Representation of Clinical Practice Guidelines For Computer-Based Implementations

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Abstract

Representation of clinical practice guidelines is a critical issue for computer-based guideline development, implementation and evaluation. We studied eight types of computer-based guideline models. Typical primitives for these models include decisions, actions, patient states and execution states. We also find temporal constraints and nesting to be important aspects of guideline structure representation. Integration of guidelines with electronic medical records is facilitated by the introduction of formal models of patient data. Patient states and execution states are closely related to one another. Interrelationship among data collection, decisions, patient states and interventions in a guideline's logic flow varies in different guideline representation models.

Keywords:
Clinical Practice Guidelines; Theoretical Models; Knowledge Representation

Introduction

Clinical practice guidelines (CPGs) are developed to reduce inappropriate variations in practice, to improve health care quality, and to help control costs [1]. Although the importance of guidelines is widely recognized, health care organizations typically pay more attention to guideline development than to guideline implementation for routine use in clinical settings [2], evidently hoping that clinicians will simply familiarize themselves with written guidelines and then apply them appropriately during the care of patients. Studies have shown that computer-based clinical decision support systems can improve clinician performance and patient outcomes [3]. Guideline-based clinical decision support systems have been proposed for this purpose [1,4-6].

To implement guidelines within a computer-based clinical decision support system, guideline representation is a critical issue. A formal model for guideline representation will provide in-depth understanding of the clinical care processes addressed by guidelines, and thus will lead to (a) more rigorous methods of guideline development (for example, verification of a guideline's logical completeness and detection of ambiguity, inconsistency and redundancy [7,8]), (b) more robust approaches for guideline implementation (for example, integration of guidelines with clinical workflow and improvements in guideline maintenance [9,10]), and (c) more effective techniques for guideline evaluation (for example, identification of variations in knowledge organization by different clinicians and resulting effects on their requirements for assistance during the process of decision making [11]).

In this paper, we review current research on guideline representation models. Our focus is on those parts of the models that facilitate computer-based implementation of guidelines, as well-structured guidelines are critical for the development, implementation and evaluation of clinical decision support systems that are based on them.

Methods

Based on a search of the literature, eight research projects with publications about guideline-specific representation models were included in our review [12-21]. Inclusion of a paper as a relevant subject in the review was based on our subjective decision.

Dimensions of the review included guideline representation primitives, structural arrangement of these primitives and patient data modeling, as these are the basic features of guidelines that need to be addressed in computer-based implementations. In case there were multiple published releases for a reviewed guideline representation model, the features discussed below were based on the most recent one.

Results

The representation primitives, structures and patient data modeling of the reviewed guideline representation models are summarized in Table 1. Below we discuss some typical features of these representation models.

Representation Primitives

All of the reviewed models contain decisions and actions as primitives in their guideline representation, and most of them also contain patient states or execution states as

Table 1 – Guideline Representation Models and Their Features

Guideline Model	Representation Primitives				Structure for Primitives		Patient Data Modeling
	Decision	**Action**	**Patient State**	**Execution State**	**Temporal Constraints**	**Nesting**	
Arden Syntax [12]	logic slot	action slot	no	no	module invocation	no	no
DILEMMA [13]	state transition	protocol	n/a	procedure state	protocol composition, state transition diagram	protocol	patient record model
EON [14,15]	decision step	action, activity	scenario, activity state	no§	flowchart	subguideline	EPR ontology
PROforma [16]	decision	action, enquiry	n/a	task state	constraints satisfaction graph	plan	n/a
GLIF [17,18]	decision step	action step	patient state step	no	flowchart	subguideline	three-layer domain ontology
Asbru [19]	condition, preference	plan	temporal patterns	plan state	plan-body	plan	n/a
GUIDE [20]	decision	task, wait, monitor	(implicit)	n/a	flowchart	task	relational
PRODIGY [21]	decision	action, activity	scenario	n/a	state transition diagram	subguideline	EPR ontology

n/a: information not available from the publications
§ EON has execution states, but they are not in the guideline representation model

another primitive. An *action* is a clinical task or intervention that needs to be performed or is recommended in the process of guideline application, for example, a medication. A *decision* is a selection from a set of alternatives based on some predefined criteria in a guideline, for example, selection of a medication from a set of potentials. A *patient state* is a description of a treated individual based on the actions performed and decisions made within the context of a guideline, for example, after a patient is found to be more than 50 years old and without any allergies for influenza vaccine, she will be in a patient state *eligible-for-influenza-vaccine*. An *execution state* is a description of a guideline implementation system based on the stages of process with regard to the decisions and actions defined in a guideline, for example, after a patient enters into the *eligible-for-influenza-vaccine* patient state, the underlying guideline execution engine will change to *ready* execution state for the influenza vaccine guideline. We specify the relationship between patient state and execution state in the discussion section below. In the following paragraphs we explain different ways in which actions, decisions, patient states, and execution states are represented by the different guideline models.

Arden Syntax has a *logic slot*, which is used to encode the decision criteria of a Medical Logic Module (MLM), and an *action slot*, which is used to encode the clinical task that should be performed [12]. GLIF has a *decision step*, an *action step*, and a *patient state step* [17,18], which correspond to decision, action and patient state. Arden Syntax does not have a primitive to represent patient state or execution state [12]. Its ability to represent complex clinical guidelines directly, which usually consist of multiple decisions, actions and patient states, is thus constrained. An alternative is the use of intermediate states to link related MLMs [22].

DILEMMA represents guidelines as a set of *protocols* within which actions are encoded. In DILEMMA, execution states are represented as *procedure states* and decisions are represented as *state transitions* [13]. A similar approach is used in Asbru, which has *conditions* and *preferences* corresponding to decisions as well as *plans* and *plan states* to actions and execution states [19].

EON distinguishes an *activity*, which is a continuous process, from an *action*, which is an instantaneous process [14,15]. Consequently, it offers both a *patient scenario*, which is used to describe the patient state with regard to decisions made and actions completed, and an *activity state*, which is used to describe the patient state with regard to the status of activities. A similar approach can be found in PRODIGY [21].

PROforma has a special type of action, *enquiry*, which is used for information collection rather than interventions [16]. This type of action does not affect patient states, but leads only to a more clear understanding of them. Similar primitives can be found elsewhere, such as *temporal query* in EON [14,15] and *get_data_action* in GLIF [17,18]. On the other hand, GUIDE has a *wait* action [20], which seems not to be a real action, but patient state may still change during this process because the underlying patient pathophysiological status may change over time. GUIDE does not define patient state explicitly [20]. But its underlying representation is based on Petri nets, which implies the existence of patient states.

Structure for Primitives: Temporal Constraints and Nesting

Primitives are the elements in a guideline representation model. Primitives themselves are not sufficient for guideline representation. Structural arrangement of these primitives is another important issue that needs to be addressed by a guideline representation model.

Almost all of the reviewed representation models provide for the representation of guideline structures as temporal constraints on representation primitives and nesting of guidelines. Here temporal constraints on representation primitives are specifications of the temporal order that primitives can be executed. Nesting of guidelines captures the composition of a complex guideline with subguidelines.

As defined in Asbru, temporal constraints such as *sequence* or *concurrence* can be represented in two dimensions, i.e., *ordering constraints*, which can take on the values *parallel*, *any order* or *total order*, and *continuation condition*, which can take on the values *all completed* or *some completed* [19]. Combinations of these two dimensions result in five temporal constraints of representation primitives, i.e., *DO-ALL-TOGETHER*, *DO-SOME-TOGETHER*, *DO-ALL-ANY-ORDER*, *DO-SOME-ANY-ORDER*, and *DO-ALL-SEQUENTIALLY* [19]. Asbru also provides a third category of temporal constraints, represented as a *cycle*. All of these constraints are represented within its *plan-body* [19]. The same approach is used by EON and then adopted by GLIF to use the *branch step* and the *synchronization step* to represent *sequence* in any order and *concurrence*, while using the *next-step* slot to represent simple *sequence*. The *branch step* of GLIF defines a point in a flowchart that is followed by multiple parallel paths or paths that can be traversed in any order [17,18]. The *synchronization step*, on the other hand, defines a point at which diverged paths converge back, with a continuation criterion defined either as a *Boolean criterion*, which is a logical expression of the diverged paths, or as a *k_of_n criterion*, which is a special case of a *Boolean criterion* [17,18]. As the continuation criterion is a logical expression, GLIF is very expressive in its temporal constraint representation. Unlike Asbru, which defines *cycle* directly with representation primitives, GLIF defines a simple *cycle* within a single primitive and a complex *cycle* in a subguideline [17,18]. Similarly, DILEMMA supports the representation of *sequence*, *parallel* and *exclusive alternatives* in its protocol composition [13]. GUIDE's underlying Petri net model supports the representation of *sequential*, *parallel*, and *iterative* logic flows [20].

EON, GLIF and GUIDE represents temporal constraints as a *flowchart* [14,15,17,18,20], PROforma represents the temporal constraints as a *constraints satisfaction graph* [16], while DILEMMA represents temporal constraints on protocols in its *protocol composition* and temporal constraints on procedure states with a *state transition diagram* [13]. On the other hand, PRODIGY models a guideline as a diagram of state transitions among patient scenarios [21]. The flexibility of this approach is very helpful for representation of chronic disease guidelines, which usually contain multiple patient scenarios in different encounters that need to be decided. The philosophy behind is that guideline users can always override any decisions made by the system [21].

Arden Syntax takes a modular approach to encoding of knowledge in MLMs. Although an MLM can invoke other MLMs, Arden Syntax itself does not model the structure of these invocations [12].

Nesting is another important representation feature, since it enables multiple levels of abstraction in guideline representation. All reviewed models except Arden Syntax support nesting. For DILEMMA, it is through recursive decomposition of *protocol* [13]; for EON, GLIF and PRODIGY, it is through inclusion of *subguideline* [14,15,17,18,21]; for GUIDE [20], it is through decomposition of *task*; and for PROforma and Asbru, it is through specification of *plan* [16,19].

Patient Data Representation

The value of guidelines can be realized only through their application in clinical practice. Unless physicians read, memorize, and then use such guidelines on their own, clinical implementation of guidelines requires their integration with electronic medical records (EMRs) and ideally, with physician order-entry systems. One of the most important requirements for achieving such integration is a standard definition of patient data, which can then be mapped to implementation-specific database access methods through a standard interface. Several large projects have been devoted to building standard controlled medical terminologies, such as SNOMED [23] and READ [24]. How to incorporate these standards in a guideline representation so that they can be used to encode patient data thus becomes a critical issue.

Arden Syntax provides a definition for the interface to patient data with its *data slot*. However, it does not support patient data modeling [12]. Patient data encoding, which is enclosed within a pair of curly braces ("{}"), is left to the local site to implement and integrate. This *curly braces problem* is one of the major hindrances for the sharability of logic modules represented using Arden Syntax [25]. EON uses an ontology approach to mapping patient data encoded in guidelines to an external EMR, while GLIF uses a three-layer domain ontology that attempts to build an internal patient data model with an interface to external terminologies [18].

Discussion

Decisions and actions are the key primitives that should be supported by a guideline representation model. This observation is supported by all of the reviewed models. Explicit modeling of patient states and execution states are also important in guideline representation. However, most reviewed models support only one of them, at least as reported in the literature. In fact, they are the two sides of the guideline application process, i.e., the patient side and the system side. The patient state reflects the status at the patient side, while the execution state reflects the status at the system side. If we consider the conditions for execution state transitions, we can see that compliances with these conditions are guideline-specific and correspond to the patient states as we defined above. Giving interventions induced by changes in guideline execution to a patient will change her patient state. In this sense, patient state and execution state are closely related to one another. This may explain the phenomenon that most reviewed models with only one type of state represented are still rather expressive. However, as patient state can be affected by changes outside the control of a guideline application, patient state and execution state may diverge from one another.

Decision-making is based on available patient data and other information. One category of actions, which we call data collection (for example, *enquiry* defined in PROforma [16]), needs to be performed before a decision can be made, although in many cases this is specified only implicitly by virtue of the use of data in a decision criterion. Patient state is often used as an entry or exit point for a guideline, but theoretically it may appear at any places in the guideline process flow. We thus define the patient state based on decisions made and actions performed in the context of a guideline. With this definition, the process to make a decision is in fact a confirmation of a patient state. Finally, another category of actions, which we call interventions (for example, clinical interventions and other actions such as *wait* defined in GUIDE [20]), is usually the cause of a change from one patient state to other patient states. The relationship among these representation primitives is shown in Figure 1.

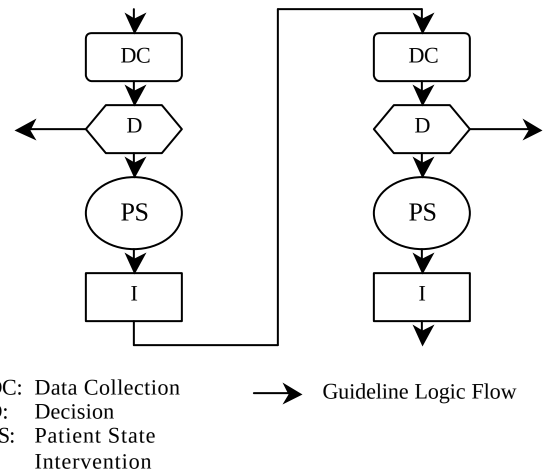

Figure 1. Primitives, Modules and Guideline Logic Flow

This review has focused on guideline representation primitives and their structural arrangement, and does not attempt to be fully comprehensive. Other guideline representation reviews include Tu's work, which focused on high-level guideline representation formalisms and the computational methods associated with them [26], Fox's work, which focused on the quality and safety aspects of guideline representations [27], and Shiffman's work, which focused on guideline implementation systems [28].

Conclusion

Decisions and actions have been consistently identified as necessary primitives for a guideline representation scheme. Patient states and execution states are important concepts in guideline representation that are closely related to one another. Guideline structures can be encoded with temporal constraints such as sequences, concurrences and iterations. Nesting of guidelines is an important representation feature that enables multiple levels of abstraction. Modeling of patient data is a critical issue for a guideline's integration with an EMR and an order-entry system.

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