right frame also shows the relationships that the concept of diarrhea has. As can be seen behind the purple blocks, diarrhea `|is a|` altered bowel function, the finding site is the gastrointestinal tract structure, it interprets a bowel action, etc. The hierarchy in which the concept is placed is shown in the bottom-left frame.

When a single concept (a pre-coordinated expression) can not capture a required clinical phrase sufficiently, SNOMED CT provides a mechanism that allows for the use of multiple concepts to be combined in a so called post-coordinated expression. There are several ways in which a post-coordinated expression can be created, but



**Figure 5.2.:** Concept of diarrhea in SNOMED CT, found with the CliniClue Xplore browser

for the sake of interoperability IHTSDO has specified a standard which is human-readable and computer processable. This standard can be found in [Int14c, RHK14]

### 5.2.2. Browsers

In order to actually find a concept, its relationships and all the unique codes related to the concept and its synonyms, a SNOMED CT browser is required. As of today, IHTSDO does not provide a complete and official browser of its own and users are therefore dependent on third party browsers. There are currently eight online browsers listed and seven offline versions which are all free to use (with only one exception)[Int14b]. All these browser differ from each other in some way, be it graphical representation or the support of certain (local) extensions. The choice for a certain browser ultimately comes down to personal preference [Dr. W.T.F. Goossen, personal communication, August 18, 2014]. In the examples that have been worked out for the CRS project, which are shown in sec. 5.5, use has been made

of CliniClue Xplore<sup>1</sup>. The example shown in Fig. 5.2, which shows the concept of diarrhea, is also a screen-shot of CliniClue Xplore.

### 5.2.3. Mappings to Other Standards

The clinical data at a healthcare organization that is encoded using SNOMED CT may include data that needs to be in a specific code system. The reasons for this can vary widely and some examples are billing claims, reports and statistical returns[RHK14]. Mapping of these specific code systems to SNOMED CT allows for these purposes while minimizing the need for additional manual data entry. SNOMED CT is seen as a common global reference terminology [RHK14], which eliminates the need for every code system in use to be mapped to every other code system. Instead, every code system only needs to be mapped once to SNOMED CT.

It is claimed that currently, SNOMED CT cross maps to other terminologies such as the International Classification of Diseases 10 (ICD-10), ICD-11 (in progress) and LOINC [Wik14b]. A meeting with an expert in the field revealed that this statement is true up to a certain point. For the most popular concepts the mappings will be there, but for the biggest part these mappings are still to be made [Dr. W.T.F. Goossen, personal communication, August 18, 2014]. This can also be done by an end-user as is described in [Int14c].

## 5.3. G-Standaard

Within this section, a description of the G-Standaard is given in sec. 5.3.1 and a discussion on the mapping of the G-Standaard to SNOMED CT in sec. 5.3.2.

### 5.3.1. G-Standaard Description

The G-Standaard is the Dutch pharmacy terminology standard and is therefore extensively used within the clinical rules developed by the pharmacy department of the CZE for the CRS project. It contains all health care products that are available from pharmacies and health care institutions such as drugs, medical tools and dressings. The G-Standaard describes medical product on three levels; generic, commercial product and prescription. the most important of these is the generic code called "generieke productcode" (GPK). The GPK is a code that links to all products with the same active ingredients, pharmaceutical shape, dosage and additional features. [Nic12].

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<sup>1</sup>CliniClue Xplore - <http://www.cliniclude.com/>



The G-Standaard also makes use of international terminology standards of which the Anatomical Chemical Therapeutical Classification (ATC) of the World Health Organization (WHO) is the most important one in this case, since it is also being used within the clinical rules in question in this thesis.

### 5.3.2. Mapping of the G-Standaard to SNOMED CT

In sec. 5.2.3 it is already discussed how SNOMED CT relates to certain other terminology standards. The G-Standaard can currently not be mapped to SNOMED CT, but work is in progress in that area. In October 2011, the following was written by the Royal Dutch Pharmacist's Association (KNMP) [RDPA11]:

At this moment, the Royal Dutch Association for the Advancement of Pharmacy is involved in a project to improve the structure of the pharmaceutical terminology of SNOMED CT. The proposed improved structure of SNOMED will fit nearly completely with the pharmaceutical level of the G-Standaard, so in future a mapping can be made.

Seeing as this publication was already three years old, an inquiry has been made into the current state of affairs. A representative of the KNMP responded that the KNMP has indeed delivered an improvement proposal, but the actual implementation by IHTSDO has not been done yet and so still no mapping between the two terminology standards exists [Leonora Grandia, personal communication, August 14, 2014].

## 5.4. Thesaurus

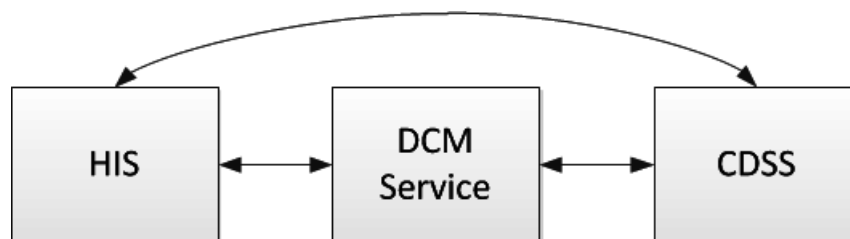
As described before, the idea is to implement the aforementioned standard SNOMED CT to the clinical rules developed by the CZE for the CRS project. This implementation will only be needed within the local rules since those are not standardized yet. However, these rules were made specific for each location for a reason. Hospitals all have their own EHRs and ways of working and entering patient data. The local rules will be standardized so each clinical rule is exactly the same for every location, but the diversity in data entry and availability will still exist. In order to overcome this, the translational part which in the current situation is done within the local rule, should be transferred outside the rule into an information model. This new component should act as a thesaurus, translating the hospital specific data into standardized SNOMED CT terms which will be used in the clinical rules. A possible solution may lie in the use of Detailed Clinical Models (DCMs) and a so called DCM Service, which will be described in sec. 5.4.1 and sec. 5.4.2 respectively.

### 5.4.1. Detailed Clinical Models

DCM organize health information via combining knowledge, data element specification, relationships between data elements, and terminology into standardized information models that allow deployment in different technical formats. A DCM is a relatively small, standalone information model designed to express a clinical concept in a standardized and reusable manner[GGBvdZ10]. The user interface, data storage and retrieval, the use of data for decision support, exchanging information through messaging and reports are all standardized[Sti08]. The storing of data in a DCM is based on unique codes from coding systems such as SNOMED CT, in order to standardize the storage of data. A proper DCM puts the concept that is modeled into medical context, has data elements that are specified extensionally and includes metadata, such as authorship, versioning and endorsement [Goo14]. A DCM provides the linkage to other medical data and can therefore be used as an intermediary information model between an EHR and CDSS. Some full examples of DCM can be found at [Nic14]. A partial DCM example is also shown in [Goo14]. It should be noted that DCMs are open source and not always of the quality one desires. In order to verify the quality of a DCM, a quality check has been developed by [AHKK13].

### 5.4.2. DCM Service

A DCM service is a web-based collection of DCM that is regularly updated. It is a service that links concepts that are used in a HIS to clinical terminology standards. The CDSS would get information from this DCM on how the required data for the CRs is structured within the HIS and would thereby be able to retrieve this information from the HIS. The placement of a DCM service is shown in Fig. 5.3. The DCM service only acts as an intermediary thesaurus and only data definitions are exchanged, not actual patient data. This allows a DCM service to be used by multiple hospitals, since patient data does not leave the hospital and thus privacy is not an issue.



**Figure 5.3.:** Systems surrounding a DCM service

## 5.5. Examples of Implementation

In order to provide some more clarity into the idea of standardizing local rules with the help of SNOMED CT, two examples are given in this section. It will be shown here how the local rules can be transformed and while doing so, some considerations will be discussed. The local rules that are transformed are chosen in consultation with A.T. Wasylewicz, the main designer of the clinical rules. A local rule for the determination of diarrhea that is included in the opiate laxative CR is discussed in sec. 5.5.1 and a local rule for the determination on whether a patient has a feeding tube or dysphagia that is included in the gastric protection CR is standardized in sec. 5.5.2.

### 5.5.1. Diarrhea

#### Description of the local support rule built for the CZE

The local clinical rule for the determination whether a patient has diarrhea or not, which is built for the CZE situation, was already shown and discussed in Fig. 3.5.

#### Generalization

In order to standardize this local rule, first the proper SNOMED CT codes have to be searched. This has been done via the previously mentioned CliniClue Xplore browser. In this case, it has been chosen to search SNOMED codes for all the yellow diamond shaped objects in Fig. 3.5. The exception here being Loperamide, since that part of the rule already has standardization behind it in the form of ATC and GPK codes. It should be noted that the red building blocks were removed from the rule. these red building blocks serve the purpose of extracting the most recent patient information, but this can also be accomplished by editing the query which retrieves this information.

The resulting standardized rule is shown in Fig. 5.4 All building blocks here are standardized with SNOMED CT preferred names and codes, ATC codes and standard time units. The found codes are placed within the brackets within the yellow diamond shaped objects. Especially the block that contained the three Dutch synonyms for denoting diarrhea in free-text is now much more reusable. A separate thesaurus would now link these three local terms to the general SNOMED CT concept.

It is arbitrary if this is the way to standardize this precise rule, since one could also replace the whole rule with just one simple question; "Does the patient have Diarrhea (with SNOMED CT code 62315008)?" and put the whole manner in which this is actually determined within a certain hospital in a thesaurus such as a DCM service. However, the alternative manner in determining whether the patient has diarrhea (other than just looking if the EHR says they do) is based on clinical evidence and

could therefore be considered standard enough. This is for the medical experts to decide.

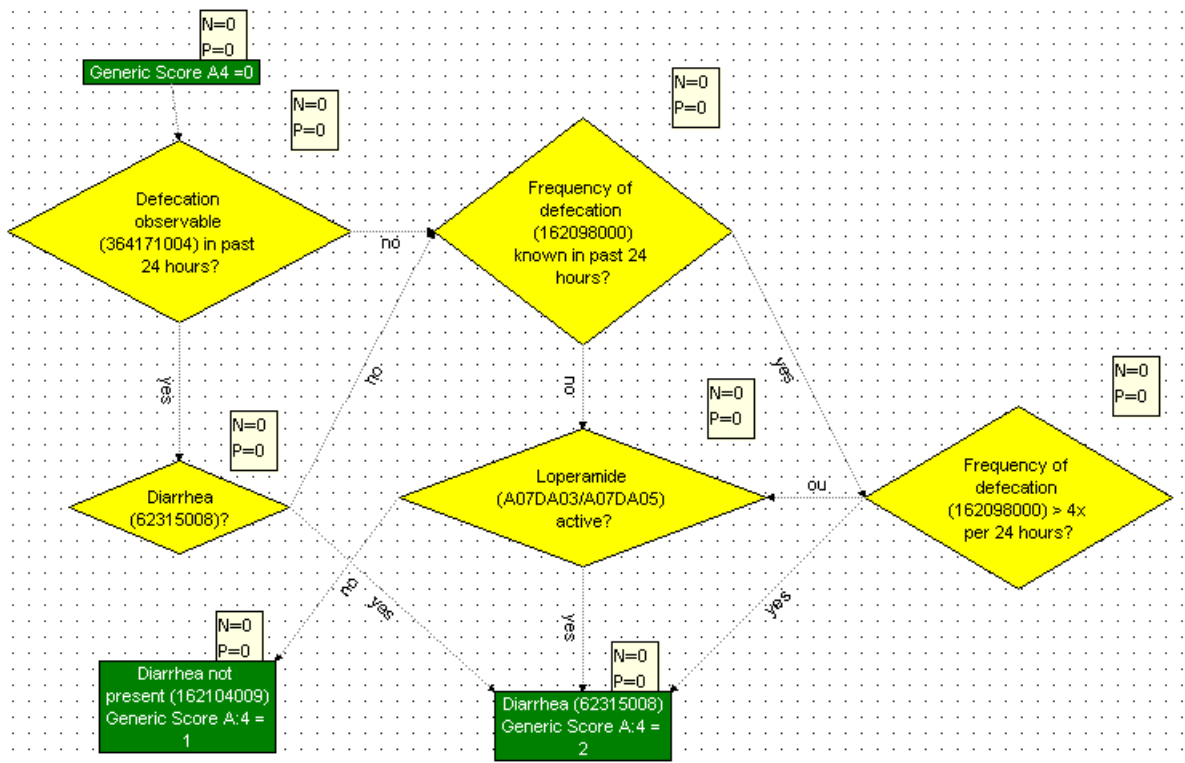


Figure 5.4.: Generalized clinical rule for determination of diarrhea

### Fit with the local support rule built for the CWZ

The clinical rule for the determination of diarrhea has been generalized with the CZE built version as a basis. Now the fit of this generalized version to the local support rule, built for the CWZ situation, is investigated. The local support rule which has been built for the CWZ can be seen in Fig. 5.5. This local rule is actually a simplified version, which only checks whether loperamide, an already standardized drug, is being administered to the patient. The generalized rule is therefore also suitable for the CWZ, since all other decision points within the generalized rule will simply result in a "no" (since the information is not available) and thus the generalized rule also only checks whether loperamide is active.

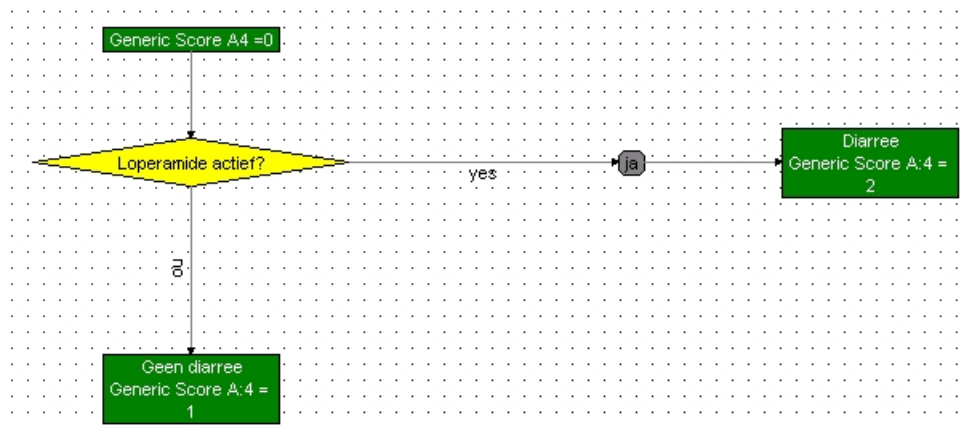


Figure 5.5.: Local clinical rule for determination of diarrhea (CWZ)

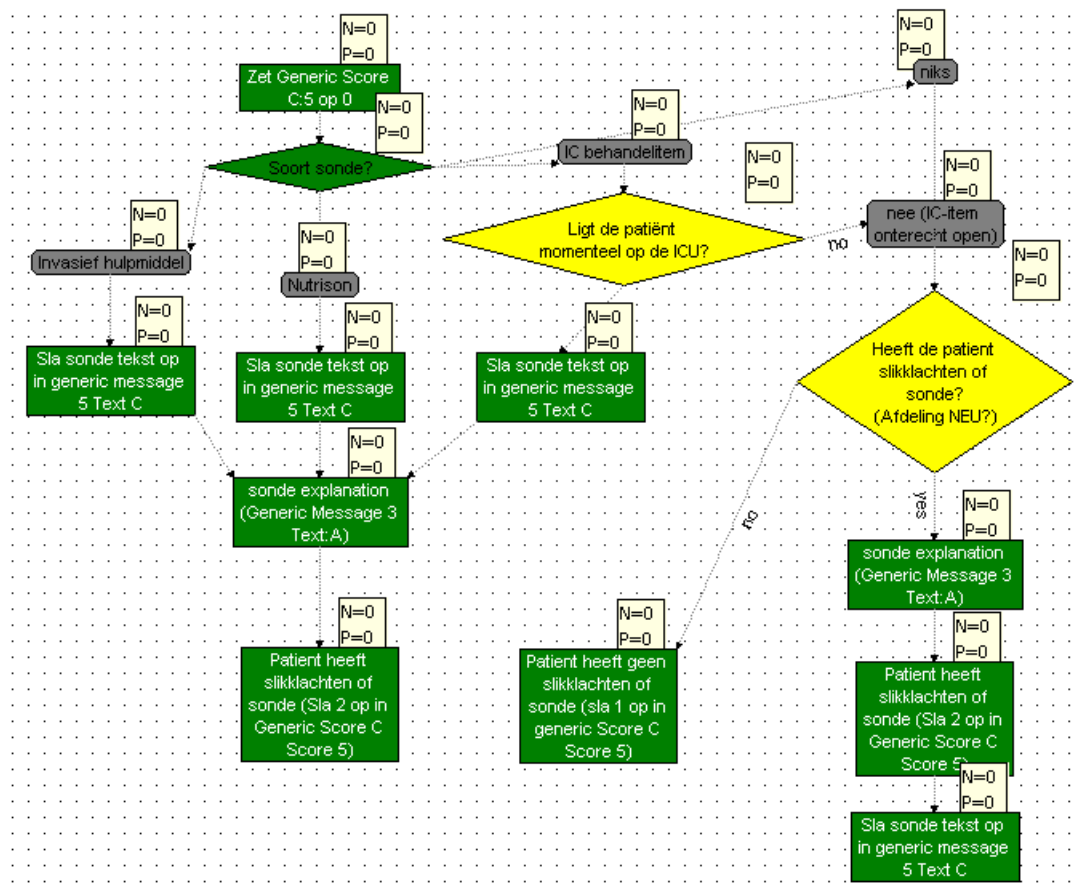
### 5.5.2. Feeding Tube or Dysphagia

#### Description of the local support rule built for the CZE

The local rule in order to determine whether a patient has a feeding tube or suffers from dysphagia (problems with swallowing) is a part of the gastric protection clinical rule. The current local version of this rule, which is built for the CZE situation, is shown in Fig. 5.6 and is in Dutch. In this local example, there are three possible ways in determining more or less directly whether a patient has a feeding tube. If a patient receives "Nutrison", nutrition that is fed to the patient via a tube, it is concluded that the patient must indeed have a feeding tube. If it is notated with the EHR in designated fields that a patient has an "invasief hulpmiddel" (invasive tool) or an "IC behandelitem" (intensive care treatment item) it is also concluded that the patient has a feeding tube. If no such notation is found, it is checked whether the patient lies on the neurology department (where 70% of the patient suffers from dysphagia), and if that is the case, it is concluded that the patient suffers from dysphagia.

#### Generalization

This rule is a perfect example why standardization is required if the clinical rule is to be reused within many different health care organizations. To only understand the rule, extensive contact was required with the author of the rule due to the ambiguous terms used. As described above, it turned out that the goal of this rule was to determine whether a patient has a feeding tube or suffers from dysphagia. Both concepts could easily be found in the SNOMED CT database and thus Fig. 5.7 was created. Arbitrary, it is an option to add a check on whether the patient lies on the neurology department as a back-up, in case no direct information on a feeding



**Figure 5.6.:** Local clinical rule for determination of a feeding tube or dysphagia (CZE)

tube or dysphagia is found. Again, the link between these standard concepts and the local way of working and entering data should be made via a thesaurus.

### Fit with the local support rule built for the CWZ

The clinical rule for the determination of a feeding tube or dysphagia has been generalized with the CZE built version as a basis. Now the fit of this generalized version to the local support rule, built for the CWZ situation, is investigated. The local support rule which has been built for the CWZ can be seen in Fig. 5.8. It looks very similar to that of the CZE, with different ways of encountering a feeding tube within the EHR. This version does not have the fall back with a check on whether the patient is situated at the neurology department. If the generalized rule is applicable to the CZE location, it is so at the CWZ as well. For both locations it depends on the ability of a thesaurus to link the different types of feeding tubes in use to the standardized concept of a feeding tube.

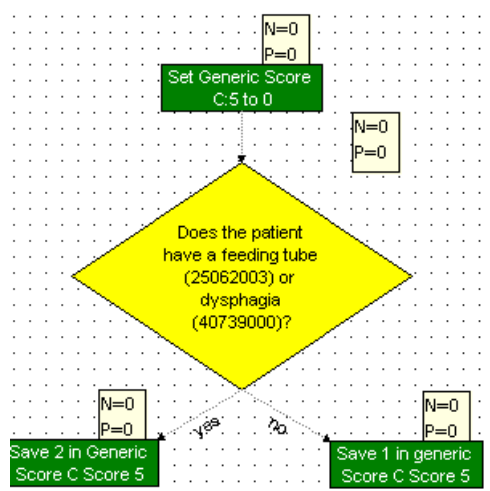


Figure 5.7.: Generalized rule for determination of a feeding tube or dysphagia

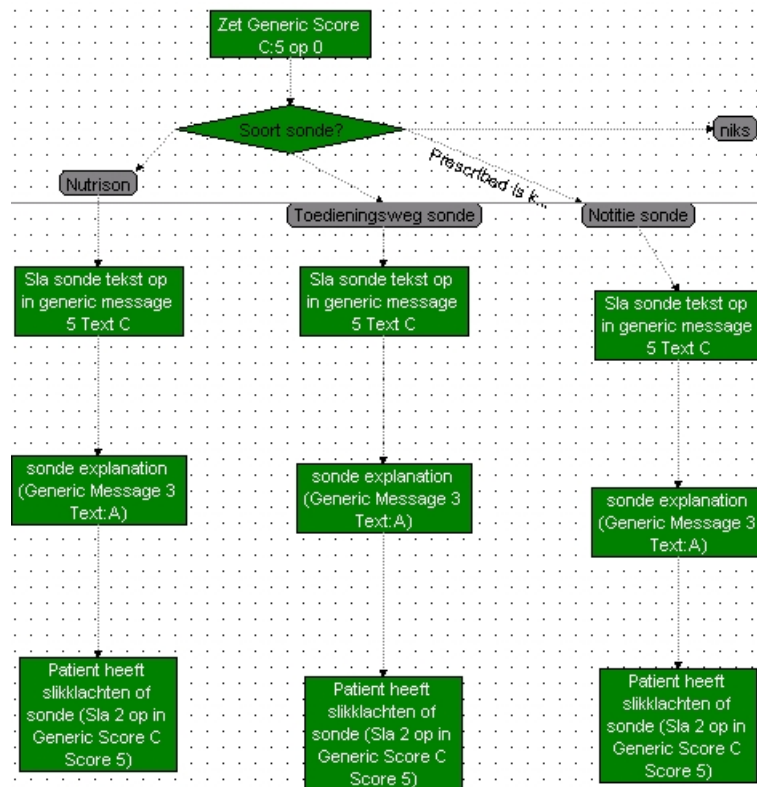
## 5.6. Discussion

In this section, the possible benefits of standardizing the clinical terms as described in this chapter are discussed, as well as the requirements and the challenges that still lie ahead.

### 5.6.1. Benefits

If all clinical terms that are used in the CR and CDSS can be standardized, this will eliminate the need for local support rules. The result will be that the parts of the CR that are now put in the local support rule can become an integral part of the master rule. In terms of the hierarchical layers discussed in sec.3.5.4, this means that information in layer 4 can be moved to layer 2. If all local support rules can be generalized (which should be further explored), layers 3 and 4 could be removed entirely. This way, there will be a single version of a CR which can be used by many different hospitals without the need for local customization. In the current situation of the CRS project, where only three hospitals participate, this customization of the CR is manageable. However, if the sharing of the developed CRs is to be extended (e.g. to a national level), different interviewees believe the customization would become too cumbersome. Instead, a translational step could be made at every hospital. This might look like a diversion of the problem, but the translation could be used for other purposes as well when it comes to the sharing of clinical data.

Furthermore, standardizing the entire rule will result in easier communication concerning the CR, since no local terms (only familiar to local medical specialists) are used. According to the CRS project leader, this improved communication will become necessary if and when the CRS project is extended to more and more hospitals.



**Figure 5.8.:** Local clinical rule for determination of a feeding tube or dysphagia (CWZ)

### 5.6.2. Requirements

In order to be able to make the changes suggested within this chapter, certain requirements should be met:

- The proper codes from the terminology standards should be added to every term used within the CRs. According to dr. W.T.F. Goossen, this could even be done by a student such as the author of this thesis. However, every found concept should be discussed with the medical experts to make sure they are indeed the valid concepts. The person browsing for the proper codes should therefore be an integral part of the CR development team.
- The CDSS should allow for such a coded meta layer. This is for the CDSS supplier to provide.
- The information systems of every hospital that uses the CRs should be connected to a thesaurus, such as a DCM service. This translational service should be maintained and linked to the CDSS.



### 5.6.3. Challenges

As stated at the beginning of this chapter, this is only an introduction into a possible solution area. Clinical terminology standards are capable of providing the clinical concepts needed for a CR, but that alone is not enough. The aforementioned DCM service could act as a thesaurus between the CDSS and its CRs and the HISs, however further investigation into this is required.

It is unclear at this point whether a DCM service is capable of translating all used concepts in a local support rule into a standardized terminology. This uncertainty is especially the case for local support rules that are build for hospital specific workflows. The second implementation example for instance, concerning the local support rule for determination of a feeding tube or dysphagia (Fig. 5.6), is designed specifically for the CZE situation where there are three kinds of feeding tubes that can be denoted in the HIS. Another hospital may use different tubes, different ways of denoting or may not denote these tubes at all. Implementing a sort of fail safe derivation such as the question whether a patient lies on the neurology department could cover for this, but it remains the question if such a fail safe is possible for every local support rule. A DCM service is definitely capable of translating terms such as "brijig", "diarree" and "waterdun" that can be seen in Fig. 3.5. Furthermore, no description is available on how such a DCM service should be connected to a HIS and CDSS. This has to be explored as well.

As stated in chapter 4, there are some organizational issues within the CRS project. Introducing another party (someone who builds and maintains a thesaurus such as a DCM service), only increases the organizational structure required and a thorough investigation on how this party should be connected within the network and where the new responsibilities lie must be done. Some initial suggestions on this subject are done in chapter 6, where the changes in the current situation, as discussed in chapter 3, are given.



## **6. Recommended Redesign in a HCBN Context**

In this chapter, the consequences of the in chapter 5 proposed standardization of clinical terms are discussed. This is done in the same four perspectives that have been used in the description of the current situation of the CRS project in chapter 3; Business (sec. 6.1), network (sec. 6.2), process (sec. 6.3) and technology (sec. 6.4). If the proposed standardization of chapter 5 were to be implemented, it would be in order to reuse the developed CRs on a larger scale than the current CRS project does with the Santeon collaboration. The four perspectives are described on a conceptual level within this larger scale context.

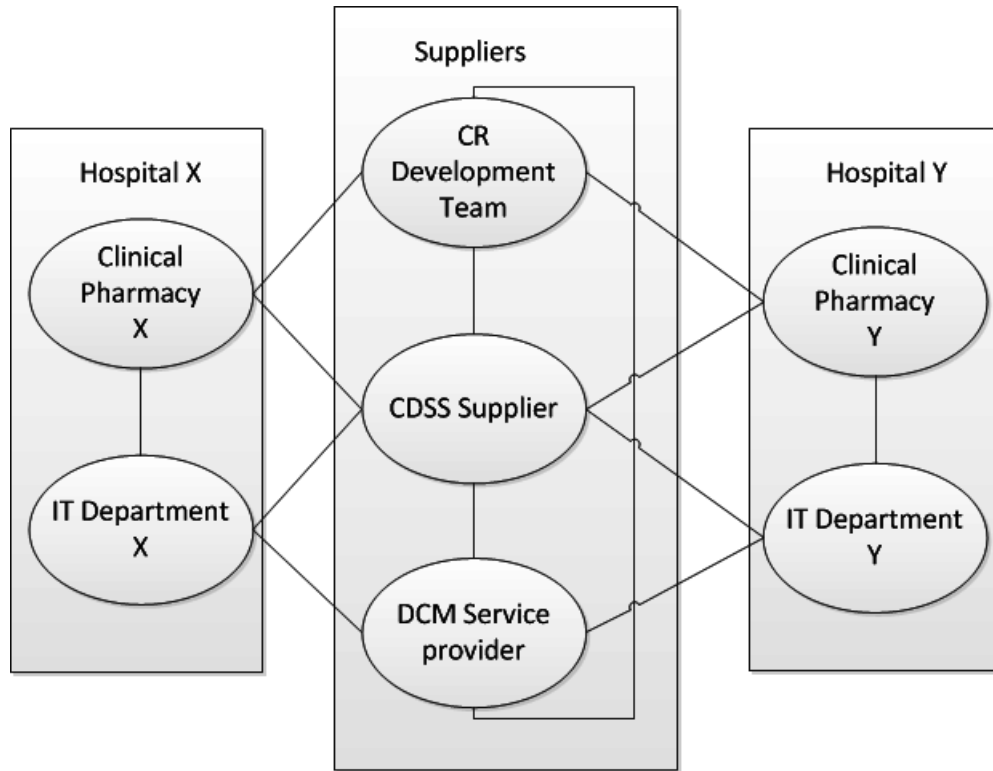
### **6.1. Business Perspective**

Within the business perspective of chapter 3, the absence of Service Level Agreements between different parties was described. If the CRS project is up-scaled and a new party (the DCM service supplier) is introduced, the need for clear agreements becomes even higher. As will be described in sec. 6.2, the use and development of CRs and surrounding services becomes more compartmentalized and thus clear communication and SLAs should be put in place.

### **6.2. Network Perspective**

The proposed network is shown in Fig. 6.1. A clear distinction has been made between suppliers of CR related services and the end-users of the CRs. The content of the CRs is currently being developed by the collaborating Santeon pharmacies and the modeling is done by the CZE project pharmacists. In the proposed situation, a team dedicated to the development of CRs is put in place, which handles the content and the modeling. Such a team could still consist of pharmacists from different hospitals, but it is no longer possible to let every hospital have a representative due to the larger scale. the CR development team should still be in contact with the clinical pharmacies of the participating hospitals in order to receive feedback and provide support. The CR development team should also be in close contact with the CDSS supplier (for support) and the DCM service provider (to provide data

which needs translation). The DCM service provider, CDSS service provider and IT departments need to collaborate on how their systems will be linked. Just as in the current situation, communication between clinical pharmacies and IT departments is needed. The biggest change is the fact that the hospitals no longer need to communicate with each other, discussion on the CRs are done with the development team.



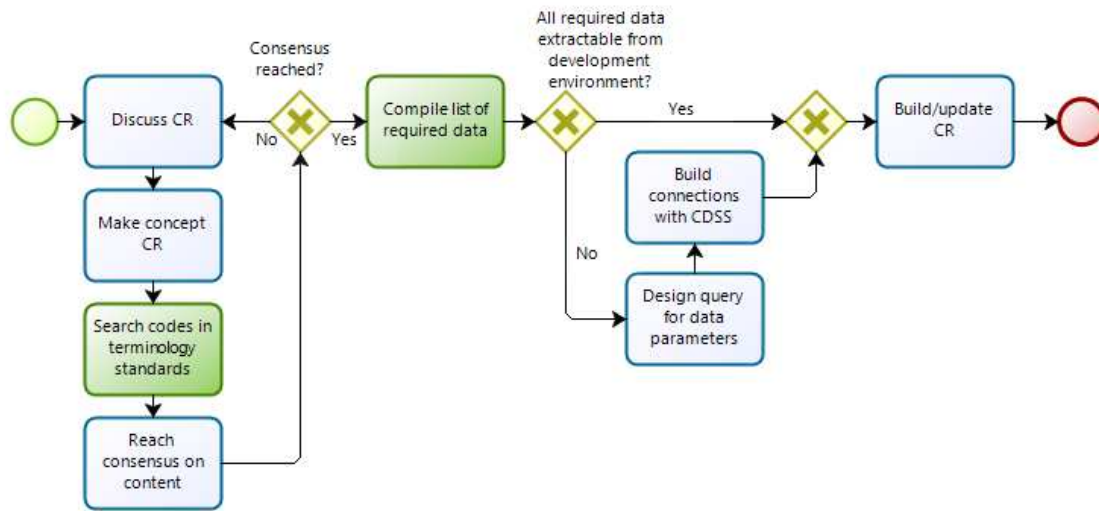
**Figure 6.1.:** Proposed network for the use and development of CRs

### 6.3. Process Perspective

In this section, the design phase and the transfer phase, previously handled in sec. 3.4, are revisited and discussed within the proposed context. Tasks that are new to these processes are colored green.

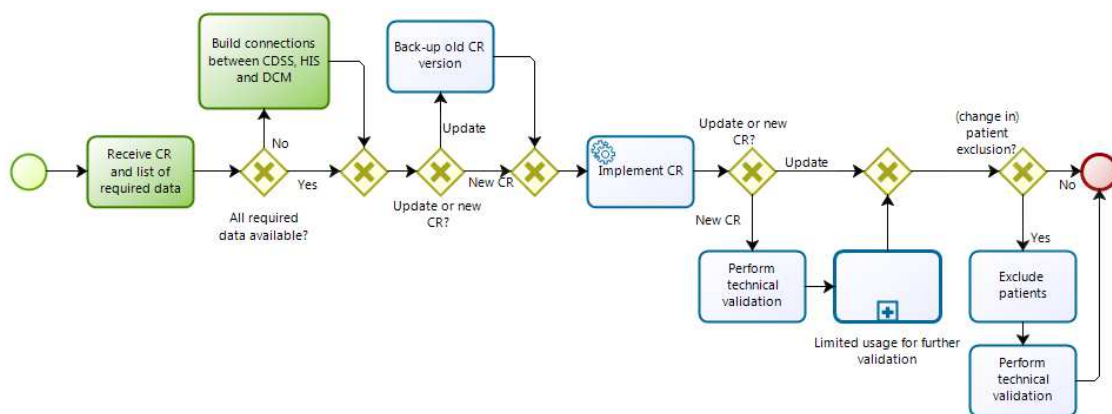
The process model of the design phase for the proposed situation is shown in Fig. 6.2. Every task regarding data transformations for local support rules is taken out, since these will not be necessary anymore. Instead, a task "search codes in terminology standards" is added. These codes are searched in that particular part of the process so they can be discussed with the medical experts. In order to be able to build and test a clinical rule, a development environment is required. In the current CRS project this environment is that of the CZE. Therefore, missing connections from

the CDSS to the HIS still have to be made in the design phase. A list of required information is also made in the design phase. This list is to be attached to the CR and is used in the transfer phase. Every step in this process is to be done by the CR development team in collaboration with the CDSS supplier.



**Figure 6.2.:** Design phase of the proposed situation

The process model of the transfer phase for the proposed situation is shown in Fig. 6.3. The process starts with the clinical pharmacy of a hospital receiving the CR and the attached list of required data. If not all data on the list is available, this data must be made available by the CDSS and DCM service suppliers. How this is done can conceptually be found in sec. 6.4. Again, all previous tasks regarding local support rules have been removed.

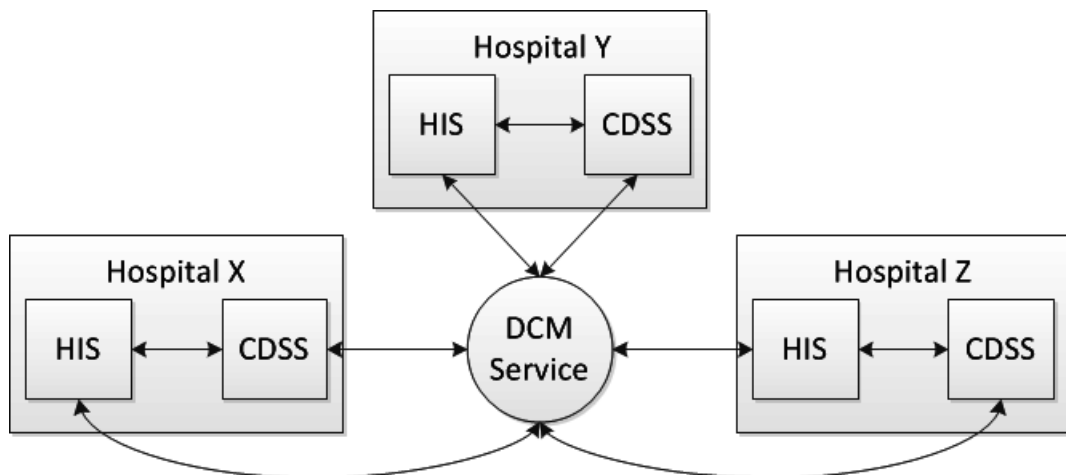


**Figure 6.3.:** Transfer phase of the proposed situation

It should be noted that validations of the CR will still take place, but if a change in the CR is deemed to be required this will be provided as feedback to the CR development team.

## 6.4. Technology Perspective

The changes within the CRs themselves are already discussed in sec.5.5. At local hospital level, the information systems will not change. Instead, the used terminologies within hospitals are translated to the terminology standards that are in use within the CRs. This is done by linking the hospital information systems as shown in Fig.6.4. The HIS and CDSS should still be connected to one another in order to read patient data, just as in the current situation. The synchronization of terminologies is provided by connecting both the HIS and the CDSS to the DCM service. This way, patient data stays within the hospitals (avoiding privacy issues), but the DCM service can be shared. It is not known at this point of time how these connections would actually be established.



**Figure 6.4.:** Information linkage in the proposed situation

## 7. Conclusions and Future Research

Within this final chapter, the conducted Msc thesis project is concluded. The research questions defined in chapter 2 are answered in sec.7.1. The limitations of this research project are discussed in sec. 7.2 and suggestions for future research are given in sec.7.3.

### 7.1. Conclusions

The conducted Msc thesis project was basically divided into two parts, which was also represented by the use of two research questions:

1. *Which problems can be identified in the organizational setting surrounding the reuse of clinical rules with the CDSS Gaston?*
2. *How can the architecture surrounding the CDSS Gaston be redesigned in order to facilitate easier reuse of clinical rules?*

In order to answer the first question, a framework-based analysis of the current CRS project was done in chapter 3 and a list of problems identified within this problem was compiled and ranked in chapter 4. This list of identified problems did not only contain issues within the organizational setting, but also technical challenges. However, the organizational problems were perceived as the most important ones by the respondents. The top 3 of issues ranked and identified consisted of:

1. Deficient communication between IT and domain specialists
2. Lack of a clear project manager
3. Unclear responsibilities

All these issues are linked to the cross organizational setting the CRS project is conducted in, where even the IT departments of the hospitals themselves are autonomous. The need for clear agreements before the actual start of such a project (e.g. in the form of service level agreements) can not be underestimated. All problems on the compiled list of issues are described in detail and offered to the CRS project leader for evaluation purposes.

The problem list was also used to select a more specific topic in which context research question 2 would be answered. The selected problem was; "Difference in recorded medical data", due to which local support rules are required within the

current situation of the CRS project. A possible answer to the second research question was found in the standardization of clinical terms as described in chapter 5. If all clinical terms that are used in the CR and CDSS can be standardized, this will eliminate the need for local support rules. This way, there will be a single version of a CR which can be used by many different hospitals without the need for local customization. In the current situation of the CRS project, where only three hospitals participate, this customization of the CR is manageable. However, if the sharing of the developed CRs is to be extended (e.g. to a national level), different interviewees believe the customization would become too cumbersome. Instead, a translational step could be made at every hospital. This might look like a diversion of the problem, but the translation could be used for other purposes as well when it comes to the sharing of clinical data.

The insights given in this section are case specific in nature. However, the conclusions that have been drawn are not only interesting for the Santeon members. The number of collaborations between Dutch hospitals is growing [KPM13] and collaborating parties engaged in similar projects can benefit from the insights gained through this Msc thesis project.

## 7.2. Limitations

On a case specific level, this Msc thesis project was limited to the situations in Eindhoven (CZE) and Nijmegen (CWZ). The third participating party of the CRS project, the Medical Spectrum Twente, could unfortunately not be considered. An attempt was made to validate the compiled problem list at the MST, but no response was given. Therefore it is not possible to say with absolute certainty that the found perceived importance of the problems is true within the entire CRS project.

A case study is hard to generalize per definition [Col14] and one must therefore be careful to draw conclusions beyond the case that was under study.

Furthermore, the proposed solution direction had to stay on a conceptual level due to a lack of resources (time) to gain further information on the role a thesaurus such as a DCM service could play in the standardization of clinical terms used in the CRs.

## 7.3. Future Research

The above mentioned limitations offer some opportunities for future research.

First off, the identified problems are based on only two hospitals and an additional study could be done to produce a more generalizable list of issues encountered within collaboration projects in a cross organizational level.



Secondly, the proposed solution direction involving the standardization of clinical terms is far from done. To be able to actually implement such an idea, further research is required into the technical details of the connections between a thesaurus, such as a DCM service, and the CDSS and HISs. Additional research is also required into the ability of a thesaurus to successfully take over the functionality of the local support rules.



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# Nomenclature

ATC	Anatomical Chemical Therapeutical Classification
BPMN	Business Process Model and Notation
CDSS	Clinical Decision Support System
CR	Clinical Rules
CRS	Clinical Rules in Santeon
CWZ	Canisius-Wilhelmina Hospital Nijmegen
CZE	Catharina Hospital Eindhoven
DCM	Detailed Clinical Model
GPK	Generieke Productcode
HL7	Health Level Seven
ICD	International Classification of Diseases
IHTSDO	International Health Terminology Standards Development Organisation
IOM	Institute Of Medicine
ISO	International Organization for Standardization
ITU-T	International Telegraph Union Telecommunication Standardization Sector
KNMP	Royal Dutch Pharmacist's Association
MST	Medical Spectrum Twente
ODBC	Open Database Connectivity
OID	Object Identifier
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
WHO	World Health Organization





# **A. Appendix - General Question list for the Interviews**

## **Business Perspective**

1. What is your job description and to which organization/department do you belong?
2. What is the main goal of this organization/department?
3. Do have any performance indicators in place?
4. Do you try to work according to those performance indicators?
5. Are there any Service Level Agreements in place between your organization/department and others?

## **Network Perspective**

1. Which parties are involved in the CRS project?
2. How do you communicate with those parties?

## **Process Perspective**

1. Can you explain which steps were taken to get a CR to the CWZ?
2. What was your specific part in this?
3. Are there any workflows defined within your organization/department concerning the CRS project?

## **Technology Perspective**

1. Which Information Systems are in use at this location concerning the CRS project?

2. How are those Information Systems connected?
3. Is data being stored according to a certain standard?
4. Which parties have access to which (parts of) systems?

## **General**

1. What issues have you encountered during your participation in the CRS project?
2. Are there any other topics that you think are important for this interview?

## B. Appendix - Process Models

The high level process a CR goes through is shown in Fig. B.1. This model and most of its sub-processes have been adopted from [Sun13]. The situation in the CRS project being discussed here and the situation at the CZE spoken of in [Sun13] are very similar. This is not surprising, since the CRS project originated from the CZE, where they were already developing and using CRs. For this reason, only the sub-processes "Design phase" and "Transfer phase" are different from the original model.

The high level CR process shown in Fig. B.1 starts with an idea for a new clinical rule or a scheduled periodical review of an existing one. The CR then goes through the design, test, transfer and usage phases until the CR version is terminated. It should be noted that the whole process can be interrupted if it is decided that a certain CR became obsolete.

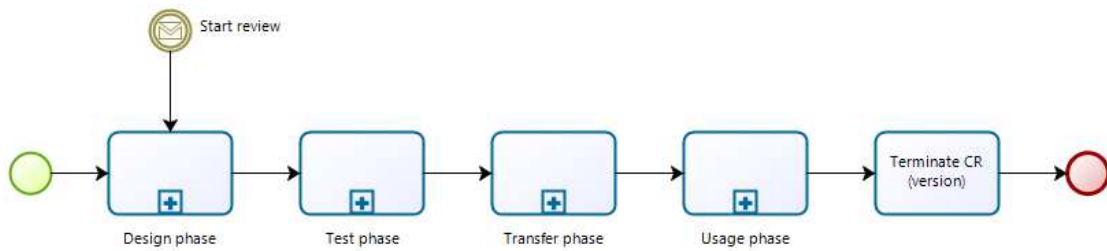


Figure B.1.: High level CR process

### Design Phase

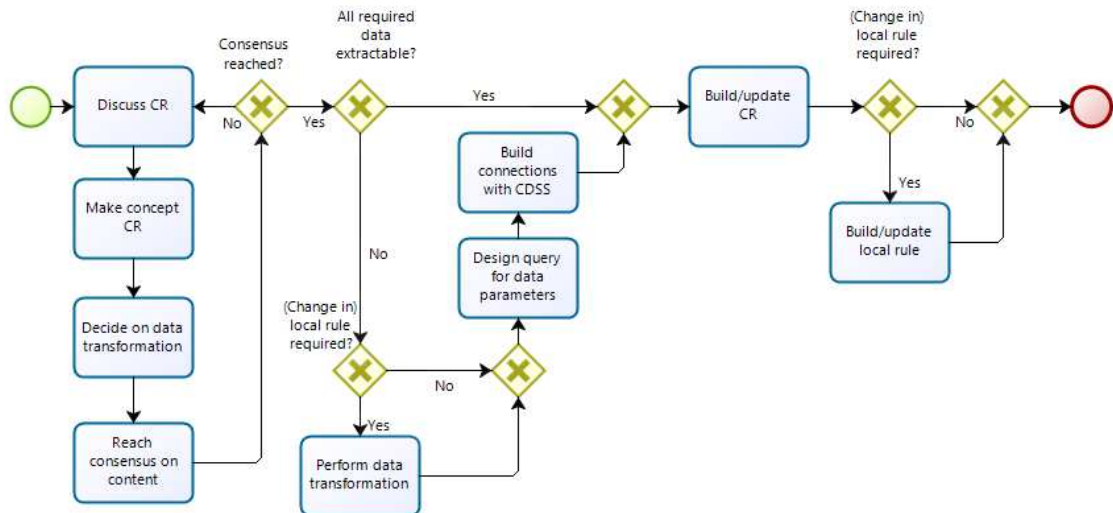
The *design phase* is a sub-process of the *high level CR process* and is shown in Fig. 3.3. The design phase is started, as indicated before, with an idea for a new clinical rule or a scheduled periodical review of an existing one. During a periodical review the problems that were encountered with the CR are discussed and the CR is completely checked, justifying usage of the same steps in the process as for a new CR.

Once the process is started, a discussion between the Santeon members is held in order to determine which CRs are selected to be developed for the different hospitals.

This is done in the monthly telephone meeting, in which two members of each location (CZE, CWZ and MST) are present. After selection of the CRs, concepts are made on paper by a project pharmacists of the CZE based on already existing CRs of the CZE and additional literature reviews. Subsequently, this concept is discussed within the monthly Santeon meeting and consensus has to be reached on the contents.

If consensus is reached and thus the content of a CR is determined, the technical part can begin, starting with a check on whether all data required for a CR is extractable from the information systems in use at the different hospitals. This data could be unavailable because no connection to the corresponding data in the IS has been made yet, or because the hospital does not have the data available at all due to different workflows. If the latter is the case, a local support rule is required, on which more can be found in sec.3.5.3. For these rules, it is decided what data transformations are needed in order to get the desired information which was not available directly from the IS. Additionally within the local support rule, it is an option to exclude certain parts of the rule or patient population. These decisions are officially all taken within the monthly Santeon meeting.

If not all required connections to the IS have been made yet, doing so is the next step. Queries to retrieve the data are designed by a project pharmacist and application manager. Building the actual connections is done by an employee of the manufacturer of Gaston, Medecs B.V. Once all data is available for the CDSS, the CR and optional local support rules are build by the project pharmacists of the CZE.



**Figure B.2.: CR Process - Design phase**

## Test Phase

The *test phase* (shown in Fig. B.3) is started after the CR has been build. Three types of validation are done in this phase, of which two (technical and retrospective therapeutic) take place in the sub-process *validation* and one (prospective therapeutic validation) takes place in the sub-process *Limited usage for further validation*. The task *Judgment w.r.t. policy fit* is an assessment done by the medicines committee and needs to be positive for the CR to continue through the process.

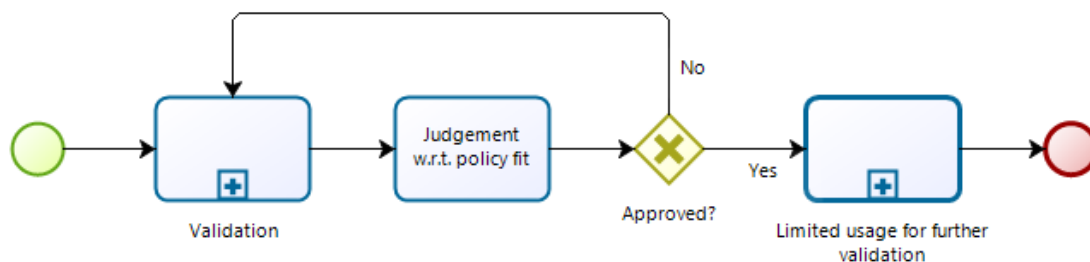


Figure B.3.: CR Process - Test phase

### Validation

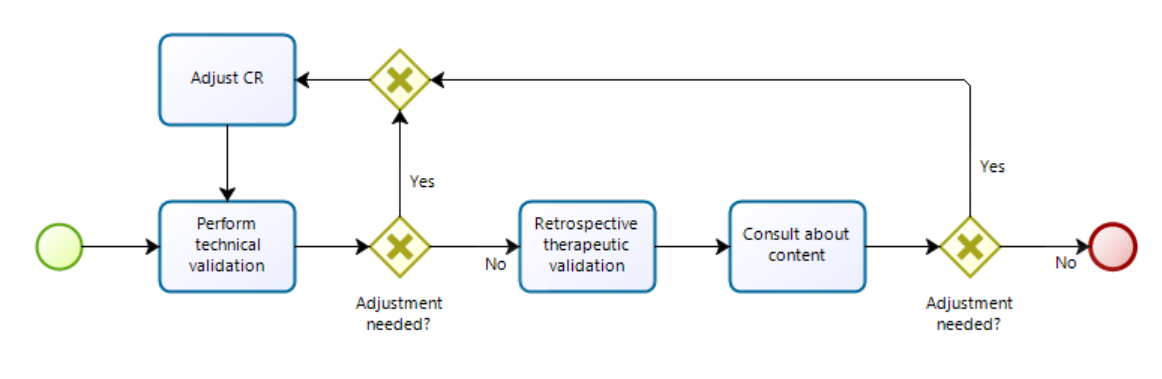
*Validation* is a sub-process of the *test phase* and is shown in Fig. B.4. First a *technical validation* (primarily a check on the links to the information systems of the hospital) is done by a project pharmacist and if needed, the CR is adjusted. Next up is a *retrospective therapeutic validation*, in which the CR is run against a database of previously hospitalized patients to check the performance of the CR and its clinical validity. The results of this validation are run by an expert team, consisting of hospital pharmacists.

### Limited Usage for Further Validation

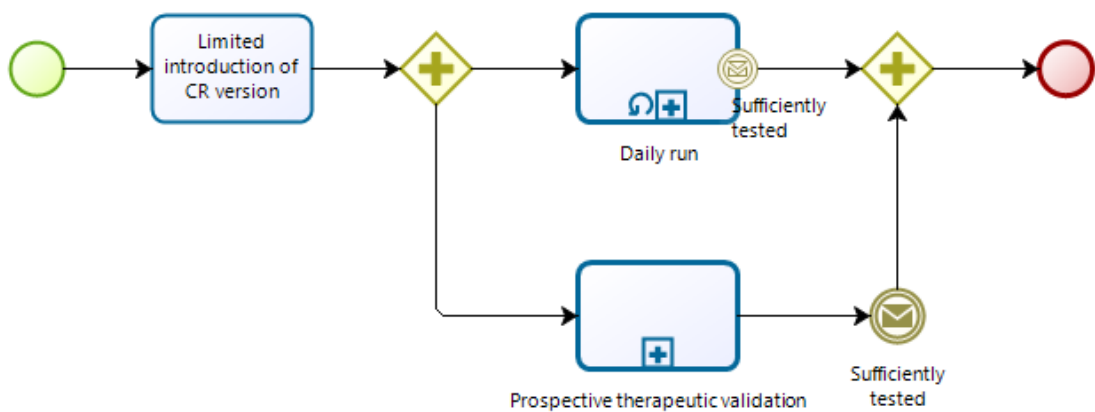
The *limited usage for further validation* (Fig. B.5) starts with the *limited introduction of the CR version*, which is done by a project pharmacist. This means that the CR is being run on actual current patient data, but the results are not visible for end-users. When the CR is introduced, the sub-processes *Daily run* and *Prospective therapeutic validation* are run in parallel, until the validation is satisfactory.

### Daily Run

*Daily run* is a reusable sub-process of *limited usage for further validation*, the *transfer phase* (Fig. B.9) and the *usage phase* (Fig. B.10). The first task within this



**Figure B.4.:** CR Process - Test phase - **Validation**

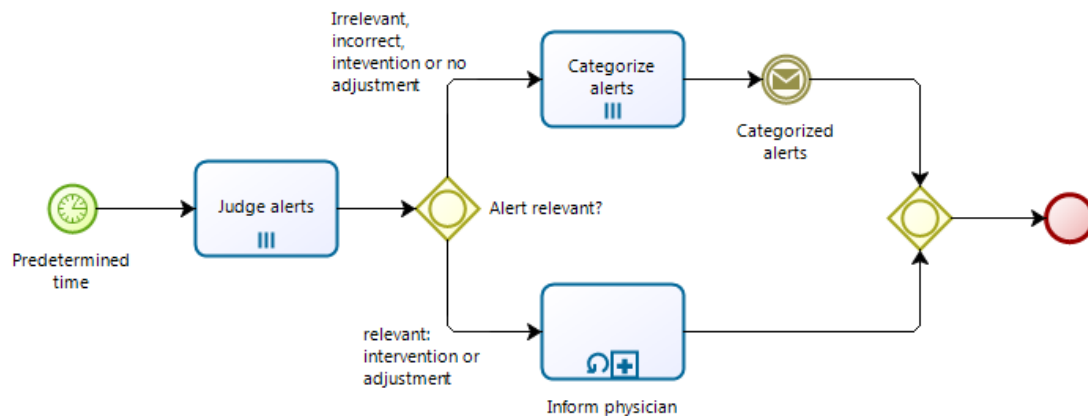


**Figure B.5.:** CR Process - Test phase - **Limited usage for further validation**

sub-process is the judging of alerts given by a run of the CDSS. This task is performed by a project pharmacist of the CZE when the CR is in *limited usage for further validation* and by a clinical pharmacist of the CWZ when the CR is in the *transfer* or *usage phase*. Alerts can be judged to be on of the following:

- incorrect: the alert is not correctly generated, it is technically incorrect,
- irrelevant: the alert is not relevant for this patient,
- intervention: the alert is relevant for the patient and leads to an adjustment,
- no adjustment: the alert is relevant for the patient, but does not lead to an adjustment because of patient specific circumstances.

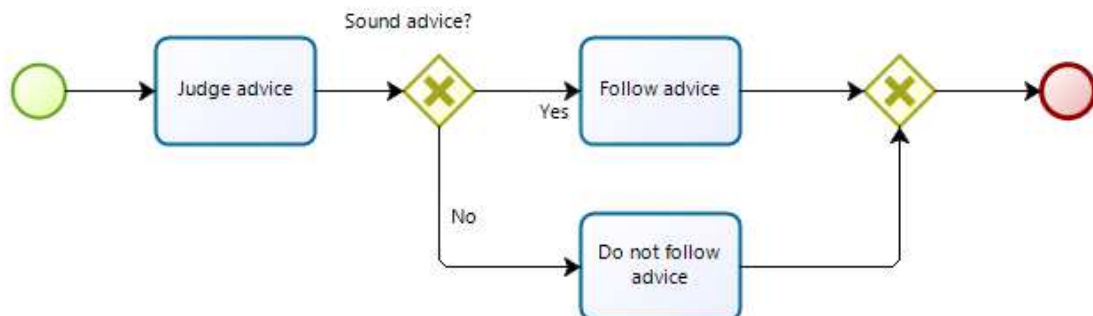
When an alert is judged as "intervention" or "no adjustment", while the CR is in the *usage phase*, the sub-process *inform physician* is started. All alerts are categorized by the acting judge and when ready, a message is send to indicate that the alerts can be evaluated.



**Figure B.6.:** CR Process - Test phase - Limited usage for further validation - **Daily run**

### Inform Physician

The *inform physician* sub-process can be seen in Fig. B.7 and shows that a physician can choose to either follow or ignore the advice given by an alert.

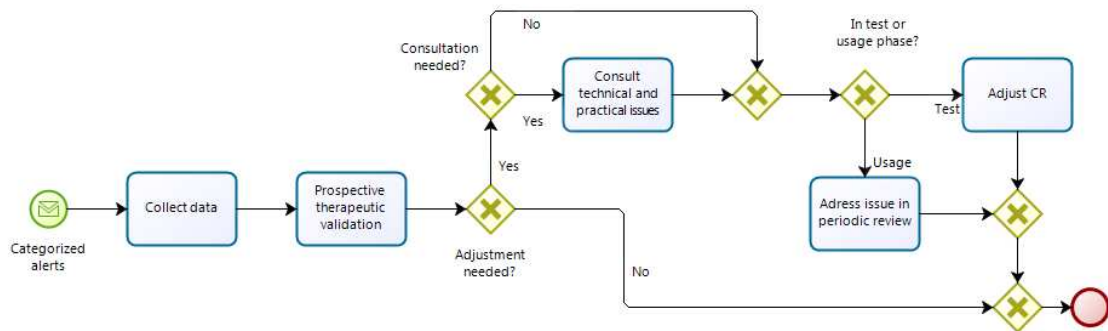


**Figure B.7.:** CR Process - Test phase - Limited usage for further validation - Daily run - **Inform physician**

### Prospective Therapeutic Validation

The *prospective therapeutic validation* is shown in Fig. B.8 and started by a message "categorized alerts" from the *daily run* process. The data is collected and the actual prospective therapeutic validation is started, which entails validating the CR with currently hospitalized patients. this is done by a project pharmacist of the CZE in the *test phase* and by a clinical pharmacist of the CWZ in the *usage and transfer*

*phase.* by looking at the categorized alerts, it is derived whether adjustments to the CR are required.



**Figure B.8.: CR Process - Test phase - Limited usage for further validation - Prospective therapeutic validation**

## Transfer Phase

The transfer phase is a sub-process of the high level CR process and is shown in Fig.3.4. After the CR is tested at the CZE, it is transferred to the CWZ. It starts by zipping the CR, placing it at a site called Lighthouse which is a service from Medecs B.V. and unpacking it at the CWZ server environment. If the CR is an update from an earlier version, a back/up is first created.

The CR is implemented at the CWZ environment with an automated tool. This implementation however, erases the previous general part (the distinction between the general part and the local support is described in sec. 3.5.3) of a CR and installs the update from scratch. Due to a future from Gaston that assigns codes randomly to elements, this changes the codes that identify the alerts. This change compromises the traceability of the alert history for a patient, a key feature of the CDSS. Therefore, the codes have to be manually reassigned, which can take up to 4 hours if no errors are made. Updates are not subjected to further testing after this and are brought in to use.

If the CR in question is not an update, but a new build, a technical validation takes place after the implementation. If this validation is satisfactory, the new CR is brought into limited use for further validation (shown in Fig. B.5) before entering the usage phase.



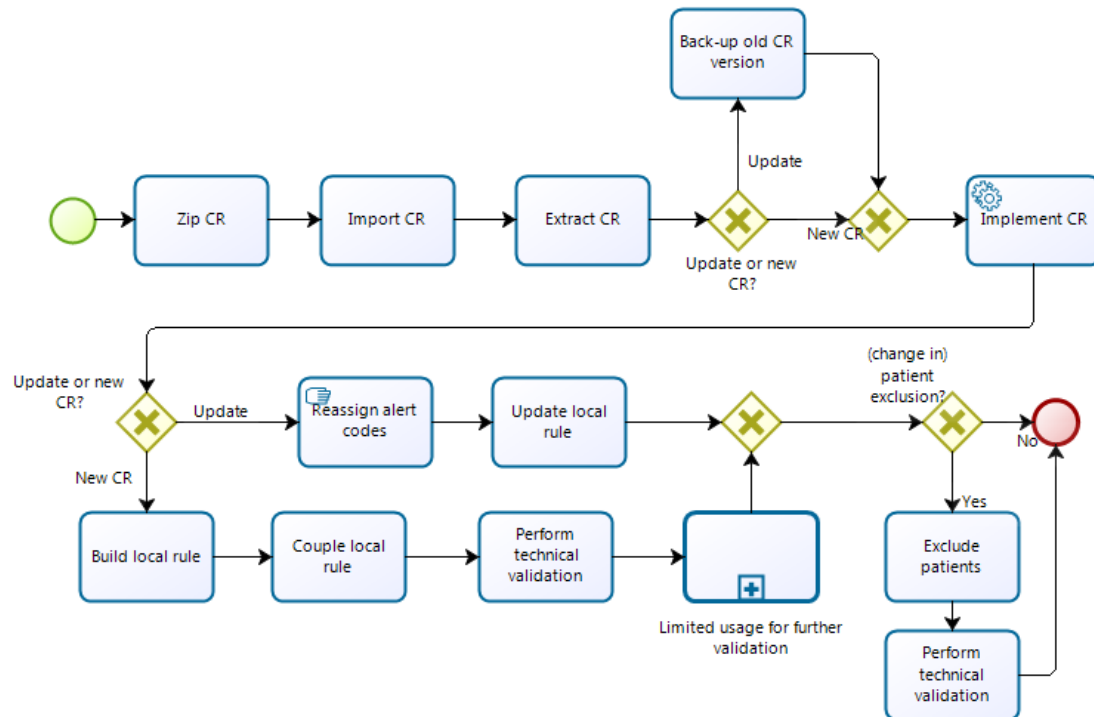


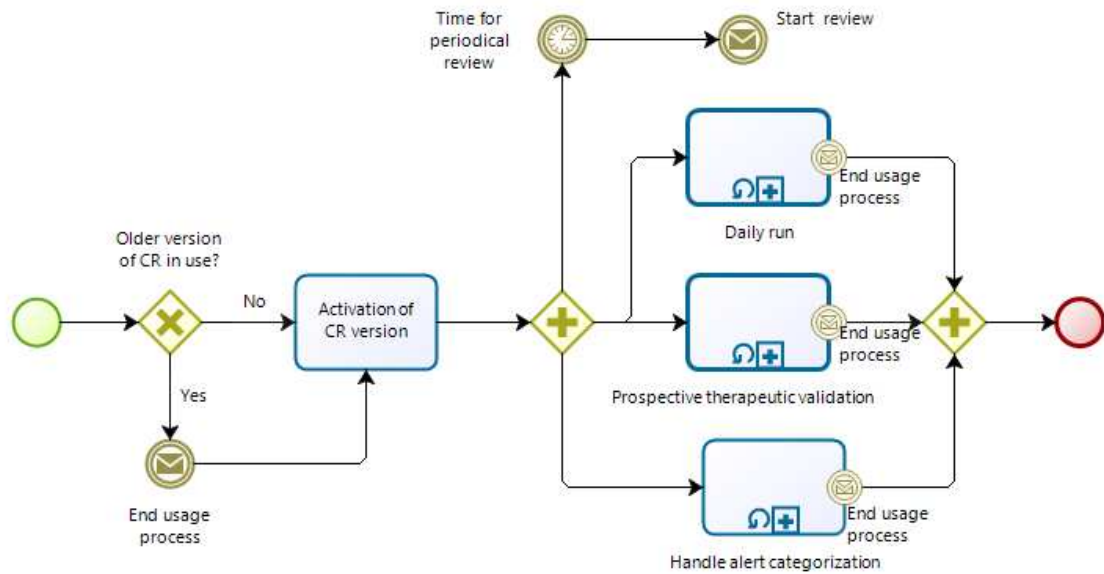
Figure B.9.: CR Process - Transfer phase

## Usage Phase

Once the *transfer phase* is completed, the *usage phase* of the CR commences, which is shown in Fig. B.10. If the CR that enters the usage phase is an update of a previous version, the previous version is first taken out of usage with the message "end usage process". During the usage phase, three sub-processes run simultaneously; *daily run* (Fig. B.6), *prospective therapeutic validation* (Fig. B.8 and *handle alert categorization* (Fig. B.11). Periodic reviews of the CR are done while it is in the usage phase and all three previously mentioned sub-process can be ended by the aforementioned "end usage process" message.

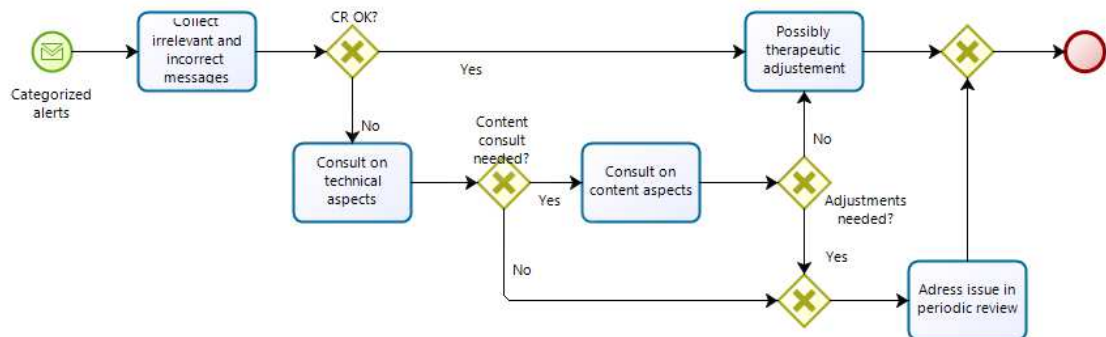
### Handle Alert Categorization

*Handle alert categorization* is a sub-process of the *usage phase* and is depicted in Fig. B.11. It is triggered by the message "Categorized Alerts", which originates from the *daily run*. Within this sub-process, The irrelevant and incorrect messages are collected and evaluated in order to determine if the CR functions correctly. If it does, therapeutic adjustments (e.g. training of the hospital pharmacists or a news letter to the physicians) might be required. If the CR is found to be not functioning properly, the step "consult about technical aspects" is performed and the project



**Figure B.10.: CR Process - Usage phase**

pharmacists discuss solutions. Thereafter, it is possible to consult with medical specialists on the content and if the content of the CR is found to be in need of adjustment, this is discussed within the monthly Santeon meeting.



**Figure B.11.: CR Process - Usage phase - Handle alert categorization**

## C. Appendix - CR Structure

In this appendix, the screen shots which support sec. 3.5.2 are shown.

### Layer 1

The top layer of the hierarchical structure of CRs is shown in Fig. C.1. It contains the start of the CRs and a collection of all the master rules.

### layer 2

The second layer of the hierarchical structure of CRs is shown in Fig. C.2. It consists of the actual master rule and within it, the third layer is embedded. The grey area in the figure represents a cut off where the master rule in reality continues. The master rule is too big to be actually shown entirely on paper.

### Layer 3

The third layer of the hierarchical structure of CRs is shown in Fig. C.3. It is a collection of all the local support rules in place within the master rule.

### Layer 4

The fourth layer of the hierarchical structure of CRs is the actual local support rule and an example is already shown in Fig. 3.5.

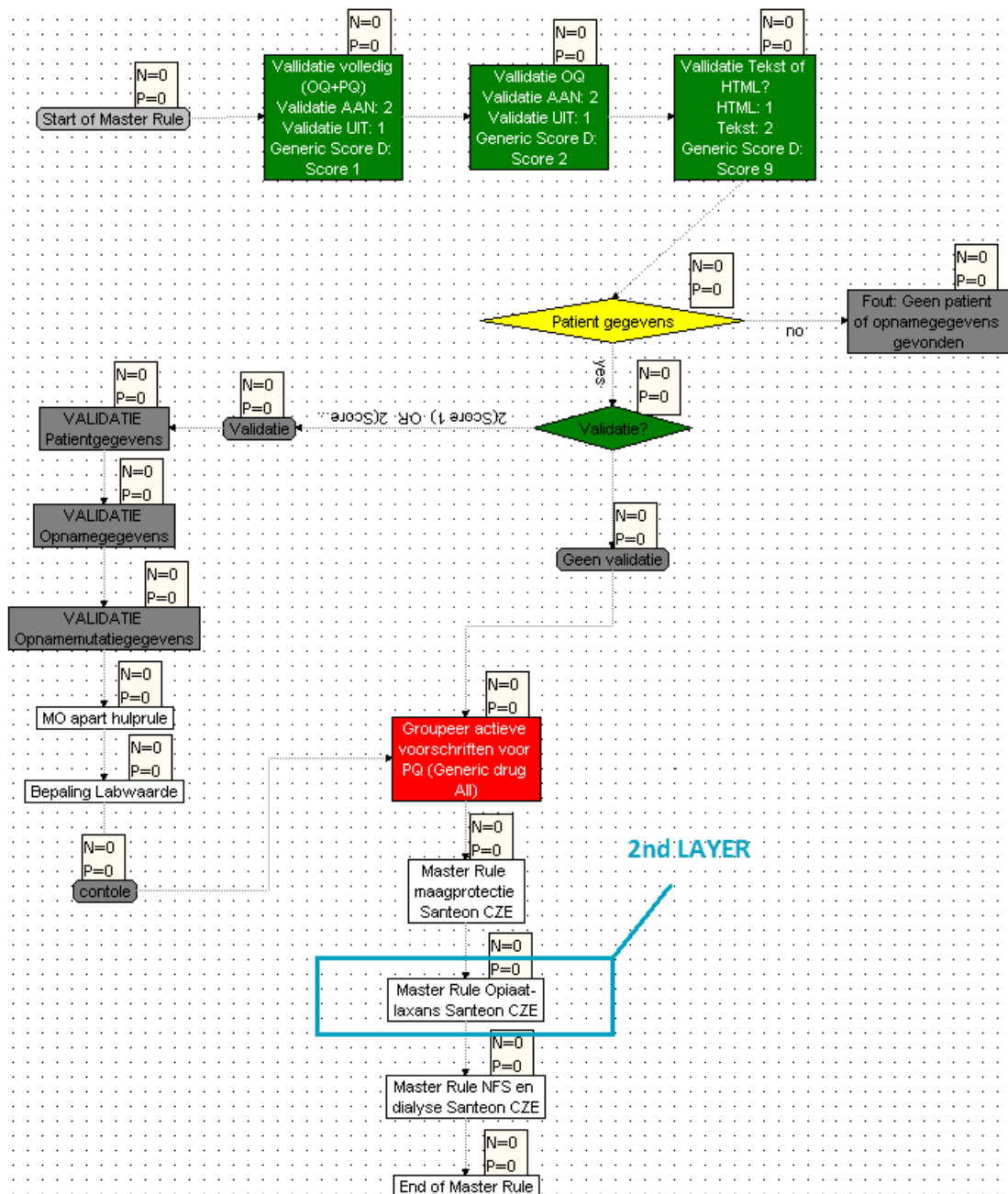


Figure C.1.: Layer 1 within the hierarchical structure of the CRs

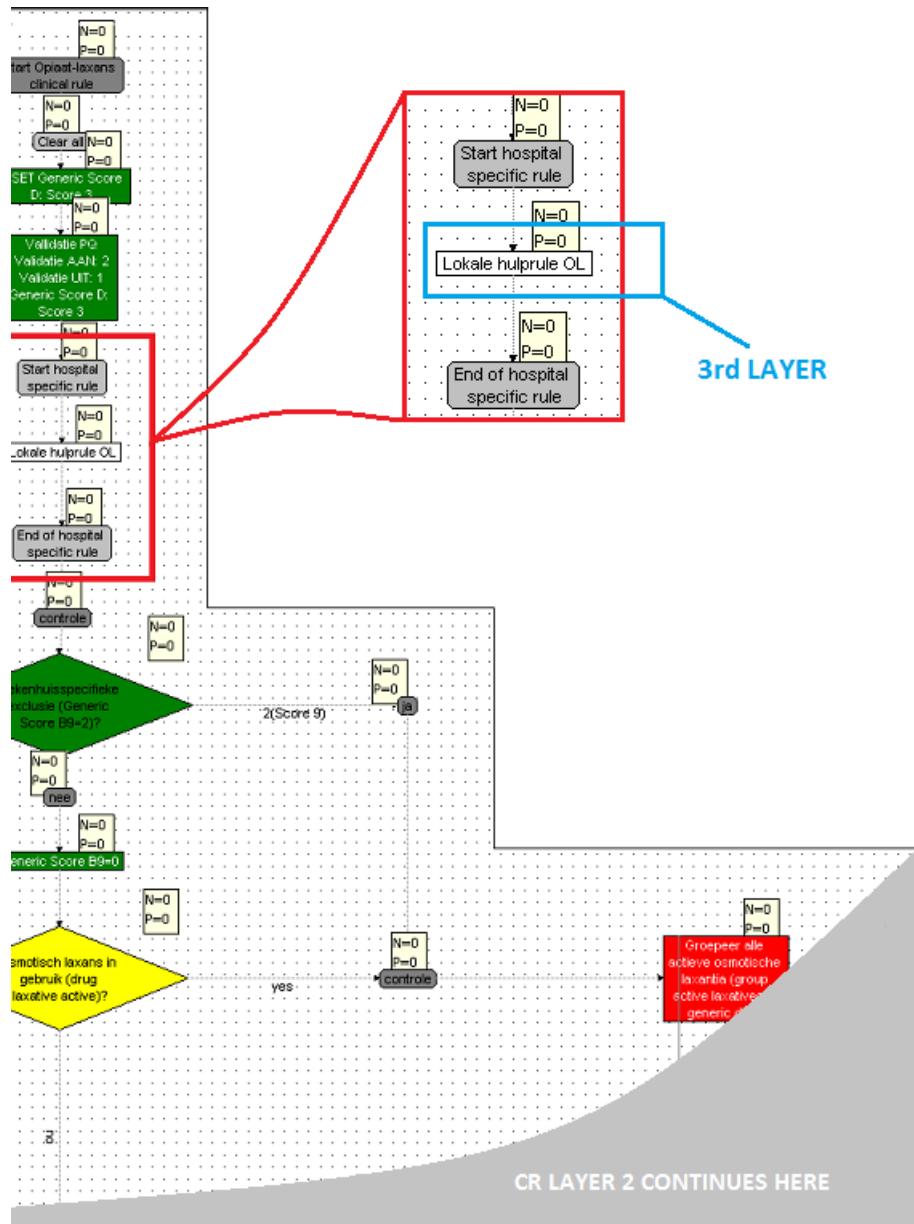
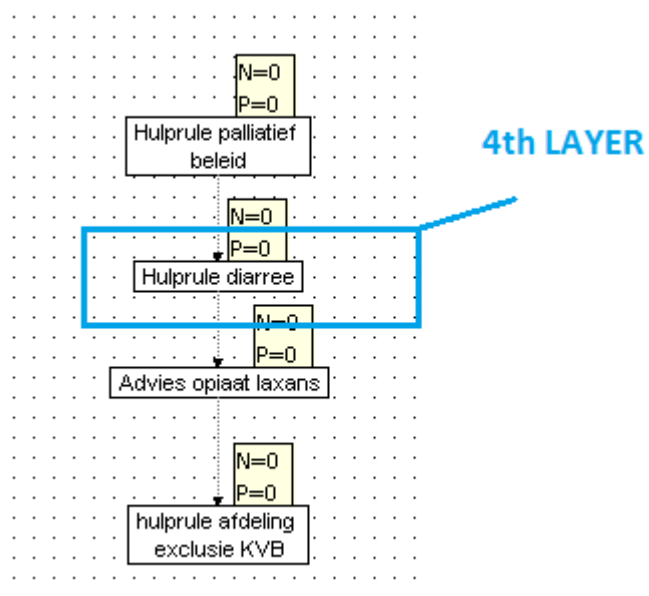


Figure C.2.: Layer 2 within the hierarchical structure of the CRs



**Figure C.3.:** Layer 3 within the hierarchical structure of the CRs

## D. Appendix - Partial DCM Example

In this appendix, a partial example of a DCM is shown. This example concerns the Glasgow Coma Scale (GCS) and all information within this appendix has been adopted from [Goo14].

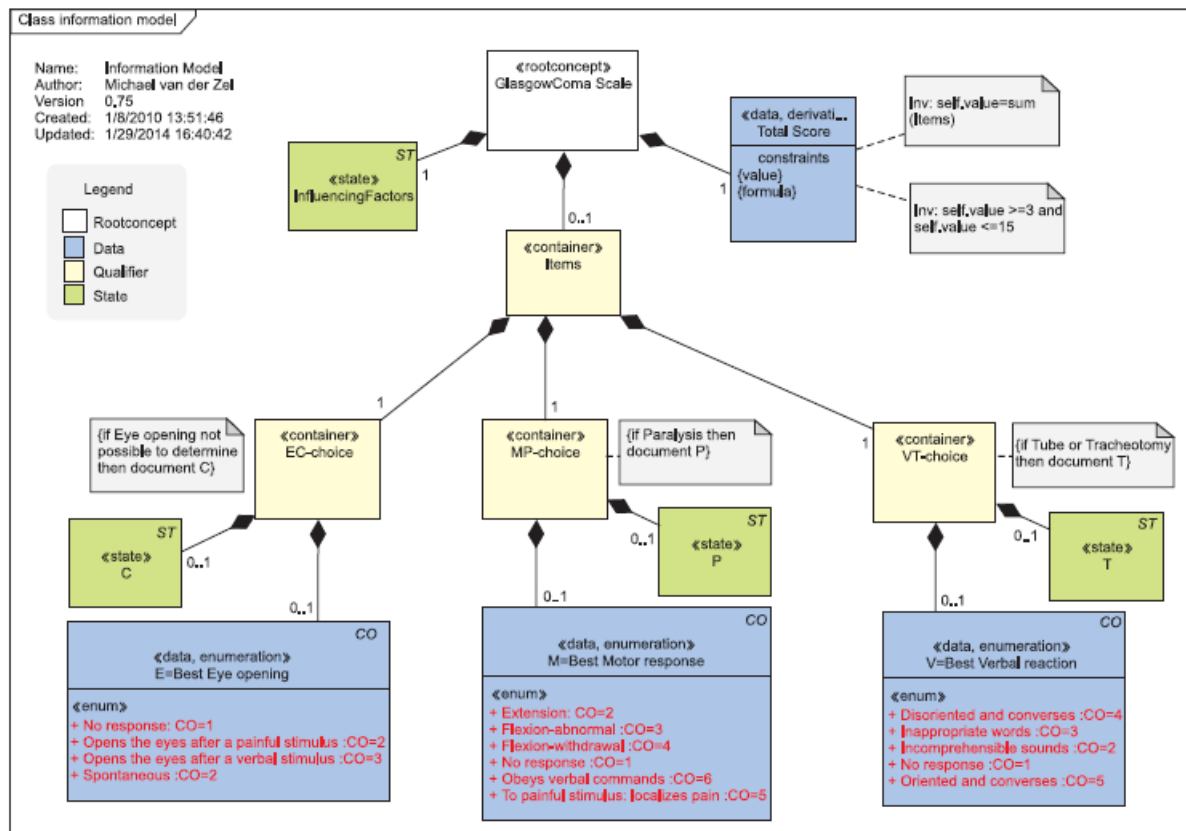
The GCS is used to determine the level of consciousness of patients after trauma, with stroke, or for other head injuries. The GCS consists of three categories of data, representing eye opening, best motor response and best verbal response that are summed up into a total score. The GCS is scored by documenting the number representing the best response for each category that could be observed with the patient. Tab. D.1 specifies the conceptual knowledge about the GCS [Goo14].

An example DCM is represented in Fig. D.1, using UML. Note that a DCM can be expressed in any logical modeling method. The DCM example in UML applies a full class diagram in which the concept is modeled; each data element is represented in a class. [Goo14].

Clinical knowledge	The GCS is used to measure the level of consciousness of a patient with respect to verbal, motor and eye movement reactions. It has a total score summated from the three underlying observations.
OpenEHR archetype	Node representation does allow identifying each of the three observations as a single data item and one for the total score. The total score derivation is defined. Each node can be linked to an external code system, e.g., LOINC 9269-2 for Glasgow Score Total.
HL7 v3 message using	R-MIM Observation Class representation for each of the individual score items and component relationships to identify hierarchical relationship with total score. Total score as separate instance of Observation Class. Each class represented for instance by a LOINC and/or SNOMED CT code: LOINC 9269-2 Glasgow Score Total, SNOMED CT 281395000: GCS eye opening sub-score.
DCM	Each data element is described as a separate UML class in the diagram. The relationship between data elements (classes) can be expressed. The derivation into the total score is expressed and class models can be drawn, including defining the hierarchical relationships. The classes can link to coding systems again, such as LOINC 9269-2 Glasgow Score Total, and SNOMED CT 281395000 for the GCS eye opening sub-score. This is currently done through tagged values. In the future OMG specification will be used for this.
EHR: Electronic Health Record, LOINC: Logical Observation Identifiers Names and Codes, HL7: Health Level Seven, SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms, DCM: Detailed Clinical Models, OMG: Object Management Group.	

**Table D.1.:** Concept level: example Glasgow Coma Scale (GCS) [Goo14]





**Figure D.1.:** Detailed Clinical Models (DCMs) in Unified Modeling Language of the Glasgow Coma Scale (2014 revised but unpublished version) [Goo14]



## **E. Appendix - CRS Project Plan**

Not available for public viewing.