Enterprise Ontology
does it care?

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Master's Thesis in Computer Science

by

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Title

Enterprise ontology, does it care?

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Abstract

The domains of healthcare and Information and Communication Technology (ICT) are very different. In healthcare, human beings are in the center of attention. When considering the domain of ICT, computing and connectivity first come to mind. It is suggested that the first step in bridging the gap between the two domains is to focus on the *essence* of care processes, independent of their realization and implementation. In other words, independent of any technology that is required to make them operational. As part of this essence, communication and (social) commitment turn out to be indispensable. Both subjects are currently insufficiently paid attention to, as this thesis will reveal. In this report, three applications of the Dutch national Electronic Health Record are analyzed and redesigned from an Enterprise Ontology viewpoint. Enterprise Ontology is an emerging field in the information sciences and engineering disciplines that has its roots in communication philosophy. It provides the required theory and a matching methodology to pursue this goal of bridging the healthcare and ICT domains. Instead of adjusting 'the business' to each individual application of the Electronic Health Record, a single shared perspective on care processes is provided. It demonstrates that the activities of the various care professionals at their core generally do not differ. Furthermore, it secures the consistency and coherence of the application designs, while presenting all important and sensible aspects in a concise way. This approach is thought to be the only correct starting point to determine, design and implement supporting information systems for the healthcare sector or any enterprise in general.

Resumé

De werelden van de gezondheidszorg en die van Informatie en Communicatie Technologie (ICT) zijn zeer verschillend. Binnen de gezondheidszorg draait het op de eerste plaats om mensen, zowel patiënten als zorgverleners. Denk je aan ICT, dan zijn het meestal niet meer de mensen, maar de informatiesystemen en bijbehorende netwerken die als eerste te binnen schieten. Het scherp afbakenen van de *essentiële* zorgprocessen zou de eerste stap moeten zijn om deze twee werelden te overbruggen. Daarmee wordt bedoeld, inzicht krijgen in de processen onafhankelijk van de manier waarop ze gerealiseerd en geïmplementeerd kunnen worden. Met andere woorden, onafhankelijk van ICT of elke andere technologie die nodig is om de processen operationeel te krijgen. Het blijkt dat communicatie als onderdeel van deze kernprocessen van zeer groot belang is. Ook blijkt dat dit aspect momenteel te weinig aandacht krijgt in de 'zorg-ICT', zoals uit deze thesis naar voren zal komen. In dit rapport worden drie toepassingen van het Nederlandse Elektronisch Patiënten Dossier (EPD) geanalyseerd en herontworpen vanuit een Enterprise Ontology oogpunt. Enterprise Ontology is een actuele tak in de informatiewetenschappen en heeft haar wortels in de communicatiefilosofie. Zij geeft de nodige handvatten, zowel op theoretisch als praktisch vlak, om op een constructieve manier te achterhalen wat de essentiële zorgprocessen zijn. In plaats van de 'business' van de gezondheidszorg aan te passen aan elke toepassing van het EPD, wordt er vanuit één business perspectief bekeken waar en op welke manier informatiesystemen mogelijk inzetbaar zijn ter ondersteuning van deze processen. Dit geeft aan dat de activiteiten van de verschillende zorgverleners in de kern nauwelijks verschillen. Een dergelijk perspectief verhoogt tevens de consistentie en coherentie van de toepassingsontwerpen én voorziet bondig in alle relevante informatie. Deze aanpak is misschien wel het enige juiste startpunt om mogelijke (zorg)ondersteunende informatiesystemen te identificeren, ontwerpen en te implementeren.

Preface

Exactly a year ago, I had just made the decision to cancel a thesis project I had engaged to regarding *business rules*; Rather than to pursue this narrower subject, I started my current project at the end of April 2009, of which the following report is the proud result. Although this decision meant another delay of four months, I am confident that this choice was the right one to make. A social and topical context - the healthcare sector and the Dutch national Electronic Health Record - in combination with a relevant and fascinating branch of the information sciences - Enterprise Ontology - turned out to be my perfect recipe for an interesting thesis project, from start to finish.

It was not the first time that I applied my engineering 'skills' in the field of healthcare. Already in 1998 there were rumors about (regionally) connecting the computer systems of primary care providers. However, my father (a general practitioner), was convinced realization of these initiatives would at least take another several years. He therefore asked me to develop a software application to assist him, in the mean time, with recording the medical information of the patients that visited him during night and weekend duties. *W@bri* (*Waarneembriefje*, Dutch for locum report), as the application was called, was built with love; and crappy code. Nevertheless, the application got sponsored by *GlaxoSmithKline* and was happily used by my father and several of his colleagues. Quite a big deal for a fourteen year old boy. Actually, at times my father still uses the application (although I am not sure whether that is a good sign). Now, more than a decade later, I am again put into touch with the processes in locum activities; however, this time on a national level. It illustrates that ICT is (indeed) trying to claim a more prominent role in the healthcare sector, but that it also is a rather lengthy process.

Executing this project and writing this thesis has taught me a lot. For one, I am certain that my understanding of Enterprise Ontology and its application has increased significantly. However, I have also come to understand that 'educating' this subject to others requires more than having the appropriate knowledge. Hence, I have learned I can still improve at making myself clear. Finally, I gained valuable insight into (part of the construction of) the Electronic Health Record. So, in the end, this report was definitely not written in vain. However, I hope that it ultimately inspires current Electronic Health Record application designers or contributes in some way to future care projects.

At last, it is time to express my gratitude to a few people closely involved with this project. For starters, I would like to especially thank my master's program supervisor, professor Jan Dietz, for his valuable feedback and encouragement during this graduation period. Next, I would like to thank Albert Vlug, manager of Nictiz's cluster Architecture & Design, for providing the opportunity to execute this project at Nictiz. Further, I would like to say thank you to my 'daily' supervisor at Nictiz, Maarten Schmidt, for assisting me when needed and providing helpful comments and directions during this project. Finally, I would like to express my sincere appreciation to my friend Kasia Celler, who carefully reviewed this report with her critical Canadian eyes. Last but not least, big thumbs up to my family and friends in general who provided the necessary distractions during this graduation!

Bas Beelen
December 21st, 2009

Delft, The Netherlands

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1. Introduction

The domains of healthcare and Information and Communication Technology (ICT) are very different. In healthcare everything revolves around human beings. On the one hand there are the patients who experience the care that is delivered to them, on the other hand one finds the care professionals providing or supporting the aid. Because people are unique, no patient is the same and no care professional alike. Comparing a surgeon with a dietitian illustrates this clearly, as they are considered to have a different *function*. Also, a leukemia patient is not considered the same as a diabetes patient. Having said that, the distinctions can be extended even further. Two surgeons with the same educational knowledge may still very well disagree about a certain diagnosis (hence the existence of second opinions). Two leukemia patients may very well choose a different direction of treatment. All these differences occur because these patients and care professionals - as human beings - are able to reason, which allows them to make judgements and decisions. Norms and values, emotions and experience are all influencing factors in the process of deciding. As a result, every care situation stands on its own and no single decision is repeated blindly a second time. It shows that people, and therefore healthcare, are not black and white. People are not 'discrete'. People are 'analog', which allows them to be "creative, resourceful and tolerant" [1].

When considering the domain of ICT, the terms computing and connectivity come first to mind. Information systems are built to compute and connect, thereby supporting human endeavor. The technologies involved are not analog. They are discrete; they are digital. Information systems are not at all tolerant or creative. They just 'do' as they are 'told'. The answers to a certain mathematical formula or the results of a database query *are* repeated blindly a second time. This is the first disparity between the two domains. Next, designers and developers of ICT solutions crave the finding of patterns. Patterns may lead to generic concepts which make complex matter easier to comprehend and in addition often allow for reusability in similar situations. In the ICT domain reusability is often associated with components: the building blocks needed for the *construction* of larger components or desired solutions. An example of the use of components is found in Object Oriented Programming: elementary components (like a character or numeral) can be combined to form larger components (like a sequence of characters a.k.a. string), which in turn can be used for the construction of even larger objects and so on. A similar approach on a higher level has recently become popular too: Service Oriented Architecture can be applied to build information systems from a combination of smaller (information) services. Individually, the services provide valuable information, but only when combined the actual desired results are obtained. To summarize, in the ICT domain the grouping of similar concepts *is* encouraged.

There is nothing wrong with the distinct characteristics of the two domains viewed separately. It is also not up to one of the two domains to judge the other. However, for a successful cooperation between the two, some connection is necessary - one way or the other - as soon will become clear.

1.1. Problem Statement

Despite their differences, the domains of healthcare and ICT are becoming more and more intertwined. A good example is the current development of national *Electronic Health Records (*EHRs*)*. Hospitals, pharmacies, general practitioners (GP's) etc. are all expected to electronically share necessary patient data with (authorized) colleagues. Applications of the EHR are being designed for the exchange of medical information in specific situations. For example, a locum GP who temporarily replaces a patient's regular GP often requires the highlights of the patient's medical history - information that is not stored in his own local patient records. The digitalization of medication prescriptions - which allows for direct communication between a GP and a pharmacy - is another example.

For this so-called *e-Health* to become (and stay) successful, a bridge between the two domains is required; a perspective on healthcare only approvable by care professionals but only devisable by (ICT) designers. Such a perspective should lack any mention of technology yet simultaneously adhere to patterns and components. A view - recognized by the health sector - that makes it at the same time easier to justify the application of ICT.

In the Netherlands, the National ICT Institute for Healthcare (Nictiz) orchestrates the design and development of a Dutch national EHR. The EHR can roughly be divided into two parts: the infrastructure and the 'infostructure'. The infostructure concerns the applications of the EHR and is therefore of particular interest for both domains. Unfortunately, the communication between the stakeholders (healthcare umbrella organizations, Nictiz, software developers) has not always been found to be optimal. Different interpretations of application designs have in the past lead to incorrect technical implementations or belated (avoidable) redesigns [2, 3]. Apparently, the above described necessary link between the healthcare and ICT domain is currently insufficient. It is a problem that Nictiz is interested in improving on.

1.2. Research Goal

Recently, *Enterprise Engineering* - an already existing field in the engineering disciplines - has experienced a revival [4]. By developing a sound theory regarding enterprises and organizations the field has risen above its current application of best practices to a scientific discipline. One of the branches of Enterprise Engineering is *Enterprise Ontology*. Dietz, author of the book *Enterprise Ontology: Theory and Methodology,* builds on the definition of ontology as provided by [5]: a formal and explicit specification of a shared conceptualization. In [4] it is specifically stressed that "an ontology of something is a conceptual *model* that satisfies the next requirements: coherent, comprehensive, consistent, concise and *essential"*.

It is believed that a formal and explicit specification of a shared conceptualization - in this case a shared conceptualization of healthcare - might be the required improvement for the sufficient bridging of the healthcare and ICT domains. The research objective of this graduation project has therefore been defined as follows:

> *To investigate the applicability and possible benefits of Enterprise Ontology in analyzing and (re)designing applications of the Electronic Health Record*

To attain this research goal, answers to the following research questions will be sought for:

a. What is the Electronic Health Record and what are its applications?

b. How are applications of the EHR currently designed?

c. How are the current application designs being used?

d. What is the idea behind Enterprise Ontology?

e. How can Enterprise Ontology theoretically improve the application designs?

f. How can Enterprise Ontology be applied and what is currently known about the application of Enterprise Ontology in the healthcare domain?

g. Does the application of Enterprise Ontology meet the expected improvements found in (e)?

h. Does the application of Enterprise Ontology contribute in bridging the gap between the healthcare and ICT domains?

1.3. Research Scope and Resources

Scope of EHR applications
Currently, Nictiz has officially published documentation on two EHR applications, namely the *Electronic Locum Record* (ELR) and the *Electronic Medication Record* (EMR). Further, several applications are still in development, including the EHR application *eDiabetes*. Previous, current and draft versions of these applications have been considered in answering the above research questions. This narrowed the scope to a manageable but representative amount of input. The ELR application is thought to be relatively simple. The EMR application is thought to be slightly more difficult because there is a larger variety of actors involved. Finally, eDiabetes is an example of the possible use of the EHR in a complete 'chain-of-care'. Therefore the three applications together cover a broad range of typical applications of the EHR.

Scope of Enterprise Ontology
An enterprise or organization can be considered as a (layered) system, as chapter 2 explains in more detail. The top layer of such a system, known as the *B-Organization*, is of particular interest in this thesis project. Healthcare professionals are likely to relate with this layer the most since it focusses on the *business* of an organization, i.e. the goods that are produced and the services that are delivered. Therefore, the mentioning of ontology in the succeeding chapters should be understood as the *ontology of the B-Organization*.

Resources
Interviews with experts on the EHR in combination with related Nictiz documentation were the requisite resources for answering research questions **(a)** and **(b)**. To answer question **(b)** more specifically, especially the scoped application designs were considered. To answer question **(c)** interviews with application stakeholders were held. Answers to **(d), (e)** and **(f)** largely depended on literature on the subject, specifically [4]. Answers to the final research questions depended on the answers to the previous questions.

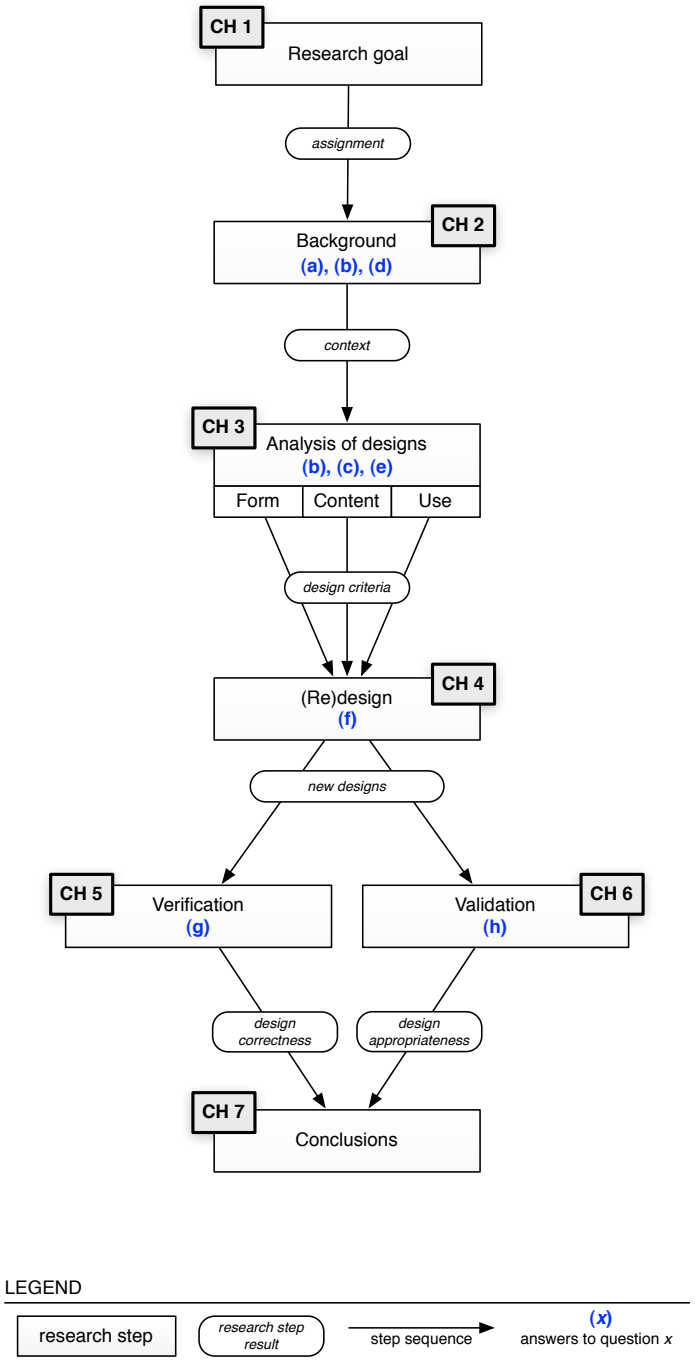

Fig. 1.1 *Overview of the sequence of research steps and their results*

1.4. Research Methodology and Report Structure

To answer the research questions defined earlier, a set of research steps were executed. Fig. 1.1 provides an overview of the order of research steps taken and their expected results. Simultaneously, fig. 1.1 illustrates the structure of this report and shows which research questions are (partly) answered in each chapter.

The current chapter obviously provides the **research goal** of this thesis project. Its definition leads to research questions that need to be answered and consequently results in a complete graduation assignment formulation.

In chapter 2, **background** information is gathered to obtain a thorough understanding of the context of this project. It is divided into two subsections. The first discusses the Dutch national Electronic Health Record (EHR), its applications and the role of Nictiz. In the second subsection the theory of Enterprise Ontology is explored in more detail. Both topics are a necessary foundation for the succeeding chapters. This chapter answers research questions **(a), (b)** (partly) and **(d)**.

Chapter 3 discusses the **analysis** of EHR application designs. It turns out there are several ways to review the designs; namely, based on their form, content and use. The analysis therefore specifically focussed on these three angles. At the end of this chapter answers to the research questions **(b), (c)** and **(e)** are presented. The answers to question **(e)** - the understanding of possible improvements in the current designs - lead to the definition of design criteria.

Based on the design criteria from the previous research step a design method was chosen. The earlier application of Enterprise Ontology in the healthcare sector was also investigated. Both contribute in answering research question **(f)** in chapter 4**.** Finally, an attempt in **redesigning** the current applications was made. These new designs served as input for the next two research steps.

Chapter 5 studies the **verification** of the new designs. Verification was done by mapping the new designs on the current designs. It revealed the completeness of the new designs and justified their correctness. These mappings in turn were discussed with experts in both the healthcare and ICT domain. Next, by testing whether or not the expected design criteria were met and if these have lead to improvements in the designs, answers to research question **(g)** are obtained.

Chapter 6 discusses the **validation** of the new designs. The redesigns were discussed with several healthcare professionals and designers to determine their appropriateness. Are the redesigns useful and do they contribute in bridging the gap between the healthcare and ICT domain? This chapter provides answers to research question **(h)**.

In chapter 7 the **conclusions** based on summaries of the previous chapters are provided. The conclusions allow for analysis of the extent of Enterprise Ontology applicability and its benefits in analyzing and (re)designing applications for the Electronic Health Record.

2. Background

The contents of the next chapters largely depends on two subjects, namely the Dutch national Electronic Health Record (EHR) and Enterprise Ontology. In this chapter, both subjects will be introduced, starting with the Electronic Health Record. First of all, the organization of Nictiz, which orchestrates the EHR's development and implementation, will be discussed. Next, a brief presentation of the functional decomposition of the EHR will be given. Finally, a few of its applications (those which were scoped) will be described. The second subsection provides a condensed overview of the foundations and theory behind Enterprise Ontology.

2.1. Nictiz

In 1999, the Ministry of Health - supported by the healthcare sector - established the ICT Platform Healthcare (IPZorg). At that time, IPZorg was given the task of coordinating and stimulating the use of ICT. However, several other important care-ICT related organizations were also simultaneously active. To prevent the fragmentation of their knowledge, many activities and projects of these organizations were consolidated, in 2002, within one central non-profit corporation: the National ICT Institute for Healthcare, also known as Nictiz.

Nictiz aims as better healthcare through better information. This goal is pursued by collaborating with patient and healthcare umbrella organizations, healthcare providers, IT suppliers and government organizations to erect a national Electronic Health Record and facilitate other kinds of nationwide electronic communication. National communication standards are therefore being developed, nationwide applicable applications of the EHR are being designed and active contributions to health-ICT policy are being provided.

To deliver these services and products, the business of Nictiz is currently divided into three clusters, as illustrated in fig 2.1 (next page). First of all, there is the cluster *Knowledge & Advice* (K&A). They investigate the needs and issues that play a role within the government and the healthcare sector. The cluster shares knowledge with these parties and helps to determine the focus and choices of (future) health-ICT matters. K&A also guides the initialization of new 'care application' projects. The second cluster is *Architecture & Design*. They design, maintain and test - in cooperation with software developers and the care sector - the national standards regarding the required central facilities and nationwide useful applications. This thesis project was mainly conducted for this cluster. The last cluster is *Operations*. For one, they manage the *National Switch Point*[1] (LSP), which will soon be explained. Next, the cluster qualifies and certifies software developers and care providers regarding the responsible manner in which they should connect their local systems to the LSP.

[1] In Dutch: *Landelijk Schakel Punt*

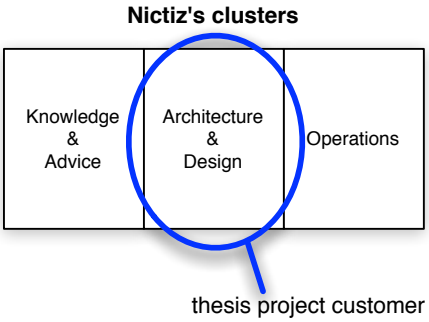

Fig. 2.1 *This thesis project was mainly conducted for Nictiz's Architecture & Design cluster*

2.1.1. Electronic Health Record

One of Nictiz's spearheads is the construction of a nationwide infrastructure which enables safe communication and authorized exchange of medical patient information between healthcare professionals. Dutch legislation requires medical information to be kept at its source. The EHR is therefore not a central database where the complete medical history of a patient is stored. Rather, it is to be understood as a virtual dossier where only the locations of the scattered information are centrally known. A healthcare provider might be specifically interested in one or more of these pieces of information. If the care professional is authorized to view the information, the request is routed to its source, i.e. forwarded to the local health information system where the information is stored (by using the known location). If all goes well, the requested information is returned and finally presented to the care professional. A simplified example of this process is depicted in fig. 2.2.

The National Switch Point is the 'traffic control tower' where the reference index to patient data is stored and to which healthcare professionals connect their local computer and information systems. These local systems have to be qualified as a 'well-managed care system'[2] (GBZ) before they are allowed to be linked with the LSP. A few of the requirements that have to be met to be qualified as a GBZ are, for example, the 'labeling' of patient information with the patient's social security number[3] (for identification), logging of incoming information requests and encryption of communication over a public internet connection. At the LSP, the necessary identification, authentication, authorization and logging mechanisms are also implemented. The LSP has been effectively operational since 2006.

The set of standards, agreements and national infrastructural facilities that enables the electronic exchange of information in the healthcare sector has been named *AORTA*. Although an infrastructure like AORTA is essential, utilizing it by means of useful EHR applications is at least as important. The Electronic Locum Record (ELR) and the Electronic Medication Record (EMR) were the first applications of the EHR to be designed. Their designs have now been officially published and implemented by various care-software developers. eDiabetes was also established as an early EHR application; however, its complexity has delayed a first official publication.

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[2] In Dutch: *Goed Beheerd Zorgsysteem*

[3] In Dutch: Burgerservicenummer

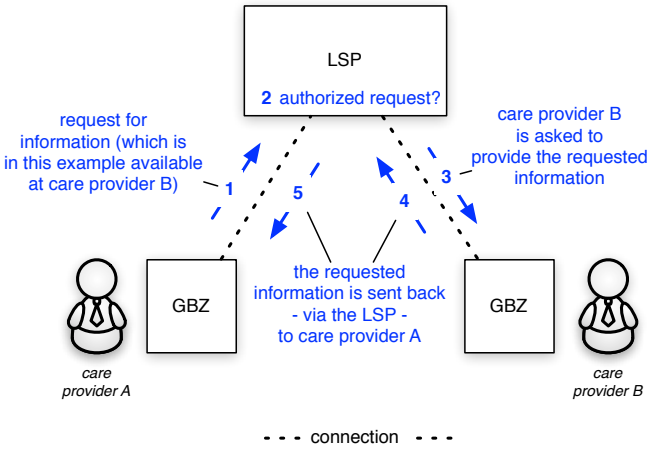

Fig. 2.2 *A simplified example of retrieving medical information from a different source*

Electronic Locum Record

The ELR[4] is an application of the EHR that is useful during night and weekend duties in primary care. A locum general practitioner (GP) temporarily replaces the patient's regular GP. Because the locum GP is usually not familiar with the patient and his medical history, the ELR application allows the retrieval of a summary of this history (which is composed from data that is stored at the regular GP's local patient record). Next, the locum GP records the patient's problem and policy that were established and executed respectively. However, as was stated earlier, Dutch law requires medical information to be stored at the (information) source. Since the locum GP only temporarily replaces the regular GP, the produced information should eventually be added to the patient record that is 'owned' by the regular GP. A second service of the ELR application allows this handover.

Electronic Medication Record

The EMR[5] is an application of the EHR that provides an overview of the medication history of a patient. Based on this information, new (probable) diagnoses may be established, for example, a suspected allergy for one of the medicaments. Secondly, based on this overview, pharmacotherapy that is compatible with the patient's current medication can be established and started. There is an extension of this application (which could be referred to as EMR+) that enables electronic prescribing (authorizing the request for dispensation of medicaments).

eDiabetes

eDiabetes was also one of the first EHR applications that was initiated by Nictiz. In 2003, the *Standard for quality diabetes care* was published by the Dutch Diabetes Federation (NDF). The standard describes the diabetes chain-of-care that should be considered for the secondary prevention of the disease (prevention of complications). ICT was considered a prerequisite for the support of these care processes [6]. ICT should, for example, provide overviews of parameters and indicators like blood sugar level and weight. eDiabetes should eventually enable communication of 'relevant information' between the active participants in the diabetes chain-of-care, which include amongst others the GP, dietician, ophthalmologist, and also the patient.

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[4] In Dutch: *Huisartswaarneemgegevens*

[5] In Dutch: *Medicatiegegevens*

2.2. Enterprise Ontology

Recall from the introduction in chapter 1 that an *ontology* is often understood as a formal and explicit specification of a shared conceptualization. Hence, an enterprise ontology could be considered a formal and explicit specification of a shared conceptualization among the stakeholders of an enterprise. In the context of healthcare, the enterprise in question is considered the healthcare system.

Although chapter 4 will reveal that a lower level focus is more convenient for developing ontological models, the term *system* is quite interesting because the Enterprise Ontology theory actually always considers an enterprise as a *system* [4]. Here, a system is understood as having a composition (a set of elements of some category, e.g. physical or social), an environment (a set of elements of the same category; the two sets are disjoint), a production (the composition elements deliver 'things' - e.g. a service - to the environment) and a structure (a set of influence bonds among the elements in the composition, and between them and the elements in the environment).

2.2.1. Performance in Social Interaction

An enterprise is considered a *social* system where the elements in its composition and environment correspond with actor roles, which are in practice fulfilled by human beings. An elementary actor role is specialized in delivering exactly one kind of 'product'. Obviously, the composition of an enterprise produces something for the environment: the employees of an enterprise deliver services or tangible goods to their customers. This is thought to be achieved by means of communication; or more specifically, *coordination*. For example, a customer *requests* for dispensation of a medicament from a pharmacist. The pharmacist may negotiate with the customer about - amongst others - the amount or brand of medicament. If they reach an agreement, the pharmacist *promises* its delivery: they have entered into a *transaction*. Now that the pharmacist has made the promise, he needs to make sure that he actually dispenses the medicament; this is understood as the *production* of the transaction. It is important to understand that it is not of any concern in this transaction *how* this medicament is made available for dispensation, i.e. it is not the medicament that is to be 'produced'. Rather, it is the *service* of dispensing the medicament that is to be delivered. Once ready, the pharmacist *states* the result of the production, i.e. he actually hands over the medicament to the customer. Perhaps the customer first makes sure that the name of the medicament on the package corresponds with the medicament's name on the prescription, but then he likely *accepts* by getting hold of the medicament. This completes the transaction.

The above sequence of coordination and production *acts* turns out to be very common in practice and is therefore understood as the *basic transaction pattern*. Fig. 2.3 shows a schematic of this pattern. However, entering into and completing transactions are always the result of negotiation. Several other coordination acts are therefore also sometimes performed; for example, one may decline a request or reject the stated result. An overview of all possible coordination acts is captured in the standard transaction pattern, available in Appendix G.

Once a coordination or production act has been performed, one can always refer to its completion: it has become a *fact*, which cannot be undone. For example, the production fact in the example above would be 'medicament has been dispensed'. An example of a coordination fact would be the acceptance of the production fact 'medicament has been dispensed'.

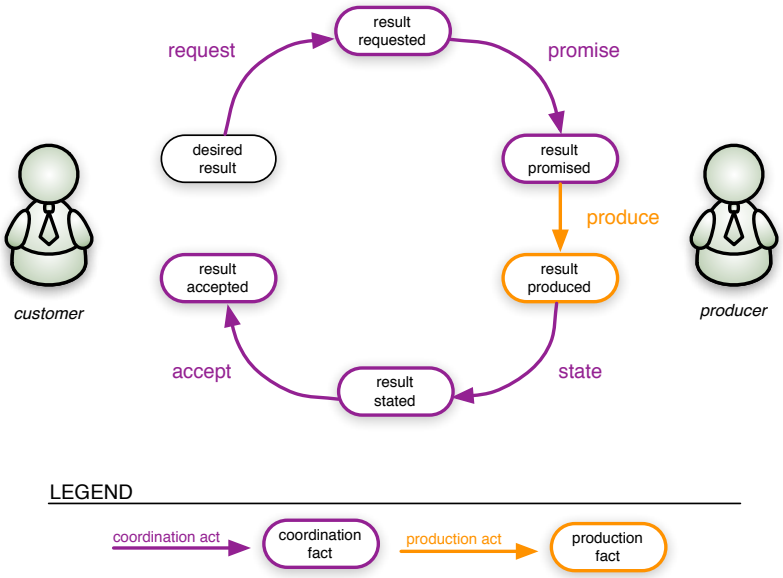

Fig. 2.3 *A schematic of the basic transaction pattern*

In an enterprise, transactions are the influence bonds of the structure of the (social) system, i.e. they bind the actor roles in the composition. This would suggest that *within* an enterprise transactions occur too. An extension of the previous example confirms this: upon promising dispensation of the medicament, the pharmacist may request a colleague to prepare the medicament that he has promised to dispense. In other words, a new transaction is entered into within the same (pharmacy) system. Recall that a system's structure also requires bindings between the elements in the composition and the elements in the environment. This was already illustrated, since the customers of an enterprise initiate the transactions to the services or goods that the enterprise wants to deliver to its environment, e.g. the dispensation of medicaments.

The coordination acts, which enable negotiation about a desired production, are performed by means of communication. Three kinds of communicative acts can be distinguished: the performative act (commitment to the coordination act is exposed or evoked), the informative act (thoughts are expressed or educed) and the formative act (information is uttered or perceived). During negotiation, the goal is to express the performative act; however, exposing a commitment cannot be done without expressing a thought, so the performative act depends on the informative act. In turn, the informative act depends on the uttering of information, i.e. the formative act.

Regarding the production acts a similar distinction can be made. Here, the *performa* ability corresponds with establishing something new (e.g. preparing a medicament or making a decision). The transactions that result in this kind of production are called *ontological transactions*. The *informa* ability corresponds with the reproduction of existing knowledge, and the computation, derivation, reasoning, etc. based on it. The transactions that result in this kind of production are called *infological transactions*. Finally, the formative production act is understood as dealing with recorded information items, also referred to as data or documents. The corresponding transactions are said to be *datalogical*. A similar dependency as for the communicative acts in coordination also holds for the different kinds of production.

The concepts introduced above are part of axioms in the ψ-theory (pronounced 'PSI-theory': Performance-in-Social-Interaction theory), which is elaborately explained in [4]. Based on these axioms, the *organization theorem* is established. It states that an enterprise is actually a layered system of three homogenous systems. Layered systems are commonplace; a human being, for example, could be considered a layered system, consisting of at least a physical,

chemical and biological system. The systems in an enterprise are called the B-Organization, I-Organization and D-Organization, and are layered as illustrated in fig. 2.4. The B, I and D stand for Business, Intellect and Data, respectively. The three systems only differ in the kind of transactions that are entered into, i.e. the kind of production result that is requested for. The B-Organization is concerned with ontological production, the I-Organization with infological production and the D-Organization with datalogical production.

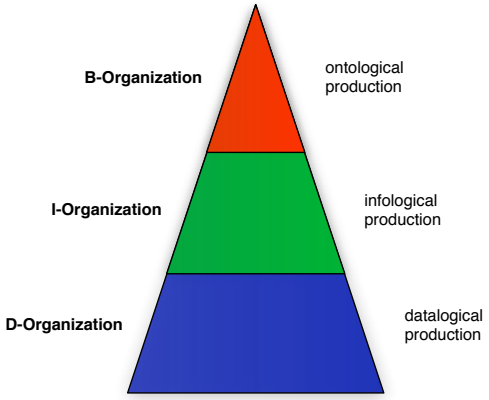

Fig. 2.4 *A representation of the organization theorem [4]*

2.2.2. Generic System Development Process

In the introduction, the terms *function* and *construction* were italicized on purpose. They are everyday words, yet in conjunction with the term *system* often incorrectly used or interpreted. However, it is important to understand their difference in order to understand how systems in general should be developed. For one, a distinction has to be made between the function and the *purpose* of a system. The purpose of a system is actually a relation between the system and its user. For example, one could use a computer system to test Newton's law of universal gravitation. However, most users agree that the purpose of a computer system is to compute (in its broadest sense); a socially agreed upon purpose is understood as the function of a system [7]. When considering the *function* of a system one is interested in its external behavior; it corresponds with a black-box model of the system. It is the common perception of a system outside the engineering sciences. When considering the *construction* of a system one is interested in its internal construction and operation; it corresponds with a white-box model of the system.

When developing a system - whether it is tangible or not - the interest is not only in the *object system* (OS), the system to be designed and developed. The (construction of the) system that is going to use the function of the object system, which is referred to as the *using system* (US), is important as well. Namely, the US's construction may depend on the OS's function; or one could say that a function supports some construction. For example, the problem establisher as part of the construction of the radiology cluster in a hospital depends on the function of an X-Ray to visualize dense tissues or bone structures. There is always an alternation of a function and construction, because a function can not support a function directly: a function does not have needs. Constructions, however, do. The dependencies of the communicative acts as discussed in the previous section already illustrated this. One can now understand the layers in fig. 2.4 in a similar way: the function of the D-Organization supports the construction of the

I-Organization, and the function of the I-Organization supports the construction of the B-Organization.

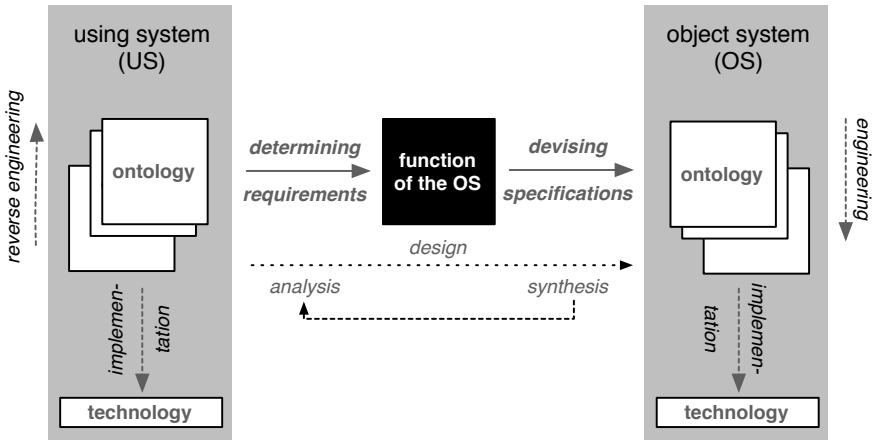

Fig. 2.5 *The Generic System Development Process [4]*

In fig. 2.5, the *Generic System Development Process* (GSDP) is depicted. Notice the US as the left pillar and the OS as the right pillar. An overview of the construction of a system, abstracted from its implementation and realization, is the *system's ontology*. In fig. 2.5 it is therefore placed at the top of the 'system pillar', exhibited as a white-box model. When designing the OS, the OS's requirements are first determined. These are specified in terms of the construction of the US and result in a black-box model (i.e. the function) of the OS. Based on this black-box model, specifications can be devised which result in a white-box model (preferably again a system's ontology) of the OS. To relate this to the organization theorem, recall that the B-Organization depends on the I-Organization. Thus, if one wants to design the I-Organization of an enterprise, the construction of the B-Organization should first be known. For example, to be able to establish a patient's problem, a medical doctor might base his judgement on the patient's previous medical problems. In other words, remembering the patient's medical history (I-Organization) may support the establishment of a new diagnosis (B-Organization). The ontology of the B-Organization can be reverse-engineered, as fig. 2.5 illustrates, from its current implementation. In other words, one has to find the actor roles and transactions (resulting in original facts) that are currently carried out by the employees of the enterprise. Note that this also indicates that human beings are the used 'technology' to *implement* an ontological model of the B-Organization.

2.2.3. Ontology, Information and Human Technology

Based on the ontology of the B-Organization, the requirements of the I-Organization can be determined (analysis phase in fig. 2.5). In turn, based on this function perspective, the ontology of the I-Organization can be designed (synthesis phase in fig. 2.5). This reveals the I-transactions required to support the B-Organization. Each of these transactions eventually still requires an implementation with appropriate technology to become operational. Since the system's category is still a social system, social individuals (i.e. human beings) are *still* the only possible way of implementing the actor roles in the I-Organization (and likewise the D-Organization). That is, the responsibility and authority to deliver a requested intellect/

information production (or data production) are assigned to human beings. However, it does not mean that remembering (and the required storing) of information always needs to take place in the minds of subjects. Intellect actors may find support in the use of so-called I-Applications, as the next section will elaborate on.

2.2.4. Ontology, Information and ICT

Recall that the production of I-transactions is - amongst others - a remembered fact or a computation. These are tasks computers are especially good at; hence, I-transactions are often supported by so-called I-Applications. However, this requires another walkthrough of the GSDP, because support from a new system is apparently desired. As the *using system* one could pick one or several I-transactions (which equals the US's construction). The *object system* will be the I-Application. First, the function of the I-Application should be determined, based on which specifications can be devised, i.e. another cycle of analysis and synthesis as depicted in fig. 2.5. Note that the construction of the object system, the I-Application, is not specified any longer in actor roles and transactions, since the social system (or more specifically, the I-Organization) has been exchanged for a system in the intellectual/conceptual category (or more specifically, an I-Application). The technology used for implementing the construction of an I-Application is commonly referred to as Information and Communication Technology (ICT). The de facto standard for specifying an I-Application abstracted from its implementation is the Unified Modeling Language (UML). To construct a true ontology of the I-Application, Dietz suggests the application of the SMART meta-model.

2.3. Conclusions

After reading this chapter, one should have obtained the answers to the opening research questions. First, the Electronic Health Record and example applications were discussed, thereby answering question (a). Next, insight into the organizational clusters of Nictiz provided a rough idea about how these applications are established, partly answering research question (b). The next chapter will further elaborate on this subject. Finally, a very compressed overview of the ideas of Enterprise Ontology was given. Especially at the end, it became rather theoretic. One should not worry if one has not grasped all addressed topics yet. The next chapters elaborate and repeat the appropriate foundations when required. For now, this section is enough to answer research question (e). The interested reader is encouraged to read the book that was discussed in the introduction: *Enterprise Ontology: Theory and Methodology* [4].

3. Analysis of EHR applications

In this chapter the results of the analysis of two EHR applications are presented. It explains the current process and progress of designing and how these designs are used. Simultaneously, it discusses whether (and if so, which) improvements are possible. The applications in consideration are the Electronic Locum Record (ELR) and the Electronic Medication Record (EMR). eDiabetes is still a work in progress and its analysis would therefore not add much value in answering the above questions. Note however that eDiabetes *was* of course necessarily analyzed in a similar way before redesigning (Chapter 4) could take place.

The EHR applications are described by Nictiz in so-called *architecture* documents. In the field of Enterprise Engineering the term 'architecture' is solely used for the *prescription* of a system: the design principles [8]. A *description* of a system, irrespective of the level of abstraction (or detail), is considered a design. It turns out that the 'architecture' documents of the EHR applications are actually especially descriptive. Therefore, to avoid confusion, these documents will be considered designs in the remainder of this report.

3.1. Analysis approach

To collect necessary input for the next research steps - the design criteria - a structured analysis approach was first defined. In [9] three aspects of communication are explained: form, content and use. Since the designs are meant for communication, the analysis specifically focussed on these three angles:

Form
The designs were analyzed on the basis of their structure. Different versions of the designs provided the formation of the layout. This aspect of the analysis largely depended on the documents; however, some information was gathered from the developers of the documents.

Content
The analysis of the content again largely depended on the documentation. Different versions of the documents provided the course of the content. Where necessary, unclear information or choices were clarified during interviews with experts on the designs.

Use
For whom are the designs intended and in what way? And are they actually used as intended? By examining the EHR applications designs and interviewing their users, answers to these questions were sought.

As explained in chapter 1, the focus of this thesis project is on the applicability and possible benefits of *ontology of the B-Organization*. Therefore, the analysis of the application designs also especially focussed on equivalent information about the business of healthcare. However, when necessary, information outside this scope was considered as well.

3.2. A focus on form

Standardizing the exchange of medical information between healthcare professionals has always been on Nictiz's agenda. Medical information is transferred through so-called *messages*. Nictiz has chosen for the standardization of these messages to rely on the HL7 version 3.0 (HL7v3) protocol, an international standard for communication between healthcare professionals. Because there were only few initial EHR applications with a relatively small scope, i.e. with only a few communication messages to standardize, a bottom-up approach was taken. Existing international HL7v3 messages were adjusted to be useful in the Dutch healthcare system. The little documenting that was initially done, followed the HL7v3 approach: descriptions and commentary were casted in HTML documents, viewable with a web browser [10].

With the arrival of new applications there came a need for better structured documentation. Keeping the various documents consistent would also contribute to the professionalism of Nictiz. As a result, TOGAF was chosen to assist Nictiz in accomplishing this endeavor. TOGAF is an abbreviation for The Open Group Architecture Framework, which suggests a framework for the development of (enterprise) architectures. However, in line with the Enterprise Engineering terminology, TOGAF is better described as a structured approach for building designs; "a detailed method and a set of supporting tools" [11]. In their approach, TOGAF distinguishes three views on the enterprise in question: business, information systems and technology. In the business view there is a focus on the actors and processes. The information systems view translates the business view to data assets and useful applications to be deployed. Finally, the technology view describes the technology - both software and hardware - that is required for supporting the services defined in the business and information systems view.

In their EHR application designs, Nictiz incorporates these three views in a similar order. The documents are expanded with an introduction on the infrastructure AORTA, references to documents that were used as a foundation, and an architecture vision which describes the EHR application in terms of motivation, goals etc. The current default document structure of the EHR application designs is summarized below:

Chapter 1: Introduction
Chapter 2: References
Chapter 3: Architecture vision
Chapter 4: Business architecture
Chapter 5: Information Systems architecture
Chapter 6: Technology architecture

As explained in the analysis approach, the analysis especially focussed on the business of healthcare. Regarding the document structure presented above this means a focus on chapter 4: the business architecture, referred to as the business perspective in the rest of this chapter. In the business perspective, the business activities, business objects, and the relations between them and the business actors are outlined.

3.2.1. Observations

Based on the form analysis of various version of EHR application designs (see Appendix A), a few interesting observations were made. For one, the latest official publications of the ELR and EMR applications have become more appealing documents than their first versions. However, there are still some remarks to make. The use of the Unified Modeling Language (UML), for

example, has its disadvantages. UML is a modeling language designed for the documentation of artifacts of a software system [12]. In a business perspective, the use of - for example - class diagrams feels inappropriate. The choice of using these diagrams was only made because the class diagrams were 'the least bad' of all available UML diagrams.

UML has another disadvantage: it lacks some necessary semantics - or perhaps it is more correct to state that UML contains useless elements. The best example is the *association* link, which is regularly used in the application designs. As this link lacks any sense of direction, one can only guess how this association should be interpreted. The labels that indicate the kind of association do not distinguish between object and subject, so these are not of much help either. An example is depicted in fig. 3.1: is the locum report used for relevant medical information, or the other way around? A similar confusion exists in example fig. 3.2. Next, the object types that the UML classes attempt to represent are barely or not even at all possible to instantiate. Instantiation is a relationship between a concept and a type [4]. For example, the concept Ibuprofen is an instantiation of the type medicament. Note that it is impossible to instantiate a concept that belongs to the generic concept 'relevant medical information'. Further, the 'dispensation' and 'administration' UML classes actually refer to events, the results of an act. Similar events do belong to a type; however, generally it is rather hard to instantiate event types because it requires a subject to construct a mental picture in his mind of the event at a specific point in time (almost automatically one pictures the generic concept, i.e. the type)

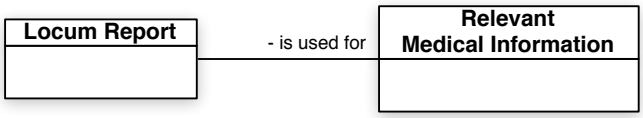

Fig. 3.1 *Ambiguity in the representation of business objects in the ELR design version 6.0.1.0*

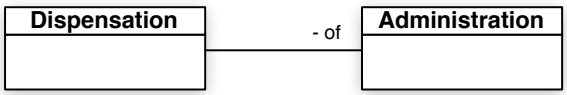

Fig. 3.2 *Ambiguity in the representation of business objects in the EMR design version 6.0.0.0*

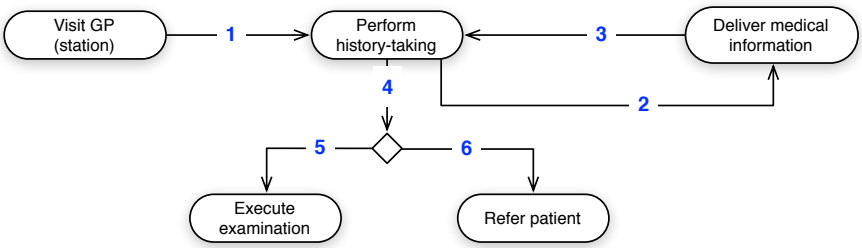

Fig. 3.3 *Ambiguity in the representation of the business process in the ELR design version 6.0.1.0*

A final comment on the use of UML concerns the schematic given in fig. 3.3. It depicts part of an activity diagram modeling the business activities in the locum situation. The rounded rectangles represent the activities. The arrows in an activity model determine the flow of the activities that are performed. In fig. 3.3, the sequence of arrows **1** - **4** - **5** or **1** - **4** - **6** intuitively shows a reasonable flow of activities. However, the sequence of **1** - **2** - **3** leads to confusion. Is the activity 'Perform history-taking' executed multiple times? The arrows **2** and **3** probably no longer represent a flow, but respectively a request for and a response of information. This shows (again) that some desired representations are not (formally) possible with UML. Unfortunately, the modeling language also does not come with a methodology to solve these problems.

Ambiguity is not an issue only found in the schematics of the designs, but also in the natural language that is used to describe and explain them. This is best exemplified with the term *medication*. The term can be used to denote the *treatment* with medicaments, e.g. to start or stop the medication, as used in [13]. The term can also be used to denote the actual *medicament*[6], e.g. to administer the medication, as used in [14]. Finally, it is rather unclear whether medication refers to one, multiple or the complete set of prescribed medicaments. Surprisingly, the frequently used term *medication* is not present in the overview of business objects of the EMR designs. Here, the Dutch equivalent of (a single) *medicament* is considered to be administered. To most care professionals this ambiguity might not seem an issue; however, for the average reader, especially from the ICT sector, this could lead to undesired miscommunication and should thus be avoided.

3.3. A focus on content

In discussing the progression of the content of the EHR application designs, one should start at their emergence. The Ministry of Health, Welfare and Sport made the choice to gradually implement a national Electronic Health Record. The ELR and EMR have been chosen to be the introductory applications in this major project [15]. It is not necessarily the ministry who requests the design and implementation of applications. The voice of healthcare professionals is also heard and responsible for the launch of new applications. Next, research done by Nictiz's department *Knowledge & Advice* also discovers 'opportunities' which lead to requests for funding and initialization of new projects [16].

Like the EHR, the content of the application designs grew gradually. The quick launch of pilot projects lead to designs with only minimum details and requirements [17]. The actual implementation of the applications lead to feedback from both software developers and care professionals. Eventually, this feedback was processed and as a result succeeding versions of the designs were extended with new (desirable) information.

The Electronic Locum Record is based on guidelines for the exchange of information between general practitioners, provided by the National General Practitioner Community (NHG). These guidelines already existed before the idea of a national ELR was established [3]. As a result of the designing of the ELR these guidelines have also been updated several times. In other words, the reciprocity between NHG and Nictiz meant documentation improvement for both. According to [3] the ELR was welcomed by general practitioners (GPs). Because the application fulfilled a wish of many GPs to exchange minimal patient information, the introduction received little resistance.

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[6] This translates to *medicament* or *geneesmiddel* in Dutch. *Medicijn* is also often used, however, the English translation *medicine* is ambiguous too, as it commonly refers to "the science and practice of diagnosis, treatment, and prevention of diseases" (Oxford Dictionary)

The EMR is also based on guidelines for the exchange of information, but these guidelines were created by the multiple stakeholders of the EMR application. These include Royal Dutch Society for Pharmacy (KNMP), the Order of Medical Specialists (OMR) and the Dutch Society of Hospital Pharmacies (NVZA). Nictiz too was involved in preparing the guidelines, as was NHG. Both [17] and [3] agree that the process of designing the guidelines and design documents was experienced as more difficult due to the many stakeholders involved. Designing the EMR application by degrees was therefore not only necessary for a quick launch of the pilot project, but also because obtaining a shared agreement on the design turned out to be harder than expected.

The ELR design currently only covers the locum situation concerning night and weekend duties, nowadays usually regulated by a 'central GP station'. In the future, the application should be extended to support locum services between individual GPs, in the case of holidays etc. Feedback given by the regular GP to the locum GP is also a future feature [18]. The EMR is being extended via the EMR Plus program. Besides viewing the current medication that is prescribed to a patient, this program aims at adding support for electronic prescription of medicaments and monitoring medication for mutual interactions [17].

3.3.1. Observations

The content analysis (see Appendix B) has shown that the newest versions of the two EHR application designs have grown - and in many ways improved - in the content they are carrying. Both have extended their (business) focus to include the bigger picture: from the patient posing his or her question to executing examinations and prescriptions. Despite their similarities, the content of the business process and business object illustrations (and their descriptions) differs. These differences were not only found between separate applications, but also between different design versions of the same EHR application.

A first example of these differences is depicted in fig. 3.4 and concerns the *coherence* between the business activities and the business objects. In the latest ELR design the business activity 'compose treatment plan'[7] is mentioned. In natural language the word 'compose' would be considered a verb and 'treatment plan' would be the object. However, there is no sign of this object among the business objects of the design. This is rather strange as there actually is a business object 'locum report' which is related to the business activity 'compose locum report'.

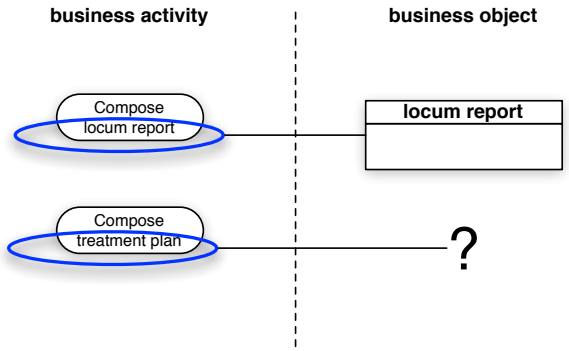

Fig. 3.4 *The coherence between business activities and objects is not straightforward*

[7] Dutch: Opstellen behandelplan

A second example concerns the *consistency* between the business perspectives of the latest ELR and EMR designs (see fig. 3.5). Both business perspectives mention the business activity 'diagnose'. The result of diagnosing would be a diagnosis. However, only the business perspective of the EMR design mentions the object 'diagnosis' in their business objects overview. One would expect the designs to have the object both included or excluded. This leads to inconsistency between the two designs.

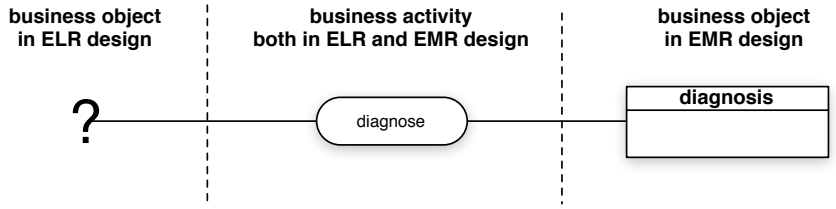

Fig. 3.5 *Inconsistency between objects in the ELR and the EMR design*

Regarding the content available in the business perspective, another observation was made. The objects gradually become more detailed during the design perspectives. As was already mentioned in section 3.2.1, business objects hardly have clearly defined mutual relations. In the Information Systems perspective these objects suddenly have more crucial details. Fig. 3.6 exemplifies this statement. First of all, there is actually another inconsistency, because in the EMR business perspective the patient is linked to a 'care question' which in turn is linked to a diagnosis. However, in the Information Systems perspective, there is a direct connection between the patient and the diagnosis. In line with designs results in the next chapter, the 'care question' object is considered irrelevant, which justifies the direct relation between a patient and a diagnosis in the business perspective as currently illustrated in fig. 3.6. In the business perspective of the EMR design, the relation between the patient and the diagnosis is defined with the label 'has' (notice that there is no direction, it could just as well be 'diagnosis has patient'). In the Information System perspective the objects have been assigned occurrence limitations which state that a patient may be associated with zero or more diagnoses. A diagnosis on the other hand is always related to one and only one patient. This kind of information should be approved by 'the business' itself, i.e. the healthcare sector. It should therefore not be 'guessed' in subsequent design perspectives that are less relevant for these stakeholders [3]. Furthermore, should a patient without any diagnoses be considered a patient? These are all points that question the *comprehensiveness* of the current designs.

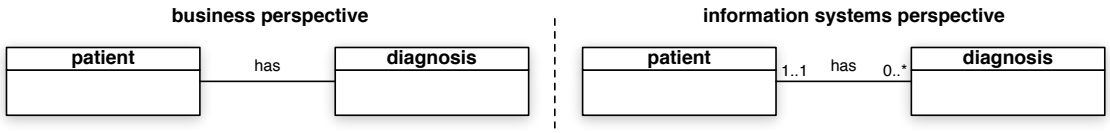

Fig. 3.6 *Object details only approvable by 'the business' are not available in the business perspective*

In another situation, redundancy is actually observed in the business perspective. Fig. 3.7 shows a part of an EMR activity diagram in the primary care situation. The activity 'history-taking' and execute examination' is actually a duplicate within the same diagram, only now considered for 'other relevant care providers'. Obviously this is superfluous information, as the important

message has already been made clear at first mention of the activity; namely that a patient's medication history might necessarily be consulted during history-taking and examination. Adding duplicate information jeopardizes the *conciseness* of the business perspective.

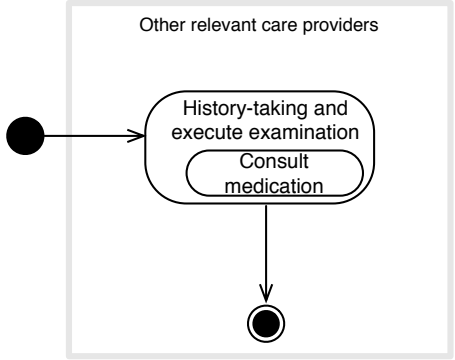

Fig. 3.7 *Superfluous duplication of an activity in the EMR design*

3.3.2. The property of essence

It is not a coincidence that the four issues just described are closely related to the understanding of ontology in [4]. Specifically these examples were chosen to illustrate how the four C's - coherence, comprehensiveness, consistency and conciseness - are currently threatened in the EHR application designs. However, the fifth and most important property of an ontological model - *essence* - has not been discussed yet. It turns out that the current designs also lack this property, but before illustrating this, its meaning and its importance will be explained. Also note that it is not the current intention of the business perspective to be 'essential'. The focus in these sections has especially been on an easily understandable section for the healthcare professionals, who actively collaborated to construct the business perspective (see Appendix B and C).

First and foremost the essence of a system is understood as the abstraction from implementation issue. Implementation is about using technology to make a system operational. A well known example of implementation is using a programming language to build an executable computer application (concrete system) from its design documents (conceptual system). Another example is the use of human beings to establish an organization (concrete system) from its enterprise ontology (conceptual system). Notice that as soon as a system is operational, people tend to forget about its construction and often only understand its function. Even the engineers who implement systems, say programmers, will recognize this shift at some point in time after the implementation of a computer program. However, as explained in section 2.2, the construction of the *using system* is required for determining the requirements of the object system. In other words, understanding the construction of the healthcare sector is a prerequisite for the correct determining of requirements for an Electronic Health Record and its applications. The content analysis has shown that both designs do not abstract from implementation. Two examples, one from both designs, can illustrate this. First, in fig. 3.8, it is shown that one and the same activity is assigned to multiple actors, i.e. the actors are the implementation of the activity 'administer medication'. By considering organizational functions - inseparably associated with human beings - instead of 'activity roles', a chance of effective abstracting has been eliminated.

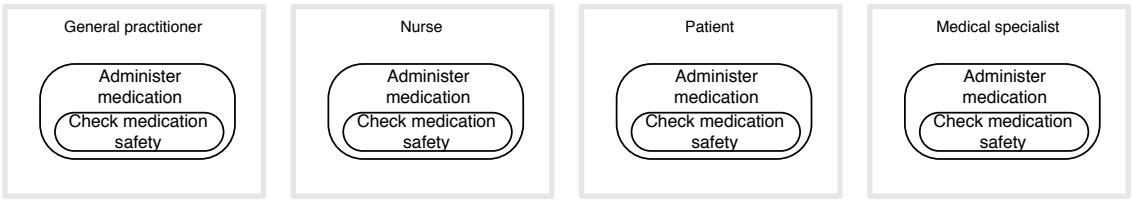

Fig. 3.8 *No abstraction from implementation in the EMR design*

The activity 'execute triage' in the latest ELR design can be considered as a last and final example regarding the lack of abstraction from implementation. The replacement of the regular GP by a locum GP is not new. In the past, general practitioners would perform locum activities directly for each other. This is sometimes still the case during holidays. Recently, however, locum activities are being performed over an area of multiple municipalities, covering far more patients (and GPs). There is one central place where general practitioners are stationed[8] for night and weekend duties and where triage nurses are situated to intercept the first contact with the patient (thereby relieving the pressure on the GPs). Obviously, the activities in the locum situation have not changed, only the way of operating has. Recall from chapter 2 that the operation of a system is the result of implementing an ontology with technology, as is also illustrated in fig. 3.9. Hence, one may rightfully conclude that the introduction of the triage nurse is at the level of implementation. To identify the actor roles assigned to the triage nurse, one should apply reverse-engineering to reveal the various transactions that get executed. However, it is not at all straightforward to obtain these transaction based on the name of the organizational function 'triage nurse'. Serious investigation is required to determine the true activities of a triage nurse. In chapter 5 it will be explained that the triage activity actually covers several transactions which one would assign (at first sight) to a certified medical doctor (e.g. establishing a patient's problem).

Even more remarkable is realizing the fact that performing locum activities is actually an implementation of care provisioning on its own. The activities performed by a general practitioner, whether it is the patient's regular GP or not, are the same in both situations.

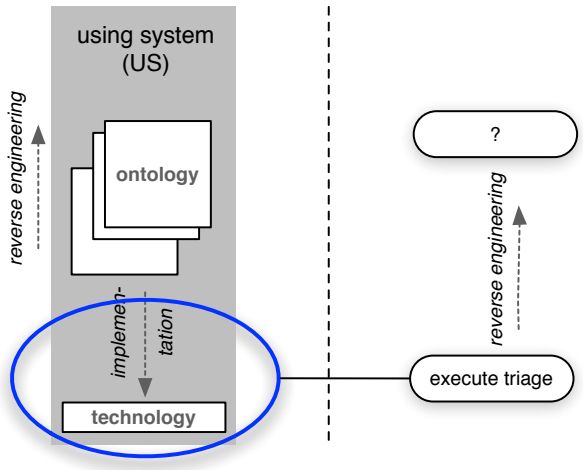

Fig. 3.9 *Reverse engineering of the activity 'execute triage' obtains its true construction*

[8] In Dutch this is called 'huisartsenpost'

There is a second perception of what to consider the essence of a system and it is related to the *separation of concerns* as introduced in [19]. It is about focussing on one aspect of a subject, while purposely ignoring its other aspects as these are considered irrelevant seen from that viewpoint. It was explained in chapter 2 that an enterprise is a layered system. The top layer, the B-Organization, constitutes the ontological production of the enterprise, i.e. the goods that are produced and the services that are delivered. Beneath the top layer is the I-Organization, which constitutes the infological production of an enterprise, i.e. (computations on) the reproduction of information about produced goods and delivered services. With separation of concerns in mind it becomes perfectly clear that during the consideration of the ontology of the B-Organization, matter belonging to the I-Organization - or even the D-Organization - is not at all essential.

To illustrate the above, again consider fig. 3.3. The ambiguity of the arrows has already been discussed; however, with the notion of separation of concerns this issue can actually be explained. The declared activity 'deliver medical information' is actually not at all an activity of the B-Organization since there is no new information produced. Rather it shows the reproduction of past information about a patient's health. The 'activity' should therefore be considered a part of the I-Organization. To be very precise, it should be considered a transaction of the I-Organization which supports the transaction 'perform history-taking' of the B-Organization.

In the EMR design this phenomenon is moderately recognized. The earlier presented fig. 3.8 shows an element ('check medication safety') belonging to the I-Organization inside an element belonging to the B-Organization. However, notice that 'check medication safety' says nothing about the *construction* (its ontology of the I-Organization). Investigating how to model the I-Organization is outside the scope of this thesis project; however, another thesis project on this subject has recently been finished. Interested readers are referred to [20].

3.4. A focus on use

Applications of the EHR are being devised and designed, but who is interested in these designs? In the introductions of the current documentation, three target groups are described: care professionals, care management and umbrella organizations collectively as the healthcare sector; the suppliers and developers of software collectively as the ICT sector; and finally Nictiz as the orchestrator of developments between the two domains. During the use analysis (see Appendix C) the intended and the actual use of the designs was investigated. Table 3.1 provides an overview of the results.

Stakeholder	Intended use	Actual use
care professional	acknowledge business	not used
umbrella organizations	acknowledge business	understand business
care management	understand business	not used
software supplier/developer	implement conceptual models	justify construction choices to customers
Nictiz	implement conceptual models i.e. building blocks AORTA, define standards	answer questions

Table 3.1 *Overview of usage of EHR application designs by stakeholders*

3.4.1. Observations

According to [16, 18] the primary goal of the application designs is to capture and describe the exchange of information between healthcare professionals. To relate this to the ψ-theory of Enterprise Ontology, the interest is in the I-Organization. This does not come as a surprise, because it is here that ICT can be applied: the building of I-Applications supporting the I-Organization (see section 2.2.4). The functions of Nictiz's AORTA, the function of local EHRs and the content of communication messages all depend on its construction. However, recall that the function of the *object system* - in this case the I-Organization - depends on the construction of the *using system* - consequently the B-Organization, i.e. the components for the production of goods or services. To give an example in the context of healthcare, consider the interpreting of the last episodes[9] of a patient. Recalling on a patient's medical history is not just done for the fun of it; this information is used as grounds for deciding about the current health problem of the patient. The reproduction of information about previously delivered services supports a new delivery of that same service. Spoken bluntly, if judging a patient's problem would not be a healthcare service, there would not be a need for interpreting a patient's medical history.

As table 3.1 shows, the current designs are not used by the healthcare sector as intended. However, the business perspective should in fact be acknowledged by them, as only the healthcare sector has the true knowledge about what they are doing. Ideally, the words 'them' and 'they' in the previous sentence should refer to each and every healthcare professional. In practice however, 'them' and 'they' are likely to be the representatives of healthcare professionals in the form of umbrella organizations. This occurs for two reasons: for one, it would be an impossible job to let *every* care professional acknowledge the designs. Second, the distinguishing between function and construction is likely not found easy for the average untrained care provider. Therefore, approving the designs is perhaps a better job for those care professionals who are not practicing anymore and who thus may find the time to delve into the designs.

Nictiz does not use the designs as much as intended either. More often, the documentation is turned to to recall design choices instead of actively justifying these choices with regard to the Technical and other EHR application designs. Apparently, the designs of the EHR applications influence the construction of the AORTA infrastructure and HL7v3 messages. For example, checking a patient's contraindications (a condition or factor that increases the risk of executing a particular care act) used to be part of the EMR application. However, later on, this function was separated from the EMR design and accepted as a new EHR application called *Medication Safeguarding*. Namely, checking contraindications turned out also to be done by stakeholders that are not concerned with a patient's medication history. However, apparently, this separation also influenced the Technical design (and therefore the infrastructure) in such a way that the construction of messages (along with their dependencies) had to be revised too. Hence, the lack of coordination among the various designs (and, the lack of an overview of required I-transactions) resulted in these costly revisions.

Finally, the software developers use the designs only sporadically. Instead, they avoid the 'trouble' of reading the documents by simply using the accompanied implementation examples (of the standardization messages). However, the designs could be used to fully understand the construction of healthcare and therefore also their own EHR applications. In theory, all vendors of patient record software could use the same ontologies as foundation of their software, thereby assuredly easing the process of information exchange among the various information systems. However, commerce probably discourages such initiatives. Nevertheless, steered by the government - as was done in Finland [21] - it could be stimulated for the sake of correct and reliable information sharing.

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9 An episode can be understood as the history of one particular health problem

Readability
The experts on the current application designs often mentioned the importance of *readability* of the business perspective. This perspective is often understood as the description of the EHR application for the healthcare professionals [16-18]. Readability is therefore regarded a criterion that should be taken into consideration in the designing of EHR applications, our any system at that.

3.5. Conclusions

Having reviewed and discussed two Electronic Health Record (EHR) application designs, answers to several research questions have been provided. Sections 3.2 and 3.3 explained the current design process of EHR applications and therefore answered question (b). By using TOGAF as a 'detailed method' for the structuring of the documents, UML as the tool for developing illustrations and by cooperating with healthcare umbrella organizations, the documents obtain form and content.

For a 'detailed method', TOGAF actually gives little hold. For one, all discussed inadequacies are the result of unclear definitions of important concepts like business activity or business object. The lack of clear definitions is - as a last illustration - once more exemplified by considering the content of the Technology perspective of the Electronic Medication Record (EMR). Namely, comparable content is placed at the Information Systems perspective in the Electronic Locum Record (ELR) design. As a result, similar content of the Technology perspective in the ELR design is nowhere to be found in the EMR design. Apparently, it is not clear how to distinguish between information system and technology. Furthermore, recall from chapter 2 that information systems support the I-Organization (which in turn supports the B-Organization). This essential step misses in TOGAF: the Business is directly followed by the Information Systems perspective (this also applies to the D-Organization which is directly replaced by the Technology view). One could stick to TOGAF to structure the documentation, as long as the B-, I- and D-Organization are also correctly dealt with.

Unfortunately, UML is not appropriate for designing business models. The modeling language was developed to document artifacts of a software information system. Recall from section 2.2.4 that a software information system has a very different composition and structure than an organization. Therefore, UML almost automatically lacks the required concepts to model a business organization.

In section 3.3 the use of the designs was discussed, thereby providing the answers to **(c)**. It turned out that the designs unfortunately receive less attention than intended. However their importance for all the stakeholders was explained in section 3.4.1.

The observations during analysis showed how the current designs could be improved, thereby answering question (e). First of all, the ambiguity of the schematics was explained. Using a formal language would in theory solve this problem. Furthermore, incoherence of the content of the designs is unwelcome and could be enhanced. Next, inconsistency between the different designs should be narrowed. Also, important information should be present in the correct perspective, yet not be unnecessary excessive. Finally, effective use of abstraction should be stimulated from a relevant perspective.

Based on these possible improvements, design criteria for the next research step can be extracted. For one, the designs should adequately reflect the true business of the stakeholders, i.e. the B-Organization of (part of) the healthcare system.

Next, new designs of the EHR applications should adhere to the following properties:

1. formal
2. coherent
3. consistent
4. comprehensive
5. concise
6. essential

The attentive reader recognizes these properties as the requirements of an ontological model. The form and content analysis was indeed executed with these characteristics in mind. In addition, the perspective on the use of the documentation revealed yet another design criterion which should be added to the list:

7. (easily) readable

Armed with this list of requirements, the search for an appropriate design technique can begin in the next chapter.

4. Redesigning the Business Perspectives

In the previous chapter it was shown that the current EHR application designs can be improved in several aspects, especially in the business perspective. In theory, Enterprise Ontology provides these improvements. However, the question remains how Enterprise Ontology can actually be put into practice. This chapter focuses on finding the suitable design method for this endeavor. It also discusses the earlier application of Enterprise Ontology in the context of healthcare and how these results are helpful during redesign. Finally, the redesigned business perspectives of the scoped EHR applications (ELR, EMR and eDiabetes) are presented.

4.1. Design methodology

The erratic results of the current designs are to the largest extent caused by the set of methods and tools that is currently used. UML lacks the necessary semantics and concepts to construct formal business models and TOGAF lacks the profundity to satisfy the C_4E properties of the designs. An obvious question then remains: are there alternative approaches that *can* guarantee satisfaction of the requirements of a (system) ontology? The answer is yes, there is one such approach for the construction of these so-called *ontological models*. The ψ-theory, which contains the fundamental ideas of Enterprise Ontology, has been the proven foundation of the *Design and Engineering Methodology for Organizations* (DEMO) [4]. DEMO provides the methods and diagrams to construct the four aspect models that together constitute the B-Organization of an enterprise, as illustrated in fig. 4.1. These models claim to satisfy coherence, consistency, conciseness and comprehensiveness, thereby capturing the essence of a business organization.

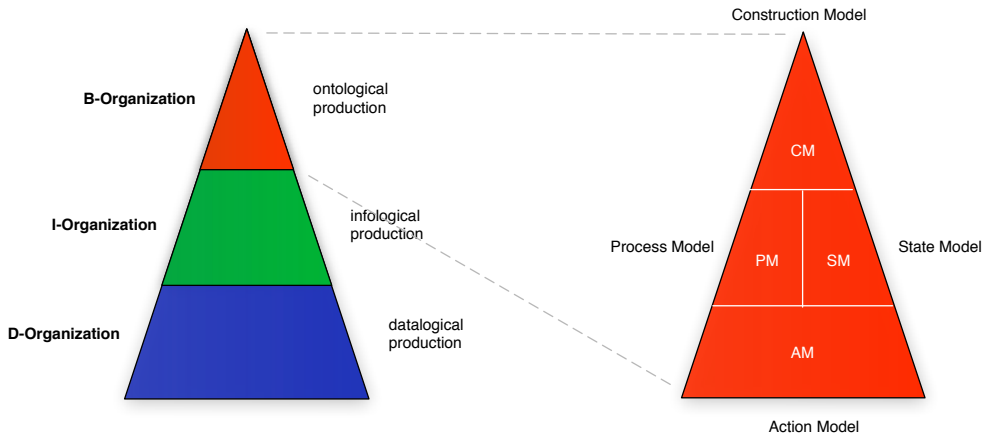

Fig. 4.1 *A zoom in on the B-Organization (right triangle) of the organization theorem (left triangle). The B-Organization is represented by four aspect models [4]*

The *Construction Model* (CM) provides the most concise overview of the construction of the system in consideration. It contains the transactions that can be entered into (see section 2.2). Although all transactions are fundamentally equal (there is always an initiator and an executor) it might be useful to distinguish between transactions that are initiated by the environment of the system and transactions that are initiated internally. The final services or goods that an enterprise delivers (its business), are situated on the system border, between the environment and the composition. The enterprise's clients are able to initiate these transactions, i.e. request their services. On the other hand, most services and goods require several production steps before being complete for handing over. The executor of a transaction can therefore (internally) request the delivery of other goods or services which are necessary for the delivery of his own 'production'. The resulting tree of transactions, starting at the transaction that is initiated by the environment, is considered a *business process* [22]. Besides insight into the business processes, the CM also helps to understand the authorities and responsibilities of the corresponding actor roles. Furthermore, it shows the information links between actor roles and information banks. The *Process Model* (PM) zooms in on each business process and shows the required coordination for the successful execution of each transaction. In other words, it focuses on the coordination acts. The *State Model* (SM) depicts the relations and laws that apply for the goods and services that are produced. In other words, it focuses on the object classes, production facts and the constraints on the behavior of an enterprise. The *Action Model* (AM) is the most detailed and comprehensive aspect model. Theoretically, the other aspect models are derived from the AM. It contains the procedures that must be executed in order to achieve a particular result.

The CM, PM and SM were found relevant for this thesis project [2]. Therefore, during redesign of the business perspectives, the focus was placed on these three aspect models. For a complete model of the B-Organization the AM would also be necessary, however, time constraints prevented its construction.

4.2. Redesign approach

This project's attempt to apply Enterprise Ontology in the context of healthcare is not the first. In 2004, Habing (a medical doctor an information scientist) et al. successfully tested the hypothesis that care processes consist of a limited number of generic transactions [23]. These generic transactions were identified by investigating the activities that take place in all the care-practices involved in delivering care for four different patient groups. DEMO was used to model the results.

After analyzing the EHR application designs and understanding the results of the study, it seemed like an obvious step to use these results as a starting point in redesigning the business perspectives of the current designs. However, only the PM and half of the CM were constructed by Habing. DEMO 3.0 was in the meantime also introduced, improving the readability of the PM and SM. Therefore, the following redesign approach was followed:

1. The current CM and PM were reformatted according to DEMO 3.0 specifications.

2. The SM was constructed and the CM was completed by creating the Interstriction Model

3. These three aspect models were used as the basis for redesigning the business perspectives of the individual EHR applications.

4.3. Definitions

The use of Habing's models as a foundation for redesigning the business perspectives first had to be justified by comparing the concept definitions in [23] with the concepts used by Nictiz as defined in the *Business Architecture AORTA* (BAA) [24]. Simultaneously, these concepts help in better understanding the various aspect models.

#	Concept	Definition
1	patient	A patient is a person (or group of persons) scheduled to receive, receiving or having received professional care
2	healthcare organization	A healthcare organization is an organization responsible for delivering professional care to patients
3	care-cluster	A care-cluster is an organizational unit of a healthcare organization responsible for delivering specialized care to a specific patient
4	care-function	A care-function is the set of authority, responsibility and/or tasks in a care-cluster
5	care-network	A care-network is the whole of care-clusters responsible for delivery of care to a specific patient at a specific point in time

Table 4.1 *Concepts definitions [23]*

Nictiz uses a similar definition for the concept of a patient, as described in [24], page 11. The second concept best fits the concept of *care provider* in [24], page 12. A care provider is defined as both the practice of independent care professionals *and* care institutions, i.e. the 'organizations' responsible for delivering professional care. The concept of care-cluster is not introduced in [24], as it is probably considered as too low-level. However, the concept of care-cluster is important as it was the focus of the research in [23]. The BAA does not contain information that contradicts the third definition, thus its use is acceptable. Regarding the fourth definition, it is necessary to explain that the BAA defines a *care-professional-function* as 'the profession with one or more related specialisms in fact executed by a care professional (...)'. The two terms look very alike; however, one should understand that Habing's definition is broader and focuses on the tasks in a care-cluster and not on the tasks of a particular care-professional (this will become clear in the next section), therefore the two definitions can co-exist. The last definition has no equivalent in [24], but is important too, as it is used as the *system* in the CM. Fig. 4.2 provides an example overview of the above introduced concepts.

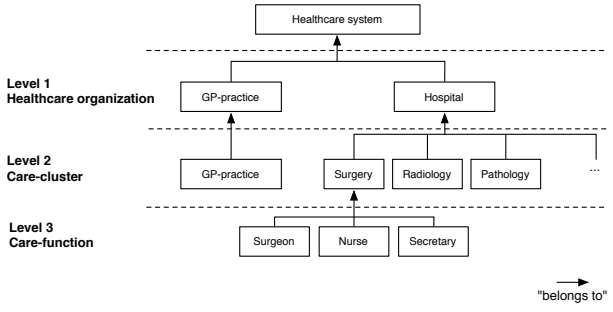

Fig. 4.2 *Example of the different levels in the healthcare system [23]*

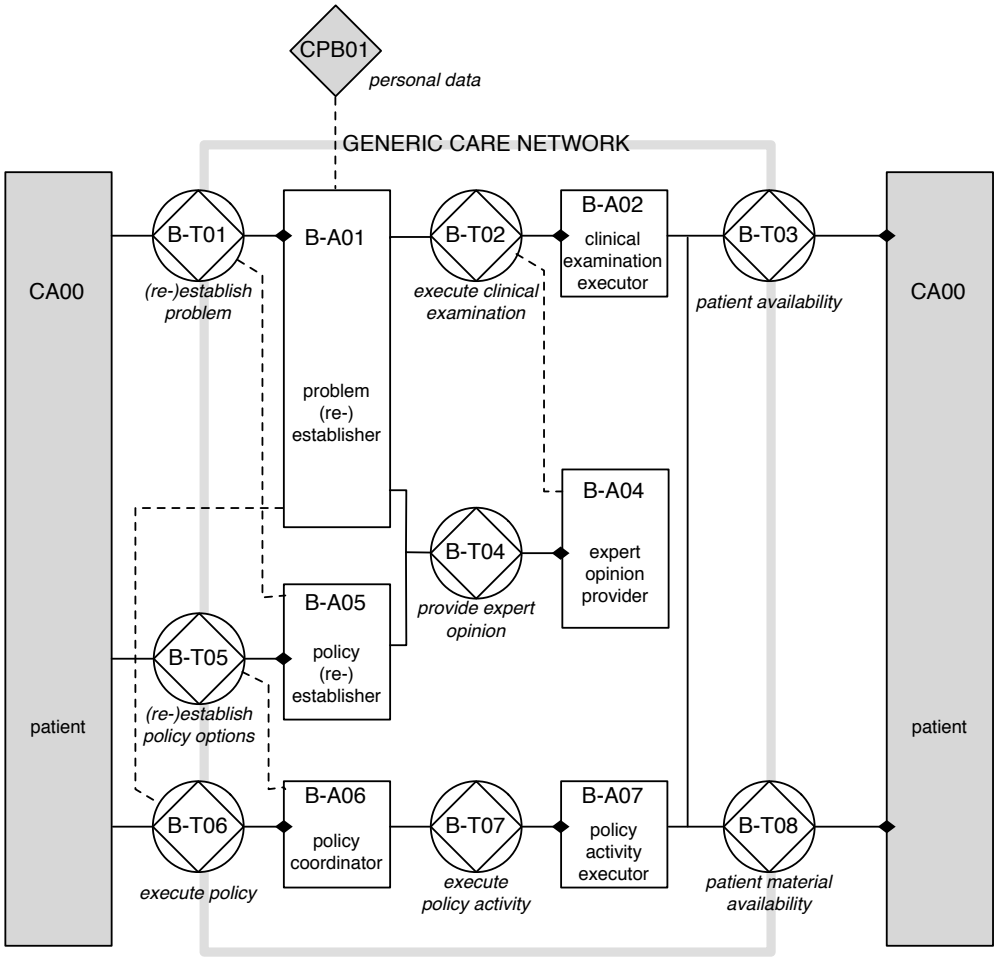

Fig. 4.3 *Organization Construction Diagram of the Generic Care Network*

T#	Transaction type	R#	Result Type (P-Fact)
B-T01	(Re)establish care problem	B-R01	[care problem] is established
B-T02	Execute clinical examination	B-R02	[clinical examination] is executed
B-T03	Availability of the patient	B-R03	[patient] is available for [care act]
B-T04	Provide expert opinion	B-R04	[expert opinion] is provided
B-T05	(Re)establish policy options	B-R05	Policy options for [care problem] are established
B-T06	Execute policy	B-R06	[policy] is executed
B-T07	Execute policy activity	B-R07	[policy activity] is executed
B-T08	Availability of patient material	B-R08	[patient material] is available for [care act]

Table 4.2 *Transaction Result Table of the Generic Care Network*

4.4. (Re)designing the Aspect Models

The results of the first and second redesign approach steps are presented in this section. For convenience, most models are given on the description's facing pages. Elaboration is therefore limited; however, the interested reader is referred to [23] and [4] for more detailed information. A legend of the most common DEMO 3.0 symbols can be found in Appendix E.

4.4.1. Understanding the Construction Model

An overview of authorities, responsibilities and information links in the *Generic Care Network* (GCN) is shown in the Organization Construction Diagram (OCD) in fig. 4.3, which is based on the Actor-Transaction Diagram constructed in [23]. The corresponding Transaction Result Table (TRT) is depicted in table 4.2. The complete Bank Contents Table (BCT) is available in Appendix F.

The patient is colored gray, indicating the notion of a composite actor (an actor possibly made up of various parts or elements). By convention, actors in the environment (thus outside the system borders) are considered composite. Regarding the concept of patient, this can be explained since nothing is known about the patient's 'construction'. The person requiring care might as well be represented by his or her parents or legal guardians.

Consider the three transactions at the left-edge system border: [B-T01], [B-T05] and [B-T06]. These are initiated by the patient and could be considered the business of the Generic Care Network. They also express the *empowerment* of the patient regarding the control of care processes. Patient empowerment is established in Dutch law [25] and indicates that a patient's (dis)agreement with the advice of a care professional should be respected. In other words, the patient is theoretically always the initiator of a new care process. Note, however, that in practice the care professional often assumes the request of a transaction in accordance with his or her advice. This illustrates the performance of an *implicit* request. This is perfectly acceptable within the ψ-theory; however, the definition of an ontology requires specifications to be *explicit*. That explains the notation of the request always coming from the patient. Besides requesting services, the patient is also requested to execute some (the right-edge system border transactions). It illustrates that a patient also has responsibilities, namely to cooperate. Without this cooperation the internal system actors will not be able to execute their tasks and thus are unable to deliver the services requested by the patient.

Transactions are executed by subjects fulfilling the corresponding *actor roles*. An actor role takes along the authority but also the responsibility (after successful negotiation) to deliver the service or good in question. Business actor roles can be implemented with 'human technology', i.e. human beings. These roles are artificial and are not strictly bound to organizational functions. Therefore, authorities of an actor role may be delegated by the responsible actor to other subjects. Consider as an example a GP fulfilling the role of Problem Establisher (B-A01). In practice, a patient rarely directly requests the establishment of his or her problem to the GP. Often, the assistant represents the GP and promises the establishment of the problem (e.g. over the phone). Hence, in practice the GP and the assistant together fulfill the role of Problem Establisher; however, only the GP actually holds responsibility for the transaction's execution.

The three business processes of the Generic Care Network do not 'actively' depend on each other. However, for their execution, the transactions *do* depend on the information produced by the other transactions. The dotted lines represent these 'passive' links between transaction executors and information banks.

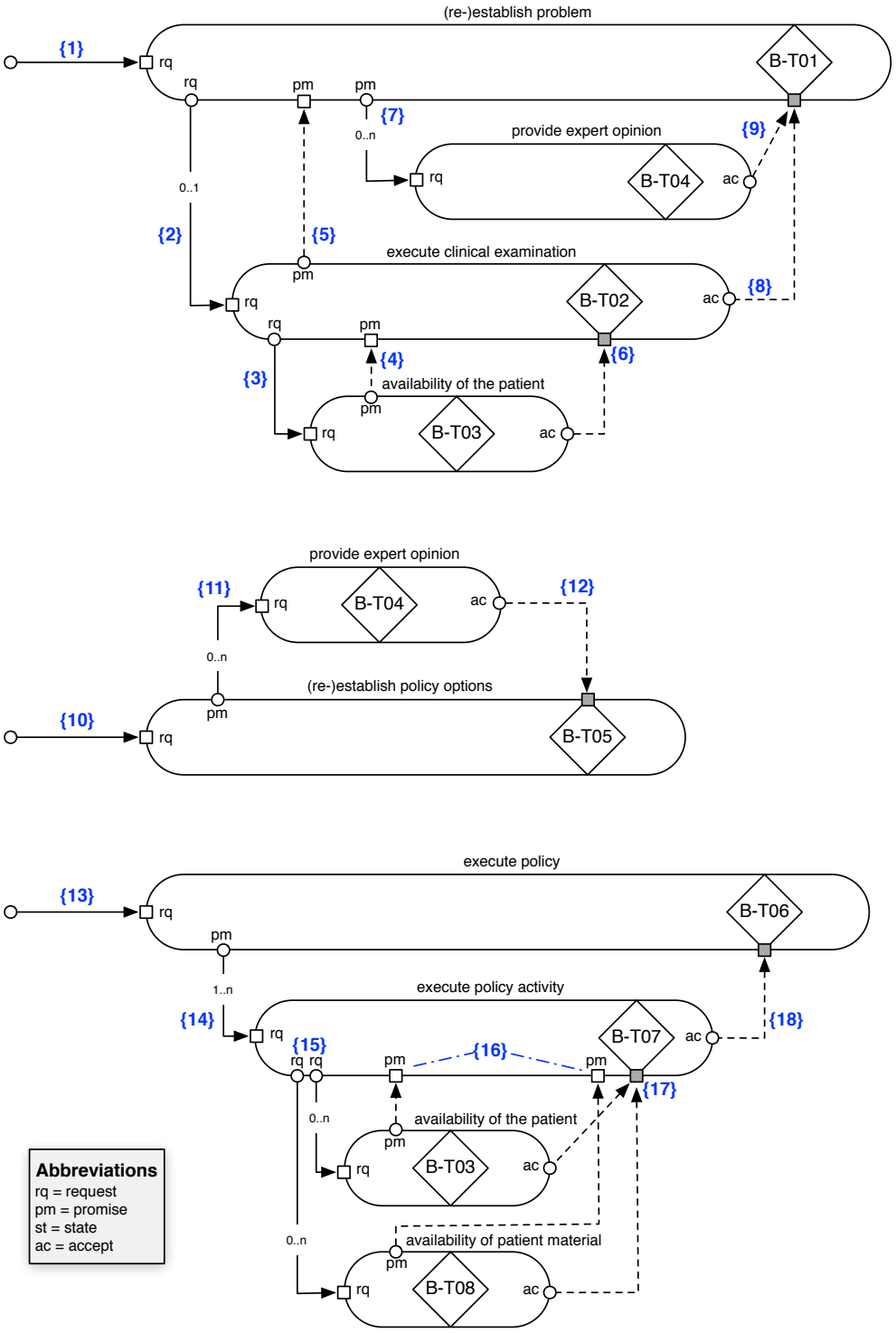

Fig. 4.4 *Process Structure Diagram of the Generic Care Network*

4.4.2. Understanding the Process Model

The OCD intentionally hides the detailed coordination acts to obtain a very concise overview of the system; however, sometimes the interest *is* in the coordination of the transactions. In fig. 4.4 these processes are exhibited in the Process Structure Diagram (PSD); the blue numbers ***{x}*** indicate explanations in the description below. The first transaction that is initiated by the patient is usually [B-T01], i.e. the patient requests the (re-)establishment of his or her problem **{1}**. In [23] a *care problem* "is 'an issue related to the health of a specific patient, as defined by a specific care provider (at a certain time).' Thus, a care problem might be described in terms of the patient's main complaint, his main symptom, a health problem or problem list, a differential diagnosis, a disease, an illness or a request for a procedure."

To be able to make a valid judgement about the (probable) problem, information needs to be gathered. To make this judgement, the Problem Establisher (PE) uses his own knowledge learned from books and practice, and he might view the patient's medical history ('old' facts) either by checking his own or a colleague's record about the patient. Furthermore, the PE may require the patient's own account of his or her medical history and current issues - or even perform a short physical examination. Notice that this last information does not exist yet, it needs to be 'produced'. Therefore, executing this 'clinical examination' is considered a separate transaction, not necessarily executed by the same actor who fulfills the role of PE. So, the PE requests the Clinical Examination Executor (CEE) to execute this examination **{2}**. This is done *before* promising the patient's request **{1}**, as availability of the patient (at a specific time or within a specific time period) must be assured. Hence, the CEE too can only promise this examination **{5}** if the patient is available and willing to cooperate. He therefore requests **{3}** and awaits **{4}** (the promised) availability of the patient (at a particular time and place). Upon actual presence of the patient the clinical examination can be executed **{6}**. The results of this examination are presented to and normally accepted by the PE **{8}**.

The PE might also seek advice from colleague experts by requesting an opinion on his findings **{7}**. Only if all requested examinations and expert opinions are accepted **{8}** **{9}**, is the PE able to combine all this information to (re-)establish the (probable) problem. He presents his results to the patient. Upon acceptance of the results transaction [B-T01] ends.

The next transaction that the patient might initiate is [B-T05], i.e. the patient requests the (re-)establishment of policy options regarding his problem **{10}**. However, it is not certain that the patient always requests the (re-)establishment of policy options. For example, if the patient's soar throat turns out to be caused by a common cold, the patient's mind might be put at rest, thereby satisfying his needs. However, if the soar throat is caused by a probable throat cancer, one would normally expect a request for policy options establishment. A policy consists of one or more *policy activities*, e.g. performing an operation, referring a patient or executing a medicament treatment. The Policy Options Establisher (POE) might again request advice from expert colleagues **{11}**. If he requested so, the POE has to wait for the opinion of the expert(s) **{12}** before he can define the definite policy options. In the end, the POE presents his results and advices the patient about the options, which completes transaction [B-T05].

Finally, the patient likely chooses one policy out of the established options (frequently in accordance with the advice of the POE) and requests its execution **{13}** by contacting the Policy Coordinator (PC). As the name suggests, the role of the PC is not to actually execute the complete policy, but rather to coordinate its execution by requesting the execution of all individual policy activities belonging to it **{14}**. Each Policy Activity Executor (PAE) may require patient material or the patient himself to be available (at a certain time and place) **{15}**. Only if the availability is secured, is the PAE able to commit to the request of the PC **{16}**. Eventually, when the patient (material) is actually available **{17}**, the PAE can execute his policy activity. If all the policy activities have been accepted by the PC **{18}**, the PC is done coordinating.

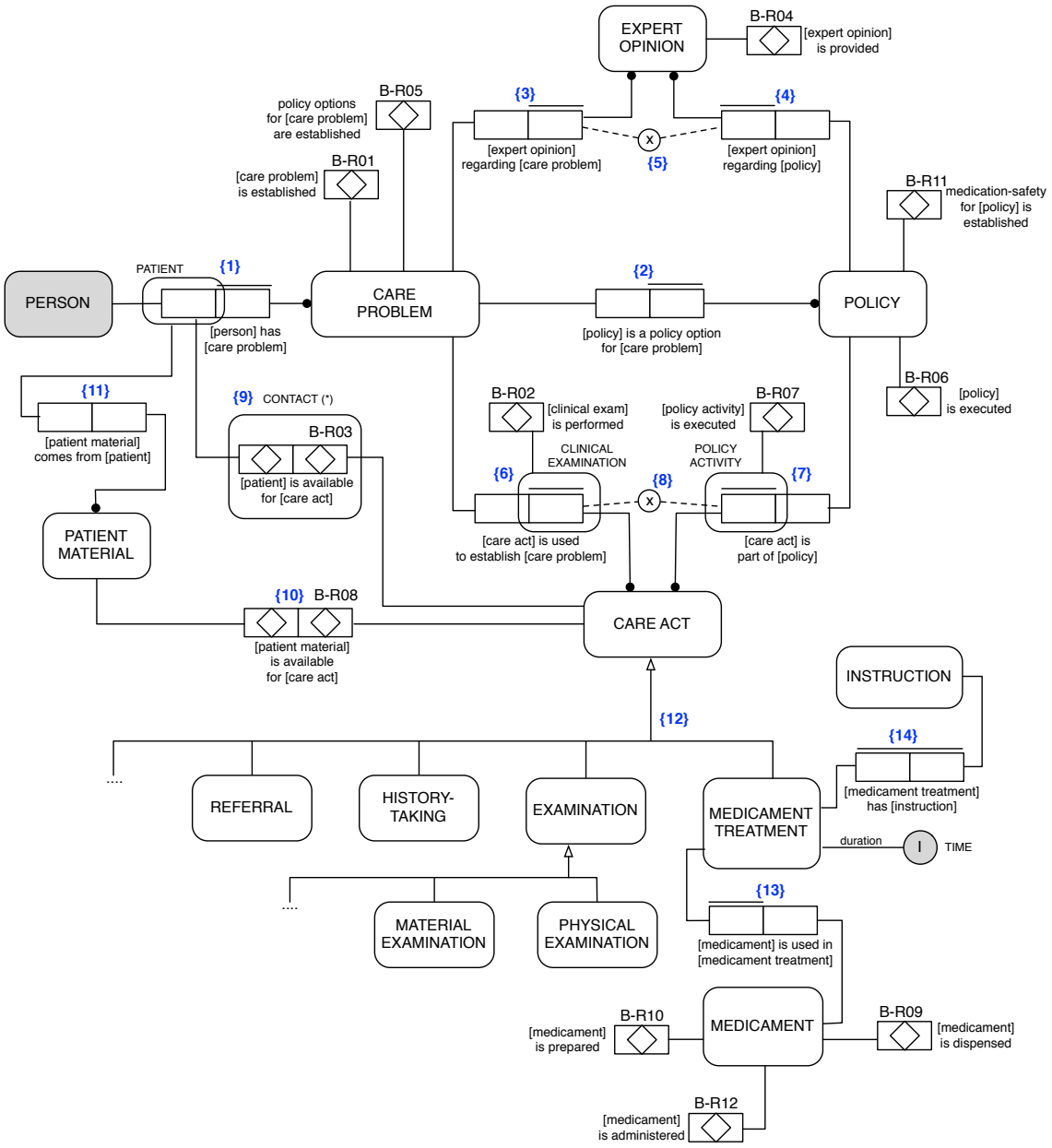

Fig. 4.5 *State Space Diagram of the Generic Care Network*

4.4.3. Understanding the State Model

The State Model provides an overview of the *production world,* i.e. the dependent and independent facts. It is represented by means of the State Space Diagram (SSD). The SSD of the Generic Care Network is shown in fig. 4.3. For one, the SSD shows a relation between a **person** and a **care problem** {1}. The care problem depends on the existence of the person, i.e. without the person it would not be there. The person is colored gray to indicate it is an external object, not created in the system under consideration. Also, the care problem is unique, which means that it is related to one and only one person. Note that the unicity law (the line above the instantiation of the care problem) is not found at the person's side, i.e. a person is allowed to be associated with more than one care problem. Finally, all instances of the person class that have a future, current or past care problem can be considered a **patient** {1}.

Next, a care problem is related to a **policy** {2}. Again, there are a unicity and dependency law effective for each policy instance, i.e. the policy cannot exist without the existence of a care problem *and* a policy is unique. However, for one care problem multiple policy options may exist (although generally only one is executed).

Experts can provide their opinion on a care problem or policy {3} {4}. Here too hold the unicity and dependency laws for the **expert opinion** instance. However, there is also another law active, namely the exclusion law. Every expert opinion either belongs to a care problem *or* a policy, it cannot be both {5}.

In the SSD, {6} and {7} correspond with **clinical examination** and a **policy activity** respectively. Actually, both are a set of **care act** instances. The difference is that a clinical examination is directly related to a care problem (to help establish it). A policy activity is part of a policy which was chosen as a reaction to the established problem. History-taking or a quick physical examination are both considered a clinical examination. Except for history-taking, a policy activity can in general be any kind of care act; from a referral to a medicament treatment {12}. Note that the results of the policy (activities) actually *also* contribute in re-establishing the care problem; however, only in a next iteration of the care process 'cycle'. Also note that every care act is unique and belongs to one and only one care problem *or* policy {8}. Note that the exclusion law could have been avoided; there are multiple ways of expressing laws and relations. Instead of using two extensions of the care act instances and adding an exclusion link (which is the current representation), one could have created two separated object classes **policy act** and **examination act**, generalizing both to the care act object class. However, to avoid confusion with the generalizations below the care act object class, the first (and current) representation was preferred.

The completion of a transaction is an event: the occurrence of a transition in the production world. In other words, the production world changes, and, in the case of a B-Transaction, something new is produced. These events (the transaction results from the TRT) are also captured in the State Space Diagram. The transaction results, B-R01 to B-R08, are connected to their corresponding object classes. Consider {9} and {10}, which correspond to the events B-R03 and B-R08 concerning the availability of the patient (material). Availability refers to the actual moment that the patient or material is physically present and thus ready to be 'worked with'. From B-R03 events, the **contacts** of a patient with a care professional can be derived.

A **medicament** is used for a **medicament treatment** (see section 4.5.2 for elaboration) {14}, which in turn has an **instruction** {13}. The existence of a medicament treatment and instruction are both unique, i.e. a medicament treatment cannot have a different instruction, and vice versa. Further, a medicament treatment concerns only one medicament. However, the same medicament instance may be used for different medicament treatments.

Keep in mind that the SSD might not be exactly complete, as only the construction of the Action Model can determine its completeness. Further, numbers {13} and {14} will be discussed later, when introducing the redesign of the EMR business perspective.

4.5. Redesign results

Based on the aspect models that were discussed in the previous section, the business perspectives of the scoped EHR applications were redesigned. First the redesigns of the ELR application will be discussed. Next the redesign of the EMR application is presented and discussed. Finally, the results of redesigning the eDiabetes business perspective are given. The correctness of the redesigns will not be discussed here, but can be found in the next chapter.

4.5.1. The ELR business perspective redesigned

It turns out that the aspect models of section 4.4 perfectly fit the business perspective of the ELR design. This is easily accounted for, since the locum situation always is an *implementation* of care processes. Recall that by applying the theory of Enterprise Ontology one abstracts from any implementation issue. What is left is therefore the equivalent of the Generic Care Network. In other words, the transactions that need to be executed to deliver care services to the patient are the same during the locum situation as during the regular situation.

4.5.2. The EMR business perspective redesigned

Regarding medication in the care processes, the aspect models of the previous section could be further specified and extended. Fig. 4.6 and fig. 4.7 depict the OCD and a part of the PSD respectively. The TRT that complements the OCD is available in Appendix F. The corresponding production facts and object classes were already shown in the SM in fig. 4.5. In section 3.2.1 the ambiguity of the term *medication* was explained. Hence, before discussing the diagrams, some alternative terms are introduced and made explicit for the sake of univocality. Table 4.3. contains these definitions.

Term	Definition
medicament	a substance used for medical treatment
medicament treatment	the set of instructed administrations of a specific medicament during a specific time period

Table 4.3 *Definitions of introduced alternative terms*

Having defined the used concepts, first notice enhancements of actors [B-A05] and [B-A06]. The label ‘medication’ has been added to the actor role names, indicating that the roles have the required authority to advise and authorize medicament treatments. Next, observe the addition of transaction [B-T11] ‘establish medication-safety’ in the CM. During establishment of the policy, the medicament treatment(s) in consideration should be tested for compatibility among each other, with the patient’s current medicament treatments as well as with the condition of the patient. Possible medicament-interactions or contraindications can be reasoned or computed (note that this happens in the I-Organization), e.g. reasoning or computing might indicate absolute (a ‘no-go’) or relative (cautions) contraindications. The Medication Safety Establisher (MSE) has the authority and responsibility to *judge* the considered medicament treatments as

safe, making use of these computations. In practice, the role of MSE is usually fulfilled by the GP or a specialist. The Expert Opinion Provider - in the context of medicaments in practice generally a pharmacist - is also able to use similar information services to check the compatibility of alternative medicament treatments to support his opinion. However, it is eventually (again) the task of the MSE to make the final judgement regarding the safety of these alternative suggestions.

Obviously, a policy may contain more than one medicament treatment. Recall from section 4.4.2 that the execution of each policy activity is individually requested; hence, so is the execution of each medicament treatment. The subject(s) who are assigned the (delegated) role of Medicament Treatment Executor (MTE) have the tasks to execute the treatment, i.e. to (let) administer the specific medicament according to an accompanied instruction for a specific time period. For example, this can be a treatment with *Trimethoprim* (for one week, one dose of 300 mg per day) or a treatment with *Levothyroxine* (for one month, one administration per day, alternating a dose of 50 mcg and 75 mcg). In primary care the patient is often assigned the role of MTE and thus becomes actively involved in the care process. In secondary care the specialist and/or nurse(s) are often assigned the role of MTE. The roles of Medicament Dispenser (MDP, to avoid confusion with the abbreviation of Medical Doctor) and Medicament Preparer (MP) are generally fulfilled by pharmacy personnel.

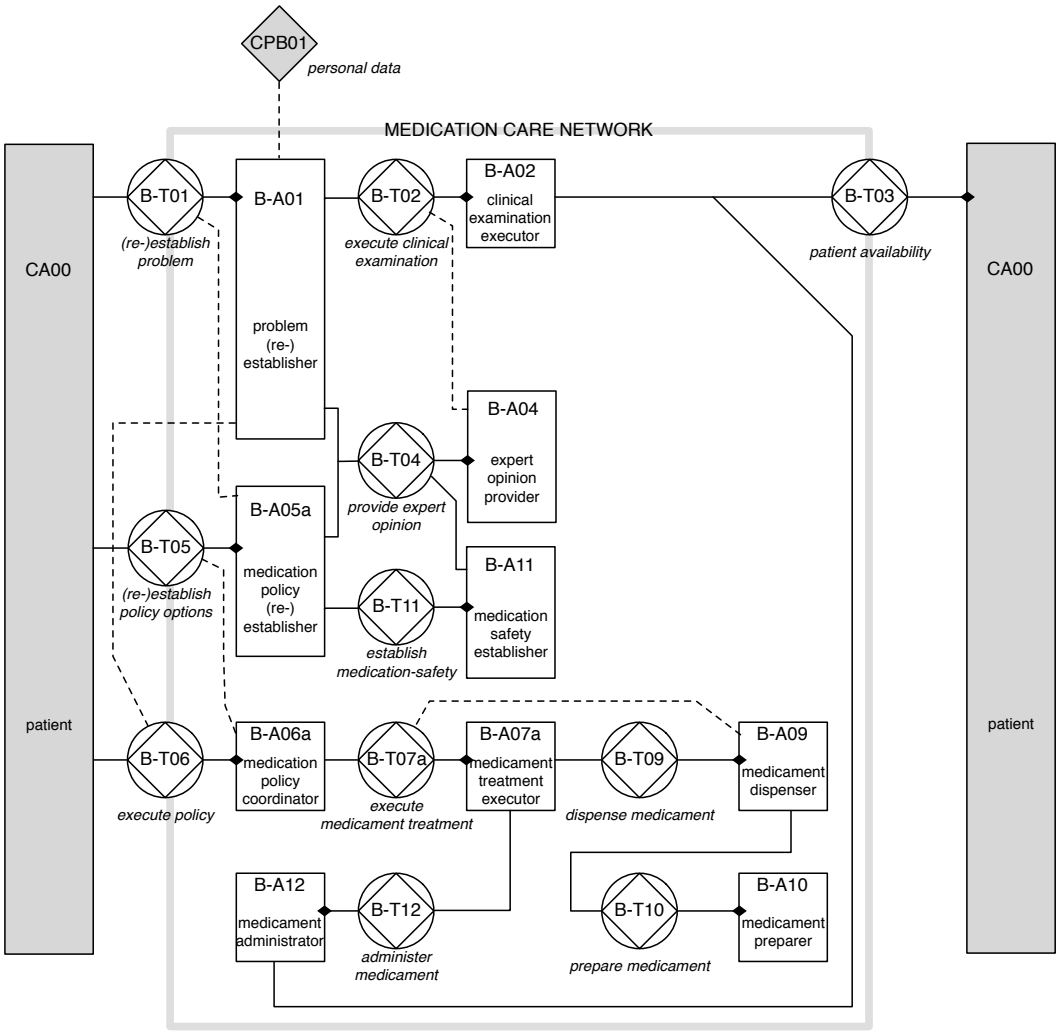

Fig. 4.6 *Medication Care Network*

Consider fig. 4.7 for an example of the process of executing a medicament treatment. To start the process, execution of the complete policy is always requested for by the patient **{1}**. For the purpose of simplicity the policy is discussed hereafter for only one medicament treatment. To be very precise, an example using only actor role names is provided first. Next, two cases of possible implementations of these actor roles are provided: one for primary and one for secondary care.

An abstract example
In this example, the Medication Policy Coordinator (MPC) requests the Medicament Treatment Executor (MTE) to execute a treatment with *Trimethoprim* (for one week, one dose of 300 mg per day) **{2}**. The MTE can only execute the treatment if he has access to the medicament. Perhaps he still has the required amount of medicament left from a previous treatment. In that case, the treatment can start right away. The MTE therefore requests the Medicament Administrator (MA) each day (for seven days) to administer the medicament **{3}** all of which have to be accepted (possibly implicitly) by the MTE **{4}**. Each administration requires the availability of the patient as explained in section 4.4.2 (transaction [B-T03]). Seven days and seven administrations of 300 mg further, [B-T07a] has completed **{9}**.

However, if the MTE does not have the medicament in his possession - or he is perhaps out of medicament halfway the therapy - he requests dispensation of the substance **{5}**. The Medicament Dispenser (MDP) may use the same information services as the Medication-Safety Establisher to double-check for compatibility of the medicament with the patient's current medicament treatments and condition. If troublesome results turn up the MDP may decline the request. In current practice, the subject in the role of MDP will often also take on the role of Expert Opinion Provider and suggest an alternative therapy to the Medication Policy (Re-) Establisher (this involves cumbersome transaction cancelations and implicit transaction requests, see section 5.3). However, if all seems fine and the request is valid (i.e. authorized by the MPC), the MDP promises the delivery; therefore he requests the Medicament Preparer (MP) to prepare the medicament **{6}**. Once prepared, the MP presents the results to the MDP who in in his turn completes the dispense medicament execution **{7}**. If the MTE considers the medicament as correct, it is accepted **{8}**, which means the treatment can be started or continued. Only when the MA has administered the *Trimethoprim* seven times (with the proposed doses), has transaction [B-T07a] been executed. Once this execution is acknowledged by the MPC **{9}**, transaction [B-06] ends.

A primary care implementation example
The general practitioner, in the role of Medication Policy Coordinator requests the patient - in the role of Medicament Treatment Executor - to execute a treatment with *Trimethoprim* (for one week, one dose of 300 mg per day) **{2}**. The patient promises this execution. Perhaps he still has the required amount of medicament left from a previous treatment. In that case the treatment can start right away. The patient therefore administers the medicament each day, for seven days **{3}{4}**. Seven days and seven administrations of 300 mg further, execution of the treatment has completed. This completion is implicitly accepted by the general practitioner **{9}**.

However, if the patient does not have the medicament in his possession - or he is perhaps out of medicament halfway the therapy - he goes to the pharmacy to request dispensation of the substance **{5}**. The pharmacist's assistant behind the counter has been assigned the (delegated) role of Medicament Dispenser. The assistant may use information services to double-check the compatibility of the medicament with the patient's current medicament treatments and condition. If troublesome results turn up, the assistant consults his boss (the pharmacist), who then considers whether or not to commit to the patient's request. The patient and the pharmacist may negotiate a slightly deviating treatment, for example, administrations of 200 mg per day. However, if the contraindications are questionable or the prescription is considered as irregular,

the pharmacist will not dispense without discussion with the establisher of the policy. The pharmacist, as the experienced representative of the patient, requests the general practitioner (as policy establisher) to reconsider his judgements, i.e. to re-establish the policy (options). At the same time, the pharmacists provides his opinion on the situation, since he is an expert in medicaments. The general practitioner reconsiders his previous judgements, together with the arguments of the pharmacist. Finally, he either sticks with his previous policy (options), in which case the current policy execution continues and the pharmacist should comply to his promise to deliver the medicament. Otherwise, a new policy is established and preferred. In that case the current policy (which is already in execution) is likely canceled by the general practitioner (as Policy Coordinator), which allows the pharmacist to cancel his promise to dispense the medicament. Next, the general practitioner discusses or assumes the execution of the new policy, which results in a new request for dispensation etc. The above sequence of coordination acts is visualized and elaborated on in section 5.3 and fig. 5.4. For now, assume that there are no contraindications and that the request is indeed authorized by the general practitioner. The assistant requests the pharmacist to prepare the medicament **{6}**. The pharmacist hands over the medicament to the assistant **{7}**, who in turn provides it to the patient. The patient gets hold of the product, thereby accepting the medicament **{8}**. He can now start or continue his treatment as explained above.

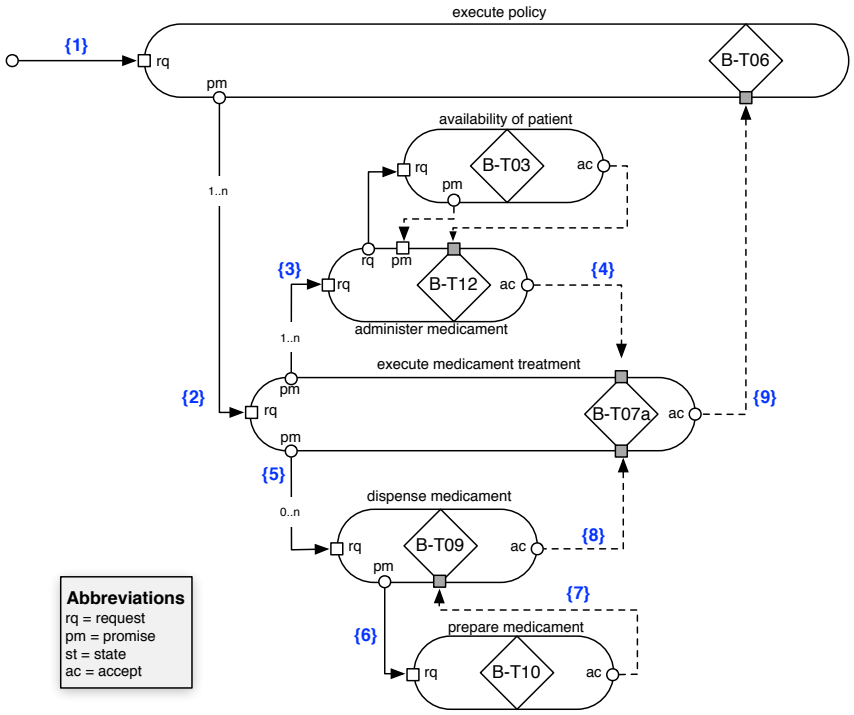

Fig. 4.7 *Execute Medicament Treatment process example*

A secondary care implementation example

After two days of using *Trimethoprim*, the patient still copes with a nasty bladder infection; it has actually gotten worse. The general practitioner therefore refers the patient to a specialist regarding these problems, for example a urologist. It turns out it is not the first time that the patient suffers from this infection. The specialist therefore suggests a surgery to prevent its recurrence. This requires hospitalization of the patient. The current medicament treatment with *Trimethoprim* is canceled by the specialist, i.e. the specialist - taking over the patient's role as

Medicament Treatment Executor - cancels the promise in the previous example to complete execution of the treatment (not illustrated). This is probably done implicitly, but it might be done explicitly by notifying the general practitioner, who has no other choice but to agree and allow the cancelation (see the Transaction Pattern Diagram in Appendix F). The specialist, in the role of Policy Establisher, requests a hospital pharmacist to provide his opinion on two (medication) policy options involving stronger antibiotics. However, the pharmacist, as a (medication) Expert Opinion Provider, eventually suggests a third policy option. The specialist concurs with the suggestion and makes sure to establish the medication-safety of this third policy option. He does this in the role of Medication-Safety Establisher, either alone or in cooperation with the hospital pharmacist. Finally, he presents only the third policy option to the patient, who probably (implicitly) requests its execution **{1}**. The specialist, in the role of Policy Coordinator, will request (actually: delegate) the ward nurses to execute the medicament treatment **{2}**. Every single administration **{3}** is therefore recorded (notice: this is a transaction in the D-Organization of the business transaction [B-T12]) and individually accepted by the specialist **{4}**. Finally, if all administrations have been performed, this is stated to the specialist. This happens either implicitly (if the specialist has already been notified about every single administration) or explicitly by providing a complete list of the medicament administration recordings. Usually, the results are satisfactory and are thus accepted by the specialist **{9}**. Notice again, that the start of the medicament treatment requires possession of the particular medicament. Hence, the specialist (or a delegated ward nurse) requests dispensation of the medicament from the (hospital) pharmacy **{5}**. A similar dispensation process as in the primary care situation is executed.

4.5.3. The eDiabetes business perspective redesigned

Diabetes is a chronic disease which can cause a lot of complications. Secondary prevention aims at early detection of these complications and requires a range of care professionals. However, the construction of the activities that are performed by these care professionals does not differ. Therefore, the Generic Care Network from section 4.4 is sufficient to illustrate the 'chain-of-care' in the diabetes care.

As soon as a patient is diagnosed with diabetes (production result B-R01, in the primary care sector usually diagnosed by the GP) secondary prevention is started. The GP, also considered the 'head-clinician', establishes policy options which, for example, contain referrals to the dietician (eating habits need to be revised as they directly influence the blood sugar level, which easily gets too high due to lack of insulin) and the ophthalmologist (there is a suspicion of diabetic retinopathy, a complication that can lead to blindness). Every policy option is discussed with the specialists (production result B-R04, tuning the right amount of medical checkups at each care network) which results in one advised policy (production result B-R05). The patient likely requests the execution of one of the policy options - often in accordance with the advice of the Policy Options Establisher. The Policy Coordinator (again likely the GP) probably prescribes some medicaments to control the blood sugar level (e.g. requests the execution of treatment with *Exenatide*, see section 4.5.2) and furthermore, he refers the patient to the dietician and the ophthalmologist ('execute referral' is an example of a policy activity). Both the dietician and the ophthalmologist, as well as any other care-specialist, are situated in different care clusters. However, the Generic Care Network fits the construction of these care clusters. In other words, once referred, the patient arrives at a moment later in time, at the dietician. Now the dietician fulfills the role of Problem Establisher, and, upon request of the patient to establish whether or not a change in eating habits is necessary, he or she likely commits to this request. The same cycle of transactions is continued as to finally come up with a policy that needs to be executed: for example, drinking less soft drinks and exercising twice a

week. A similar cycle of transactions is carried out when the patient arrives at the ophthalmologist or any other care-cluster.

The current business perspective considers every policy activity in the policy as a *contact*. A contact can have a state, e.g. desired, planned or executed. The choice for this term is rather unfortunate. Within the Care Network the interest is *not* (specifically) in the contact, but in the care act (that is, *every* care act, whether or not a 'contact' is required). So, a 'desired contact' is actually the execution of a care act (or policy activity for that matter). A 'planned contact' is to be understood as an appointment. Making appointments is part of negotiating, and therefore part of every transaction. Recording this agreement or appointment is a transaction that belongs to the D-Organization. Finally, an 'executed contact' equals the result of transaction [B-T03]: the patient was actually available.

4.6. Conclusions

Using DEMO, the Design and Engineering Methodology for Organizations, it is possible to apply the theory of Enterprise Ontology. DEMO claims to satisfy the design criteria that were identified in the previous chapter, and is therefore the appropriate design methodology for redesigning the Electronic Health Record (EHR) applications. This answers the first part of research question (f).

Next, during research for the previous application of Enterprise Ontology in the context of healthcare, a transaction based Generic Care Network (GCN) was discovered. It claims that care processes in general can be constructed from a set of generic transactions. It turned out that these generic transactions served well as the foundation in redesigning the business perspectives of the scoped EHR applications: ELR, EMR and eDiabetes. Research question (f) has now been fully answered.

Finally, after updating and completing the Construction Model (CM), Process Model (PM) and State Model (SM) of the GCN, the redesigns were presented. The business perspective of the Electronic Locum Record (ELR) application could be completely explained with the existing GCN. This was clarified by the *essence* property of an ontological model, which requires abstraction from implementation. Locum activities obviously are a way of implementing care processes; thus, upon abstracting, the core transactions from the Generic Care Network appeared.

The business perspective of the Electronic Medication Record (EMR) needed some additional transactions and enhancements. However, one Medication Care Network was finally designed, which eliminates the current distinction of medication activities in primary and secondary care. Further, it claims to be free of ambiguity by clearly distinguishing between the various meanings of *medication*. The model also captures well the intention of prescriptions as used in practice: namely, the request for the execution of one ore more treatments with a medicament *and* (the confirmation of) the authorization of the request for dispensation of one or more medicaments. Next, it reveals the one and only place where medication-safety is actually ('ontologically') established. Finally, the model rightfully considers dispensation as a component possibly needed for the execution of the treatment, i.e. administrations of the medicament do not necessarily depend on an actual dispensation.

To conclude, the business perspective of eDiabetes did not actually need any revisions of the Generic Care Network. The iterative (or even 'recursive') use of the Generic Care Network was explained in the chain-of-care that is required for secondary prevention of diabetes complications.

5. Verification of the redesigns

It is not unlikely that mistakes get made during redesign, e.g. one could forget or wrongly interpret the models of the present designs. However, sometimes current knowledge is intentionally left out of the new design; for example, if it belongs to one of the supporting layers of the B-Organization. And yet, it is possible that the new designs contain facts that were previously unavailable. Next, it is important to check that the redesigns actually meet the criteria that were established in chapter 3: *formal, coherent, consistent, concise, comprehensive* and *essential* (*easily readable* is left for discussion in chapter 6). This chapter discusses these verifications. It determines the *correctness* of the redesigns.

5.1. Verification approach

In theory, redesigning should not cause a 'downgrade' of the available content that is found in the blueprints. It should therefore be possible to map every element of the present designs to an equivalent element in the new redesigns. If an element cannot be mapped, absence of the particulars should be justified. Simultaneously, elements in the redesigns to which nothing from the old design could be mapped reveal the presence of new information. To achieve these mappings - and thus the verification of the redesigns - the following approach was followed:

1. The previous business activities were categorized as ontological, infological or datalogical by coloring them red, green and blue respectively. Next, the ontological elements were mapped to corresponding transactions and - if possible - coordination acts. If elements were recognized as infological or datalogical, an attempt was made to relate them to an existing ontological transaction.

2. The previous business objects were categorized as ontological, infological or datalogical by coloring them red, green and blue respectively. Next, the business objects were mapped to corresponding object classes, instances and production facts in the State Model.

3. The mappings of step (1) and (2) were discussed with experts in the field of healthcare and designing.

4. The redesigns were checked to meet the form and content criteria.

Note that the correctness of the redesigns to a large extent depends on the correctness of the current designs, since these are used for the mapping process. Because the current designs are official publications (except for eDiabetes), which have extensively been discussed with relevant healthcare umbrella organizations, the current designs are assumed to be reliable for this verification approach.

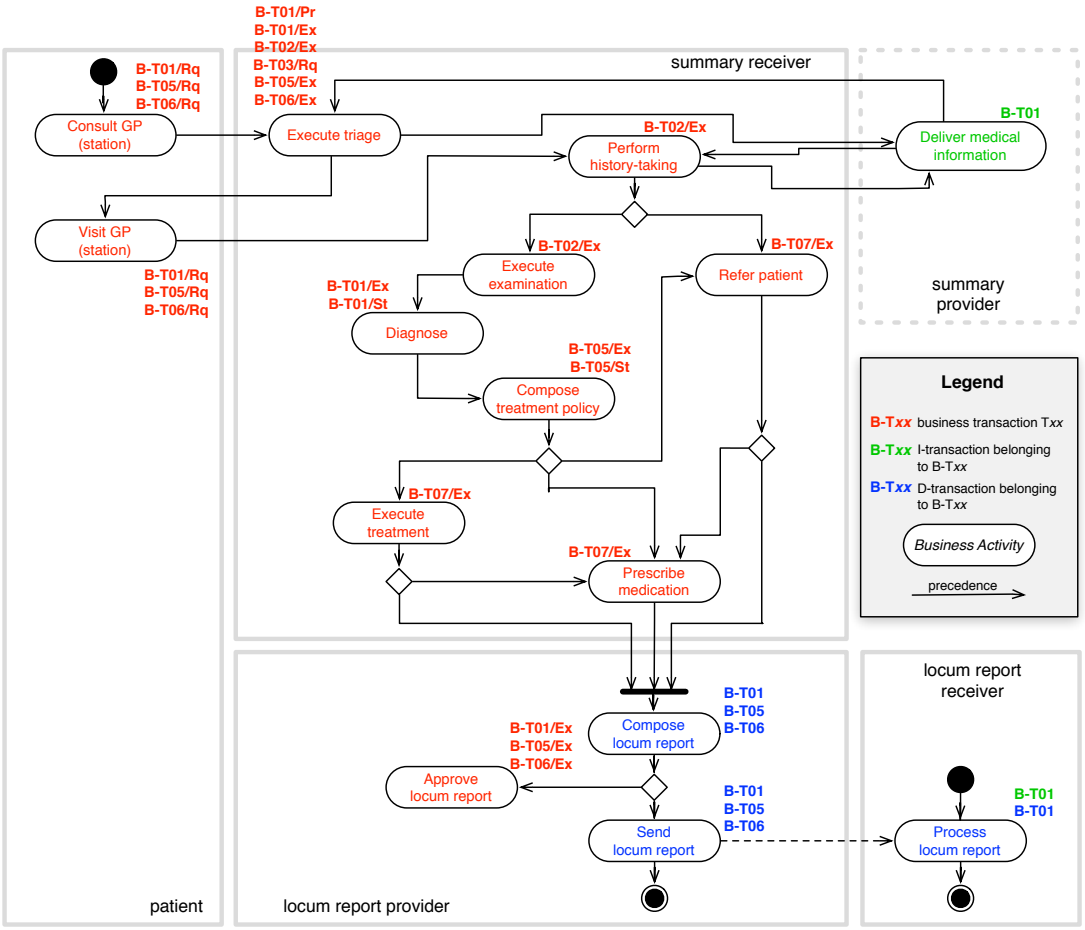

Fig. 5.1 *Mapping the ELR business activities to transactions of the GCN.*

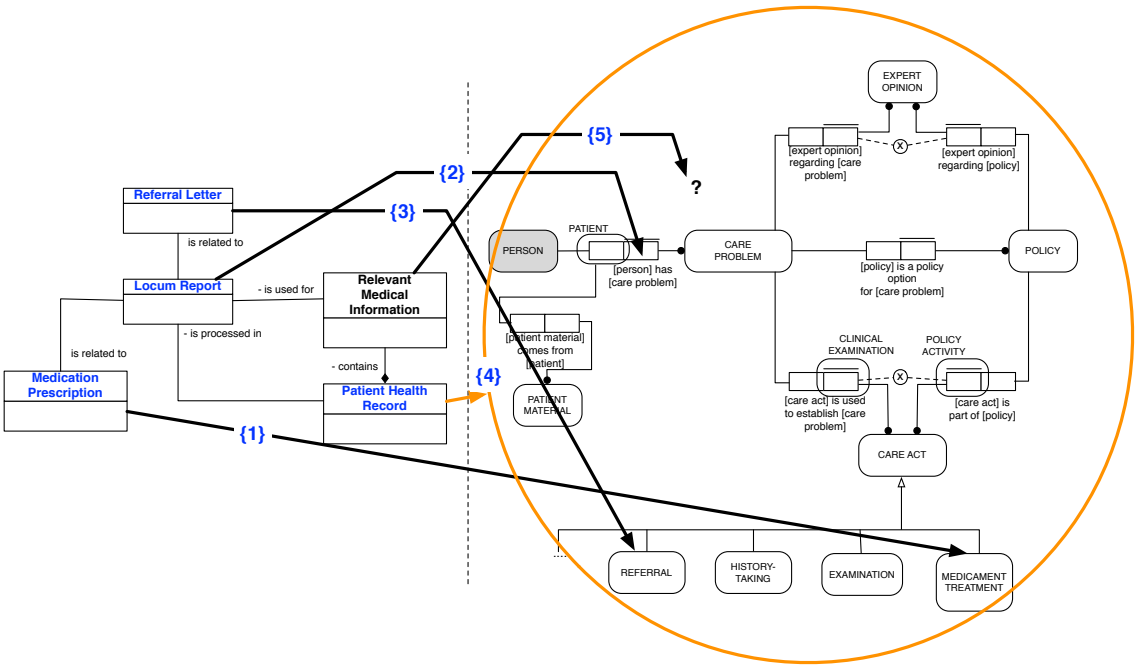

Fig. 5.2 *Mapping the ELR business objects (left) to the simplified SM of the GCN (right).*

5.2. Verification of the ELR redesign

The business activities of the current ELR design can all be mapped to one of the transactions in the Generic Care Network (GCN). The ELR activity model in fig. 5.1 illustrates the workflow of the locum situation. Most striking is that only the top-left part of the diagram is colored red, which indicates that only these activities can be considered ontological. The diagram also well illustrates how *workflow* differs from *construction*: in the schematic, history-taking is done before diagnosing; however, construction-wise history-taking is a 'component' of establishing the (probable) problem.

Only one activity is colored green and considered an infological transaction: a requirement for medical information. This transaction supports the establishment of the problem, thus an I-transaction in [B-T01]. Whether or not the transaction also *directly* supports history-taking is debatable. Establishing the problem and history-taking are tasks often both assigned to the same care professional, which makes it difficult to draw a clear dividing line between the information that is processed. For example, during iterative hypothesis testing (a form of history-taking), the questions asked are limited and based on known medical information. However, it is believed that the clinical examination execution is truly an 'executory' activity, requested for and *instructed by* the Problem Establisher. Nevertheless, this I-transaction is not the concern in the B-Organization, and only the complete construction of the I-Organization of both B-transactions will reveal its true place. Note that this explains the ambiguity of fig. 3.3 as discussed in ch. 3.

The activities in the bottom of fig. 5.1 correspond to datalogical actions and are considered to be in their 'implemented form'. These activities mean to say that the executed transactions are registered and sent to the regular GP. Hence, this takes place in (the process of) transactions [B-T01], [B-T05] and [B-T06]. It is recognized that implementation of these activities at some point in time has to be dealt with; however, according to the theory of Enterprise Ontology, the view on the B-Organization is not the appropriate place for this attempt.

The activity 'execute triage' is also an implementation of various transactions. The triage nurse actually tries to establish (the severity of) the problem (an action that needs to be authorized by a GP). Support is therefore needed from existing medical information about the patient and perhaps some history-taking. The triage nurse may complete [B-T01] (and next [B-T05] and [B-T06] also by telephone) or decide that the GP has to finish the establishment of the problem (in which case an appointment is made and availability of the patient is secured).

In Enterprise Ontology the objects in the SM correspond with the production of the system. The system is portrayed as a white-box model, i.e. in terms of its construction and abstracted from any implementation issue. Therefore, the corresponding production is *also* on the same level of abstraction. In fig. 5.2 the business objects of the current ELR design are exhibited. The blue colors indicate that the objects are datalogical, which is not a surprise, as the objects are considered to be tangible objects: implementations of the ontological production. A prescription 'document' represents a medicament treatment **{1}**. The (construction of the) locum report represents the instance of the established problem (and the related policy, etc.) **{2}**. The referral letter is an implementation of an instance from the referral class **{3}**. The patient health record is of course not a product of the system, rather it is an implementation of the complete SM **{4}**. Finally, the 'relevant medical information' is actually irrelevant **{5}**. There is obviously no equivalent in the SM, since relevance is not an inherent property of any of the objects.

The mappings show, for one, that the generic care transactions satisfy the activities of the locum situation. Some transactions, like [B-T04] were not mapped, which indicates these are not considered as important in the ELR design. However, for a complete model of the primary care process this transaction should definitely be included. Furthermore, the SM contains at least the equivalent information that the business objects try to advertise. The SM also reveals 'new' objects, like *Policy*, which were not found in the current design. The mappings were discussed and positively verified with several general practitioners and an expert on the design.

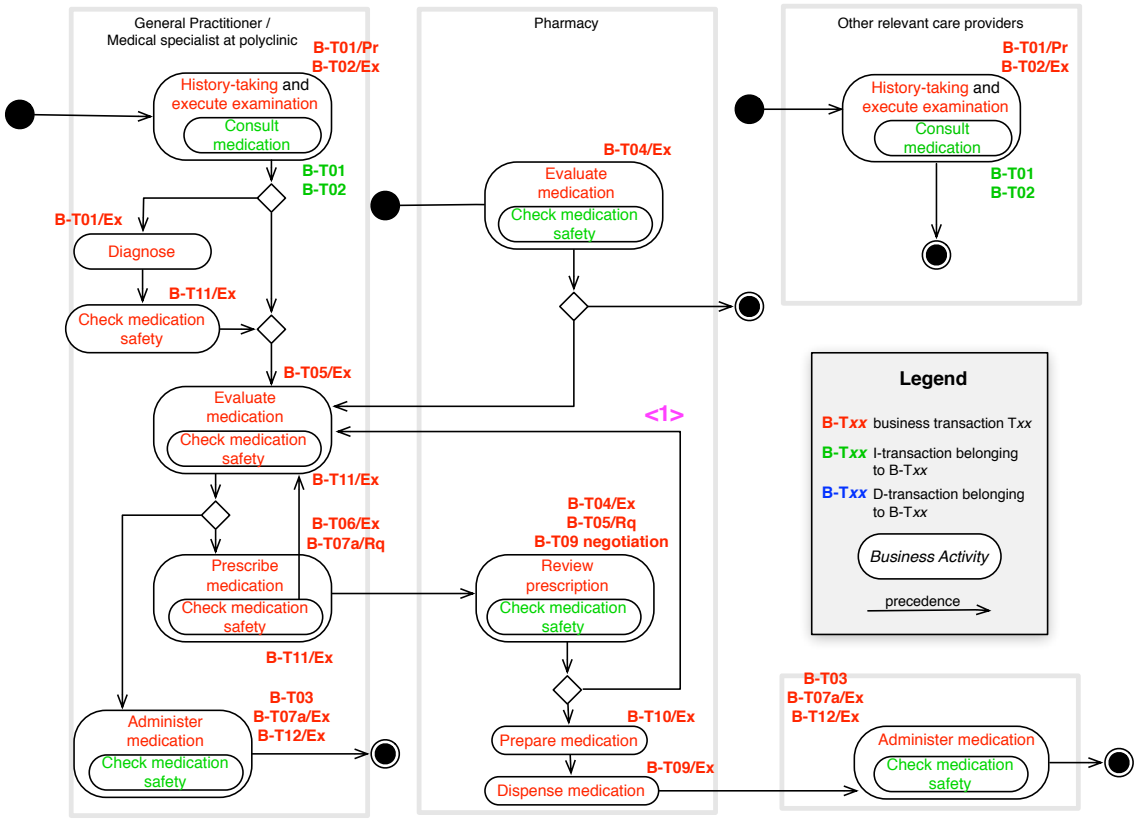

Fig. 5.3 *Mapping EMR primary care business activities to transactions of the Medication Care Network*

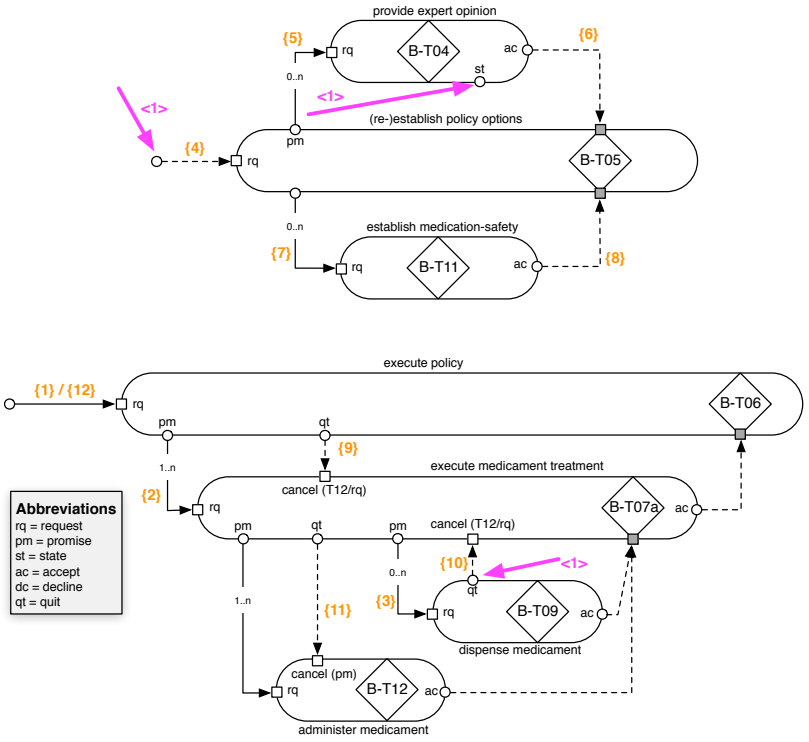

Fig. 5.4 *Actual semantics and coordination process of arrow <1> in fig. 5.3*

5.3. Verification of the EMR design

The current EMR design distinguishes between (the flow of) medication activities in the primary and the secondary care situation. In fig. 5.3 the business activities in the primary care are depicted; Appendix G contains the mapping of the secondary care situation. Recall that the GCN was extended and further specified to construct the complete Medication Care Network (MCN). All transactions of the MCN are now used to map the activities in fig. 5.3. Further, the difference between workflow and construction is once again well illustrated; for example, in the sequence of medication preparation and dispensation (preparation is a component of dispensation, but comes first in the workflow view).

The mapping reveals two different infological actions, namely recalling information about the medication history of the patient and checking the medication safety. The same discussion as in the previous section can be held about whether or not inspecting a patient's medical history supports the establishment of the problem or *directly* supports the history-taking. However, it is more interesting to focus on other activities; for example, the activity 'review prescription'. It matches two different transactions: providing an expert opinion (the pharmacist is the medication expert who suggests alternative therapies) and dispensation of the medicaments. Clearly, it is a choice of the current construction that the pharmacist provides alternative medication suggestions when dispensation of the medicaments has already been requested for. Ideally, however, the pharmacist should provide his opinion on the (medication) policy *before* the policy is actually in execution, i.e. before the patient or any other subject in the role of Medicament Treatment Executor (MTE) arrives at the Medicament Dispenser possibly in vain.

Consider fig. 5.4 which illustrates the actual semantics of arrow *<1>* in fig. 5.3. It is assumed that the initial policy options have been established and that the patient has requested execution of the advised policy (which, for simplicity, consists of only one medicament treatment) **{1}**. Therefore, a GP authorized to approve pharmacotherapy has requested execution of a medicament treatment **{2}**. In this example, the patient has to execute the treatment himself, but does not have the medicament in his possession. He therefore goes to the pharmacy and requests dispensation of the medicament **{3}**. In normal circumstances, the dispenser promises the delivery (there is no wait condition for this coordination act; it is therefore not shown). However, upon checking the medication-safety regarding the requested medicament, he notices relative contraindications which make him decide to stall execution of [B-T09]. The dispenser requests the establisher of the policy for reconsideration of the policy (as the representative of the patient) **{4}**. As the expert in medicaments, he also provides his opinion (e.g. 'the relative contraindication might not be worth the risk, there is an alternative available'), which the policy establisher gladly accepts **{5}** **{6}**. The policy establisher also recalls his previous judgements (notice, this is the remembering of existing information, thus an I-transaction). The policy establisher rejudges the policy (options), by reconsidering his previous decision along with the opinion of the medicament expert. The policy re-establisher may stick with his earlier decision, in which case the current policy in execution is continued, and which requires the dispenser to comply with his promised dispensation. Otherwise, a new policy may be established and promoted as preferred (after a final medication-safety establishment **{7}** **{8}**). If so, execution of the current policy is canceled **{9}** (often by the same subject in the role of policy establisher). As a result the dispenser may also cancel his promise to dispense the 'troubled' medicament **{10}**. As a consequence, scheduled medicament administrations need to be canceled **{11}**. At the same time of cancelation of the old policy execution, the execution of a new policy may be requested for **{12}**, and so the cycle repeats.

Further, notice that a patient - according to the schematic in fig. 5.3 - is only able to administer his medicaments after they are dispensed; it was shown in the previous chapter that dispensation is not a necessary activity for the patient to successfully execute his therapy.

Next, observe the presence of 'check medication safety' as part of almost every activity.

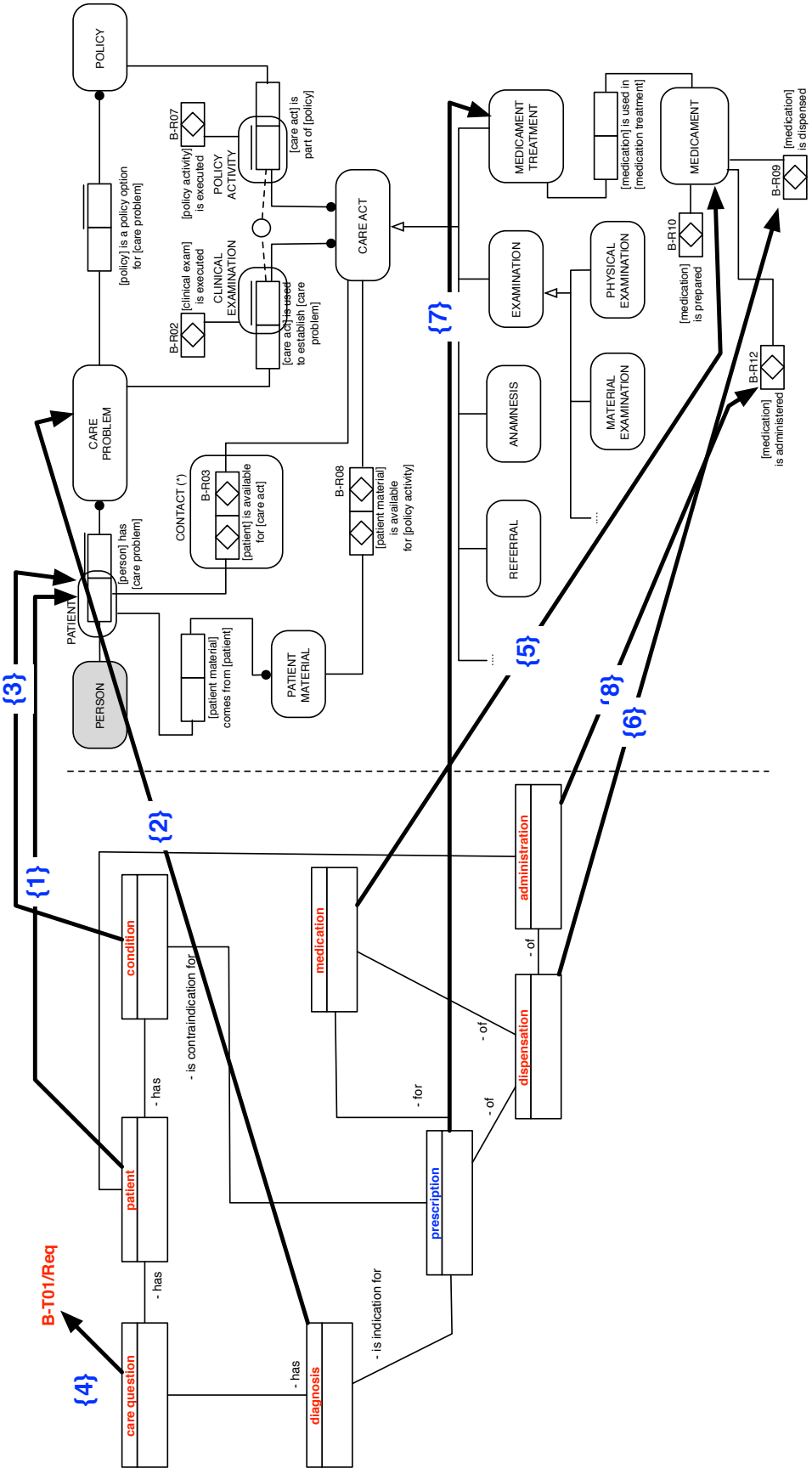

Fig. 5.5 *Mapping the EMR business objects (left) to the SM of the Medication Care Network (right)*

This is done because "checking medication-safety takes place at moments that conditions or medication may change" [14]. Viewed from the construction perspective, establishing the medication safety only makes sense as a component of (re)-establishing the policy. This is the only place where medication policies can be (re-)established. Notice that a new condition (i.e. establishment of a new problem) requires establishment of the medication safety *only as part of* a possible re-establishment of the policy. It is important to understand the difference between having the authority to actually *judge* the safety of medication and using (computed) information about medication safety to support other judgements. For example, a nurse who administers the medicaments to a patient may suspect a possible allergy due to the patient's changed condition (before administering) or reaction (after a first administration). This moves him to use the ICT application to check for contraindications. If the results indicate that the patient's medication may cause trouble with the suspected allergy, he requests a cancelation of the therapy. This illustrates that the information was used to decide whether or not to continue his task of administering the medicaments and *not* to judge whether or not the patient's medication is actually safe. That explains why the 'check medication safety' in most balloons is colored green as an infological transaction.

Contrary to the business objects of the ELR design, most of the objects in the EMR design can be considered ontological, as fig. 5.5 shows. Also, the overview shows more resemblance with the SM than the ELR objects do. The patient maps to the patient **{1}**. The diagnosis corresponds to the (established) care problem **{2}**. The condition of a patient can be considered a 'property' of the patient, which can be derived by gathering all 'active' care problems **{3}**. The care question object actually corresponds with the request of the patient to establish his or her problem, thus [B-T01/rq] **{4}**. Medicament obviously corresponds with medicament in the SM **{5}**. The dispensation object is actually an event - a production fact. It matches the transaction result [B-R09] 'medicament is dispensed' **{6}**.

The prescription object is the only blue colored object in the EMR design. It is a 'tangible' object, i.e. an implementation, and therefore almost automatically datalogical. Abstracting from implementation and considering its intention, a prescription in the first place corresponds with (the request for) a specific execution of a treatment with a medicament (e.g. *Trimethoprim* for one week, 300 mg once a day). This explains the mapping of the prescription object with the Medicament Treatment object class **{7}**. A single administration of a medicament, as part of the medicament treatment, results in the event 'medicament is administered' **{8}**. In turn, the completion of the treatment (which concerns at least one administration) corresponds with the execution of a policy activity [B-R07]. A prescription also authorizes the request for dispensation: coordination act [B-T09/rq]. However, this kind of authorization is not part of the ontology of the B-Organization, because the actor *roles* are always authorized to request the transactions they are dependent on. When actually implementing these roles this concern has to be dealt with: e.g. is the patient indeed in the role of Medicament Treatment Executor, as requested by a GP in the role of Policy Coordinator?

Discussion with a general practitioner and expert on the current design lead to the question whether the term 'administer medicament' is a better fit than 'execute medicament treatment' (since it is the common terminology currently used). However, note that a Medicament Treatment is the implementation independent equivalent of the prescription object, which contains the execution instruction (dose per administration, administrations per day, etc.). These properties do not suit the medicament object directly. However, to still be able to identify every single administration, transaction [B-T12] 'administer medicament' was eventually considered to be a component of transaction [B-T07a] 'execute medicament treatment'.

In Appendix G the mapping of the secondary care situation is also available. What differs is the implementation; ontologically the two are equal. The fact that in the current design the business objects are the same for both processes actually already illustrated this: the same production takes place using the same transactions.

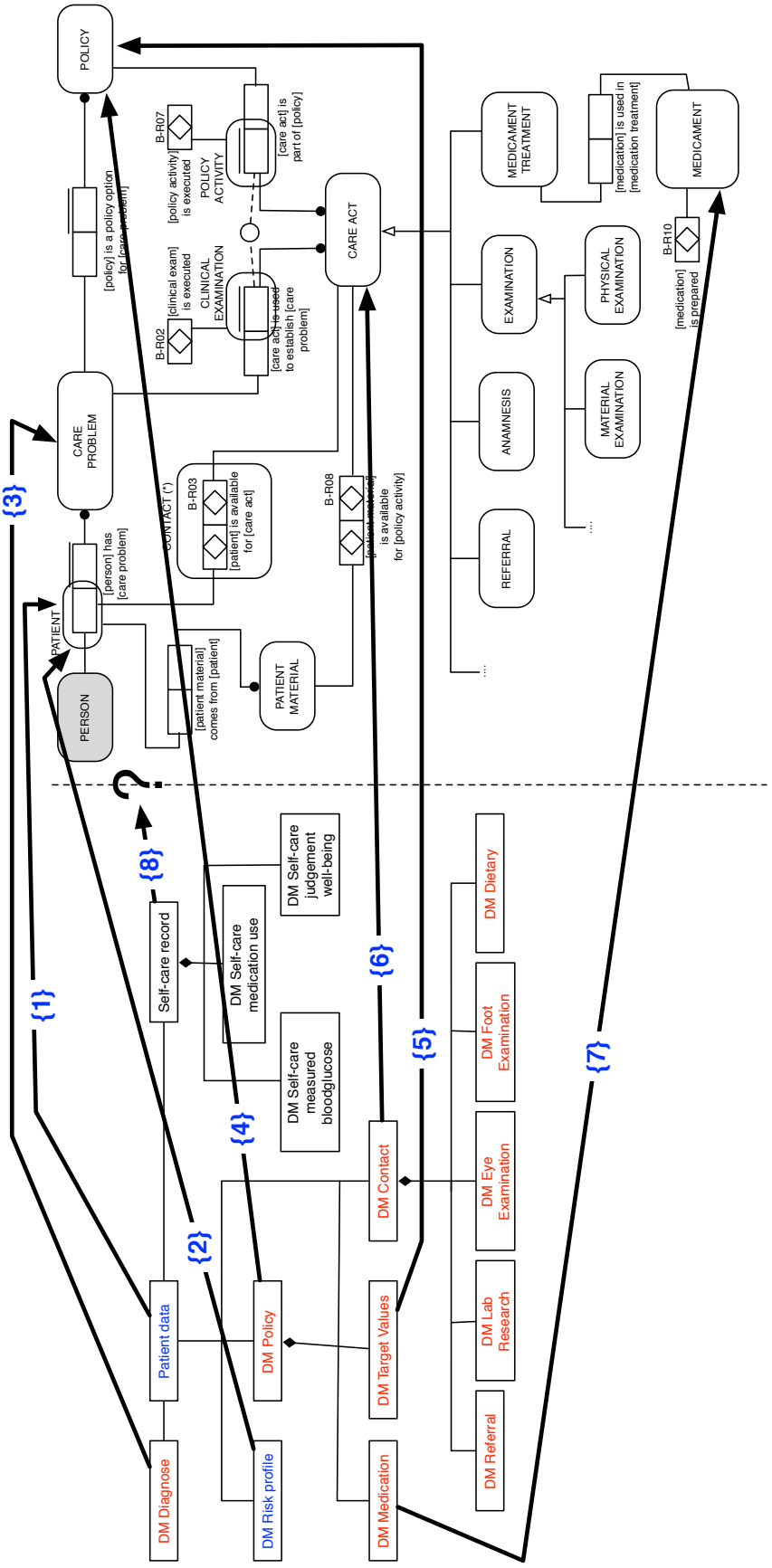

Fig. 5.6 *Mapping of the eDiabetes business objects to the SM of the GCN*

5.4. Verification of the eDiabetes redesign

The eDiabetes business perspective was also analyzed on its form and content, in a similar manner as the designs of the two applications of the EHR as discussed in chapter 3. Similar mappings of the activity and object diagrams to the Generic Care Network were made to identify possible missing components.

As fig. 5.7 illustrates (next page), the eDiabetes business activities are less detailed than the activity diagrams of the other two application designs. Most of the mappings speak for themselves. Notice that the use of swimming lanes 'flattens' the diagram. The activity 'examination/treatment' as performed by the co-clinician (and referred to by the head-clinician) actually corresponds with the patient requesting services from another care-cluster. For example, discussions with a dietician revealed that the whole 'cycle' of transactions is also applicable to the *Dietician Care Network*: the problem is established (e.g. overweight due to fast food eating habits) which leads to establishing and executing a policy (exercises and lots of vegetables). It makes the GCN 'recursive'; it has depth.

Further, the eDiabetes activity diagram shows the activity 'self monitoring' performed by the patient. This is again an example of considering implementations. Abstracted from implementation, this activity corresponds to an 'examination' policy activity, e.g. 'examine blood sugar levels' performed by the Blood Sugar Levels Examiner. Hence, there is no difference in this activity (and its results) performed by the patient or the co-clinician.

The business objects in fig. 5.6 to a large extent map to the SM of the Generic Care Network. For one, patient data corresponds with the patient class **{1}**. Patient data is, not surprisingly, datalogical. In the ontological world, focus is on the 'actual' patient, not the data. Patient data does not have a care problem, a patient does. Next, the risk profile that is mentioned is actually a (datalogical) implementation of properties of the patient, e.g. what is the patients ethnicity, is he or she a smoker, does he or she consume alcohol? This explains the match of the risk profile with the patient **{2}**. It was already explained that the diagnosis object corresponds with the care problem class **{3}**. The policy object obviously corresponds with the policy class **{4}**. The target values are actually properties of the policy, e.g. in a policy the target weight and the target blood pressure can be captured, hence the link to the policy class **{5}**. It was already explained in section 4.5.3 that a (desired) contact actually refers to the care-act **{6}**. The contact property 'planned' actually refers to the contact appointment object class in fig. 4.8. The property 'executed' corresponds with transaction result [B-R03]. Further, the medicament object corresponds with the medicament object class in the SM **{7}**. Finally, the self-care record requires some attention **{8}**. A self-care record is obviously not a product of the Generic Care Network. The fact that the patient becomes active in the care processes (assigned an 'examiner' role) and that this information is perhaps to be treated differently (with caution), is a very different concern. The focus is on the production of the system: the produced information is always the same; for example, the values of the current blood sugar level.

The mappings explained above were reviewed and accepted by an expert on the current application design.

5.5. Verification of the redesign criteria

Now that the individual redesigns have been checked for their correctness, it is necessary to discuss whether or not the promised improvements have been met. In this section, the focus is on the form and content criteria: formal, coherence, consistency, conciseness, comprehensiveness and essence. The other requirement - readability - is left for discussion in the next chapter.

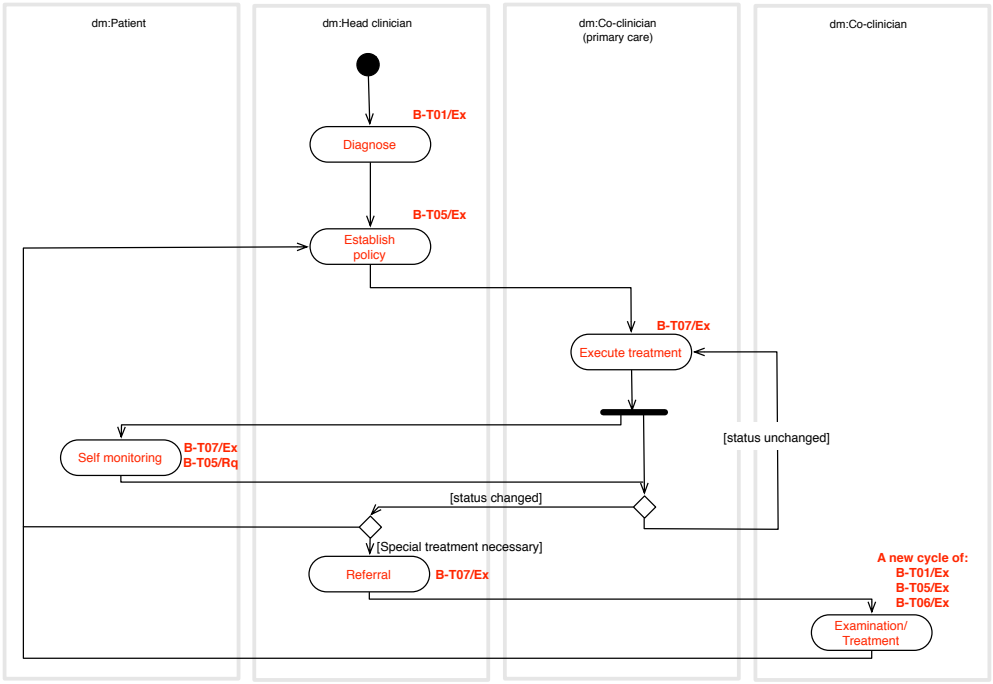

Fig. 5.7 *Mapping of the eDiabetes business activities to the transactions of the GCN*

5.5.1. Formal

During analysis of the EHR application designs, resolving ambiguity was established as the first possible improvement. The use of a formal language to express the models would theoretically solve this problem. The models that were produced by following the chosen redesign methodology have rich semantics which are fully explained in the DEMO 3.0 diagram legends [26]. Next, some 'self-evident' definitions were explicitly defined, thereby obtaining single meanings for each concept used in the designs.

At the beginning of this graduation project one of Nictiz's employees noted skeptically that no single design would ever become unambiguous. There is a realistic truth in this thought, namely that in practice effort is still required by both designers and users to correctly work with the models. The designers should be capable of applying the semantics of the (elements in the) models in the right way. The users should be aware of the semantics in order to correctly interpret them. Having said that, it cannot be denied that the chance of ambiguity is far lower when using a modeling language with clear semantics than when using a modeling language with poor or no semantics.

To give an example of the rich semantics of DEMO, notice that the Organization Construction Diagram (OCD) - which shows the transactions of an organization in a very concise way - purposely avoids the use of arrows. For one, a transaction always consist of multiple coordination acts. Instead of visualizing every coordination act between two actors, the coordination and production acts are grouped together to represent one complete transaction. The only requirement now is to be able to distinguish between the initiator and executor of the transaction's production. An arrow would obviously not make sense in this situation since there is no single direction of communication; this explains the use of the small black diamond instead (the symbol of production) to denote the executor. Next, by not specifying the sequence of coordination acts, it is recognized that the successful negotiation - which is required for the production of a transaction - is variable and case specific. Still, the Process Model (PM) can be used to elaborate on the required coordination of a transaction; however, one should be aware

that such an elaboration in principle focuses on only one of various possibilities. The example in section 5.3 about the impact of a single arrow illustrated this well (as opposed to the 'default' process model in fig. 4.7). Furthermore, awkward activity flows - like the sequence of activities after 'compose treatment policy' in fig. 5.1 - become obsolete, since such decisions do not have to be made anymore in the diagrams. Rather, the construction-oriented focus allows concurrent, optional and repeated transaction initiations, while worries about the sequence (i.e. arrows) are not necessary anymore (consider **{14}** in fig. 4.4 for a comparison).

5.5.2. Coherent

Although coherence can (also) be understood as the cohesion of different organization layers, it refers in this report to cohesion of the various models in the business perspectives. In the previous designs this property was considered subpar since the connection between the activity models and the business objects seemed rather random (see section 3.3.1). The redesigns have complete cohesion thanks to DEMO's way of working [27]. For one, the transaction results that were determined in the Construction Model are incorporated in the State Model (SM). This ensures that the SM contains at least the object classes that the production facts apply to. For example, the result of transaction [B-T06] ('policy is executed') ensures that there is an object class 'policy' to which the result is rightfully attached. Compare this to activity 'compose treatment policy' in fig. 5.1. The execution of this activity would result in the 'production fact' 'treatment policy is composed', which would require an object 'treatment policy'; however, recall that this object is not present in the current design, as fig. 5.2 once more illustrates.

The Bank Contents Table (BCT) combines the transaction results, object classes, fact types, and other..., and is therefore also dependent on the SM. Remember from section 5.5.1 that the coordination and production acts together are represented by means of the transaction symbol. The transaction symbol actually also symbolizes the coordination and production *banks*, i.e. all the information that is available as a result of the transaction. For example, the knowledge that patient *x* has care problem *y* is stored in production bank [PB01], which is represented by the diamond in the transaction symbol of [B-T01]. Upon request to establish policy options for this problem, the Policy Options Establisher accesses [PB01] to recall the details of problem *y* of patient *x*. This explains the information link (dotted line) between the Policy Options Establisher and production bank [PB01] in fig. 4.3. In other words, the *fact type* that was established in the SM turns out to be of importance in the CM and illustrates another example of the coherence between the various models.

5.5.3. Consistent

Consistency is an important property for the designs that Nictiz delivers. For every application of the EHR a separate design is produced. However, these documents are often used and reviewed by the same (group of) users. It is therefore reasonable to ask for consistent design structures. The use of the DEMO 3.0 legend, together with DEMO's new way of working, results in the 'predictable' development of aspect models.

Consistency also has to do with elimination of contradictions. In the current designs contradictions occur when one document states something that the other does not. One would expect the documents to both include or exclude the information. In a way one could say this concerns the 'coherence' of the various designs (as opposed to coherence of the various models in an individual design). By depending on a sound theory, the DEMO methodology has clearly defined concepts which help to determine what to consider a *business process, business object, business rule* etc. and thus guarantee consistency.

The redesigned business perspectives are consistent since they share the same foundation, namely the Generic Care Network (GCN). The GCN is sometimes extended and further specified, as in the case of the EMR redesign. In general, it is recognized that there is actually only one business perspective, instead of one business perspective for every EHR application. This applies especially to the objects in the State Model of the 'healthcare enterprise'. The existing laws and relations between the objects certainly do not change when switching between care-clusters or care-networks. Rather, additional objects or specializations of existing ones may be appended as a result of such a switch. Although this is acknowledged by various Nictiz designers, the business objects in the EHR application designs currently show otherwise.

5.5.4. Concise

Designs should be as concise as possible, i.e. only contain information that is relevant for their purpose. For one, repeating similar information is superfluous and should be avoided: it does not provide anything new, yet increases the risk of inconsistency in the long run (when changes to the information are only partly carried through). In section 3.2.2. an example was presented that showed four repetitions of the same activity. By naming the actor role according to the activity that is performed (instead of using organizational functions) one gets rid of the redundant information and at the same time keeps the options open for future subjects to fulfill the role.

Conciseness is obviously a relative concept, related to comprehensiveness. DEMO's Construction Model provides a succinct overview of an organization's construction, thereby purposely ignoring details about the coordination. The larger the organization, the bigger the impact. Consider the EMR business activities in primary care in fig. 5.3. This relatively small overview of the business process already contains many arrows in many directions (and for those for whom this schematic is new, notice that it is hard to understand or 'read' without accompanied descriptions). Imagine the schematic to be twice as big; one would get dizzy from the amount of arrows. It is safe to say that DEMO effectively distinguishes between the need for a quick overview of the transactions on the one hand and a truly useful overview of the coordination required for the transactions (i.e. the process) on the other hand. What is meant with 'truly useful' is that one could actually read and understand the process directly from the diagrams, not necessarily with accompanied descriptions and directions (this, of course, requires knowledge of the DEMO legend). Thus, to recall that conciseness is relative, DEMO's Process Model might not seem concise at all at first introduction. However, these models are as succinct as possible for their function, which is to provide insight into the required coordination for entering into transactions.

5.5.5. Comprehensive

In the previous section the criterion comprehensiveness was already mentioned. It is understood as containing (nearly) all elements or aspects of something, in this case the models. The comprehensiveness (and conciseness) of the Construction Model and the Process Model were just discussed. However, the State Model still deserves some attention. The differences between the State Model in fig. 4.5 and the business objects schematics in, for example, fig. 5.5 and fig. 5.6 are huge. Although it was possible to map (almost) every single object to one of the elements in the State Model, the relations between them were not at all consistent and very brief. According to Dietz, *verification by instantiation* not only helps to determine the correct relations between objects (fact types), but it also allows for specifying of important dependence and existence laws. Since the State Model is a model of the 'real (system) world' these laws and relations actually provide a complete and honest overview of the objects.

Currently, the business objects are said to lack such details on purpose [17]; in the information system perspective they are further elaborated. However, these relations have nothing (directly) to do with information systems. Also, because of the absence of correct relations and laws, the care professionals and healthcare umbrella organizations who review the designs, cannot do otherwise than question the vague or incorrect objects overview. In other words, the State Model perhaps looks (overly) comprehensive; however, it is only so because the 'real world' *is* this comprehensive.

5.5.6. Essence

Actually, the criteria discussed above are met because of the property of essence. In section 3.3.2 the meaning of 'essence' was already discussed. Recall that the essence of a system is understood as abstraction from implementation (i.e. without concern about the technology that is required to make the system operable) *and* abstraction from realization (i.e. without concern about other systems that the system in consideration depends on). Both have already extensively been discussed in the previous sections and chapter. Abstraction from implementation is met by considering a construction perspective, thereby ignoring organizational functions and (most) 'tangible' objects. Abstraction from realization is met by considering an enterprise as a layered system. Separation of concern is applied, thereby concentrating on only one aspect at a time: in this project, the production of original facts in the healthcare system, also known as the B-Organization.

5.6. Conclusions

In this chapter the correctness of the redesigns was verified and it was checked whether or not the redesign criteria (defined in chapter 3) were actually met. Verifying the correctness of the redesigns started with mapping the current business activities to the transactions in the construction model. The change from a workflow focus (activities) to a construction focus (transactions) requires a rather drastic paradigm shift. Straightforward mapping was therefore challenging. The activities were categorized based on their production: the production of new information, the re-production of old information or the storage of information, i.e. whether they were ontological, infological or datalogical activities. Only the ontological activities return in the redesigns since the B-Organization is the focus of this project. This justifies the visual absence of activities from the other categories. Note, however, that zooming in on a single transaction will reveal its I-Organization and D-Organization: the parts of the system where these activities eventually show up.

Mapping the elements of the Electronic Locum Record (ELR) design to the Generic Care Network (GCN) revealed that the transactions of the GCN are sufficient for representing the B-Organization of the delivered care in the locum situation. Further, the ambiguity of the arrows as discussed in chapter 3 was clarified with the layered structure of an enterprise. This also explained how the locum report is in theory constructed. Next, by abstracting from implementation, the triage activity was considered to cover at least two of the GCN's generic transactions; this revealed duplication in history-taking and problem (severity) establishment. Because of the abstraction from implementation, the model can now also be used in the case of locum activities during holidays. Finally, the business objects comparison revealed a strange set of current ELR objects (at least from the perspective of Enterprise Ontology).

The mapping of the Electronic Medication Record (EMR) design was, as suspected, a bit more difficult. First of all, most activities were identified as ontological, often matching one transaction of the GCN in particular. Zooming in on one of the arrows of the activity diagram -

thereby exhibiting the corresponding process from a construction perspective - illustrated the impact of a single arrow. Insight into such processes are vital when constructing supporting information system. Next, the various mentions of the use of medication safety information systems were discussed, which resulted in a distinction between one ontological transaction, i.e. actually deciding whether or not the medication is safe, and a few infological transactions, which are used to support other (ontological) judgements. Finally, all the objects of the current EMR design could be mapped to equivalent elements in the State Model. However, the State Model still contains important objects that are not currently present and provides a more comprehensive overview of the relations and laws that hold for the objects.

The current design of eDiabetes is still in development. However, the defined activities and business objects could still be mapped to the GCN models. The biggest revelation is perhaps the 'recursive' use of the GCN. For every care-cluster involved in the diabetes chain-of-care a similar set of transactions can be performed. Most business objects could be mapped to the State Model. However, the 'self-care-record' object was explained as inappropriate, since it contains similar production results as the 'medical-care-record'. Next, 'care acts' should be recognized as the content of a diabetes policy as opposed to 'contacts' (for example, referral is an important care act, but could not be considered a moment of contact). Overall, regarding the business objects, the same conclusions could be made as for the other two Electronic Health Record (EHR) applications: the designed State Model presents a far more realistic overview of the 'healthcare world' than the current business objects schematics do.

Finally, the redesigns were verified to meet the form and content criteria that were established in chapter 3, which answers research question (g). It turns out that the models in the redesigns are indeed coherent as a result of the iterative approach of the Design and Engineering Methodology for Organizations (DEMO). Next, the redesigns are indeed consistent, i.e. the content that should be available in the business perspectives of the reviewed (but also future) EHR applications is 'predictable'. Further, the redesigns are comprehensive in that they provide a complete story, yet concise, since superfluous information from the current designs was intentionally left out in the redesigns. Finally, these criteria were considered to be met because of the property of essence, as explained in section 3.3.2.

6. Validation of the redesigns

In chapter 4, the redesigns of the business perspectives were presented. The previous chapter compared these designs with the current ones to check that the intended information was still present or was otherwise rightly absent. The redesigns were also verified to meet several criteria regarding form and content. What is left for discussion in this chapter concerns the *appropriateness* of the redesigns. In other words, do they meet the expectations of the (future) users regarding purpose and practicability. As a final point, this chapter tackles the last criterion - readability.

6.1. Validation approach

As was shown in section 3.4, the designs distinguish three target user groups, namely the healthcare umbrella organizations, Nictiz and software developers. Research during the *Leverancierstweedaagse* confirmed that this last target group barely uses the business perspective of the designs, if they use the designs at all. Because the redesigns consider precisely this perspective, the software developers were not involved in this initial validation process. Rather, the redesigns were discussed with those users closer to the business perspective:

- The National General Practitioners Community (NHG), one of the healthcare umbrella organizations
- Several care professionals unfamiliar with the current designs
- Several designers and (non-practicing) GPs working at Nictiz.

6.2. Discussions with NHG

The current designs of the scoped EHR applications have all been reviewed by NHG. For starters, NHG recognizes that the current designs can be improved. They consider the current designs tedious and often cannot find important information at places they would expect to find it (or even find it at all). Further, they are concerned about the divergence of the designs at the lower (implementation) levels. NHG shares the opinion of Nictiz that a formal design is required (possibly in conjunction with informal versions) [2, 3].

For one, the content of the redesigns was to the largest part understood and recognized. Although the structure and symbols were perhaps not *immediately* clear, NHG was convinced that they, as well as the other healthcare umbrella organizations, have the right people available who are capable of reading and understanding the DEMO models. Next, the idea of a shared foundation between the various EHR applications was met with approval. Having one point of departure at the top of the designs is a prerequisite for suppressing divergence elsewhere (be it at the I-Organization, D-Organization, or even at the level of implementation).

One thing that became clear during the discussions is that the purpose of the business perspective is currently not clear enough. When healthcare professionals - or specifically GPs, for that matter - are asked about the activities they perform, various answer will be obtained, ranging from abstract replies to very detailed workflows. Explanation of Enterprise Ontology, and how it combines abstraction from implementation and separation of concerns to specifically focus on the production transactions, resulted in the response "we have never looked at it that way". The structured approach of deciding what is relevant and what is not clearly seemed a small yet welcome revelation [28].

6.3. Discussions with care professionals

The redesigns were also discussed with a general practitioner and dietician who were not familiar with Nictiz's current designs. The very first and pertinent questions they asked were *why* is the business perspective needed and *why* should it interest us? Explaining that it is an overview of construction of the services they deliver, needed to identify the information that is required to complete them, was seen as a satisfying answer [29, 30]. Without explicit boundaries as to what to consider a transaction, a business process, a business object etc., the care professionals tended to recall (probably rightly so) the uniqueness of the care situations (both stated that care situations are not all "black and white"), as was already mentioned in the introduction of this report. Information and communication technology and related matters were viewed with suspicion by the care professionals.

After reviewing the redesigns (and accompanied descriptions) it became clear that 'arbitrary' care professionals are not used to read (formal) designs: "It felt like learning a new language," they stated. However, after some introductory discussions they found the redesigns (the Generic Care Network, which is equivalent to the ELR and eDiabetes redesigns) understandable and recognizable. The construction perspective on the processes was also found a very interesting approach: "like playing with LEGO bricks," they noted.

To summarize, if the 'unexperienced' care provider is willing to put some effort in gaining basic knowledge on the DEMO legend (and perhaps the basic theory behind the methodology), he is certainly able to understand and discuss the redesigns. However, one should ask oneself whether the arbitrary care professional is an appropriate target user of the (re)designs.

6.4. Discussions with Nictiz

Like the two previous validation groups, the employees at Nictiz generally had little to no experience with Enterprise Ontology and its methodology. Being not at all experienced in educating others in the theory, it was found difficult - especially at the beginning - to sensibly explain to the designers about the differences (and strengths) of Enterprise Ontology compared to the current approach. Also, many employees involved with the EHR application designs regard(ed) the purpose of the business perspective as a 'tool' for engaging the healthcare sector [16, 18, 31]. This probably partly explains why the designs are gradually fleshed out. The importance of the criterion of *readability* was therefore also mentioned a couple of times.

Once the first redesign attempts were presented - which made the theory and methodology practical and tangible - the responses were cautiously optimistic [32]. One of the *lead architects* had always wanted to construct a generic healthcare process model, but had never attempted due to warnings from the healthcare sector who indicated this was an impossible task. Further, the fact that the models are now reusable (opposed to, for example, the current ELR activity diagram) was much appreciated. The construction approach, which reveals the components in

an organization, was also found to be very powerful. However, there were concerns too; for example, about how to incorporate (the knowledge of) the new models in a way that suits the current way of working. Further, appropriate tooling was also one of the first worries.

To wind up, the designers of the EHR applications are (for now at least) familiar with Enterprise Ontology and DEMO to only a limited extent. They have experienced the possible improvements; however, fear of the unknown makes them cautious.

6.5. Readability

In the previous chapter the redesigns were verified to meet all but one design criterion. Unlike the other criteria, readability cannot be verified in a purely rational way,. Evaluation of the criterion depends on the opinion of the reader, which explains the shift of the readability discussion to this chapter. In the previous sections it was already shown that most readers had difficulties with intuitively understanding the models. There is no sense in arguing *these* opinions, since opinions are personal. However, a few rational remarks can be made regarding readability of the designs in general, which possibly influence the stance of those readers.

For one, it should be noted that the criteria *formal* and *readable* are in a way each others opposites, like *time* and *cost* in project management. Of course, whether or not a model (or language) is formal is not open for discussion; it is a property with one simple answer: yes or no. The range of possible forms of a model becomes limited when the property 'formal' is also required to be satisfied. In other words one could say that the freedom of presentation becomes restricted. Since a formal design was one of the requirements of this project, it is of utter importance to judge the readability of the models with this requirement in mind. Furthermore, bear in mind that the choice for a formal design is often exactly made to get rid of the 'intuitive reading', which might also bluntly be referred to as 'guessing', which would occur otherwise.

Next, one should realize that there is no harm in actually taking the time to learn and grasp a new subject. Remember that Rome was not built in one day. Hence, if an approach - in this case Enterprise Ontology - shows promising results, it would be a bit odd to leave it aside because of its alien appearance. In fact, a little effort in understanding the theory and DEMO legend will reveal that the models are actually well thought-out and (eventually) logical. Actually, to a large extent it is probably not the form of the models that makes one conceive the models as troublesome. The (necessary) switch from a functional to a constructional perspective - thus, at the level of content - probably provides this awkward feeling, since, recall from chapter 2, it is the functional perspective of a system (or model) that has been dominant in society [4].

Finally, one should be aware of the function of the redesigns. As has been explained in chapter 2 and section 3.3.2, the construction of the B-Organization is required to properly devise the required functions of the I-Organization. Or, in other words, information (I-Organization) is used in (supports) the services of the healthcare system (B-Organization). Hence, the construction of the B-Organization is a serious requirement and the ultimate starting point for determining and engineering information systems and alike to support the business processes. This illustrates that a constructional perspective - which the DEMO methodology delivers - is indisputable. Whether or not these redesigns should *also* be used for the purpose of engaging the 'arbitrary healthcare professional' is a very different discussion. As was shown in section 6.3, it takes the average healthcare professional relatively more effort to read the DEMO models. It is therefore probably a good idea, as also advised by NHG, to develop informal documents as a way to 'educate' and apprise individual care professionals.

6.6. Conclusions

The redesigns of the EHR applications were discussed with several target user groups. The National General Practitioners Community (NHG) acknowledged the benefits of formal designs. They found the ideas of Enterprise Ontology and the Design and Engineering Methodology for Organizations (DEMO) promising, to the extent they were familiar with the subject. At least they were convinced that NHG, as well as other healthcare umbrella organizations, (will) have the right people available to understand and discuss the DEMO models.

At Nictiz, the designers were also cautiously optimistic. Never before had such a generic approach been available to them. The reusability of the models was much appreciated and the construction perspective was found to be very powerful. However, the readability and incorporation in the current way of working were concerns still left unaddressed.

The concern about readability was put in a different light by arguing that formality and readability of designs are each others opposites. Also, one should not be afraid to take the time to learn and grasp a new subject, if its opportunities sound promising. Finally, it was refuted that the function of the business perspective is to engage care professionals to use or educate the Electronic Health Record (EHR) application or EHR in general. Rather, a strict and complete business perspective is a serious requirement as a starting point to devise supporting information systems and the like. Seen from that light, the redesigns are as readable as is possible.

The above illustrates that DEMO should be considered a serious candidate as a new formal design approach, something Nictiz is currently looking for. The approach has certainly made clear that the business perspective should be the point of departure which reveals the opportunities of ICT, instead of the current understanding, where the business is ‘suited’ to the EHR application. In that respect, research question (g), whether the application of Enterprise Ontology contributes in bridging the gap between the healthcare and ICT sector, can be answered positively. Since the redesigns have not actually been used yet among the stakeholders of the designs, one can only speculate whether or not the mutual communication will be improved. However, the benefits as explained above and in the previous chapter would suggest so.

7. Conclusions

The previous chapters provided detailed insight into how Enterprise Ontology could be used to analyze and redesign three applications of the Electronic Health Record (EHR). This means the end of the investigation that was set as the research goal of this thesis project is near. However, one last important question still deserves an answer: namely, whether or not the ideas of Enterprise Ontology are worth considering to (re)design other (future) applications of the EHR. In other words, does Enterprise Ontology really matter? Or, considering the context, does it care? Before phrasing the final thoughts to answer this question, the conclusions of each individual chapter will first be briefly recalled.

7.1. Recapitulation

In chapter 2, the context of this thesis project was presented. It was explained that the Dutch national Electronic Health Record (EHR) is not a central database, as the name would perhaps suggest. Instead, the patient's medical information is kept at the local systems of the care professionals. For care professionals to mutually communicate, an advanced infrastructure called *AORTA* has been developed. To make use of this infrastructure, specific applications of the EHR are being developed. Three of these applications were investigated in this thesis, one concerning locum activities, one concerning medication and one regarding diabetes (section 2.1). In the same chapter, an enterprise ontology was explained as the construction of the *essence* of an enterprise: a construction independent of the way it is implemented or realized. To achieve such an overview, an enterprise is considered as a (layered) social system; a system in which the elements are social individuals, i.e. subjects. The subjects are abstracted from in order to concentrate on the actor roles they fulfill. Actors (subjects fulfilling an actor role) contribute to the *production* of an enterprise by entering into and complying with mutual commitments about (a part of) the final product or service that is to be delivered; this is understood as *coordination*. These coordination and production acts occur in patterns, called transactions. Three kinds of transactions are recognized and they differ only in their resulting production. The focus of this project was on transactions regarding the production of original new things: facts that cannot be derived from other facts, also understood as *ontological transactions* (section 2.2).

In chapter 3, the business perspectives of two current EHR application designs were closely analyzed based on their form, content and usage. The business perspectives have gradually been developed in cooperation with healthcare umbrella organizations to construct satisfiable documentation for all stakeholders. Although each design is currently found practicable, analysis from an Enterprise Ontology viewpoint has revealed several issues that the designs could be improved on. Regarding form, ambiguity was observed when different concepts were found to be expressed by the same term. Likewise, various schematics were identified as ambiguous (section 3.2.1). Next, regarding content, the designs were determined to be mutually inconsistent. Also, the coherence between the different aspects within the business perspective was found to be subpar. Furthermore, the content was thought to be redundant at times, while expected additional matter was, at the same time, absent. In most cases, these inadequacies were thought to be caused by dissatisfaction of the essence property as introduced

above (section 3.3). Finally, the use analysis showed that the business perspectives are to the largest extent not used as intended. It was also discussed that this perspective is actually of equal importance for the three main stakeholders: healthcare umbrella organizations, Nictiz and software developers (section 3.4). The theory of Enterprise Ontology helped in these analyses by providing the required concepts and definitions of what to consider as the essence of a business. It became clear that the current design approaches (TOGAF and UML) lack the profundity and appropriate concepts to correctly model this understanding of business. A different design approach was therefore established as a requirement to redesign the business perspectives. The criteria that the redesigned models should adhere to were (not coincidently) determined as *formal, coherent, consistent, comprehensive, concise* and *essential*. These criteria are understood as properties of an *ontological model*. Finally, the design criterion *(easily) readable* was also recognized as important.

In chapter 4, the *Design and Engineering Methodology for Organizations* (DEMO) was chosen as the new (re)design approach, since it has the theory of Enterprise Ontology as its proven foundation. The methodology also claims - in advance - to produce models that satisfy all but the last of the design criteria (section 4.1). Secondly, an earlier application of Enterprise Ontology within the context of healthcare was found. The *Generic Care Network* (GCN) that resulted from this application served as the basis in redesign of the business perspectives of the three EHR application designs. First, the models of the GCN were revised, reformatted and explained (section 4.2-4.4). Next, these models were extended where needed to reflect the business *processes* and business *objects* in the current EHR application designs (section 4.5). This revealed that the designs (should) actually share an equal *business* and that the construction of their processes is generally the same. The design concerning the locum situation could be completely explained with the GCN. The GCN also proved its value in the diabetes 'chain-of-care'; it revealed the depth of the GCN, that this chain-of-care is actually 'recursive' and that the same GCN is useful to express the various healthcare clusters. Lastly, the GCN required several enhancements to better reflect the components in the process structure of medication prescription and dispensation. However, eventually it was shown that these processes in primary and secondary care in their essence do not differ. Next, it became finally possible to visualize complex, but 'real-life' transaction negotiation. The construction perspective also unveiled that medicament dispensation is a component of executing a medicament treatment, illustrating that dispensation is not necessarily required for a successful medicament treatment. To conclude, it also provided a clear distinction between the various meanings of *medication*.

By mapping the elements from the current schematics to the redesigned business models, their completeness was verified in chapter 5 (section 5.2-5.4). It illustrated well how *workflow* differs from *construction*. A workflow diagram is limited in expressing occurrences of realistic situations. The current workflow diagrams exhibit the sequence(s) of possible actions, thereby losing the actual structure of the process. As a consequence, the required coordination for the successful execution of an 'activity' is lost. The importance and impact of coordination acts was exemplified in the case of negotiating the dispensation of a medicament (section 5.3 and fig. 5.4). Next to these remarks on the process view, the business objects and their relations were also found to be subpar. The redesigned diagram presents a far more accurate and comprehensive overview of the state of the 'healthcare world'. Finally, the redesign criteria that were determined in chapter 3 were verified. First of all, the DEMO methodology provides fully-explained and rich semantics, which indeed resulted in the development of formal and unambiguous models. Next, the iterative design approach of DEMO also leads to coherence of the different diagrams in the business perspective. The redesigns were also identified to be consistent: the content of the business perspectives is 'predictable'. Finally, the redesigns were established as comprehensive: they provide a complete story, yet concise, since superfluous matter from the current designs was intentionally left out. All these criteria were considered to

be met because of the property of essence, i.e. by abstracting from any implementation and realization issue (section 5.5).

Chapter 6 gave insight into the appropriateness of the redesigns according to several user groups. For starters, the results were discussed with NHG, one of the healthcare umbrella organizations closely involved with the applications of the EHR. They recognized the importance of formal designs. The idea of a shared business foundation between the various EHR applications sounded promising. “We have never looked at it that way”, they stated. Although it was their first introduction to DEMO, they were convinced that the healthcare umbrella organizations (will) have the right people available to understand and discuss such models (section 6.2). Next, the redesigns were discussed with a general practitioner and a dietician who were not familiar with any of the designs and redesigns of the EHR applications. The first question they asked was *why* it should interest them. Apparently, application designs in general are not suitable for engagement of the individual care professional. However, after introductory discussions, the construction perspective was found very interesting: “like playing with LEGO bricks”, they noted (section 6.3). Finally, the redesigns were discussed with several designers and/or care professionals at Nictiz. They responded with cautious optimism. They found the construction approach powerful and liked the idea of truly reusable models. Never before had they seen such an overview of generic care processes. However, there were concerns too, especially regarding appropriate tooling and how the models could in theory be incorporated in the current way of working (section 6.4). Especially the designers at Nictiz argued that the models in the business perspective should be easily readable. However, readability of the redesigns was put in a different light by arguing that (required) formality automatically restricts the freedom of presentation. Next, the believe that the business perspective is meant to engage the average care professional to use or educate on the EHR (applications) - a thought that lives in the minds of many designers - was refuted. Rather, a strict and complete business perspective is a serious requirement as a starting point to devise supporting information systems and the like. Finally, it was thought that an ‘awkward’ first experience with the models is not necessarily due to their alien appearance, but rather the (necessary) paradigm shift to a construction-oriented viewpoint. Actually, the DEMO symbols and models are considered to be well thought-out (section 6.5).

7.2. Enterprise Ontology, does it care?

The world we live in is inevitably one that is implemented and realized. If not, *this* report would certainly not exist. As a consequence, people have their very own visualizations and associations regarding all that surrounds them. However, when initiating large scale projects like an EHR, these subjective views need to be suppressed as much as possible to sensibly discuss what the exact problem and their context is, before valuable solutions can be devised and put into effect. By abstracting from any implementation and realization issues regarding a specific topic of interest, conceptual models are obtained that are as close to objective as one can get. Clearly distinguishing between function and construction is also very important, since a functional view is still subjective; however, constructions are not. This is exactly the aim of enterprise ontology. Hence, this suggests that Enterprise Ontology indeed matters. Next, these essential views on, for example, the healthcare sector are at the same time far more resistant to change, unlike their implementations. Consider, for instance, the locum situation (which was actually determined as an implementation itself). The shift to the use of central GP stations has only been a decade ago. However, the structure and tasks of healing have been around for ages. It clearly shows that implementation-free models (hence, *not* considering the GP station and the triage nurse etc.) are more beneficial in the long run. Thus, again, this is another illustration that Enterprise Ontology indeed matters. Finally, based on the recapitulation presented above, one

may conclude that Enterprise Ontology has been proficient in analyzing and redesigning applications of the Electronic Health Record. Most remarkable is probably the demonstration that the similarities between the business processes in the various healthcare clusters are far greater than many designers and healthcare professionals would expect. This actually means that there is an approach at hand that provides the handles to develop one single business perspective, thereby better reflecting reality. Based on this overview, the information transactions that are required to execute each single business transaction can be determined. Every single identified information transaction is in theory a candidate to get support from an information system. Recall that identifying possible ICT opportunities is currently assigned a task of Nictiz's cluster *Knowledge & Advice*. This actually means that the cooperation between K&A and *Design & Architecture* could also be enhanced. Namely, one 'master business perspective' could be utilized by K&A to (let) pinpoint (in consultation with the healthcare sector) which information transactions are thought to gain from a new application of the EHR. This is another illustration that Enterprise Ontology could indeed be beneficial. To conclude, applying Enterprise Ontology inescapably makes one think (at least) twice before acting. Hence, in the end it helps eliminating unavoidable (and probably costly) mistakes. For now, this should be considered a final example regarding the advantages of Enterprise Ontology.

So, yes, Enterprise Ontology cares.

7.3. Recommendations

Below are a few initial recommendations on how to proceed if the opinion is shared that Enterprise Ontology indeed cares.

First of all, the supporting layers of the B-Organization have to be determined. This thesis project focussed on the ontological production of care networks, i.e. the production of original facts in the B-Organization. Every single B-transaction requires support from an I-, and D-Organization (thus, support from existing facts, which are stored somewhere). These are not yet developed. Content of the current business perspectives that was intentionally left out in the redesigns is likely to be of use in these layers (however, one should be aware that these layers too require abstraction from implementation to become truly ontological, recall section 2.2).

Next, based on the I-transactions, future supporting applications of the EHR can be established and pinpointed. The existing applications can also be determined and placed on the single business perspective 'map'. One should decide whether or not to separate the business perspective from the I-application designs (recall section 2.2.4).

If Nictiz is interested in Enterprise Ontology and is seriously considering the incorporation of DEMO in their current way of working, they should investigate the possibilities of tooling [33]. At the start of this project there were rumors about introducing ArchiMate as 'architecture tool'. In a recent article, ArchiMate and DEMO are both theoretically and practically compared and it is concluded that the two can successfully be combined [34].

Next, it would be important to have at least several designers (but preferably all) to become familiar with the theory of Enterprise Ontology and acquire the skills to develop valid DEMO models.

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Translations

English	Dutch
administer (medication)	toedienen (van medicijnen)
dispense (medication)	verstrekken (van medicijnen)
Dutch General Practitioner Society	Nederlands Huisarts Genootschap (NHG)
Electronic Health Record	Elektronisch Patiëntendossier
Electronic Locum Record	Huisartswaarneemgegevens
Electronic Medication Record	Medicatiegegevens
Electronic Medication Safeguarding	Medicatieveiligheid
Locum General Practitioner	Waarnemend huisarts
ophthalmologist	oogarts

Abbreviations

AM	Action Model
C_4E	Coherent, comprehensive, consistent, concise and essential
CEE	Clinical Examination Executor
CM	Construction Model
DEMO	Design & Engineering Methodology for Organizations
EHR	Electronic Health Record
ELR	Electronic Locum Record
EMR	Electronic Medication Record
GCN	Generic Care Network
GP	General Practitioner
ICT	Information and Communication Technology
LSP	National Switch Point
MA	Medicament Administer
MCN	Medicament Care Network
MD	Medical Doctor
MDP	Medicament Dispenser
MP	Medicament Prepaper
MSE	Medication Safety Establisher
MTE	Medicament Treatment Executor
NICTIZ	Dutch ICT Institute for Healthcare
OCD	Organization Construction Diagram
PAE	Policy Activity Executor
PC	Policy Coordinator
PE	Problem Establisher
PM	Process Model
POE	Policy Options Establisher
PSD	Process Structure Diagram
SM	State Model
SSD	State Space Diagram
TOGAF	The Open Group Architecture Framework
TRT	Transaction Result Table

Appendices

Appendix A - Form Analysis

Versioning
With the switch made from bottom-up HTML documents to structured top-down TOGAF-based documents, the need for distinguishing different versions of the documents grew too. Less thought-out during introduction of the first documents, the designs were simply numbered with two digits; one for major and one for minor (change) publications. Soon it became clear that more detailed versioning was desired. Since 2008 the design documents are provided with a version number of four digits. The first one is reserved for the global publication of AORTA. Hence, it indicates which version of AORTA was considered during the design process. The second number is for updates and additions on the designs. If for a certain reason a mistake has been made in the documentation a patch will be published; the third number will be incremented to indicate this patch. The last number is rarely used, but might be applied to denote minor changes to the documentation [10].

The semantics of the 'four digits versioning' explain the gap between the digits of the different versions of the EMR and ELR designs. Starting both with version '1.0', the second publication became '6.x.x.x'. Confusion is avoided with the knowledge that the version number semantics have changed between the two publications. Thus, there haven't been lost four 'in between' publications.

The form of the Electronic Locum Record design

Version 1.0
With the introduction of the global course of the form of the care application documentation, one should have a closer look on the individual documents. This paragraph portrays (the evolution of) the form of the ELR design. Currently, two noticeable versions of the ELR have been published: version 1.0, published on May 31 2007 [35]; and version 6.0.1.0, published March 31 2009 [36]. Both versions are considered in this analysis.

The initial design - with the name *Waarneemdossier voor Huisartsen* - spends twenty-nine pages on the description of the business, information systems and technology views. The architecture vision as described by TOGAF is missing in this initial version.

The topics in the business view generally start with an illustrative overview. A description of (the elements in) these illustrations are explained with accompanied written text. The drawings have been made with the Unified Modeling Language (UML). An example of such an illustration is presented in figure 2. Overall the business description is brief.

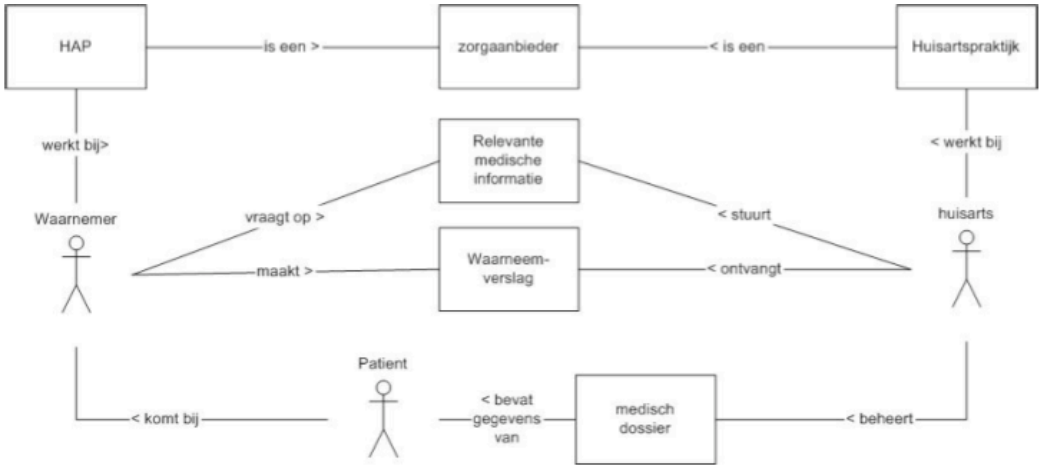


figure 2. Example UML illustration of business entities in ELR design version 1.0

The information systems view exists entirely out of written text, except for one UML use case diagram. Tables with an illustrative icon indicate 'sidetracks' or meta information; commentary on described decisions, references to relevant literature or indications of insufficient information to complete a certain topic. Figure 3 presents an example of such a table.

	In de [AUTOR RL WDH]staat beschreven dat een patiënt het recht heeft op het expliciet NIET versturen van een waarneemretourbericht.

figure 3. Example of sidetrack information in ELR IS view in version 1.0

Finally, the technology view follows more or less the same form approach as the other views. To the largest extent, describing is done by plain written text. A single UML sequence diagram finds its way in this perspective. This final perspective has a more structured feel to it due to the use of tables. Figure 4 presents an example of such a table.

Gebruiks-scenario	Bericht te sturen door een GBZ-applicatie aan de ZIM	HL7v3-interactie	HL7 handleiding	Toepassings-rol
Scenario rapportage waarneeminformatie				
4.3.2.1 Verzenden waarneemretourbericht	Waarneemretourbericht	in: REPC_IN990003NL br: REPC_MT004001NL-WR cw: MCAI_MT700201 tw: MCCI_MT000100	[IH HL7v3 WDH]	Waarnemer (aanmaken) Dossierhouder (verwerken)
0 Aanmelden patiëntstuk (eerstelijnsdossier)	Aanmelden Gegevens	in: MFMT_IN002101 br: MFMT_MT002002 cw: MFMI_MT700702 tw: MCCI_MT000100 gs: Care Provision (460320)	[IH generieke berichten]	Waarnemer (aanmaken)

figure 4. Example of the use of tables in the ELR Technology view in version 1.0

Version 6.0.1.0

This publication follows the default document structure presented earlier, although some extra chapters have been added: *current situation, addendum on requirements* and *changes with previous release*. Also, from this version on the name has been changed to *Huisartswaarneemgegevens*. Overall the document appears neat and clear. A large part of the description is still done using words, however there's also been made more use of (detailed) illustrations, which seem to require less explanation.

The business perspective has been extended compared to the previous version. A UML activity diagram has been used to describe the business process (see figure 5). A UML class diagram is used to represent business objects (see figure 6). Finally, there has been made use of tables for the representation of the relations between business actors, business activities and business roles.

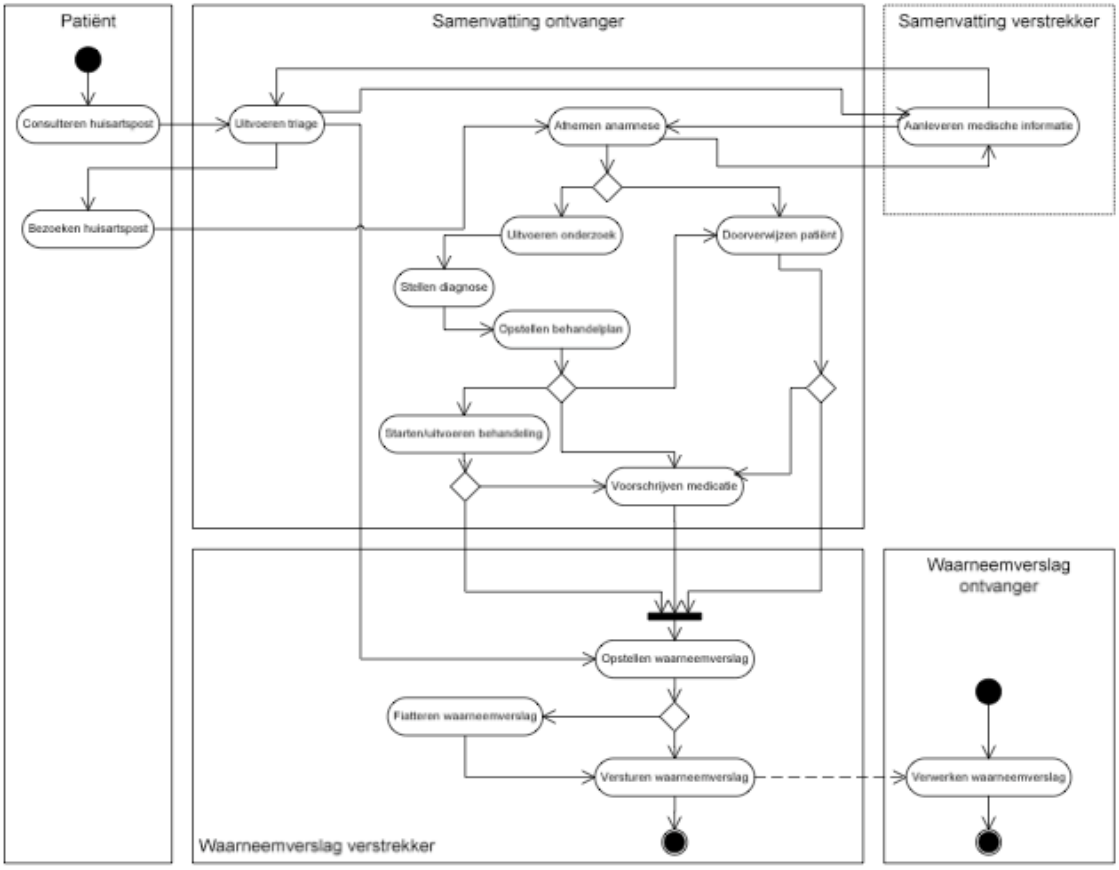


figure 5. UML activity diagram to describe business processes in ELR design version 6.0.1.0

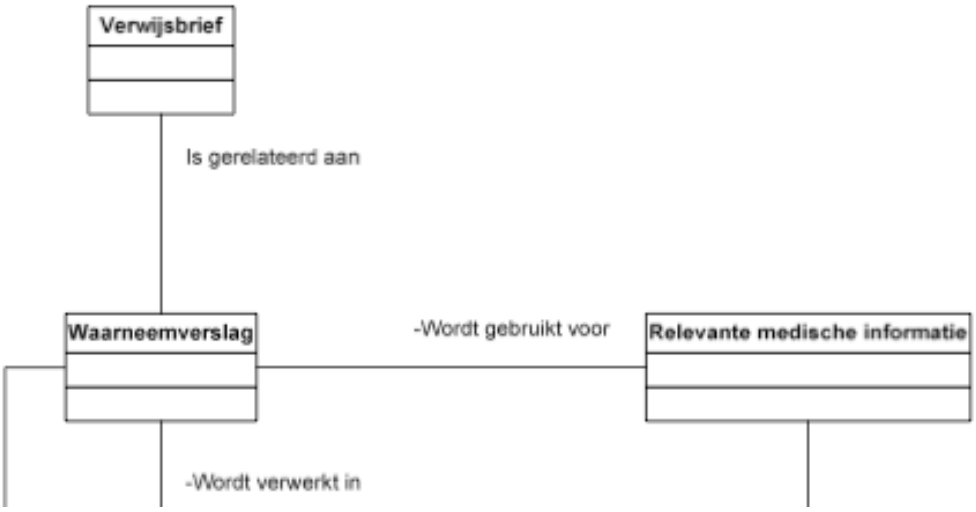


figure 6. UML class diagram to describe business objects in ELR design version 6.0.1.0

In the information systems view some changes have been made too, compared to the equivalent view in version 1.0. There has been made more use of tables, UML sequence diagrams and UML use case diagrams. An example diagram is illustrated in figure 7.

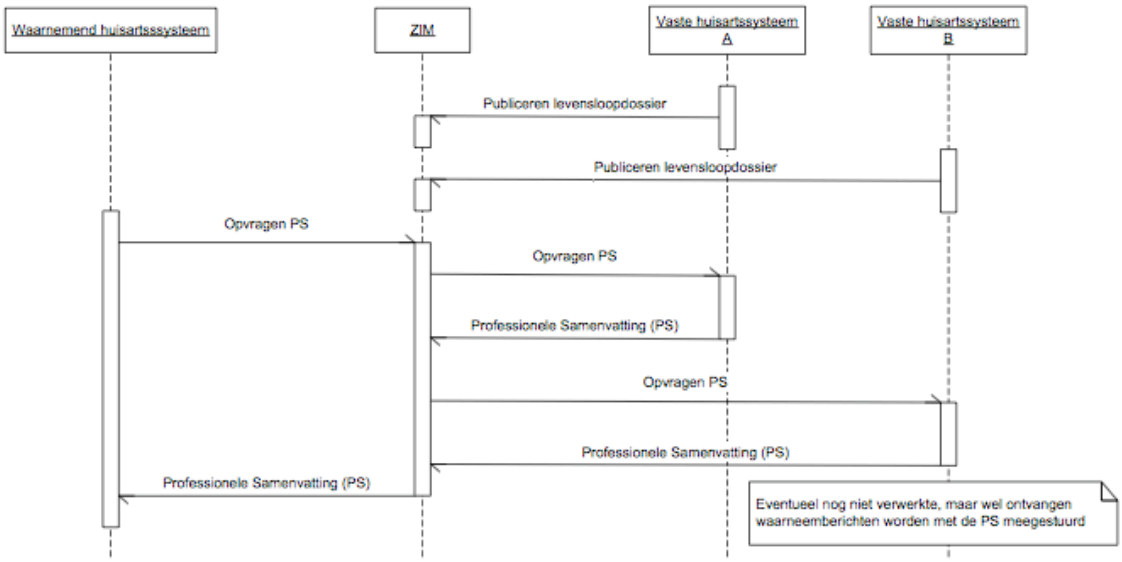


figure 7. An example sequence diagram in the information systems view of the ELR design version 1.0

The technology view has shrunken in this latest publication. Again, written text dominates the description, assisted by a few tables for better structuring the information.

The form of the Electronic Medication Record design

In the analysis of the form aspect of the EMR documentation two publications and one concept version will be considered. The first publication dates May 31 2007 with version number 1.0 [37]. On October 31 2008 version 6.0.0.0. was published [14] and the concept version under consideration is stamped January 21 2009, version 6.1.0.0j

Version 1.0
The initial design of the EMR - which carries the name *Elektronisch Medicatie Dossier* - spends forty-five pages on the description of the business, the information systems and the technology perspective. This first publication too lacks the architecture vision chapter from the default document structure. Next, an extra chapter has been appended to the documentation - *additional requirements* - which prescribes what is demanded of the information systems to get certified.

The business perspective in the EMR design broadly follows the format of the first ELR design. An overview of the topic in question is illustrated with UML followed by an explanation and description using natural language. A similar example of business entities as was presented for the ELR is shown in figure 8.

The information systems perspective again follows a similar format as was used in the first ELR design. A few use case diagrams have been drawn to illustrate particular scenario's, all other describing is done using words. A sample UML use case diagram is portrayed in figure 9.

Regarding the technology perspective, no new interesting observations were done.

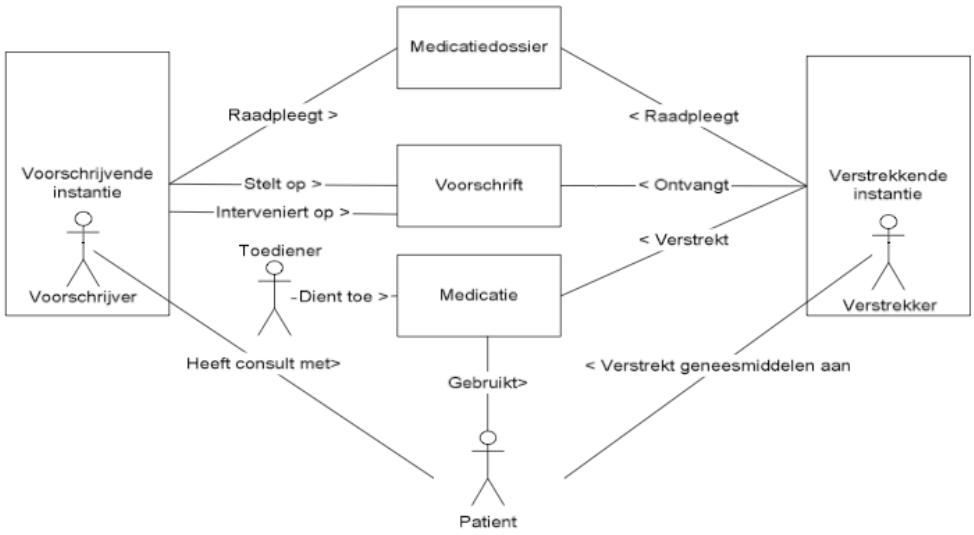


figure 8. Example of UML business entities in version 1.0 of the EMR design

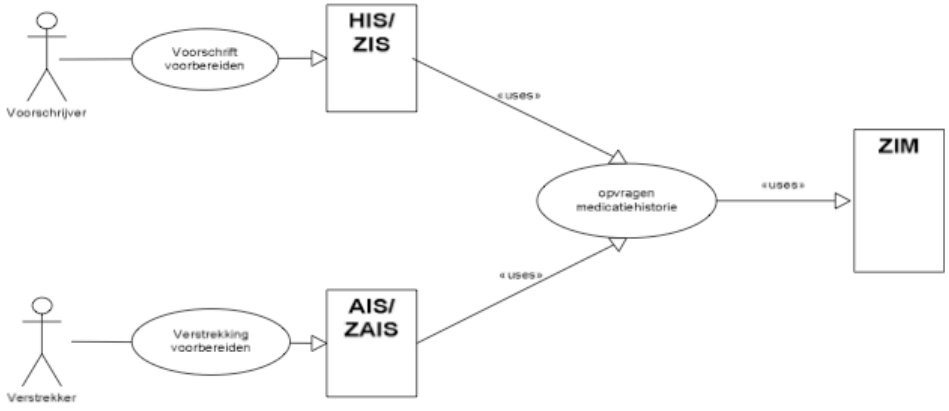


figure 9. Example of UML use case diagram for the description of scenario's in EMR v1.0

Version 6.0.0.0
This version of the EMR design exactly follows the default document structure that was presented earlier. The changes on form that were made from version 1.0 to 6.0.1.0 of the ELR design have also been applied in the EMR situation.

In the information systems a model that wasn't seen in the previous version or in the ELR designs has been added. It concerns a detailed overview of information objects, see figure 10.

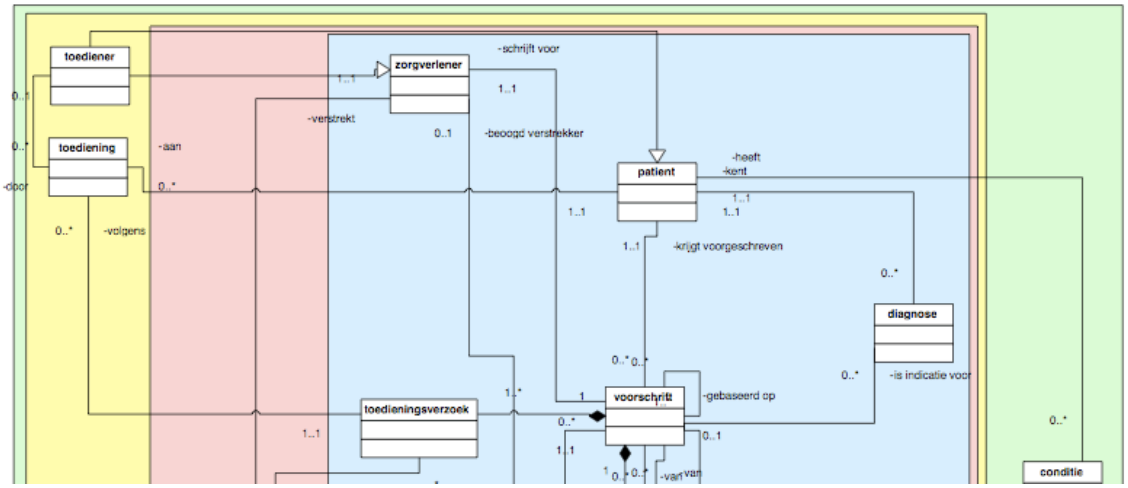


figure 10. Example of (a part of) a detailed information model in EMR design version 6.0.0.0

It is remarkable that the UML sequence and use case diagrams which in the ELR design could be found in the information systems view, have found a place in the technology description of the EMR documentation. The EMR technology view lacks any tables that were present in the technology view of the ELR design.

Concept version 6.1.0.0
There haven't been any changes in format compared to the latest publication of version 6.0.0.0.

Appendix B: Content Analysis

The content of the Electronic Locum Record design

The Electronic Locum Record is not a very complicated application. It supports the situation in which a general practitioner requires information on the medical situation of a patient that is not 'his own'. Every general practitioner tracks a so-called *professional summary* of each of his or her patients. This summary is available to authorized healthcare professionals who are in need of this information.

This section describes how this situation was documented in the first and the latest version of the ELR design. As mentioned earlier the emphasis in this analysis is on the business (processes). The information systems view will be considered if needed. Concerning the content of the ELR there is less interest in the technology view.

Version 1.0
Despite the mentioning that locum services during evening, night and weekend duties can be delivered between individual GP's, the choice is made to focus on locum services as performed in a central facility called a HAP. In the business view the processes are marked to be the most important, but to be able to describe them well the related actors and entities are first illustrated.

There are only a few actors in this process. There is a **Locum** available for duty and a **General Practitioner (GP)** who's tasks are being conveyed to the Locum. Finally, the **Patient** is mentioned and related to the GP as his or her regular GP. The Patient has a relation with the Locum in case of a severe situation outside the regular GP's availability. It is explicitly mentioned that some actors have not been included, like a Triage Nurse or GP assistant.

Next, entities are described and related to the defined actors. A **Medical Record** is managed by the (regular) GP and contains the medical information of a Patient. A **HAP** is a **Care Deliverer,** as is a **GP Facility.** The Locum works at the HAP and the GP works at the GP Facility. A Locum requests **Relevant Medical Information** from the regular GP. Finally, the Locum informs the regular GP about the actions taken through delivering a **Locum Report**. A graphical representation was presented during the form analysis in figure 2.

In describing the entities, the process has actually also already been described. The Locum requires Relevant Medical Information to make a valid judgement. This information is gathered from the Patient and from the regular GP. The other process step is the informing of the regular GP about the judgement and the related actions taken.

In the information systems view of version 1.0 scenarios are described how the information systems (which implement the support for the above process) communicate with each other and in relation with the infrastructure AORTA. A third scenario has been added to describe the transfer of the responsibility on patient information. Next, the entities described in the business view have been 'translated' to information objects, so they can be used in the information

systems. The **Professional Summary** is the information object equivalent of Relevant Medical Information. A **Locum Respond Message** is the equivalent of the Locum Report.

The technology view first details about the various aspects of the AORTA infrastructure. Next it describes the interactions between the information systems. These are based on HL7 interactions. These details are irrelevant in this analysis.

Version 6.0.1.0
With a 26 page increase the newest version of the ELR design has also increased in content. The scope of the application hasn't changed. It has only been made explicit that other forms of locum services (during holidays or sickness) are (still) not considered. The complete transmission of a medical record to the (new) regular GP is also not yet included.

In the business view the actors involved in the locum process are again illustrated. This time the Locum has not been mentioned explicitly. Both the regular GP and the locum GP are categorized under the same actor **General Practitioner.** New since the previous version are the explicit mentioning of a **Doctor's Assistant, Triage Nurse** and **Nurse.** Descriptions on all actors have grown. For the GP the distinction between regular and locum is explained, as well as various possible combinations of work relationships. The Doctor's Assistant may assists in both administrational and peri- and paramedical tasks (depending on education). The Triage Nurse prioritizes (severe) situations by either settling with personal advice or by referring to the locum GP. Finally, a Nurse is someone with qualified eduction to deliver basic care.

Unlike the initial design, the business processes are not anymore described in terms of actors. Rather, business processes are illustrated in a flow of the following business activities:

- Consult HAP
- Triage
- Visit HAP
- Question patient's medical history
- Request patient's medical history
- Examine patient
- Diagnose
- Prepare treatment
- Start treatment
- Refer patient
- Prescribe medication
- Prepare locum report
- Approve locum report
- Send locum report
- Process locum report

figure 11. Overview of locum activities

These activities have been grouped in five categories, indicated as business roles. Besides the **Patient** role, the following roles have been declared: **Summary Receiver**, **Summary Sender**,

Locum Report Sender, and **Locum Report Receiver**. These roles are not yet described until the end of the business view. The link between the roles, actors and activities is made at the end too. In the form analysis this new business process overview was illustrated in figure 5.

In this new version the business entities have been replaced with business objects. Although there is a small overlap, the intention of the business objects is to represent 'information units' relevant in the context of locum activities. Objects like **Relevant Medical Information** and **Locum Report** could also be found in the previous design. New are **Reference Letter**, '**Life record**' (the complete patient record containing medical, financial, logistical and personal information) and **Prescription.**

At the end of the business view the relation between business roles and business objects are portrayed. These relations are pretty straightforward and link the Locum Receiver and Locum Sender to the Locum Report. The Summary Receiver and Summary Sender in turn are connected to the Relevant Medical Information object. At last the Summary Sender is related to the 'Life Record' as its manager.

In the information systems view it is explained during what business activities certain business objects are created or used. Next, it contains information objects, similar as in the previous design, which relate to the business objects. These information objects are said to be suitable for 'automatic processing or exchange'.

Use cases (globally) describe the way the Health Information Systems contain the functionality to support the business activities. Unfortunately these illustrations are pretty unclear, however this is just an observation not specifically relevant for this analysis.

Newly added to the information systems view is a list of authorizations. What actor may take on what role and through what method.

The technology view is (again) ignored. It still contains details on HL7 interactions, but these also are irrelevant for this analysis.

Observations on the ELR content
With the update of the ELR documentation in the beginning of 2009, the design has become more complete in terms of content and consistency. The introduction of business roles relates to the way of thinking found in the DEMO methodology. It allows for an abstraction that makes reusability both in designing as well as in implementation possible. In line with the ideas of DEMO, business objects have also been improved. In the initial version the choice of entities perceived to be random. At least in the newest design a clear choice has been made what (not) to include as a business object.

Still, to consider the design to be perfect would be exaggerating. Some choices are questionable or could probably be improved. At least, a first impression is that a redesign (of the business view) with the DEMO methodology will provide different results.

For one it has become clear from [18], [16] and [17] that the care applications designs primarily should capture and describe where information is being exchanged. With the extension of the business processes in the new design, the transactions between actor (roles) have been neglected. In the initial design these were available, albeit little. DEMO has an excellent model for the representation of transactions (the question whether these would be ontological or infological deserves yet an answer).

Next, the doubling of actors is perhaps not necessary. Thinking in 'organizational functions' makes the process more complex, jeopardizing the reusability of the design and models as a result. Combining the approach of the initial version where transactions were considered, together with the current approach of thinking in business roles will probably lead to the best possible business model.

Scrapping unnecessary content in the business view adds to complexity reduction and thus readability. The business activities shown seem not always on the same level of importance and that raises the question why are *these* the business activities? Should some be excluded or could other activities rightfully be included? Revisiting these business activities will likely result in a well-founded business process.

The content of the Electronic Medication Record design

In contrast to the ELR application, the EMR is more complex due to the involvement of a variety of stakeholders. The program was initiated to exchange information on the medication a patient is or has been using. In updates of the program, support for electronic prescribing and monitoring of the medication for contra-indications was added.

Version 1.0
The initial design of the EMR focuses on the delivery of medicines in combination with a so-called *medication profile* of a patient. Because prescription is inseparable of delivering medicines, the process of prescribing is also considered.

Four actors are considered and in contrast to the ELR design these are actual actor *roles*. A **Patient** is identified, there is a **Supplier** of medicines and a **Prescriber** of medicines. Finally an **Administer** has been declared who might dose the medicines to the Patient. It is explicitly mentioned that some actors are not shown because these assistants and nurses are simply mandated by one of the 'leading actors' to fulfill a specific task or role. Also, there are certain healthcare professionals, e.g. physiotherapists or psychologists, who are not allowed to prescribe, but *do* need the information on the current medication of a patient. Because the guidelines regarding their authorization are not clear yet, they are left out of the scope of this version of the EMR design.

Next, the entities that are relevant in the environment of medication prescribing and delivery are illustrated. There is a **Medical Record** which can be viewed by both the Supplier and the Prescriber. There is a **Prescription** entity which leads to **Medication**. The four actors have also been incorporated. The actor Prescriber has become the entity **Prescribing Instance** and equally the actor Supplier has been baptized to **Supply Instance**. An illustration of these entities was used in the form analysis and can be found in figure 8. In the descriptions of the entities it is often mentioned that the entities might be different or have different names (in real life) depending on primary or secondary care.

As was the case in the initial version of the ELR design, the describing of the entities and their relations with the defined actors reveals a lot of the process. Still, the process is described separately, this time without any graphical support. The process is described from the patient posing his problem to the prescription of medicines. Because the differences between ambulant and clinical processes are minimal no distinction has been made in describing this process,

unless necessary. Specific process steps are detailed further on in the process description. The activities being recognized are listed in figure 12.

In the information systems view the various systems involved are highlighted. Also, the entities that were described in the business view are 'translated' to information objects useable for automated processing. To give an interesting example, a Prescription from the business view which can contain requests for multiple medicines is in the information systems view divided into Prescription Messages for each medicine. The information systems view is concluded with use cases which focus on the information systems being used.

Similar to the ELR situation, the technology view is of less interest for this analysis.

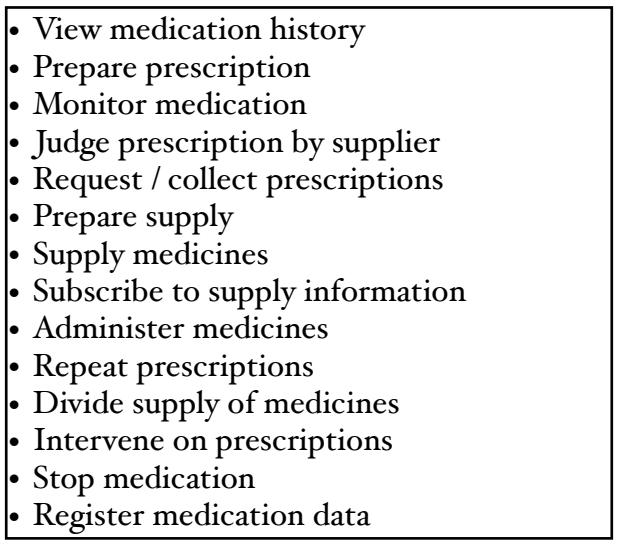


figure 12. Overview of prescription activities

Version 6.0.0.0
With an increase of only five pages and the addition of a few chapters it might seem like the design has shrunken on its previous contents. It turns out that more use has been made of illustrations.

From the start of the business view in the new design it becomes clear that some changes have been made since the previous version. Actors are not anymore described as actor roles, but rather as 'organizational functions'. Also, this time the distinction between ambulant and clinical setting is explicitly made. In clinical care a patient is hospitalized. The reason for making this distinction is because there is more emphasis on the responsibility for the managing and administering of medication. [17] explains that these business processes better reflect who cooperates with who and what systems are in use and how they are used.

Two main actors are presented, the **Care Professional** and **Care Providers**. Care Professionals are the individual actors like General Practitioner, Hospital Pharmacist or Nurse. Care Providers

are the instances where a Care Professional works, like a GP facility, Hospital or Hospital Pharmacy.

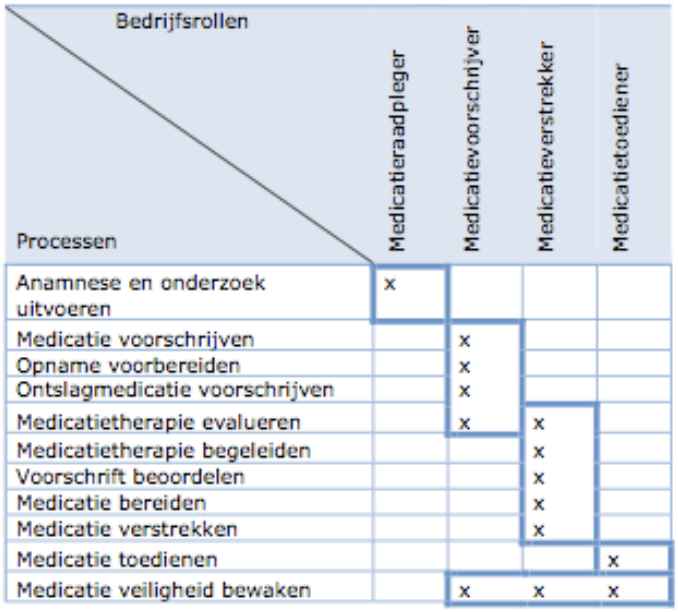
Next the business processes are described, both for ambulant and clinical care. The approach differs from the ELR design. First, there is made use of *swimming lanes* to illustrate the order of actors involved. Next, the activities are assigned to actors rather than actor roles. Between the ambulant and clinical process dissimilarities can be found too. For example, in both situation a Medical Specialist is involved. However, the Medical Specialist in the ambulant (poly-clinical) setting performs more *business* (like examination etc.) then its colleague in the clinical setting. In the clinical setting some process steps are extended, to portray more responsibility. An example of this is the activity **Medication therapy guidance and intervention.** This is more or less the equivalent of the ambulant activity **Judge prescription**.

Compared to the initial design, the business activities have been revisited. For example, **view medication history** is not available anymore in the current design, although this was said to be the main focus of the care application design. In the next paragraph this observation will further be elaborated on. Also, new activities have been added like **Evaluate Medication Therapy**. A complete enumeration of the process steps in the new design are listed in figure 13.

- Question and examine patient
- Perform additional examination
- Prepare treatment
- Execute Treatment
- Diagnose
- Prepare medication
- Administer medication
- Monitor medication
- Supply medication
- Prescribe medication
- Evaluate mediation therapy
- Prescribe resignation medication
- Prepare intake
- Refer
- Judge prescription
- Medication therapy guidance and intervention

figure 13. Overview of prescription activities in version 6.0.0.0

Like the current ELR design ended the business view with an overview of business objects, so does the EMR business view conclude. Compared to the initial business entities this overview is extended to include for example **Care Question**, **Diagnoses**, **Patient**, **Suppliance**, **Dose**, **Condition**. After presenting the overview of objects it is explained how these objects are related to the business processes. This is done in ICT terms like *create, read* and *update*. Depending on the similarities how certain actors are related to the objects, roles are defined.



Bedrijfsrollen / Processen	Medicatieraadpleger	Medicatievoorschrijver	Medicatieverstrekker	Medicatietoediener
Anamnese en onderzoek uitvoeren	x			
Medicatie voorschrijven		x		
Opname voorbereiden		x		
Ontslagmedicatie voorschrijven		x		
Medicatietherapie evalueren		x	x	
Medicatietherapie begeleiden			x	
Voorschrift beoordelen			x	
Medicatie bereiden			x	
Medicatie verstrekken			x	
Medicatie toedienen				x
Medicatie veiligheid bewaken		x	x	x

figure 14. Relations between business roles and business activities

These are the same as the roles that were found in version 1.0 of the EMR design; **Medication Prescriber, Medication Supplier, Medication Administer** and **Medication Viewer**. Finally, these roles are also connected to the business process. See figure 14 for an overview.

In the information systems view four systems are defined for the support of the business just described. These four systems are related to the four roles that were declared at the end of the business view. Use cases describe the functional requirements of the systems. It is out of the scope of this analysis to thoroughly visit the content of the information systems view. The last thing to mention is the information model that is presented. It is an extension of the business objects illustration and contains more details about the relations between objects. For example a Prescription has zero or more Administer Requests or a Prescription is for exactly one Generic Product. The illustration can be found at figure 10.

The technology view is neglected.

Version 6.1.0.0j
In this concept version the business processes have again had a revision. For example, **View medication history** has returned, yet not as a worthy process step but as part of the activity **Question and Examine Patient.** Next, some actors have been merged like General Practitioner and Medical Specialist. New actors were also added, like **Other Relevant Care Professional**. These changes were made to both the ambulant as well as the clinical setting.

An addition has also been made concerning the business objects, there **Medication History** (for now) completes the list. These changes have not lead to the declaration of new business roles.

Observations on the EMR content

At first glance the newest version of the EMR document seems to follow the same template as the ELR design. However, the content of the illustrations differ in some ways. For example, the business processes are illustrated in relation with 'organizational functions'. As a result the illustration has a low reusability factor and in fact it causes the explicit distinction between the ambulant and clinical process.

Similar as in the ELR design some business activities are questionable. Why is the current list of business activities the correct list? The list doesn't follow a structured pattern. The *kind* of activities differ and contain ontological, infological and also datalogical actions.

Appendix C: Use Analysis

The primary goal of the application designs is to capture and describe where information exchange takes place between healthcare professionals [18] [16]. But who is interested in this information? The introductions of the care application designs denominate care professionals, care management, software developers, umbrella organizations in healthcare and Nictiz (management, architects and HL7 modelers) as target groups, see figure 15. According to [18] the care professionals are not personally interested in the designs. Only umbrella organizations will (should) take the time to acknowledge the chosen path. As such, three main stakeholders can be distinguished; namely Nictiz, umbrella organizations in healthcare and last but not least the software developers. In the next few paragraphs the use of the application designs will be portrayed.

Stakeholder	Intended Use	Actual Use
care professional	acknowledge business view	not used
care management	understand business view	not used
umbrella organizations	acknowledge business view	understanding
software developer	understand and use the design to develop software	sometimes used to answer questions / explain choices to customers
Nictiz	reuse of designs, developing building blocks AORTA,	answer questions (mostly)

figure 15. Overview of application design stakeholders. There are three main stakeholders: umbrella organizations (green), software developers (red) and Nictiz (blue).

Nictiz

Recently a survey has been held regarding the internal use of the AORTA documentation [38]; the documentation of which the care applications are part. Nictiz is thought to be the most extensive user of all current stakeholders [2]. However, the survey concludes that even within Nictiz the care applications designs are used relatively little. The cluster Design & Maintenance (O&O) outruns the other clusters in using the documentation. The clusters mostly use the designs of the applications that are relevant in their activities. That means that Knowledge & Advice is most interested in the designs of the newest applications whereas Operations especially uses the designs of the applications that are currently being implemented and launched. Both these clusters use the documentation primarily to be able to answer questions.

For Design & Maintenance the designs are also useful to estimate the impact of changes. The designs help in internal communication about the care applications.

The survey shows that Nictiz employees think the documentation does not serve the stakeholders enough as it should / could. The suggestion offered is to better tune the content and form of the documentation for each target group. Also, the documentation should be 'rationalized'. Duplicated or unused information should be cleared from the designs, the different views should only show the content of the corresponding conceptual level, e.g. no technical details in the business view. Clear terminology is also a must.

It seems these results match the conclusions made so far in this analysis. The following quote from the survey strengthens this: 'The structure of the documentation is largely standardized, however designers may make different choices regarding the completion of content.' Applying the DEMO approach will help in performing this 'rationalization' process.

Umbrella organizations

The umbrella organizations in the healthcare sector don't actively use the care application designs [18] [3]. However, during the development of the designs they do provide their feedback; after all the professionals they represent will become the future users of the care applications. [3] explains the umbrella organizations (NHG in this case) only 'use' the designs to understand what Nictiz is up to. In the case of the ELR design some interesting and relevant roles were 'borrowed' from the designs to be used in the HIS Referential Model.

The representatives of the healthcare professionals are the ones who are able to acknowledge the correctness of the business view. It is therefore found strange that some business information is filled in at the information systems level. The business view should contain all the right and complete information to reassure the healthcare professional (representative) that information systems will correctly support the business. 'Now I have to review the entire document to make sure and find out that important details have been taken into consideration' [3].

Having to rely on umbrella organizations for the judgement of the (business) views does not necessarily make the views entirely correct. Those representatives are only a small group representing the larger professional population. It is not unlikely that these umbrella organizations review at their interest, which might not correspond with the view of other care professionals [16]. The implementation of care processes might be very different in different areas of the country [39]. For example, locum services at the *Wadden* islands are implemented differently than on mainland. And care processes in Amsterdam - with lots of 'voluntary' medicine students - also differ from care processes in the *Achterhoek*. Because the implementation of care processes differs and it is thus tricky to rely on the processes as known by the representatives, the business view should be described independent of any implementation. This is exactly the aim of Enterprise Ontology.

Formalizing the designs might have consequences for the untrained to read these documents. Still [3] is assured a formal design would be necessary to capture a complete and true (business) design. A readable (simplified) business view would be a good addition for 'dummies'.

Software developers

The last of the main stakeholders are the software developers of health information systems. The care application designs provide the context, the information to be exchanged and the basis of the message structure. During the *Leveranciers Tweedaagse* (18-06-2009) it became clear that the application designs are not much used. Only a very small percentage of the developers

used the top-down approach, that means first reading the design documentation to get an overview of the applications environment and choices before going into the details of implementing. This is actually considered the intention of the application designs for these developers! Instead, the developers often base their implementation on example messages. There might be a few reasons why the documentation is used this little. For one, the developers can't seem to find what they are looking for. The documents being too large might be the cause. Some find the illustrations nugatory which still requires them to read the complete descriptions. Others complain about the relation with other (care application) designs which would not be evident.

Software developers have used the application designs to answer and discuss questions of their software users. Also, when message structures are not completely clear, the designs provide guidance to trace their emergence.

Using a formal language like DEMO to describe where information is being exchanged should crop the size of the documentation. This makes it easier to start reading. The conceptualization being used is not likely to cause difficulties, as software developers are used to think in formal ways. Understanding the semantics of the models will not take them long. Actually developing these models would be another story, but this is not a concern for the software developers.

Appendix D: Interviews

Interview Manon Kuilboer

2009-05-19 9:00 - 10:00

Manon Kuilboer is a medical scientist (informatics) and General Practitioner. Within the Nictiz organization she is entitled *Product Manager "Huisartswaarneemgegevens"*. As such she manages the e-Health application *Electronic Locum Record*, specifically at the area of the application's global design ('architecture'). The flow of information or Information System layer suits her better than the Business layer.

Role of documentation (architecture)

- to record and communicate standards
- standardization of messages and technique (partly)
- necessary for exchange of information and security

Communication healthcare receivers / senders (patient / professionals)

- misinterpretations, mainly because of lack of (good) information
- link between patient/professionals and architecture seems 'optimistic', probably not feasible

What Nictiz does

- Nictiz standardizes messages which are required for the (safe) communication of information. To deliver information in those situation that this information might be valuable.
- Is a knowledge institute in cooperation with profession groups and other stakeholders
- nothing more, nothing less

What does this mean in Locum situation?

- the Locum GP (GP post) requests patient information when necessary, diagnoses situation and reports to regular GP.
- Future: Single Locum GP to other GP (during holidays etc.)
- Future: Regular GP to provide feedback to Single Locum GP (to 'learn')
- Future: move patient (data) to another location/GP (source)

How was this architecture developed?

- architecture developed in cooperation with NHG (*and other stakeholders?)*. Around 5-6 years ago
- Manon sinds last year active on ELR
- Currently in the stage of 'further developing'
- Changes in documentation / architecture through experience and feedback of the software developers 'deliverers'
- not direct development, but in phases

Have there been many changes in the architectures? And are there previous versions of the documentation available?
- Content wise there hasn't been changed much.
- Selection of required information is determined by 'profession group'
- There is only one big 'process item': the allowed possibility to perform an 'episode'
- contact with GP takes place, diagnoses, 'episode',
- that has been redefined new in messages,
- inclusion of 'episode' has been made a requirement since a year and a half

There has been a switch in Locum process: from locum activities between GPs to a central GP-post where this takes place. Did this have an effect on the (business) architecture? Shift on responsibilities?
- the development of the ELR was (coincidentally) in parallel with the shift to Locum activities at a central GP post.
- it is the old-fashioned way that 'payed the price'. This is for example the case during holidays.
- The holiday case will be added to the architecture in the near future.
- in future expansion as a result of new information needs, change of responsibilities not likely.
- the availability of information [by an actor] might mean a shift in responsibilities.
- Tilburg University report on liabilities/responsibilities concerning EHR.

A Business Architecture has explicitly been designed. How is this important? How is it used?
- based on BA it should (logically) be clear what the messages should look like, what are the 'rules of the game'?
- consists of use cases, some specifications, data types, message types
- sometimes specific requirements on reporting / receiving / processing.
- only functional level, no 'interface?'
- should be understandable by the deliverers (software developers)

What went wrong in the ELR pilot in Twente?
- it was not wrong per se, many things learned
- lot of unknown business: authentication, encryption etc.
- green field, no past experiences
- to test all of these in one pilot results in much feedback on technique, contents and usability.
- for example, the usability of the UZI pass was subpar. Long waiting times, frustration

Feedback lead to improvement, but still question remains: do we have the information we need?
- this is a serious question. it works, but is what we do enough?
- will the information flow be as desired?
- 'as of today' the patient should also be able to see his medical information. **This is not a new request**,

Other examples
- media deliver news on GP declining their own medical data (as a patient) to be available through the ELR
- this was to expect: there is a lot of confusing and misinformation about what the situation comes down to
- e.g. they think the EHR is a centrally stored database, they think insurers have access, they think everybody can change their information.
- political story. LHV provided incorrect information to GP's and patients

For each of the stakeholders, Nictiz tries to be a 'catalyst' and tries to align all of them.
- With all these stakeholders we try to create something rather complex
- Minister wants to see some results, he begins to push. Patient should be able to view information.
- This is not recommended. Health professionals are not ready yet. They don't even have to confidence themselves (because of incorrect information).
- Patient has information need too, but currently available information is not of the desired format.
- this leaves more frustration and unclear information, than clarification.

In what way is the Nictiz pillar 'Knowledge and Advice' active with ELR?
- not anymore (or at least should not be)
- k&a long term research, what are important developments?
- if interesting, then pre-research, plan etc.
- as soon as this is finished, product manager will be available (O&O)
- ELR currently not k&a, is more 'operations'

What other colleagues might be of importance for the research?
- project scope not totally clear, only then suitable advice can be given
- But, just for ELR:
- Hedde van de Lucht, leadarchitect e-Health applications
- Tom de Jong, hl7, not at first, but maybe later of interest, is good at explaining at different abstraction levels
- Jacqueline neijenhuis: responsibilities, authorisation, able to provide well written stories on e-Health applications
- Anton Ekker, jurisdiction, not yet though
- Marcel Settels

What about contact with other stakeholders, pilots?
- VWS is responsible for pilots
- Nictiz does guide the pilots though (operations)
- Ron van Holland, internal reseach on how architecture documents are used
- In june this will be checked with the software developers (face to face)

Interview Jacqueline Neijenhuis (Responsibilities)

Wednesday, June 3 2009 17:15 - 17:45

Jacqueline Neijenhuis has been assigned the function 'secretary authorization'. She knows all on authorization and responsibilities of the stakeholders of the EHR. From healthcare professionals, to government / ministry etc.

It is said there are interesting and 'simple' story lines regarding authorization and responsibilities?

- I've got some paragraphs and some books which might be interesting
- it's only 'part of the truth', the EPD concerns more than just the primary care (processes)

How steady are the responsibilities or do they change often?

- not much change
- in theory there are discussion if it should
- regarding 'super nurses' there is a shift to what is allowed
- tasks do shift (target: cost reduction)
- because of better technology (diagnostic research, care strategy) more care is handled directly at primary care, where it used to be second care (long waiting periods)
- other hand, e.g. obstetricians refer pregnant women more often to gynaecology for top clinical care (so from primary to second)
- doctor keeps his responsibilities, nurse is 'extra arm' and is under responsibility of the doctor
- there might be few exceptions that would take some extra investigation, but for 99% this is the situation
- patient has therapeutic relation with his regular GP. A student GP has this relationship when he meets a patient, but after consult the relation is again with his regular GP.

How is this knowledge available to the architects of Nictiz?

- they know the main story
- sometimes questions from professionals / helpdesk, special situations always, then specialists will be sought.
- they know there is a necessary therapeutic relationship with a regular GP, there are codes of ethics (privacy), patient should give permission for sharing of information etc.
- they shouldn't know anything more, because Nictiz has lawyers for the details

It is important that business processes (and their responsibilities) are known, because the ICT applications are just a support of the care processes and should thus be in line with them.

- every doctor and nurse (and specifically the combination) are different and therefore the (work) relationship is different in every situation.
- this marks the limits of ICT, because ICT is discrete (0 or 1), it can't be fuzzy, which can be the case in real life

Are there situations (specifically in the EMR or ELR) where responsibilities are questionable?

- perhaps not so much in responsibilities
- discussions between regulatory framework on one hand and the concept of the EHR on the other hand in relation with practical use
- yes, there is always a relationship with regular GP, that's regulations
- technical implementation provides a check on this relationship

- in practice, assistant/HAIO/etc. requires patient information / lookup etc. but not implemented
- delegation is in practice a spoken agreement, but with EHR mandating requires strict procedures (beforehand)
- there is no perfect solution in EHR

Could this have been prevented / considered by the architects (earlier?)
- no, architects should design based on the regulatory framework
- there has been a lot of experience gained from other sectors like social affairs, education or developers of healthcare applications.
- never introduced such a large system which should be usable nationwide
- large differences between for example Limburg and Amsterdam
- the process implementation on the islands very different, they are used to work with palmtop and ICT, due to practical reasons (infrastructure)
- difference between regions, cooperation between primary and second care etc.? Not much attention being paid here at Nictiz
- all these institutions have different information needs.
- In Amsterdam healthcare professionals have a lot of contact with students (2 universities, 2 HBO, lot of research being done). Compared to Drenthe where there is no healthcare education near. This leads to a very different implementation of primary and second care (less volunteers etc.)

What is the situation with the triagist in HAP?
- triagist is often a nurse or assistant, establishment of situation, how should be handled?
- responsibility under responsibility of the 'medical manager' of the HAP
- this manager is often not a GP, however, a patient should always have a therapeutic relationship with his/her GP.
- this results in a customized EHR situation
- GP's are not too happy, they feel they get more responsibility with
- triagist can requests patient information only when patient and doctor is known. But often, doctor is not known (maybe no GP will be necessary). Then what GP should be 'set' as the responsible GP?
- sometimes just 'randomly' a responsible GP will be chosen for all 'triages'.
- doctors opt for direct responsibility of the medical manager, which is again not always possible (not always GP)
- same situation in ePathology.
- this occurs in every situation where research is done beforehand by an actor who is not a GP.

Interview Michael Tan (Productmanager Medicatiegegevens)

Wednesday June 10, 2009 9:00 - 10:00

Audio: 20090610_Gesprek_Michael.caf [00:51:48]

Can you introduce yourself?

- Delft University, waterbouw
- work: ICT related, in the beginning logistics, not yet in Health
- @ fujitsu Health related
- 2001 @ nictiz, number 18, nictiz was small
- from the start related with medication records. hl7 experts cooperation
- therefore became manager of the programme medication records
- describe programme, EMD+, large complex programme
- later GGZ (failed),
- penelatogy (2003), starting programme
- pathology productmanager
- busy man :)
- EMD: electronic prescription, testing/pilots. When prescription, then also mutations of these prescriptions (future)
- processes in architecture: philosophy AORTA is de-centrally stored data. Meant for 'consultation','retreiving data'
- opponent architecture XDS from IAG is different: centrally stored
- don't make standards, but make use of it (radiology)
- some Nictiz programmes, like eLab, compete with this system
- EMD+ -> send prescription -> push / pull situation. traditional.
- our view: prescription stays at HIS and any pharmacy is able to retrieve this prescription, so patient can choose his own pharmacy
- advantage push: medicines are already available when patient arrives
- both processes should probably exists (this has consequences for AORTA)

push/pull: this is more on information side, not on business process? [00:12:06]

- a lot of business possibilities are unknown in the health sector
- hospitals use fax to communicate with GPs etc.
- Nictiz has to think ahead and find a way that is workable for healthcare professionals
- also, political weight: patient becomes more and more an active actor.
- pharmacy wants to be regular pharmacy for patient, this is registered at GP
- pharmacy pay GP (software/connections etc.) to lead patients to their pharmacy
- nictiz tries to design from a neutral position.
- patient should control who is regular GP and should be able to edit information flow. he should be able to select his own preferred regular pharmacy
- start nictiz: share information between same healthcare professionals. later more interaction: GP wants to know from pharmacy: has patient collected his medicines? etc.

three versions of architecture: first, current, and concept. Process diagrams change. shouldn't be the case? correct conclusion? why? [00:21:13]

- at first, start with the minimum required

- standars publications, lot of stakeholders nationwide who also influence the (business) architecture
- description of when use to use standard. and what is exchanged?
- compared to HL7, there are only storyboards, swimminglanes and walkthrough
- later, consistency (other designs)
- in the end, most optimal situation is reusability of designs
- a defined process should be usable in another design/context
- process comparing, and relation with AORTA
- there are 2 groups within Nictiz, one works on infrastructure, other more focussed on care applications. As I work on care applications, I don't care about HOW that's going to be implemented
- the former group is interested in "detailed" architecture. how to create generic functionalities for all applications. in the latter group, responsibilities of implementation is with the software developers.
- software developers chooses filtering / sorting / combinations of information etc.

Nictiz creates standards, so standardization of architecture is also a requirement? [00:27:50]
- grey area, where do responsibilities of nictiz stop and those of IT developers begin?
- you want to comply with standards, then these are the requirements
- we can't check all these configurations/implementations
- CIBG uzi has had a lot of trouble because of they only recognized the simple situation where every professional has its own system. but for example in a hospital this is by far not the case.
- now token authentication

business architecture: ambulant and clinical process. Despite different implementation probably the same tasks? [00:31:00]
- reflection of who people cooperate and systems are in use
- document written for clinical processes, will send
- different implementations 'emergencies' or GP

but does this reflect in the way HL7 messages are developed? are these different in these different situations? [00:33:10]
- Hl7 could be viewed as a large box with tiles and one can choose to fill in each tile or not
- in clinical setting some is used and other not, and other way around etc.
- this is related with responsibilities
- in some situations applications are shared (hospital), this makes exchange of informations and thus hl7 messages unnecessary
- specialist barely ICT -> delegation. so temporary assignments, with different statuses, related to responsibilities.

business objects in architecture, and information objects in (information system) architecture. these information objects contain much more details. but shouldn't the business actors contains this information, as they can approve the correctness? [00:36:30]
- start with business architecture, graduation of details -> more at information systems level
- business architecture should be readable by professionals
- busy people, so let ict fill in the details
- not many professionals are interested in the ICT opportunities etc.

medication monitoring has been split from the EMR architecture, why? [00:39:30]
- from the start it has been a start of the EMR

- request for patient characteristics
- in this context of prescription (and how this is safe/possbile)
- this lead to a generic piece. for example, in Diabetes the same building block could again be used

the request for patient characteristics, is that modeled in a HL7 message? [00:40:50]
- yes, conditions from patient request messages.
- medication monitoring misleading name as it can also be used in other context
- but, with medication monitoring and other situations there is again the topic of authorization.
- two ways: one describes one can only requests, and therefore i need to know this and that... other side: requester can not define what he wants to know, but source decides
- request for conditions: request is general, but not all information will be presented and thus
- in the context of medication monitoring, only the important information will be filtered (table 40)
- in other context, like diabetes, other filter can be used
- BUT, the messages are equal!

what about future of mutations? [00:44:30]
- can prescribe
- but, in process one should be able to intervene
- be able to stop, to change,
- why? wrong prescription... or specialist overwrites prescription of GP
- information gap in healthcare is between primary and secondary care
- prescription (push/pull)... same for mutation: active pushing to pharmacy (but limited)
- pull, to check the latest status of patient

other experienced architects in EMR?
- tom de jong, lots of experience and knowledge how field works.... but very busy
- alexander henke, view from customer

Interview Hedde van der Lugt (Lead Architect care applications)

Tuesday, June 9 2009 9:00 - 10:00

Hedde van der Lugt has been assigned the function Lead Architect Care Applications. As a lead architect he not only works on Nictiz' architectures, but he also manages and oversees the activities and designs of running projects. He is responsible for the policies etc. concerning design choices and patterns.

[explanation of graduation project / enterprise ontology]

- Hedde is familiar with DEMO
- He recognizes that DEMO models might be of value / provide valuable insight
- However, DEMO models hard to use in practice (in this environment)
- There are several care applications in development. EMD & WDH are almost finished. Others being worked on are: diabetes, Spoed, Lab
- This resulted in research whether or not to standardize the way to model message exchange
- a lot of tasks within the health sector seem related (e.g. request lab info, request ambulance)
- DEMO models seemed complex, not understandable for 'non ICT' (**problem 1**)
- documentation is being written to accomplish shared agreement between professionals, developers and Nictiz
- as a result, the concepts behind DEMO were used, generic model was developed (requests -> "order management")
- care applications designs "reverse engineering" to this higher level order management model
- good results, but in practice support from the profession groups is necessary to elevate these applications. As such Nictiz is required to go along with these groups/developers. Nictiz has chosen to do this in this way.
- The current processes in healthcare are thus followed, but this leaves gaps [in terms of transactions not being completed etc.]
- It is not Nictiz's responsibility to change the processes, but to support the current processes. Existing processes, existing systems. If not followed, the designs won't be used at all (**problem 2**)
- so, conclusion: **1)** models rather complex, and out of scope of implementation possibilities [with AORTA probably?] **2)** in practice there is not worked in this way.

Ok, problems, but I'll still continue my research :) So these processes, they are now delivered by the 'profession groups'?

- care applications are being developed/designed by following standardized processes / templates. in practice: every domain requires something specific for their situation
- organizations are different, professions groups are different. e.g. with Diabetes, there might be 10 different healthcare professionals, and thus 10 different profession groups, and 10 different information systems (XIS's).
- other situation than for example 'Lab', where there are GP's and laboratoria.
- pharmacies same situation, also far in ICT usage, different organization.
- sometimes by requirements analysis / process analysis findings on situations which are not allowed (by regulations). or difficult situations where it's not clear who's responsible, nobody wants to take responsibility.
- in practice this goes well however.... but mapping on a model is thus not straightforward/ possible.

- for example. what if somebody changes prescription: responsibility of prescriptor or of pharmacy (who delivers). nodoby takes responsibility.
- this results in 'scary' knowledge / insight. but Nictiz can't do anything about that (soon) (it is not their task / they don't want angry faces)

But it would be very useful to provide the healthcare professionals with this information?
- yes, this does happen
- nictiz doesn't deliver care, but stimulation of standardized message exchange.
- nictiz is not able to change the processes in care.
- care is often aware of the 'fuzzy' situations, but not in their advantage (at least that's how they see it) to change the situation
- but, this doesn't mean it can't be valuable to compare the designs with the 'ideal' situation (thus the DEMO models).
- be compatible with this model in the future
- transaction model for Lab request or medication exchange: messages being made standard ('accept' message?)
- hedde suggested to build these default messages like 'accept' or 'reject' in AORTA
- this allows better understanding / communication
- difficult, because for example for Lab it was chosen to work with the IHE standards. There are a lot of 'standards' possible.

Designing of new care applications, how is it initiated and is there overview on what's to come?
- paying and agenda by VWS
- research questions from other areas. e.g. JGZ was suggested by Dönner to be added to the EHR
- there are a few health domains where applications can make an important difference
- so, or assignment from healthcare sector or VWS OR Nictiz requests subsidies for development of own research (K&A)
- K&A make a plan how to develop a new applications, interviews with healthcare sector etc.
- what information requirements, what interactions?
- care application architectures should not be called 'architecture'. these documents are analyses.

we'd call it a design
- hedde agrees

it seems there is not much consistency between the care application documents, is this on purpose?
- yes, i think so
- care situations differ
- some actors only need medication prescription and others only need locum records app.
- not everybody needs an implementation of all these applications
- some will be required by law, but e.g. with Diabetes one can choose what to implement or not
- we describe 'roles' which each can implement when desired
- e.g. physiotherapist only takes on role of 'physiotherapist' (in e-diabetes)
- decoupled building blocks which have to cooperate
- sometimes similar 'functions' (e.g. lab or medication in Diabetes), but not fully implemented because 'Dietitian' is only to view medications necessary which are related or have influence on diabetes.
-

- there is a relation between the two, but can be implemented apart from each other

would it have potential to better align these applications on the business level (more consistency?) it seems for example that processes in ELR and EMR do overlap a lot
- that's not how i see it
- e.g. with ELR the communication is only between GP's
- EMR differs, more 'order management'.. other actors (pharmacies)
- i would understand the viewpoint to describe how a GP works
- from GP, lab request, medication requests, provide access to patient info etc.
- that's from a viewpoint of HIS. but our viewpoint is horizontal, thus per application with all actors (care domains)
- Nictiz isn't there to build a HIS, but to realize the exchange between XIS's
- there is no need for describing of GP processes (or other actor)
- we need to know where information exchange takes place between actors !

at the end of the business architectures, roles are established. From this abstract viewpoint there is no difference between a GP and for example a hospital.
- in a way that is true
- it would be interesting to make an abstract overview of the entire 'health sector'
- in health sector there would be only a few actors from abstract viewpoint
- GP should be taken separately (unique in what they do) - large domain, specialists, pharmacies, laboratoria
- the way healthcare sector is implemented and changes influences the processes and the way of information exchange (need also?)

there is more focus on the information architecture than on the business architecture, that's because information exchange is considered more important? [36:55]
- that correct
- national system, based on 'viewing', it is limited, but the best model to choose
- suboptimizing should not be stimulated, unfortunately it happens.. it makes things too complex

are there examples of miscommunication between stakeholders based on (business) architecture? [38:10]
- health sector is large, we communicate with 'profession groups'... but that's only one specific voice and its not certain everybody agrees with their opinion.
- there is a lot at stake for these stakeholders. GP's want to be THE source of a patient.
- if information exchange works, it should be possible to go to every GP who is available (opinion)
- pharmacy want to be THE pharmacy for that patient.
- not miscommunication per se, but it makes it difficult sometimes to communicate as there are different opinions
- Nictiz view is that a healthcare professional has their own XIS. But in some situations these XIS's are built into one large single KIS ('keten informatie systeem')
- these KIS deliverers don't want/need information exchange, as it jeopardizes their system, they lose their position
- how many kis's are needed then??
- the fact there is movement in sector implementation and the fact that there is a lot at stake for stakeholders, pharmacies getting less money etc. etc. .... all this together makes disagreement on business model

application 'patient access', what's the story? [44:30]
- this wasn't necessarily unexpected
- developments of Microsoft Health Fund, Google health, patient empowerment etc.
- discussion: who is owner of patient information?
- there is no law/regulation that describes this.
- government decided that patient should get access to his info
- the launch of the EHR is chained with the patient access of his information, this was not expected
- access to logistic information: who has had access to my information
- access to medical information is new! consequences -> these are not suitable for exchange to 'outsiders'
- technical consequences little -> no authentication. happens now with DigiD, but has always been thought to be ENIK (passport with chip).
- business statement to allow DigiD and later switch 'lacks power'

contact 'profession groups'? [50:10]
- contact at NHG (K&A)
- these groups currently don't do anything with the business architecture. But they should!
- Using DEMO models would not work, too complex. Use a powerpoint presentation to describe where information exchange takes place.
- split architectures and use "business architecture" as a contract and this where information exchange on 'high level'. they should be signed by healthcare professionals. should bridge the gap between ict and healthcare. be understandable by professionals!

Interview Tjeerd van Althuis (NHG)

Monday June 22, 2009 10:30 - 12:00

Introduction Tjeerd van Althuis

- GP, worked in Africa (e.g. namibia)
- been at NHG now for 12 years, GP automation
- in Namibia, implementing HIS (health information system). gathering EPD information
- NHG scientific community of general practitioners
- LHV is family member, deals with interests of GPs
- ICT is both. NHG's view is on how can ICT support GP in the best way
- but for implementation there is a need for money -> LHV
- within NHG two main streams; one is regarding (medical) guidelines and principles, support and implementation is the other (patient information, prevention etc.), education, and automation (ICT).
- ICT large capacity, primary regarding guidelines and principles. functional and content focus. e.g. HIS referential model, description of what HIS should be capable of.
- code tables: communication and therefore standardization. transfer medical records from one to another etc.
- despite custom work is required, the exchange of information between HIS's is working (due to the standardization: code tables)
- guidelines regarding the use of HIS
- guidelines regarding exchange of information to other disciplines (in cooperation with Nictiz)
- (digital) products that need to be incorporated with each HIS (consultwijzer e.g.)

How is NHG involved in the designing of the care applications

- with WDH the guidelines for exchange of information were provided by NHG, these were there even before the realization of the application
- 3 versions have been created, updated with requests from care professionals
- has lead to some ambiguity, not so much within Nictiz, but for software developers
- intensive cooperation with Nictiz in 'klankbordgroepen'
- with EMD not directly involved. later, in EMD+ there was involvement: advice... and sometimes participation
- code tables like EMD+ is a national list with contra-indications which are relevant to medication security. what icpc codes are relevant, and that maps to a G standard cic table

Design documents are divided in business, information systems and technology; is the business view the same as the guidelines that were provided by NHG?

- take for example eDiabetes, Nictiz makes choices how information is stored and who owns this information, who is allowed to view this info etc.
- WDH is very simple model, GP has the information. Only one GP at a time is the rightful owner. Leads to return message of requesting.
- puzzles come into existence when one wants to answer a question like: what happens in time when new information exists at HAP which are not yet processed by GP, or at HAP new information should be transferred back to GP because patient doesn't want that to happen.
- these are just rare details
- with EMD it is simpler, but with EMD plus caution: implicit assumptions health professionals how they have access or own data. Nictiz makes assumptions on data, here are many levels and nictiz considers data on the lowest level, e.g. blood pressure, lab reports, weights,

lengths..... how about data which are text based? how to provide / present the summary or conclusions of information?
- with EMD this works fine, medication has a high standardization. code tables etc. which are actually used by healthcare professionals.
- with wDH and EMD+ is more difficult. WDH has text, not codified. with EMD+ no explicit formulation on information management.
- this is also the case with eDiabetes
- with elab epathologie care professionals have been involved which do not have a direct relation / interaction with the patient.
- gp shall say, i requested the lab report, i get the results, so i own the lab report. Nictiz says the lab is the owner. But that means that the relation of the patient with the lab should be captured also, and this is not straightforward.

Does NHG have influence on such situations?
- no, these are decisions made by Nictiz
- at least that's my feeling
- this is more with AORTA, not so much the applictions.
- Nictiz desires the "medical care content" guidelines and changes them as they fit best in their designs.
- this results in more 'puzzles', also for 'koepels'
- some of these puzzles can be seen in advance, but in some situations Nictiz doesn't make any decisions because they also don't know what's best yet.
- this related with the focus on exchange of information
- Nictiz 'grabbelton', management of information, reliability of information etc?? Within Nictiz is sometimes feels the ICT people think very lightly/simple about what e.g. a diagnosis is.
- With writing of guidelines about HIS there is a struggle how to capture that. e.g. for a GP a diagnosis can be 'cough'. but implicitly this could be interpreted as 'blablabla'. often implicit in primary care.
- GP doesn't often also not know what it's going to be, because of time (early stage).
- differential diagnosis not often made by primary care, only within secondary care.
- most of the complaints lead to a diagnosis which is known what pattern will follow.

This means that what has been written down can be interpreted in another way by other professionals?
- yes
- medical specialists can't even communicate with each other
- gp jargon is good to communicate basic medical information, but there should be more communication languages, e.g. for communication between specialists

Should this be decided in care application designs (by Nictiz)?
- this is part of the issue 'consistency of languge'
- snomed, loinc? there is much to discover and much to learn on usage and interfaces.
- don't walk away to fast with terminology which is used in care, because the semantics are not clear for all different discipilines!
- it would also not be a good idea to capture everything in code tables/ standardizes codes etc, if there is no goal for it yet!
- it is useful to encode if being used for counting, security by computer... the rest: analog communication.
- european perspective, only look where it is useful and only translate capture this information that is possbile to share (correctly)

- to come back to WDH, i've asked Nictiz to explore with the care professionals, HL7 data model and document model.
- both would be useful. would help to explain to software developers /

What are the HL7 document and data model?
- in hl7 communication : data from a to B.
- with document model : aggregated data, the consistency between the data is imporant too. context of data.
- data semantic operability is essential. with document model only part semantic operable.
- hospital resignation letter.. combination of data which together form a 'story'. the elements (diagnosis, lab reports, medication etc.) should be processable.

is this possible to capture in an architecture?
- it would be
- what are the consequences of information exchange in the long run? how are copied data saved?
- does everyone understand this?
- in document model: can received data be use to transfer again in another message. how is this captured in the architecture? or not possbile at all?
- history of nictiz: we do focus on the XISs, only the communication, in the first 4 years. therefore AORTA, HL7. But what about XIS systems: resend info etc. ? process of received information?
- in the beginning: "raadplegen" is view with your eyes. It is shown on your computer. But this data is actually stored in your computer then, so what about it?
- receiver should be capable of reenter received information
- architecture: describe about information management.

More AORTA?
- also applications. e.g. emd: what can receiver do with received data?
- primitive systems. traditional....
- GP has in system for example: prescription.
- who makes these: the GP. now online with pharmacies etc, they send back a return message. XIS can't handle this
- resignation of hospital: letter with medicatino prescription.
- no difference between prescription made by GP or prescription made by hospital expert and entered into HIS by GP.
- lots of duplications.
- with EMD or WDH more and more exchange of information.
- dutch language: data exchange? what is it? what is meant?

That might be one of the reason that Nictiz wants to formalize the designs with models etc.

NHG is stakeholder. How are they used by Nictiz?

- not used, only to understand the concepts at Nictiz.
- not directly used. but where understandable and agrreed: use in HIS referential model. e.g. logging... roles....
- WDH rather simple. WRB: is influenced by NICTIZ and NHG together.
- HIS referential model is no system architecture -> it is functional description.

that is more towards the business / process view?
- with WDH not much of process is described.

- HIS RM: implicit. common knowledge.
- only recently there is change: change of HAP etc.
- how is the process in HAP or GP

is there a need for better documentation on these processes?
- I like it that for some domains nictiz wants to describe the processes.
- GGZ did it for themselves
- for some sytems it would be beneficial.
- well written processes with architecture for the 'keten zorg'
- for GP? HIS RM adequate for now.
- but is on agenda to look at new developments and processes.
- there still is a lot to learn and to look before a correct process can be described

the documents EMD + WDH are seperated, but in the process they are related to each other. should there be more consistency between the two?
- on a higher level that would be efficient
- a generic document which is developed to desribe (on higher level) guidance and direction.
- these should be developed with more cooperation with the healthcare professionals.
- we all seem to agree that the highest goal would be to exchange information on a national scale, but the steps Nictiz takes in some designs sometimes insufficient with the professionals

what i understood is that Nictiz wants to think about that, formalize their documents and take that as a point of departure for what's to come.
- it would be important to rethink some taken steps.
- not EMD or WDH per se (these are actually the less 'omstreden'), except the implementation, via AORTA
- in the Nictiz advice committee white paper discussion. technical view and relibility model there could refinements.
- it would not be the case to just formalize the designs which leads to acceptance of all stakeholders. in my opinion some solutions have been found in a wrong way

in theory there should be a point of departure from which to further design and develop?
- yes thats true.
- what makes it difficult is that everybody talks in their own language which leads to miscommunication.
- some talk about national communication 'conceptually' while the other in technical terms and that collides. if not on the same page then its very difficult to communicate

is this reflected in the current designs, have they lead to miscommunication?
- i have no idea how many have read the nictiz documents
- i read eDiabetes. 120 pages read, now 130, where are the changes??
- at NHG we do this, but software developers etc. how do they do that?
- the details at the end are often signifcant. so the entire document has to be read to get the overview. one cannot simply only read the business view to get the feeling that all will be well

should this be changed? should there be more details in the business view? at least this is the place where stakeholders (professionals) can acknowledge their correctness?
- yes that would be necessary.
- business view is too less.

- this leads to interepretations without any support
- sometimes you think it is written down correctly, but still doesn't understand. so, iterative process.
- also difficult: do you want to support the current processes or look in future which could perhaps work well in ten years. large difference.
- i think dynamics can only be set into motion when is started with the current situation
- WDH is good example. it is (for most of them) a wish of the GP's. it relates to what GPs desire.
- with EMD more problems. with every consult EMD should be viewed because of uncertaintiy that your own information is correct and complete.
- it should be more clear about ownership. for example. town pharmacy should have the status regarding medications at all time (same as GP carrying professional summary)
- and knows about medication and contra-indications. probably also for patient way better
- change of culture: GP is trust, nearest pharmacy a little less, but no way others will be trusted that easily
- don't build your system for those 5% YUPs who are always and everywhere all the time. that's what nictiz has build :)
- i think we have stand still for the past 6 years, that's why industry is taking own initiatives again.
- process: resignation out of hospital. with letter to pharmacy and to GP.
- 2000 gps connected to 'zorgdomein', quarter of all gps
- nictiz has nothing there.
- emd is A way to fill in the needs care professionals have, but certainly not THE way

with formalizing documents / designs there will be a choice about (directly) readable they become. the more formal the less natural.

- you should have both.
- with our own documents we have the same situation
- terminology which is the norm makes it difficult for people. GBZ to thick...
- who are stakeholders of the document? not professionals, they will certainly not read these documents.
- policymakers from 'koepels' who should 'do something' with these documents. regional policy makers... software developers
- developers go straightforward to technical view, don't udnerstand WHAT they're doing, which leads to mistakes!
- guidelines WDH was documented pretty straightforward - i think - sill nobody understood that corresepence and lab reports should be included into lcoum message. both gp's as well as software developers didn't understand that from the text
- trial and error, iterative process...
- people only talk about what they know (edifact: regional, nictiz: national)
- LHV has written report which mixes up everything
- KNMG to VWS.... not understandable.
- it is for those people difficult to write and speak 'zuiver' about such subjects, they are not used to it either
- Nictiz: how are connections with patient aplications / care applications (others)?? standardization!
- there is also a commercial side!

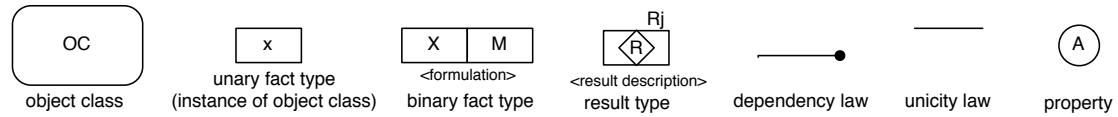
other contacts from other 'koepels'?

- michiel sprenger (nictiz) @ ziekenhuis information
- beatrijs willems (knmp)

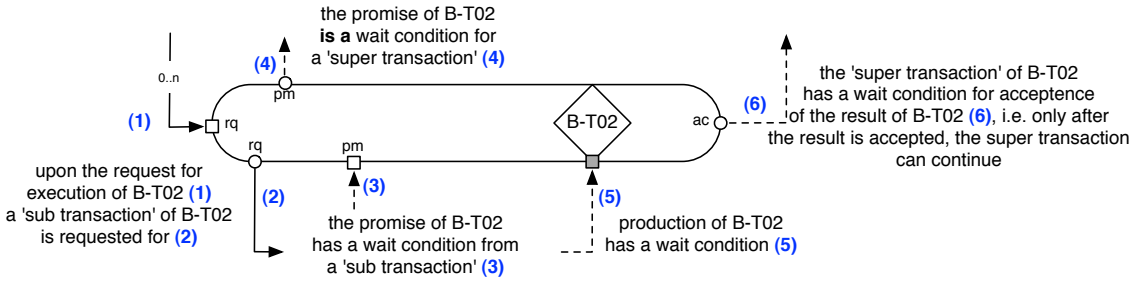
Appendix E: DEMO 3.0 Legend

CONSTRUCTION DIAGRAM

STATE SPACE DIAGRAM



PROCESS STRUCTURE DIAGRAM



COMPLETE LEGEND AVAILABLE AT WWW.DEMO.NL

Appendix F: Redesign Results

object class, fact type or result type	P-bank
CARE PROBLEM	PB01
[person] has a [care problem]	
[care problem] is established	
CLINICAL EXAM	PB02
[care act] is used for establishing [care problem]	
[clinical examination] is executed	
[patient] is available for [care act]	PB03
EXPERT OPINION	PB04
[expert opinion] regarding [care problem]	
[expert opinion] regarding [policy]	
[expert opinion] is provided	
policy options for [care problem] are established	PB05
POLICY	PB06
[policy] is a policy option for [care problem]	
[policy] is executed	
[care treatment] is executed	PB07
PATIENT MATERIAL	PB08
[patient material] comes from [patient]	
[patient material] is available for [care treatment]	
PERSON	CPB01
date_of_birth (*)	

Table F.1 *Bank Contents Table of the Generic Care Network*

T#	Transaction type	R#	Result Type (P-Fact)
B-T01	(Re)establish care problem	B-R01	[care problem] is established
B-T02	Execute clinical examination	B-R02	[clinical examination] is executed
B-T03	Availability of the patient	B-R03	[patient] is available for [care act]
B-T04	Provide expert opinion	B-R04	[expert opinion] is provided
B-T05	(Re)establish policy options	B-R05	policy options for [care problem] are established
B-T06	Execute policy	B-R06	[policy] is executed
B-T07a	Execute medicament treatment	B-R07a	[medicament treatment] is executed
B-T09	Dispense medicament	B-R09	[medicament] is dispensed
B-T10	Prepare medicament	B-R10	[medicament] is prepared
B-T11	Establish medication-safety	B-R11	medication-safety for [policy] is established
B-T12	Administer medicament	B-R12	[medicament] is administered

Table F.2 *Transaction Result Table of the Medication Care Network*

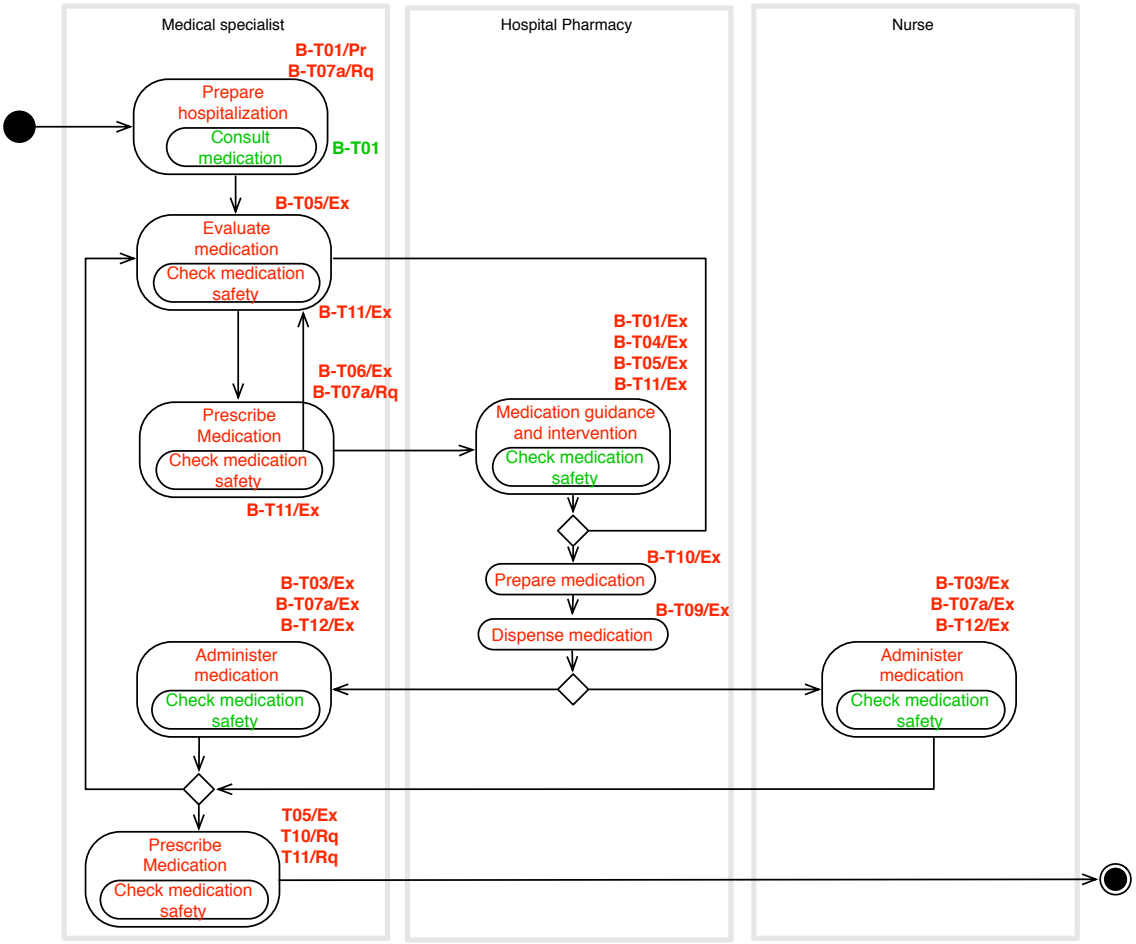


Fig. F.1 *Mapping EMR secondary care business activities to transactions of the MCN*

Appendix G: Transaction Pattern Diagram