

A Domain-Independent Semantically Validated Authoring Tool for Formalizing Clinical Practice Guidelines

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Abstract. Clinical Practice Guidelines (CPGs) are promoted as a powerful tool for standardization of the medical care quality and improvement of patients' outcomes. However, CPGs need to be formalized in a computer interpretable format (i.e. as Computer Interpretable Guidelines or CIGs) for their implementation within Clinical Decision Support Systems (CDSS). But, maintaining the reliability of these guidelines when deploying them in different clinical settings is still a challenge. On the one hand, the complexity of the medical language complicates the adoption of the guidelines in different clinical institutions. On the other hand, the continuous discovery of new evidence needs to be included within CPGs, updating their contents and providing tools for evidence assessment. Furthermore, although nowadays' clinical decision-making tends towards a personalized process, guidelines are designed for a general population. In this paper, we present an Authoring Tool (AT) that allows clinicians to take an active role in the process of CPG formalization. This AT enables them to introduce new clinical knowledge and create personalized CIGs for their local application, which best fits their clinical needs. The proposed system also allows the use of ontologies to facilitate the standardization and interoperability of the created guidelines. Finally, the content included in the CIGs can be evaluated using standard systems for grading clinical evidence.

Keywords. Authoring Tool, Clinical Decision Support System, Clinical Practice Guidelines, Computer Interpretable Guidelines, Ontologies.

1. Introduction

Clinical Practice Guidelines (CPGs) are a set of criteria developed in a systematic way to help professionals in the decision-making process, providing the latest evidence-based diagnostic or therapeutic options when dealing with a health problem or a specific clinical condition [1]. Over the past years, CPGs have been widely promoted to be implemented as Computer Interpretable Guidelines (CIGs) within Clinical Decision Support Systems (CDSS). Nevertheless, there is still work to be done in the maintenance and personalization of these guidelines in order to maintain their reliability when implementing them in different clinical settings. On the one hand, the complexity of medical language makes the comprehension and interoperability of the

CPGs a complicated issue, since different guidelines modeling the same clinical domain could differ in the provided knowledge. In this context, semantic web technologies such as ontologies are promoted for a standardized medical vocabulary. On the other hand, the evolving nature of medicine and the continuous discovery of new evidence needs to be included in CPGs, assessing the quality of the formalized evidence in a continuous way. To solve this issue, methodologies that assess the quality of the formalized evidence and the strength of the recommendations are promoted. Furthermore, CPGs are developed considering a population as target, not individuals, thus assuming the existence of a “standard” patient, which is not representative of all possible individual cases [2]. In this sense, personalizing guidelines using clinicians’ own experience, patient preferences or local protocols of institutions can be helpful to increase clinicians’ compliance to CDSS [3].

In this paper, an Authoring Tool (AT) that enables clinicians to formalize actively personalized CPGs in a user-friendly way by introducing new clinical knowledge and create CIGs that can be adapted to their local protocols is proposed. First, an approach for the semantic validation of the content in the guidelines leaning on an ontology is presented. Second, the methodology used for the CPG formalization process is described. Lastly, a use case in Gestational Diabetes Mellitus is shown to illustrate the proposed methodology.

2. State of the Art

The formalization process of CPG into CIGs is a complex, time-consuming task requiring technical and clinical skills to be done successfully. As a result of this, it is difficult for clinicians to create or edit the contents of existing CIGs, making necessary the involvement of a knowledge engineer for CIG management and implementation [4]. In order to solve this issue, Authoring Tools (AT) are proposed as tools for facilitating and actively taking part in the creation of CIGs by clinical domain experts. To avoid the technical encoding, clinicians are provided with user-friendly and interactive interfaces that ease the formalization process [5].

For example, Dunsmuir et al. [6] developed an AT in order to enable anaesthesiologists to include their clinical knowledge in a rule-based CDSS. Their AT allows users to introduce and edit clinical rules, but requires the user to have knowledge about XML files in order to edit the terminology and parameters used by the AT. Furthermore, the format used to encode clinical rules is designed for its use in anaesthesiology, which makes it too specific for its adoption in other clinical domains.

Another example would be in the case of Ali et al. [7], who propose a framework that makes use of HL7 standard and ontologies in order to generate shareable CIGs. Rules are created and edited using an ontology-linked AT, and Arden Syntax is used to represent them. While the constructed rules follow a standard to encode the clinical knowledge, no standard systems for grading clinical evidence are used.

In this work, following the approach by Muro et al. [8], an AT for developing domain independent CIGs is presented. This proposal uses the Decisional Event (DE) structure to store the clinical information regarding the decision-making process. Using this structure it is possible to compute the quality of evidence and strength of recommendation for each of the rules, as described in [9]. As our platform is based on this DE concept, the strength of the recommendations in the CIG can be assessed.

3. Methodology

The proposed AT, within the architecture shown in Figure 1, is composed by:

- (i) a module for interacting with external knowledge models, such as ontologies, to provide the needed clinical domain knowledge during the formalization process,
- (ii) a user-friendly Graphical User Interface (GUI) as the frontend of the system for introducing rules that will compose the final CIG, and
- (iii) a backend, which is responsible for creating the final CIG.

To ease the technical comprehension of this chapter, it is supported by a use case in the management of gestational diabetes.

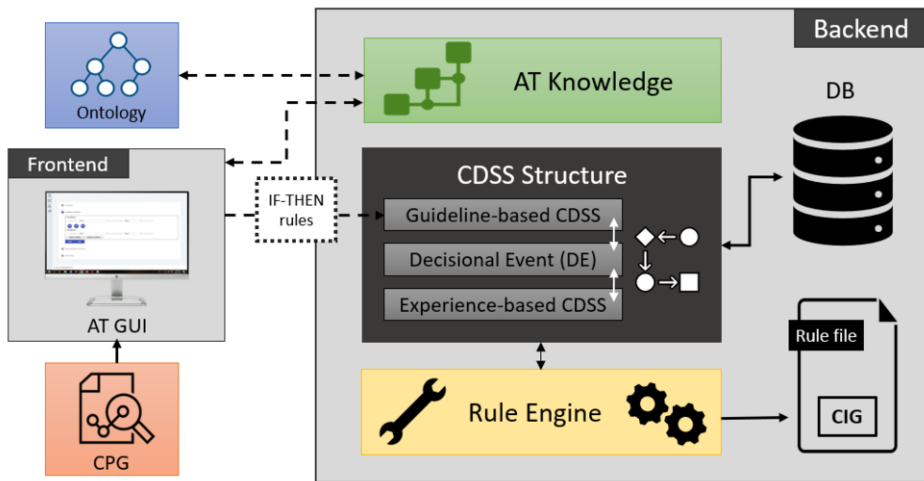


Figure 1. General view of the framework.

3.1. Interaction of the AT with ontologies

Ontologies formalize the clinical knowledge in a standard, flexible and interoperable way. In this approach, ontologies are externally queried to provide the needed clinical domain knowledge during the formalization process. After a research on different APIs for the integration of ontologies with the CDSS, Apache Jena¹ was selected, as it allows our development to integrate ontologies using RDF or OWL models in an easy way.

For the interaction of the AT with the ontology, different web services are used to:

- (i) get the list of variables (classes) from the ontology for defining the variable names within a rule,
- (ii) obtain the possible values of the selected variables, and
- (iii) receive the list of recommendations for completing the consequent part of the rule. This interaction can be seen in Figure 2, where the possible values that a

¹ <https://jena.apache.org/documentation/ontology>

variable (“*CurrentPhysicalActivityLevel*”) can take (left) and a recommendation as the consequent part of a rule (right) are shown.

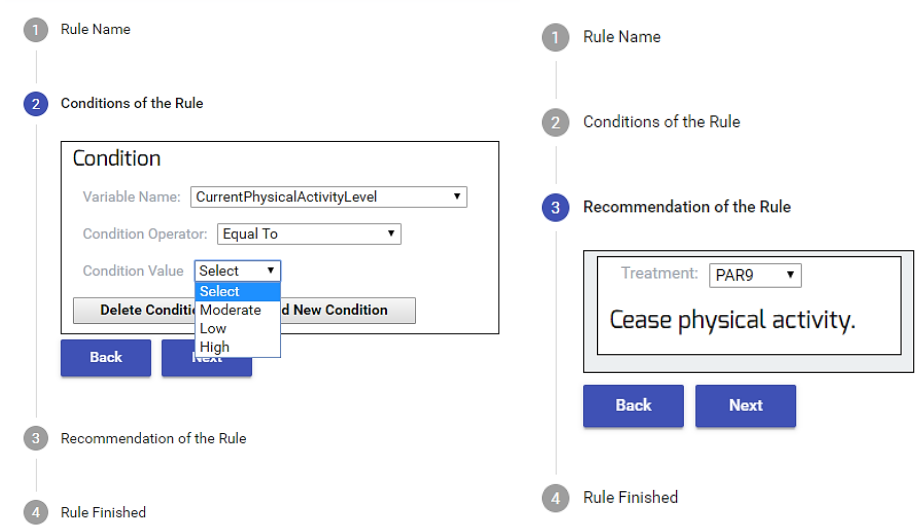


Figure 2. Introduction of conditions (left) and recommendations (right) of rules in the AT.

3.2. CPG formalization

The process of CPG formalization is the result of a continues interaction between the frontend and the backend of the system. The proposed GUI allows the user to formalize rules following four simple steps (see example in Figure 2). First, the name of the rule is defined, which defines the clinical content in a textual way. Afterwards, the conditions of the rule are introduced, defining the statements to be accomplished by the studied patient. Next, the recommendation for the formalized rule is specified as the consequent part to be provided. Finally, the rule is sent to the backend where it is stored and added into the knowledge base of the CDSS to be triggered for new cases study.

The backend supporting this AT is composed by (i) a knowledge layer linked with external knowledge models, such as ontologies, to provide the needed clinical domain knowledge during the formalization process, (ii) a structure layer that gathers all this clinical knowledge and formalizes it in a technology-independent way relaying in the DE concept explained in [9], (iii) a rule engine that integrates a rule file generator for automatic triggering of the formalized knowledge, and (iv) a database (DB) that stores the formalized rules.

With the interaction between the frontend and the backend of the system, the rules in the formalized CIG can be retrieved for their edition and update. Moreover, the used DE structure allows to write down CIGs in any document-based format (e.g. .drl, .xml, .json), since the knowledge is built in a java-based structure [8]. Finally, using the information stored in the DE concept, it is possible to apply standard metrics for

grading clinical evidence such as GRADE² to assess the quality of the evidence included in the guidelines.

4. Conclusions and Future Work

In this paper an Authoring Tool (AT) for the formalization of CPGs into CIGs is presented. This AT allows clinicians to take an active role in this process, as it enables them to formalize CPGs and personalize them according to their own experience. Also, the system facilitates the maintenance and shareability of this knowledge, as the followed DE structure can be exported into other clinical standards. With the use of this DE concept, the clinical evidence of the recommendations obtained from the system can be evaluated. In addition, the proposed system is domain-independent, allowing to formalize CPGs from different domains using the same AT. The generated CIG can then be integrated in a CDSS to provide patient-specific recommendations. Furthermore, new clinical knowledge can be added to the CIG using the AT GUI in order to update its contents with the latest evidence-based clinical practice.

Overall, the presented tool eases the formalization of CPGs into CIGs for clinicians or knowledge engineers, while also allowing to edit and update the introduced knowledge. Furthermore, tools for assessing the reported clinical evidence in the CIGs are provided, avoiding the inclusion of erroneous or low evidence-based knowledge.

Future work will include a visualization of the constructed rules to aid the clinicians' understanding how the introduced knowledge is being formalized. Finally, an ontology editor will be implemented for visualizing its classes and easing the manipulation of the ontology's contents.

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² <http://www.gradeworkinggroup.org/>