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# Compliance Check of Health Care Process Models

Stephan Bögel

*Virtimo AG*, [boegel@virtimo.de](mailto:boegel@virtimo.de)

Hannes Schlieter

*University of Technology Dresden*, [Hannes.Schlieter@tu-dresden.de](mailto:Hannes.Schlieter@tu-dresden.de)

Werner Esswein

*University of Technology Dresden*, [werner.esswein@tu-dresden.de](mailto:werner.esswein@tu-dresden.de)

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# Compliance Check of Health Care Process Models

**Stephan Bögel**  
Virtimo AG  
boegel@virtimo.de

**Hannes Schlieter**  
TU Dresden  
Hannes.Schlieter@tu-dresden.de

**Werner Esswein**  
TU Dresden  
Werner.Esswein@tu-dresden.de

## ABSTRACT

Improving medical care quality and reducing care costs requires the interaction of patients, healthcare professionals and medical associations. Patients want to be informed about treatments, healthcare professionals demand easy access to best practice information and medical associations need to communicate evidence based guidelines. The configuration of medical care workflow systems and the compliance check of care processes according to national and international guidelines is the motivation for this paper. We are following a process model based approach for the management of health care networks. We present a method for the compliance check of process models and enable a configuration of information systems with process models. The application of the method as well as the discussion of the practical benefits is illustrated by a real world case study.

## Keywords

Conceptual Models, Vertical Integration, Conflict Management, Health Care Network, Service-Oriented Method, Care Process Compliance

## INTRODUCTION

A great challenge in the health care sector is to improve the medical care quality and at the same time reduce costs. Standardization becomes more and more important to face this situation. Clinical Practice Guidelines (CPGs) and Clinical Pathways (CPs) are two central concepts to specify evident medicine and disseminate it into clinical practice. We assume that both CPGs and CPs are best communicated and maintained using conceptual models.

An integration of CPGs and CPs is demanded in the literature but has not been completely realized (Wollersheim et al. 2005, pp.188-192). The proposed method is the linking element between those studies which demand a consideration of the CPGs (Leigemann and Ollenschläger 2006, pp.690-698; Schnabel et al. 2003, pp.1156-1166) and medical informatics approaches that are dealing with the implementation of CPs in the formal – machine-readable – syntax to a central assistance system like decision support systems (Seyfang and Miksch 2007; Peleg et al. 2003, pp.52-68).

The first result of an integration of CPGs and CPs is that clinical paths are compliant with the relevant guidelines. The second result of the integration is the support of a context sensitive help in CPs to navigate to the relevant parts in the CPGs. The output of the proposed method is an integration model that can also be used to support business process reengineering. Major challenge of the compliance check is the unraveling of integration conflicts. The essential objective of our research is the development of an integration method that explicitly uses the knowledge of the domain experts. We therefore follow the Design Science approach (March and Smith 1995, pp.251-266). In a case study we examine the situation of Stroke Network Saxony (SOS-NET).

In the second chapter, we present the case scenario. In the following chapter, the use of conceptual models in health care sector is theoretically discussed. We derive an organizational framework that helps to classify health care models and their relations. Subsequently, the integration conflicts in the health care domain are identified using a literature review. Afterwards we present the integration method “Vertical Model Integration (VeMol)”. The paper closes with a discussion of research implications and identifies opportunities for further research.

## CASE STUDY

In industrialized countries, the stroke is the third major cause of death and the most frequent reason of lasting physical handicaps (Kolominsky-Rabas et al. 2006). In acute stroke care, the capabilities of therapy worsen with each minute the stroke is not diagnosed and treated accordingly. An immediate medical intervention is necessary to avoid consequential damage.

This is especially important for radiological findings. Further characteristics for an acute stroke are short delay for decision-making, limited local transfer possibility and symptoms that are difficult diagnosed. In 2007, the SOS-NET was founded to build a telemedical infrastructure for regional stroke care. The goal of the network is to treat all stroke patients consistently and independently from distance to the next stroke expert over the whole region. Within two years the SOS-NET is growing to an important stroke care network in Saxony (Germany).

Presently, there are fourteen hospitals participating in the network. 580 telemedical consultations were carried out in 2009. The suspicion of stroke was confirmed in 79% of the telemedical presented patients. 89 lyses-therapies were indicated. If the indication can be done at early stage, this therapy allows an almost complete rehabilitation of special stroke cases.

The different suspension of employees and the differences of the technical infrastructure necessitate a defined responsibilities and process within the network. Therefore, the stroke center as the core of network allocates CPGs for the partners of the network (stroke units). They help to set standards for the cooperative work in the network and to guide the CPs development of the network members. Conceptual models are used to exchange knowledge (best practice or common practice) about treatment processes. The stroke-center allocates 9 process models as CPG. In our investigation, we compare them with 11 individual CP of a network member, a university hospital.

## CONCEPTUAL MODELS IN HEALTH-CARE SECTOR

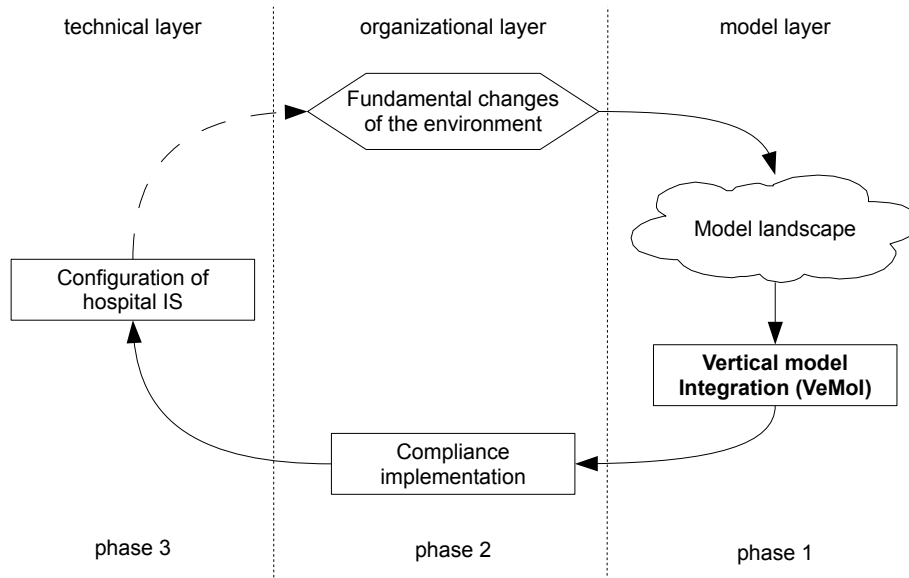
To improve the medical care, Clinical Practice Guidelines (CPGs) and Clinical Pathways (CPs) are used to communicate best practices and establish a standard care quality (Schlieter and Esswein 2010; Wollersheim et al. 2005). Conceptual models are used to express CPGs and CPs (Frank 1999).

CPGs provide decision guidance for health care providers (e.g. hospitals) that are based on evident practice for specific indications (diseases). CPs describe clinical processes for a specific diagnosis that is adapted to the local situation, e.g. in a specific hospital. National and international medical associations (e. g. the European Stroke Association) release CPGs. CPs are created by the medical care provider according to their specific organizational structure. A meta-analysis of 17 high quality studies finds that CP seems to be effective especially for stroke care (Rotter et al. 2008).

In our case study we observed that there is neither standardization nor integration of the different models. In the health care domain, different models are constructed simultaneously for the same indication by different groups of interests. We call this set of models “model landscape”. The problem with this unstructured model landscape is that despite the guidance character of the CPGs, a connection between the clinical pathways and the CPGs is not clear.

For the health-care professionals that have to use the clinical pathway (CPs) models, the relation to the guidelines (CPGs) needs to be clear. We address this issue by designing a context sensitive navigation in CPs to find the relevant parts of the corresponding CPGs. Furthermore, the CPs need to be compliant with the CPGs to guard the health care provider for example against lawsuits. To our knowledge, there are no holistic approaches that provide the alignment or integration between CPG and CP models.

**Life-Cycle of Conceptual Health-Care Processes**



**Figure 1: The Life Cycle of Medical Care Processes**

In figure 2 we introduce the life cycle of the medical care processes that represents the big picture of the integration problem. The life cycle can be divided into three phases and layers. The first layer is the model layer that is a representation of the organizational layer using conceptual models. The organizational layer represents the real world (people, resources, etc.). The technical layer incorporates the information system infrastructure of the health care providers.

The starting point is the model landscape in the first phase where models are isolated and inconsistent. With the help of the proposed method, the models are vertically integrated. The integration on the model layer is the prerequisite for the next two phases. On the organizational layer in phase 2, the result of the model integration is used to guide the compliance implementation. To be compliant with the guidelines, operational procedures and organizational structures have to be adjusted. On the technical layer, the hospital information system is configured to support the execution of the medical care processes using the integrated models. The life cycle re-starts if the environment fundamentally changes, e.g. due to new laws. Because of the exceptional relevance of the model layer for the organizational and technical layers, this paper focuses on the first step, i.e. the integration of the health care models.

**A Framework for Conceptual Health-Care Models**

On the basis of analysis of the models that were found in the case study, the framework in figure 3 shows three different and initially independent model layers. On the topmost layer, professional associations and local experts create CPGs. CPs are located on the middle layer and are used by the hospital staff. A CPG concentrates on general clinical advises and is normally less detailed than clinical pathways. The hospital information system is shown on the bottom layer. The information system might be configured using workflow models via a XML-transformation. The sort of the layers follows the path clinical recommendations are typically transferred in practice. Conversely, it shows the way that clinical findings flow back into CPs and CPGs.

The care process life cycle presented in the preliminary section is referenced through the different phases. In phase 1 the clinical pathways are checked against the appropriate CPG. The compliant models are then used in phase 2 to implement the organizational structures and, in phase 3, to configure the hospital information system.

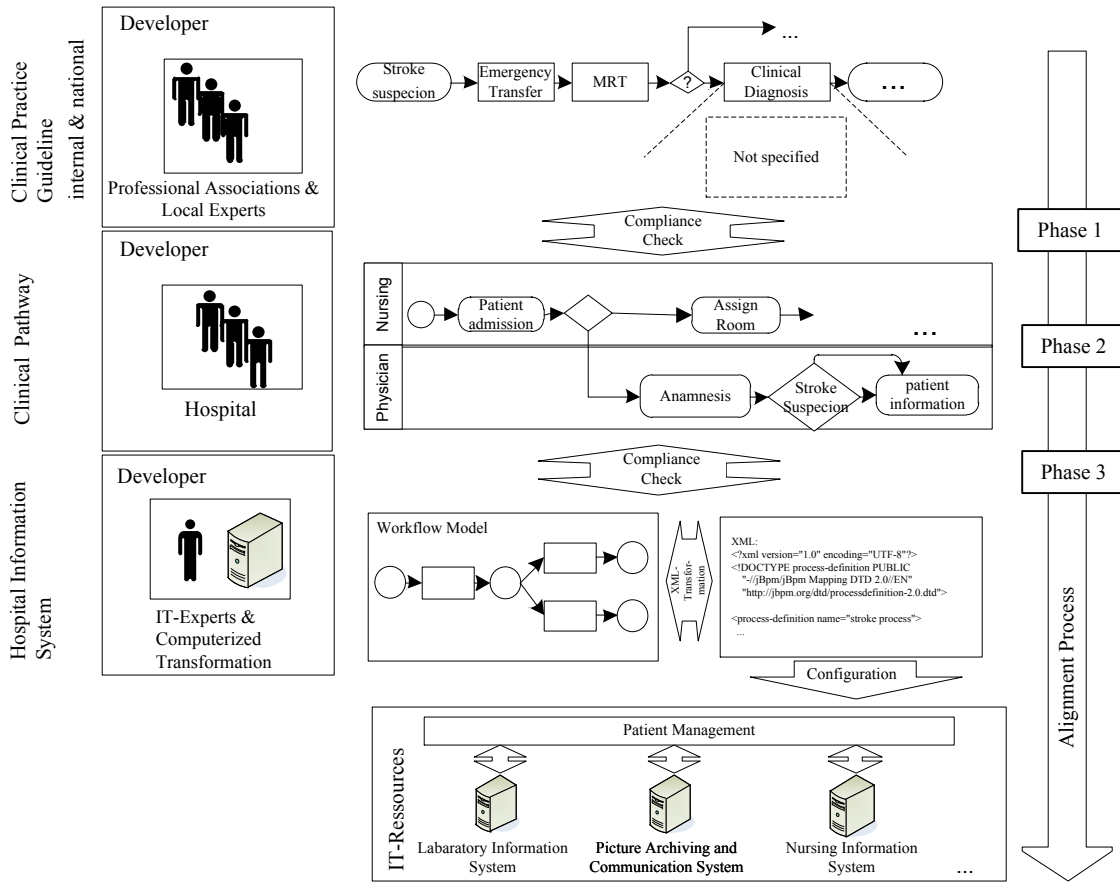


Figure 2: Framework for Medical Care Processes

**Potential of Integrating Health-Care Models**

The integration of the layers delivers great potential to improve the recommendations themselves and thus the quality of clinical care. The following cases reflect the main goals of integration in the SOS-NET:

- Case 1: Compliance check: The vertical integration makes a check of models concerning superordinate layer possible. The models are compliant, if all necessary advises are considered in the underling layer. Compliance should guarantee that the goals of care are reached as it is defined in the subordinate layer. Compliance is no structural or syntactical conformity. It depends largely on the content wise correspondence.
- Case 2: Context sensitive help: If a link between the different layers exists, users can track where information come from. They can also get further information for special steps of the treatment or clinical decisions.
- Case 3: Support of business-process-reengineering (BPR): In BPR it is necessary to know the current situation of the processes and the limits of BPR. The integration model could help to determine the flexibility for the restructure. Furthermore, the integration could help to identify weak parts in the processes.

**THE CHALLENGE OF MODEL INTEGRATION**

The high potential of integrating health-care models is challenged by the problem of vertical model integration, which will be explained in the next sections.

**Vertical vs. Horizontal Model Integration**

In the context of model integration vertical and horizontal integration of model layers needs to be distinguished (Bögel and Esswein 2010). We speak of vertical integration if the integrated model layers concern the same part of the universe of discourse (Morgan and Routh, 1846), but differ in the viewpoint (Easterbrook et al. 2005). If we look on CPGs, the universe of discourse is a specific disease, while the viewpoint is the evident guideline viewpoint on this specific disease. For a

corresponding CP, the universe of discourse is the same disease, but the viewpoint is that of a specific process in a certain hospital.

In contrast, the horizontal integration of two models on the same layer, differ in the universe of discourse but have the same viewpoint. Heterogeneity in vertical integration is therefore a result of different viewpoints.

**Integration Conflicts**

The heterogeneity of models leads to integration conflicts between those models. Diverse classifications of integration conflicts can be found in the literature. For the construction of our method these classifications have to be consolidated. We show that the conflicts can be divided into two groups. One group of conflicts concerns the (artificial) modeling language and the other group concerns the (natural) domain language.

A common classification distinguishes type, structural and name conflicts (Pfeiffer and Gehlert 2005; Pfeiffer and Becker 2008; Rosemann 2002; Hars 1994). A type conflict is caused by using different modeling languages or by using different constructs of a modeling language to express the same issue (Pfeiffer and Gehlert 2005). By using the entity relationship model language, a certain issue can be modeled as attribute or as entity (Batini et al. 1986). If a part of the real world is modeled semantically different in two models this is denominated as structural or semantic conflict (Pfeiffer and Gehlert 2005). Dependency conflicts, abstraction conflicts and level of detail conflicts are distinguished (Kashyap and Sheth 1996).

Dependency conflicts arise if the same structure is modeled by mutually exclusive relations between elements. Different multiplicities or different generalization- or specializations relations are examples for a dependency conflict (Kashyap and Sheth 1996). An abstraction conflict occurs if the same issue is modeled in a differing level of abstraction or generalization. For example in one model an issue is modeled as book, in the other model as publication (Kashyap and Sheth 1996). A level of detail conflict arises when the models have a different level of comprehensiveness compared to each other (Kashyap and Sheth 1996). If the domain language is used differently this is denominated as name conflict (Batini et al. 1986). Synonyms and homonyms are typical examples for name conflicts. The triple part classification of name, structure, and name conflicts goes back to database schema integration. According to our understanding of integration, this classification is based on the horizontal integration.

Whereas (Dijkman 2008) considers the horizontal integration of similar process models. He differentiates authorization, activity and control-flow conflicts. Weidlich et al. (2009) extend the list by process and data conflicts. Those conflicts relate to constructs of a modeling language. Others like (Daniel Pfeiffer and Jörg Becker 2008) are differentiating homonym, abstraction, separation, type, synonym, annotation and control-flow conflicts.

We consolidate these classifications according to table 1. In the first dimension a conflict is related to the domain language or the modeling language. The second dimension represents the three layers of the semiotics: syntax, semantics and pragmatics.

	Domain language	Modeling Language	Solutions
Syntax	Name conflict (homonym conflict, synonym conflict)	Type conflict	Ontologies, syntactical model comparison
Semantics	-	Authorization conflict, Activity conflict, Process conflict, Data conflict, Dependency conflict, Abstraction conflict, Level of detail conflict, Annotation conflict, Control-flow conflict, Order conflict, Separation conflict	VeMoI
Pragmatics	-	-	-

**Table 1: Integration Conflicts**

A modeling language consists of a grammar and a set of domain expressions. The grammar defines the relations between concepts. Concepts of modeling languages are constructed by abstracting one or more domain expression (symbols) to a concept (Pfeiffer and Becker 2008). For example the domain expressions “customer”, “bill” and “product” can be abstracted to the concept “class”. The previously mentioned conflicts relate either to symbols of the domain languages or to concepts of modeling languages. Name conflicts, for example, relate to symbols of the domain language. Type conflicts relate to concepts of modeling languages. The conflicts mentioned by Dijkmann and Becker et al. also relate to concepts of the modeling language by using concepts for describing these conflicts.

In the dimension of semiotics, the conflicts can be classified by looking at their occurrence. Name and type conflicts can be identified at the level of the syntax (for example, through the comparison of strings or two type identifiers). All the other conflicts mentioned (Dijkman 2008; Daniel Pfeiffer and Jörg Becker 2008) can only be detected by looking at the semantic layer. No conflicts could be found on the pragmatic layer. This is because the intension of the model creator is not accessible for a third person. The universe of discourse, depicted by the models we observe, is of material semantics. In this case, the semantics cannot be reduced to syntax. This can be justified by the nonunderpinnability of language (Holenstein 1982). According to Wittgenstein, semantics are constituted by the use of the symbols of a language. The mapping between syntax and semantics is an on-going process executed by human beings. Humans use symbols corresponding to his or her intentions and therefore constitute semantics.

As a consequence, for the solution of these conflicts, the next semiotic level has to be considered. To solve a (syntactical) synonym-conflict, the semantics of the symbol have to be consulted. To resolve semantic conflicts, the intention of the model creator has to be considered, i.e. the pragmatics. To solve a control-flow conflict, the intention of the model creator has to be consulted to clarify whether the conflict is a result of the freedom of the modeler or if the order of the activities is mandatory. This check requires knowing the model creator and model user as well as the model purpose.

#### **THE VERTICAL INTEGRATION METHOD - VEMOI**

A method consists of a collection of techniques, a description of how they can be applied (procedure model), and a description of roles and responsibilities for the method execution (Brinkkemper et al. 1999). Two major roles are needed to execute method. Firstly, the domain expert is responsible for interpretation of domain knowledge. Secondly, the integration expert has knowledge about the method and their application. The domain expert specifies the goal of integration, and the integration expert helps to achieve this.

We introduce a service-oriented method based on the following considerations. First, the health care network requires a distributed architecture. Second, we gain flexibility in the orchestration of the services so we can integrate preliminary work, e.g. the integration of ontologies for resolving name conflicts. We can also interchange non-automated steps with automated steps, if such services are available. A hospital or care network may also decide to outsource certain services like the classification step. In summary, our procedure model is described by orchestrating services and not by modeling a process diagram. Following this approach a method fragment is represented by a service. In Figure 3 three services: “classification”, “anchor identification” and “domain conflict identification” and their orchestration are depicted.

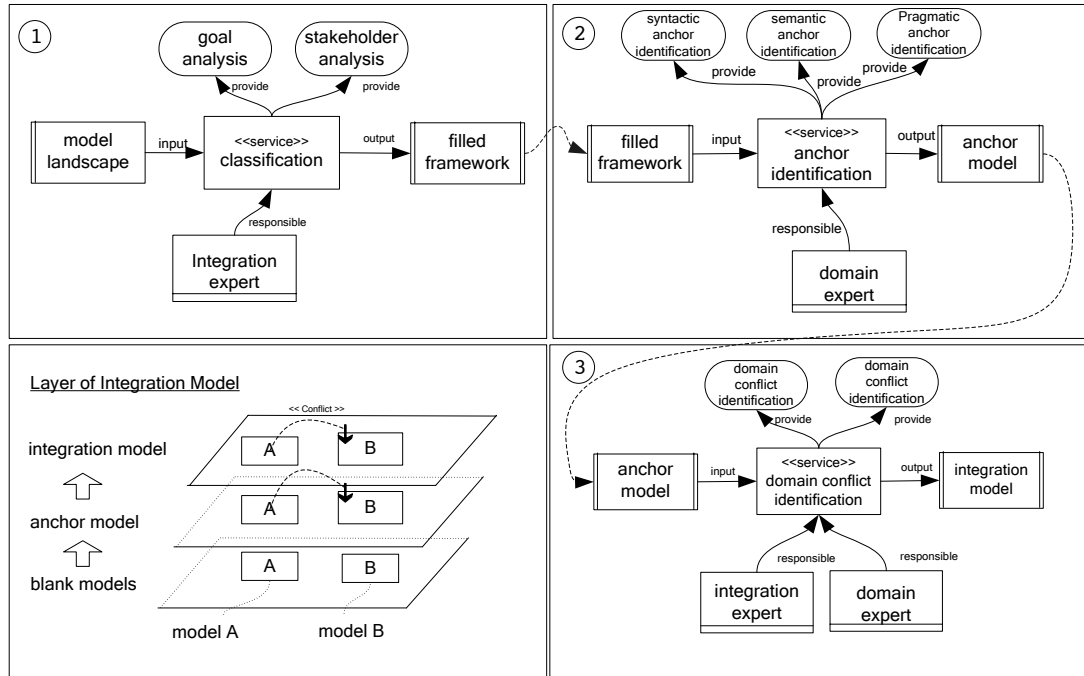


Figure 3: The VeMoI – Service Model

The method starts with the definition of the integration goal. The goals outlined in **Fehler! Verweisquelle konnte nicht gefunden werden.** guiding us in the description of the next steps and the evaluation of the method.

**Classification of Model Landscape**

In this step the models found in the model landscape are classified using the formerly proposed framework. The following criteria can be used to carry out the classification. A first criterion is the stakeholder of the model. A second criterion is the goal of the model. For example, if the model creator is the “scientific medical society” and the goal of model is “knowledge aggregation of evidence based medicine” and the consensus about best medical practice, the model can be classified as the CPG layer. In our example we will use general CPG of the German stroke organization and the internal CPG of the SOS-net stroke unit.

**Anchor Identification**

The result of the comparison can be identity, equality, similarity or non-conformance of sets of model elements. Identity means to elements are physically identical. Equality means the all attributes are equal. Similarity means one or more attributes are equal but not all. Non-conformance means there is no relation between the elements. Anchors can be applied in the first three cases.

Result of the model analysis is the anchor model. It can be visualized as conceptual model or table. Figure 7 is an excerpt from the anchor model of the diagnosis model. On the left side, the national CPG is depicted and on the right side the CP. Three anchors where identified:

1. A syntactic anchor was found by comparing the symbols: “Initial diagnosis” and “Basis diagnosis”.
2. A second semantic anchor was found by comparing the diagnostic sections in the two models.
3. A semantic anchor was found by interpreting the MRT region in the CPG and the corresponding region in the CP.

**Domain Conflict Analysis**

The goal of the conflict analysis is to evaluate if the anchor relations are integration conflicts. A syntactic anchor can be a



type or a name conflict. It is also possible that there is no conflict. A semantic anchor can be a structural conflict, e.g. an order conflict (see table 1). Pragmatic anchors show goal conflicts between models that are the result of different intensions. They indicate implicit knowledge of the modeler, which was not represented in the model.

These conflicts have to be refined to domain conflicts that are understood by the domain expert. This is the communication interface between integration and domain expert. Syntactic conflicts are easy to understand or solved by the integration expert. This applies for the first syntactic anchor. “Initial diagnostic” and “Basic diagnostic” can be identified as synonyms. Semantic conflicts should be described in the language of the domain experts.

We observed that an order conflict, for example, can be a diagnosis procedure conflict or a treatment procedure conflict. Whereas a different order of activities is allowed in the diagnosis, this does not apply to the order of activities in a special treatment, for example in the emergency stroke care. This applies for the second anchor. It can be identified as diagnosis procedure conflict because the order of the diagnosis steps differs in the two models. The third anchor can be identified as level of detail conflict, because the CPG demands a “Posterior circulation” check. In the example, this leads to an “uncertainty conflict” because the health care professional might not consider a “Posterior circulation” check although recommended by the CPG. Result of this step is the domain conflict relation model, which is a refinement of the anchor model, depicting the domain conflicts. For a better understanding of the anchor model, figure 6 shows the corresponding meta-model including an overview of the domain conflicts.

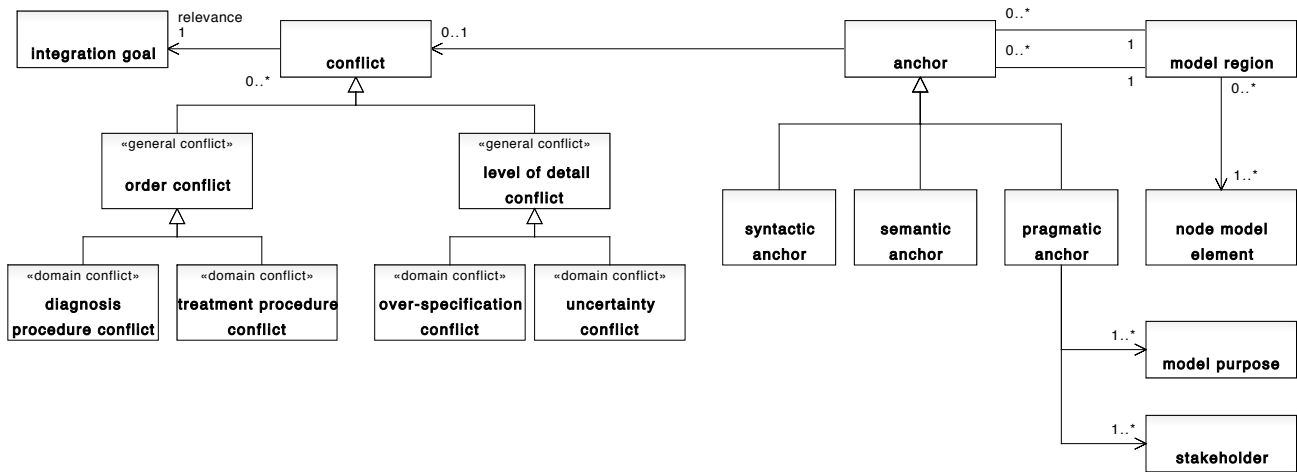


Figure 4: Meta Model of the Integration / Anchor Model

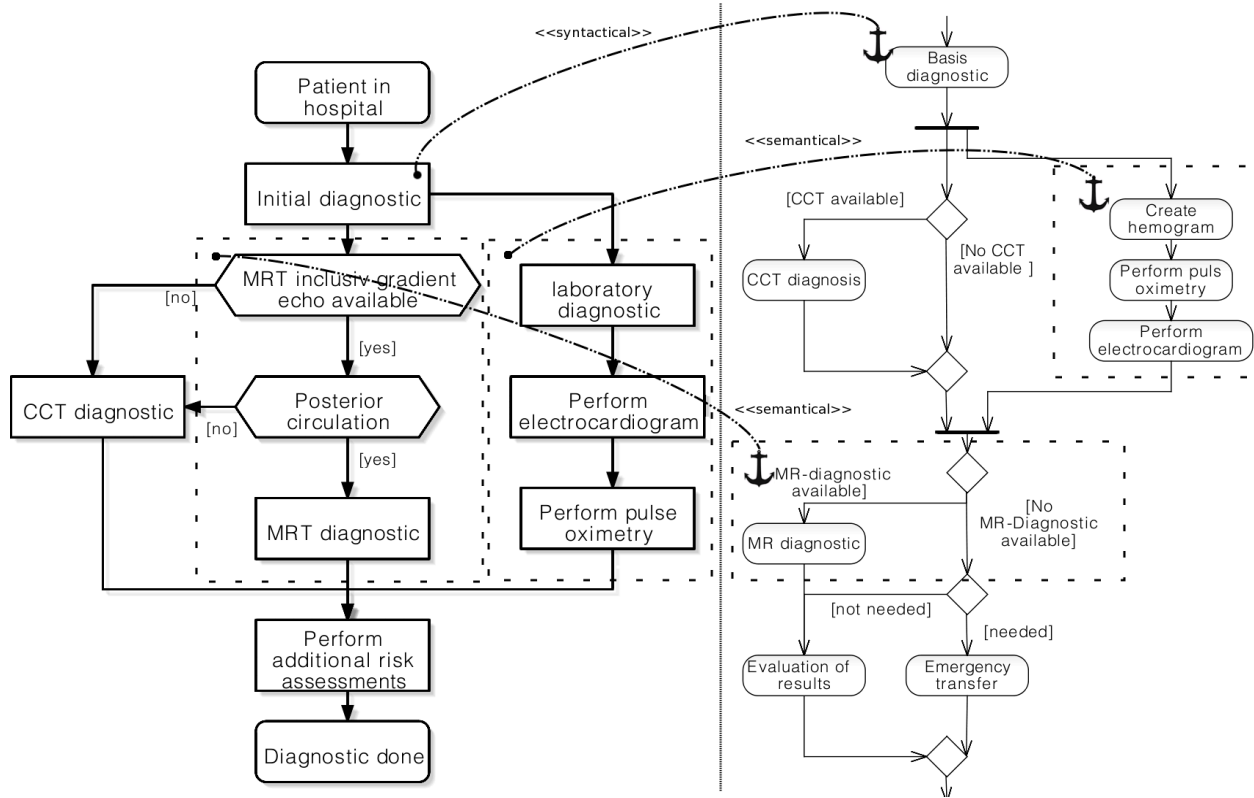


Figure 5: The Anchor Model

Not all of the conflicts are relevant due to the integration goal. A domain expert has to decide if a certain conflict is significant or not. Result of this step is a revised conflict relation model, in which every conflict is attributed as relevant or not, due to the integration goal.

In the general CPGs a certain order of steps for the diagnosis of strokes is modeled. First the hemogram has to be created, second a computer tomography is completed and third the electrocardiogram is performed. In contrast to this, the specific CP contains a different order. A conflict will be detected and evaluated as irrelevant in regards to the compliance against the general CPG because the order of the steps itself is irrelevant as long as all steps are carried out.

The final “revised conflict relation model” enriches the former unrelated models with additional information for compliance checks or model navigation. The model has a layer structure as shown in Figure 3 (bottom left) that is stepwise enhanced through the method.

**Use of the Integration Model**

The integration model can be used in the former mentioned scenarios as follows.

- In the compliance check case, it is detected that the CP is less specific than the CPG (anchor 2, level of detail conflict). For example in the CPG a “Posterior circulation” check is recommended, while the CP doesn’t consider this check. This is a level of detail conflict and in this case an uncertainty conflict. This implies a revision of the CP. The CP is now enriched by the integration model and is immediately more precise. Meanwhile, the revision of the CP takes place.
- Context sensitive help can support the physicians in clinical practice. The basic procedure here would be as follows: A patient with a complex diagnosis comes to the hospital. The attending doctor makes the anamnesis and assigns the patient to the CP. In a later step, the doctor is unsure about a decision care and wants to inquire the CPG. This is made possible by the context sensitive help, which uses the model relations of the integration model to find the appropriate section of the CPG. To check whether magnetic resonance tomography (MRT) is needed or not, as

depicted in figure 7, the doctor places his mouse over the decision node and the corresponding section of the CPG will pop up. It includes a reference to the original guideline on the bottom. The guideline shows that a posterior circulation necessitates a MRT diagnostic.

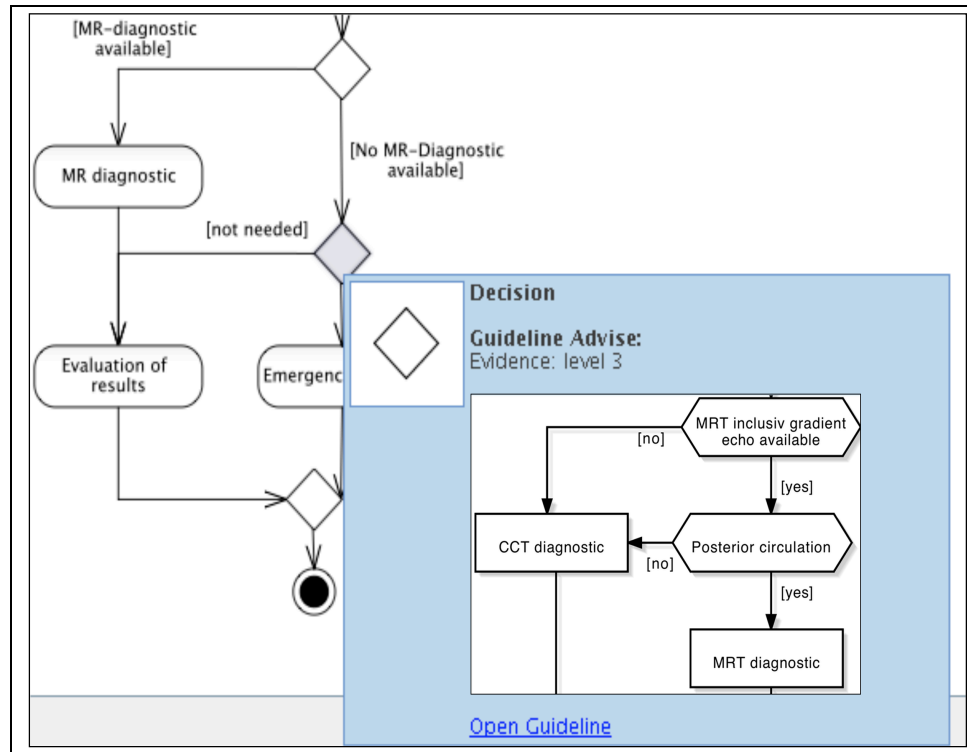


Figure 6: Example Context Sensitive Help

- In case of BPR, the integration model could help to figure out which processes are recommended by the CPG or which are adaptable to the hospital specific processes. Our hospital bundles the electro cardiogram diagnosis. For this reason, this step should be the last in the diagnosis. The integration model shows that these steps are interchangeable and therefore a business process restructuring is possible without reducing the care quality.

#### Validity of the Method

In the case study we did an analysis of 9 CPG models and 11 corresponding CPs. In the preliminary section we have shown in detail how three conflicts could be solved using the proposed method. One syntax conflict and two semantic conflicts, one order conflict (diagnosis procedure conflict) and one level of detail conflict (uncertainty conflict) were resolved. Not considered were conflicts concerning time aspects in treatment procedures due to the limits of the process modeling languages. During further research we will carry out a greater empirical analysis of this domain conflicts in the stroke network.

The first application of VeMoI in SOS-NET tends first to a general improvement in model quality. A harmonization of the models was achieved. The method was also used for auditing the CPs against the CPGs in a pre-test with two network members. On the one hand, it helps new members in the auditing team to check the models systematically. On the other hand, it accelerates the CP validation. Further research will continue on the investigation the economical effects of the approach.

#### CONTRIBUTION AND OUTLOOK

Main contribution of this work is the proposal of the VeMoI method for the vertical integration of medical care process models. This is an important prerequisite for the organizational compliance implementation and the model-based configuration of the hospital information system. With this method we show a domain language based approach for conflict handling in heterogeneous model landscapes. The method was evaluated in a case study by looking at three important use

cases. In contrast to existing approaches, which use data mining techniques and model comparison on syntax level, our approach allows the methodologically guided use of the knowledge of domain experts.

The identified domain conflicts allow compliance checks against the CPG. The process of identifying conflicts also shows relations between two models that can be used, as shown, for context sensitive enrichment of the medical care process models. As a third use case, the relations and domain conflicts can be used for business process reengineering. The enriched process models allow the identification of reengineering potential.

Although our approach involves some manual activities, the resulting integration models can be used at least in the three proposed use cases, which are vital for the acceptance of medical care process models. We are using the proposed research results to analyze the ability to configure hospital information systems. In the further research, we will investigate the usability in a greater empirical evaluation and the ability to transfer the research result in other context like logistic networks or virtual organizations.

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