A Guideline-Derived Model to Facilitate the Implementation of Test-Ordering Rules within a Hospital Information System

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Abstract

The culture of evidence-based practice includes also the field of laboratory medicine. Clinical laboratory expenditure is growing rapidly for various reasons including increased utilization. Delivering decision support to requesters at the point of care is one of the main incentives for implementing laboratory guidelines. Laboratory guidelines were analyzed to extract test-ordering rules. Each rule was explicated in at least one clinical situation with triggers that launch the execution of the implemented rule. The Unified Modeling Language was used to represent the categories of information elements found in the guidelines and underline the information elements that need to be structured and coded in the EHR. These information elements are related to conditions including clinical conditions, habits, family history, demographic information, medical treatments, laboratory tests, and non-laboratory test procedures. Timestamping of each event is also important for implementing laboratory prescription rules. A linkage between the conditions of this model and HL7 RIM was feasible. Use of this model facilitates the implementation of evidence-based test-ordering rules and clarifies the EHR requirements for successful implementation of guidelines.

Keywords:

Test ordering; Computer-Assisted Decision Making; Practice Guideline; Medical Laboratory Science; Health Level 7.

Introduction

In order to optimize patient care, health professionals must modify their practice behavior in response to advances and changes in medical knowledge and technology. Laboratory testing has an important role in patient care process: 60 to 70% of the critical decisions, including admission, medication, and discharge, rely on laboratory test results [1]. Clinical laboratories are currently facing an increasing number of requests. There are various reasons, including greater patient knowledge and demands, fear of litigation, deployment of modern technology, the availability of new tests, and lack of knowledge about appropriate test use [2]. Irrational and inappropriate laboratory test requests affect medical care and may waste health care resources. Between 25% and 40% of requested test have been assessed to be overuse of laboratory resources [3]. Extraneous test requests impose an additional cost and could potentially lead to more false results. Eliminating additional test requests would therefore benefit both patients and healthcare resources. Underuse and misuse of laboratory tests are possible but the rates are difficult to evaluate. Improving the appropriateness of test-ordering behavior is thus a major issue for quality improvement. Several approaches have been proposed in the literature to rationalize physician's test-ordering behavior. They include educational programs, expert feedback to requesters, displaying test costs, changing the format of ordering sheets, and structured web-based diffusion of laboratory guidelines [4–10]. These strategies have been shown to decrease the number of tests ordered to varying extents; however these interventions may be too expensive such that their development and implementation do not result in overall reductions in expenditure [11]. One potentially beneficial approach to improving cost-effectiveness is the implementation of clinical decision support systems (CDSS) in electronic health records (EHR) [12].

Assistance Publique – Hôpitaux de Paris (AP-HP), the largest European academic hospital grouping, includes 44 hospitals with 23,000 beds in the Paris region. The expert panels of AP-HP have formulated evidence-based laboratory guidelines to reduce laboratory errors, especially in ordering and sample-collection phases. Furthermore, the French national health authority (HAS) and the French drug and health products safety agency (ANSM) have published practice guidelines on a national level containing findable statements concerning laboratory medicine. A detailed analysis of these laboratory guidelines indicates the necessary information elements to be appropriately structured and coded in EHR for their successful implementation.

Health Level 7 is an organization that provides standards for the exchange, management and integration of clinical data. The source of the data used by HL7 is conceptualized in an information model entitled the Reference Information Model (RIM). In this article we present a model for implementing test-ordering rules. We then present a mapping between our model and the HL7 RIM standard. Exploiting international standards results in a model generalizable across information systems, guideline knowledge bases, and execution engines.

Methods

Materials

Thirty evidence-based laboratory guidelines formulated by the expert panels of the AP-HP and two national guidelines for dyslipidemia were analyzed to develop a model. Six interna-

tional laboratory guidelines were used to validate the model obtained. These laboratory guidelines cover various fields in laboratory medicine including biochemistry, microbiology, immunoglobulin analysis, cardiac markers, and others. All of the guidelines were in plain textual form and therefore difficult to use at the point of care.

Extracting test ordering rules, disambiguation, and defining clinical situations

We examined the data line by line in each guideline and listed all of the recommendations concerning the prescription and/or represcription of laboratory tests in the different guidelines. To clarify the prescription rules, we analyzed each test-ordering rule and tried to define each information element that appeared to be fuzzy. We considered an information element to be fuzzy if we could not understand the exact meaning. For example, for the prescription rule "Screening for dyslipidemia in children is warranted in children with overweight or familial history of hypercholesterolemia", the word "children" (at which age?), and "overweight" (which BMI?) were ambiguous. Information elements that could be divided into a set of other information elements that required definition were also considered to be fuzzy: for example, "statin therapy" is considered fuzzy and needs to be defined as a set (atorvastatin, fluvastatin, lovastatin, etc.). Then, the situations in which each implemented rule must be applied were clarified and relevant alert messages were produced. For example, for the first example of a test-ordering rule above, two clinical situations are considered: a) screening for a dyslipidemia (lipid panel test) is requested in a child without overweight or family history of hypercholesterolemia; b) the lipid panel test is not requested for an overweight child or one with a history of familial hypercholesterolemia. In the first situation, the alert message must avoid the overuse of the lipid panel test whereas in the second situation, the alert message must remind the physician to order the lipid panel test. Expert panels of the AP-HP then validated disambiguated test-ordering rules and alert messages for different possible clinical situations.

Modeling test ordering rules for implementation

Each test-ordering rule extracted from the laboratory guidelines included information elements constituting conditions and underlying actions. We analyzed these test-ordering rules to categorize the elements of information within them. Therefore we sorted through the rules and extracted and categorized the conditions. Whenever a condition element did not match a previously-encountered category, a new category was added. The categories of conditions found in recommendations were thereby discovered and listed incrementally. For example, the conditions for reordering a test may be persistence or a change of the underlying disease, the administration of a new treatment, weight gain, or simply a time interval between two consecutive test orders. These different conditions belong to different categories, including conditions related to pathological disorders, conditions related to medical treatments, and conditions related to previously-ordered tests. Each of these conditions may be found in different structures of the EHR and saved with different coding systems.

Our goal was to identify the knowledge requirements that fulfill the conditions of guideline rules once these rules are implemented. The next step was therefore to see how, and in which structure, this knowledge should be coded and stored in the EHR to be easily accessible by the query engine of the hospital information system. We used Unified Modeling Language (UML) to model explicited laboratory test ordering

rules found in the guidelines, taking into account the information types to be coded. The message recipient and the explicated clinical situations and relevant alert messages were also included in the model, with their characteristics including the triggers for launching alerts.

Validation of the model

The model developed was then validated by asking four individuals (two of the authors who did not participate in the development of the model and two other medical informatics experts) to instantiate the test ordering rules in the model. For this purpose a questionnaire containing the elements of the model obtained (for example pathological condition, condition related to habits, condition related to age, etc.) was designed and the evaluators were asked to put each extracted condition in its place. If the evaluator was unable to put a condition in the provided category, he checked the "not mentioned" option. In addition, six international guidelines from different sources and relevant to different topics - including preoperative tests, diagnostic testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum*, viral hepatitis, and appropriate ordering of serum tests for Vitamin D - were analyzed to evaluate whether the model was able to represent all the test-ordering rules contained in these guidelines.

Mapping to the HL7 RIM

After developing the UML diagram, we mapped the conceptual contents of the condition classes to HL7 RIM classes. We used the condition subclasses (specialized condition classes) for this mapping. The methodology is provided by HL7 for deriving domain-specific messages from the RIM [13]. Each specialized class representing conditions for test-ordering was mapped to appropriate RIM classes with the attributes required.

Results

The AP-HP guidelines included recommendations for ordering and reordering of tests, in addition to other types of recommendations including those related to specimen collection, the interpretation of results, and the assessment of guideline effects. The national guidelines for dyslipidemia included more types of recommendations relevant to screening, diagnostics, treatment, follow up, etc. Analysis of guidelines revealed that the structures of the documents are highly heterogeneous. The reasons for this were that they were written by different expert panels and addressed different topics in different fields of laboratory medicine.

The information structure concerning test-ordering rules found in these guidelines together with the clinical situations and relevant alert messages are represented in our UML model (Figure 1). Each test-ordering rule has one or more conditions determining the application of the recommendation and leads to a suggested action: that the physician either request or not request a test. Automatic decision attribute in action class allows distinguishing decisions that can be made automatically by CDSS from those that need user judgment. Each test ordering rule may have a unique or a set of conditions related with operators AND or OR. These conditions are important for implementing test-ordering rules because the system needs to search for and check the presence or absence of the conditions as initial inputs that launch automated reasoning leading to the production of outputs that are automated reminders. We as-

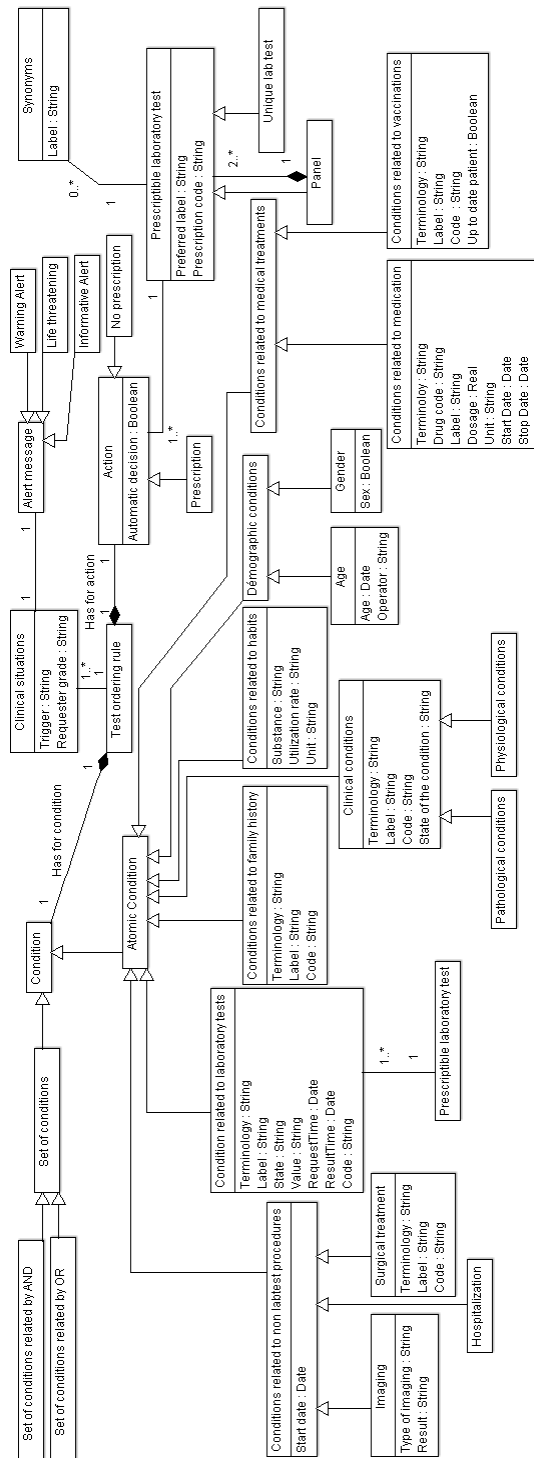signed the conditions of test ordering rules to seven major categories:

Figure 1- UML diagram describing the organization of information elements in test ordering rules

The clinical conditions subcategory covers conditions including the patient's signs, symptoms, pathology, and physiological state (pregnancy for example) that may be criteria neces-

sary to determine whether to order a laboratory test. The state attribute defines whether the clinical condition is a suspicion, an actual diagnosis, or a personal antecedent.

The family history subcategory includes the clinical conditions present in the family history of the patient.

The demographic subcategory includes data for the age and gender of patients, with an operator that determines age above or below that mentioned in the guideline; for example in the rule "in patients more than 80 years old, screening for dyslipidemia is not indicated", the value of the operator is "superior".

The medical treatment subcategory includes data for the drug classes and vaccines administered. The start time and stop time of medical treatments are required for implementing some test-ordering rules.

The habits subcategory includes information about the patient's dietary habits, alcohol use, and use of other substances. There is a substance attribute, and a unit attribute for the unit used for measuring the substance consumption (for example, the number of cigarettes for smoking or glasses for wine consumption). The utilization rate attribute defines the measure of consumption.

The laboratory tests subcategory contains the information about laboratory tests, including ordering and results. The state attribute differentiates laboratory result from a test order. The non-lab test procedures category contains all procedures performed for the patients including imaging, surgical interventions, and even hospitalization. The start date of the procedures allows calculation of the time intervals contained in some test ordering rules. For example, if the patient is hospitalized for more than three days, standard stool culture is not indicated and only testing for *Clostridium difficile* is sufficient.

Terminology, label, and code are attributes used in several condition classes. Terminology indicates the applied terminology or coding system (for example, SNOMED CT, LOINC, or the local terminology). The name and code of the condition in the applied terminology would be stored in label and code attributes, respectively.

Each test-ordering rule was explicated in at least one clinical situation with a trigger condition that launches the execution of the implemented rule to produce a relevant reminder message. Some examples for triggers are a new laboratory prescription, a new drug prescription, the arrival of a laboratory result and its value, or noting a specific clinical problem in the EHR. Another attribute of the clinical situation is the requester's grade: this allows personalization of the reminders according to the grade of test requesters (medical students, interns, residents, and specialists). Consequently, not all reminders need to be displayed to all users. A medical student may need to be alerted more than an experienced specialist clinician. This helps decrease clinician 'alert fatigue'. The reminder message is designed to present different levels of importance: informative, warning, and life threatening. The use of visualization techniques including color codes or iconic codes could convey this characteristic more effectively. Finally, a prescriptible laboratory test may be a single laboratory test or a panel of tests.

All of the four evaluators successfully instantiated the test ordering rules in the model obtained. None of them used the "not mentioned" option. Some feedback about some attributes and the graphic design of the model were taken in to account. The model was also validated with six international laboratory

guidelines: this validation found that the model was able to represent all of the test ordering rules contained in these guidelines.

We mapped the condition classes to HL7 RIM. Table 1 illustrates condition classes from the model obtained mapped to HL7 RIM classes and attributes.

Table 1 - Mapping condition classes to HL7 RIM

Condition classes	Mapping to HL7 RIM classes and attributes
Imaging, Family history, Pathological conditions, Physiological conditions, Habits	Observation MoodCode: EVN Code: CD Value: ANY
Surgical treatment	Procedure MoodCode: EVN Code: CD
Hospitalization	PatientEncounter MoodCode: EVN EffectiveTime: GTS
Laboratory test	Observation MoodCode: EVN/RQO Code: CD Value: ANY ActivityTime: GTS EffectiveTime: GTS
Age	Person BirthTime: TS
Gender	Person AdministrativeGenderCode: CE
Medication, Vaccination	SubstanceAdministration MoodCode: EVN Code: CD EffectiveTime: GTS DoseQuantity: IVL <PQ> RateQuantity : IVL<PQ>

Several condition classes were mapped to the RIM Observation class. This class has several attributes, only five of which were used in our mapping. The attribute MoodCode Event (EVN) refers to something that has already happened (for example a test result). The MoodCode could be time stamped by EffectiveTime (states clinically relevant time of the act) and ActivityTime (states when the act itself occurs). For example, for a laboratory request, the effective time is needed, which is the time that the sample is requested to be taken (the activity time in laboratory request is the time the request is made); for a laboratory test result, the activity time is needed, which is the time the test was performed (the effective time in laboratory result is the time the sample is taken from the patient). The MoodCode Request (RQO) is a request or order for a service. The Code attribute defines a particular coding system (SNOMED CT for example) for the specified Observation. CD data type in HL7 enables complex post-coordinated expressions to be exchanged. The Value attribute relates a specific value for an observation at a point in time (a laboratory result value for example). The value data depends on the data's nature. Data types used for time attributes are GTS (general timing specification), IVL (interval of time) and TS (point in time). Procedure, Person, PatientEncounter and Sub-

stanceAdministration are other classes of RIM that were used in this mapping. In our application, substance administration is used in Event mood code to record that a medication has been administered to a patient. CE data type allows a term to be coded in more than one way. PQ is a HL7 basic data type involving Physical Quantity (a quantity with units).

Discussion

We report an analysis of laboratory guidelines that made it possible to identify the elements of information necessary for structured inclusion in EHR. These elements must be entered using appropriate terminologies and coding systems if they are to be exploited to implement guidelines and generate automatic reminders. The structure proposed in the model contributes to the implementation of laboratory test-ordering rules. The model facilitates the understanding of these information elements and the existing relations amongst them. A quick look at our proposed model helps the editor of EHR forms assess whether the structure of data entering in a form is adapted for launching automated reminders. CDSS developers could use this model to implement guideline rules and integrate them into EHR. The mapping to HL7 RIM classes evidences its usability in standard international systems and indicates its interoperability.

The model clarifies the information elements that have to be formalized and coded in EHR. This formal representation is required to make the implementation of test-ordering rules possible. The coded information is easily accessible by the query engine of the system once the rules have been implemented. The values of any coded condition can launch the execution of the rules and the production of the relevant reminder messages. The model is designed in a way that is not restricted to a particular terminology and coding system, such that its use can be generalized and it can be adapted to local or international coding systems. Test orders, laboratory results, clinical conditions, procedures, medical treatments and vaccinations must be coded in the EHR. Various terminologies and coding systems may be used for each category of information. However, applying international and widely used coding systems including SNOMED CT (for clinical problem list, procedures, and laboratory prescription), LOINC (for laboratory results), and ATC classification system (for drug treatment) would enhance interoperability between different medical establishments. At a local institution, the standard definition of information elements including patient data needs to be mapped to terminologies used locally to allow the implementation in the local EHR. In addition to the coding systems, both the traceability of demographic information and timestamping of each event are necessary.

A formal model for guideline representation provides an in-depth understanding of clinical care processes addressed by clinical practice guidelines. Other studies reporting guideline representation models have also evidenced the usability and helpfulness of models to integrate guidelines in computer-interpretable formats [14,15]; a formal model for patient data is considered to be essential for the integration of guidelines into EHR and order entry systems [15]. A large number of these models are declarative and do not incorporate a formal computational model aimed at guideline execution. Furthermore, we were interested in laboratory guidelines, particularly test-ordering rules. We decided that we would create a new model; one which best answers our needs for implementing test-ordering rules.

If there is an overload of decision support alerts, the response of clinicians to the alerts will decline. This is called alert fatigue, and it is one of the common causes of clinicians overriding decision support systems alerts; this can indirectly impair patient safety [16,17]. The ability of the model to show the reminders according to the user makes the CDSS to bring the guideline information not only in appropriate clinical situation and at the point of care, but also only to the relevant health care professional to overcome the alert fatigue phenomenon.

Evaluators checked the generalizability of the model, instantiating the test-ordering rules found in the guidelines. The model could represent all test-ordering rules extracted from the studied guidelines but this does not guarantee that the model can store all possible types of test-ordering rules. Further evaluation of the model, with international laboratory guidelines, would confirm the validity of this model; however, the development of laboratory guidelines for determining appropriate and inappropriate use of laboratory tests is not very considerable [18] compared to other types of clinical guidelines. The modeling reported here is exploratory and the mapping is preliminary. We only mapped the condition classes as the most important part of our model and the intent was to evaluate the feasibility of representing test ordering conditions, contained in the guidelines, with HL7 standards. Further development and mappings are suggested with the cooperation of HL7 RIM developers to map other classes, add details, and check for consistency.

Conclusion

Retrieving clinical information for every biological investigation and for the right health care professional will improve the quality of laboratory medicine. Using the proposed model for the implementation of laboratory medicine guidelines may facilitate decision support tasks by defining what is required in the EHR structure and the elements of information to be coded. It is possible to link guideline-derived conditions for ordering tests to HL7 RIM. This is important for exchanging data between different information systems. Implementing test-ordering rules enables further evaluation of reminder effects, such as resulting level of alert fatigue. This model may also contribute to the formulation of new laboratory guidelines.

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