

Representing the Patient's Therapeutic History in Medical Records and in Guideline Recommendations for Chronic Diseases Using a Unique Model

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Abstract

Computer-interpretable guidelines (CIGs) are more likely to affect the clinician's behavior when they deliver patient-specific and just-in-time clinical advice. CIGs must take into account the data stored in the patient's electronic medical records (EMR). For chronic diseases, the outcome of past and ongoing treatments (therapeutic history) is used in the clinical guidelines. We propose a model for the conceptualization of therapeutic history, facilitating data sharing between EMRs and CIGs and the representation of therapeutic history and recommended treatments in clinical guidelines.

Based on medical literature review and an existing treatment model, a core structure is first defined taking into account drug and non-drug treatment components and treatment type (e.g. bitherapy). These elements together with additional concepts obtained by analyzing a sample guideline relating to diabetes, are then organized into an object-oriented model, using UML formalism.

We show how this model can be used to store the patient's therapeutic history in the EMR, together with other attributes such as treatment efficacy and tolerance. We also explain how this model can efficiently code guidelines therapeutic rules.

We evaluated this model, using additional guidelines for hypertension, hypercholesterolemia and asthma. We found it capable for representing guideline recommendations in several domains of chronic diseases.

Keywords:

Computerized Medical Records; Computer Interpretable Guidelines; Decision Support Systems; Treatments; Models; Chronic Diseases

1. Introduction

Evidence-based clinical guidelines are developed to improve the quality of medical care but their impact depends on their optimal implementation in real practice. Studies have shown that computer interpretable guidelines are most likely to affect the behavior of a clinician if they deliver patient-specific and just-in-time clinical advice [1, 2]. Efforts have therefore been made to develop methods linking computerized guidelines to data concerning the

patient stored in electronic medical records (EMR) [3]. However, few published studies have dealt with the automation of EMR-integrated guidelines for the management of chronic diseases [4-6]

Treatment decisions for chronic diseases depend on previous decisions and actions and the outcome of those actions [7]. Thus, automatic systems must be able to use the EMR to reconstitute previous treatments and their outcome, to trigger the new strategy recommended by a guideline. Therapeutic recommendations in the guidelines can be considered as rules composed of *conditions* and *actions* [8]. For chronic diseases, *conditions* are usually expressed as combinations of *clinical* and *therapeutic criteria* [9]. Two major aspects of patient's past or ongoing treatments (referred to hereafter as therapeutic history) are considered in *therapeutic criteria*: what has already been prescribed and the outcome of this treatment in terms of efficacy and tolerance. *Actions* in this context are sets of therapeutic options, generally expressed in terms of therapeutic classes, but sometimes expressed in other ways, as a particular type or group of therapeutic agents, for instance. An example of a therapeutic rule for type 2 diabetes management is, "If oral monotherapy with maximal doses of sulfamide or metformin associated with lifestyle changes is not effective, then the monotherapy should be replaced by oral bitherapy."

The automatic use of these kinds of rules in guideline-based reminders requires the correct and structured storage of outcome of the patient's treatments in the EMR. Drug prescriptions are often stored in the EMR as independent prescription lines without structured information concerning efficacy and tolerance. They do not help distinguish different treatments in a prescription (e.g. biotherapy for hypertension). Moreover, as seen in the example, specifying information concerning treatments in both *condition* and *action* parts of the guideline rules requires the use of terms or concepts in various levels of abstraction. The main challenge for reminder systems is therefore the integration, at the appropriate level of abstraction, of data from past prescriptions into the decision flow. If these systems are to produce reminders with the minimum human interaction, they should also compare, at an appropriate level of abstraction, the recommended action to the physician's prescription.

Several models and methods [8, 10] have been developed for the representation of medical knowledge, but they do not provide specific structures for representing and sharing treatment details in ways convenient for both EMRs and therapeutic rules.

During the two first phases of the ASTI project [11], dealing with the implementation of guidelines for hypertension and diabetes, we looked for a generic representation of therapeutic history applicable to various therapeutic domains. We present here the main results of this research, in terms of the building and evaluation of an object-oriented model.

2. Materials and Methods

Building the conceptual model

Based on a preliminary review of several clinical guidelines [12] and using some concepts of the prescription model of Sene et al. [13], we first defined the essential components of treatments and the major concepts required to describe information about those components. We then analyzed the recommendations of a sample guideline [14] and turned them into rules comprising *conditions* and *actions*. We identified the words or expressions describing therapeutic criteria as the rule *conditions* or proposing treatment in the *actions*. Based on methods used for the modeling of pharmacokinetics concepts [15], we grouped the terms on the basis of semantic similarity and linked them to general concepts. We then added labels characterizing their semantic content. This resulted in the formation of additional required concepts, elements or attributes, which were then reviewed and

arranged into classes and objects. Relationships between the concepts and possible values of elements or attributes were then determined.

The obtained concepts and elements were finally organized according to classes, attributes, generalization, composition or association relationship, into an object-oriented model representation based on Unified Modeling Language (UML) formalism.

Preliminary evaluation of the model

We selected three guidelines covering various aspects of chronic diseases (hypertension, hypercholesterolemia and asthma) [16-18]. All guideline rules including conditions related to data about treatments or proposing therapeutic actions were extracted. The words or expressions delineating therapeutic criteria or treatment strategies were identified. Two physicians were then asked to determine whether they could be represented using the model.

We checked that all concepts from the guidelines could be structured into the model, ensuring that no concept was missed. The proportion of concepts included provided an assessment of the completeness of the model for representing guideline knowledge about treatments.

We then assessed the model comprehensibility by checking that all users converted the text into the model in the same way. We then calculated the ratio of the number of concepts identically modeled to the total number of concepts.

3. Results

We will first describe the core of the model representing information about treatment and will then show how the model can be used to store treatments and their outcomes in the EMRs or be used to represent guideline therapeutic recommendations.

The core of the model

As the model applies to management of chronic diseases, in which non-drug treatments such as diet and physical exercise are important therapeutic components, the treatment model must represent information relating to not only drugs, but also non-drug components (Figure 1).

The overall combination of drug and non-drug elements results in a treatment with a particular attribute *Treatment Type*, e.g. bitherapy. Most guidelines predefine treatments in terms of several treatment types. Recommendations such as “prescribe bitherapy” can therefore be represented in the model, using this *Treatment Type* attribute. However, recommended treatments are sometimes addressed indirectly by specifying a strategy such as “replace monotherapy”. We therefore introduced the attribute *Intended Strategy* into the treatment, enabling the direct transfer of the concept to the end user or to a calculating algorithm.

We also introduced, as *Treatment Objective*, attributes representing the *Reason* for treatment (e.g. hypertension), the goal to achieve (e.g. blood pressure under 14/9) and the estimated time to achieve the goal (e.g. 3 months).

The drug components of the treatment can be specified based on pharmacological group, therapeutic class, non-proprietary name or trade name. Dosage may be represented quantitatively (e.g. 1 g per day) or qualitatively (low, intermediate or high dose). The non-drug component, including any therapeutic lifestyle change that the patient is advised to make in addition to taking the prescribed drugs, has a denomination and an intensity (e.g. for representing moderate or intense physical exercise).

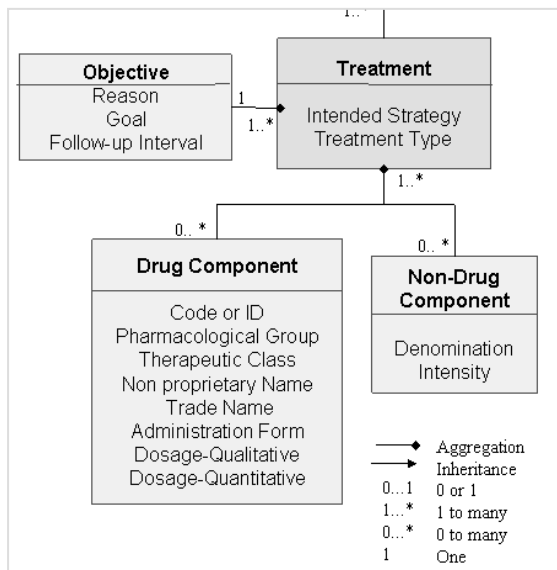


Figure 1-The core of the model, representing major concepts concerning a treatment

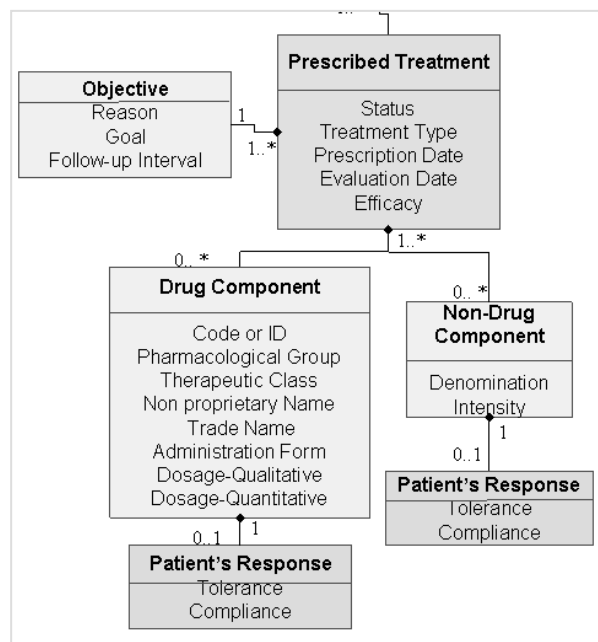


Figure 2 Model for storing prescribed treatments and their outcome in EMR

Using the model in EMRs

This core structure of the model can be used to store the therapeutic history of the patient in EMR (Figure 2). The distinction of treatments in a prescription according to therapeutic indication of each prescription line, makes it possible to attribute the outcome of the evaluation to the appropriate elements at every visit. As seen in figure 2, it is to the *Treatment* (i.e. the combination of related components) that *Efficacy* is attributed while *Tolerance* and *Compliance* are associated to each separate component.

We also added an attribute *Status*, with two values “past” and “ongoing” to make it possible to distinguish representations of treatments currently in use from those previously used.

Using the model to represent guideline recommendations

We can also use the same model to represent condition and action parts of guideline rules (figure 3). Based on the data from *Efficacy* and *Tolerance* of the ongoing treatment, characterized by *Therapeutic Criteria* in the condition part, new treatments are proposed in the action part. Treatment is usually specified in terms of the *Therapeutic Class* and/or international non-proprietary name (*INN*) of each component, but may also be expressed using high-level concepts such as *Treatment Type*, or *Intended Strategy*.

The action part of a recommendation may be the prescription or prohibition of a treatment. We therefore added the attribute *Proposition Type*, which may take the values “Prescribe” or “Do not prescribe”.

Evaluation of the model for representing guideline rules

The model was found to represent therapeutic recommendations accurately in 99% of cases. For the very few terms that could not be entered directly into the model, a simple interpretation of the rule made representation entirely possible.

The ratio used to evaluate concordance between modeling results was found to have a value of 90 %. The main difficulty encountered was ambiguity in the text of the guidelines.

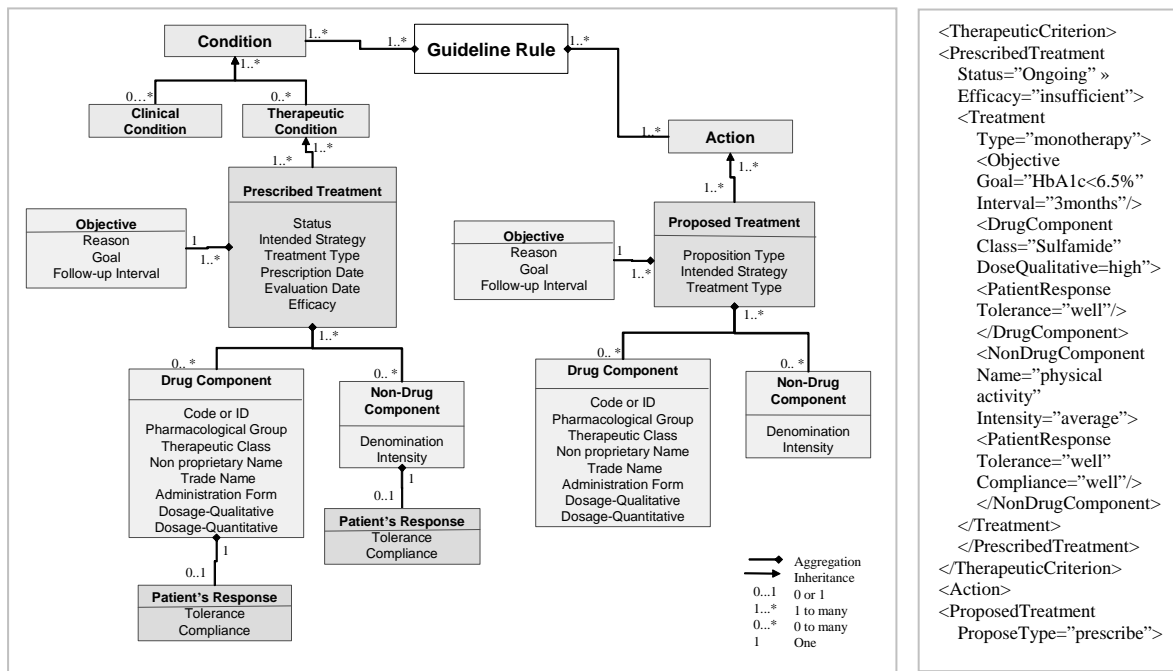


Figure 3 : Representing therapeutic history and proposed treatments in guideline rules accompanied by an implementation example in XML

4. Discussions and Conclusion

We used an approach based on medical literature review and analysis of a guideline for diabetes, in which we thought that therapeutic history was likely to be extensively used and a variety of modifications were seen on the type, group, class or dose of the drugs as new treatment propositions. The demonstrated applicability of this model to other domains shows that this model has the potential to represent treatment concepts in medical knowledge in a generic manner.

Some of the concepts used in our model may already have been included in existing guideline models, but this model seems to facilitate the sharing and representation of data concerning treatment outcome and other details. It also facilitates switching between abstraction levels, making it possible to compare data at the appropriate level in automatic systems.

This model is based on the usual working practices of physicians, who tend to combine drug and non-drug components to obtain an efficient treatment. The physician then assesses at the next visit, the overall efficacy and evaluates the tolerance to each independent component of treatment. This representation corresponds to the most frequent cases, but it should be possible to find specific cases in which each drug component of a treatment is well tolerated by the patient when taken alone, but the combination of drug components is poorly tolerated. However, such situations do not appear to be frequent.

Dose description has been simplified by using qualitative rather than quantitative dose information, as they are generally specified in guidelines. This matter is also reported in other models [13].

A first-step translation of narrative guidelines by the model generates information in a format that can be processed by the computer. However, it can do little to resolve the ambiguity of paper-based guidelines, for which the resolution is left to the user.

Further evaluation of this model is required to confirm its generic nature. Chronic disease or other domains in which there are many different modes of treatment could be used for these subsequent evaluations.

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