Modeling guidelines using domain-level knowledge representation components

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The Guideline Interchange Format (GLIF) defines primitive steps such as those for actions and decisions in the specification of guidelines as flowcharts. Modeling of guidelines using only primitives has several limitations including difficulties in authoring, variable specification of guidelines, and development of visually complex guidelines. Version 3 of GLIF (GLIF3) introduces a new construct called "macro". A macro is a scalable approach for representing domain-level concepts. A macro allows mapping of a domain concept to a flowchart of GLIF steps thus enabling declarative specification of a procedural pattern. We analyzed guidelines to extract patterns of domain concepts from different types of guidelines. The patterns were used to design macros for these types of guidelines. Preliminary testing of authoring guidelines indicates that macros provide expressiveness required for complete and accurate representation of the designated portions of the guideline algorithm.

INTRODUCTION

Clinical guidelines are being developed and disseminated in order to improve quality of care, decrease unnecessary variations in medical practice, and reduce the costs of care [1]. Potential uses are in many different application settings including screening, risk assessment, diagnosis, treatment, and monitoring of patients [2] for a variety of medical problems ranging from the acute to the chronic, and from urgent care to continuing management.

To most effectively integrate guidelines into the clinical environment and to enable decision support, they need to be in well-structured, computer-interpretable form and to interface with clinical information systems. Several formats for computer-interpretable guidelines have been developed [3-5]. The Guideline Interchange Format (GLIF) is one such format for the representation of guidelines that are sharable among institutions [6]. GLIF describes an object-oriented model of constructs used for specifying guidelines.

Guidelines in GLIF are represented as a flowchart consisting of five basic classes or types of steps as its nodes. Action steps contain the guideline's recommendations. Decision steps describe decision criteria for the selection of paths through the guideline. Branch and synchronization steps are used to specify multiple simultaneous paths through the guideline. A patient state step is used for identifying a clinical state that characterizes a patient. GLIF contains other classes for specifying details of recommendations, patient data, and decision logic.

These low-level or *primitive* steps provide the flexibility to compose different types of guidelines such as those listed earlier. However, just using low-level steps may cause authoring of guidelines to be cumbersome and time-consuming [6]. Furthermore, the flexibility provided by the steps leads to variability in how guidelines are modeled by different individuals, in terms of sequence and content of guideline steps [6, 7]. We hypothesize that modeling guidelines with primitive steps is cognitively difficult and may cause incorrect representation of a guideline.

Guidelines modeled only with primitive steps also have drawbacks for the clinical user. First, modeling decisions made during authoring have implications regarding the way a guideline is applied during patient care. That is, inaccurately specified guidelines, when implemented would give rise to incorrect recommendations. Second, specifying guidelines using low-level steps can lead to large and visually complex flowchart representations as illustrated in Figure 1. For the user, it may be difficult to visualize the overall approach because of the detail, or to navigate the guideline flowchart easily. GLIF tries to partially solve this problem by providing a nesting mechanism, whereby detailed subguidelines can be contained inside action and decision steps. However, this approach has the drawback that the user has to "zoom" into the nested step to find out the details of

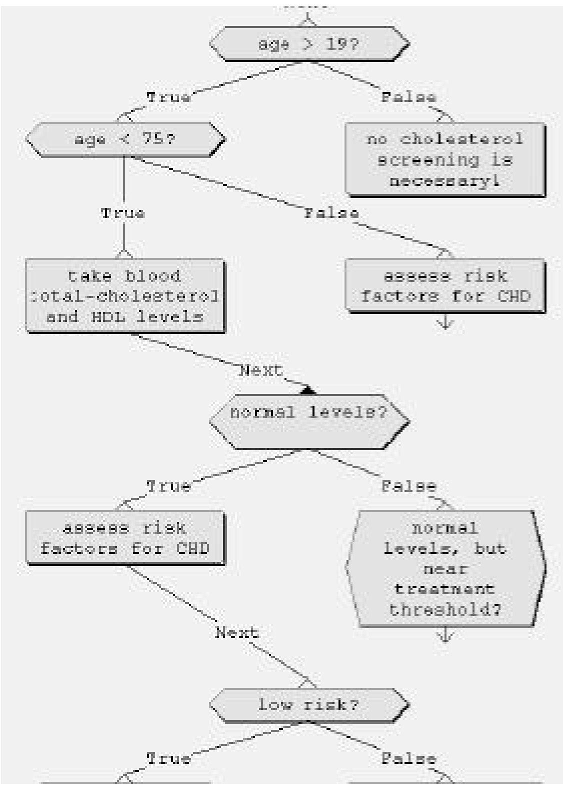

Figure 1. Lipid screening guideline specified in primitive GLIF steps.

the step. Finally, the guideline is represented as a sequence of primitive steps. A clinical user may find that a guideline represented in terms of domain-level concepts is easier to understand than a representation that uses primitive constructs only. For example, a more intuitive description of a clinical trial could be as a graph whose nodes represent visits for screening, treatment, and follow-up. Each node could contain information on time-schedule, patient care actions, and pointers to case report forms for that visit.

Following the analysis of disadvantages to modeling guidelines using primitive steps only, it would be desirable for a guideline representation language to have the following characteristics:

1. Similar guidelines should lead to similar representations.
2. The representation language should allow representation of high-level concepts taken from the clinical domain of the guideline.

As a way of approaching this problem, new classes could be introduced in the guideline representation language for modeling of high-level concepts specific to domains and applications. However, this can lead to a proliferation of classes. This may hinder the ability to easily share guidelines and potentially complicates verification and validation of guidelines. Software tools that manipulate guidelines, particularly software for interpretation of guidelines, would need to recognize a variety of concepts in order to share guidelines that are developed at other institutions.

This paper describes a scalable and flexible approach that we are developing for the representation of application-specific concepts in GLIF. This approach allows mapping of domain-level knowledge components to primitive GLIF steps thereby providing scalability. Flexibility is supported by allowing institutions to define their own macros, which after being mapped to primitive GLIF components, could possibly be executed in any GLIF execution engine.

METHODS

Representation of domain-level concepts

A new construct called macro is introduced into GLIF. Macros enable declarative specification of a procedural pattern that is realized by a set of primitive GLIF steps. Most importantly, macros can be used to represent patterns of domain level concepts. Subclasses of the macro class represent different types of domain-level concepts. Objects of the subclasses and their attributes describe actual instances of domain concepts.

The macro abstracts and encapsulates a potentially larger sequence of GLIF steps into a single object. Domain concepts that are represented as macro subclasses can be expanded or mapped to a flowchart composed of primitive GLIF steps. The ability to map between macros and primitive GLIF steps enables sharing guidelines that contain macros. That is, domain concepts in guidelines can be exported as macros or as a sequence of primitive GLIF steps. Sites and software tools that recognize the domain concepts can take advantage of that representation for authoring, visualization, and execution. The ability to visualize and edit at a domain-level is lost when a site or a tool does not support a particular type of macro. However, these sites and tools can still share and comprehend guidelines because of the ability to map a macro to primitive GLIF steps.

Development of macros for different types of guidelines

To develop the definition of macros, we analyzed guidelines of different types published by the National Guideline Clearinghouse [8]. The guidelines were examined to identify patterns of domain concepts that occur in each type of guideline. Based on the concepts identified, preliminary designs for several macros were developed. Some examples of the macros that were identified are listed in Table 1.

Table 1. Examples of domain concepts identified from screening and risk assessment guidelines. These were derived from the analysis of guidelines from the National Guideline Clearinghouse by recognizing patterns of knowledge represented in them. These domain concepts were modeled using macros.

Guideline type	Guidelines examined	Domain concepts identified
Screening	Breast cancer screening Cervical cancer screening	At-risk population, Screening schedule, Result categories, Follow-up recommendations
Risk assessment	Risk for ischemic heart disease	Risk factors, Risk computation (categorical and continuous), Recommendations based on risk-level and specific risk-factors

As another product of the analysis, we created forms that provide templates for generating instances of macros that can be used in modeling guidelines. Figure 2 illustrates a section of a form for a screening guideline macro. The templates may be used to describe the complete algorithm of a guideline or portions of it. If needed, the flowchart of primitive GLIF steps can then be automatically generated from the macro. Figure 3 illustrates the mapping into GLIF steps of the screening guideline described in the form in Figure 2.

The macros and forms were created after examining a number of guidelines of each type. Through iterations of testing and analysis of other guidelines, the forms were generalized for each type.

Testing and refinement of macros

We conducted exploratory testing of the forms and macros that we had developed. The purpose of the testing was to assess potential advantages of using macros and understand problems that may be encountered in their use.

The test involved authoring guidelines for colorectal cancer screening, cholesterol screening, and unstable angina risk assessment. The guideline authors were three medical informatics fellows in our laboratory. The authors had medical training and were familiar with GLIF.

The authors used a guideline-authoring tool to encode the guidelines in primitive GLIF steps only [9] and used forms to author guidelines with macros. The authors were provided with the *Complete Summary* of the guideline from the National Guideline Clearinghouse. The guidelines were authored at a non-executable high-level only. That is, recommendations and logical conditions were described textually and not fully encoded in the structured GLIF syntax for these concepts.

We reviewed the encoded guidelines for completeness and accuracy of the algorithm. The authors also provided us with feedback on problems and issues they encountered in encoding the guidelines. First, this review indicated that the forms afforded sufficient expressiveness for specifying the guidelines. However, a few minor problems were found in the forms. For example, the screening schedule macro could not be used to specify combinations of screening tests. This macro was then modified accordingly. Second, the authors perceived that it was easier and faster to author guidelines with macros using the forms than with primitive GLIF steps. Time required for authoring was not measured. Third, authors also reported that the macro forms helped in their analysis of the guidelines.

DISCUSSION

We were able to discern patterns of domain concepts within guidelines. These patterns can be exploited in representations and tools for guideline authoring and execution. Representation of guidelines using domain concepts has several advantages discussed in the following paragraphs.

Test(s)	Screening interval	Criteria for patient group
Total cholesterol and high-density lipoprotein	Every 5 years	Adult patients, otherwise normal
	Every 5 years	Patients at high-risk for CHD
	Every 1 year	Recent ischemic event
	Every 6 months	Previous cholesterol levels near treatment threshold
Low density lipoprotein	Every 6 months	Elevated total cholesterol, otherwise normal
	Every 3 months	Elevated total cholesterol and recent ischemic event

Figure 2. Form for the screening schedule macro. A hypothetical cholesterol screening guideline is used to for illustration purposes.

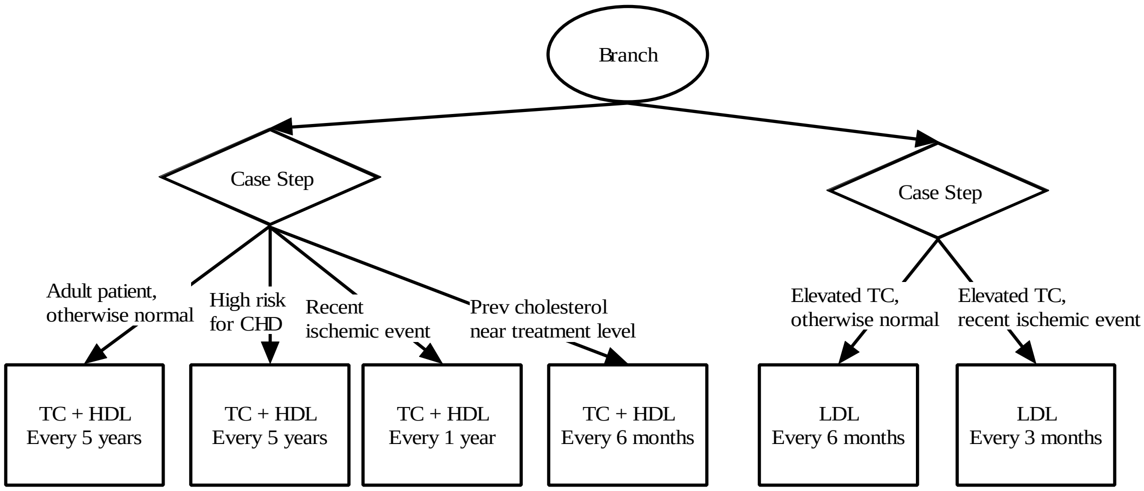

Figure 3. Mapping of the macro from Figure 2 into primitive GLIF steps. Each set of tests is mapped as an action step; screening interval is mapped to the frequency attribute of the action step; criteria are mapped to conditions of a case step, a type of decision step (TC=Total Cholesterol, HDL = HDL Cholesterol, LDL = LDL Cholesterol).

Macros may have benefits during authoring of guidelines as indicated by the results from the exploratory tests. Potential benefits during authoring include

1. Guideline authoring with macros might be a conceptually easier task than with primitive GLIF steps. Macros can provide authors with more familiar concepts for representation.
2. Guidelines might be more rapidly authored using macros. However, this needs to be demonstrated in comparative studies.
3. Carefully designed macros might help the authors to analyze and represent the guideline more correctly completely.

Visualization of the guideline as a flowchart of domain-level concepts may also have several advantages. As compared to guidelines authored in primitive GLIF steps, the guideline may be less complex and more easy to understand. Additionally, unlike nested guidelines where information is hidden at deeper levels, in macros all relevant information can be presented at the top-level of the guideline without the need to zoom in. Furthermore, macros provide a consistent representation for similar types of guideline that could improve comprehensibility because of familiarity with the format.

We are also exploring the use of macros to support sharing and implementation of guidelines. For example, we have designed a macro representing a Medical Logic Module (MLM) in Arden Syntax [10]. Arden Syntax is a standard for representation of medical rules that is implemented in commercial clinical information systems. The macro for specifying MLMs provides a means to implement a recommendation in a guideline encoded in GLIF as an MLM [11]. This MLM can then be executed using existing infrastructure. The MLM-macro is a concept taken from the application domain, and not from the clinical domain.

An issue with the use of macros is that they may limit the expressiveness required for completely and accurately representing guidelines. For the screening and risk assessment guidelines we used in testing, we found that macros could be used to express the knowledge in these guidelines. However, results indicated that careful analysis and design is required for development of macros that can be generalized for variations of the domain concepts.

At this phase of the development, the exploratory testing proved beneficial in providing directions for further development and refinement of macros. A more rigorous experiment will be conducted later to compare macros and primitive GLIF steps as representations for guidelines.

FUTURE WORK

We will be incorporating support for macros in our guideline tools in the near future. We will then be able to conduct more extensive and controlled studies to evaluate the usefulness of macros in guideline representation and issues involved in specifying guidelines using macros.

We will analyze additional types of guidelines to develop new macros. Chronic disease management guidelines and clinical trial protocols are of particular interest. The GEODE model [12] for guidelines is particularly suited for chronic disease management guidelines. The GEODE model uses a state transition paradigm for the representation of guidelines and suggests macros such as “clinical state”.

Clinical trial protocols are similar to guidelines from the representation perspective and have been described using guideline representation formalisms [13]. The National Cancer Institute is developing models of protocols as part of the Cancer Information Infrastructure (CII) [14]. A format based on GLIF and appropriate macros (e.g., *visits*, *adverse events*) will be proposed as a means for specifying and sharing protocols in the CII.

We plan to develop a schema language for macros. Schemas will allow a formal, programming language- and software-independent description of the mapping between macros and primitive GLIF steps. The schema will serve three purposes: (1) it will provide a standard specification for the semantic meaning of a macro; (2) it will provide a method for mapping between primitive GLIF steps and the macro; and (3) it will enable institutions and authors to define new macros within the GLIF representation.

CONCLUSIONS

Macros are a scalable and flexible approach for representing patterns of domain concepts in a guideline representation language. Macros can potentially simplify authoring and visualization of guidelines. Further work is required to develop macros and to evaluate their expressiveness.

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