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Online Treatment Compliance Checking for Clinical Pathways

Zhengxing Huang · Yurong Bao · Wei Dong · Xudong Lu · Huilong Duan

Abstract Compliance checking for clinical pathways (CPs) is getting increasing attention in health-care organizations due to stricter requirements for cost control and treatment excellence. Many compliance measures have been proposed for treatment behavior inspection in CPs. However, most of them look at aggregated data seen from an external perspective, e.g. length of stay, cost, infection rate, etc., which may provide only a posterior impression of the overall conformance with the established CPs such that in-depth and in near real time checking on the compliance of the essential/critical treatment behaviors of CPs is limited. To provide clinicians real time insights into violations of the established CP specification and support online compliance checking, this article presents a semantic rule-based CP compliance checking system. In detail, we construct a CP ontology (CPO) model to provide a formal grounding of CP compliance checking. Using the proposed CPO, domain treatment constraints are modeled into Semantic Web Rule Language (SWRL) rules to specify the underlying treatment behaviors and their quantified temporal structure in a CP. The established SWRL rules are integrated with the CP workflow such that a series of applicable compliance checking and evaluation can be reminded and recommended during the pathway execution. The proposed approach can, therefore, provides a comprehensive compliance checking service as a paralleling activity to the patient treatment journey of a CP rather than an afterthought. The proposed approach is illustrated with a case study on the unstable angina clinical pathway implemented in the Cardiology Department of a Chinese hospital. The results demonstrate that the approach, as a feasible solution to provide near real time conformance checking of CPs, not only enables clinicians to uncover non-compliant treatment behaviors, but also empowers clinicians with the capability to make informed decisions when dealing with treatment compliance violations in the pathway execution.

Keywords Compliance checking · Clinical pathway analysis · Ontology model · Semantic web rule language (SWRL)

Introduction

Health-care organizations seek for a better control of their medical services not only to satisfy treatment requirements but also to leverage cost-saving opportunities through
standardization of treatment behaviors in clinical pathways (CPs) [1–6]. With this respect, compliance checking is important as it ensures that treatment behaviors of a healthcare organization act in accordance with the established CP specifications [7]. Once non-compliant cases of treatment behaviors are detected, healthcare organizations can either update their CP specifications to cover the respective case, or they can impose new mechanisms to enforce the best clinical practices [8–11]. Therefore, compliance checking is a central piece in the puzzle of advancing a healthcare organization towards a higher degree of CP maturity.

Traditionally, clinical analysts measure CP compliance by looking at aggregated data seen from an external perspective, e.g., length of stay (LOS), cost, infection rate, and so on [1, 11]. As valuable as these measures, they restrict the attention to an external perspective of CP compliance checking and in a posterior manner. In terms of CP compliance checking, to look into the essential/critical treatment behaviors of the pathway is more important than only to inspect the outcome of the pathway. In addition, although it is beneficial to provide posterior analysis for answering the questions such that if an established CP specification was adhered to at a period during the past, the main interest of clinicians lies in the future. Ideally, they envision having a continuous auditing service that gives them real-time insights into violations of the established CP specification [12]. Apparently, this is not feasible if done manually. And there is an urgent need for better techniques and software tools that make it possible to check treatment compliance automatically and in near real time in patient-care journey. Therefore, how to provide clinicians real-time insights into patient careflow under the guidance of the established CP regulation knowledge becomes the starting point of this study.

In this paper, we present a rule-based CP compliance checking system for a timely assessment of treatment behaviors in patient careflow. To do so, there are two questions need to be addressed:

1. What treatment regulations should be checked for a CP? and,
2. When should the compliance checking actions be fired during the CP execution?

For the first issue, we extract a set of compliance rules for describing the underlying treatment regulations from the established CP specification. These compliance rules can be employed to inspect actual treatment behaviors in patient careflow. Since a CP specification supports neither inference nor rules, so a first required step is to allow describe a CP specification using an ontology language such as OWL-DL that supports integration with compliance rules. The principles for describing a CP specification using Web Ontology Language-Description Logic (OWL-DL) were sketched in [13, 14]. Following our previous work, we provide a formal grounding for the proposed CP compliance checking system. In particular, compliance rules are expressed by OWL and Semantic Web Rule Language (SWRL), and be used to measure the adherence between actual treatment behaviors and the designed treatment regulations in a CP specification.

Regarding the second question, we argue that the compliance checking actions should naturally be aligned with the CP. Thus, it is necessary to integrate the established compliance rules into the CP workflow so as to provide a comprehensive compliance checking service as a parallel-ling activity to the patient treatment journey of a CP rather than an afterthought. To this end, we embed compliance rules into particular clinical stages of a pathway, and specify when these compliance rules should be executed during the CP execution. In this way, the proposed system can work in two modes: it can report violations of compliance rules in the form of a report to the management of the healthcare organization, or it can send a reminder or an alert to clinicians in near real time. In the latter mode, the detected violations can be exploited by clinicians to prevent further violations of the established pathway specification or to enact a compensation action in patient careflow. In this regard, the proposed system has potential to provide continuous monitoring of the relevant treatment behaviors and independently checking on whether these treatment behaviors conform to the designed treatment regulations during the execution of a CP.

The paper is organized as follows. Section “Related work” provides a brief review of related work. Section “Case description and treatment constraints” illustrates a case description for the unstable angina clinical pathway. A clinical pathway ontology model, i.e., CPO, is proposed in section “CP ontology model for compliance checking”. Section “Compliance rules”, based on CPO, discusses how to model the relevant treatment constraints into SWRL rules. In section “Integrating compliance rules and CP workflow”, we illustrate how the established compliance rules are integrated into the CP workflow to support the automated CP compliance checking in patient careflow. Section “Online compliance checking for clinical pathways” presents the system implementation and describe practical experience in the compliance rule evaluation illustrate in some concrete examples. Finally, we conclude the paper in section “Conclusions” with a description of future work.

**Related work**

There is a considerable amount of work in the area of treatment compliance checking and analysis in health-care. For instance, Quaglini et al. performed a non-compliance
ana "thesis of the data stored regarding the clinical guidelines’ impact on hospital stay and cost outcomes [15]. In addition, Ouaglini et al. found that economic benefits can be achieved such that treating patients according to guidelines resulted in lower costs because on average length of stay in the hospital was two days shorter in the patients [16]. In [17], Micieli et al. examined associations between clinical guideline compliance and survival and disability in patients with first-ever ischaemic stroke. In [18], Duncan et al. checked that adherence between post-acute rehabilitation AHRQ guidelines and patient outcomes as measured by functional recovery. In [19], Rood et al. employed a computerized guideline for glucose regulation in the intensive care unit in order to improve both guideline adherence and glucose regulation. In [20], Milchak et al. presented a thoroughly study on treatment compliance on 22 different criteria.

Undoubtedly, these current research efforts have paved the way for CP compliance checking in a health-care domain. However, from the literature review given above, it can be concluded that most of the research efforts mainly focus on the posterior analysis of the violations of the knowledge regulations (c.f. clinical pathway in this study), and typically look at aggregated data seen from the measures, e.g., LOS, mortality, and infection rate, etc., and thus restrict the attention to an external perspective of treatment compliance checking and analysis. To the best of our knowledge, little efforts have been put into online auditing on essential/critical treatment behaviors during the execution of a pathway, which is an important part of our contribution. In fact, CPs are evolving and clinicians typically have an oversimplified and incorrect view of the actual treatment behaviors in patient careflow. Health-care organizations, therefore, require to provide insights into CPs to measure the compliance between actual treatment behaviors and the prescribed treatment regulations in the established CP specification in near real time [21].

In this context, process mining [22, 23], as a general method in business process analysis, is gaining increasing attention in health-care [2, 4, 24]. The idea of process mining is to analyze underlying business processes from event logs that record the execution information of the processes. With respect to compliance checking, there are three kinds of process mining techniques, i.e., process discovery, conformance checking, and logic-based property verification [25, 26]. Process discovery is to (re-)construct process models from the event logs such that delta analysis between predefined process models and the derived models can be conducted. Conformance checking is to detect inconsistencies between a prescribed process model and its corresponding real-life process instances. And logic-based property verification is to analyze specific process properties of the individual process instances, such as activity preconditions, activity ordering, etc. Being transferred into medical settings, process mining techniques may be applicable. For instance, Klundert et al. developed dynamic programming formulations for compliance measurement in clinical pathways [7]. In our previous work, we presented a probabilistic topic model for discovering the underlying treatment patterns from clinical event logs [3], which discloses essential features of CPs by combining different classes of distributions. The derived patterns that shared by most of the patient traces can be used as a compliance measure.

More broadly in business process management domain, there are various process mining techniques that have been proposed for measuring compliance between a log and prescribed process models. For example, Förster extended UML Activity Diagrams to express complex constraints and thus can be used to check the compliance regarding the process behaviors [27]. Hoffmann et al. devise a framework where processes are annotated to capture the semantics of task execution, and compliance is checked against a set of constraints posing restrictions on the desirable process states [28]. In [29], the authors used Petri net to model business processes and then calculate the fitness between an event log and a Petri net. As indicated in [25], most of these techniques for compliance checking are based on state concepts. However, clinical decision makings are mainly based on patient health status, which is clearly outside the state-space that the traditional process mining techniques rely on. Although many process mining techniques can tell us which treatment behaviors are performed and in which order in accordance with established CP specifications, they seldom provide the measurements on the quantified temporal information between the critical medical interventions which are explicitly defined in CP specifications, while compliance checking on these quantified time intervals between medical interventions is very important as it allows clinical analysts to make differences between different situations in CPs that have same treatment behaviors, but different time spreadsings [2].

Case description and treatment constraints

To describe the proposed approach, we illustrate a specific clinical pathway, the unstable angina pathway established by the cardiology department of the Chinese People Liberate Army (PLA) general hospital, as a case in this Section. The unstable angina is a major type of cardiovascular diseases. It is a kind of chest discomfort or pain that occurs in a continuous and unpredictable way. The cause of angina is commonly the poor blood flow in coronary vessels caused by atherosclerosis and the lack of oxygen supply to the myocardium. The unstable pain can result from the disruption of an atherosclerotic plaque in narrowed coronary vessels with lessened flexibility, embolization and
vasospasm. The unstable angina lay its symptoms between exertional stable angina and acute myocardium infarction and a further sudden death. While the risk of the unstable angina is high, the population of the unstable angina is huge, especially for aged people and those with associated disease such as hypertension and diabetes [30]. To this end, reliable propositions in the form of the unstable angina pathway is of significant value and interest. The established unstable angina pathway can provide clinicians explicit suggestions of treatment actions to influence medical quality in concern for the patient’s benefit. In clinical practice, a patient whose first diagnosis is unstable angina without myocardial infarction, aortic dissection, pulmonary embolism, and acute pericardities is selected in the unstable angina pathway. The standard LOS of the pathway is from 6 to 8 days. The pathway can be divided into several clinical stages, i.e. the preoperative preparation phase, the surgery phase, the postoperative recovery phase, and the discharge phase. Table 1 shows part of the unstable angina CP specification, which is designed and implemented in the Cardiology department of the Chinese PLA general hospital.

Patient treatment behaviors must meet the relevant treatment requirements or regulations that are explicitly defined in the established CP specification. In this study, we call all these requirements/regulations as treatment constraints, which specify medical quality objectives that need to achieve in patient careflow. Examples of treatment constraints for the unstable angina CP are collected in Table 1, which correspond to the supporting medical quality requirements and regulate the quality assuring measures for achieving the expected treatment objectives. Obviously, it is important to effectively enforce these treatment constraints to ensure that treatment behaviors meet the medical quality criteria.

Note that current CP specifications are not explicitly presented in the structural form presented in Table 1. Most treatment regulations are presented as texts, whether paper or electronic, whilst in the best case a CP specification may be presented as a checklist of treatment constraints. Although the identification of treatment constraints may not be straightforward, CP specifications can be converted to the form specified by a set of constraints. With respect to the unstable angina CP, it is subject to compliance rules that stem from domain-specific treatment constraints. These treatment constraints are explicitly defined in the established CP specification, and prove a certain standard of the audited treatment behaviors to patients. These constraints are the common way to represent treatment regulations of a pathway, and compliance rules formulated from these constraints can verify actual treatment behaviors recorded against the designed regulations of the established CP specification. Online compliance checking on the treatment constraints might help clinical analysts to adjust patient careflow so as to avoid instantiations of non-compliant pathways.

**CP ontology model for compliance checking**

The purpose of using the ontology-based approach is to describe the domain concepts as abstract and generic concepts, including the relationships between these elements, which can facilitate a shared common understanding about a CP between clinicians. In addition, it can capture vast medical knowledge and reuse this knowledge in order to provide valuable support for clinical decision making in relation to performing medical interventions on individual patients. In our previous work, we have designed and implemented a CP ontology (CPO) model, which contains terms and knowledge to represent patient state, medical intervention and temporal constraints in CPs [13]. In this work, we revise and extend the proposed CPO to support CP compliance checking as a second stage of our proposed framework. In particular, we represent run time information of patient careflow in an ontology and incorporate this ontology into the CPO model. This allows us to reason over both the static CP specification as well as the pathway execution in a single formal representation.

The CPO is depicted in Fig. 1, including classes and properties for describing both design time entities, e.g., Pathway, Intervention, Patient, etc., and run time entities, e.g., Log, Trace, and Event, etc., along with their interrelationships, which are illustrated as follows:

- **Class Pathway** represents an abstract generic CP. A Pathway, designed for a specific type of Disease, contains a set of medical interventions, which are represented by the concept Intervention with two subclasses: AtomicIntervention and CompositeIntervention. Atomic Intervention has seven major sub-classes: Medication, Nursingcare, Surgery, LabTest, Examination, Diet and MiscellaneousOrder, etc. Respectively, they represent pharmacotherapy, nursing activities, surgeries, laboratory test/monitoring, physical examinations, diet, and other medical works, which are carried out by medical resources (i.e., clinicians or information systems) to achieve a particular clinical goal.

- **Class Log** records various treatment behaviors in patient careflow. A log consists of a set of patient Trace. Each Trace, associated with a particular Patient, records the actual treatment behaviors in pathway execution. A patient Trace has a set of global data entities on that patient, e.g., Age, Gender, etc., and is composed of a set of Event occurred in the pathway execution. A clinical Event has a set of properties, which can be
Table 1 Part of the specification of the unstable angina clinical pathway, designed and implemented in the cardiology department of the Chinese PLA general hospital

Conditions for entering the unstable angina clinical pathway

\[ c_1 \] Patients whose first diagnosis is unstable angina
\[ c_2 \] Patients without myocardial infarction, aortic dissection, pulmonary embolism, acute pericarditis
\[ \ldots \] 

Preoperative preparation (preoperative evaluation) in 0-3 days after admission

\[ c_3 \] Required medical interventions: Routine blood test, Blood type test, Routine urine test, Electrolytes, Chest X-ray, Electrocardiogram, Echocardiography, \ldots
\[ c_4 \] Myocardial ischemia assessment (low-risk patients)
\[ c_5 \] Dual antiplatelet drugs: generally, aspirin and clopidogrel are used simultaneously.
\[ c_6 \] Intravenous injection of GPIIb/IIIa is a considerate choice for patients in medium-risk level or high-risk level who plan to perform PCI surgery
\[ \ldots \] 

Surgery in 0-3 days after admission (if it is necessary to undergo a surgery).

\[ c_7 \] Anesthetic method: Local anesthesia
\[ c_8 \] Surgical approach: Coronary angiography, Stent implantation
\[ c_9 \] Surgical implant: Coronary artery stent
\[ \ldots \] 

Post-operative recovery (in 3-5 days after surgery)

\[ c_{10} \] Required inspection items after operation: Routine blood test, Routine urine test, Electrocardiogram, Myocardial injury markers
\[ c_{11} \] Observing myocardial ischemia
\[ \ldots \] 

Conditions for discharge

\[ c_{12} \] Stable vital signs
\[ c_{13} \] Myocardial ischemic is effectively controlled
\[ \ldots \] 

represented as object properties between the concept Event and the general concepts defined in the CPO model. For example, we include the relation hasInterventionType between Event and Intervention. Additional, we include the relations hasTimeStamp between Event and TimeInstant, hasPerformer or consumer between Event and medical Resource, and the data property hasPatientData between Event and a set of Patient data entities, respectively. Note that the data property hasPatientFeature can be further classified into five sub categories: hasBasicFeature (e.g., Age, Gender, etc.), hasPhysiologicalFeature (e.g., CK, CKMB, etc.), hasSymptom (e.g., hasHeartEventRecently, Smoke, etc), hasVitalSign (e.g., HR, BP, etc.), and hasDiseaseType (e.g., Unstable_Angina, Acute_Myocardial_Infraction, etc.). All these relations can be used to track the properties of a clinical event, i.e., what and when a clinical event is performed, and which patient features are observed during the execution of the event.

Compliance rules

A CP specification may be considered as being composed of a set of rules. Each rule is effectively a predicate (i.e. a logical statement which may be evaluated to true or false), together with a conclusion (i.e. compliance or violation of
the CP specification). Rules may be classified as either an obligation (e.g., ‘the CP specification is complied with only if the medical intervention \( x \) is performed at the time instant \( s \) in patient LOS’), or a prohibition (‘the CP specification is not complied with if the medical intervention \( y \) is performed at the time instant \( t \) in patient LOS’).

Compliance rules may be considered as having some metadata such as describing which operations they apply to, what data may be used to assess compliance etc. The CPO provides common and typical metadata to CP compliance checking. Based on the proposed CPO, the treatment constraints’ knowledge imposed by the regulations can be clearly and unambiguously defined via specializing and instantiating the generic concepts and relations in the CPO model, such that they may potentially be interpreted by an information system and automatically checked in patient careflow. Note that much procedural knowledge, including CPs, are often modeled using a declarative approach, leading to a very active interest in rule-based systems. How-

ever, inference capability among the multitude of current rule-based systems is limited. The Semantic Web Rule Language (SWRL) \([31]\), which is based on OWL, has emerged as a solution to allow users to write rules to reason about OWL individuals and to infer new knowledge about those individuals \([32]\). To develop semantic rules for CP compliance checking, we employ SWRL to represent rules. An SWRL rule typically consists of an antecedent (body) and a consequent (head), each of which consists of a set of atoms. Informally, meaning to the rule is: if the antecedent holds (is true), then the consequent must also hold. An empty antecedent is treated as trivially holding (true), and an empty consequent is treated as trivially not holding (false). Rules with an empty antecedent can thus be used to provide unconditional facts. Non-empty antecedents and

\[
a_1 \land a_2 \land \cdots \land a_n \rightarrow b_1 \land b_2 \land \cdots \land b_m
\]

where \( a_1, a_2, \ldots, a_n, b_1, b_2, \ldots, b_m \) are OWL atoms of the following forms:

- \( C(\textit{x}) \): If \( x \) is a variable, an individual, or a data value of the class \( C \), then \( C(\textit{x}) \) holds;
- \( PO(\textit{x}, \textit{y}) \): If \( x \) is related to \( y \) by object properties \( PO \), then \( PO(\textit{x}, \textit{y}) \) holds, \( x \) and \( y \) are either variables, individuals or data values.
- \( PD(\textit{x}, \textit{y}) \): If \( x \) is related to \( y \) by data properties \( PD \), then \( PD(\textit{x}, \textit{y}) \) holds, \( x \) is variable or individual of a class, while \( y \) is a data value.
- \( B(\textit{x}_1, \textit{x}_2, \ldots) \): If \( x_1, x_2, \ldots \) are related to each other by built-in relations \( B \), then \( B(\textit{x}_1, \textit{x}_2, \ldots) \) holds, \( x_1, x_2, \ldots \) are either variables, individuals or data values.

The mechanism of representing compliance rules as SWRL enables CP compliance checking as a parallel task to patient treatment journey, and provides the level of flexibility needed such that clinicians can add or modify the set of governing rules and regulations. This feature is useful, since a pathway specification may often changes. Another benefit is that SWRL is a descriptive language that is independent of any rule language internal to rule engines, which decouples the rules from the technical implementation of the rule engine.

A partial patient trace typically contains conditions on near real-time information, e.g., patient data, and events, etc., in patient careflow. The compliance checking of a partial patient trace against the designed treatment regulations
of a pathway can be realized by checking the partial trace on the treatment constraints, which are modeled as a set of compliance rules. Here, typical provisions are selected as examples for the aforementioned two types of treatment constraints, i.e., the treatment inspection constraints and the control-flow constraints.

The treatment inspection constraints are related to the set of inspected objects to ensure their compliance to the relevant treatment regulations. The inspected objects refer to any entities, e.g., medical interventions, patient data entities, resources, etc., governed by treatment regulations defined in the CP specification. The inspection constraints assure treatment behaviors are performed accurately and timely during the execution of the CP, and any quality defect should be detected in time to prevent rework and cost increase. In this study, we transform the treatment inspection constraints into one or a set of SWRL rules. For example, the constraints $c_1$ and $c_2$ shown in Table 1, can be modeled in the following SWRL rule.

$$
\xi_1 : \text{Patient}(p) \\
\wedge \text{hasAuditTrail}(p, \sigma) \\
\wedge \text{follows}(p, \text{Unstable_Angina_Clinical_Pathway}) \\
\wedge \text{Unstable_Angina}(p, \text{true}) \\
\wedge \text{Myocardial_Infarction}(p, \text{false}) \\
\wedge \text{Aortic_Disseaction}(p, \text{false}) \\
\wedge \text{Pulmonary_Embolism}(p, \text{false}) \\
\wedge \text{Acute_Pericalditis}(p, \text{false}) \\
\Rightarrow \text{obeyRBTIn3DaysAfterAdmission}(\sigma, \text{true})
$$

Rule $\xi_1$ indicates that the criteria of entering the unstable angina pathway should be inspected to check whether a patient can follow the treatment regulations of the pathway. The inspected objects can also be medical resources involved in the execution of medical interventions in patient careflow. For example, the constraint $c_3$ indicates that a specific type of implant, i.e., $\text{Oronary\_artery\_stent}$, should be used in $\text{Stent\_implantation}$ intervention. This constraint can be modeled in the following SWRL rule.

$$
\xi_2 : \text{Trace}(\sigma) \wedge \text{hasEvent}(\sigma, e) \\
\wedge \text{hasInterventionType}(e, \text{Stent\_implantation}) \\
\wedge \text{consumer}(e, \text{Oronary\_artery\_stent}) \\
\Rightarrow \text{obeyStentImplantationRule}(\sigma, \text{true})
$$

The control-flow constraints specify certain medical interventions must always be executed or should never occur after the execution of another intervention. Different with the traditional business processes, a temporal condition in a control-flow constraint request not only to set a relative order of the occurrences of medical interventions, but also ask one to provide quantified time span between these interventions. In the process of CP compliance checking, this quantification is very important as it allows the researcher to make differences between different situations in CPs that have same treatment behaviors, but different time spreading. Indeed, different time spreading of the same set of treatment behaviors may indicate, for example, that the same patient treatment behaviors are realized in different contexts [2]. Taking $c_3$ shown in Table 1 as an example, it denotes a specific temporal condition that the required medical intervention, e.g., $\text{Routine\_blood\_test}$, must be performed within 3 days after $\text{Admission}$. It can be represented as a compliance rule as follows:

$$
\xi_3 : \text{Trace}(\sigma) \wedge \text{hasEvent}(\sigma, e_1) \wedge \\
\text{hasInterventionType}(e_1, \text{Admission}) \wedge \\
\text{hasTimeStamp}(e_1, \tau_1) \wedge \text{hasEvent}(\sigma, e_2) \\
\wedge \text{hasTimeStamp}(e_2, \tau_2) \wedge \text{hasInterventionType}(e_2, \text{Routine\_blood\_test}) \\
\wedge \text{swrlb : subtract}(\text{duration}, \tau_2, \tau_1) \wedge \\
\text{swrlb : lessThanOrEqual}(\text{duration}, 3) \\
\Rightarrow \text{obeyRBTIn3DaysAfterAdmission}(\sigma, \text{true})
$$

During the execution of a CP, patient data entities are produced, used or manipulated. To ensure treatment compliance, it might be needed to ensure that patient data entities in a partial patient trace assume a certain state once a dedicated medical intervention is about to be executed. Taking the control-flow constraint $c_4$ shown in Table 1 as an example, it indicates the precondition, i.e., $\text{patient\ is\ in\ the\ low\ risk\ level}$ in order to execute a certain medical intervention $\text{Myocardial\_ischemia\_assessment}$. Here, a dependency is modeled by the respective patient data associated to the specific intervention. This constraint can be represented as $\xi_4$.

$$
\xi_4 : \text{Patient}(p) \wedge \text{riskLevel}(p, \text{"Low")} \wedge \text{Trace}(\sigma) \\
\wedge \text{performedOn}(\sigma, p) \wedge \text{hasEvent}(\sigma, e_1) \\
\wedge \text{hasInterventionType}(e_1, \text{Admission}) \wedge \\
\text{hasTimeStamp}(e_1, \tau_1) \\
\wedge \text{hasEvent}(\sigma, e_2) \wedge \text{hasTimeStamp}(e_2, \tau_2) \\
\wedge \text{hasInterventionType}(e_2, \text{Myocardial\_ischemia\_assessment}) \\
\wedge \text{swrlb : subtract}(\text{duration}, \tau_2, \tau_1) \\
\wedge \text{swrlb : lessThanOrEqual}(\text{duration}, 3) \\
\Rightarrow \text{obeyMIAssessmentIn3DaysAfterAdmission}(\sigma, \text{true})
$$

In this study, we use Protège to assist the users to edit visualized classes, properties and OWL individuals of the proposed CPO, define logical class characteristics as OWL expressions, and edit SWRL rules. Protège is a free,
open source ontology editor and knowledge-base framework [33]. As shown in Fig. 2, the classes, properties, and their restrictions are defined in Protégé 3.5. All compliance rules are modelled using the SWRL rule editor, namely SWRLTab, which is a plug-in and editor integrated in Protégé.

**Integrating compliance rules and CP workflow**

For the purpose of online compliance checking in CP workflow, an integration of CP workflow and the established compliance rules is inevitably required. In other words, compliance rules need to be embedded into specific clinical stages of the pathway workflow. During the CP workflow execution, compliance rules can be fired gradually such that treatment behaviors can be checked accordingly and timely.

The proposed CPO defines basic concepts and relations common to CPs, thus provides a semantic foundation for describing application knowledge and enabling a general formal representation of information in CP workflows. As shown in Fig. 3, a CPO-based workflow model contains a series of clinical stages. Each stage has specific time intervals and consists of a set of medical interventions. In general, a CP workflow is first described as a sequence of high-level interventions of different clinical stages, which are represented by simple processes and can expand to corresponding composite processes.

The established compliance rules are integrated into the different components of the pathway workflow model, so that these rules can be fired if specific trigger events occur in the pathway workflow execution. In this study, we define three types of trigger events, i.e., intervention-based trigger events, time-based trigger events, and user operation-based trigger event. The first two types of trigger events are related with medical intervention and time information of the pathway, respectively. For example, if a medical intervention PCI surgery is (being) performed in patient careflow, a predefined trigger event can be ignited to inform that particular treatment behaviors need be checked against the PCI surgery related compliance rules. In addition, time information can be used in triggering compliance checking. For example, if two days have passed in patient LOS, a trigger event might be ignited to inform that treatment behaviors in the past two days need to be checked. Note that intervention-based and time-based trigger events are generally predefined to ensure that the related compliance rules are triggered timely and automatically at the special time instant of the pathway workflow. Regarding user operation-based trigger events, they can be performed by clinicians at any time instants of the pathway workflow. In this regard,
users can select interesting compliance rules to check the compliance of treatment behaviors manually.

In this study, we use Drools rules to describe the combinations between triggering events and compliance rules. Drools rule files have a .drl (Drools Rules Language) extension, and can be flexibly loaded into the working memory of the Drools rule engine. Note that Drools rules are different from compliance rules. In general, a Drools rule consists of an anticipant trigger event and the consequent actions using compliance rules. Thereby, a Drools rule specifies not only what and how treatment behaviors need to be checked but also when and in which condition treatment behaviors are checked. Figure 4 shows simple example Drools rules.

Note that, incorporating Drools into the proposed system, it can provide more flexibility and intelligence in CP monitoring. In clinical practice, medical staff in different disciplinary may have different requirements on CP monitoring. This can be achieved through the customization of monitoring plans. We are building a CP monitoring Editor based on Drools Editor, on which users can input their monitoring requests. And then individual monitoring plans can be generated based on users’ input. The skeletons for major monitoring activities in an organization are predefined in the knowledge base of the system. A customized monitoring plan is generated through the integration of a monitoring skeleton and individual monitoring requests from the user. For instance, physicians are likely to monitor the executions of treatment activities to ensure appropriate treatments being performed on right patients at appropriate time instances, while hospital managers might be interested in monitoring patient infections, mortality, and drug abuse, etc. By the aid of the proposed system, the user can choose an appropriate monitoring skeleton to monitor the pathways of specific patients. After choosing this skeleton, the user can input his/her individual monitoring requests for this skeleton, such as monitoring interval, monitoring scope,
critical monitoring items, and so on. As result, users can create their individual monitoring plans and receive specific responses (e.g., reminder, alert, or warning) during CP execution.

**Online compliance checking for clinical pathways**

Figure 5 shows the top-level architecture of the proposed compliance checking system for CPs. During the pathway execution, the Electronic Medical Records (EMR) system records all relevant clinical events of partial patient traces. This runtime data is sent to the proposed compliance checker to measure whether the actual medical behaviors conform to the treatment regulations designed in the established CP specification, and alerts/reminders can be sent back to clinicians. The generated alerts/reminders can lead to either remedial actions against the possible violations, or to the conclusion that the deviations should be allowed. The compliance checker can be run at any time by communicating with EMR system, thus providing a way to support online compliance checking in patient careflow.

The implementation environment of the proposed compliance checker is shown in the bottom of Fig. 5. The building blocks of our system mainly include three steps:

1. Event listening and preprocessing. The received runtime data mainly consists of clinical events and trigger events. Clinical events are treatment behaviors occurred in the pathway execution. And trigger events are those events that can ignite compliance checking actions on treatment behaviors in a near real-time. In general, clinical events could be in unstructured representation. For efficient CP compliance checking, clinical events need to be structured such that CP concepts can be recognized. In this study, we are interested in the classes, e.g., observations, interventions, and time stamp, etc., and their individuals defined in the proposed CPO model. Note that the intent in using CPO is to map the received runtime events to existing CP classes and their individuals where possible. To this end, we employ NLP techniques to clean and normalize the original data so as to extract CP classes and individuals. In particular, a open source-code tool for Chinese NLP, i.e., Pangu [34], was adopted in this study. Based on Pangu, CPO-oriented entities can be generated from the received clinical events. For example, let “Performing Coronary angiography, PTCA and Stent surgery under local anesthesia) be a received clinical event, it can be preprocessed by Pangu such that the specific entities, i.e., “local anesthesia”, “Coronary angiography”, “Percutaneous Transluminal Coronary Angioplasty, PTCA” and “Stent implantation”, are recognized from the event data, where local anesthesia, Coronary angiography, PTCA and Stent implantation are specific individuals of class Intervention.

2. Patient trace interpretation and semantic facts generation. The received data about clinical events of a partial patient trace needs to be interpreted such that the trace can be annotated by the proposed CPO, and the corresponding classes (e.g., event, intervention, and observation) and the relations between them are realized as members of. In this study, Pellet is selected as the reasoner due to its ability to track the exact source axioms and instances in the case of a logical inconsistency [35]. Using Pellet, the data of partial patient traces can be interpreted and a set of semantic facts can
be generated. Note that based on Pellet, the proposed compliance checker can perform inference. As compliance rules fires, new assertions will come into being, and then these assertions can be transformed into OWL/SWRL and stored back into the knowledge base.

3. Online compliance checking and feedback. The treatment behaviors of the interpreted patient trace are checked using the established compliance rules. As shown in Table 1, CP compliance rules describe the specific treatment constraints at the particular clinical stages of the pathway. Thus, the established compliance rules should be well managed and checked at the right time instant such that efficient feedbacks can be generated to send to clinicians during the CP workflow execution. For this purpose, we used Drools rules to integrate compliance rules and CP workflow, as described in Section VI. Furthermore, we developed a CP compliance checker based on Drools rule engine. Using Drools rule engine, the proposed compliance checker can be informed when a trigger event is received, such that Drools rules whose antecedent trigger event are picked up to fire the requested compliance checking actions. This implementation gives the control to the compliance checker to decide and notify what and when treatment behaviors need to be checked in the CP workflow execution, and what feedbacks can be generated and sent back to the EMR system. Thus, it allows timely and efficient CP compliance checking.

Figure 6 depicts how the compliance checking is performed in the pathway workflow execution. When a patient trace $\sigma$ is in admission, a clinical event with the intervention type Admission is generated and sent to the compliance checker. As well, a specific Admission-based trigger event is received by the compliance checker, and the corresponding Drools rule $\mathcal{R}_1$ (given in Section VI) is selected to fire. Because the consequent compliance checking action of $\mathcal{R}_1$ is the compliance rule $\zeta_1$ (Given in section “Case description and treatment constraints”), $\zeta_1$ is ready to fire as a result. If atoms in the antecedent part of $\zeta_1$ are satisfied, rule $\zeta_1$ is fired, and the consequent data property obeyUAEnteringRule is set as true. It means that $\sigma$ obeys rule $\zeta_1$. Otherwise, an violation alert will be generated to send back to the EMR system. Furthermore, during the execution of the pathway trace $\sigma$, the established compliance rules are ready to check treatment behaviors when their trigger events occur. For example, in the second day of the pathway, the compliance checker receives a timer-based trigger event, and fire the corresponding Drools rule $\mathcal{R}_2$. As results, the compliance rules $\zeta_3$ and $\zeta_4$ are ready to fire. Taking $\zeta_3$ as an example, the compliance checker automatically deduces and fills in the
antecedent axioms of $\zeta_3$ using Pellet, and check if they are satisfied with the partial patient trace $\sigma$. If the antecedent axioms of $\zeta_3$ are satisfied, it is fired and the data property $\text{obeyRBTIn3DaysAfterAdmission}$ of $\sigma$ is set as $\text{true}$. We say that $\zeta_3$ is obeyed by $\sigma$. Otherwise, the system can send a reminder to the EMR system to remind clinicians that the medical intervention $\text{Routine blood test}$ is not yet performed on that patient in 2 days after Admission. Note that the proposed compliance checker can report a violation to clinicians to test the severity of the violation. For example, if $\text{obeyRBTIn3DaysAfterAdmission}$ of $\sigma$ is $\text{false}$, and the intervention $\text{Routine blood test}$ is performed after 3 days of Admission for that patient, the violation is repaired, the impact of the violation on $\zeta_3$ may be less than the situation that the constraint remains violated. From this scenario, we can see that the compliance rules enable the treatment constraints to be integrated with patient careflow, and thus CP compliance checking can be regarded as a paralleling activity to patient careflow rather than as an afterthought.

**Conclusions**

At present, the work of CP compliance checking is mostly from the external perspective, e.g., LOS, cost, infection rate, etc. Although these measures are valuable, they restrict the attention to an external perspective of CP compliance checking and in a posterior manner. In this study, we propose a rule-based system that can provide insights into patient careflow, and support online compliance checking between actual treatment behaviors and the designed treatment regulations of the established CP specification, by integrating OWL and SWRL with the reasoning services of Pellet. The proposed system can be connected to the EMR system but is not a part of it. The assumption is made that all relevant clinical events in patient careflow are passed to our system. In this way, the proposed system can build an independent image of the state of the pathway and treatment behaviors performed on patients in their careflow. Based on this image compliance checking can run in parallel to patient careflow. The proposed approach is demonstrated through a case study of the unstable angina clinical pathway in the cooperation with the Cardiology department of Chinese PLA general hospital.

The proposed approach enables clinicians to uncover non-compliant behaviors, and empowers clinicians with the capability to make informed decisions when dealing with treatment compliance violations in the pathway execution. By exploiting the merits of the proposed system in further clinical collaborations, clinical practice might eventually benefit from this innovation, e.g., to adjust/suspend/cancel specific treatment behaviors that exhibit non-compliant behaviour in patient careflow.

There are several aspects in this work that need elaboration. First of all, there clearly is a lack of expressiveness in the model of compliance rules. The proposed approach is limited to catering for treatment preferences and reason on the active obligations and permissions on specific medical interventions. To address it, we plan to extend our approach by incorporating the deontic logic with the concepts of
OWL-DL. In addition, we would also like to answer several open questions within our current formalism, e.g. which treatment behaviors cause the violation? why these non-compliant behaviors occur in patient careflow? which strategies can be performed to mitigate non-compliant treatment behaviors? etc. With this respect, diagnostic information on compliance violations should be analyzed, and the root cause of a compliance violation must be identified, which provide feedback in a comprehensible way when compliance requirements are not satisfied. Furthermore, we plan to investigate resolution strategies to mitigate non-compliant behaviour in terms of adjustment of the prescribed treatment behaviors in the CP specification, which can be derived automatically in many cases.

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