Supporting the Systematic Assessment of Clinical Processes: the MedFlow Method

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Summary

Objectives: Healthcare is characterized by complex cooperation between highly specialized healthcare departments. This often leads to inefficient clinical processes. In order to improve these processes, a systematic assessment method is needed. Such methods are still missing. The objective of this paper is to propose and evaluate a method to support the systematic and semi-automatic assessment of clinical processes, with special focus on the quality of information logistics.

Methods: Criteria for the quality of information logistics were collected based on literature research and system analysis. Appropriate quality checks for these criteria were developed. An extended process modelling notation was developed. The method was evaluated in a pilot study.

Results: An own model integrates four sub-models with each concentrating on distinct process aspects (i.e., control flow, data flow, tool usage, organizational information). In order to assess the quality of a process, selected process details are combined in "views". Weak points are then detected by applying specific rule-sets on these views. Each rule-set represents a pattern of critical cross-points which are searched for in the appropriate view-matrix. The MedFlow method was evaluated in a first pilot study in radiological departments – applying quality checks for the detection of e.g. media cracks or testing the transcription of information objects.

Conclusion: The MedFlow method is best used to assess clinical processes regarding their control flow and information handling. The latter directly influences the quality of communication and thus the quality of whole processes. However, this must be evaluated in further studies.

Keywords

Process assessment (healthcare), process measure, health informatics, information system

Methods Inf Med 2007; 46: 586–594

doi:10.1160/ME9061

1. Introduction

Healthcare is characterized by a close cooperation of highly specialized healthcare departments, each of them comprising actors of different professions, own workflows and specific information systems. Patient-oriented cooperation and communication in this environment is difficult (e.g. [1]). This often leads to inefficient clinical processes [2-4]. In order to measure and improve the quality of clinical processes, comprehensive and systematic assessment methods are needed (in accordance to Deming's Plan-Do-Check-Act cycle [5]). They also help to monitor the processes to determine the degree of improvement [6] (in accordance with the concept of Business Process Reengineering, BPR [7]).

Detailed models of the clinical processes can support such a systematic quality assessment [8]. Process models should describe for instance how information objects are stored, how many tools are used, whether data transcription occurs, etc. In fact, there are established methods for modeling processes regardless of their professional context (e.g., UML Activity Diagrams [9]), some of them able to additionally present certain monetary or temporal process measures (e.g. the ARIS toolset [10]), as well as specialized methods like MOSAIK-M [11] or MLDesigner [12].

However, even models of clearly outlined processes soon become large and complicated due to the increasing amount of activities and alternatives. In order to cope with this, current process evaluation methods provide sophisticated measurement functionalities. But still the detection of possible weak points within the assessment results has to be regarded as an interpretive act that requires a lot of experience. The completeness of the assessment strongly depends on the viewpoint and abilities of the evaluators.

Thus, the objective of this paper is to propose and evaluate a method to support the systematic and semi-automatic assessment of clinical processes, with special focus on the quality of information logistics.

2. Methods

The MedFlow method was developed in the following four steps:

2.1 Selection of Quality Criteria for Information Logistics within Clinical Processes

Based on experiences from earlier work in the area of process assessment and system analysis (e.g. [13-15]) we conducted a review on available literature. This review and the criteria selection were done by an interprofessional working group that consisted of three scientists from the fields of computer science and biomedical informatics. The working group was additionally supported by one quality management specialist.

First, we separated quality into three parts (according to Donadebian in [16]), i.e. quality of structures, quality of process execution, and quality of outcome. Each criterion finally defined was assigned to exactly one of these three aspects.

According to the project objectives, we focussed on quality criteria that deal with information processing within clinical processes. In order to outline the scope of information processing, we considered definitions like "information logistics" (i.e., delivering right information and knowledge at the right time and place in the right form to the right people, so that these can decide correctly) as defined by Augustin in [17].

Altogether, the review included literature on quality management (e.g. [18]), reports on optimization projects in hospitals (e.g. [19]), on concepts of workflow management systems (e.g. [20-22]), process management and process assessment (e.g. [6, 16, 23, 24]).

We verified the preliminary list of quality criteria by conducting a process assessment in selected departments of a university hospital including interviews with healthcare professionals, observation of workflows and document analysis. The resulting criteria were examined several times in order to eliminate redundancies and criteria that could not be clearly assessed. The latter especially affected content-related quality criteria (e.g., correctness or accuracy of information objects like order forms etc.).

The final list contained 19 quality criteria we chose as relevant for the assessment of the information logistics within clinical processes. For example, a quality criterion is "Existence of media cracks" (see Table 2 for further explanation). The complete list is presented in Section 3.1 in Table 1.

2.2 Development of Quality Checks

For each quality criterion we developed an appropriate quality check which can be used to assess the quality criteria in an automatic way. The quality checks describe how information from the process model should be used and connected to assess a given quality criterion. For example, to assess the criterion "Existence of media cracks" (i.e., changes in the storage media – how each information object is stored physically – of information objects during their transcription), details regarding the information objects of a process and the according media information are analyzed.

Table 1 The selected quality criteria for the assessment of information logistics

Quality aspect	Sub-aspect	Quality criteria
Quality of structures	Quality of documentation	Relevance, number of distinct input information objects, distributed access on paper-based information objects, confidentiality and security, transcription of paper-based information objects, degree of standardization
	Quality of physical tools	Adequacy, availability/accessibility, versatility, stability & reliability
	Quality of integration	Controlled redundancy of data
Quality of processes	–	Efficient information logistic, adequate number of tools, information acquisition and usage, existence of media breaks
Outcome quality	–	Efficient communication, usage of mobile information processing tools, redundancy of (final) results/documents, duration of information object storage

2.3 Development of a Process Modeling Notation

We conducted an intensive analysis of available process modeling methods like Bonapart [25], ADONIS [26], UML Activity Diagrams in version 2.0 [9], the ARIS extended Event-driven Process Chains (eEPC) [10] as well as existing extensions of these (e.g., Eriksson-Penker Extensions (EPE) [27] or object-oriented EPC [28, 29]). Due to the focus of the MedFlow on information processing, we also regarded modeling methods that aim to support the management of complex medical information systems (e.g., the Three Layer Graph-Based Meta-Model (3LGM²) [30]). On this basis we developed a process meta-model that collects all information needed for process assessment (see also Section 4.1 for results of a comparison of different process modeling approaches). As process model notation, we chose UML Activity Diagrams and extended it by adding those elements not covered by it. For example, we added information objects which can reside in different media states (i.e., persistency levels) in order to model information processing and transcription.

2.4 Evaluation of the Developed Method

We evaluated the MedFlow process assessment method by using it in a first pilot study in different radiological departments: Here, we chose a typical, complex and interdisciplinary clinical workflow: the ordering, executing and reporting of radiological information. The evaluation and its results are explained in more detail in Section 3.4.

3. Results

We will first describe the MedFlow metamodel, then present the concept of quality checks and the extended notation. Finally, we will describe its application and evaluation in a pilot study.

3.1 The Selected Quality Criteria

Table 1 contains the 19 quality criteria we identified as relevant for the assessment of the information logistic within clinical processes. The criteria are grouped according to three main aspects: "Quality of structures" (it refers to the availability of technical or human resources needed for information processing), "Quality of processes" (it deals with the quality of information processes necessary to meet the user's needs), and "Outcome quality" (it describes whether the goals of proper information logistics have been reached). A further separation of each aspect into more distinct sub-aspects seemed only feasible for "Quality of structures".

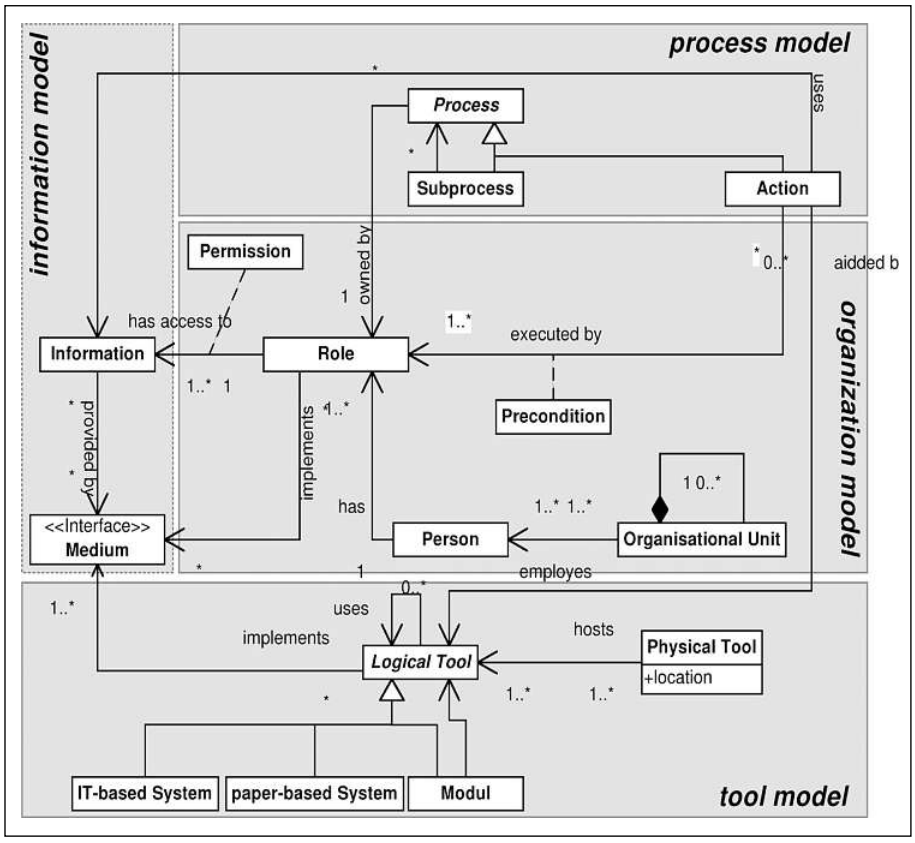


Fig. 1 The MedFlow meta-model for process assessment

Table 2 Example of the assessment of quality criteria within the MedFlow method: Each quality criterion is listed with the corresponding quality check (i.e., view- rule-set pair) and a description of a possible weak point that may occur. The combination of relevant sub-models, elements or attributes is expressed by "×".

Quality criteria	Quality check		Possible weak point
	View	Rule-set	
Existence of media cracks	Information Model × Media Information	All copies of information objects which differ in their storage media from the original	Media cracks occur when the storage media changes during the transcription of data. Errors may occur during transcription and lead to inconsistencies.
Transcription of paper-based information objects	Information Model × Media Information	All copies of paper-based information objects	Transcriptions of paper-based information objects are time-consuming and possibly erroneous
Number of distinct input information objects	Information Model × Process Model	Multiple information objects per action	The process possibly gets stuck due to missing information objects.
Distributed access on paper-based information objects	Information Model × Organizational Model × Media Information	(Multiple actors per information object) AND (All paper-based information objects)	Paper-based information objects could possibly be a bottle neck for process execution if several actors need to access them.
Duration of information object storage	Information Objects × Persistency Levels	All information objects not archived permanently	Information objects (e.g., final reports) are not stored permanently and thus are missing for later examinations.

3.2 The Process Assessment MedFlow Meta-model

The MedFlow process meta-model comprises four sub-models: process model, information model, tool model, and organizational model, each of them concentrating on distinct aspects of processes (i.e., control flow, data flow, tool usage, organizational information). Figure 1 presents the major elements of this meta-model.

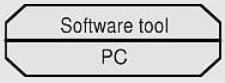
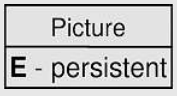
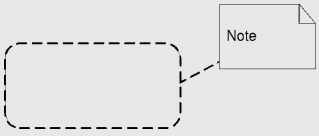
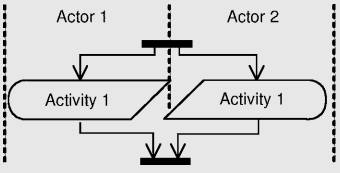
Based on this meta-model, we defined quality checks for the 19 quality criteria we identified as relevant during our analyses. Each quality check describes which elements of the meta-model must be used in order to assess the respective quality criteria. For example, to assess the existence of media cracks, a combination of the information entity with details from the tool model (accessible through the medium-interface) is needed (see left part of Fig. 1). Thus views were defined that focus on certain parts of the meta-model. In order to assess the quality of a process model, a specific pattern ("rule-set") is searched within the appropriate view. The combination of view and rule-set defines a quality check.

Table 2 gives examples on the definition of the quality checks for some of the quality criteria that are listed in Table 1. The first column names the quality criteria, the second lists the combination of sub-models used to examine the quality criteria and the third column describes the rule-set which has to be applied to detect violations of the criteria. The last column gives an example for weak points which might occur when the specific quality criterion is violated. Views can combine elements from one or more sub-models.

3.3 The MedFlow Process Assessment Notation

The notation for the MedFlow meta-model is mainly based on the UML Activity Diagrams, with several elements added – such as *persistency levels* which describe how durable each information object is stored electronically or paper-based (i.e., using paper forms). Table 3 shows some of the newly introduced modelling elements.

Table 3 Some new model elements introduced within the MedFlow-approach

	Element	Meaning
Tool model		A *tool* – represents an IT- or paper-based application system (e.g. software tool) and the implementing physical system (e.g. PC). Besides it can store the information about the location of the physical system.
Information model		An *information object* – is an abstraction of a real-world entity. It can represent a patient record or a picture etc. The lower layer tells how the information object is stored/transmitted ('E' = electronic, 'P' = paper). Additionally, each information object can reside in different persistence states – depending on how long and how safe it is stored. In total, there are four distinct persistency levels: "archived" (i.e., stored with high reliability for a long time e.g. on a long-term archive), "persistent" (i.e., stored for distributed access with reasonable reliability on e.g. department information system), "local persistent" (i.e., stored on a local PC with the possibility of being easily deleted), "transient" (i.e., notes or spoken words which are only stored for a very short term).
Process model		The *alternative process flow* – marks the beginning and end of a process segment which has several possible alternatives.
		The *alternative process actors* – represent those alternatives which only differ in the actors who perform the highlighted activities. All affected activities are grouped in the frame. The note contains information about the alternative actors.
		*Shared activity* – represents an activity which is performed simultaneously by several actors. Thus the affected activity is split into activity parts. The synchronization bars show that these parts are performed in parallel.

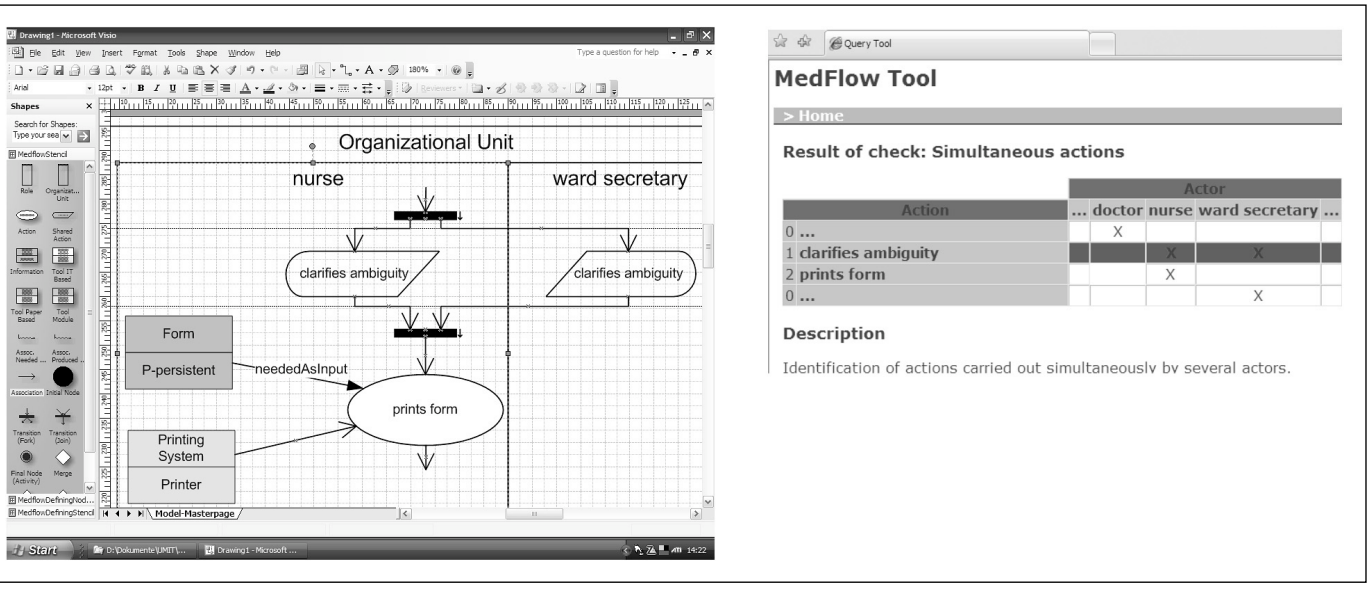


Fig. 2 Screenshot from the MedFlow tool – left: modelling GUI implemented as extension of MS Visio, right: output window of the prototypic MedFlow assessment component, presenting the result of a check.

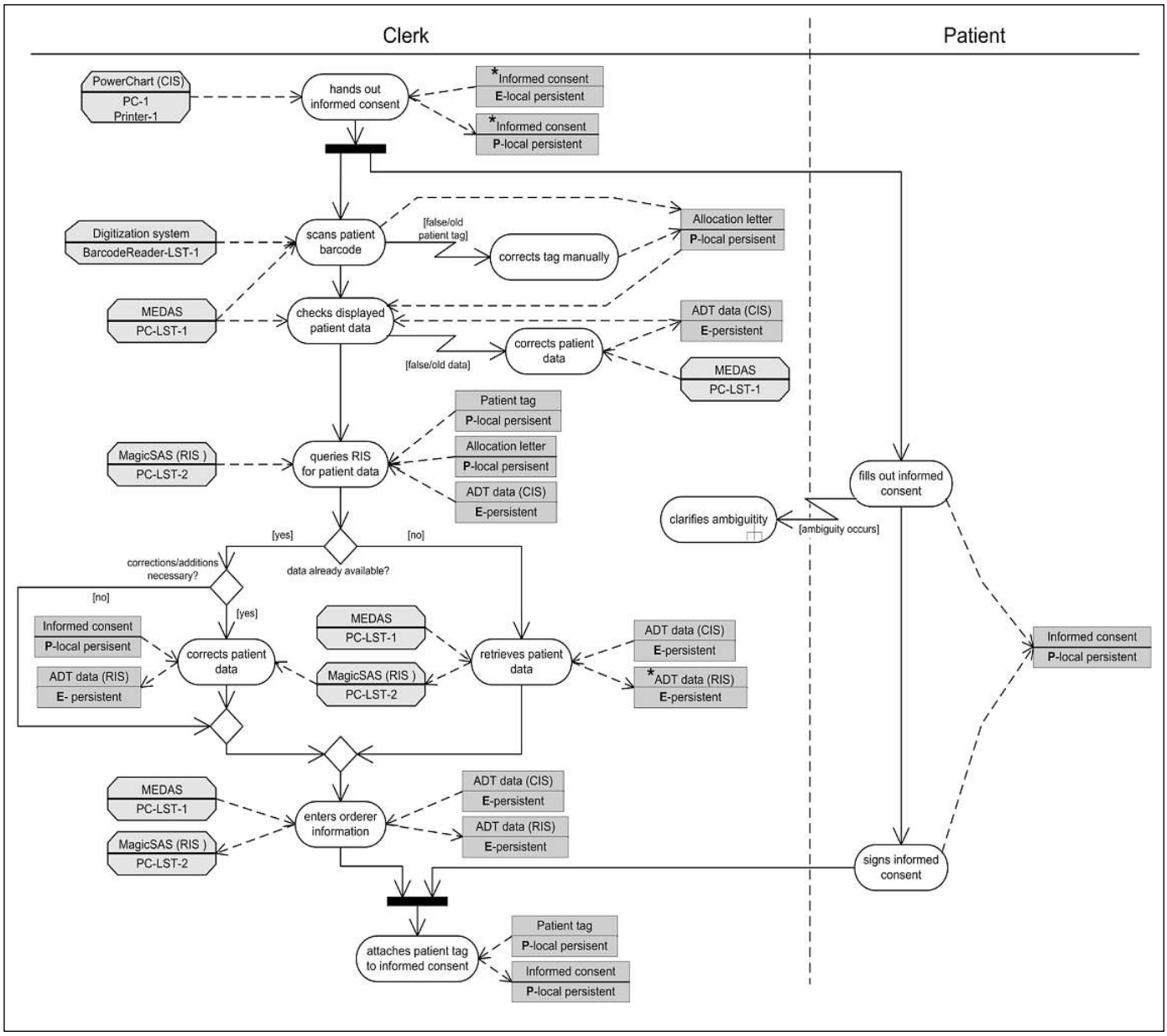


Fig. 3 Excerpt from the process model of "ordering radiological examinations" – Included application systems are: MEDAS (software application for patient administration), MagicSAS (application system used as radiology information system), PowerChart (application system used as clinical information system), Digitization system (application system used for scanning patient bar codes). Each application system is deployed on a physical system that is uniquely identified (e.g., "PC-LST-1" assigns a PC of the requesting department). For explanation of the different information object states (e.g., "E-persistent") see Table 3.

3.4 The MedFlow Process Assessment Tool

To support process modeling and process assessment, we developed a process modeling tool. It supports the extended MedFlow notation and allows the automatic execution of quality checks.

3.5 Evaluation of the MedFlow Method in a First Pilot Study

In a first evaluation step, the MedFlow method was used to model the process of ordering radiological examinations and result reporting. The goal was to examine whether it is practically possible to detect weak points with the help of the newly developed method.

In total the ordering processes of five different hospital departments (ambulatory and stationary) as well as the process of performing the examination in the radiological department were modeled and assessed. In the modeling stage the project team was separated into two independent observation

teams that visited the departments. Each team consisted of four project members. The teams visited the departments several times to clarify remaining or new questions. Here, each team was assisted by members of the observed department. One project member was assigned responsible for summarizing all gathered details and to include them into the process model. After each iteration the process model was discussed by all project members. These steps were repeated until all remaining questions were answered and a common agreement was found on the completeness of the process model. The final model was then validated with members of the observed department. It comprises 121 activities (including 20 instances of the newly introduced process element "shared activity"), 21 different types of information objects, 13 different types of logical tools (e.g., software applications) on 21 distinct physical subsystems (e.g., servers).

Based on the created process model, all quality checks were tested, that means the views were automatically derived, and the rule-sets applied. The observations that were made in that stage are summarized in Sections 4.2 and 4.3. In the following, we will present two examples in which quality checks are applied on the process model excerpt shown in Figure 3.

3.5.1 Example 1: Media Cracks

Media cracks are defined as changes in the storage media (i.e., how each information object is physically stored) of information objects during their transcription [15]. This kind of transcription is critical because it can cause inconsistencies. Media cracks can be detected with the MedFlow method by using a view that lists all elements of the information model together with their media information (see Table 4).

An extraction of such a view is shown in Table 4 – it was automatically generated out of the model excerpt shown in Figure 3: The lines of the matrix contain the information objects (e.g., informed consent which is created, read, written or copied in the process). The columns contain the possible media states in which information objects can reside (e.g., in Table 4 "E-persistent" means that the information object is stored permanently on a server where it is available for distributed access). Each information object can reside in only one media state. If copies are made, it must be examined whether their storage medium differs from the original. All copies of one information object (including the original one) are represented by a single row of the view. For each of the media states of these information objects cross points are entered in the appropriate column. A cross point means that an information object is represented at least once in the process in this state. Thus, multiple cross points in one row with different media types indicate a media crack. This is the case for the information object "Informed consent" in Table 4.

Table 4 Excerpt from a view that detects media cracks – the view lists all information objects whereas the quality check highlights all redundant information objects which are stored on different media types.

Inform. object \ Media information	…	E-local persistent	P-local persistent	E-persistent	P-persistent	…
Informed consent	…	×	×			…
Allocation letter	…		×			…
Patient tag	…		×			…
ADT data	…			×		…
…	…	…	…	…	…	…

Table 5 Excerpt from a view that detects possible information object shortages – the view lists all process activities whereas the quality check highlights all activities which read more than one information object.

Activity \ Information object	…	Informed consent	Allocation letter	ADT data (CIS)	ADT data (RIS)	Patient tag	…
…	…	…	…	…	…	…	…
Queries RIS for patient data	…		×	×		×	…
Corrects patient data	…		×				…
Retrieves patient data	…			×			…
Enters orderer information				×			
…	…	…	…	…	…	…	…

3.5.2 Example 2: Number of Distinct Input Information Objects

Possible process interruptions due to information shortages can be detected by combining elements of the information model with the process activities. The columns of this view are filled with information objects. The activities are filled into the rows of the view. Cross points are entered where activities require reading-access on information objects. The accessed information objects are supplied by different sources. The more information objects are required the merrier single information objects are potentially missing. Thus, the check filters all activities with more than one accessed information object. All rows with more than one cross point are highlighted (see Table 5).

4. Discussion

The MedFlow method is meant to support the structured assessment of clinical processes: An own model integrates four submodels with each concentrating on distinct process aspects (i.e., control flow, data flow, tool usage, organizational information). In

order to assess the quality of a process, selected process details are combined in "views". Weak points are then detected by applying specific rule-sets on these views. Each rule-set represents a pattern of critical cross-points which are searched for in the appropriate view-matrix.

The quality criteria on which the quality checks are based were acquired by an interprofessional working group that consisted of three scientists from the fields of computer science and biomedical informatics. This working group was additionally supported by one quality management specialist.

This paper presented examples from a first application of this method. These examples resulted from a first formative evaluation of the MedFlow method. We implemented some quality criteria that we selected because of their relevance for the clinical domain, but also because of their applicability within the MedFlow method. We did not yet implement and test all quality criteria.

4.1 Comparison to Other Approaches

Methods for the systematic assessment of clinical processes are rarely found [31]. A systematic literature review showed that the methods for assessing clinical processes can be categorized into the following three groups.

4.1.1 Informal Methods

These methods are motivated by a financial-focused background (e.g. [32]). Clinical processes are described with modeling methods like Flow Diagrams or Swim Lane Diagrams which are not based on formal definitions (i.e., Petri-nets or finite state machines) – these models are rather intended for communication purposes. Thus, the elements of the resulting models cannot be assessed automatically. Besides the process control flow only participating roles and activity costs are regarded. Process assessment in these approaches (e.g. [33, 34]) mostly focuses on financial improvement. The costs for each activity are recorded (e.g. average maintenance costs), summarized for the whole process and compared with the financial income of the department or hospital [33]. This is done by controlling or a task force of domain experts [34]. Thus, the feasibility of the assessment and the derived improvements directly depend on the expert's expertise. Further, details regarding the information object logistics which are essential for clinical processes are mostly ignored.

The MedFlow method especially emphasizes information object logistics including the involved information processing tools. Weaknesses in information logistics can also manifest in financial disadvantages.

4.1.2 Semi-formal Methods

Methods which are developed based on established BPR-methods like ARIS EPC – that are formally based on e.g. Petri-nets – and extend these by domain-specific details. For instance, the approach of Gospodarevskaya emphasizes in [35] the importance of the commitment of involved roles. Therefore, a "mixed-method" approach was used – combining interpretative field study with process modelling on basis of EPC. Recommendations were made for expanding the EPC. However, assessment capabilities that evaluate the emphasized human-aspects are not introduced. The feasibility of the process assessment depends on the generic methods of the ARIS toolset.

A more IT-focused method is introduced by Lenz et al. in [36]: It is meant to facilitate the adoption of a hospital's information system to already detected improvements. Clinical processes are modeled with the MapDoc-notation which includes elements equivalent to MedFlow process models.

In contrast to MedFlow, process models are neither analyzed in order to detect possible weak points nor considered for measuring any improvements. Instead, Failure Mode and Effects Analysis (FMEA) is performed – again relying on questions like "What could go wrong?" or "Why would the failure happen?".

4.1.3 Formal Methods

These methods are meant to support process control flow improvement. They were developed to cope with complex processes which also show big variations in execution [37]. Clinical processes are modeled based on adopted Petri-nets (e.g. [38] or MOSAIK-M [11]), finite state machines (e.g. [39]) or combinations of both (e.g., MLDesigner [12]). Process models used for simulation and formal methods like reachability analysis are applied, in order to determine bottlenecks and best performing variations [40]. However, the feasibility of these methods relies on "what if"-questions of the methods' users or the comparison of the current process with a planned one. Thus, there is no direct systematic support during the assessment so that possible weak points can be missed or forgotten. In this way, the completeness of the assessment strongly depends on the viewpoint and abilities of the evaluators.

In contrast, the MedFlow method supports the systematic and semi-automatic assessment of clinical processes with all quality checks which have been identified as relevant in advance.

Recapitulating, it can be stated that although there are powerful process assessment methods, systematic support during the assessment is still missing – the detection of possible weak points within the assessment results can be seen as an interpretive act of either one or more assessing persons. The MedFlow method is meant to support the systematic assessment by providing concrete checks for specific weak points that can occur in the processing of information objects.

4.2 Strengths of the MedFlow Method

The following observations regarding the strengths of the MedFlow method were made during the evaluation:

- The concept of view/rule-set seems rather flexible and generally applicable. New quality checks can be defined

quickly on the basis of elements which are available in the meta-model (see Section 3.2).
- The assessment results comprise only those details that are essential for the selected quality check and the underlying assessment question.
- The process assessment bases on quality checks which are collected in a structured table (see Table 2 for an excerpt). All checks can be applied automatically on process models. In this way, none of the checks are skipped.

4.3 Limitations of the MedFlow Method

The general limitations of our approach are common to all model-based assessment approaches: the feasibility of this kind of assessment directly depends on the correctness, consistency and completeness of the specific process model. Guidelines for process analysis and modelling should be developed to guarantee a sufficient model quality (see for instance the guideline of MOSAIK-M [11]). The whole model and assessment process is time-consuming, complex and needs to be carried out carefully. Therefore, it is only feasible for single clearly outlined processes that should be restructured and should be carried out by an inter-professional working group.

Further limitations comprise:
- Limitations due to the implementation-specific meta-model: The meta-model describes the relationships within and between sub-models. In order to use it for building a model repository which can be queried for its details, the meta-model must be translated into a machine-useable form (i.e., database scheme for a central model repository, see [41] for details). The implementation of quality checks required sophisticated database queries. Some of the required relations could not be realized. Thus, not all necessary views could be generated by the prototype.
- Limitations due to the expressiveness of views: Some quality checks require process details that cannot be represented in form of a view (i.e., combination of process details – see also Section 3.2).
- Limitations due to the validity or rather adaptability of the used quality criteria: Certain quality criteria cannot be handled by our meta-model, such as criteria on the quality of documentation (e.g., "confidentiality and security" or "degree of standardization"). Their checks would require the representation of content within the meta-model. Whether this is possible has to be further examined in more detail.

In total, we were able to implement 14 of the 19 quality checks. The quality checks that were not implemented are: "confidentiality and security", "degree of standardization", "adequateness", "usage of mobile information processing tools" and "redundancy of (final) results/documents" (see Table 1 for all quality criteria).

Overall, the MedFlow approach seems to be suitable for assessing aspects of the quality of processes such as the quality of information logistics. This is because the media type information and the defined storage states within the information model support the basic assessment of the information object life cycle. In contrast, aspects such as staff overview, quality of communication and cooperation etc. cannot be represented. Further case studies are planned in order to examine the applicability and suitability of the MedFlow approach.

5. Conclusion

The MedFlow method is best used to assess clinical processes regarding their control flow (i.e., the sequence of involved activities – including control elements like associations, conjunctions and disjunctions) and information handling. The latter represents criteria like "duration of information object storage". The information-handling deals with the acquisition of new information objects (e.g., final report or ordering of examination), their manipulation and storage. The correct handling of information objects directly influences the quality of communication between involved actors or hospital departments. This in turn is essential for good treatment processes.

The presented approach could help to improve the documentation and communication within clinical processes. This also includes the involved infrastructure in terms of logical tools (e.g., software applications) and physical tools (e.g., server). Therefore, further developments should concentrate on these aspects. After this, the resulting method could be used to derive performance indicators, e.g. by analyzing the result-sets for critical patterns. Tools which will be implemented on the basis of this approach could be used in scope of strategic and tactical information management.

Acknowledgments

The MedFlow project was supported by the Austrian Ministry for Economy and Labor. It was realized in close cooperation with the Institute of Computer Science (University of Innsbruck), the Department for Information and Software Engineering (UMIT), and the Information Technologies for Healthcare GmbH. Earlier versions of this work have been presented at MIE2006 and GMDS2006.

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