

Comparing Computer-Interpretable Guideline Models: A Case-Study Approach

Running head: Comparing guideline decision and action models

Mor Peleg, Ph.D.^{1*}, Samson Tu, M.S.¹, Jonathan Bury, M.B.Ch.B.², Paolo Ciccarese, M.Sc.³, John Fox, Ph.D.², Robert A Greenes, M.D., Ph.D.⁴, Richard Hall, M.Sc.⁵, Peter D. Johnson, M.B.B.S.⁵, Neill Jones, M.B.B.S.⁵, Anand Kumar, M.B.B.S.³, Silvia Miksch, Ph.D.⁶, Silvana Quaglini, Ph.D.³, Andreas Seyfang, M.Sc.⁶, Edward H Shortliffe, M.D., Ph.D.⁷, and Mario Stefanelli, Ph.D.³

¹ Stanford Medical Informatics, Stanford University School of Medicine, Stanford, CA, USA

² Advanced Computation Laboratory Cancer Research UK, London, UK

³ Medical Informatics Laboratory, Department of Computers and Systems Science, University of Pavia, Pavia, Italy

⁴ Decision Systems Group, Harvard Medical School, Brigham & Women's Hospital, Boston, MA, USA

⁵ Sowerby Centre for Health Informatics at Newcastle, University of Newcastle, Newcastle upon Tyne, UK

⁶ Institute of Software Technology and Interactive Systems, Vienna University of Technology, Vienna, Austria

⁷ Department of Medical Informatics, Columbia University, New York, NY, USA

Reprint requests and all communication should be addressed to:

Mor Peleg, Stanford Medical Informatics, Medical School Office Building x208, 251 Campus Drive, Stanford, CA 94305-5479; Phone: (650) 723-7711 Fax: (650) 725-7944; E-Mail: peleg@smi.stanford.edu

Abstract

Objectives: Computer-interpretable clinical guidelines (CIGs) are being developed to support decision-making during clinical encounters. CIGs use “Task-Network Models” for representation but differ in their approaches to addressing particular modeling challenges. Our purpose has been to understand commonalities and differences, so as to identify issues to be resolved if a consensus on a set of common components is to be developed.

Design: The models compared were Asbru, EON, GLIF, GUIDE, PRODIGY, and *PROforma*.

Collaborators from each group that created these models represented, in their own formalism, portions of two guidelines: the American College of Physicians – American Society of Internal Medicine’s guideline for managing chronic cough, and the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

Measurements: We compared the models according to eight components that capture the structure of CIGs. The components enable modelers to encode guidelines as plans that organize decision and action tasks in networks so as to fulfill plans’ goals. They also enable linking of the encoded guidelines with patient data—a key requirement for enabling patient-specific decision support.

Results: While we found consensus on a number of components including plan organization, expression language, conceptual medical record model, medical concept model, and data abstractions, differences were most apparent in underlying decision models, goal representation, use of scenarios, and structured medical actions.

Conclusion: We identified guideline components that the CIG community could adopt as standards.

Some of the participants are pursuing standardization of these components under the auspices of HL7.

Keywords: clinical guideline, computer-interpretable guideline, modeling, Asbru, EON, GLIF, GUIDE, PRODIGY, *PROforma*

I. INTRODUCTION

Clinical guidelines are increasingly being used to support clinicians' decision-making. Such guidelines are intended to improve the quality of patient care, reduce variations in quality of care, and reduce costs. It has been demonstrated that clinician behavior is most effectively influenced through patient-specific advice, particularly if delivered during patient encounters^{1,2}. However, conventional narrative guidelines present population-based recommendations, and the information contained within such guidelines may be difficult to access and apply to a specific patient during the consultation. Guideline-based point-of-care decision support systems have the potential to address this problem. A prerequisite for the development of such systems is the creation of computer interpretable representations of the clinical knowledge contained in clinical guidelines. A number of groups are actively developing computer interpretable guideline (CIG) representation languages for this purpose³⁻⁸. Groups have adopted different approaches reflecting their interests and expertise. Nevertheless, many of the approaches have in common a hierarchical decomposition of guidelines into networks of component tasks that unfold over time. This approach has been described as the "task-based paradigm"⁹; here, we use the term Task-Network Models (TNMs) to describe guideline-modeling formats based on this approach.

There is understandable interest in developing a standardized, consensus guideline representation language, or at least in identifying common components that different formats may share. Previous reviews of the field have relied on published descriptions of individual methodologies¹⁰⁻¹². Although such reviews have identified some commonalities and differences, more systematic and objective comparisons are required. In this study, we have undertaken a direct comparison of six different guideline representation languages by studying in detail how developers of each language model two sample guidelines.

II. BACKGROUND

The Arden Syntax¹³ is perhaps the best-known language for representing clinical knowledge needed to create patient-specific decision-support systems. The Arden Syntax is a rule-based formalism developed for encoding individual clinical rules into Medical Logic Modules (MLMs). Augmented Decision Tables

(ADTs)¹⁴ have been used to model guidelines. ADTs go beyond Arden's rule-based formalism by augmenting decision-table rules with additional information such as probability and utility information. Although the Arden Syntax has been adapted for the representation of guidelines by employing interacting MLMs¹³, neither MLMs nor ADTs, provide full support for conceptualizing a multi-step guideline that unfolds over time. The TNM approach has arisen in response to this problem. TNM languages typically provide modeling primitives specifically designed for the representation of complex, multi-step clinical guidelines, and for describing temporal and other relationships between component tasks. Unlike rule-based systems, alternative pathways or sequences of tasks (i.e., control flow) can be explicitly modeled, and tools for the visual representation of plans and the organization of tasks within them are provided.

Guideline-modeling methodologies compared in this study

Asbru⁷ is being collaboratively developed at Ben Gurion University and the Vienna University of Technology. Asbru is a time-oriented, intention-based, skeletal-plan specification language that is used to represent clinical protocols¹⁵. Skeletal plans capture the essence of a procedure, but leave enough room for execution-time flexibility in the achievement of particular intentions. The developers of Asbru have enriched skeletal plans by (1) characterizing plan attributes such as intentions, conditions, and affects, (2) adding a rich set of ordering of plans, and (3) defining temporal dimension of states and plans. Uncertainty in both temporal scope and parameters can be expressed by bounding intervals.

EON⁵ was developed at Stanford University and is intended to provide a suite of models and software components for creating guideline-based applications. It views the guideline model as the core of an extensible set of models, such as a model for performing temporal abstractions. EON uses a task-based approach to define decision-support services that can be implemented using alternative techniques¹⁶. EON's guideline execution server uses formalized clinical guidelines and patient data to generate situation-specific recommendations. A temporal data mediator supports queries involving temporal abstractions and temporal relationships. A third component provides explanation services for other components¹⁷.

The Guideline Interchange Format version 3 (GLIF)³ has been collaboratively developed by groups at Columbia, Stanford, and Harvard universities (working together as the InterMed Collaboratory).

GLIF stresses the importance of sharing guidelines among different institutions and software systems. GLIF tries to build on the most useful features of other guideline models, and to incorporate standards that are used in health care. Its expression language was originally based on the Arden Syntax¹⁸ (a subsequent object-oriented language, GELLO¹⁹, is now being refined for consideration as an HL7 standard), and its default medical data model is based on the HL7 Reference Information Model (RIM)²⁰.

GUIDE⁸ is part of a guideline modeling and execution framework being developed at the University of Pavia. It supports (1) integrating modeled guidelines into organizational workflows, (2) using decision-analytical models such as decision trees and influence diagrams, and (3) simulating guideline implementation in terms of Petri nets²¹. GUIDE considers issues such as patient data, the implementing facility's organizational structure, and resource allocation. This paper considers the guideline model as presented in the GUIDE tool, which is a graphical authoring tool that a modeler uses to create a guideline flow.
PRODIGY⁴ was developed at the University of Newcastle upon Tyne. Its purpose is to provide support for chronic disease management in primary care. The PRODIGY project has aimed to producing the simplest, most readily comprehensible model necessary to represent this class of guidelines. Teams of clinicians have used Protégé's knowledge engineering environment²² to encode three complex chronic-disease-management guidelines. Over 150 guidelines encoded in PRODIGY's simpler Release One model have been translated into the current model. Two vendors have integrated identical PRODIGY components into their clinical information systems for general practitioners²³.

PROforma²⁴ was developed at the Advanced Computation Laboratory of Cancer Research, UK. It combines logic programming and object-oriented modeling²⁴ and is formally grounded in the R²L Language⁹. One aim of the PROforma project is to explore the expressiveness of a deliberately minimal set of modeling constructs. PROforma supports four tasks: actions, compound plans, decisions, and enquiries. All tasks share attributes describing goals, control flow, preconditions, and post-conditions. The simple task ontology should make it easier to demonstrate soundness and to teach the language to encoders.

III. RESEARCH QUESTION

The research question was to identify the similarities and differences among the various guideline-modeling methodologies, and to identify the purposes, goals, or approaches that accounted variabilities among them. A secondary question was to determine the extent to which areas of similarity could facilitate the development of a shared consensus model.

IV. METHODS

The study was coordinated by MP and ST with members of the groups responsible for each of the modeling methodologies invited to participate by submitting models of the same two clinical guidelines represented in their particular modeling language. These models were then systematically analyzed according to predefined axes of comparison.

Selection of guidelines: The study coordinators selected two clinical guidelines for collaborators to model. These were sections of larger guidelines relating to the management of cough²⁵ and the treatment of hypertension²⁶. These sections were chosen because, between them, they presented modeling challenges in each of the eight dimension of comparison described below, whilst being concise enough to allow efficient modeling and analysis.

Dimensions of comparison: Eight dimensions of comparison were identified by ST and circulated to all collaborators at the start of the study. These dimensions fell into two broad categories – structuring guidelines as plans of decisions and actions, and linking the guideline to patient data and medical concepts. The dimensions defined are: (1) organization of guideline plans, (2) goals, (3) model of guideline actions, (4) decision model, (5) expression language, (6) data interpretation/abstractions, (7) medical concept model, and (8) patient information model.

Analysis: MP and ST carried out the analysis of the resulting guideline models. As far as possible, models were studied using the authoring groups' own modeling environments. Thus, we used Protégé to study models in GLIF, EON and PRODIGY and Arezzo to study the two models in PROforma. For the AS-

BRU language, we studied AsbruView²⁷ screen shots showing the overall organization of the models, and the XML code representing details of attributes. Similarly for GUIDE, we viewed screen shots for the GUIDE authoring tools and the associated relational database schema and SQL queries showing model details. The reviewers worked in close collaboration with representatives of each of the formats throughout the analysis, ensuring that the submitted models represented the guideline sections as fully as each format would allow and enabling clarification of modeling details. The results of the analysis were iteratively collated by MP and circulated to all contributors until consensus was reached.

V. RESULTS

All groups were able to satisfactorily model each of the two guidelines in their respective formats. Analysis of the different models revealed a number of differences in how the different formats approach various aspects of guideline modeling. The results of our analysis are presented here categorized by the dimensions of comparison described above. More detailed information is provided online^{28, 29}.

Dimension 1. Organization of guideline plan components

a. Plans and nesting of components.

A unifying feature of TNM languages is the decomposition of guidelines into networks of component tasks and the ability to express various arrangements of these components and interrelationships between them. Although all the languages use the term ‘plan’ to describe collections of tasks, there are differences in the way the term is used. Here, we simply use the term in accordance with definition in the Merriam-Webster dictionary: “an orderly arrangement of parts of an overall design or objective”. Asbru, PRO-*forma*, and GUIDE each use only a single, generic class of plan object, whilst PRODIGY and EON distinguish between *Management Guidelines* (disease-state maps) and *Consultation Templates* (context-dependent recommendations on actions that are not part of a management decision, data to collect or display, and patient education). GLIF also has two kinds of plans: Guidelines and Macros. GLIF *Guidelines* are similar to EON’s Management Guidelines. Macros provide a means to declaratively specify a procedural pattern that appears in guidelines as a single construct that is realized by a set of GLIF steps³. All

the methodologies studied provide nesting mechanisms to simplify top-level plans and support the reuse of sub-guidelines (Figure 1).

b. Plan components

The various modeling formats use different terminology to refer to the various types of plan components. However, with minor variation in implementation, all formats provide constructs of some form for the representation of **decisions** (Dimension 4), **actions** (Dimension 3), and nested **subplans**. In addition to these core constructs of action, decision, and plan / subplan, the different modeling languages provide various other primitives (Table 1).

A **Scenario** (EON and PRODIGY) or **Patient State** (GLIF) is a plan component that defines a particular patient management context. It is characterized by patient conditions (e.g. hypertension), and/or their treatment (e.g., taking low-dose thiazide diuretic), and possibly clinical settings (e.g. outpatient clinic)¹². Scenarios serve as entry points into guidelines and are useful in multi-encounter guidelines, in which patients may enter the guideline at different places in the plan (see d, below). In EON and PRODIGY, consultation templates are associated with scenarios to describe scenario-specific actions.

Branch Steps (EON, GLIF, PRODIGY, and GUIDE) and **Synchronization Steps** (EON, GLIF, and GUIDE) model parallel paths in the guideline plan. PROforma and Asbru can achieve parallel as well as sequential execution without having branch and synchronization steps (see below).

Wait Step in GUIDE is used to introduce delays. GUIDE's **Monitor**-task checks for conditions at specified durations. It can be used to monitor goal conditions, GUIDE measures the monitored variable with a certain frequency, and the modeler can specify actions that should occur, depending on the value.

c. Sequential, parallel, cyclical and iterative plans

Care processes may involve sequenced, iterative, and possibly concurrent activities occurring over time. All the methodologies support these modes of plan organization. All the methodologies except PROforma use different constructs to specify sequential versus parallel plan execution. PROforma uses scheduling constraints to govern task execution, and both sequential and parallel execution are implicitly supported (Figure 1).

All the modeling methods can combine guideline steps in directed cyclical graphs. All except PRODIGY have explicit constructs to support iteration or cycling of plans and/or plan-components. Generally, iteration is specified by providing the time or trigger of the first repeat, the duration of each cycle, the repeat frequency, the maximum number of repeats, the completion condition, and the abort condition. Asbru, EON, and GLIF can define fuzzy iteration frequency (e.g., take drug every 3-4 hours).

Note that sequential-, parallel-, and cyclical-execution define part of the control flow of guideline plans. Other elements of control flow are typically handled by decision models (Dimension 3), which conditionally direct control flow into selected branches of the guideline model.

d. Entry points into guideline plans

Representation of multi-step clinical processes, which may take place over several encounters, must allow for different ‘entry-points’ into a guideline. Ideally, CIG-based decision-support systems should keep track of a patient’s state at one encounter and use this information to automatically provide an appropriate entry-point at subsequent encounters. Although this is complicated by the fact that a patient’s health status can change between encounters, all the methodologies aim to support multiple entry points into a guideline. Two distinct approaches were identified. PRODIGY, EON and GLIF use specific modeling components to represent entry points; these are referred to as Scenario or Patient State components and are used to facilitate the automatic entry of a patient into the appropriate guideline plan or sub-plan. An alternative approach used by other models is to use expressions referring to patient states in decision criteria or pre-conditions that affect guideline control flow.

Dimension 2. Specification of goals/intentions

Guideline modeling methods fall into two groups according to how they model guideline intentions or goals. PRODIGY and GLIF specify goals as text strings. The objective is that this text is presented to users or used for indexing and searching libraries of guidelines. The other methods represent intentions and goals as formal expressions used to control the execution-state of plans. Asbru represents plan intentions as context-dependent temporal patterns (e.g., “give three courses of chemotherapy within three

months”). Encoders can specify that an intention *achieve, maintain, or avoid a state or action*, either *during* a plan’s execution or *after* it has terminated. Thus, Asbru can specify a total of 12 different types of intention (Figure 2). Although this particular syntax is perhaps the most developed of those studied here, EON, PROforma, and GUIDE also represent goals formally and use the resulting expressions to influence control flow, recommendation generation or interpretation.

Dimension 3. Model of guideline actions

Guideline actions are the modeling primitives used to represent the actual tasks described by a clinical guideline (e.g., medication prescription, clinical investigation). Table 2 summarizes the characteristics of these constructs. Nesting, iteration and cycling of actions has been discussed under Dimension 1.

a. Structuring of medical actions

While all the guideline models can specify medical actions, not all of them do so with specialized structured classes. Medical actions in GLIF, EON, PRODIGY, and GUIDE contain slots for mapping their instances into controlled vocabulary terms. In GLIF, guideline encoders specify medical actions by defining the attributes of a Patient Data item according to the data model of the HL7 Reference Information Model (RIM)²⁰. The HL7 RIM is general enough to represent the data structure for a wide range of medical data and concepts in a uniform manner while using a small number of classes. Patient data can simply be modeled as *observations, medications, and procedures*. These classes contain a *mood* code that distinguishes how they can be conceived: as an event that occurred, a definition, intent, order, etc.

Figure 3 shows a Patient Data Item that represents a medication order for ACEI. EON and PRODIGY can represent many specialized medical actions. They include referrals, acute prescriptions, scheduling, asserting conclusions, and modifying drug treatments.

b. Action refinement

In PRODIGY, refinement of drug choice is made through a model of drug regime (e.g., ACEI), regime component (e.g, low-dose ACEI) and prescribable item (e.g., Captopril 12.5mg 0.5 tablets bd. A drug regime component is refined to prescription details, accounting for drug interactions, contraindications

and patient sensitivities. Preference strategies that account for previous use of the drug, formulary status, and guideline-specific criteria suggest the best product choice. EON refines drug choice through a drug ontology: a selected drug category (e.g., ACEI) is refined to specific preferred formulary drugs (e.g., lisinopril). The other guideline models can provide similar functionality of action refinement by defining a subplan that expands the details of a drug-order action.

c. Temporal constraints

All the guideline models can specify constraints on the start time of guideline plan components. The models differ in their ability to specify constraints on end time and duration. Figure 2 shows a “latest start time” constraint in Asbru.

d. System actions

All methodologies model patient data queries and message sending in roughly the same way. The actions of the methodologies differ in their ability to accept parameters, return results, assign variables with values, and inherit knowledge roles, such as complete and abort conditions.

e. Representing and reasoning with effects of actions

Asbru and *PROforma* are the only modeling languages that support the expression of the effects of a plan and thus allow reasoning about plans based on these effects. In Asbru, plan effects can be used to select among alternative plans and to express causal relationships (e.g., chronic cough is caused by PNDS with a likelihood of 0.33). *PROforma*'s post-conditions are semantically different in that they represent assertions that become true after an action is completed (e.g. a post-condition of the administration of chemotherapy is that a patient will be immunocompromised). Task selection on the basis of such post-conditions has not yet been implemented in *PROforma*, although post-conditions can be used to affect downstream control flow.

Dimension 4. Decision Model

Decision-making is central to most clinical guidelines. The guideline modeling methodologies studied use a variety of decision models including switch constructs, argumentation schema, decision trees and

influence diagrams. Some support multiple decision models (Table 3). Some of the methods also support decision-making through calls to external functions.

a. Switch constructs

Switching describes the mutually exclusive branching of guideline control flow where this branching is deterministic. GLIF, EON, and GUIDE all use specific primitives to model such switching. These test whether an expression matches one of a number of constant values and force execution to branch accordingly. The other formats do not use explicit constructs to represent switching, but achieve similar behavior through mutually exclusive expressions in pre-condition or argumentation rules, for example.

b. Argumentation rules for/against choice alternatives

Several methods use argumentation schema to express preferences for alternative candidates of non-deterministic decisions (i.e., decisions where more than one alternative may be justifiable for a patient). Different options are associated with different sets of *arguments* – conditions, which if true provide some, possibly negative, degree of support for that option. These degrees of support may be expressed numerically as in cost/utility schemas. Alternatively, symbolic weights, such as *for*, *against*, *confirming* and *excluding*, may be used. Both symbolic and numeric approaches require the use of methods for the aggregation of weights. Figure 4 shows PRODIGY rules for and against adding a diuretic to an ACE inhibitor.

c. Decision Trees and Influence Diagrams

GUIDE uses decision trees or influence diagrams to represent non-deterministic choices²¹. GUIDE provides a link to Java applets that build and use decision trees or influence diagrams that are specific to a situation addressed in a guideline.

d. The relationship between decision-making and control flow

In all of the methodologies except for *PROforma*, decision-making is explicitly coupled to commitment to a decision alternative (switch constructs are one example of this). Action sequencing in *PROforma* is governed by the satisfaction of the scheduling constraints and preconditions of indi-

vidual tasks, rather than through the use of explicit 'go to' relationships between tasks. If the result of a decision is intended to govern subsequent tasks, the decision's outcome can be referred to in the precondition expressions of relevant subsequent tasks.

e. Authorizing decisions

All of the groups recognize that user intervention or confirmation may be required during the decision-making process. All except PRODIGY allow some decisions to be automatically made by the guideline enacting system. Decisions in PRODIGY always require confirmation. This reflects the PRODIGY team's philosophy that the autonomy of clinicians should be maintained, and their goal of producing interactive systems for use during the clinical encounter rather than autonomous applications such as background process monitors.

Dimension 5. Expression/criterion languages used to specify decision criteria

The guideline modeling methodologies use expression languages to represent decision criteria, including pre- and post-conditions of guideline plan components, criteria that control plan execution states (filter, setup, suspend, reactivate, complete, and/or abort conditions in Asbru), rules for and against decision alternatives, goal criteria, and definitions of patient states. All models support various standard logical, arithmetic and comparison operators. The different languages use quite different expression languages, although EON and PRODIGY share some criteria templates defined as objects with certain attributes. Note that at the time the study was conducted, GLIF used the Guideline Expression Language (GEL) to specify criteria and expressions³⁰. GLIF now uses GELLO¹⁹, an extensible object-oriented expression language which supports a superset of the functions supported by GEL.

a. Presence Criteria

Presence criteria check for patient data items (e.g., presence of diabetes). PRODIGY, EON, GLIF, and GUIDE model presence criteria by giving an explicit definition of the term to be checked, together with a method for looking for the term in the local EMR. Figure 5(a) shows a presence criterion in EON.

PROforma and Asbru model presence criteria by defining a Boolean data item called ‘concept present’, where that data item is treated like all other data items.

b. Template-based criteria

EON and PRODIGY have template-based languages used by clinicians to encode relatively simple decision criteria. The template criteria look for qualitative and quantitative observations, medications, and other types of EMR entities (see Dimension 8). They can declaratively express simple temporal constraints on these entities of the form “within a certain interval of a time point” (Figure 5a).

c. First-order logic criteria

EON uses Protégé-2000’s axiom language (PAL) to define constraints in a subset of first-order predicate logic written in the Knowledge Interchange Format syntax¹⁷. Figure 5(b) shows a PAL criterion for ACE Inhibitor contraindications. PROforma is a first-order language, and Arezzo – a PROforma toolkit – supports a number of first-order logic features through the use of open formulae in its criterion language (i.e., variables in conditions). These features are particularly useful in decision-making (in arguments, and in rules that generate candidates for a choice and rules for committing to a choice). GUIDE uses SQL to write decision criteria. It thus supports some first-order logic criteria.

d. Temporal criteria

All the methodologies support temporal criteria. Temporal criteria may refer to time stamps of data and task enactment events. An example of a temporal criterion in EON is shown in Figure 5 (c). The methodologies differ in the complexity of temporal expressions that they can represent. Asbru and EON support temporal abstractions, as discussed in Dimension 6. GLIF supports the temporal operators of the Arden Syntax logic grammar¹⁸.

e. If...then...else and switch statements

GLIF, Asbru, and PROforma’s toolkit Arezzo can use *if...then...else* and *switch* statements in their expression languages. For example, the following PROforma expression assigns a value of 140 to the

variable *TargetSBP* if the value of the variable *Target_BP_decision* is equal to Standard. Otherwise, *TargetSBP* is assigned the value 130.

TargetSBP = if(result_of(Target_BP_decision) = Standard, 140, 130);

f. Context-dependent expressions

Asbru supports expressions that depend on special context variables such as “presence of diabetes mellitus”. Values of context variables can be Boolean or qualitative symbols. They can be set through user input, obtained through data abstraction from other parameters, or set by plans in the course of execution. Context expressions are used in setting limits of parameter definitions and in specifying temporal patterns, argument dependencies on measurable parameters, and plan effects.

Other models do not have special constructs that hold the context of parameters. However, in EON and PRODIGY, scenarios define contexts for actions and expressions encoded in the consultation guidelines associated with them. The other models can use their general expression constructs to set context. The example of Dimension 5f shows an expression in *PROforma* that sets the target systolic blood pressure to 140 in the context of standard blood pressure goal (no diabetes and no proteinuria).

Dimension 6. Data interpretations/abstractions

All the models define abstractions that aid conceptualizing guideline logic and interpreting data. We found four types of abstractions. Three of them are discussed below. Scenarios and patient-state steps are abstractions that were discussed in Dimension 1.

a. Temporal abstractions/temporal patterns (trends)

Asbru and EON can use systems that perform temporal abstractions to abstract clinical conditions (e.g., chronic cough) that hold over an interval of time, based on raw, time-stamped values²⁹.

b. Definitions of abstract terms

All the methodologies can use formal expressions to define abstract terms based on given data. For example, *isolated systolic hypertension* can be defined as situations in which patients not taking anti-

hypertensive agents have systolic blood pressures of at least 140 mm Hg and diastolic blood pressures of less than 90 mm Hg. Note that this definition requires definition of anti-hypertensive agent (concept).

c. Terminology abstractions via classification hierarchies

PRODIGY, EON, and GLIF can create hierarchies of medical concepts and reason about them by writing expressions that utilize the concept hierarchies. In a taxonomic hierarchy, a concept that is a parent of other concepts creates an abstraction for the lower-level concepts. For example, *ACE inhibitor* is an abstraction of specific drugs, such as *lisinopril*. PRODIGY has a terminology mediator that uses hierarchies in READ codes to map specific term to abstract terms. EON creates taxonomic hierarchies using Protégé's frame-based knowledge-engineering environment. GLIF can define hierarchies of concepts using the Concept_Relationship class, with a relationship-type of "is-a". In GUIDE, each guideline task can be associated with a single SNOMED code that represents a clinical task (e.g., cardiovascular stress testing). The hierarchy of SNOMED codes is also utilized for reasoning: when a user disagrees with a task proposed by the GUIDE engine, he must select a different code that corresponds more closely to the desired task. The terminology server displays a set of tasks that are at the same hierarchical level of the SNOMED taxonomy. The rationale here is that a physician may wish to use a different method to that specified in the guideline to achieve a particular goal.

Dimension 7. Representation and use of a medical concept model

In *PROforma* and *Asbru*, the concept to which a variable refers is represented by the variable's name. In contrast, other models have medical concept models that include classification hierarchies (Dimension 6c), concept definitions, and relationships between concepts that convey medical knowledge.

In all systems that use some kind of concept model, concepts are defined, at least in part, through mapping to terminology systems. In EON, concepts in hierarchies can also be defined through explicit definitions of abstract terms, as explained in Dimension 6b.

Medical knowledge representing contraindications, indications, and drug interactions is modeled in *PROforma* as part of arguments for decision alternatives. Medical knowledge is not repre-

sented as part of Asbru's guideline model, but Asbru can access medical knowledge by using function calls. GUIDE can represent knowledge in relational database tables. In GLIF and EON, modelers can represent medical knowledge as instances of *Concept_Relationships*. In addition, EON and PRODIGY model medical knowledge as classes in the medical ontology (Dimension 3b). PRODIGY also models this kind of knowledge as part of the rules for selecting an action for a relevant scenario (Figure 4), or it can use queries to refer to outside information sources.

Dimension 8. Patient information model

The patient information model is concerned with the representation of patient data and its mapping to institutional EMR data models. The patient information model defines the terminologies to be used (e.g., the codes to represent route of administration), and the structure of patient data (e.g., the properties of a medication order).

All the modeling methodologies can represent and manipulate complex data items that group related data values in a single structure. *PROforma*, GUIDE, and Asbru do not constrain the classes of complex objects that are possible. PRODIGY, EON, and GLIF define a constrained set of patient data and concept classes. PRODIGY and EON view patient data as instances of *virtual medical record (VMR)* classes³¹. These VMRs abstract from actual medical records a small set of patient data classes that are needed in decision support applications. These classes include: Qualitative Observation (such as a note entry indicating presence of a disease), Quantitative Observation (such as a laboratory-test result), Medication Authorization, Procedure (such as a pancreatectomy), and Allergy State. GLIF defines data items by associating them with controlled vocabulary codes, and by structuring patient data according to medical data models that guideline developers may choose (Figure 3). The default data model used in GLIF has been based on the HL7 Version 3 Reference Information Model (RIM)²⁰, discussed in Dimension 3b.

By fixing the structure of patient data and the necessary terminology, the patient information models of EON and PRODIGY facilitate mapping of concepts and data to institutional EMRs. The develop-

ers of EON, PRODIGY, and GLIF plan to make their patient information models consistent with HL7 Version 3 RIM and will rely on HL7's messaging standards for their instantiation. Fixing the structure of patient data could facilitate mapping guideline terms to EMRs, but is not required for mapping. For example, in GUIDE, tables such as the one shown in Figure 6, define mapping between the EMR and data needed by the guideline. PROforma and Asbru use a similar approach.

VI. DISCUSSION

Authoring CIG models in any format can be time consuming and may require both clinical knowledge and technical skill. The ability to exchange guidelines encoded in one format into systems using other formats would help reduce duplication of effort in guideline encoding. The GLIF project originally intended to devise an interchange format to facilitate translation from one guideline-formalism to another. However, the developers of GLIF have acknowledged that this is at present impractical, and revised their goal to the creation a versatile modeling language which aims to allow the sharing of guideline models across different institutions and software platforms. GLIF is being developed with an evolutionary life-cycle approach, in which the functional requirements for the sharable CIG language are continuously refined, and incorporate those features of other modeling environments that are considered most important.

The aim of this study has been to facilitate standardization by a rather different route – specifically, the identification of common components that the CIG community could adopt as standard, whilst allowing the groups to continue exploring their individual approaches to those aspects of guideline modeling for which consensus has not emerged. If it is were possible to map large parts of the different methodologies to a common representation, then sharing of significant components of encoded guidelines across different models might be feasible. Guideline formalization could also support authoring, designing, and maintenance of guidelines. We have identified both areas of considerable similarity between models and areas where groups have adopted diverse approaches to specific challenges. We discuss both of these areas, and the implications of these findings for standards development.

Common components and the implication for standards development

We have been able to identify a number of areas where the various groups have adopted broadly similar approaches. A degree of cross-format standardization may be possible in these areas.

The underlying computational models of the methodologies studied vary significantly^{12, 28, 32}. Nevertheless, all of the methodologies, except for PRODIGY, organize guidelines as plans that unfold over time, by linking plan components in sequence, in parallel, and in iterative and cyclic structures, thus defining control-flow. In addition, all of the models support nesting of plans, as well as expression of temporal constraints on plan components. As part of the HL7 Clinical Decision Support Technical Committee (CDSTC), some of the authors have been evaluating the Workflow Management Coalition's (WfMC) Workflow model as a common control-flow model³³. The Workflow model has constructs for expressing nesting, loops, activities, branching, and synchronization, and can express temporal constraints. By specializing activities into guideline-specific tasks, such as enquiries and decisions, the different guideline models should be able to map to this formalism. Indeed, the developers of the GUIDE model already map their guideline representation to this Workflow model. As well as being a tested standard of the WfMC, the Workflow model has well defined formal foundations derived from Petri Nets (PN)³⁴. It remains to be seen whether the clinical guideline extensions to the workflow model would allow mapping into PNs. Such mapping should support formal verification of a guideline model's properties.

Standardization of the expression language used by the various guideline models may also be possible. Such a standardized expression language could be used for specifying and sharing decision and eligibility criteria, patient state definitions, conditions, and system actions. It would need to support operators that are common to all models (logical, arithmetic, and comparison operators), function calls, presence criteria, and temporal expressions. The CDSTC is evaluating GELLO, the expression language that was developed by the InterMed team at Harvard, as a possible standard.

A third component that would benefit from standardization is a patient information model. An object oriented Virtual Medical Record (VMR) would ease the process of mapping guideline patient data

items to real EMRs, allowing decision criteria, eligibility criteria and patient states to be defined by in guideline models by reference to the VMR rather than specific EMRs. In addition, structured medical actions can derive their structures from the VMR classes, as is done in GLIF. Another action item being considered by the CDSTC is standardization of the VMR, based on experiences with the patient information models of PRODIGY, EON and the HL7 RIM, which is also the basis of GLIF's default patient information model.

A standard medical concept model would also be beneficial. However, standardization is currently out of reach. This is because existing vocabularies have not been explicitly designed for clinical decision support and have limitations for such applications (e.g., mixed hierarchies and missing abstractions). Standardizing definitions of abstract terms would only be possible after a common expression language, patient information model, and medical concept model have been standardized.

Significant differences and their causes

A key difference between formats is their intended scope. Some groups, such as the developers of Asbru and PROforma, have deliberately not attempted to include methods for the representation of static knowledge such as medical concept models and ontologies of actions, for example. Instead, they emphasize the provision of clean interfaces to access such information held externally. A different scoping decision was made by PRODIGY, which focuses on chronic disease management guidelines. These variations in scope probably reflect both pragmatism and differences in the research interests of the various groups, rather than any strong conviction that the representation of a particular class of knowledge is fundamentally unnecessary for guideline-based decision support systems.

The PRODIGY methodology emphasizes a scenario-based approach, in which a guideline is organized as a collection of clinical contexts, where in each context selection among relevant clinical actions is made. Influenced by PRODIGY, EON and GLIF also support scenarios. The other methodologies can support some of the functionality of scenarios by using expressions referring to patient states in decision criteria or pre-conditions to affect guideline control flow. It has been argued that the latter approach enables guideline modeling to remain task-based, rather than state-based^{11,35}. However, clinical scenarios are intuitive concepts that domain experts may find useful when authoring

scenarios are intuitive concepts that domain experts may find useful when authoring and browsing guideline models, and thus their explicit representation may be advantageous⁴.

There is significant variation in the decision models used. GLIF, EON, PRODIGY, and GUIDE have adopted extensible approaches, their philosophy being that extensions to the core language to represent a specific decision model are legitimate. The Arezzo tool does not provide support for adding predicates, functions, and task subclasses, but the *PROforma* developers will support extensibility of tasks and functions in future tools.

The modeling methodologies vary considerably in the way that clinical goals are represented and utilized. Only Asbru, EON, *PROforma*, and GUIDE represent goals formally and allow reasoning about goals. Similarly, only Asbru and *PROforma* represent effects of plans and reason with them. Representing goals and the effects of actions is central to Asbru's approach. Guidelines are viewed as plans that may fulfill goals, and plan selection can be based on satisfying preconditions or on matching the effects of a plan to target states. PRODIGY and GLIF adopt a more limited approach with goals represented as text strings. This allows clinicians to browse goals of a guideline, without allowing machine reasoning about those goals.

Limitations of our study

This study has identified a number of areas where various groups have adopted different approaches to particular aspects of guideline modeling. However, where such differences have been identified, we have not attempted to judge whether one approach is superior to another. There exists no normative framework to allow such a judgment, and it may be that only experience will show which particular approach to specific problems in guideline modeling will prove most effective in the long term. However, we hope at this stage that by identifying, analyzing, and describing modeling challenges for which diverse solutions are currently being proposed, this paper will serve as a starting point for focused discussions on the relative merits of these different approaches.

Our study is obviously limited by the dimensions of comparison we used. We chose to focus on dimensions concerned with modeling guideline logic. In practice, wide scale deployment of CIG-based clinical decision support systems (CDSS) will require other services.

CIG models will require documentation. For example, a CIG model's authorship, the nature of the evidence the guideline is based on, and its intended context of use all need to be captured and made available. A common set of documentation attributes such as those described by the GEM formalism³⁶ may well be of value. The CDSTC is currently considering the requirements for such standardization of documentation attributes.

Software tools are required to support the authoring and editing of guideline models. As discussed, the modeling languages themselves provide various facilities to manage complexity, such as nesting of sub-plans, separation of guideline knowledge from consultation templates in EON and PRODIGY, and action refinement. However, the features of authoring and editing software environment will also be important in determining how easily authors can create, edit, and interact with guideline models. Although all the modeling methods that we considered use graphical environments for guideline authoring, we did not consider this aspect in our study. The successful deployment of CIG-based CDSS will also require suitable software to allow clinicians to interact with guideline models to derive decision support. We studied the expressiveness and syntax, but not how they are used to encode guidelines that are part of real clinical decision-support systems.

Many of the differences between modeling approaches relate to the particular classes of intended applications that motivated the choice of features in the various modeling languages. Adding a new feature to a model is easy, but it may not be practically implementable, or it may add such complexity to a model as to make its learning curve too steep. Thus, a feature-rich model may not be the model of choice for many users. Furthermore, a feature may have hidden limitations that are not uncovered until used by clinicians. In this respect, we are limited by the fact that neither GLIF nor Asbru has a currently working execution engine.

A second limitation concerns the case study examples. We compared only portions of guidelines. Moreover, we used only two guidelines for the comparison. Although these guidelines cover the dimensions of comparison, and we believe that they represent a variety of situations that often arise in narrative guidelines, we cannot be sure that we covered all of them. Several studies have addressed classification of guidelines^{37,38}. However, their classification is based on clinical distinctions (e.g., clinical area, clinical setting). Most of the classification schemes do not classify guidelines in terms of an engineering-perspective relating to the types of modeling problems. Bernstam et al.³⁷ address some engineering issues, including ranking of computability, but the ranks are not defined by formal criteria.

VII. CONCLUSION

Our comparison study identified guideline components that the CIG community could adopt as standards. We outlined how some of us are pursuing standardization of these components under the auspices of HL7. We recognize, however, that because of the different goals of various research groups, such a consensus model will be acceptable to the research groups only if it concurrently is to allow them to continue their investigations of unique features.

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Table 1. Terms used by guideline modeling methodologies to refer to plans and actions.

Model	Plan	Plan component					
		Branching	Action	Decision	Scenario	Special	Subplan
Asbru	Plan	Plan type	Plan	Plan precondition			Recursive plan
EON	Management Guideline	Branch Synchronization	Action	Decision	Scenario		Subguideline step
	Consultation Guideline	Consultation-branch	Consultation-action				Consultation guideline part of scenario
GLIF	Guideline, Macro	Branch Synchronization	Action	Decision	Patient-state		Guideline or Macro called in Action or Decision steps
GUIDE	Guideline	Synch-&, Synch-Or	Task	Deterministic decision, non-deterministic decision		Wait Monitor	Any task can be decomposed
PRODIGY	Decision/Management map		Action		Scenario		Subguideline Step or called in Action step
	Consultation Template	Consultation-branch	Consultation-action				Consultation template part of scenario
PROforma	Plan	Action, Enquiry, Decision	Action, Enquiry	Decision			Plan task

Table 2. Characteristics of actions that are modeled by different guideline modeling methodologies. The comment “See (1) “ refers the reader to Dimension 1 for further explanations.

		Asbru	EON	GLIF	GUIDE	PRODIGY	PROforma
Medical actions		+	+ (Structured)	+ (Structured)	+ (Structured)	+ (Structured)	+
Action refinement		+	+ (Using concept model)	+	+ (Using concept model)	+ (Using drug model)	+
Nesting		+ See (1)	+ See (1)	+ See (1)	+ See (1)	+ See (1)	+ See (1)
Temporal constraints on actions/ activities	Start time	+	+	+	+	+	+
	End time	+			+	+	+
	Duration	+	+	+	+	+	
System actions	Actions accept arguments	+		+			+
	Actions return values	+		+ from sub-guideline to higher-level decision			+ (decision)
	Inheriting action knowledge roles	+ (e.g., complete conditions)					
	Variables assignment actions	+		+	+	+	+
Iterative and cyclical actions		+ See (1)	+ See (1)	+ See (1)	+ See (1)	+ See (1)	+ See (1)
Representing and reasoning with effects of actions		+					+

Table 3. Decision models used by the different methodologies. The symbol +/-, which appears in the “Authorization required” row, means that the guideline encoder may specify that user authorization is required.

The symbol + in that row means that user authorization is mandatory.

	Asbru	EON	GLIF	GUIDE	PRODIGY	PROforma
Switch	+ (task preconditions in XOR)	+ (Case)	+ (Case)	+ (deterministic one-of)	+ (using argumentation rules)	+ (plan preconditions in XOR)
Argumentation rules		+	+		+	+
Decision trees / influence diagrams				+ (non-deterministic one-of)		
External functions	+		+	+	+	+
Extensibility		+	+	+	+	+
Decision-making commits choice of alternative	+	+	+	+	+	not necessarily
Authorization required	+/-	+/-	+/-	+/-	+/-	+/-
Preferences	Symbolic		+	+	+ preferred option	+
	Weighted numeric					+
	Cost function	+			+	+
	Formal utility theory				+	

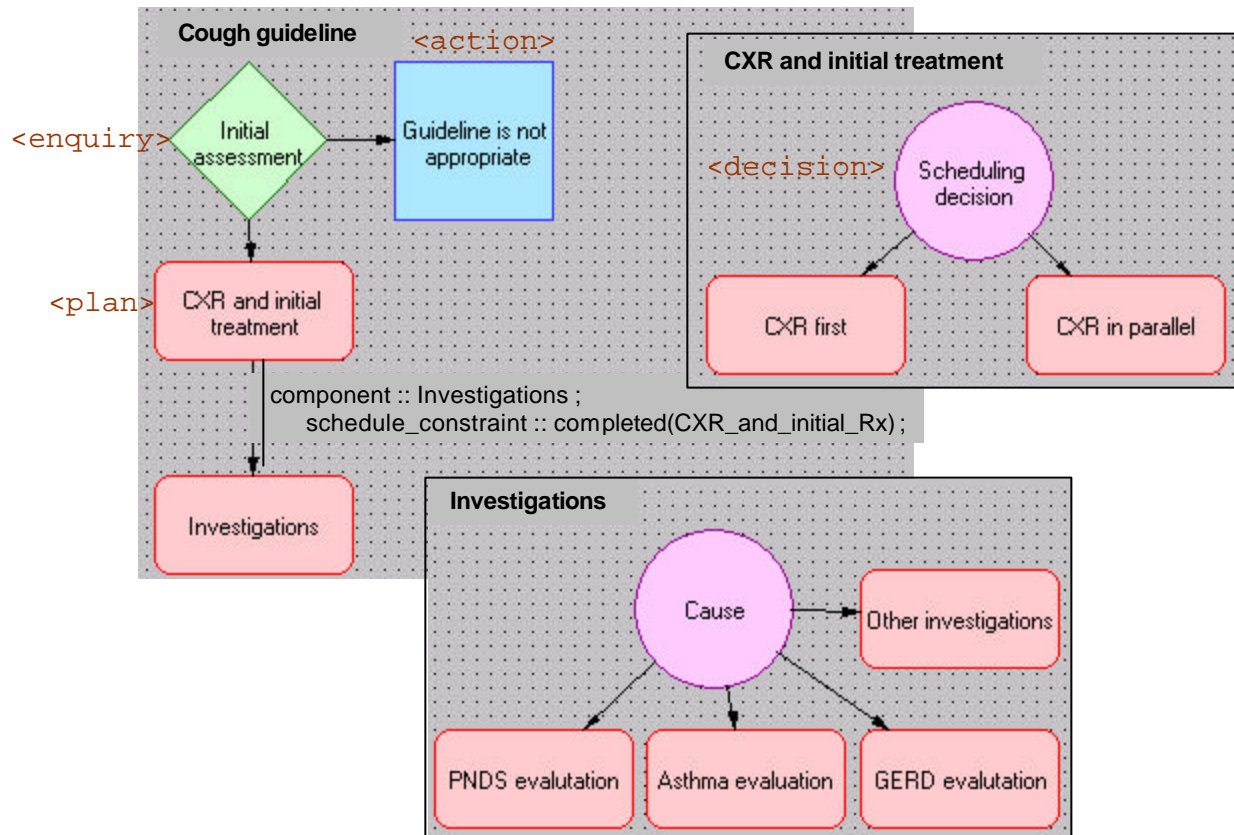


Figure 1. Arezzo’s graphical view of the cough guideline encoding in PROforma. The top-level cough guideline is shown on the top left. The two inserts show nesting of the two plans of the top-level guideline. The scheduling constraint in the top-level guideline states that the component “Investigations” should not be done until the component “CXR and initial treatment” has completed.

```
<plan name="hypertension-treatment">
  <intentions>
    <intention type="overall-state" verb="achieve">
      <parameter-proposition parameter-name="systolic-blood-pressure">
        <value-description type="equal">
          <qualitative-constant value="normal"/>
        </value-description>
        <time-annotation>
          <time-range>
            <starting-shift include-limit-value="yes">
              <latest>
                <numerical-constant unit="month" value="1">
                </numerical-constant >
              </latest >
            </starting-shift>
          </time-range>
        </time-annotation>
      </parameter-proposition>
    </intentions>
```

Figure 2. Expressing intentions in Asbru. The “hypertension-treatment” plan has an intention of achieving an overall state of normal systolic blood pressure within one month of the plan’s execution.

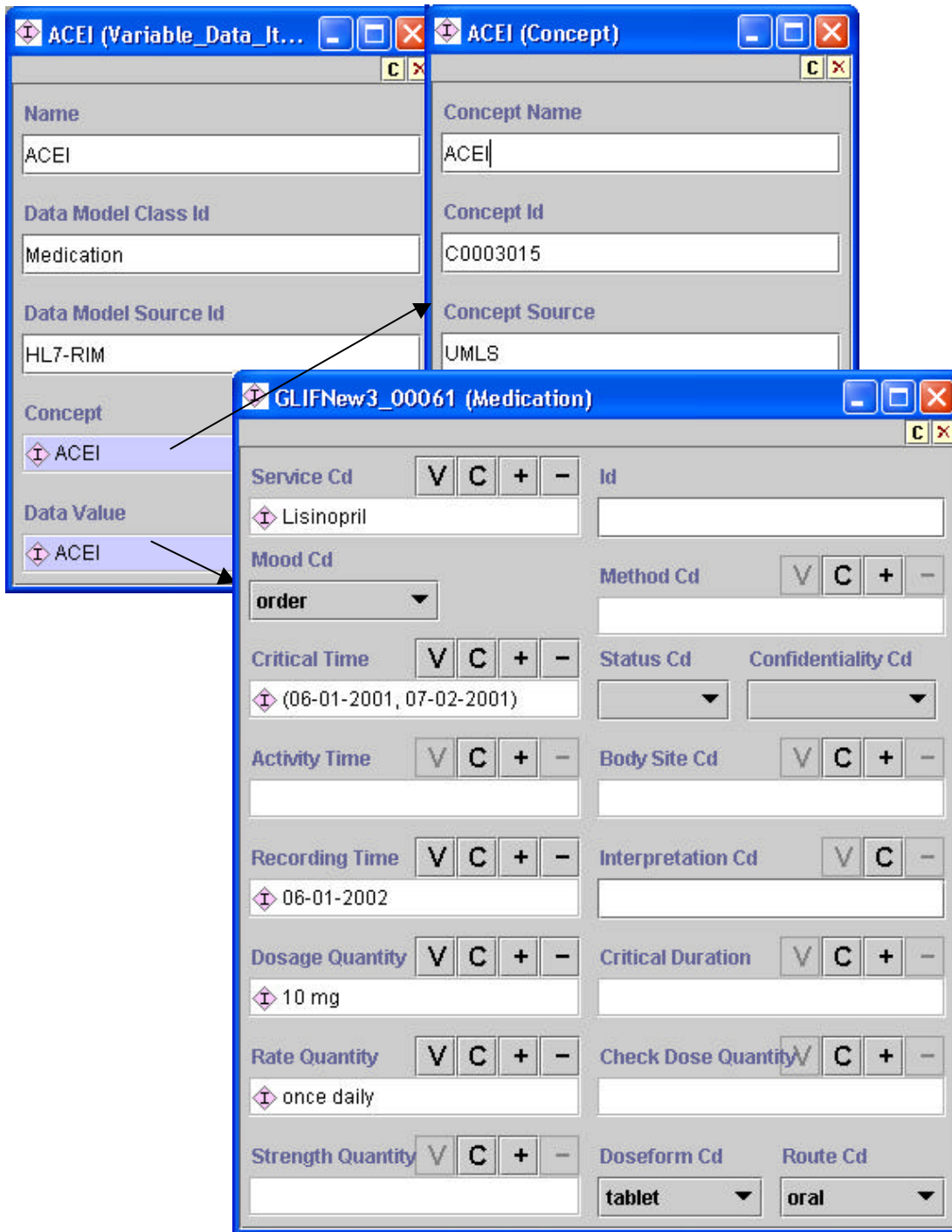


Figure 3. A Cough data item defined in GLIF is defined by a concept whose code is taken from UMLS (shown on the right), and by an HL7 RIM Observation class (shown in the lower part of the figure).

Figure 4. The PRODIGY choice model. Note the rules for and against giving diuretics to a patient who is already on an ACE Inhibitor. The “Rule-in condition” expresses strong preference for an alternative. The “greyed-in condition” is a possible argument for the alternative. The “greyed-out condition” is an argument against the alternative”. The “rule-out condition” is a rule excluding the alternative. These rule-in and rule-out conditions are objects that include formal criteria that can be evaluated against patient data and natural language descriptions of the criteria. The figure shows only the natural language form. In case none of the rule-in, rule-out, greyed-in and greyed-out conditions apply, one of the alternatives of a choice can be marked as “preferred” by default.

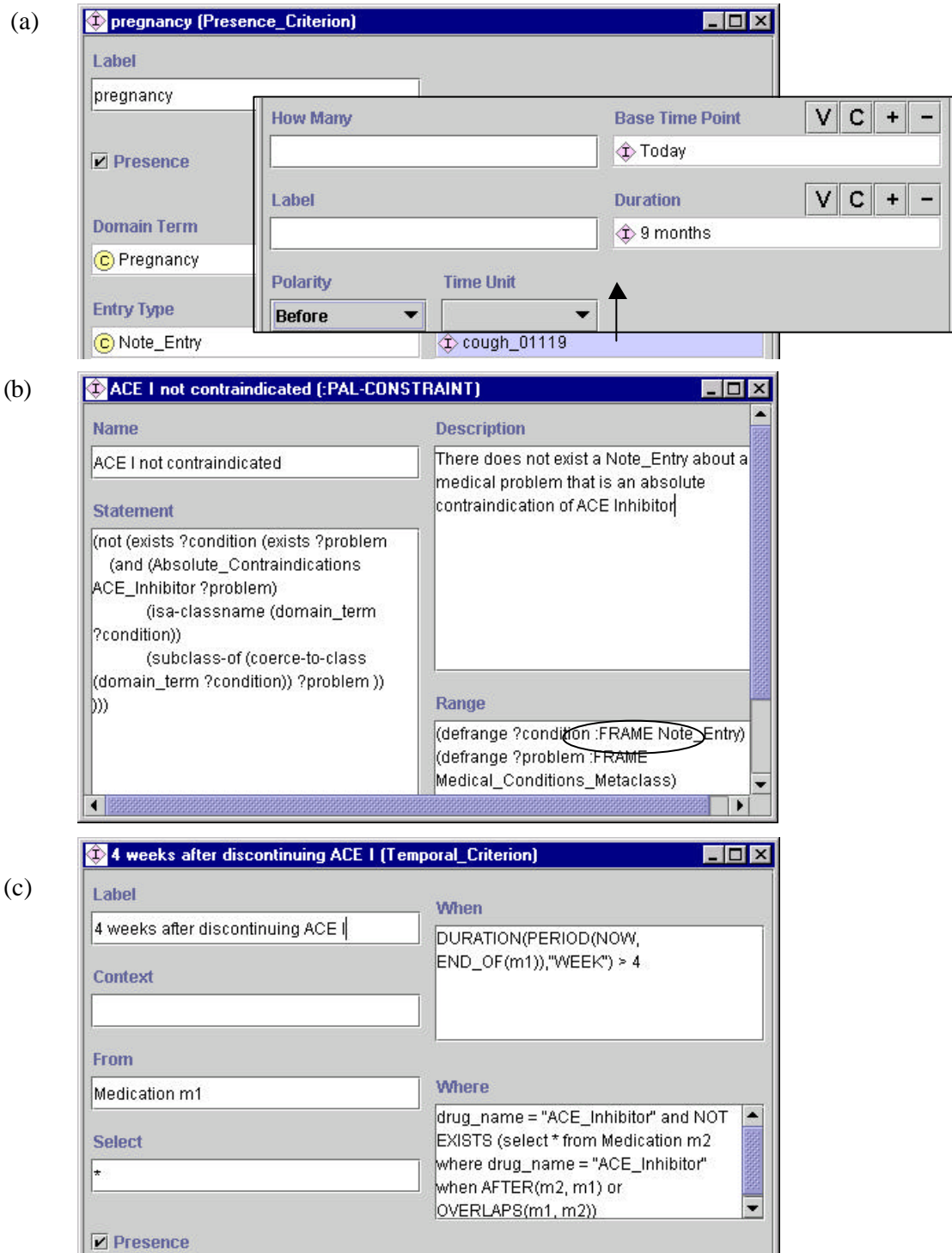


Figure 5. Criteria languages in EON. (a) A template query for a presence criterion that checks for Pregnancy in note entries dating up to nine months before the current date. (b) A first-order logic criterion that checks whether ACE Inhibitor is not contraindicated. (c) A temporal query that checks whether four weeks have passed since the administration of an ACE inhibitor.

Guideline_Outputs				
Code	Description	Table name	Data Type	Guidelines
111	Patient_id	Patient_anagraphic	Number	GERD
112	Pregnancy	Patient_table2	Boolean	GERD

Figure 6. Mapping guideline data items to EMRs in the GUIDE model. The description column gives the name of the data item that guidelines use (Guidelines column). The three other columns are related to the EMR; code is a unique code for that attribute. If possible, it is the SNOMED code. Datatype is the data type of the attribute, and tablename is the name of the EMR table where the attribute value is stored.

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