Model-based Integration of Clinical Practice Guidelines in Clinical Pathways

Katja Heiden

University of Applied Sciences and Arts, Faculty of Medical Informatics,
Emil-Figge-Straße 42, 44227 Dortmund, Germany
katja.gippert@fh-dortmund.de
Supervised by Professor Dr. Jakob Rehof

Abstract. Healthcare providers are facing an enormous cost pressure and a scarcity of resources, so that they need to realign in the tension between economic efficiency and demand-oriented healthcare. Clinical Practice Guidelines (CPGs) and clinical pathways have been established to improve the quality of care and to reduce costs at the same time. CPGs have a positive impact on the health outcome. However, their influence on the clinical routine is still very low due to their narrative and non-formalized form. This paper presents a model-based approach, how CPGs can be operationalized by transforming the CPGs in clinical pathways and therefore translate the abstract recommendations in concrete process flows. A metamodel will be developed to represent guideline-compliant pathways and to support the users in the derivation process by information technology.

Keywords: Clinical Practice Guidelines, Clinical Pathways, Business Process Management, Metamodel, Health Level 7

1 Introduction

Clinical practice guidelines (CPGs) and clinical pathways have been established as instruments for the quality assurance and process optimization in the healthcare domain. Both concepts define a standardized best practice for a specific disease. CPGs are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [4]. CPGs provide evident medical knowledge for diagnostic and therapeutic issues and contain aggregated information for one specific medical indication. The European Pathway Association (E-P-A) defines a clinical pathway as "a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period" [21]. In addition, the E-P-A indicates several characteristics, which should be considered by clinical pathways; e.g. "the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives" [21]. Thus, clinical pathways can be seen as a road map of patient management.

The positive impact of clinical practice guidelines on the quality of care has been scientifically proven in Grimshaw et al. [5]. However, their influence on patient care in Germany is still very low [15]. A decisive factor for the success of CPGs is the provision of the knowledge at the point of care [10]. The guideline recommendations are abstract and therefore not directly applicable. Thus, these recommendations have to be implemented and tailored to local settings. Clinical pathways are appropriate for that purpose; they can adapt the content of clinical guidelines in form of concrete process flows [10]. That way, the latest scientific findings can be applied in everyday healthcare and therefore lead to a best quality of patient care [17].

1.1 Significant Problems

The consideration of CPGs during pathway development is highly recommended, but there are no standardized mechanisms, which ensure a guideline-compliant care. The research of pertinent CPGs, the extraction of the relevant medical knowledge and the integration of these recommendations in the pathway development process is very time-consuming and resource-intensive. A further problem in this context is the publication of CPGs in narrative form, e.g. as text or hypertext documents [10]. Thus, they are not directly applicable. The first step towards a computer-based process support is the formalization of the guideline content [10]. This translation is burdensome, because the narrative guidelines needs to be mapped onto coded data. Therefore, domain knowledge is required as well as knowledge about the target language to describe the CPG.
The definition of the pathways is done by domain experts. For this purpose, an interdisciplinary team is built composed of all professional groups involved, e.g. physicians, nurses, medical controllers, quality assurance representatives. The results of the development process are text documents or informal process models, which describe the clinical pathway. Thus, they cannot directly be interpreted by IT-systems; a formal logic is needed and additional technical information for the enactment of the pathways needs to be defined, e.g., mapping of service calls or forms to specific tasks. The implementation of clinical pathways is a separate step, which is performed by IT-specialists. It is an error-prone task, because these experts often do not have detailed domain knowledge and sometimes the pathway definitions are ambiguous. There is a high need for communication between the domain- and the IT-specialists [16]. Several cycles are necessary to implement the pathways in the information systems. Thus, a gap between development and implementation of clinical pathways exists as well as a media break between both process steps.
The CPGs offer a lot of additional information, which are not directly relevant for the control flow of the patient treatment. For example, complications or guiding symptoms of a disease are pointed out. This information is often not considered in the pathway development process, although it would mean an increase of information during patient care. Clinical pathways are used for training and education purposes, where they represent reliable action guidelines especially

for young professionals. The additional information from the CPGs could create added values and should be integrated in pathway models.

1.2 Research Questions and Objectives

To adress the problems mentioned in Sect. 1.1, the main research question is "how clinical pathways can be derived from clinical practice guidelines and how the interdisciplinary team can be supported in the translation process by information technology".
Therefore, a model-based integration of CPGs in the clinical pathways should be realized and a metamodel is being developed to describe evidence-based pathways[1]. Structures and elements of both concepts are merged to one generic model. This approach supports the entire process and life-cycle of clinical pathways by one metamodel.
The research objectives are:

1. Development of a concept describing the derivation process of clinical pathways from CPGs
2. Collecting all pertinent information pieces and translate them into components of a generic metamodel
3. Implementation of an editor to support the domain experts in the derivation process
4. Development of algorithms, which translate the clinical pathways described by the metamodel into the target language of a specific system
5. Evaluation of the results in a concrete setting[2]

2 Related work

Different methological approaches exist to implement guideline recommendations in the operational practice. Those show considerable differences concerning the aim or result of the translation process (defining clinical pathways or creating alerts and reminders in form of computer-interpretable guidelines). Additionally, they vary in the degree of automation (highly manual vs. semi-automated approaches):
One approach is to formalize the content of the CPGs by the help of guideline representation languages (see [9, 19]). The narrative CPGs are translated in a computer-interpretable form, which can be processed in decision support systems. It is cumbersome and error-prone to map prose text to coded data [10], because CPGs can partly be ambiguous, incomplete, and even inconsistent [12]. Several guideline representation languages exist, which differ in the degree of formalization; task network models, which formally represent medical guidelines

[1] The term *evidence-based pathway* should illustrate that the metamodel combines characteristic information of the evident CPGs and the clinical pathways (see [8]).
[2] This is done in a cooperation with a German hospital.

and medical knowledge (e.g. GLIF [2], Asbru [13], PROforma [20]) or XML representations for structuring guideline documents (e.g. GEM [18]). If computer-interpretable guidelines (CIGs) should be used by a hospital in order to provide the medical knowledge in everyday healthcare, the hospital information systems (HIS) need to have the ability to interpret and use those formalizations. The result of this translation process is not a clinical pathway by definition; rather computer-interpretable guidelines are created, which support the decision making process during the patient treatment. It provides one way to implement guidelines in daily routine, but, according to [10], the translation of CPGs into alerts and reminders does not support the patient treatment as a unit.
The second approach is a highly manual process, where clinical pathways are developed on the basis of related CPGs (see [1, 6, 14]). The pathway development process starts with an extensive literature research, where pertinent CPGs for the clinical pathway can be identified. This analysis needs to be done manually by the interdisciplinary team. In some hospitals even a special group is built to perform this time-consuming task. The recommendations from the CPGs can be used as an input for the pathway development. The content of the medical guidelines needs to be tailored to local conditions and therefore a consensus among the participating health professionals needs to be reached [10]. Information technology is mainly used for modeling tasks. The result of this development process is a clinical pathway for one specific healthcare facility. Additionally, it is an informal or even a paper-based description, which needs to be implemented in the IT-system of the institution. This approach is very time-consuming and resource-intensive. Information technology is not used for the whole life-cycle management of clinical pathways.
The last approach focuses the systematic derivation of clinical pathways from CPGs by the help of a model-based methodology (see [3, 8]). Jacobs et al. [8] developed a reference model for the methodical transfer of CPGs in clinical pathways. The reference model was exemplary deduced from the breast cancer treatment. Jacobs et al. try to derive an universal pathway for one CPG, which can be adapted to a special institution in a further step. Schlieter et al. used the results from Jacobs et al. and carried them forward. They chose a different representation language for the modeling of clinical pathways. They added rule sets to the reference model in order to define the adaption and extension of specific models. That way they offer a description how to use the formalized CPG in an institution. Both approaches only use the clinical algorithms to derivate clinical pathways and to link both concepts; additional information of the CPGs are not employed.

3 Proposed Solution and Preliminary Result

We propose a model-based approach for deriving clinical pathways from CPGs (Fig. 1 shows the main steps of this process).
The first step is done by the domain experts. They design a clinical pathway by considering the recommendation from the CPG and by adding additional infor-

mation, which cannot be found in CPGs, e.g. resources, responsibilities, costs, nursing care. The experts are supported by an interactive editor, which facilitates the extraction of pertinent information from the CPGs and which provides functions to record further information. The second step has to be prepared by IT-specialists. Every clinical pathway is described through the metamodel. In order to use the clinical pathways in different HIS or Workflow Management Systems (WFMS), they need to be transferred in the target language of a specific system (mapping process). This is the precondition for the translation process, which generates the formalism of the target system. Thus, the metamodel has two key tasks; it provides a formalized representation and a vendor independent description of evident pathways. The whole life-cycle management of clinical pathways is taken into account.

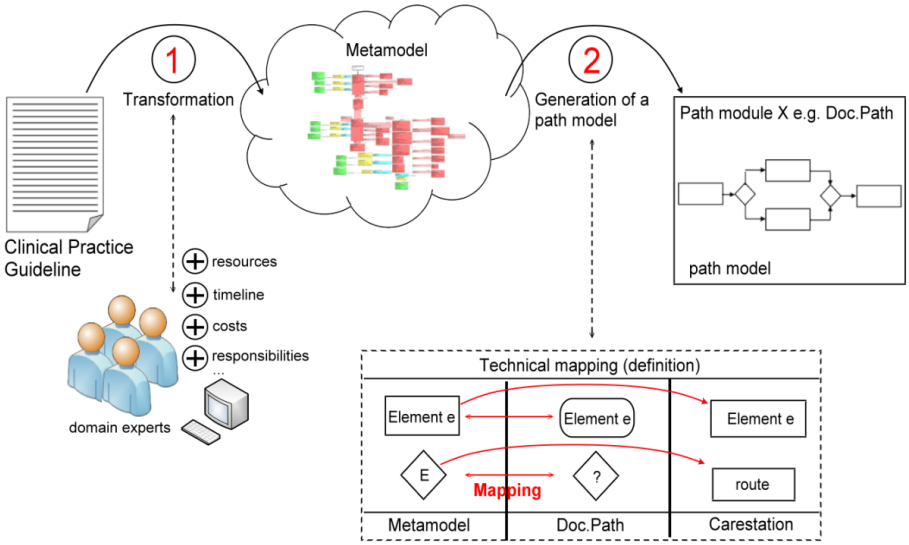

Fig. 1. Proposed Solution

3.1 Conceptual Comparison

For the purpose of deriving clinical pathways from CPGs, we firstly compared both concepts based on the following criteria: 1. representation; 2. structure; 3. content; 4. key users; 5. development; 6. dissemination; 7. implementation; 8. standardization; 9. quality improvement; 10. cost effectiveness; and 11. liability. We performed a detailed literature research to point out the differences and similarities. Tab. 1 summarizes our findings and outlines the main aspects. These findings are further used to define the derivation process. The comparison points out, which information can be extracted from the CPGs, which information has

to be added by the users to describe clinical pathways, which community functions needs to be provided by the editor to support the development process and how the information extraction from the CPGs might be realized.

Table 1. Comparison between CPGs and clinical pathways

	CPGs	**Clinical Pathways**
1.	arbitrary; prose; tables; clinical algorithms	paper-based pathways: comparable to CPG representation; eletronic pathways: formalized; process-oriented
2.	no binding agreement; very different	clinical pathway; sub processes; elements; attributes; values
3.	abstract recommendations; statements for diagnostic and therapeutic issues; additional information; strength of evidence; quality indicators	medical and nursing activities; resources; responsibilities; timeline; costs; treatment goals; inclusion and exclusion criteria
4.	physicians; patients; insurance providers	physicians; controlling; patients
5.	initiative of the physicians; national, regional and local developments; cyclic process; systematic approach	initiative of the health organization; local development; interdisciplinary team; cyclic process
6.	passive dissemination; electronic and paper-based media	active dissemination
7.	combining different implementation strategies; the most effective strategy: integration in IT-systems	implementation is done by IT-experts; integration in the HIS creates the most added values
8.	reduction of variances; standardization of the decision making process	standardized treatment; coordination of responsibilities; unification of the documentation; elimination of variances
9.	best practice; evident knowledge; consensus among experts; reliable data	quality improvement of the processes, structures, outcomes; improvement of education purposes; controlling
10.	benefit-cost analysis; elimination of ineffective, outdated and cost-intensive procedures	reduction of average length of stay; resource-efficient treatment; transparency of the treatment costs
11.	legally non-binding	legally non-binding; deviations must be documented (variance documentation)

3.2 Development of the Metamodel

CPGs and clinical pathways show considerable differences (see Sect. 3.1). Thus, a metamodel is required, which provides a formalized reflection of evidence-based pathways. We used different sources of information to gather pertinent elements for the metamodel (see Sect. 4). The identified components were transferred into a preliminary metamodel. The elements can be classified into five categories, (1) descriptive elements to represent guideline information, e.g. title, validity range,

(2) structural components, e.g. phases and stages of the treatment process, (3) constructs for the definition of the control flow, e.g. branches, synchronizations, decision steps, (4) components to describe the activities, e.g. medical and nursing activities, and (5) components to define responsibilities, e.g. competences and resources. Additionally, there are information, which cannot be directly mapped to any of the five categories. The CPGs provide a lot of unstructured additional information, e.g. epidemiological facts, causes, risk factors, or complications. Those information will be represented by a generic parameter system in order to find a consistent description of this information.
The selection of an appropriate representation for the metamodel was done by the evaluation of three guideline representation languages, namely Asbru [13], GLIF [2], GEM [18]. Additionally the Health Level 7 Care Plan Model[3] [7] was taken as a reference. We analysed, which language or model can depict most of the elements. None of them can describe all components of the metamodel; the guideline representation languages do not provide elements e.g. to describe responsibilities or resources. The HL7 Care Plan Model does not provide all required elements to describe the guideline information, e.g., strength of evidence. Tab. 2 shows the results of the analysis. It outlines the quantity, how many elements of the metamodel can be depicted (X), partly depicted ((X)), and which components cannot be described (-) by the representation language.

Table 2. Analysis of the representation languages

	X	**(X)**	**-**
Asbru	11	8	10
GLIF	12	8	9
GEM	9	7	13
HL7 Care Plan Model	19	1	9

The HL7 Care Plan Model is the most feasible approach to represent the metamodel. It is not a normative standard yet; rather it is a draft, which is steadily being refined [7]. As a consequence, it can be used as a basis and new RIM[4]-compliant artifacts can be added to represent the remaining elements. In addition, the HL7 standard is accepted worldwide and it ensures that individual solutions for specific target systems and proprietary formats can be avoided. The HL7 Care Plan Model was extended by defining the following RIM-compliant elements, which are not provided by the original model:

1. assignment of CPGs to a clinical pathway (evident basis)

[3] HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of the stakeholders in the healthcare domain (see [7]). The HL7 Care Plan Model can be used to define action plans for various clinical pictures.

[4] HL7 version 3 information models are derived from the Reference Information Model (RIM), which is an information model for health care data.

2. structural components to define intersectoral pathways as mentioned in the CPGs; mapping of different clinical pathways to one specific treatment phase, e.g. diagnostic and therapeutic care, follow-up, rehabilitation
3. specification of costs, strength of evidence and recommendation, etc.
4. defining the detailed control flow (integrating the HL7 Workflow Control Suite of Attributes)
5. providing additional information, which are pointed out in CPGs; e.g. complications, and guiding symptoms

3.3 Derivation Process

The conception of the derivation process is still being defined. The findings from the comparison between the CPGs and clinical pathways (see Sect. 3.1) already show, that the translation is a semi-automated process, which will be completed by decisions and interactions of the interdisciplinary team. The main requirements for the editor can be defined based on the present results:

1. Model component (a clinical pathway should be derived gradually based on a CPG; functions for the information extraction and recording of additional information are as well provided as functions to support the division of labor, e.g. version control, groupware functions, reviews)
2. Translation component (it is a multi-level process to translate the evident pathways into the formalism of the target system; the technical definition of the mapping between the elements of the metamodel and the target system is done here)

There will be some challenges to meet concerning the creation of concrete path models, e.g. how to deal with the information, which cannot directly mapped to an element of the target system?; can the additional information create added values for the users?; how can they be displayed e.g. by a wiki, which can be perceived on demand (f.i. by young professionals)?
A detailed requirements analysis will be done in cooperation with a German hospital, where the local development process will be investigated.

4 Research Methodology

In order to investigate the main research question mentioned in Sect. 1.2, we conducted a detailed literature review of related approaches, which focus on the automated or partly automated translation of CPGs in clinical pathways (see [8, 9, 17, 19]). We gathered information about remaining problems in that research area and specified them by consulting an experienced process manager and path designer. That way, a problem-solving approach could be investigated based on the findings of the literature review and the practical evaluation in a healthcare facility.
Components for the metamodel were gathered through the analysis of guideline

representation languages (GEM [19], GLIF [2], Asbru [13]), existing CPGs[5], clinical pathways and path modules[6]. Thus, characteristic information of both concepts could be collected and transferred to a preliminary metamodel. The analysis of existing languages and models substantiate the hypothesis, that there is no language or model, which can merge the information contained in the CPGs and the clinical pathways.
The resulting system prototype will be evaluated in a concrete local setting.

5 Expected Contributions

This model-based approach supports hospitals or other healthcare facilities in considering the CPGs during the pathway development process and therefore in transferring the latest scientific findings into everyday healthcare. The editor should enable the domain experts to model the clinical pathway on their own and therefore closes the gap between development and implementation (domain- vs. IT-specialists). The result of the translation process is the ready-to-use clinical pathway for a specific target system. In addition, the HL7 representation ensures a non-proprietary solution; for IT systems, which can import clinical pathways using a HL7 interface, the last translation step is not even required. In contrast to other approaches in that research area, the whole development process (definition, implementation, life-cycle management) is supported by information technology. Each presented approach in Sect. 2 covers only one aspect of the entire derivation process; a formal representation (see CIGs), the development of concrete clinical pathways for one specific institution (manual process), or the systematic translation (model-based approach). With the aid of information technology it is expected that the development time of clinical pathways can be reduced and the definition of guideline-compliant pathways can be ensured.

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[5] We chose CPGs with different complexity, scope, and degree of interdisciplinary. We analysed in a first step CPGs for the following medical indications: chronic cardiac insufficiency, breast carcinoma, and calculous biliary disease. The metamodel needs to be verified by further CPGs.

[6] We evaluated different HIS modules for the enactment of clinical pathways: Carestation (http://www.commed-kis.ch/), iMedOne (http://www.tieto.de/branchen/healthcare/KIS), and Orbis (http://www.agfahealthcare.com/germany/de/main/)

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