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Specification of business rules for the development of hospital alarm system: application to the pharmaceutical validation

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Abstract. Although clinical alert systems are part of the knowledge management setting within healthcare organisations, modelling of business processes related to decision support and knowledge representation of decision rules are seldom described. We propose a customization of the Unified Process that takes into account user requirements for clinical alert systems by introducing the Semantics of Business Vocabulary and Business Rules (SBVR). This methodology was applied to the design and implementation of a clinical alert system for pharmaceutical validation at the European Hospital Georges Pompidou (HEGP). Rules were implemented using the IlogJRules Business Rule Management System. We produced 3 business rules patterns and 427 instances of rules. As SBVR is close to natural language, pharmacists were able to understand rules and participate to their design.

Keywords. Decision Support Systems, Clinical; Knowledge Representation (Computer); Knowledge Management; Decision Making, Computer-Assisted; Unified Process; Business rule.

1. Introduction

Many publications evaluating the errors of prescriptions justify the presence of alert systems at the time of the prescription [1,2,3]. Computerized alerts systems implemented in Computerized Physician Order Entry (CPOE) systems have been proposed in an attempt to reduce these errors. However, their effectiveness depends not only on their intervention mode in the CPOE [4] but also on the compliance of prescribers to follow advice. In a study by Van der Sijs et al., prescribers override the alerts in 49% to 96% of the cases [3]. A second railing of prescriptions validation by hospital pharmacists, before drugs dispensation and administration can be assumed to be effective in preventing errors.

Since 1991, French legislation has mandated analysis and validation of drug prescriptions by pharmacists in hospitals [5]. A patient information system, integrating an electronic patient record and a CPOE (Dx-C@re, Medasys™) [6] is implemented throughout our 800-beds hospital. The CPOE is used for every prescription of biology or radiology whereas it is used for drugs prescription only for 300 beds, the remaining

prescription being done with paper and pencil. This organization allows the pharmacists to only validate computerized prescriptions, which already requires four full time pharmacists. The objective is to reach 650 beds in 2009. In order to maintain maximum safety, it is not envisaged to allow computerized drug prescription without pharmaceutical validation. Since it is not considered to increase the number of pharmacists for this task, we turn to a solution which consists in introducing an alert system which could enable us to program a rule-based system targeted to both the physician at the time of prescription and the pharmacist at the time of validation.

DoseChecker [7] is one of the rare expert systems introduced as an alert system for pharmacists. In this study and in the majority of the studies published on the alert systems there are no details on the methodology that led to the implementation of the system. To ensure that the alert systems can deliver “good knowledge to the right people, in the right form and at the right time”, the designers of alert systems must take into account two important criteria, which represent two real challenges [8].

First the developer needs to identify and model business processes (actors and business scenarios) in which the alert system works. Several authors proposed an approach based on the object paradigm and more precisely on UML (Unified Modelling Language) for the modelling and design in a couple of decision support systems [9,10]. In these studies it is not specified if the use of the UML formalism is framed by a design method which takes into account the entire software life cycle (from the feasibility study to the maintenance). The authors of UML recommend the use of the Unified Process (UP) to cover all the steps related to the life cycle of the application.

Second the developer needs to model the knowledge associated with the decision rules with an appropriate language. Several languages have been proposed for the modelling of clinical practice guidelines (CPGs): EON, GLIF, Asbru, Proforma, GUIDE or PRODIGY [11]. However these languages present unnecessary complexity because they provide features to represent specific features of CPGs which are not part of rule based systems. The Arden syntax presents many limits: the data model is not object oriented, it is atomic and does not allow expressing the concept of time [12]. GELLO addresses the limits of Arden syntax, but it is based on a language intended for designers (OCL, Object Constraint Language) which involves a complexity in the writing and the reading of the business rules [12]. Ideally, the formalism selected should be articulated with the chosen design process and avoid complexity of writing or reading for the end user. It is the case of SBVR (Semantics of Business Vocabulary and Business Rules) [13].

Assuming that the same kind of rules can support alerts for prescribers and pharmacists, we concentrate on the modelling of the business processes of the pharmaceutical validation in the context of the HEGP central pharmacy. We aim at testing two research hypotheses (1) The Unified Process and UML notation are adaptable to allow business rules identification starting from business processes modelling intended for alarm system design, (2) SBVR allows the modelling of knowledge necessary to the writing of business rules. To examine these hypotheses we used UP and UML for the modelling of the business processes. We used SBVR for modelling business rules in our alert system for pharmaceutical validation. We implemented these business rules through a Business rule management system (Ilog JRules) and assessed the value of UP, UML and SBVR in our application context.

2. Materiel and method

Our method is articulated around the various phases and activities of UP. We propose and justify an adaptation of UP to our business and applicative context. The Unified Process is a development and design software process. UP manages the design process according to several phases: Inception phase, Elaboration phase, Construction phase and Transition phase [14]. Each phase is composed of several activities (requirements, analysis...) more or less significant according to the applicative context and the phase in which the project is. We describe in what follows only the adaptations that we bring in the Elaboration and Construction phases.

2.1. Elaboration phase: Formulation and analysis of needs

In this phase we focus our attention on the requirements and analysis activities. Main goal of the requirements is the development of a model of the system to be built. The redaction of the system use cases constitutes an excellent way to proceed with the creation of this model.

The specification of the business rules and their introduction into the design cycle are not described in UP. It is thus necessary to introduce a new stage which supplements the activity of formulation of the needs in the Elaboration phase as recommended by Nijpels [15] and Ambler [16]. This stage begins by identifying what are the business rules that have the greatest impact on the work of pharmacists in the context of the pharmaceutical validation. Then we establish outlines of business rules called *rules written pattern* according to Ambler's terminology.

- The first approach consists in using the data of the HEGP hospital information system (HIS) to evaluate the different clinical situations at risk at the time of the prescription and measure their frequency.
- The second approach is to consult the pharmacists in charge of the validation to identify the most significant business rules in the context of their activity.

2.2. Construction phase: design, implementation and testing

We associate for each use case a "use case realization – design". That passes by the identification of design classes formalized by the UML class diagram. The design class diagram related to one of *the rules written pattern* corresponds to our Business Object Model (BOM). The BOM corresponds to the business entities (business classes) of the UML class diagram resulting from the construction phase of our design method. To instantiate the corresponding rules in this BOM, it is necessary to identify the relevant relations between classes and to name them. Then, by using the mapping rules between SBVR syntax and the BOM [17,18], we instantiate a business rule. For example class noun of the BOM corresponds to: noun concept in SBVR syntax and class name relation of the BOM corresponds to: <Role1>Verb<Role2> 'Fact type' in SBVR syntax. We repeat this procedure for each drug pertaining to the list of the drugs established with the pharmacists for each *rules written pattern* BRx by taking into account every related active ingredient. This produces all instances of rules.

The business rules of the alarm system are managed by a Business Rule Management System from ILOG: JRules. The implementation of our business rules outcome of the design stage in *JRules* starts with the implementation of the eXecution

Object Model (XOM) corresponding to our class diagram. The XOM is the model from which the business rules are implemented. The XOM maps a Java class to each class of the BOM and a Java attribute to each BOM attribute. The XOM can be built from: Compiled Java Classes (called: Java XOM), XML Diagram or Web services (called: Dynamic XOM). We generate one test case for each *rules written pattern* with a wizard provided by JRules. We edit the corresponding code source in order to enter typical conditions of use such as name of the drug, age of the patient, potassium level in input. The test case is successful when the rule is fired for abnormal conditions such as inappropriate potassium level or glomerular filtration rate.

3. Results

The results which we present follow the sequences of activity and the phases previously defined. To illustrate the application of our method we describe the successive stages of our method in one use case: 'To validate prescriptions'.

3.1. Business use case model and system use case model

We identified in consultation with the pharmacists in charge of the validation 7 business actors and two business use cases. The business use case "To validate the prescriptions" comprises one main scenario and 14 alternative scenarios. By taking into account the evaluations of the pharmacists in charge of the validation during various iterations, we identified in this stage three system use cases and three system actors related to the business use case "To validate the prescriptions" and corresponding to the three *rules written pattern BRx*.

The first *rules written pattern BR1*: 'control of the hyperkalemic drug prescriptions' was identified according to the first approach. The number of hyperkalemic drug prescription in patients with potassium level ≥ 5 mEq/L was 88 (1.2% for potassium supplementation) in one year. The second *rules written pattern BR2*: 'the adaptation of drugs dosage according to the Glomerular Filtration Rate and the third *rules written pattern BR3*: 'the adaptation of anticoagulant drugs dosage according to the International Normalized Ratio (INR) and the anti-Xa activity' were identified according to the second approach.

3.2. SBVR business rules

The BOM in Figure 1 corresponds to our patterns of business rules BRx. The mapping rules between SBVR syntax and the BOM allowed us to instantiate our business rules in their textual form (Figure 2).

- 247 business rules for the pattern of rules BR1.
- 156 business rules for the pattern of rules BR2.
- 24 business rules for the pattern of rules BR3.

Test cases corresponding to each *rules written pattern* were successful. For example we selected the following values for the business rule in figure 2:

- The attribute 'Speciality' of the class 'Drug' gets 'Heparin sodium',
- The attribute 'Wording' of the class 'Route' gets 'Continuously',

- The attribute 'clinical situation' of the class 'validation data' gets 'deep vein thrombosis',
- The attribute 'TCA' of the class 'patient' gets '2',
- The attribute 'anti Xa activity' of the class 'patient' gets '0,45'.

JRules triggers the corresponding rule and assigns to the attribute 'Wording' of the class 'Message' the value 'Valid prescription' that is displayed by the system to the user.

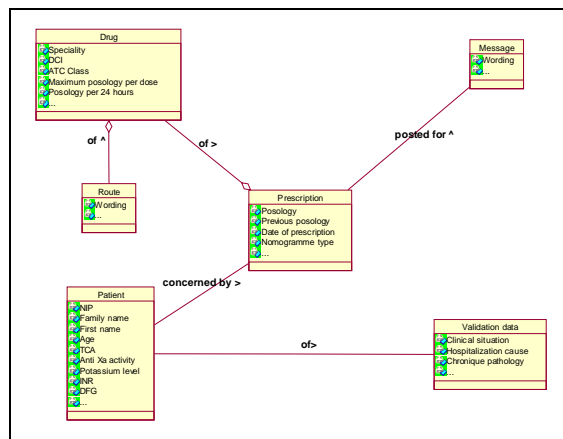


Figure 1. The BOM corresponding to the rule pattern BR3

if the speciality of the drug of the prescription is Heparin sodium and the wording of the route of the drug of the prescription is continuously and the clinical situation of the validation data of the patient concerned by the prescription is deep vein thrombosis and (the TCA of the patient is equal to 2 times the witness or anti Xa activity is between 0,4 and 0,6) then the wording of the message posted for the prescription is valid prescription

Figure 2. Rule instance of the BR3 rule pattern following the SBVR syntax

4. Discussion and conclusion

The choice of SBVR as a specification formalism of the business rules enabled us to write business rules with a vocabulary which mirrors the natural language. SBVR allows to instantiate rules starting with a design class diagram. That implies that there is no dichotomy between the adaptation of UP which we propose and the use of SBVR.

The design class diagram which we highlighted in the construction phase is the result of only two iterations. An improvement would be to supplement our class diagram with an already existing object oriented model for the modeling of the drugs prescriptions [19]. The rules which we implemented in our system are intended for the dosage adaptation according to biology results. The extension of the system to other categories of rules in particular those which address contraindications (interactions drug - disease) is a significant perspective [20]. In order to carry out more precise tests, the rules implemented in JRules should be integrated in the HIS of HEGP to exploit the patient's data of DxCare. An additional desirable data-processing development is to couple the rule system with a drug knowledge base.

All the studies which we listed within the background of our work do not give and do not recommend precise method for the implementation and the design of based rule

alarm systems. This work represents a first stage in the establishment of a design methodology for the implementation of alarm systems.

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