Agility in medical treatment processes – A model-based approach

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Abstract: The economic view on today's health care organizations insists on the integration of standardized process descriptions by Clinical Pathways and information technology (IT). The individuality of several treatments then again requires mechanisms for a flexible and agile alignment oft a treatment process at any time. This paper delineates an IT-system for an agile execution of medical treatment processes based on process models of Clinical Pathways. It will be shown which information occurs and where it can be used in terms of an agile process management and a continuous process improvement.

1 Agile processes in health care

In the era of the system of Diagnosis Related Groups (DRG) and growing competition in terms of quality and efficiency, a comprehensive quality and process management is a fundamental part of modern healthcare organizations [Wie04]. In this context, clinical pathways have been established as a promising tool, addressing evidence-based expertise of clinical practice guidelines and describe organization-specific recommendations for action and best practices. Next to effective treatment of patients, these highly standardized process descriptions allow an improvement of economic efficiency in terms of cost and duration of treatment. Thus, they are additionally enhancing the quality of care and patient satisfaction.

Simultaneously, medical treatment processes must consider several factors that preclude a complete standardization. Clinical pathways are characterized by a variety of decisions that are made during the execution and treatment of the patient. These decisions consider the patient's individuality and enable a unique course of treatment. In combination with appropriate IT systems, clinical pathways can officiate as decision-support instruments and submit treatment proposals. However, the final decision is always taken by the attending physician. Consequently, there is a dependency between the resulting treatment process

and the medical expertise. Not least, changes of the evidence-based knowledge of clinical practice guidelines by new scientific insights and also changes of the legal frameworks are affecting medical treatment processes.

These explanations suggest that the real individual course of treatment of a patient is difficult to plan and hardly predictable in detail. On the one hand, clinical pathways as well as IT systems must feature components and mechanisms to facilitate and flexibly design the planning. In terms of a genuine process agility on the other hand, it must be possible to adequately respond to unexpected impacts. Hence, innovative information systems and solutions are needed to meet these requirements.

The integration of a multitude of actors involved and the pooling of services in a network of medical providers leads to a high degree of complexity of the treatment processes which is beyond the complexity of traditional industrial processes [EK07]. Currently, existing workflow technologies can cope with this complexity inadequately. Though there is a discrepancy between the possible potential and the prior use of modern information technology in hospitals [EK07, LR07]. The current focus of research is still at the conceptual level.

This paper will show, how to support a hospital's process organization and how the integration of the individual layers can be made up to the IT on the basis of modeled process knowledge. An IT system for planning and executing medical treatment processes using process models of clinical pathways will be outlined. The focus of the work is also on the identification and implementation of flexible and agile process components and mechanisms to respond agile to individual impacts during the execution of clinical pathways. The results will be consolidated in a concluding section and provide an approach for integrating a comprehensive agile process management in health care.

2 Model-supported process management

2.1 Agility vs. Flexibility

The further use of the central terms flexibility and agility requires an unequivocal distinction between these two elements. Flexibility in the context of medical treatment processes is described as the ability of reacting quickly and experienced to changing conditions (diagnosis, results of examinations) by changing between predefined and predictable scenarios and the corresponding necessary actions [VF98]. A flexible treatment process is characterized for example through the disposability of various alternatives of treatment. The execution of these alternatives that have been identified previously is controlled by decisions.

In addition agility stands out due to the ability to handle unexpected and unpredictable changes [SZ99]. Agile treatment processes or rather IT-Systems which are supporting those provide corresponding mechanism for responding adequately to effects that did not attract interest during the planning process because of their unpredictability. Thus, the individuality of the respective patient can be regarded perfectly.

The degree of flexibility of a treatment in the context of clinical pathways is already established during the definition of the process. The higher the number of decisions or the alternatives of decisions within a clinical pathway, the higher is the number of the respected effects and the more flexible can be designed the individual treatment of the patient.

In contrast the degree of agility of the treatment process is not determined by the process itself but rather by the environment of the implementation. From the organizational point of view, this environment includes the spontaneous availability of personnel and resources. In line with the supporting IT-System the treatment process is agile, if there are several functions for controlling, monitoring and documentation in order to handle unpredictable effects.

The consideration of flexibility and agility in current research regarding the information systems in health care varies [LR07, RvdA05, ZLN+09, LDML06, MJ11, EK07]. Flexibility in this case constitutes an acknowledged claim to successful workflow management systems [MJ11, EK07]. Different variations and alternatives of clinical processes are comprehensively integrated into modeling approaches. All predictable scenarios are transferred in models complete as possible. Agility is only considered as far as that processes are designed with the aim to open up new possibilities for human intervention instead of excluding it. Generally, the workflow management systems in health care is assigned high potential and relevance for further research [LR07, RvdA05].

2.2 Process models as knowledge base

At the organizational level clinical pathways have been established in recent years as a tool to ensure an adequate description of the processes in a clinic and to cope with the conflicts between the optimal treatment of the patient and the cost-effectiveness [DBDDW+06]. Now it is up to the hospital information systems (HIS) to reflect the arrangements of the clinical pathways and to support and standardize the decision-making of the physician as well as the (planning of treatment).

Finally the integration between standardization and the daily business operations can be reached only, if the process knowledge of the clinical pathways is integrated in the HIS, the treatment is supported on this basis and if the findings obtained at the operational level flow back.

The current usage of clinical pathways is usually constricted on the organizational level, so that the pathways are used just as descriptions and documentation of the treatment and provide only minimal operational support. Therefore the pathway-driven IT integration fails mostly because of an excessive distinction of process design and process implementation.

In order to close this gap a model-based approach can be used. We use the term model following the construction-oriented model definition. Models could be understood as the result of a construction done by a modeler, who examines the elements of a system for a specific purpose [Sch98]. Essential benefit is attained through reduction of complexity by abstraction, which facilitates analysis of complex systems. Thus conceptual modeling provides an approach to describe complex information systems like hospital organizations

in a diagrammatic form [Fra99].

The description of clinical pathways as process models improves on the one side the acceptance by human task managers and on the other hand it facilitates the access to information due to the schematic and clear illustrations compared to purely textual descriptions. Simultaneous semi-formal models of IT systems can be interpreted and processed. Consequently models of pathways can be used as integrative, consistent knowledge base for the whole HIS consisting of human task managers and technical application systems ([Kas99, SJS01, Sch98].

2.3 Modeling, planning and execution of clinical pathways

With regard to the modeling of clinical pathways, there are various approaches in the scientific community. Usually domain-specific modeling languages are preferred because of the distinctive characteristics of the medical application area [SL04]. The modeling concepts conform to the requirements of clinical problems and they are able to reflect the domain better than standard languages. Many of the existing modeling languages such as GUIDE, ProForma, GLIF [PTB+03] focus more on using models to formalize medical treatment algorithms rather than combining the organizational and the technical level of the organization and also on being a central part of the business [Sch05]. In order to ameliorate this issue a comprehensive analysis of the requirements and an evaluation of the named languages have been conducted. As a result a new language has been developed, that is based on existing languages, whose concepts have been expanded. On the one hand the simplicity of the language improves the accessibility. On the other hand the expansion improves the possibilities of the problem-based modeling of medical issues. Concerning the research of analysis of the requirements and the used modeling language it is referred in place to [BSE11].

The starting point of the model-based approach for process planning and execution is the management system of the hospital. As to be seen in figure 1, the management system provides the processes of the hospital as a repository. In addition to management and administrative activities this also includes clinical pathways. These again provide a basis for the IT-supported interpretation and deduction of the operational workflow.

The typical course of model-based process control can be separated into modeling, planning and execution phases. The modeling phase covers the basic illustration of the treatment process. During the planning phase the process model is extended by organization-specific parameters. Finally during the execution phase, the pathway models are instantiated for individual patients, so that their treatment follows one possible way through the pathway and is controlled accordingly. This individual way is hereinafter referred to as a pathway instance that sets itself apart from his pathway model by integrating patient-customized treatment data, results and decisions.

The basic process modeling with illustrating domain-specific workflow patterns is supplemented by the integration of evidence-based information concerning upcoming decisions. This allows a decision support during the execution of a treatment based on defined com-

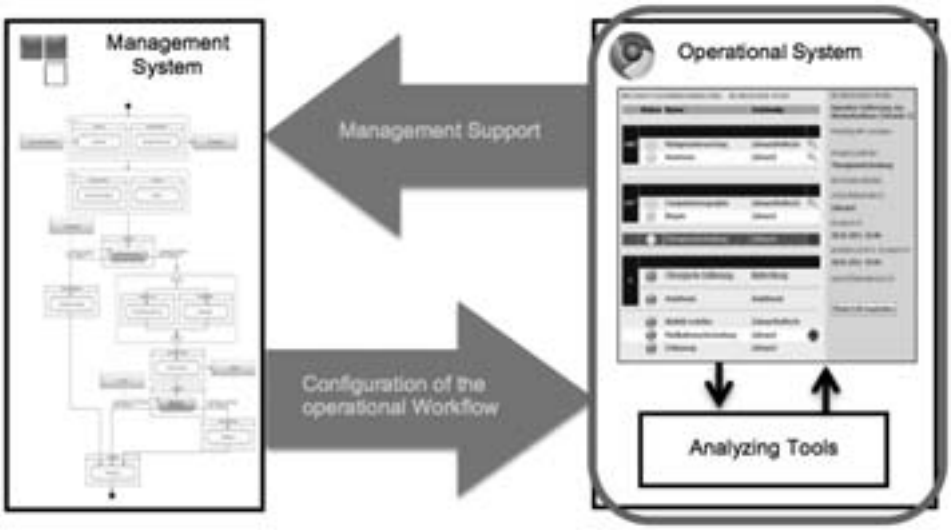


Figure 1: Arrangement of agility in the context of process management

mand variables and the current patient condition. The specification of different pathway variants by declaring occurrence probabilities for different decision alternatives includes empirical values of the treatment team already into the creation of the model and supports decision making of future treatments during the execution of the pathway. The allocation of responsible roles organizes competencies and provides a basis for an authorization management of the particular process steps. For integrating the system into an existing HIS, treatment steps can be linked to according modules or functions. Hence, it is possible to load the picture archiving and communication system (PACS) out of the corresponding treatment step during an X-ray examination. Modeling information flows between process steps and documents provides and ensures a comprehensive integration of documentation along the treatment process through control mechanism.

The pathway execution links the model data to patient-customized information. Thereby, the individual course of treatment is forecasted as a route through the pathway (see arrow in figure 2). Based on the model data, the treatment steps are scheduled and illustrated in a pathway overview. A system of traffic lights indicates the patients current position within the pathway and controls the execution of the particular steps corresponding to the modeled workflow description. This is shown on the right of figure 2, illustrating the treatment of a wisdom tooth as an example. Here, the compulsory anamnesis and X-ray examination have already been carried out. In the context of the optional treatments, a CT has been done while the biopsy has been resigned.

While executing a clinical pathway, a recommendation is generated for each decision during the process. This is based on the evaluation of patient-customized data concerning the modeled command variables. On deviations from the planned course of treatment, a

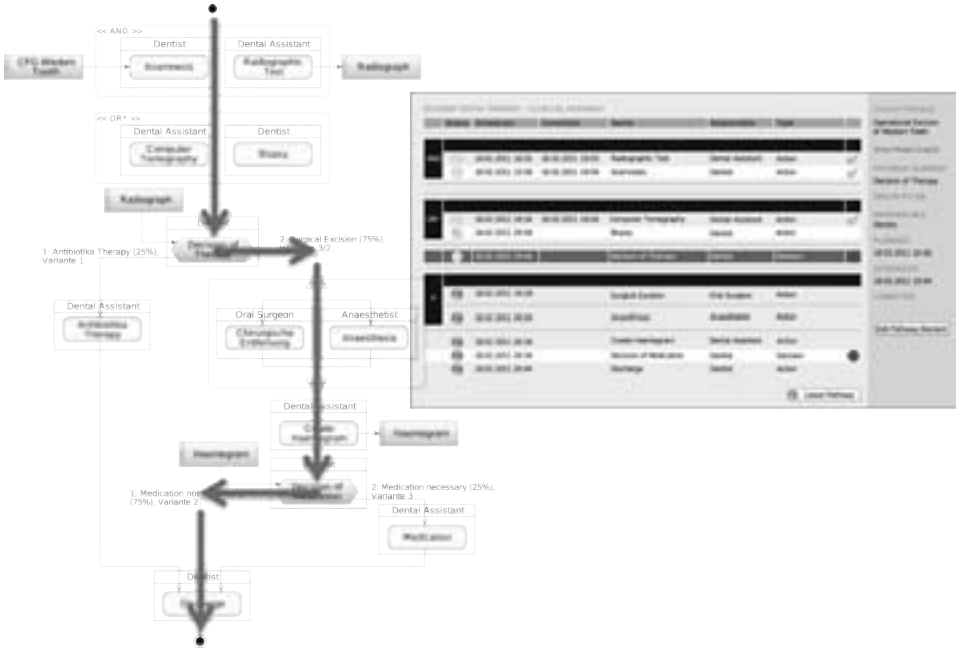


Figure 2: Modeling and execution of a treatment process

forecast of further treatment is needed again. In the exemplary pathway of figure 2, this could be the possibility within the decision of therapy (medicinal vs. surgical) as well as within the decision of further medication (yes vs. no).

The current treatment progress in the example needs to check the indication for a surgical excision next, to decide for an appropriate therapy. An indication-corresponding recommendation is generated by the parameterization of the decision.

3 Recommendations for implementation

The recommended application system contains two components, one for process modeling and one for process execution. For the modeling of clinical pathways, the Cubetto Toolset [Gre10] is used. This generic modeling tool is a standalone JAVA-application and provides for the definition of a modeling language using the E3-notation [Gre04]. This is a language especially designed for method engineering and allows the illustration of the abstract syntax as well as the concrete syntax of a modeling language. A web application as the second component provides the functionality for planning and particularly for the execution of pathway instances. This is implemented on a local Apache web server. The communication between the two subsystems is done by a platform independent data

exchange format. Therefore, an XML file format being geared to the XML Process Definition Language (XPDL) is used, because of the characteristics of the pathway models as process descriptions. The specified architecture is shown in figure 3. The model transformation into an independent XML format allows the application of the model data within different system environments and simplifies the integration into an existing HIS. The transformation is implemented as a plug-in for the Cubetto Toolset, providing a simple integration of additional functionality.

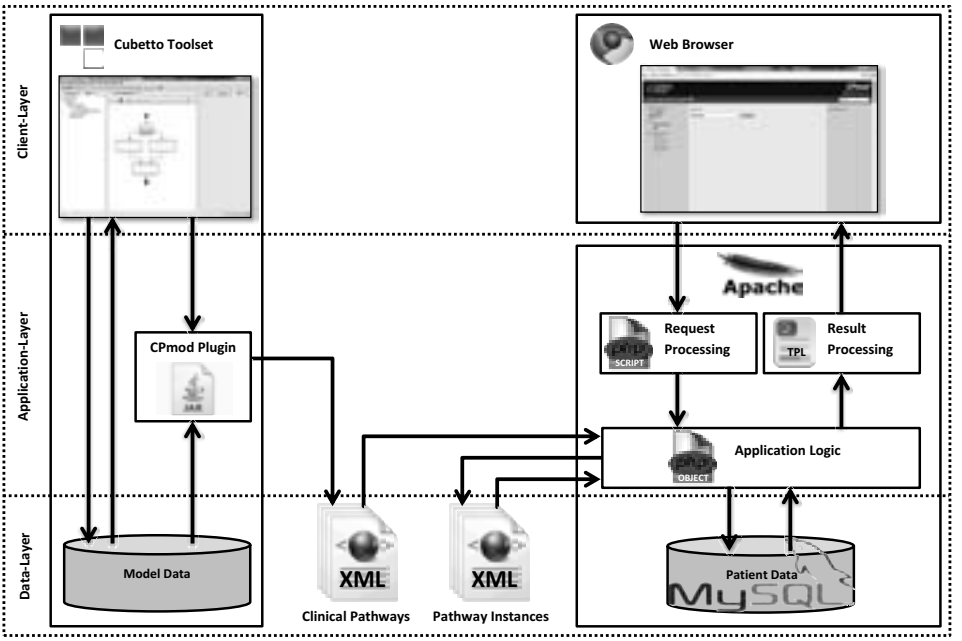


Figure 3: System architecture of the prototype

In the vertical direction the structure of the application system follows a 3-tier architecture for the separation of functionality and the reduction of complexity. The client layer represents the user interface and displays all the information. For this purpose, Cubetto Toolset comes with a graphical user interface while the browser is the client for the web application.

The application layer provides the business logic of the application server side. In addition to the management of the models as the internal functionality of the modeling tool, the application layer within the web application is divided into several components. Processing user requests is done by PHP-scripts that initiate the according business logic. This has an object-oriented structure corresponding to the concepts of the modeling language. The presentation of results and information from the business logic is done using fixed templates for a clear separation of structure, content and presentation.

Within the data layer, the Cubetto Toolset manages the model data in an internal database.

To simulate a real HIS, the web server is complemented by an SQL database containing fictitious patient data. Additionally, this database provides information regarding the patient-customized treatment cases that are linked to the generated XML files of the pathway instances. The exported model data is supplemented by patient-customized information during the instantiation of a pathway and stored in parallel.

The model transformation into an independent XML format enables the use of model data within different system environments and facilitates the integration into the existing HIS. The transformation is implemented by a plugin in Cubetto Toolset providing an easy integration of additional functionality.

4 Model-based management

Process models document the core activities of enterprises. As well as enterprises are subjected to permanently change their processes, process models also do [DRR11]. Especially in clinical domain, the further development of the medical knowledge implies regular process changes. The hospital is responsible to identify and to adapt these changes in daily practice. If this is based on a binding communicated enterprise model, then we can speak of a ”model-based” management.

Beyond these external events, additional process information can be gained on the operational layer. They are often hard to identify because a great bunch of individual decisions and process parameters are not documented. In worst case, the hospital is even not aware of these informations. Furthermore, the individual medical case as well as the professional expertise of the physician and not least the independent decision of the patient frequently imply changes from standardized processes. However, the permanent completion of the pathways, would mean a dilution of the knowledge base and affect the rapid accessibility for clinical stuff. Due to the medically evidence obligation and the process management, agile adaptations of standard processes should be possible and consistently documented in the workflow though (table 1).

Perceptions incurred in day-to-day business must rather flow back permanently into an improvement of the hospital-customized pathways, in terms of a management cycle. The specified model-based approach therefore provides a conceptual foundation. An individualized clinical treatment process is documented in the system for each patient. This patient-customized path is the pathway instance. It is composed of the occurrence of a variant of the pathway supplemented by the adaptations made during execution. In the prototype agile adaptations of the processes at run time are supported. These adaptations can be divided into process-related, decision-related and document-related changes. According to this classification, all options for change the system provides at run time are documented in table 1.

For example process-related changes can be performed if it is possible, due to the medical expertise, to ignore an intended therapy step in a standard process for one patient (see A2 in table 1). In such a case, the physician would open the suggested step and select the option ”skip” instead of confirming the execution. After giving a brief justification for skipping,

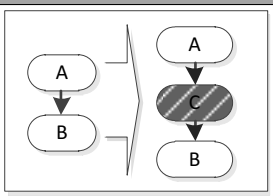
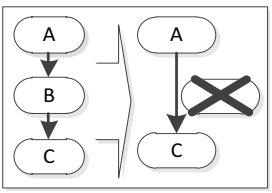
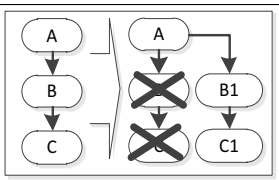
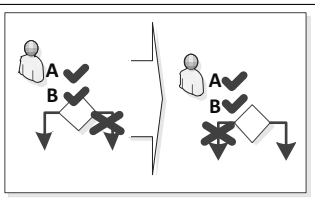
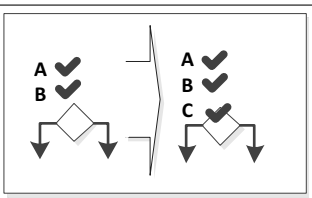
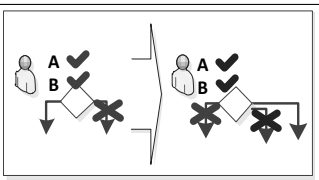
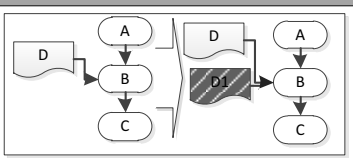
A. Process-based modifications		
	1. Physicians can add treatment steps that are not part of the clinical pathway.	
	2. Mandatory treatment steps of the clinical pathway can be omitted.	
	3. Proposed treatment branches can be changed in favor of an other treatment plan or in favor of an individual treatment.	
B. Decision-based modifications		
	1. Patients can be assigned to other pathways, even though they do fulfill the criteria of inclusion.	
	2. Physicians can ignore the proposed decision recommendation.	
	3. A decision can be extended with further criteria. For example, they can serve as additional justification of the medical decision.	
	4. It is possible to add variants to a decision, which are complete different to the standard pathway, but end again in the standard flow.	
C. Document-based modifications		
	1. Additional documents deviating from the pathway are used for treatment decisions or documentation of the results.	
D. Organization-based modifications		

Table 1: Types of agile process modifications

this step would now be grayed out while the subsequent step would be enabled. Also in the decisions (section B in table 1) lot of modification types are provided at run time. Thus, as described for the example B4 below, a complete decision branch can be added, which in turn flows back into the standard process. An example could be the addition of an alternative treatment, which is carried out differing from the standard due to a patient's wishes.

If a patient refuses a surgical as well as a medical therapy, a radiation therapy may be prescribed, while the subsequent treatment is the same for all three alternatives.

Organizational changes are prohibited, as they usually mean a violation of work competencies. An anamnesis for example, can only be carried out by a physician, but not by a nurse.

Thus, information to support management decisions can be aggregated from the multitude of pathway instances. For example, it can be used to add frequently performed modifications to the pathways on management side (see figure 4). To this, defined management processes are necessary using the pathway models as a key instrument for storage, discussion and development of the organizational process knowledge. Furthermore, there must be rules determining at what frequency and what kind of modification run into the decision making process for the review of clinical pathways.

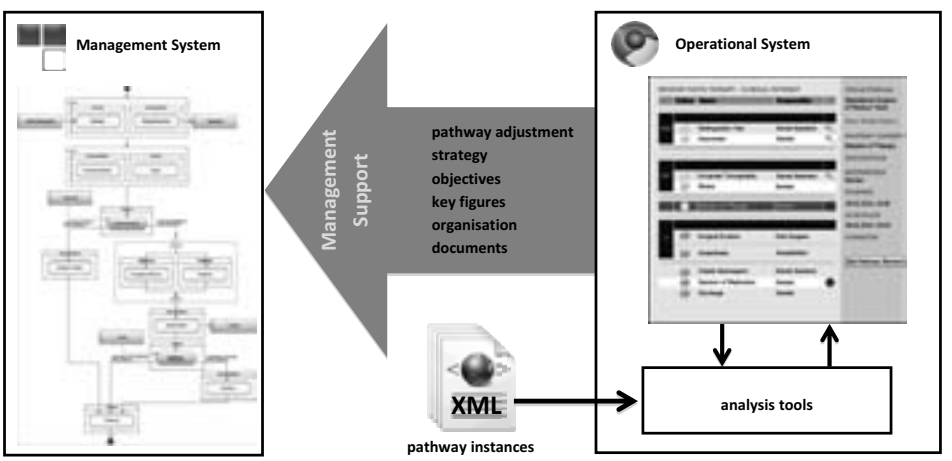


Figure 4: Potentials for the model-based management support

Regardless, all modifications should be reviewed and evaluated by the process measurement in the context of the quality management. The modifications should be reflected and evaluated in a responsible group. The following categories could be used for a classification: indication given, relative indication, contraindication. The latter expression would mean a violation of treatment. Should correspond to this organization are also responding appropriately to avoid in the future, such deviations from the standard. An appropriate organizational response to this also is necessary to avoid such deviations from the standard in the future.

The support for the process measurement is directly made by the prototype. Thresholds may be defined, above which it falls to the hospital, to question and if necessary to adapt existing treatments or procedures that are anchored in the clinical pathway.

Furthermore, information occurs which may be useful to the enterprise controlling (costing) as well as the corporate governance in the strategic design of the hospital's process landscape. This closes the model-driven management cycle. The initially created opportunity to execute processes with the help of clinical practice guidelines and clinical pathways and to adapt them at run time now deserves the continuous improvement process and the feedback of information.

Thus, the prototype is to provide a management cockpit, being able to query the pathway instances in real-time. At the current development state of the prototype is itemized, e.g. which pathways are abandoned and how often. In context of a process analysis, these deviations can be used to discuss, if the pathways are inexact or even incorrect or if a treatment, that was not indicated or not sufficiently justified, has been recommended. Moreover, the monitoring provides the determination of the actual frequency of a pathway variants execution.

Following up theses considerations (not regarding the general data protection), it is possible to creating work and load profiles for the medical staff with reference to a particular treatment, analyzing processing times for particular patients or patient types, identifying usual treatment patterns or evaluating the actual resource allocation.

As to be seen in figure 4, potentials not only of the interplay between predefined pathways and actual pathway instances but also between the executive level and the levels of middle and top management result from this approach.

5 Conclusion

Based on modeled process knowledge, this work showed, how to support a hospitals process organization and how to integrate it into the HIS. Thus, a closer link between organizational knowledge and the operational level is achieved. The identification of possible impacts on the medical treatment process during the execution of a pathway instance is the basis for the mechanisms of the operating system, to react appropriately and to accordingly enable necessary adaptations to the course of treatment in terms of process agility.

A system according to the proposed approach ensures the planning and execution of standardized treatment processes according to the specifications and instructions of the current state of medical science on the one hand. On the other hand, it offers extensive opportunities for individual adaptations of treatment to the needs of an individual patient. This ensures the efficient allocation of available resources as well as an optimal care at any time. The use of operational information for the adaptation of the pathway models deserves the integration of a comprehensive process and quality management and enhances the long-term quality of care and therefore the patient satisfaction.

Further research is mainly seen in the interface between operational data and the manage-

ment-relevant information. The defined thresholds and queries in the management cockpit must be further systematized and evaluated in practice. Furthermore, the usability of the system is empirically examined and gradually improved using case studies in the next steps.

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