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Martin Burwitz

Technische Universität Dresden, Chair of Information Systems, esp. Systems Engineering, Dresden, Germany,
martin.burwitz@tu-dresden.de

Hannes Schlieter

Technische Universität Dresden, Chair of Information Systems, esp. Systems Engineering, Dresden, Germany,
Hannes.Schlieter@tu-dresden.de

Werner Esswein

Technische Universität Dresden, Chair of Information Systems, esp. Systems Engineering, Dresden, Germany,
werner.esswein@tu-dresden.de

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Modeling Clinical Pathways - Design and Application of a Domain-Specific Modeling Language

Martin Burwitz, Hannes Schlieter, and Werner Esswein

Technische Universität Dresden, Chair of Information Systems, esp. Systems Engineering,
Dresden, Germany
{martin.burwitz,hannes.schlieter,werner.esswein}@tu-dresden.de

Abstract. Networking and collaboration in clinical care are increasingly entailing new requirements on supporting medical processes. The information technology (IT) in public health accordingly earns strategic relevance and encounters new potentials as well as challenging demands. The application of conceptual models in health care domain is almost entirely restricted to documentation tasks. Approaches like Model-Driven-Architectures or Workflow Management Systems have shown that the application of models, e.g. transformation, execution and formal interpretation, has huge potential. This article presents a modeling language for modeling clinical pathways. Three scenarios show the potential of conceptual models in health care domain and provide foundations for language requirements. Presenting a state-of-the-art of modeling languages for clinical domain and evaluating existing approaches to the requirements provide the gap to develop a domain-specific language. The potentials of the language and the use of corresponding models in medical treatment are demonstrated exemplarily including a discussion on model-driven management.

Keywords: Domain-specific Modeling Language, Medical Treatment Process, Clinical Pathway, Workflow Model

1 Introduction

1.1 Current Challenges of Hospital Organizations

The introduction of the Diagnosis-related Groups (DRG)-system initiated a paradigm shift in public health care. The new system of payment forced the hospitals to organize a process-based alignment of their care structures. The overall social development (demographics, multimorbidity) drives the system to a high degree of specialization and division of labor along the treatment chain.

For this reason hospitals are facing two essential challenges. There is a need for instruments and description facilities on the one hand, to instruct and to control the internal communication. On the other hand, breaking up traditional structures raises new demands pertaining the IT-support of the process-aligned health care. Conceptual models therefore can be used to face these challenges providing a knowledge base with clinical, medical and administrative knowledge, as well as formal process de-

scriptions as the foundation for future IT of hospital information systems (HIS), e.g. workflow management systems [1-2].

To further delineate the context of model usage in health care, we outline three different scenarios in section 1.2. Those scenarios are very challenging for hospital organization and show the potential for the application of conceptual models within health care domain. Therefore, we apply a framework that reflects the link of medical treatment instructions to the context of hospital organizations (Figure 1). Professional societies set common standards for medical treatments by publishing clinical practice guidelines (CPGs) that reflect current findings of medical science [3] (upper layer). These lead to clinical pathways (CP) within the organizational introduction (middle layer) in combination with the local clinical structure. The CPs can further be adapted to the HIS-Layer, where medical treatments are supported by CP-based IT systems (bottom layer). To provide the necessary information of the treatment to the medicating physician as the primary stakeholder, conceptual models of CPs should focus the middle layer. Therefore, CP-models represent the current medical scientific knowledge in combination with institution-specific facts and prepare it as best practices, e.g. a handbook for treatment in a human understandable form. The transformation for an IT-support of treatments is obviously possible but only a subordinate objective.

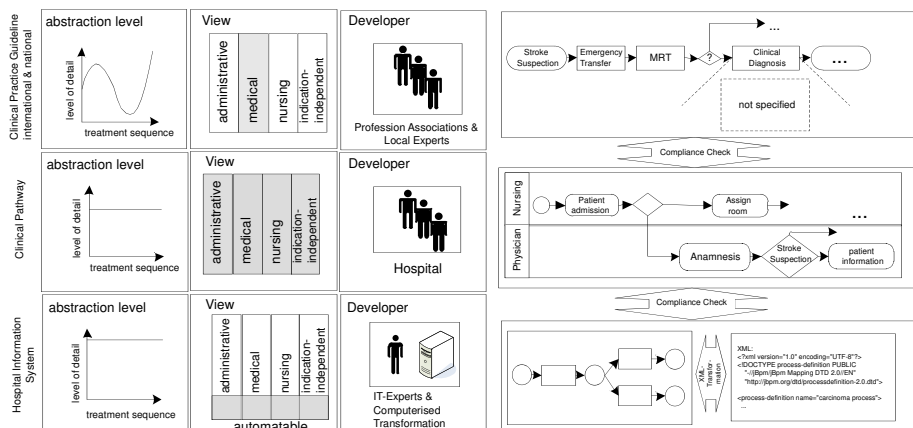


Fig. 1. Framework of CPG and CP in context of hospital organizations [4]

1.2 Scenarios for the Use of Conceptual Models in Health Care

Scenario 1: Implementing and Utilization of Clinical Pathways. Actually, hospitals increasingly need instruments and description approaches to guide and check the internal communication as well as to set standards for treatment processes. On organizational level, CPs have been established in recent years as a promising tool to ensure an adequate description of hospitals processes and to manage the balance between economic efficiency and the best medical treatment of patients [1], [5-6]. They are specific, standardized descriptions of clinical processes for defined combinations of

symptoms that are adapted to clinical conditions [7-8]. They are the integration medium for actual operating procedures, checklists, decision trees, and national as well as international suggestions as well as tool for resource management and continuous process improvement. One challenge of building CPs is the selection of modeling method. On the one hand the modeler should not be limited describing clinical treatment processes. On the other hand for model user, the physicians, the models have to be intuitively understandable.

Scenario 2: Integration of Clinical Practice Guidelines into Clinical Pathways.

CPGs are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [9]. They provide decision guidance for health care provider that is based on evident practice for specific indications (diseases). Hospitals adapt recommendations of CPGs into CPs, but physicians require transparent information, where does a recommendation of CP come from or what is source of evidence. Firstly, between the layer of CPG and CP, there is the challenge of adapting a CP according to a CPG. Secondly, CPG information has to be integrated into CPs. This link can be used, e.g. if a CPG is under revision and some recommendations are changed.

Scenario 3: Clinical Workflows.

Last but not least, the integration of standardization and daily business operations will only be reached, if CP-positioned process knowledge is integrated into the HIS and furthermore supports the medical treatment and if perceptions, gained on the operational level, flow back (bottom layer, Figure 1). The current application of CP usually remains on the organizational level. The pathway-driven IT-integration predominantly fails due to an excessive separation of process design and process execution. The break-up of traditional structures comes along with new requirements for the health care IT-support. The development of hospital information systems has been shaped by an evolutionary development of modules in the field of laboratory, radiology, nursing, image archiving systems and administrative, accounting-related systems. The actual supervision of patients instead, using evidence-based processes, was neglected since the systems rather tended to dealing with accountings than to an appropriate process support. HIS typically including a heterogeneous network of program systems from different manufacturers is the consequence of this development [10].

1.3 Research Method and Structure of Work

The essential objective of our research is the development of a modeling language, which covers the requirements that result from the previous illustrated challenges of the scenarios. Thus, this work is assigned to the design-oriented branch of management information science, the design science [11]. The principle of design science is based on the engineering paradigm in development of information systems. It focuses on solving practical and theoretical problems by creating new and innovative artifacts [11]. Core of design science is to eliminate arbitrary design results. Moreover, the design process should follow strict rules [11]. IT artifacts are the result of design sci-

ence. MARCH ET AL. differ four types of artifacts: constructs, methods, models or instantiations [12]. PEFFERS ET AL. propose a procedure for design science research [13]. The main steps of procedure are problem-centered initiation, definition of objective of a solution, design and development of the artifact as well as the demonstration and evaluation.

According to these steps, the paper is structured as follows: After introducing current challenges in health care and describing scenarios for using conceptual models, related work showing the state-of-the-art of modeling CPs is presented in section 2.1 followed by a presentation of requirements for a model-based building of pathways in section 2.2. This paragraph ends up in a comparison of existing modeling approaches with reference to the formulated requirements. In section 3, we present a domain-specific modeling language, which fulfills the requirements that are derived from the scenarios. The application of a pathway model is exemplarily illustrated by the treatment of a wisdom tooth in section 4. The paper closes with a discussion of research implications, and opportunities for further research in section 5.

2 Modeling Clinical Pathways

2.1 Related Work

The diagrammatical description of treatments and esp. treatment logics is encountered in various scientific disciplines with different objectives. Thus, a comparison of approaches for modeling CPs is difficult without revealing the intended goals of them. The most important approaches come on the one hand from the field of IT, esp. Health Informatics, and on the other hand from the field of Management Information System (MIS). While the former approaches are focusing on formalization of treatment procedures in a computer interpretable format, the latter ones aim to describe treatments in a human understandable form. In IT the models serve as a bridge between human and machine. In MIS, they are primarily an instrument for a standardized communication between humans, e.g. between medical specialists and medical assistants or between medical societies and hospitals. However, they can also be used to derive a more formal treatment description, which can be applied by a decision support system. This differentiation is also illustrated in Fig. 1. Physicians (middle layer) work with CPs (scenario 1 & 2). Therefore, they have to be in a human understandable form, which also means that it is mostly not suitable for a computer-based application (scenario 3).

In IT science, there are a variety of projects that investigate the area of construction and application of computer-interpretable CPs, which are namely: Asbru [14], EON [15], GLIF [16], GUIDE [17], PROforma, Prodigy [17-18]. They often use CPG as templates to demonstrate the applicability of the methods. The goal of all these approaches is to transfer the algorithmic structure of a clinical treatment into a formal shape. These models are in turn transformed into a computer readable form, e.g. proprietary XML dialects or the Arden-Syntax [19].

The MIS discipline concentrates on abstraction of Information Systems, their elements and relations. Therefore a variety of modeling language has been developed.

They can be divided into the branches of general-purpose languages (GPL) and the Domain Specific Modeling Languages (DSML) [20].

GPLs that are typically used for modeling CPs are the flowchart notation, Business Process Modeling Notation (BPMN) [21] as well as Activity Charts of the Unified Modeling Language (UML) [22].

In contrast, DSML are also applied for CP modeling. The Clinical Algorithm as one of the most popular notations goes back to the Society for Medical Decision Making, who promotes this language for the description of fundamental treatment logic in a diagrammatical way [23]. The notation is oriented to particular concepts of the flow chart. The purpose is to find a solution to the problem using a finite sequence of decisions and if-then-conditions, based on a clearly defined initial state [3], [18]. Without considering organizational aspects and individual patient data, the modeling of clinical algorithms takes place exclusively on the level of clinical process guidelines. This notation is also the basis for projects like GLIF [16] or GUIDE [24].

2.2 Requirements for Pathway Modeling Languages

The following set of requirements is derived by the analysis of the specified scenarios and typical treatment procedures supported by common experiences in process modeling. While IT-oriented approaches have developed several requirements under formalization aspects [25-26], the basis for the requirement analysis are MIS-approaches [27-28] focusing the organizational use of CP-models (middle layer in Figure 1).

Considering the key characteristics, the processes of clinical service provision can be perceived as medical business processes. Focusing the patient, these are defined by goal-oriented flows of activities (treatment steps) and decisions being initiated by patient states. The process model supports the task of controlling and optimizing these flows considering the available resources and including the illustration of input-output-relations between process steps and organizational units as well as information objects.

Requirement R1. *A language for modeling clinical pathways should provide the basic concepts of the medical business process modeling (patient state, treatment step, decision, process flow) and the ability to integrate information objects and responsibilities.*

Due to the properties of a treatment process as a service to the patient, the individual treatment steps are usually carried out sequentially. However different process analysis of existing use cases revealed that the specific order may vary from one process instance to another (variable flow). Also some treatments are recommended as optional or as a set of actions, where each, some or at least one of these has to be done.

Additionally, there are medical dependencies between several treatment steps, compulsory requiring a simultaneous and parallel execution (parallel flow). Furthermore, treatment process have often activities which are repeated permanently until the patient's condition is changing (iterative flow).

Requirement R2. *A language for modeling clinical pathways should provide concepts for describing indefinite order relations as well as compulsory parallel relations between treatment steps and iterating treatment steps.*

CPs are developed on the basis of CPGs and evidence-based knowledge (see scenario 1). However, compared to common process modeling techniques, there are no concepts to define the class of evidence of a recommendation given by a model element. This has to be considered within a modeling language. It would help to link the recommendations of CPGs more closely to the organizational standards of CPs.

Evidence knowledge is also important for decisions. In context of workflow execution (scenario 3), on the basis of patient-customized values of decision criteria, the further course of treatment is decided on during the pathway's execution. Therefore rules, generating decision-supporting recommendations resting upon the value combinations, can be defined already during modeling and planning the pathway. Additionally a medical decision against the system-generated proposal should naturally be given the higher priority along with an appropriate documentation and justification. The documentation later facilitates the traceability of occurred pathway deviations and their analysis [29].

Requirement R3. *A language for modeling clinical pathways should provide concepts for describing evidence-class of any recommendation and linking the source of evidence. Additionally, a concept to describe evidence-based decision is required.*

In medical treatment, especially in acute care, the compliance of waiting times as well as time limits is an important fact. For example, some medications can only be given exclusively within the specified time frame.

Requirement R4. *A language for modeling clinical pathways should provide concepts to describe temporal dependencies and explicit time events.*

Table 1 summarizes the compliance of the requirements of existing language approaches, categorizing them into the fields of Management Information Systems and Health Informatics. In the latter field, only languages that use diagrammatic concepts were investigated, since this is assumed as a critical need for human understandability. The detailed description of an approach that lead to this evaluation result can be found in the particular literature mentioned in section 2.1 on related work. In the comparison, it becomes obvious, that the researched model-based description approaches suffer from deficits, especially in the field of domain-specific requirements. Hence, the need for the development of a comprehensive domain-specific modeling language resp. at least for a language extension arises, improving the existing concepts and eliminating deficits by language extensions.

Table 1. Compliance of requirements of the modeling approaches

| Requirement | R1 | | | | R2 | | | R3 | | | R4 | |
|-------------|--------------------|----------------|----------|--------------|------------------------------|---------------|---------------|-----------|--------------------|-------------------------|------------|---|
| | Clinical state | Treatment step | Decision | Process flow | Resources & responsibilities | Variable flow | Parallel flow | Iteration | Evidence indicator | Evidence-based decision | Time event | |
| Approach | | | | | | | | | | | | |
| MIS | BPMN | ● | ● | ● | ● | ● | — | ○ | ○ | — | — | ○ |
| | Activity Chart | ● | ● | ● | ● | ● | — | ○ | ○ | — | — | ○ |
| | Clinical Algorithm | ● | ● | ● | ● | — | — | ○ | ○ | — | — | — |
| IT | GLIF | ● | ● | ● | ● | ○ | ○ | ○ | ○ | ○ | — | ○ |
| | Guide | ● | ● | ● | ● | ○ | ○ | ○ | ○ | — | — | — |
| | PROforma | — | ● | ● | ● | ○ | — | ○ | ○ | ○ | — | ○ |
| | Prodigy | ● | ● | ● | ● | — | — | — | — | ○ | — | ○ |
| | EON | ● | ● | ● | ● | ○ | — | — | ○ | ○ | — | ○ |

● Requirement met ○ Requirement partly met — Requirement not met

3 Modeling Clinical Pathways – CP-Mod

The Clinical Algorithm provides the basic concepts of the below presented modeling language for CPs (CP-Mod). It is a common approach for the organization-focused modeling of CPGs and part of the “Leitlinienmanual”, a guide for a standardized development of CPGs in Germany, that concepts are often used for modeling CPs [17], [26–28]. However, it is lacking from several deficits regarding the requirements as Table 1 shows. Therefore it will be extended by additional language concepts that are especially used for modeling complex health care processes and reduce the existing deficits by addressing the requirements that are only partly or even not met.

3.1 Basic Concepts

The Clinical Algorithm already provides the basic process modeling concepts for treatment processes. *Clinical states* describe different constitutions of the patient type. The treatment according to the instructions of the pathway then hopefully improves the constitution of the patient and turns into another state at the end. A clinical state can also represent intermediates as milestones for the treatment. Clinical states can be further specified by a characterizing property, e.g. to describe the progress of the treatment or the indication. Clinical States at the beginning of a process can either occur exclusively (XOR) or simultaneously (AND).

Clinical states are transformed by actions, representing elementary activities or treatment steps. To improve the domain-specific semantic, an action can be catego-

rized by a type attribute, differentiating between diagnoses, therapy and supporting activities (see Figure 3). Only for these actions, which are not parts of diagnosis or therapy (e.g. prevention, after-care or rehabilitation) or which cannot be explicitly assigned, the generic action without specified type should be used. Supporting activities are rarely used, since CPGs and CPs focus medical processes, however it could be used e.g. for nursing activities.

Further basic concepts are decisions for modeling alternative process flows and information objects representing needed and resulting information. The sequence of treatment steps is defined by a control flow, a directed edge, which can be split using decisions (see section 3.2) or parallelization nodes. The latter is needed for parallel activities where the process is split into concurrent strands. The execution of these strands is enabled simultaneously and finally synchronized into a joint process flow. Moreover, loops and regions are used to describe iterative flows respectively pools of activities where an explicit execution order is not definable and individual due to the disposability of needed resources or where some treatment steps are compulsory or optional. Information objects can be integrated using the information flow type, which is also a directed edge, but using another concrete syntax to visualize the semantic difference. This could be used to integrate the cycle of necessary documents (e.g. lab reports) to support the obligatory documentation requirement. For modeling explicitly defined responsibilities, we used the lane concept of the BPMN 2.0.

The concrete syntax for each of the basic modeling concepts is designed under the premise of human understandability and can exemplarily be seen in section 4. Concerning the remaining requirements, the following section provides improvements of existing concepts and further extensions of the modeling language.

3.2 Extended Concepts

Evidence-based Medicine and Decision Support. Clinical practice guidelines, developed without a systematic research and analysis of the evidence of recommendations, do not meet the international quality standards. Accordingly, the demand for documenting to what extent recommendations draw upon results of clinical studies or expert opinions exists among others. Thus, various classification systems provide a quality assessment of particular sources of knowledge and information and so the quality assessment of the CPG. To evaluate process components within a treatment regarding its evidence and to comply the demand for documentation, the concept of the evidence indicator can be used (see the excerpt of the meta model in Figure 2). An evidence indicator can be attached to every process concept, such as action or decision, to allow the classification of the attached component according to the system of evidence levels of the AWMF [3]. The evidence indicator can contain further information to provide the relevant source of evidence, e.g. a reference to the corresponding section or page of the clinical practice guideline as depicted in scenario 2 in section 1.2.

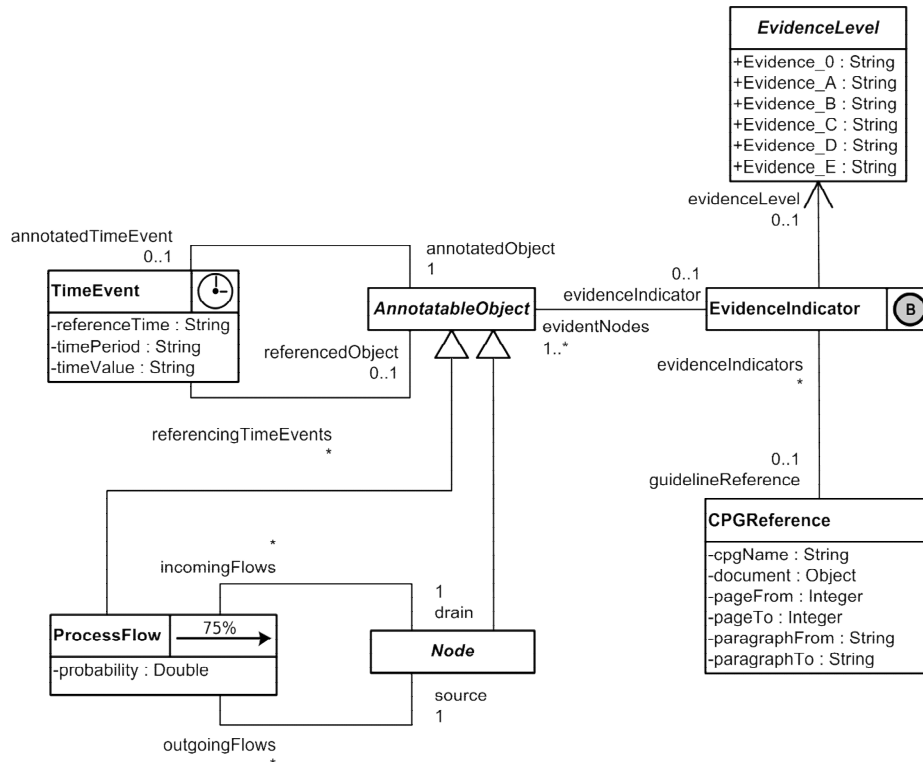


Fig. 2. CP-Mod meta model excerpt – Evidence Indicator and Time Event

To provide for decision support using evidence-based knowledge, the decision has to be extended furthermore by some constructs. Hence, it should be possible to define different decision criteria. Additionally, the description of decision logic provides a recommendation based on these criteria during the execution of the pathway. The attributes and dependencies of those concepts are illustrated in the excerpt of the meta model in Figure 3.

To illustrate an example, the decision for a medication of a patient could be affected by its blood sugar level. Hence, the model should contain the blood sugar level as criterion including a usual interval of values and allocate this to the decision of medication. The particular medication depending on the blood sugar level can then be described using logical expressions, allocated to the decision and concerning the defined criteria. During the execution, a model-based IT-System as part of scenario 3 (section 1.2) could use the logic and apply it to the current treatment, to suggest the recommended medication.

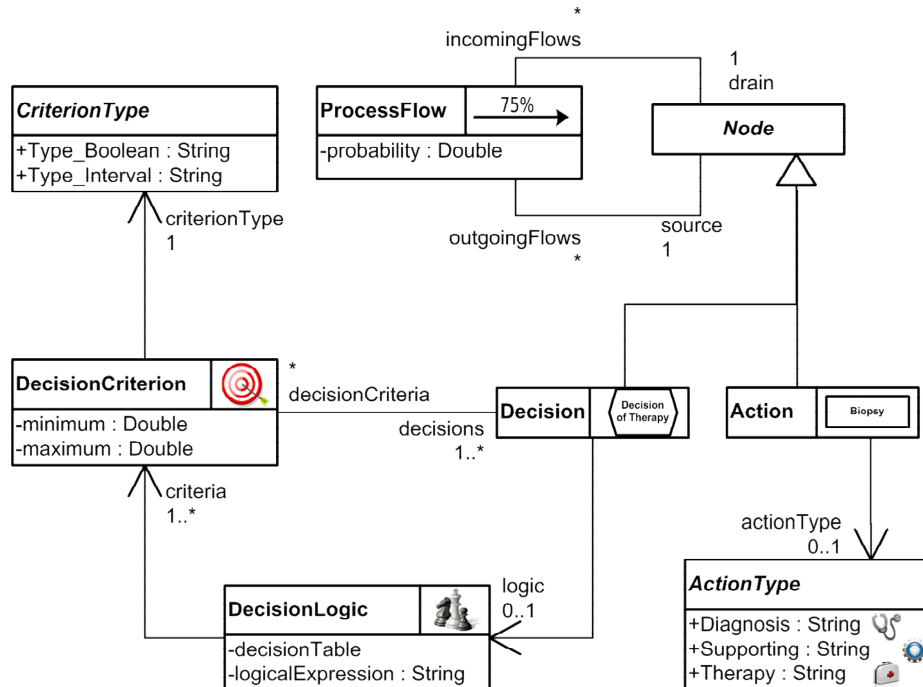


Fig. 3. CP-Mod meta model excerpt – Evidence-based Decision and categorized Action

Classification of Different Treatment Alternatives. Depending on the condition and progress of the patient resp. its convalescence, the decisions within a clinical pathway lead to different pathway progressions. For an optimal planning of a treatment it should be possible to forecast the pathway variant the patient will supposedly follow. Hence, process flows coming out of a decision (alternatives) can be attributed with an according *probability* (see Figure 3). The combination of all decisions shows the pathway’s total alternatives and their total probabilities as usual in a decision tree. As part of a continuous model improvement, these statistics are typically derived on an institutional level by a clinic board through analyzing past treatments. Due to the formal aspects of a CP model and its application for treatment execution, this analysis can be supported by IT based on the execution model (CP instance). Hence, the integration of probabilities could deserve different challenges of each above-mentioned scenario.

Time Events and Waiting Periods. Especially for process modeling in acute care, where intervals between individual treatments are relevant, appropriate approaches are needed to represent critical time slots, waiting periods or temporal dependencies between process steps. Therefore, the *time event* is added to the modeling language to adequately fulfill that requirement. In addition to the specification of a time value or a time period (e.g. within 4 hours), the relation to other time events and hence to other treatment steps can be drawn using a temporal reference point (e.g. within 2 hours

after surgery), so that a suitable representation according to the problem domain can be effected.

4 Demonstration

The developed modeling language for CPs (CP-Mod) was implemented in a meta-CASE-tool to demonstrate the modeling of a CP according to the CPG of a wisdom tooth treatment as an example. The resulting model is shown in Figure 4. Furthermore we implemented a prototypical workflow engine, which uses the created model to support the execution of a pathway during the treatment of an individual patient [27], [30].

The overall process is aligned to the responsible actors using lanes. The treatment starts with the obligatory actions of anamnesis and a radiographic test. Since the order of these steps is not explicitly determined, we can use an AND-region containing both. The radiograph created is necessary for the later decision of therapy, which is expressed by the information flow. Computer tomography and biopsy are additional but optional explorations expressed by an OR*-region. All these actions are diagnostic, which is illustrated by the corresponding icon. Since the dentist decides for a surgical excision, this action has to be supported concurrently by an anesthesia and therefore modeled using a parallelization. The following hemogram creation needs to be done within the first 3 hours, expressed by the time event. Since there is a need for further medication, this action has to be repeated until the hematocrit value fits a specific interval, shown by the loop. Evidence indicators are attached to each action, decision and information object, expressing the evidence level. The radiographic test and the anamnesis e.g. are highly approved by the current medical science, which is why we used the A-level classification. Finally, there are issues, which are not visible in the model presentation but integrated as attributes. The decision of therapy has several decision criteria (e.g. radix aberration [true/false], carious defect [true/false]) and decision logic, expressing that if a patient has a radix aberration and no carious defect, the antibiotics therapy is usually preferred.

For a treatment of an individual patient with indication for wisdom tooth troubles, the modeled treatment steps can be scheduled and illustrated in a pathway overview using a workflow engine. A system of traffic lights indicates the patient's current position within the pathway and controls the execution of the particular steps corresponding to the modeled workflow description. A recommendation is generated for each decision, based on the evaluation of patient-customized data concerning the modeled decision criteria and logic.

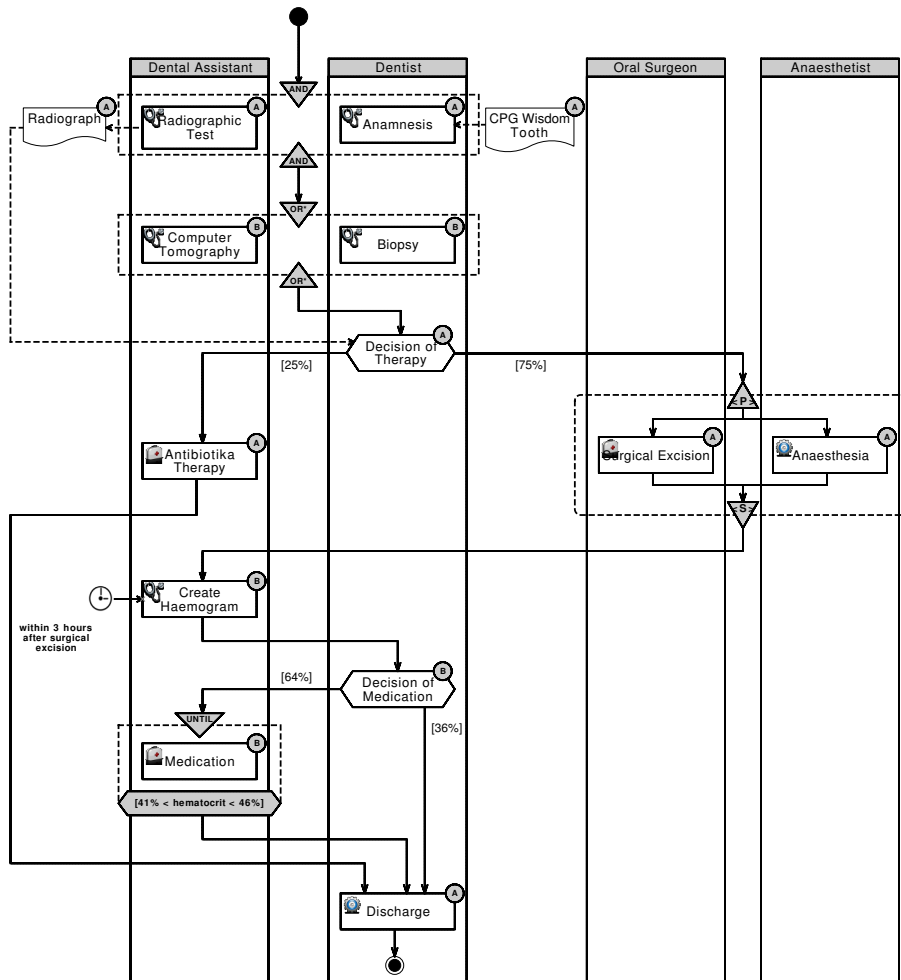


Fig. 4. CP model for a wisdom tooth treatment using CP-Mod

5 Conclusion

In the paper, we present an innovative approach for modeling CPs. Therefore, we outline three different scenarios in section 1.2, which show the potential range of model usage in health care. On the basis of these scenarios, requirements have been derived for an adequate modeling of CPs, which further have been applied to related work to evaluate existing approaches. It was shown that there are deficits in the area of integrating evidence information, i.e. of CPGs, modeling variable processes or time restrictions. Hence, a modeling language has been developed, which considers concepts for these aspects (see evaluation result in Table 2). The application of the designed language was demonstrated on the example of wisdom tooth treatment in

chapter 4. Therefore, we implemented the language in a meta-CASE-tool and used it in a prototypically developed workflow engine. Thus, we can show how the introduced modeling language fosters the scenarios.

Table 2. Compliance of requirements of the developed modeling language

| Requirement | R1 | | | | R2 | | | R3 | | R4 | |
|-------------|----------------|----------------|----------|--------------|------------------------------|---------------|---------------|-----------|--------------------|-------------------------|------------|
| | Clinical state | Treatment step | Decision | Process flow | Resources & responsibilities | Variable flow | Parallel flow | Iteration | Evidence indicator | Evidence-based decision | Time event |
| Approach | | | | | | | | | | | |
| CP-Mod | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |

● Requirement met ○ Requirement partly met – Requirement not met

The recent explanation of the present work mainly focused on the adequate modeling of CPs (Scenario 1) considering the aspects of Evidence-based medicine (Scenario 2) and execution on a workflow management system (Scenario 3). However, many perceptions incur during the process execution in day-to-day business, which are usually hard to identify, because a multitude of decisions and process parameters are not documented or are even not aware to the hospital.

However, these perceptions should be transferred back into the conceptual level of CPs. Hence, further research should focus on information of the pathway instances, esp. in case of ad-hoc modification on instance level can flow back systematically and permanently into an improvement of the hospital-customized CPs, in terms of a management cycle.

Furthermore, information would be gained, serving the enterprise controlling (activity-based costing) as well as the top management on the strategic design of the hospital's process landscape. So the model-driven management cycle is closing. Extended by the possibility of executing agile processes based on CPGs and CPs, the presented approach now serves the continuous improvement process and feedback of information.

Additionally, further research should focus on the integration of resources, which are necessary for the treatment of patient regarding CPs. These considerations (not regarding the general data protection) for example would enable the creation of work and load profiles for the medical staff with reference to a particular treatment, analyzing processing times and costs for particular patients or patient types, identifying usual treatment patterns or evaluating the actual resource allocation.

The specified modeling language, CP-Mod, therefore, provides a conceptual foundation. Furthermore, a modeling language that covers all domain-concepts fosters building adequate process knowledge for hospitals, which not at least create a clear market advantage in the competitive health care market. With respect to the use of GPLs, another promising investigation would be the domain-specific extension of the BPMN meta model. The BPMN also tries to integrate human understandability and IT

formalization for business processes by providing an intuitive concrete syntax as well as specifications for transforming models into computer-interpretable workflow descriptions. The research task therefore is to evaluate the extensibility and improvements of BPMN and to find solutions for integrating concepts for health care specific problems, e.g. evidence-based aspects. This could be a great contribution in the field of pathway modeling and IT-support for medical treatments and could advance to an internationally wide accepted management instrument.

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