

Sharable Computer-Based Clinical Practice Guidelines: Rationale, Obstacles, Approaches, and Prospects

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Abstract

Clinical practice guideline automation at the point of care is of growing interest, yet most guidelines are authored in unstructured narrative form. Computer-based execution depends on a formal structured representation, and also faces a number of other challenges at all stages of the guideline lifecycle: modeling, authoring, dissemination, implementation, and update. This is because of the multiplicity of conceptual models, authoring tools, authoring approaches, intended applications, implementation platforms, and local interface requirements and operational constraints. Complexity and time required for development and structure are also huge obstacles. These factors argue for convergence on a common shared model for representation that can be the basis of dissemination. A common model would facilitate direct interpretation or mapping to multiple implementation environments. GLIF (GuideLine Interchange Format) is a formal representation model for guidelines, created by the InterMed Collaboratory as a proposed basis for a shared representation. GLIF currently addresses the process of authoring and dissemination; the InterMed team's major focus now is on tools to facilitate these tasks and the mapping to clinical information system environments. Because of limitations in what can be done by a single team with finite resources, however, and the variety of additional perspectives that need to be accommodated, the InterMed team has determined that further development of a shared representation would be best served as an open process in which the world community is engaged. Under the auspices of the HL7 Decision Support Technical Committee, a GLIF Special Interest Group has been established, which is intended to be a forum for collaborative refinement and extension of a standard representation that can support the needs of the guideline lifecycle. Significant areas for future work will need to include demonstrations of effective means for incorporating guidelines at point of care, reconciliation of functional requirements of different models and identification of those most important for supporting practical implementation, improved means for authoring and management of complexity, and methods for automatically analyzing and validating syntax, semantics, and logical consistency of guidelines.

Keywords:

Clinical practice guideline, knowledge representation, standards development

Introduction

Clinical practice guidelines define recommended strategies for managing health care in specific clinical circumstances. The goal is to reduce practice variation and foster adoption of best practices. Attention focused on medical errors by the Institute of Medicine's 1999 report, *To Err is Human* [1], has served to elevate the issue of quality, not just error prevention, as a primary health care systems agenda.

There is much interest in finding ways of implementing computer-interpretable guidelines in health care applications, especially those that can deliver patient-specific guideline recommendations at the point of care. A wide variety of potential applications can utilize guidelines, ranging from passive retrieval and review to more interactive applications such as risk assessments and consultations, or background applications that monitor and critique ongoing health care processes, generating alerts and reminders, or supporting quality review and management. Guideline logic can also be implemented in the form of referral criteria or appropriateness determinations. Clinical trial protocol design is a variant of guideline design. Workflow applications can be driven by guidelines that define actors and sequences of interactions.

Limitations of traditional guideline development and dissemination. The interest in computer-interpretable guidelines stems from limitations of traditional guidelines. A huge number of guidelines exist, and more are being created, often under sponsorship of government agencies, professional specialty organizations, or health care delivery systems. Their authoring is an arduous and expensive process, involving detailed review of literature, evaluation of alternatives for all actions, specification of optimal sequences of decisions and actions, and documentation of the basis for recommendations. The ideal is that each recommendation be evidence-based, but where such evidence is lacking or insufficient, a consensus process is used.

Dissemination is by multiple means, including books, journals, CDROMs, and the Web. With respect to the latter, guidelines from many sources are indexed, abstracted, and accessible via hyperlink by the National Guideline Clearinghouse (www.guidelines.gov), sponsored by the US Agency for Healthcare Research and Quality. Most guidelines are disseminated as read-only documents, however, usually in narrative form, sometimes instead or in addition including a graphical flow chart. Neither narrative guidelines nor even the flow charts are typically formally structured, with precise definition of all terms, and unambiguous specification of all logic and process flow, as would be required for execution. Thus their impact depends on the assumptions or hopes that clinicians will access them, will learn their recommendations, and will later apply them in patient-specific circumstances. Experience has not shown, however, that such read-only dissemination is highly effective in altering practice.

Computer-interpretable guidelines. The major requirement for computer-based applications is that the guidelines underlying them be well structured, and capable of unambiguous interpretation, and thus amenable to execution. Given the range of possible applications mentioned above, active experimentation is focused on identifying workable and effective paradigms for guideline use at the point of care. Challenges relate to the difficulties in determining settings and applications in which guidelines can be most helpful, least obtrusive and demanding, and most congenial to workflow constraints. Evaluation of effectiveness of various approaches is preliminary at best.

Despite vigorous activity, progress on the above appears to be impeded by the multiplicity of design approaches, variety of target applications, requirements for implementation in existing health care systems, and the impact of these on requirements for authoring and dissemination of guidelines. The remainder of this paper focuses on an approach to these issues that involves a common shared formal representation and an open process of development. Current progress and future challenges are described.

The computer-interpretable guideline lifecycle

As a basis for exploring issues and possible approaches, it is helpful to consider the lifecycle for development, dissemination, and use of computer-interpretable guidelines, as diagrammed in Figure 1.

Conceptual modeling. Guideline development must begin with a model of the functional requirements of an intended application. This serves to define details and characteristics that must be captured in guidelines. Work by many groups on the development of conceptual models is aimed at identifying functional requirements for specific kinds of applications or uses of guidelines. This in turn is reflected in efforts to formalize the authoring of guidelines so as to capture the specifications needed for those functional requirements, and to formalize also the representation format for encoding of the guidelines. Conceptual models, authoring methods, and

applications have become an area of intense activity, evidenced by a number of conferences on this topic; the most recent AMIA 2000 Annual Symposium. In Los Angeles, CA, featured 20 papers on computer-based guidelines.

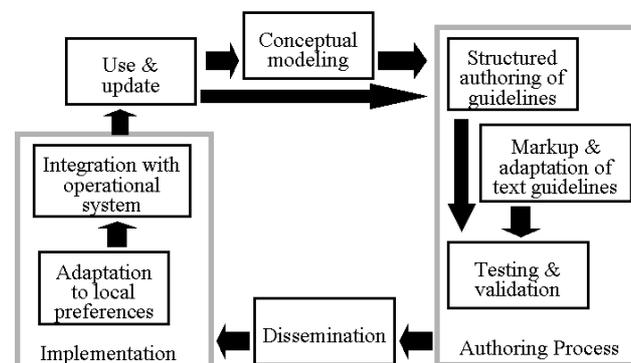


Figure 1 – Guideline lifecycle. This diagram depicts several sub-steps of the authoring and implementation tasks.

Authoring process. Guidelines must be created and documented in an unambiguous way. This is most straightforward if the authoring is done with the aid of an authoring tool designed to capture the details needed by a particular model, with the intent of being used in the kind of application supported by that model (e.g., for consultation or for chronic disease management). It does not solve the problem of how to modify guidelines created for other purposes (with features as required by their models, e.g., for workflow support), or how to add the necessary structure to a guideline originally created in narrative form.

Testing and validation. This can be considered a step in authoring, aimed at determining that structured elements are precise, unambiguous, and syntactically and semantically correct (terms defined, with details for attributes such as units and allowed ranges), and that logical expressions and pathways are consistent and fully specified.

Dissemination. Following authoring, a guideline with all the details that specify the functional requirements of the guideline model must be encoded in a form that can be later retrieved and interpreted by an application.

Local adaptation and implementation. Incorporation of a guideline into an application is easiest if the application is has been designed by the model developer, and if authoring and dissemination have been done in a form consistent with that model. This is a quite limited subset of all situations, however. Multiple possible kinds of applications exist, as well as huge numbers of potential guidelines, and many possible implementation platforms. Not only is it desirable to adapt guidelines for use in a variety of kinds of applications, but also they will need to be adapted to local constraints. These include adaptation of the medical content of guidelines, to conform to situational distinctions, such as the lack of availability of certain resources specified in a guideline (e.g., no MRI scanner), local preferences (e.g., for one medication vs. another in the same class), or contextual differences (e.g., field, home, office, hospital). Lastly, the application may need to be implemented in a variety of information system settings, with differences in platform, user

interface, workflow, and encoding of data and knowledge. With respect to the latter, the data elements and actions referenced in a guideline must be mapped to database codes and procedure invocations, respectively, in the host environment.

Use and update. As authoritative guidelines change over time, it is necessary to identify the impact on local adaptations and on implementations in which guidelines are embedded, so they can be updated appropriately.

As implementation and update experience is gained, and as particular applications and approaches are found to be most successful, or lack of features is found to be an impediment, these findings serve to influence changes in conceptual models, which in turn influence the nature of authoring and dissemination, thus completing the cycle.

Obstacles

Support for the guideline lifecycle is complex and a number of impediments to achieving it exist, primary among which appear to be the following:

1. There is little agreement yet on the most effective applications for computer-based guidelines. As a consequence, it is not clear which functional requirements, and thus what conceptual models and development environments are most likely to be important. The variety of modeling approaches reflects this, and the developer community has not yet converged on identifying a common set of requirements.
2. The specification of functional requirements has a major effect on an already burdensome authoring process. Guidelines can either be developed generically, leaving to the implementers the adaptation for various kinds of applications; or improved authoring tools need to be created that make it easier to manage complexity, and to support the inclusion of detail as separate layers in the specification.
3. Dissemination needs to be the bridge between the modeling approach and the anticipated delivery environment. If this is one-to-one, (implementation within a closed environment and platform), then the dissemination format can be agreed-upon straightforwardly. If it is many-to-many, (guidelines developed for many possible purposes, or generically, to be implemented in many possible target environments, in multiple different kinds of applications), then a common format for encoding the functional requirements (e.g., in XML or RDF) needs to be agreed upon. This is the easiest of the obstacles to solve.
4. Despite their interest in providing guideline support, implementers of clinical information systems, both commercial and those in medical centers, are not generally poised to do significant development or evaluation in this arena, and want ready methods for going

from model to delivery. For successful application of guidelines in clinical settings, it is utterly essential that the providers of such systems be enabled with tools that facilitate the incorporation of guideline applications, e.g., for customizing the guideline logic, adapting to workflow requirements, mapping of data elements and actions, and integrating user interfaces.

5. Update is generally an unsolved problem. Local implementations will have modified authoritative guidelines to adapt to local constraints, and will have done considerable work to interface them to their platforms and settings. As recommendations of authoritative guidelines change, local implementers must be notified of these changes, and must modify their local versions. Maintaining version control and revision history are critical to this task, and means of automating or facilitating the changes required will be needed.

Toward a shared representation

Many of the above problems could be addressed in a more cohesive manner if a common shared representation were to be mutually developed by modelers and implementers. If the functional requirements of various models were to be incorporated in a shared representation, and if guideline authoring produced output in the shared representation format, this could function as a single point of convergence from various modeling environments and authoring systems. If guidelines already existing in narrative form were to be modified by adding structure to them in such a manner that they too would be encoded in the shared representation, this would add significantly to the corpus of available guidelines in that format. Applications could then be built and interfaced to various implementation environments using the shared representation as a starting point. This reduces the problem of a many-to-many mapping between models and delivery environments to a many-to-one mapping between models and dissemination format and one-to-many mapping between dissemination format and implementation platform.

A schematic of the potential interactions among developers, authors, and implementers that could be enabled by such an approach is shown in Figure 2.

There are many challenges to address in supporting the interactions and capabilities described in the above figure. We report here on an approach that has been pursued by the InterMed Collaboratory to create a shared representation,

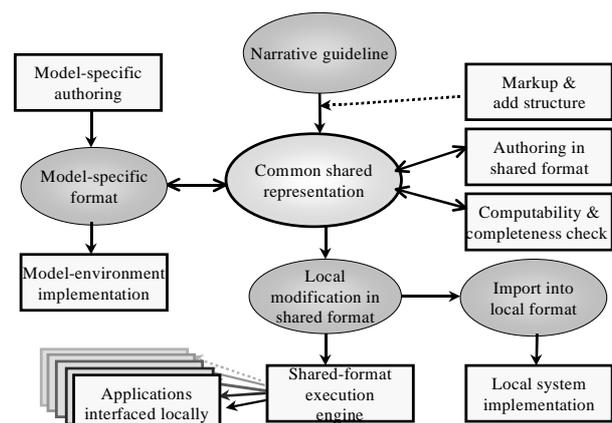


Figure 2 – A shared representation as a common pathway for delivery to application environments. Authoring tools must export to the shared representation or work in native mode producing the shared representation. This representation can be interpreted directly by an execution engine, or imported back into model-specific or local system environments.

GLIF. InterMed is a joint project of medical informatics groups at Harvard, Columbia, and Stanford Universities, along with other participants, which has been working on GLIF since 1996. A specification for GLIF version 2.0 (GLIF2) was published in 1998 [2]. Prototype tools for authoring, navigating, server support, and execution have been developed [3, 4]. GLIF3 [5] is an evolving version of GLIF, intended to more completely address implementation (see www.glif.org). GLIF is based on an object-oriented logical model of concepts, and has an RDF-based syntax. Guidelines in GLIF are modeled as a network of guideline steps that represent clinical decisions and actions, as well as patient states. GLIF3 builds upon the GLIF2 framework but augments it by introducing several new constructs and utilizing a more formal definition of decision criteria, action specifications, and patient data.

The process of modeling a guideline in GLIF involves three levels of representation. First, medical domain experts define a conceptual flowchart of clinical actions, decisions, and patient states. This aids in human comprehension for the guideline authors and for users who wish to follow the guideline logic.

Then, informaticians specify the computable level, or abstract machine representation. This specification can be executed by an interpreter, and its syntactical correctness and logical consistency and completeness can be analyzed. The computable level of specification is supported by two important extensions of GLIF2 that are incorporated in GLIF3. The first is the inclusion of a modification of the logic grammar of Arden Syntax [6] as a formal expression language for specifying decision criteria and patient states. The second extension is a domain object model that enables GLIF3 steps to refer to patient data items that are defined by a controlled terminology that includes standard medical vocabularies (e.g., the UMLS [7]) as well as standard data models for the medical concepts (e.g., HL7's Unified Service Action Model [8]). These, along with an action specification hierarchy, enable GLIF3 to have a computable level of specification where the logical criteria, definitions of patient data items, clinical actions, and the flow of the guideline are formally defined. Because of this formal definition of guideline components, the guideline could be validated for logical consistency and completeness. Figure 3 shows part of the GLIF3 encoding of a guideline for stable angina [9].

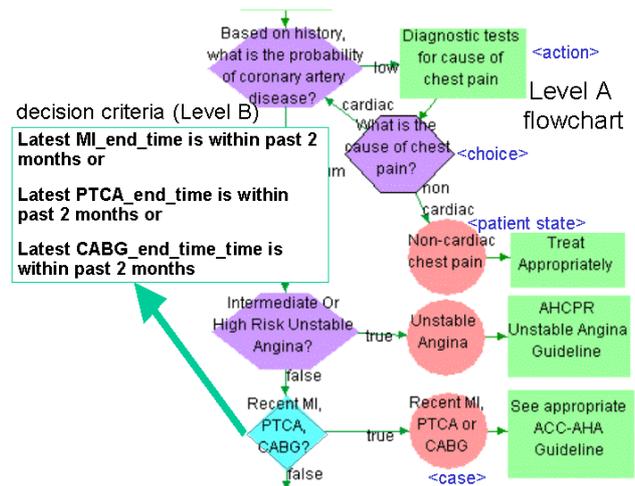


Figure 3 –GLIF encoding of part of a guideline for stable angina

The third level of representation is not fully supported yet. It will concern issues related to integration into application environments, such as application-specific data and procedure mappings and locally generated modifications.

Creating an Open Process. A desired goal is to have a common platform for supporting the full lifecycle of guideline modeling, authoring, dissemination, implementation, and use. However, the scope of such work is beyond the ability of a single team, with limited resources and funding. The InterMed group came to the conclusion that the best way to foster the long-term goal of full lifecycle support is to have this occur as an open process in which the larger community of modelers, developers, implementers, and other stakeholders is engaged. Accordingly, InterMed hosted an invitational workshop in March, 2000, which drew 82 participants from 10 nations, from government, professional specialty organizations, health care delivery systems, academic medical informatics, health care finance, and commercial vendors. The focus was on identification of goals for a shared guideline representation, and was addressed in breakout sessions with respect to functional requirements, representation issues, special needs of clinical trials, infrastructure and tools needed, and the appropriate organizational framework for further pursuit of these topics.

An outgrowth of that meeting was the establishment by the HL7 organization, in September, 2000, of a GLIF Special Interest Group, under a newly formed Decision Support Technical Committee (which also, as a result of this reorganization, includes the Arden Syntax SIG). A first meeting of the GLIF SIG was scheduled for January, 2000, as part of the HL7 Annual Meeting.

This step is an important milestone, because it corresponds with the point at which the InterMed group sees its work on GLIF transitioning from being the efforts of a single research team to an open, non-proprietary collaborative activity under a standards development organization. To be successful, a broad spectrum of participants must have a stake in it, and contribute to its further growth and development.

Challenges and Prospects

Currently, the various conceptual models are sufficiently different that it is unrealistic to build a single common model that incorporates all of their features. Without such a complete common model, developers of conceptual models that wish to take advantage of a common model's ability to support multiple implementations, must create ways to export guidelines developed in their modeling format into the common representation. This may lose some functional detail, if it is not supported in the common model. The reverse capability, that of importing guidelines developed (or now encoded through export from other modeling environments) in the common format is also limited, as considerable modification will be required to add the detail for model-specific features.

Thus convergence on a common model would be highly desirable if this could occur. A possible scenario for this happening is as follows: As noted earlier, activity in this field is likely to be influenced greatly by the success of particular implementations, which will determine most important applications on which to focus in the future. This will in turn focus on the functional requirements for that class of applications, and on the tool requirements for supporting their implementation. The common shared representation will need to evolve, as will the authoring tool for producing guidelines in the shared representation to support those functional requirements. Over time, the shared representation can be expected to become increasingly robust, and authoring, dissemination, and implementation will increasingly follow a common pathway. The community at large will work to enhance the common representation and the tools for authoring, implementation, dissemination, and update.

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