

From Guidelines to Practice: Improving Clinical Care through Rule-Based Clinical Decision Support at the Point of Care

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Abstract. Healthcare Information Technology (HIT) is a dynamically evolving industry due to continuous advancements in healthcare technologies. This necessitates the availability of highly dynamic applications that accommodate frequent changes in business logic. The automation of Clinical Decision Support (CDS) in particular is most liable to changes in health business logic or rules. In terms of system's architecture, there is a need to separate business logic and rules from the implementation/functionality of the Electronic Health Record (EHR) application, providing processes and rules as reusable components. We propose an architecture utilizing rule-based technologies to facilitate Decision Support to promptly adapt business logic changes, that are reflected immediately in application behavior. This allows real-time and robust CDS for the physician at point of care. Our rule-based implementation (Business Process Modelling Notation (BPMN)+Rules) was successfully used to emulate Clinical workflows, using as an example, the NICE Lung Cancer Clinical Guideline (CG121) as a test scenario.

Keywords: Rule Based Technology, Clinical Decision Support, Clinical Guidelines, Service Composite Architecture, BPMN.

1 Introduction

The implementation of Evidence based medical (EBM) practices at the point of care confirms the best possible clinical care at low costs [1]. EBM encompasses best practice and standardization for clinical practice. These standards are based on scientific evidence from the Medical literature, clinical trials and the latest research providing the physician with adjudicated data to make informed decisions when formulating patient-specific diagnosis and treatment strategies. A practical implementation of EBM is Clinical Guidelines (CGs). Clinical practice guidelines (also called pathways) assist a healthcare practitioner with managing individual patient conditions. CGs represent a health care procedure as a systematically developed process defining the necessary information in a sequence guided by clinical rules that are appropriate for specific patient needs. Guidelines promote interventions during clinical practice to replace the use of inefficient medical practices with evidence-based practices to improve clinical outcome.

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Clinical Decision Support (CDS) has been described as one of the key enablers of improved clinical outcomes. A decision support service (DSS) takes as an input the patient data (problems, observations etc.) and yields patient-specific inferences as output enabling a physician to make informed decisions at the point of care. [2] suggest that a computerized CDS service can be beneficial if “decision support is provided automatically as part of clinician workflow”. Hence incorporating CDS knowledge within a healthcare workflow can serve as a mechanism to assist a physician to make informed decisions. [3] identify challenges to implementing successful CDS within the healthcare workflow. From an architectural point of view the following two issues are critical, 1) Disseminate best practices in CDS design, development, and implementation and 2) Create an architecture for sharing executable CDS modules and services. To disseminate best clinical practices integrated into a CDSs, clinical guidelines have been incorporated into the CDS functionality of an application used by a physician [4] [5] . Service Oriented Architecture provides a way to manage CDS knowledge as reusable components that can be shared among disparate electronic healthcare environments.

Rule-based systems are by far the most extensively utilized models for decision making in CDSs. We have developed a framework for CDS knowledge representation, processing and execution following a rule-based approach. We propose an architecture that maps clinical knowledge encapsulated in clinical guidelines to a workflow. Traditionally, a number of complex approaches have been adopted to express clinical guidelines, for example, Arden Syntax¹. The challenge using this approach is that it is tightly coupled with underlying technologies and does not provide a graphical representation of CGs within a workflow. We have used BPMN to model a clinical guideline. All the clinical knowledge embedded in the guideline has been expressed as business processes (in this case, clinical processes and clinical rules). The aim of this research is two-fold. Firstly, separate Clinical knowledge from EHRs. We achieve this by expressing Clinical knowledge as rules. Secondly, enable sharable CDS knowledge. This is achieved by maintaining SCA Composite of the business processes.

2 Methods and Tools

2.1 Methodology: Agile Business Rule Development Methodology

We have followed the Agile Business Rule Development Methodology (ABRD) for this project [6]. This methodology consists of six iterative steps starting from Rule Discovery to Rule Deployment as shown in Fig. 1. The iterative nature of this cycle ensures that CDS knowledge encapsulated in the rules can be updated as needed. Based on ABRD, we apply the following steps:

1. **Harvesting:** Identify the rules as reusable CDS knowledge components for a clinical guideline.

¹ <http://www.hl7.org/Special/committees/arden/index.cfm>

2. **Prototyping:** Design a model to represents the rules as part of a clinical process and validate the rules against the business logic they represent.
3. **Building:** Build executable rules, deploy the rules in a runtime environment, and expose them as web services to be consumed by the requesting application.
4. **Enhancing:** Follow an iterative approach to modify existing rules and integrate changes as they appear in a clinical scenario

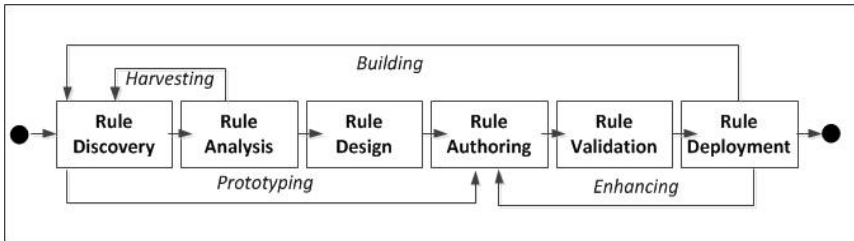


Fig. 1. Agile Business Rules Development Methodology [6]

2.2 Architecture: Technologies and Standards

1. Service Component Architecture:

Service Component Architecture (SCA) is a “set of specifications which describe a model for building applications and systems based upon SOA principles” [7]. In our implementation, we define components representing a particular functionality (in this case medical rules) . A component can either be independently exposed through an external protocol or can be wired together by a process, (a clinical guideline), in a way that is communication protocol neutral (Web Services, Java Messaging Service, Enterprise Java Beans etc). The unit of deployment of SCA is called an SCA Composite. An SCA composite can consist of components, services, references, and wires that connect them together.

2. Tolven eCHR™:

To capture patient information and display CDS alerts, we used the EHR application Tolven eCHR™ [8]. This EHR was selected given its user friendly interface to record and display patient information . Secondly it is an open source platform that allows interoperability with other applications.

3. Tolven Plugin:

In order to receive and send patient medical data, a Java EE based plugin was developed. This plugin interfaces with Tolven eCHR™, allowing it to receive patient data, transform and validate it against vMR format and transfer the vMR as a web service to be utilized for rules processing in the CDS Rules Service. After the rules have been processed the plugin transfers the desired results (in this case, alerts) back to the EHR.

4. CDS Rules Service:

This framework is developed using open source tools and technologies as shown in Fig.2. It includes JBoss jBPM² workflow engine, JBoss Drools³ rules engine, Apache Camel⁴ for message routing and Enterprise Service Bus Switchyard⁵. SwitchYard pro-vides the SCA runtime and is the middleware that lies between business applications and routes and transforms messages along the way [9] [10] .

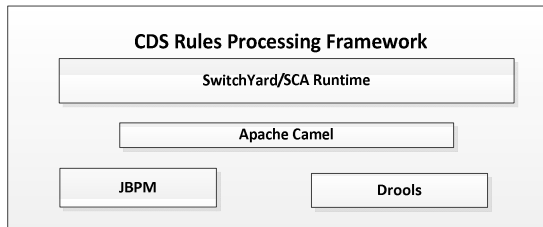


Fig. 2. CDS Rules Processing Framework

5. Eclipse BPMN 2 Modeler:

We modelled the clinical guidelines as workflows using BPMN 2.0 [11], to graphically represent the processes and rules in a medical workflow. The clinical workflow modelled using BPMN is shown in Fig. 3

6. HL7/OMG CDSs:

As a standard for CDS data communication and standard, we use the HL7/OMG standard for clinical decision support. The HL7/OMG Clinical Decision Support Service was designed to enable CDS services to be leveraged using a standard interface [12]. It exposes the CDS functionality as a web service.

7. HL7 Virtual Medical Record (vMR):

The HL7 Virtual Medical Record (vMR)⁶ is specifically designed to enable mapping clinical data from EHR technologies for use in CDS. It is based on Health Level Seven Inc. HL7 version 3. The version 3 classes encapsulate patient data in a standardized manner. This data includes Patient demographics, problems, orders, observations, medications and results [13].

2.3 Clinical Scenario for CDS

We have selected NICE UK's Guideline "The diagnosis and treatment of Lung Cancer" (CG121) to test our CDS architecture solution [14]. The guideline provides a

² <http://jbpm.jboss.org/>

³ <http://drools.jboss.org/>

⁴ <http://camel.apache.org/>

⁵ <http://switchyard.jboss.org/>

⁶ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=271

sequence of actions that need to be performed by the physician in order to consider a diagnosis for Lung Cancer. We test the initial symptoms of lung cancer by our CDS service, and represent these symptoms as business rules in a workflow. After the rules have been processed, we provide as a result, that is an alert to the physician for considering diagnosis of lung cancer as well as instructions for urgent Chest X-Ray immediate referral. This result is displayed as an alert in the EHR. Fig. 3 shows a BPMN representation of the guideline.

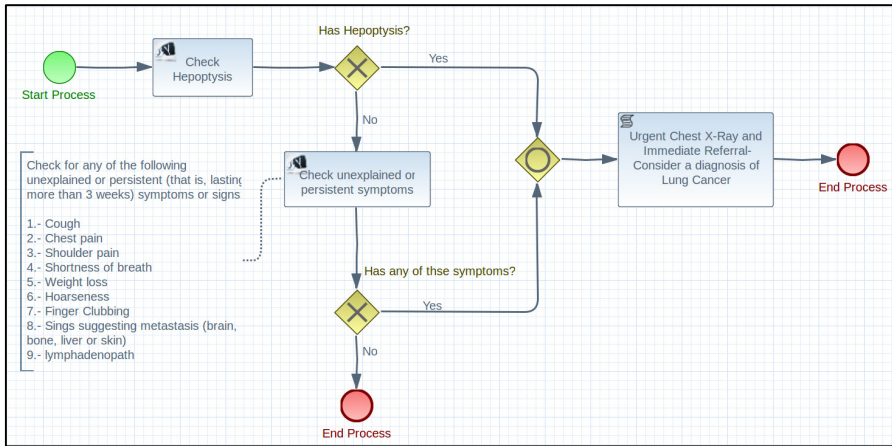


Fig. 3. BPMN Process for Diagnosis of Lung Cancer

2.4 The CDS Service Processing Steps

1. The process initiates as soon as new problems for a patient are entered in the EHR by the physician, and the patient record is modified.
2. The Tolven plugin collects this patient data and transforms it into HL7 vMR format.
3. The vMR is then sent as a CDS request to CDS Service . There is a verification performed against the vMR standard conformance for the incoming request.
4. The problems list encapsulated in the vMR are converted into independent SCA Components. The SCA Composite for Lung cancer guideline is shown in Fig. 4. There are two rules associated with this process. 1) Check Hemoptysis and 2) Check Unexplained or Persistent Symptoms (this includes nine symptoms). These components are wired together to a process called Lung Cancer Clinical Guideline (NICE_Lung_Cancer_Clinical_Guideline). The CDS Rules Service checks if either of these are represented as problems in the vMR. If either of them is true, a message “Urgent Chest X-Ray and Immediate Referral” is generated and sent as a response to Tolven eCHR interface. This message is shown as an alert to the Physician at the point of care. This message is displayed as an alert to the Physician at the point of care as shown in Fig 5.

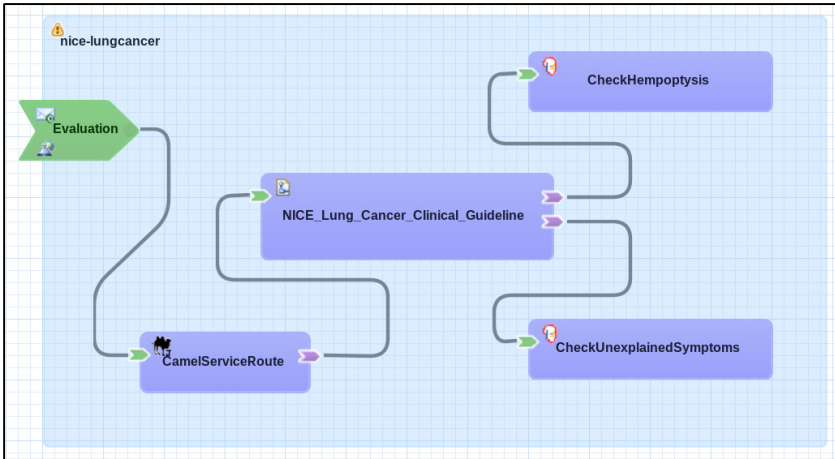


Fig. 4. SCA Composite for Lung Cancer Guideline

Problems		Document	Alerts	
03/26/2014	Widespread metastatic malignant neoplastic disease (disorder)	ACTIVE	03/26/2014	CDS Service: Urgent Chest X-Ray and Immediate Referral
03/26/2014	Shoulder pain (finding)	ACTIVE	03/26/2014	CDS Service: Consider Diagnosis for Lung Cancer
03/26/2014	Hemoptysis (disorder)	ACTIVE		
03/26/2014	Lymphadenopathy (disorder)	ACTIVE		
03/26/2014	Finger clubbing (disorder)	ACTIVE		
03/26/2014	Hoarse (finding)	ACTIVE		

Fig. 5. Tolven eCHR user interface showing Alerts

3 Results

3.1 Testing

According to the Clinical Decision Support Consortium, an effective CDS service has to be less than a second [15]. We have used the open source load testing software, LoadUI⁷, to measure the results of performance testing. We measured the service response times to test the scalability of the service. The service was tested for 30, 50 and 60 simultaneous users respectively for a period of five minutes. Our results are shown in Table 1.

Table 1. Evaluation testing results for CDS Rules Service

Time (min)	No of Users	No of Requests	Response Time (ms)
05.00	30	881	274
05.00	50	1504	567
05.00	60	1779	987

⁷ <http://www.loadui.org/>

3.2 Performance Evaluation

The average response time of our CDS service is less than a second with a maximum of 60 users. If we increase the number of users and the number of simultaneous requests, the response time is likely to increase. For managing a relatively small number of requests, this service is suited for integration with an EHR for a small to medium sized healthcare setting.

4 Discussion

We developed a standardized representation of the clinical rules by mapping the clinical guideline as a healthcare workflow. Using BPMN to model clinical rules in a guideline can specify the clinical knowledge that can serve as CDS capability within a workflow as well as independently from the workflow model. Using standards such as vMR, there is no need for separate EHRs to maintain proprietary structures for messages. Secondly, the java based interface plugin (Tolven Plugin) can validate any incoming patient data against the vMR, hence promoting a standardized data format. Our SCA composite for the Lung Cancer Diagnosis scenario can be exposed as a web service for other clinical diagnosis scenarios. Every component in the composite can act independently of one another and can be wired to other processes, thus allowing reusability. Rule governance is to ensure efficient maintenance of all the processes that are deployed as CDS services. This is achieved through assigning roles and responsibilities to members involved in the clinical scenario. These include rules author, rule analyst, rule administrator, business policies owner. All of these members are responsible for performing their tasks by following the agile business rules development methodology. This ensures monitoring and management of the rules life cycle in an iterative manner. Additionally, it allows updating rules as new evidence base becomes available, provides a scalable solution to CDS.

5 Conclusion

The aim of this research was to provide a mechanism for leveraging a rule-based approach for implementing clinical guidelines to provide robust and flexible clinical decision support. We have demonstrated that BPMN and Rules, can together serve as a CDS Service at the point of care. To address the features of an SOA based solution, we leveraged Service Component Architecture (SCA) infrastructure, that provides reusable CDS rules and processes in the form of an SCA Composite. We have shown that this CDS service can be integrated with a commercial EHR to provide clinical decision support integrated within a healthcare workflow. The proposed architecture successfully automates the processing of symptoms presented by the patient in the EHR application, hence initiating an alert in the Tolven eCHR™ user interface, calling for an urgent chest X-ray and immediate referral to specialist services. Additionally, we demonstrate an important functionality of reusability, by retaining SCA Composite, BPMN and DRL Files, as reusable services. Finally as rules in Clinical

Guidelines are liable to changes over time, we use agile business rules development methodology to monitor and track changes in all the processes that constitute the clinical workflow, thus ensuring rules management and governance over a sustained period of time. The future work involves testing this system using a real-time scenario in a healthcare setting.

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