Separating Business Logic from Medical Knowledge in Digital Clinical Workflows Using Business Process Model and Notation and Arden Syntax

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Abstract. Background: Evidence-based clinical guidelines have a major positive effect on the physician's decision-making process. Computer-executable clinical guidelines allow for automated guideline marshalling during a clinical diagnostic process, thus improving the decision-making process. Objectives: Implementation of a digital clinical guideline for the prevention of mother-to-child transmission of hepatitis B as a computerized workflow, thereby separating business logic from medical knowledge and decision-making. Methods: We used the Business Process Model and Notation language system Activiti for business logic and workflow modeling. Medical decision-making was performed by an Arden-Syntax-based medical rule engine, which is part of the ARDENSUITE software. Results: We succeeded in creating an electronic clinical workflow for the prevention of mother-to-child transmission of hepatitis B, where institution-specific medical decision-making processes could be adapted without modifying the workflow business logic. Conclusion: Separation of business logic and medical decision-making results in more easily reusable electronic clinical workflows.

Keywords. Guideline Adherence; Decision Support Systems, Clinical; Automatic Data Processing; Hepatitis B; Obstetrics and Gynecology Department, Hospital

1. Introduction

Clinical guidelines contain detailed instructions for the diagnosis and treatment of specific diseases or coping with difficult clinical situations. Their aim is to guide physicians in the decision-making process and introduce standard-based patient care [1]. In the ideal case, clinical guidelines are evidence-based, thereby identifying and integrating the most recent advances in prevention, diagnosis, treatment, prognosis, and cost-effectiveness in patient care [2]. As such, clinical guidelines have great potential to improve quality management and patient safety [3].

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Although evidence-based clinical guidelines are accepted among patient caregivers, they are frequently neglected in clinical routine because of their poor accessibility or time constraints on the part of clinicians. One solution to these limiting factors is to integrate clinical guidelines as computerized workflows in hospital or departmental information systems [1].

Clinical guidelines are usually documented as narratives containing descriptive texts, partially structured if-then statements, annotated decision tables, and/or narrated decision trees. In order to be integrated into an information system and processed automatically, the narratives need to be transformed into a standardized representation language and compiled into a computer-interpretable program. Several guideline models and execution engines are available for clinical use [4, 5].

One property of most guideline models and execution engines is that medical knowledge is combined with business logic. This restricts their reusability because healthcare institutions may have the same or similar workflows, but employ different underlying medial decision-making processes. We decoupled a clinical workflow's business logic, i.e. logic describing *which actions to undertake and when* during a diagnostic process, from medical decision-making, i.e. medical knowledge on *how to perform these actions*.

We adopted the Business Process Model and Notation (BPMN), version 2.0, Object Management Group (OMG) standard [6] to represent clinical guidelines in abstracted workflow form, and the Health Level Seven (HL7) knowledge representation standard Arden Syntax [7] to represent digitized medical knowledge. BPMN is a graphical representation language designed to model business processes and transform them into a set of activities. Several authors who reported on the implementation of clinical guidelines in BPMN noted significant improvements in their decision-making processes [8-10]. Arden Syntax is an international standard for medical knowledge representation and processing, extensively applied for clinical decision support (CDS).

The aim of our project is to devise a set of best-practice methods on the implementation and deployment of digital clinical guidelines in order to ensure and optimize the quality of patient care. In the present study, we focus on an important subproblem, namely how business logic can be separated best from medical decision-making when constructing an electronic clinical guideline. As a use case, we implemented a clinical workflow from the department of obstetrics and gynecology at the Vienna General Hospital (VGH), which contains evidence-based instructions on how to prevent mother-to-child transmission of hepatitis B.

2. Methods

This study addresses the implementation of the "Check for hepatitis B status at an outpatient visit of pregnant women" (HepBPW) guideline. This clinical guideline provides evidence-based instructions on how to prevent mother-to-child transmission of hepatitis B during pregnancy, and is part of the quality management framework at the department of obstetrics and gynecology, Vienna General Hospital [11].

The HepBPW guideline describes how outpatients are tested for their hepatitis B status, using hepatitis B antigen test results as well as quantitative hepatitis B polymerase chain reaction (PCR) test results. Based on the availability and outcome of these results, patients are instructed about breastfeeding (Table 1) and coached on adhering to these recommendations (such as how to wean a newborn from breastfeeding).

Table 1. Hepatitis B breastfeeding recommendations for HBsAg-positive patients. Table adapted from [11].

Test results		Positive[1]	Hepatitis B PCR Negative[2]	Unknown
HBeAg	**Positive**	Don't breastfeed or wean from breastfeeding	Breastfeeding after immunization possible	Don't breastfeed or wean from breastfeeding
	Negative	Don't breastfeed or wean from breastfeeding	Breastfeeding after immunization possible	Breastfeeding after immunization possible
	Unknown	Don't breastfeed or wean from breastfeeding	Breastfeeding after immunization possible	No recommendation possible until data is available

[1] *Positive corresponds to >2*10^6 genomes/ml*
[2] *Negative corresponds to ≤2*10^6 genomes/ml*
Note: HBeAg, hepatitis B envelope antigen; PCR, polymerase chain reaction

2.1. Data Collection and Storage

For workflow development and testing purposes, patient cases covering all possible guideline scenarios were provided by the department of obstetrics and gynecology at the VGH; these data were stored in a MySQL database.

2.2. Business Process Model and Notation

To design BPMN-based workflows we used core elements of the BPMN standard, which include *flow objects*, *connecting objects*, *swim lanes*, and *artefacts*.

Flow objects are the main elements describing workflow, and consist of *events*, *activities*, and *gateways*. Events are basic elements that trigger or terminate a process, such as start and stop events. Activities constitute an actual sequence of tasks that need to be executed in the process. Finally, gateways are constructs that determine control flow.

Flow objects are joined by connecting objects. They comprise *sequences*, *messages*, and *associations*. A sequence flow shows the order in which activities are performed, a message flow indicates the messages exchanged between workflow participants, and associations associate an artefact or text with a flow object.

Two swim lane components exist: *pools* and *lanes*. These serve as visual mechanisms that organize and categorize activities. A pool consists of major participants in a process, such as different organizations or different organizational branches. Lanes are used to organize and categorize activities within a pool.

Artefacts enable developers to annotate models with additional information in order to improve their readability. These comprise *data objects*, *groups*, and *text annotations*. Data objects show which data are needed or produced in an activity. Groups are used to categorize different activities without affecting the model's flow. Finally, text annotations are used to improve the readability and comprehensibility of the model.

We employed the open-source Activiti BPMN 2.0 Platform for the development of BPMN workflows, This framework offers the following components among others [12, 13]:

- the Activiti Engine, a Java process engine that runs BPMN 2.0-defined workflow processes;
- the Activiti Explorer, a web application that provides access to the Activiti Engine runtime;

- the Activiti Designer, an Eclipse plugin which permits the operator to graphically model BPMN 2.0 compliant workflow processes.

2.3. Arden Syntax and ARDENSUITE

We used Arden Syntax for the implementation of medical data access and knowledge-based clinical rule evaluation. Arden Syntax is a knowledge representation and processing standard capable of computerized representation and processing of medical knowledge, such as rules, decision trees, tables, and scores. Constituent medical rule sets and procedures are known as medical logic modules (MLMs) [14], and usually contain sufficient logic to make at least a single medical decision. Such a decision may result in a clinical alert, reminder, recommendation, or a circumscribed activity in a clinical guideline [15-17].

We used the ArdenSuite CDS technology platform for the execution of Arden Syntax MLMs, [18]. ARDENSUITE consists of an ARDENSUITE server with an Arden Syntax engine and a connector to relational databases, which is used for the storage, management, and execution of MLMs. Furthermore, it contains an ARDENSUITE integrated development and test environment (IDE), which serves as an authoring and test tool for Arden Syntax MLMs. Bidirectional access to MLMs is provided via representational state transfer (REST) or simple object access protocol (SOAP) requests and responses [18, 19].

2.4. Electronic Workflow Construction Principles and Restrictions

A guiding principle in constructing electronic workflows was to retain the original structure of the workflow and not introduce optimizations. In doing so, the workflow remained recognizable to our clinical partners, which promotes the acceptance of our method among clinicians. Furthermore, the workflows are implemented in such a way that they are not directly dependent on patient data, but rather on classification labels, thus improving their readability and reusability. The following guidelines and restrictions were used in modeling:

1. Every medical *action*, such as test ordering, test result communication, or medical examination, is by default modeled as a *user action*.
2. Every non-medical process, such as data preparation, abstraction etc., is implemented as a *service task*.
3. Every medical *decision*, such as decisions and labels generated on patient data to advance patient diagnosis or treatment, is implemented in Arden Syntax and implemented as a *remote service task*.

3. Results

Figure 1 shows the Activiti implementation of the HepBPW guideline.

The contents of the workflow results include instructions for:

- Active and passive immunization after childbirth, if necessary
- Specific breastfeeding recommendation according to Table 1
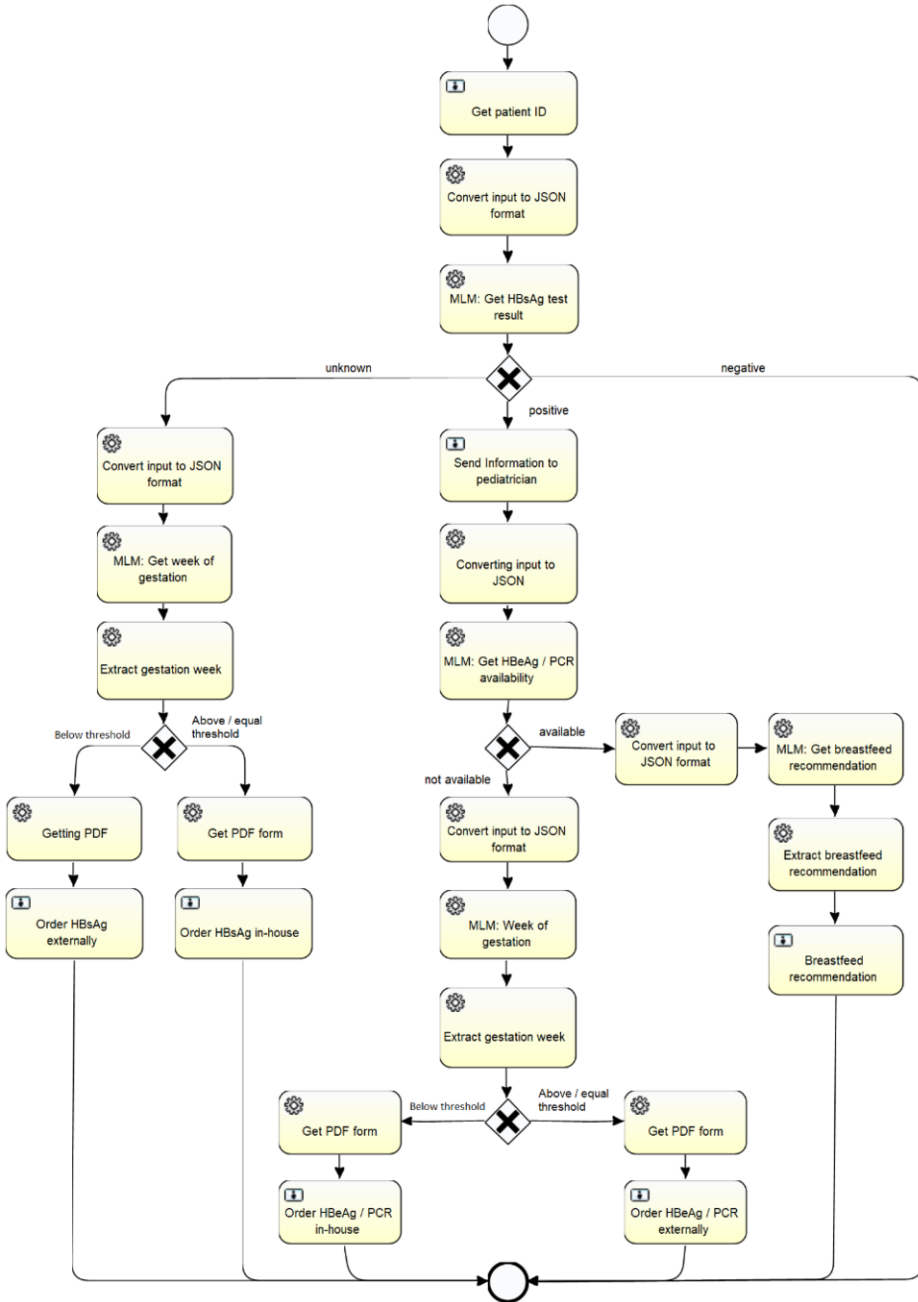- Referrals for hepatitis B antigen and/or hepatitis B PCR testing

Figure 1. Activiti BPMN workflow for the HepBPW clinical workflow.

For the clinical use case, we constructed four MLMs that were responsible for clinical data retrieval and interpretation, including the hepatitis B breastfeeding recommendations shown in Table 1. Table 3 provides an overview of these MLMs and their descriptions.

Table 2. Activiti service tasks created for the clinical use case and their description.

Activiti service task	Description
Convert input to JSON format	Converts a string input to JSON format
Extract gestational week	Extracts a patient's gestational week interpretation
Extract breastfeeding recommendation	Extracts breastfeeding recommendations for a patient
Get PDF form	Retrieves an institute-specific PDF form
Tasks with prefix *MLM:*	Calls institute-specific evaluations implemented in Arden Syntax. These activities function as a wrapper for a REST call to the ARDENSUITE

Finally, in order to orchestrate uniform interaction between Activiti and the ARDENSUITE, we developed a service in Java that can call MLMs over REST communication and receive the results of an MLM call. In this service, parameters and responses are both formatted in JavaScript object notation (JSON).

Table 3. MLMs for the provision and interpretation of medical data related to the HepBPW workflow.

MLM name	Description
BreastfeedDecision	Implements the hepatitis B breastfeeding recommendation as stated in Table 1. The parameters for this decision are read from institute-specific medical data repositories.
GestationWeek	Reads the patient's gestational week from the medical database and determines whether it is below or above an institute-specific threshold related to an action in the workflow.
HBeAg-PCR-Availability	Checks in the institute-specific medical data repositories whether hepatitis B antigen and/or hepatitis B PCR test results are available for a patient.
HBsAgResult	Reads the patient's hepatitis B surface antigen test result from the institute-specific medical data repositories.

Note: HBsAg, hepatitis B surface antigen; HBeAg, hepatitis B envelope antigen; PCR, polymerase chain reaction

4. Discussion

We presented a clinical workflow solution that combines a BPMN-based workflow model with Arden Syntax MLMs. This solution permits the simplification of complex clinical guidelines by dividing them into an evidence-based general workflow layer, and an institute-specific medical decision-making layer. It is an essential step for integrating evidence-based clinical guidelines into the patient care process, and aids in the widespread dissemination and use of such guidelines.

Compared to other reports on the use of BPMN for modeling clinical pathways [8-10], we present a more transparent model of individual clinical workflow parts. Moreover, our method facilitates CDS.

As we developed our solution in a controlled environment, several limitations need to be considered. First, the solution needs to be evaluated by different stakeholders because the guideline was not tested across different clinical departments. As this is only a preliminary technical and clinical feasibility study, an acceptance study is yet to be performed. Finally, as the workflow contains sensitive patient data, the safety and security of data communication between platforms need to be assessed.

As clinical guidelines tend to be neglected in clinical routine, this approach is an innovative milestone in the electronic marshalling of such guidelines with the purpose of achieving the highest quality of patient care. The next step will be to test this approach

in a real-time clinical environment and study workflow results directly in clinical routine; previous projects have already shown how Arden Syntax MLMs can be directly integrated into clinical routine [20, 21].

5. Conclusion

Creating a BMPN-based clinical workflow in combination with an Arden-Syntax-based rule engine proved to be an efficient method of representing and automatically processing clinical guidelines. The use of Activiti enabled us to implement the content of an evidence-based clinical guideline as a BPMN-based clinical workflow, while the ARDENSUITE server and rule engine software instantiates the necessary data access and knowledge-based tasks. This solution permits the implementation of human-readable guidelines and sets a milestone for further clinical informatics research as well as the implementation of clinical guidelines and processing using established standards from two organizations, namely OMG and HL7 International.

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