A Model-driven and Tool-supported Proposal for Defining Automatic Clinical Practice Guidelines

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Abstract

Modern clinical practices for treating pathologies are underpinned by evidence-based clinical knowledge, which is usually defined and formalized in a textual format using clinical practice guidelines (CPGs). This textual formalization causes a certain level of ambiguity, subjective interpretation of the clinical recommendations to be suggested and actions to be performed, and variability in clinical practice by different healthcare professionals facing similar clinical circumstances. This paper presents an industrial experience (GIMO-PD project) that proposes to improve formalization and reduce the clinical variability that exists when CPGs are followed by healthcare professionals during their professional activity. Specifically, this paper proposes a domain specific language for modelling CPGs without ambiguity, as well as model-driven and tool-supported mechanisms for the development of Web applications from a CPG model. At present, our proposal is being developed and validated in a real scenario of patients with Parkinson's disease.

Keywords: Model-driven Engineering, Clinical Practices Guidelines, Web Applications

1. Introduction

Today, companies and organizations require innovative and flexible solutions to digitize and automate their business processes [1] in conjunction with new technologies [2]. In fact, the convergence between digital innovation and process automation could be seen as a relevant and necessary factor to improve the digitization of companies and increase their business positioning in markets [3].

However, the digitization of a process is a task as complex and hard as the process to be digitized is complex due to its own intrinsic features, what often causes the development of partial solutions. This paper is focused on healthcare process, whose management and digitization are essentials to ensure adequate patient care, as well as facilitate the work of healthcare professionals in an area where it is essential to take of decisions based on the best available biomedical knowledge. This practice is known as Evidence-Based Medicine (EBM) [4] and it is the fundamental basis of modern clinical practice for treating pathologies. This evidence-based clinical knowledge is usually defined and formalized in a textual format using Clinical Practice Guidelines (CPGs) [5].

A well-defined CPG is beneficial to both healthcare professionals and patients [6] because it makes it possible to reduce variability during clinical practice and improve the quality of clinical professionals' performance and decision-making, it pools clinical knowledge obtained applying formal techniques that guarantee clinical and systematic validations of different clinical scenarios, and it facilitates effective, reliable interventions based on empirical evidence.

However, CPGs usually present drawbacks in their formalization because they are usually defined and formalized in a textual format what causes a certain level of ambiguity, subjective interpretation of the clinical recommendations to be suggested and actions to be performed, and variability in clinical practice by different healthcare professionals facing similar clinical circumstances [7].

The above-mentioned factors restricting the adoption of CPG, but it could be mitigated using software systems which could improve decision making during the execution of the clinical process. In this sense, this paper proposes a tool-supported DSL (Domain Specific Language) for modelling CPGs without ambiguity, as well as model-driven mechanisms for the development of web applications from a CPG model. This proposal has been carried out within the industrial environment of a multidisciplinary health project (GIMO-PD [12]) between software engineers and a public health organization in Andalusia, Spain. At present, our proposal is being developed and validated in a real scenario of with patients suffering from Parkinson's disease. Space restrictions limit the length of this paper, but a technical and detailed explanation of our proposal, as well as an example of application of the CPG for Parkinson's disease, are presented in an external technical document, which is referenced in [13].

Following this introduction, this paper is structured as follows. Section 2 describes our proposal of model-driven theoretical framework, which allows to define automatic clinical practice guidelines. Later, Section 3 describes our supporting tool and case study. Finally, Section 4 states conclusions and introduces future lines of research.

2. Model-driven Theoretical Framework

This section briefly presents an overview of our model-driven framework, which manages the lifecycle of CPG using models. This framework proposes systematic and automatic mechanisms to facilitate the development of software systems, which allows to define and execute CPG. For this purpose, the benefits of applying model-driven principles by the industry (e.g., in terms of quality and maintainability) compared to traditional software development processes [8] are considered by our proposal. Our purpose is to apply these principles to improve and facilitate the design and development of software systems capable of friendly managing CPGs in a process-oriented information system.

In this context, we describe the theoretical overview of our model-driven framework and the technological architecture of its support tool. The model-driven framework is based on next three phases, in which healthcare professionals and software engineers collaborate to achieve our objective:

1. ***Discovery and modelling phase*** (c.f., Section 2.1) aims to (1) obtain the clinical knowledge in a structured manner (i.e., identifying roles, activities of the healthcare process, clinical rules, clinical recommendations, for instance), and (2) model this knowledge in the CPG.
2. ***Development phase*** (c.f., Section 2.2) aims to systematically obtain the executable model (based on BPMN-XML and Java code) from the CPG model once the CPG has been modelled.
3. ***Deployment and configuration phase***, in which, the software engineer completes the platform-dependent configuration of the executable code generated in the previous phase to manually deploy it in our technological platform (c.f., Section 3).

2.1. Discovery and Modelling Phase

In this first phase, the framework considers collaborative work between software engineers and healthcare professionals using product design techniques (such as Design Thinking) and abstract representation languages (i.e., metamodels).

Once the clinical knowledge is obtained, engineers and professionals jointly model the CPG to be executed by instantiating the *«CPG Modelling Metamodel»*. The definition of this metamodel is carried out with two main components: (i) an abstract syntax (platform-independent metamodel), which defines modelling concepts and their relationships, and (ii) a concrete syntax (in the form of UML-Profile) to use our metamodel in real environments. Space restrictions make it impossible to describe the metamodel in detail, but it is briefly illustrated in Figure 1.

The *«ClinicalPracticeGuideline» metaclass* is the epicenter of the metamodel and is the element around which the rest of the elements of the metamodel are orbiting. With this metaclass it is possible to represent any CPG. To describe the necessary actions, each CPG is composed of a *«HealthcareProcess»*, which is composed by activities (human, orchestration and complex) and control elements. In human activities, the healthcare professional could also record patient's data using the *«ClinicalData» metaclass*. In addition, our proposal includes the *«ClinicalRule» metaclass*, which allows decision-making to be supported when activities or process control elements are achieved. These rules are formed by logical clauses, constituted in turn by clinical data to be evaluated, a mathematical operator and the value with which to compare. When a clinical rule is verified, the associated clinical recommendation is suggested to the healthcare professional by the support system.

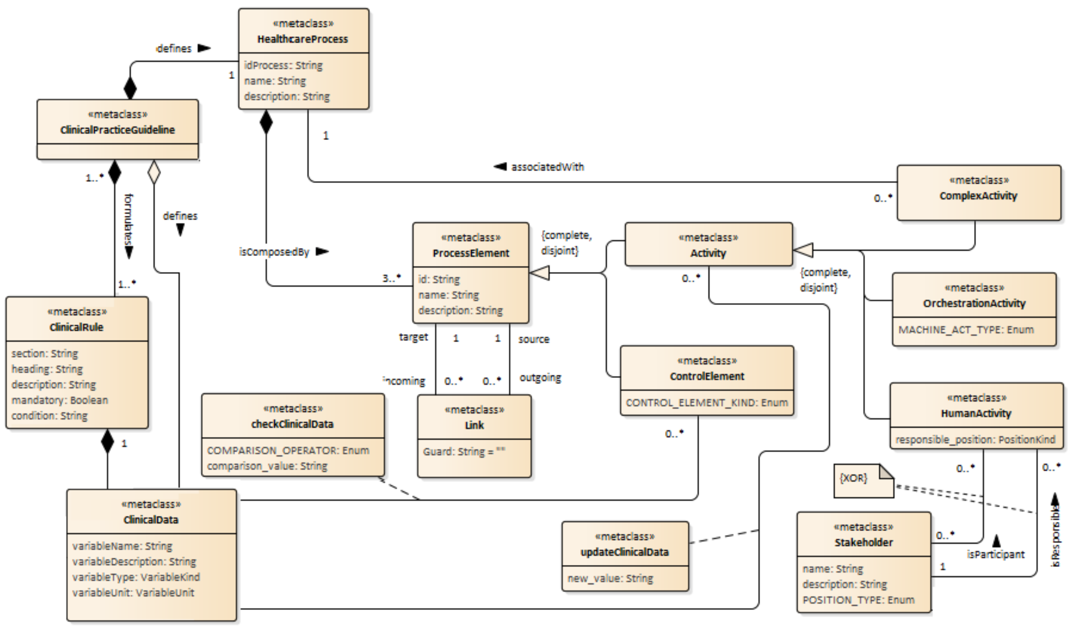

Fig. 1. CPG modelling metamodel (simplified excerpt)

2.2. Development Phase

This phase aims to systematically obtain the executable model (based on BPMN-XML and Java code) from the CPG model. This executable model contains necessary information to deploy and execute CPG models into execution process engines or BPMS (Business Process Management Suite) [9]. In this sense, the framework defines *model-to-text* transformation rules using MOFM2T [10]. This transformation a protocol will not be explained here, since they are out of the scope of this paper and it would become too extensive, but it is possible to find further information in [11]. Anyway, we have been able to generate executable code from the definition model of the CPG. On the one hand, BPMN-XML code is generated because most BPMSs support this standard format [12] and it is used but the process engine selected in our project (see Section 3). Additionally, we generate Java code to execute each clinical decision rule (which is modelled in previous phase) in the decision rule engine selected in our project (c.f., Section 3). Although these kinds of code are related to our design and technological solution, it is important to mention that our MDE-based framework is independent of the technological platform and could be adapted to any other.

3. Case Study and Supporting Tool

Our proposal was applied to model the CPG associated with the clinical follow-up of patients with Parkinson's disease. In short, this CPG consists of identifying the patient's family clinical history, measuring their motor deterioration and assigning specific medication to mitigate the effects of this disease (considering the patient‘s current state because this disease is degenerative). The process is complex because it contains 7 activities and 42 clinical recommendations and rules, and involves several stakeholders (patient, neurologist, and nurse, among others), but Figure 2A presents a simplified view of this model and shows the user working space of our modelling tool. It allows building models visually and graphically by dragging and dropping elements from the CPG toolbox (Figure 2B) obtained after implementing the CPG UML-Profile.

This case study is supported by several general-purpose supporting tools to facilitate its use by any kind of organization that need to manage CPG and its healthcare process. Specially, the framework includes:

(i) A modelling tool, which allows to instantiate the *«CPG Modelling Metamodel»* (c.f., Figure 1). This modelling tool has been integrated into Enterprise Architect[1] (EA) to facilitate its application in real software engineering environments because EA provides a suitable technological foundation to implement our model-driven framework thanks to its UML-Profile extension and MDE mechanisms, as well as its wide presence in software companies.

(ii) A process engine which allows, the execution of models and follow-up of clinical rules. This tool is based on *BonitaOS*[2] *(process engine) and Drools*[3] *(decision* rule engine). These tools are based on Java technology.

After modelling the Parkinson's CPG, our modelling tool automatically generates skeleton source code according to BPMN-XML (associated with the process of the Parkinson's CPG) and Java code (associated with database structure for clinical data). This code is deployed in the BonitaOS tool. Space restrictions make it impossible to explain and show the full code associated with the Parkinson's CPG, but Figure 2C shows BPMN-XML code snippet associated with this CPG. Once this code is generated, this one is manually configured in the BonitaOS platform by software engineer who designs the web user interfaces of each activity according to the clinical data defined in the model CPG. Finally, Figure 2D shows the user interface associated with the *«assessment of refractory symptoms» activity* of the Parkinson's CPG (note: refractory symptom means the symptoms that cannot be adequately controlled with the available treatments.

4. Conclusions and Future Works

MDE in health is also a new research line, little treated *over last years* and innovative in terms of potential results that allows its application. In this context, t*his paper presents* an industrial experience (GIMO-PD *project)* that proposes to reduce the clinical variability that exists when CPGs are followed by healthcare professionals during their professional activity. For this purpose, this paper proposes a metamodel or domain specific language for modelling CPGs without ambiguity, as well as model-driven and tool-supported mechanisms for the development of Web applications from a CPG model.

At present, our proposal is being developed and validated in a real scenario of patients with Parkinson's disease, but, as future works, we plan to extend, improve, and apply our proposal to other pathologies, as well as integrating predictive analysis techniques which allow improving the clinical recommendations offered by the GIMO-PD platform.

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[2] BonitaSoft. Website. Last access 2022.
[3] *Drools*. Website. Last access 2022.

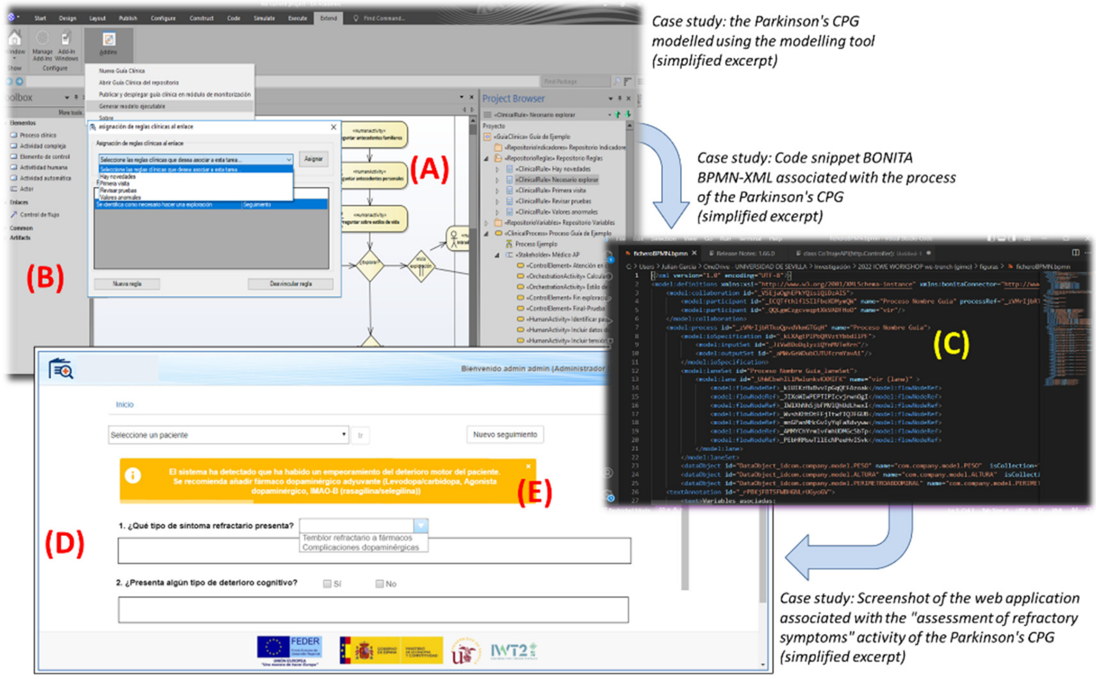

Fig. 2. CPG modelling tool and model of the case study (simplified excerpt)

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