

A process mining-based investigation of adverse events in care processes

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Abstract

This paper proposes the Clinical Pathway Analysis Method (CPAM) approach that enables the extraction of valuable organisational and medical information on past clinical pathway executions from the event logs of healthcare information systems. The method deals with the complexity of real-world clinical pathways by introducing a perspective-based segmentation of the date-stamped event log. CPAM enables the clinical pathway analyst to effectively and efficiently acquire a profound insight into the clinical pathways. By comparing the specific medical conditions of patients with the factors used for characterising the different clinical pathway variants, the medical expert can identify the best therapeutic option. Process mining-based analytics enables the acquisition of valuable insights into clinical pathways, based on the complete audit traces of previous clinical pathway instances. Additionally, the methodology is suited to assess guideline compliance and analyse adverse events. Finally, the methodology provides support for eliciting tacit knowledge and providing treatment selection assistance.

Keywords (MeSH):

Clinical Pathways; Medical Informatics; Quality of Healthcare; Hospital Information Systems; Information Storage and Retrieval

Introduction

Healthcare management is under pressure and not only because of financial constraints. The 1999 'To Err is Human' report (Kohn, Corrigan & Donaldson 2000) made clear that safety issues are common in hospitalised patients. Next to human contribution to medical failure, system failures are among the main reasons that lead to adverse events and inefficiency (Committee on Quality of Health Care in America IoM. 2001). Healthcare managers should therefore identify and understand how healthcare processes work.

Facilitating the organisation of healthcare around the patient's perspective and needs (which requires identification of their priorities), rather than around types of professionals and organisations, is advocated (Committee on Quality of Health Care in America IoM. 2001). In 2007, Michael Porter defined three main strategies to change the future of healthcare: (1) The goal must be value for patients, (2) Medical practice should be organised around medical conditions and care processes and (3) Results—risk-adjusted outcomes and costs—must be measured and followed-up (Porter, Olmsted & Teisberg 2007). Savitz, Kaluzny and Kelly (2000) suggest focusing on clinical process innovations not only to set clinical processes around medical conditions as the primary focus of the organi-

sation, but also to standardise and continuously improve them.

One method of innovation in clinical processes is the development and implementation of clinical pathways, also known as care pathways, critical pathways or sometimes even as care programs or shared baselines (Pearson, Goulart-Fisher & Lee 1995; Vanhaecht et al. 2012). Clinical pathways have been used since the 1980s and are defined as complex interventions for the mutual decision making and organisation of care for a specific patient group during a well-defined period (Vanhaecht, Sermeus & van Zelm 2010). The use of mechanisms from clinical process innovations and clinical pathways can lead to significant changes. This was recently demonstrated by James and Savitz in their paper describing how Intermountain Healthcare trimmed healthcare costs through robust quality improvement efforts (James & Savitz 2011). These improvements were only possible because Intermountain Healthcare understands how their care processes work and learns from its data on variation. Understanding processes and variation was possible because of the availability of recent and reliable data. As more hospitals are investing in electronic patient records (Bates et al. 2003), data will become more readily available, but one of the chal-

lenges will be to analyse this data jungle and translate the findings in an appropriate way that is understandable to both healthcare managers and clinicians.

In this paper we elaborate a method for clinical pathway analysis with process mining techniques.

Clinical pathways and process mining techniques: a brief overview

In this section we first define clinical pathways and discuss their typical characteristics, followed by a discussion of the analysis techniques that can be used for clinical pathway analysis.

Clinical pathways and typical characteristics

Several research contributions have identified the lack of a uniformly accepted definition of a clinical pathway. Kinsman et al. (2010) undertook an extensive literature review and suggested the following definition:

A clinical pathway is an intervention with a structured multidisciplinary plan of care plus three out of the four following criteria: (i) the intervention was used to translate guidelines or evidence into local structures, (ii) the intervention detailed the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other inventory of actions (iii) the intervention had timeframes or criteria-based progression and (iv) the intervention aimed to standardise care for a specific clinical problem, procedure or episode of healthcare in a specific population (Kinsman et al. 2010: 8:31).

Business processes, on the other hand, are defined as sets of activities that allow the realisation of certain goals within a specific business environment and a particular organisational context. The environment may dictate certain constraints for a business process, for example on the activity sequence or activity allocation. Applying this definition to the healthcare industry uncovers many similarities with clinical pathways: both are multidisciplinary, specify a standardised plan to achieve a certain goal and contain restrictions (e.g. relative time-based constraints such as activity precedence constraints) (Gooch & Roudsari 2011). These activity patterns may include a wide variety of activities such as diagnostic tests, the administration of specific medication or activities related to treatment and rehabilitation. Note that while describing the workflow might be considered as the predominant perspective on business processes, other perspectives do exist, namely the organisational perspective and the data perspective (Curtis, Kellner & Over 1992).

Clinical pathways represent prescriptive models of the standard healthcare procedures that need to be undertaken for a specific patient population (Stead

et al. 1997). Instances of the clinical pathways (also known as cases) describe the actual diagnostic-therapeutic cycle of an individual patient. Typically, real-life clinical pathways are characterised by the following unique set of properties:

- *High flexibility.* Patients most often do not come with exactly the same mix of medical conditions (e.g. heart conditions, pregnancy, allergies) (Ye et al. 2009). Additionally, medical experts have to deal with uncertainty during treatment, for example unexpected outcomes such as adverse drug reactions, drug allergies, heart failure or other complications.
- *Complex decision making.* While the medical knowledge used in the decision process comes partially from published research contributions and widespread medical guidelines (with various kinds of evidence levels), it is generally accepted that the decision process is profoundly influenced by the expertise and experiences of the involved medical experts. High levels of autonomy are commonly awarded to the experts, which results in a high responsiveness in critical situations (Ball 1971).
- *Network of specialists.* While a horizontal job specialisation allows those experts to acquire a deep knowledge within a specific medical discipline, it often renders it impossible for an expert to execute every activity in a clinical pathway. Consequently, clinical pathways are predominantly performed by a network of collaborating medical specialists, all with high levels of autonomy to decide on their working procedures (Vanhaecht 2007). Clinical pathways enable coordination between medical experts and their specific activities.
- *High information needs.* Within clinical pathways there exist high information requirements in terms of both accuracy and availability. Patient-specific and situational information are crucial for the decision making processes of individual medical experts. Consequently, a large variety and amount of patient specific information must be exchanged between actors both within a pathway instance and between different pathway instances (Blaser et al. 2007). As a patient can be involved in multiple pathway types, inter-pathway information exchanges may take place between pathways of different types.
- *Continuous evolution.* A strong academic background, experience-based insights and technological developments as well as economic and governmental pressures contribute to an often implicit but continuous evolution of medical practices and the related clinical pathways (Pace et al. 2002).

While we expect the instances to strongly adhere to the prescriptive clinical pathways, deviations for specific situations are often required. This high degree of process variability and non-repetitiveness in clinical pathways is the direct result of the previously mentioned characteristics.

Process mining principles and perspectives

During the performance of a clinical pathway a multitude of relevant *events* may occur. Events may represent transitions in the clinical pathways (i.e. the execution of activities), but also changes in the environment (e.g. an adverse drug reaction or a cardiac arrest). All these events occur at a specific time and are of special interest in the treatment of specific patients.

Contemporary information systems store a multitude of information on these events in a structured manner. An *audit trail*, also known as a trace or event sequence, for each specific pathway instance is precisely recorded in the event logs and represents the full diagnosis-treatment cycle of a specific patient. An extract of such an *event log* can be found in Table 1. For each event in this extract the information system recorded the patient identifier (the case ID), the medical activity (the event type), the treatment code, the originator’s department, the diagnosis and the exact time of occurring (the timestamp).

Process mining techniques enable the translation of huge amounts of event data, covering the interaction of patients with the hospital, into a well-organised description of the real pathways. Accordingly, the models obtained through process mining are descriptive, which is in sharp contrast with the modeling efforts (typically resulting in prescriptive models)

that have been undertaken in the context of clinical pathways (Stausbert et al. 2003; Lenz, Peleg & Reichert 2012).

A wide variety of analysis techniques has been proposed in the process mining literature. These techniques can be easily classified according to the main purpose of the analysis (the *process mining perspective*), which is comparable to the process model perspectives presented in Curtis, Kellner and Over (1992): *First*, the functional analysis deals with the existence, absence or coexistence of certain process elements (e.g. specific activities). *Second*, process analysis focuses on the exact ordering of the events and activities; typical analyses include control-flow discovery, gap analyses and bottleneck identification. A *third* application focuses on analysing the human resource aspect of a process, typically resulting in an analysis of responsibilities, authorisation issues or social networks. The *fourth* set of process mining analyses, related to the case perspective, takes into account any other type of information that has been recorded in an event log. Therefore, these techniques are well suited for identifying process variants, root cause analyses and correlation analyses.

Building a case for process mining based clinical pathway analysis: three suggested application areas

In this section we introduce three broad application areas for process mining techniques in a healthcare setting: (i) analysing recurring patterns, (ii) pathway variants and (iii) exceptional or adverse events. Each of these applications can be performed using the four different process mining perspectives. Figure 1 provides a schematic overview.

Table 1: Event log extract

CASE (PATIENT)	EVENT TYPE	TREAT.	DEP.	DIAGNOSIS	TIME (TIMESTAMP)
155	follow-up polyclinic consultation	61	SGNA	gyn. tumors	1-Jan-05
156	cytological examination vagina	61	LVPT	gyn. tumors	1-Jan-05
156	histological examination	61	LVPT	gyn. tumors	1-Jan-05
275	teletherapy	13	RATH	gyn. tumors	1-Jan-05
275	follow-up polyclinic consultation	13	SGNA	gyn. tumors	1-Jan-05
336	potassium flame photometry	603	CHE2	malign cervix	1-Jan-05
336	differential count	603	HAEM	malign cervix	1-Jan-05
336	determination trombocyte level	603	HAEM	malign cervix	1-Jan-05
336	count of leukocytes	603	HAEM	malign cervix	1-Jan-05
10	count of leukocytes	113	HAEM	malign cervix	4-Jan-05
10	determination trombocyte level	113	HAEM	malign cervix	4-Jan-05
72	differential count	3101	HAEM	malign ovary	16-Jan-05

Discovering recurring patterns in clinical pathways

Highly specialised medical experts are often confronted with ‘similar’ instances of this cause-effects-solutions relation and, as a consequence, they might unconsciously develop optimisations of the clinical pathways.

Process discovery and visualisation techniques summarise full and precise insights on the clinical pathways reality in one visual report. Process discovery techniques, such as alpha (van der Aalst, Weijters & Maruster 2004), alpha ++ (Wen, Wang & Sun 2006), fuzzy (Günther & van der Aalst 2007) and heuristics miner (Weijters, van der Aalst & Alves de Medeiros 2006), can be used to obtain models of the as-is pathways. Frequency and dependency measures are frequently used in these techniques and enable the analyst to respectively determine the most common executions trails and the confidence in mined activity sequences.

Whereas process visualisation techniques have traditionally focused on the process perspective, other pathway analyses might be of interest. Potentially interesting techniques include the performance sequence diagram analysis (van der Aalst et al. 2009), the originator-by-task matrix (van der Aalst et al. 2009), social network miner (van der Aalst, Reijers & Song 2005) and the bottleneck analysis (van der Aalst 2009).

Analysing and characterising clinical pathway variants

The medical condition of patients is determined by a broad set of characteristics and factors (e.g. type and location of the tumor, age of the patient, pregnancy, allergic reactions). The uncertainty can be reduced (and consequently the quality improved) by defining a clinical pathway’s variants and specifying the unique factor combinations for each variant. By comparing the specific medical conditions of patients with the factors used for characterising the different clinical pathway variants, the medical expert can identify the best therapeutic option.

Different approaches can be used for identifying new clinical pathway variants. First, the analyst could perform a correlation analysis on the factors, which are usually hidden in the data perspective. After the uncovering of important factor correlations, traces can be filtered and the common process characteristics for this process variant can be documented. Secondly, a trace clustering technique can be used to cluster pathway traces (i.e. a form of unsupervised learning), followed by an analysis of the factors in each cluster (Bose & van der Aalst 2012). Finally, an expert can propose interesting factor combinations (e.g. combination of treatment and diagnosis code).

Identifying and analysing exceptional medical cases and/or adverse medical events

Two broad sets of techniques are of main interest for uncovering both exceptional cases and adverse events:

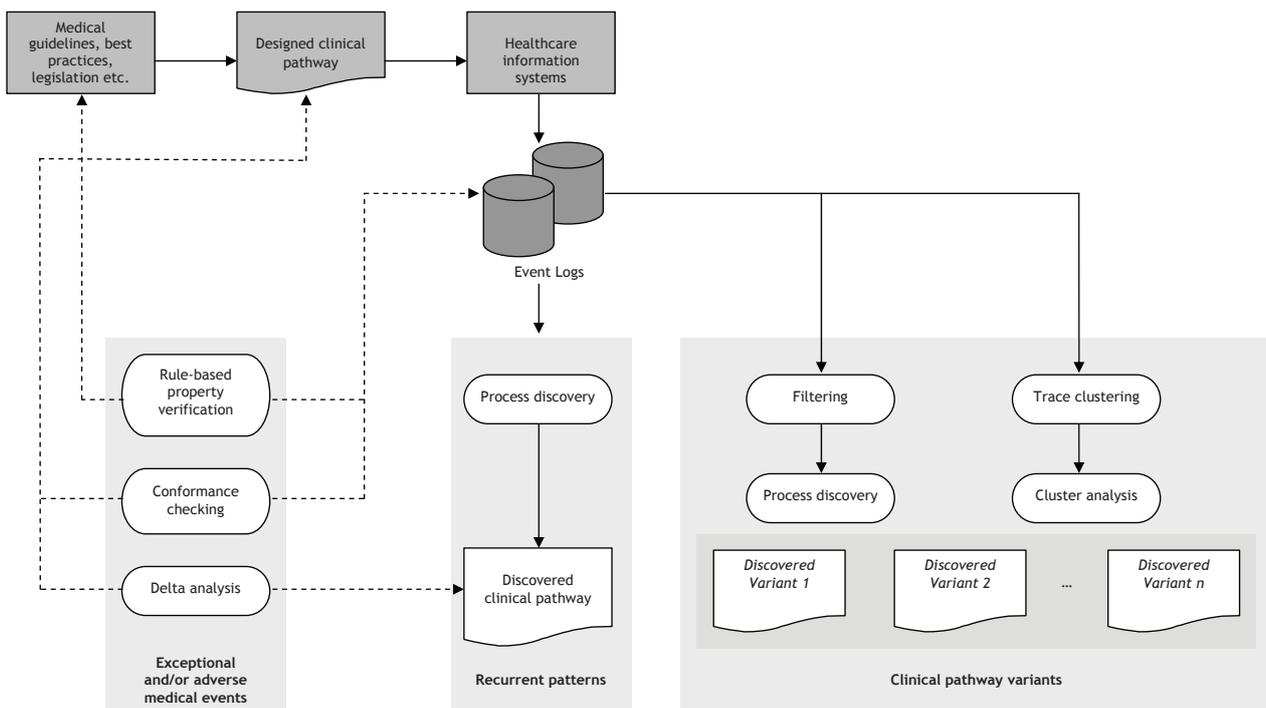


Figure 1: Process mining architecture for clinical pathway analysis

conformance checking and delta analysis techniques and rule-based property verification techniques.

Conformance checking and delta analysis both aim at detecting inconsistencies between a designed prescriptive model of the clinical pathway and its corresponding real-life process (Rozinat & van der Aalst 2008). The major difference lies in the comparison base for the real-life pathway: conformance checking uses the event log while delta analysis uses a derived process model. These techniques allow for an in-depth analysis of the deviations on the process model. In contrast metrics for the recall or fitness dimension, provide an indicator of the extent to which the behaviour in the event log can be associated with valid execution paths in the prescriptive process model.

Rule-based property verification approaches provide support for verifying specific questions, based on medical knowledge, guidelines and best practices.. Examples of properties the analyst might want to check include the presence of a consultation, task allocation restrictions and specific activity preconditions. The following ProM plug-ins provide application-independent rule-based support: LTL-checker (van der Aalst, De Beer & van Dongen 2005), semantic LTL-checker (Alves de Medeiros, van der Aalst & Pedrinaci 2008), SCIFF checker and configurable CLIMB rules (Montali 2010).

Proposing a method and roadmap for clinical pathway analysis

In this section we propose and characterise our clinical pathway analysis method (CPAM), followed by the elaboration of an extensive description of the roadmap that can be used for clinical pathway analysis projects.

Characterising the clinical pathway analysis method

Multiple methods could be used to obtain insight into healthcare operations, including observation, simulation and interviewing medical experts. However, most techniques are confronted with intrinsic limitations such as the difficulty of uncovering tacit knowledge through interviews. *Process mining-based* analytics enables the acquisition of valuable insights into clinical pathways based on the complete audit traces of previous clinical pathway instances.

The goal of this process mining-based analysis method is to provide *focused analyses on targeted subsets* of the event logs to support the described applications. This method should comprise the project definition, the extraction and preprocessing of data, the actual analyses and the indication of potential pathway improvements. Combining focused analyses

and targeted subsets for clinical pathway analysis results in the following properties. First, process mining techniques are highly suitable for *synthesising pathway data/information* using one of the four process mining analytic techniques. Second, as the primary focus will be on the clinical pathways, an extensive *interplay* between analyst, medical domain experts and research and local experts will be required. Third, in order to produce meaningful analysis results this method incorporates the notion of *perspectives on clinical pathways* (e.g. diagnosis, treatment, department or drugs perspective). Fourth, this methodology can be employed in the context of *need-driven* (i.e. pathway exploration, efficiency and effectiveness improvements or quality assessment, monitoring and improvement) or *pro-active/knowledge creation* projects.

The clinical pathway analysis method roadmap

The *roadmap* related to the *clinical pathway analysis method* consists of seven distinct phases, for which a relaxed sequential path is proposed. An overview can be found in Table 2.

The three process mining application areas will be present in the analyses performed in the context of both the exploratory pathway analysis phase and the advanced pathway analysis phase. The discovery of recurring patterns and variants will be more suited for exploratory analyses, whereas the identification and analysis of exceptional medical cases and adverse medical events area will be more common in the advanced pathway analysis phase. The identification and analysis of exceptional cases and events might directly result in suggestions for further improvement of the clinical pathways.

Typically, a clinical pathway analysis starts with determining the *project definition*. The analyst and the involved medical experts agree on the pathway scope, the timeframe interval and practical issues. In terms of pathway scope, a trade-off will be made between overview and understandability. While a larger pathway scope tends to enable broader analyses, the resulting models tend to become more complex and less understandable. The selection of the timeframe may have repercussions for the behaviour present in the event log, for example recent changes in medical practices might become irrelevant if the timeframe is set too wide.

After the project definition has been formulated the event sources should be identified. Contemporary healthcare organisations are supported by a multitude of event generating information systems (e.g. pathway support, cost-registration systems, operating systems of certain high-end medical equipment). Additionally,

Table 2: A roadmap for the clinical pathway analysis method (CPAM)

Phase I	Project definition & event log extraction			
	<ul style="list-style-type: none"> Define pathway scope definition Identify event sources Select event log attribute Construct event log 			
Phase II	Event log preprocessing			
	<ul style="list-style-type: none"> Select log format and transform event log Deal with log divergence Event log specific operations, e.g. (re)grouping of activities, scrambling personal information, etc. 			
Phase III	Perspective selection			
	<ul style="list-style-type: none"> Identify interesting perspective (patient, treatment, diagnosis, department or drug) Perform necessary log filtering operations Identify and describe potential information losses, provide a solution to deal with the information losses 			
Phase IV	Exploratory pathway analysis			
	Functional analysis	Process analysis	Organisational analysis	Data analysis
	<ul style="list-style-type: none"> Existence/absence of activities Activity co-existence Additional analyses 	<ul style="list-style-type: none"> Workflow discovery Process variant analysis Additional analyses 	<ul style="list-style-type: none"> Social network analysis (teams, hand-overs, interactions) Task allocation Additional analyses 	<ul style="list-style-type: none"> Data-driven conditions Correlations data and pathway structure Additional analyses
Phase V	Medical confirmation			
	<ul style="list-style-type: none"> Review by medical expert(s) of results Comparison with medical guidelines Determine whether the results represent local conditions Externalisation of knowledge 			
Phase VI	Advanced pathway analysis			
	Efficiency analysis		Quality and conformance analysis	
	<ul style="list-style-type: none"> Bottleneck analysis Number & duration of diagnosis & treatment cycles Performance analysis and comparison Additional analyses 		<ul style="list-style-type: none"> Rule-based pathway analysis Conformance & delta analysis Analysis of adverse events Root-cause analysis for variation Additional analyses 	
Phase VII	Improvement of pathway			
	<ul style="list-style-type: none"> Adapt clinical pathway models according to new insights Reinforce existing to-be models 			

the analyst might combine events from different sources. Notice, however, that linking events from different sources to the same pathway instance can be challenging. Another important *event log construction* challenge is the selection of event attributes. Selecting an overly limited set of attributes can affect the quality of the analyses as the analyst might not be able to detect certain correlations between medical factors and pathway variations. Overly large sets, on the other hand, may seriously reduce the performance of the process mining tools.

Generally, the *event log preprocessing* (i.e. the second phase), starts with the selection of a suitable

event log format (e.g. the MXML or XES format). Furthermore, the pathway analyst can be confronted with divergent event logs, event logs containing audit trails for which one activity is registered several times for a specific process instance. For example, cost-tracking or billing information systems might register multiple units of a drug for the same treatment cycle, which could result in a misinterpretation of the number of treatment cycles. Aggregated activities should be created when confronted with divergent event logs, this could be done automatically with the activity clustering plug-in (van der Aalst 2009). Finally, the second phase is ended with some event log specific

operations. These operations can include scrambling personal information and (re)grouping activities (e.g. grouping all frequently coinciding general lab tests).

The third phase, the *clinical pathway perspective selection*, is fundamental as it might seriously improve the understandability and focus of the resulting models and analyses. In addition to the patient perspective on clinical pathways, we have identified four distinct perspectives on clinical pathways (i.e. treatment, diagnosis, department and drug perspective). Those perspectives look at the clinical pathway elements (e.g. activities, sequences, originators) in the context of respectively a treatment, a diagnosis, a department a specific drug (across multiple treatments). Additionally, the combination of different perspectives may result in interesting conclusions. Once the perspective (combination) has been chosen the necessary filtering operations need to be performed and the analyst should reflect on potential information losses. If the goals described in the project definition span over multiple perspectives (combinations), it will be necessary to perform this and the following phases at least once for each chosen perspective.

Once the event log has been constructed and the perspective selected, the analyst can start with *exploratory pathway analyses*. A broad spectrum of process mining techniques can be used for functional, process, organisational and data analyses. Results of the exploratory analysis can be discussed with the involved *medical experts*. They are most suited to review the results, compare them with existing medical guidelines and with local conditions and/or specify additional exploratory analysis (iteration between phase four

and five). If, after a specialist's evaluation, the results are regarded as medically valuable and valid, the fifth phase can end with an externalisation of the results.

While phase four consists of broad open-minded exploratory analyses, phase six consists of more *advanced and goal-driven (efficiency, quality and conformance) analyses*. General efficiency analyses include the identification of bottlenecks, the number and duration of the treatment cycles and performance comparisons between treatments for the same diagnosis. Quality and conformance analyses may include the evaluation of medical rules, conformance analysis (model-based) and analysis of adverse events and their causes. If the project definition only consists of checking the conformance of clinical pathways (specified as medical rules), phases three, four and five can be skipped.

Ideally, clinical pathway analyses should result in recommendations for *improvement*, that is the adaption of pathways to new insights. The logical next step in this methodology would be the continuous monitoring and controlling of the (improved) clinical pathways. This continuous monitoring and controlling, however, falls beyond the scope of this contribution.

Discussion of the proposed approach

Figure 2 graphically summarises the proposed clinical pathway analysis method. The seven phases can be regrouped in three main categories: definition and event data collection activities, pathway analysis activities and pathway improvement activities. In this section we look at the opportunities, the attention points and future research direction for the CPAM.

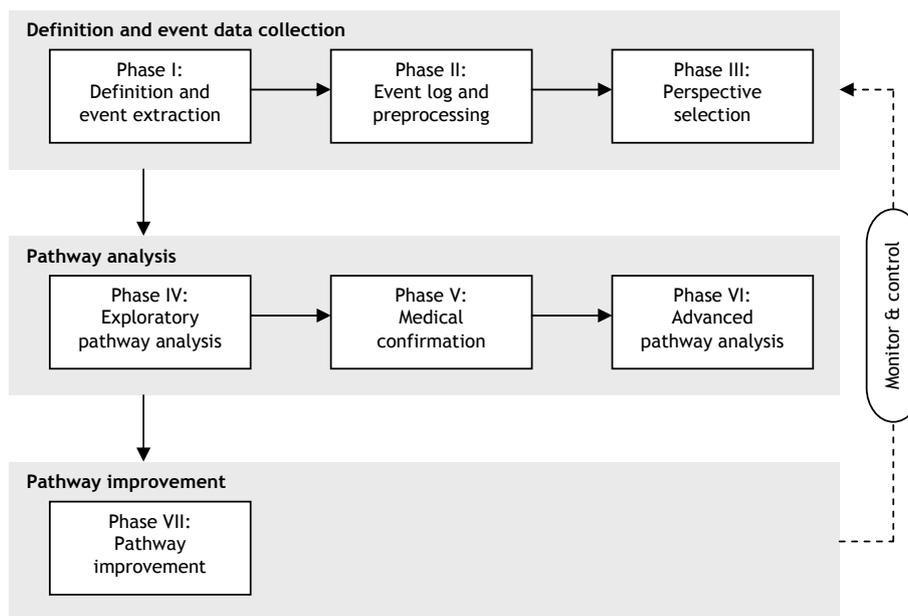


Figure 2: Clinical pathway analysis method (CPAM) roadmap

The major **opportunities** of the application of CPAM in a medical informatics setting include:

- *Acquiring insight in the clinical pathway reality.* Process mining analyses enable experts to acquire a profound insight into a healthcare organisation and uncover non-trivial information on its operations and dynamics. The uncovered set of clinical pathway models can be used as an input for healthcare reorganisation efforts that pursue improving patient outcomes, promoting patient safety, increasing patient satisfaction and optimising the use of resources. Moreover it fits in the requirements of healthcare accreditation agencies (Haute Autorité de Santé 2009) and international standards on quality management (Staccini et al. 2005; Sim 2000).
- *Dealing with guideline compliance and adverse events.* Rule-based property verification analyses can be used to assess the pathway's overall level of conformance with medical guidelines and to identify deviating events. Moreover these techniques could be used as a monitoring and assessment system as described in The Bristol Royal Infirmary Inquiry (2001).
- *Knowledge acquisition and treatment selection assistance.* Medical knowledge gained through experience often remains tacit (Stefanelli 2004; Nonaka and Takeuchi 1995). The CPAM can be employed as a methodology to explicitly document and structure this tacit knowledge. Additionally, the identification of pathway variants can improve the safety and quality of the healthcare by selectively providing medical knowledge in the context of the patient's specific conditions (Lenz & Reichert 2007).

Clinical pathway analysts need to pay attention to the following elements in order to perform high quality clinical pathway analyses:

- *Event log quality.* The event logs of the medical information systems must contain a true representation of the events, must prevent any data tampering and ensure a timely and precise recording of the events.
- *Medical confirmation.* Deviations from medical guidelines seemingly without any plausible reason, might be justified by the possible imperfections of the guidelines, evolution of knowledge or adaption to the local conditions (as described in Riha et al. 2002).
- *Completeness assumptions.* A completeness assumption, that is all possible behaviour is present in an event log, can be easily challenged in a healthcare setting. The analyst should be careful with selecting the timeframe and event sources.

Conclusion

Healthcare is typically considered as human-centric, flexible, evolving, complex and multi-disciplinary. While acquiring an insight in the real dynamics of a clinical pathway can result in unexpected and interesting insights, it may be an arduous task. This contribution aims at introducing both a methodology and a roadmap for an efficient and effective analysis of the pathways.

In this contribution we have identified the application areas of process mining in the context of clinical pathways: the discovery of recurring patterns in the clinical pathway executions, the analysis and characterisation of clinical pathway variants and the identification of exceptional medical cases and adverse medical events; followed by the creation of a complete methodology and the determination of the most valuable individual analyses for clinical pathways.

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