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Modeling Guidelines for Integration into Clinical Workflow

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Abstract

The success of clinical decision-support systems requires that they are seamlessly integrated into clinical workflow. In the SAGE project, which aims to create the technological infrastructure for implementing computable clinical practice guidelines in enterprise settings, we created a deployment-driven methodology for developing guideline knowledge bases. It involves (1) identification of usage scenarios of guideline-based care in clinical workflow, (2) distillation and disambiguation of guideline knowledge relevant to these usage scenarios, (3) formalization of data elements and vocabulary used in the guideline, and (4) encoding of usage scenarios and guideline knowledge using an executable guideline model. This methodology makes explicit the points in the care process where guideline-based decision aids are appropriate and the roles of clinicians for whom the guideline-based assistance is intended. We have evaluated the methodology by simulating the deployment of an immunization guideline in a real clinical information system and by reconstructing the workflow context of a deployed decision-support system for guideline-based care. We discuss the implication of deployment-driven guideline encoding for sharability of executable guidelines.

Keywords:

Guidelines, Clinical decision support, Structured Vocabulary Standards

Introduction

It has been widely recognized that the success of clinical decision-support systems (DSSs) depends heavily on how the system is integrated into the workflow of the care process [1]. Interpretation of the integration problem, however, varies widely. For alert-and-reminder systems, integrating into the workflow can mean the timing, modality, and format of notification [2]. For implementations of chronic-disease guidelines in the primary care setting, workflow considerations may be used as factors in the design of the user interface and decision-support services that a system provides [3]. In hospital environments, the protocol for managing a specific medical condition may drive the workflow that sequences care tasks and schedules resources [4].

The SAGE (Standards-Based Sharable Active Guideline Environment) project, a collaboration among research groups at IDX Systems Corporation, the University of Nebraska Medical Center, Intermountain Health Care (IHC), Apelon, Inc., Stanford University, and the Mayo Clinic, seeks to create the technology for integrating guideline-based decision support into enterprise clinical information systems. As a provider of decision-support services to such systems, the SAGE technology will not be in control of host systems' workflow management. Instead, the SAGE system will respond to events in the care process and deliver, through existing functions of the clinical information system, guideline-based recommendations appropriate for members of a care team. Thus, for example, physicians might see "Inbox" notifications of guideline-based recommendations, while nurses might be presented with an active care-reminder flowsheet that is populated with a pre-authorized order set. Toward this goal, we created a deployment-driven methodology for developing guideline knowledge bases where the knowledge requirements derived from clinical scenarios and guideline literature drive the guideline formalization process. We evaluated the methodology by simulating the deployment of an immunization guideline in the IDX clinical information system and by performing a retrospective analysis of the ATHENA hypertension advisory system [5] that has been deployed at a number of Department of Veteran Affairs sites. We conclude with observations about characteristics of guideline knowledge bases constructed using this methodology and implications for sharability of these guidelines.

Methods

The SAGE guideline knowledge encoding methodology consists of six main steps depicted in Figure 1. After the decision to implement a guideline, clinicians must first create clinical scenari-

os that are detailed enough to support integration of executable guideline content into real clinical workflow. For the immunization guideline, for example, clinicians on the project defined a number of clinical scenarios that were eventually combined into four:

- Neonatal orders for immunization
- Primary care immunization with standard care protocol in place
- Primary care immunization with required , physician confirmation
- Population-based reminders to patients or providers

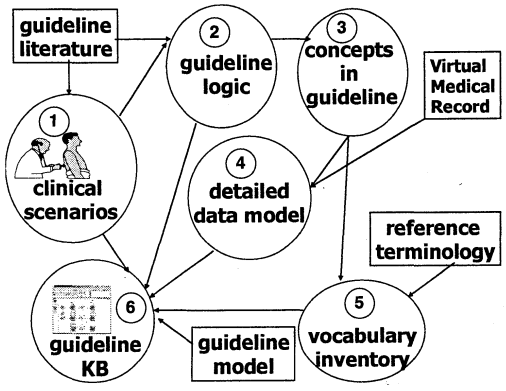

Figure 1 - Steps inmodeling clinical practice guidelines for integration info workflow. The arrows represent information flow

For each scenario, user-interface screens were created to simulate the interactions between care providers and the clinical information system. The information content of desired guideline recommendations (e.g. immunizations that are due or the dates of those that are expected in the future) and sequence of interactions (e.g. a primary care nurse interviews and records vaccines administered elsewhere before documenting presence or absence medical conditions that may contraindicate specific vaccinations) were carefully documented and evaluated using a usability laboratory at the Mayo Clinic [6]. UML sequence diagrams were then created to formalize the interactions in these guideline usage scenarios.

In the second step of the methodology, clinicians with informatics training analyze the desired guideline recommendations and distill, from guideline texts, medical literature, and their clinical expertise, the knowledge and logic needed to generate these recommendations. This distillation process requires clinicians to select, interpret, augment, and operationalize guideline statements in terms of unambiguous concepts and of patient data that may be available. For example, the term 'contraindication to Hep B' in Figure 2 was given a specific definition ("anaphylactic reaction to hepatitis B vaccine").

In the third step, clinical concepts used in the distilled guideline logic are identified. Thus, terms like "hepatitis B vaccine" and "anaphylactic reaction" were extracted and recorded.

```
IF NO CONTRAINDICATION TO HEP B AND
 NO REASON FOR DEFERRAL AND
 NUMBER OF HEP B VACCINE DOSES=3 AND
 1ST DOSE GIVEN WITHIN 7 DAYS OF BIRTH AND
 3RD DOSE GIVEN BEFORE 6 MONTHS AGE AND
 TIME FROM LAST DOSE IS >= 8 WEEKS AND
 AGE < 19 YEARS
THEN
 ADVISE HEP B VACCINE DUE
```

Figure 2 - Distillation of guideline logic in unambiguous terms

In the fourth step, concepts identified as part of the required guideline logic are instantiated as detailed data models that correspond to constraints on classes of a "virtual medical record" (vMR) [7]. A vMR is a view of a patient medical record that is simplified for decision-support purposes. The vMR supports a structured data model for representing information related to individual patients, domains for values of attributes in the data model, and queries through which guideline DSS can test the states of the patient. A detailed data model for a guideline concept spells out precisely how patient data corresponding to that concept would be represented as instances of a vMR class. For example, in the SAGE vMR, we model allergy information as instances of an 'Allergy' class that has attributes such as 'code,' 'allergen,' 'reaction,' and 'effective time' (time during which a patient is presumed to be allergic to the allergen). Figure 3 shows a detailed model for "Anaphylactic reaction to hepatitis B vaccine" which spells out the possible attribute values of the Allergy class for data representing that allergy.

```
Anaphylactic reaction to hepatitis B vaccine is
an Allergy where
   code is 'vaccines allergy'
   allergen is 'hepatitis B vaccine'
   reaction is 'anaphylaxis'
```

Figure 3 - A detailed data model for the guideline concept "Anaphylactic reaction to hepatitis B vaccine"

The fifth step of the methodology calls for specifying guideline concepts in terms of standard terminologies. To implement a computerized guideline in a particular institution, terms used in a guideline knowledge base to describe patient states must be mapped to corresponding terms in that institution's electronic patient record. We employed only standard reference terminologies, including SNOMED CT and LOINC, which provide the necessary shared semantics for such mappings and which have been recommended as core record terminologies by the National Committee for Vital and Health Statistics [8].

Current standard terminologies, however, do not contain all concepts needed to encode existing clinical practice guidelines. A compositional reference terminology, such as SNOMED CT, allows us to define some of the missing terms, a process called post-coordination. A 'contaminated wound lesion,' for example, can be defined as a 'wound lesion' (SNOMED CT:23915507) with an associated morphology of 'contaminated laceration' (SNOMED CT:17097001). More complicated terms, such as

'chronic pulmonary disease excluding asthma' can be defined as Boolean combinations of existing terms (Figure 4). Others, such as 'Haemophilus influenza type b Conjugate Vaccine' simply have to be added and defined as new terms using the reference terminology definitional model.

```
chronic pulmonary disease excluding asthma =
  ('Chronic respiratory disease:
    17097001' AND
  'Disease of lower respiratory
   system:128272009') AND
  NOT 'Asthma:195967001'
```

Figure 4 - Specification of guideline concepts in terms of standard terminologies. Codes used in the figure are SNOMED CT concept ids.

The final step in the guideline knowledge development process is the translation of the clinical scenarios and guideline logic into a computer-interpretable model of guidelines. The SAGE methodology calls for explicit modeling of guideline usage as part of the executable guideline specification. Because of our assumption that a guideline does not dictate the workflow in a clinic, the guideline knowledge base specifies how a decision-support system *reacts* to events in the care process. The computational processes that define these interactions are modeled as *activity graphs* in the SAGE *recommendation-set* formalism [9]. A recommendation set is a collection of related recommendations that are applicable in one or more shared contexts and that are organized according to a computable formalism. Activity graphs are recommendation sets that allow specification of computational algorithms or medical care plans as processes consisting of: (1) Context Nodes that specify a clinical setting (e.g. outpatient encounter in a general internal medicine clinic), the care providers involved in the recommendation process, necessary clinical resources, relevant patient states (e.g. patient age), and possibly a triggering event (e.g. patient checking into the clinic), (2) Decision Nodes that are loci of decision knowledge organized according to some decision model (e.g. a Boolean precondition for an action), (3) Action Nodes that encapsulate a set of work items that should be performed either by a computer system or by a healthcare provider, and (4) Routing Nodes that are used purely for branching and synchronization of multiple concurrent processes.

In terms of the immunization guideline that the SAGE project implemented, we modeled a clinical usage scenario as an activity graph that specifies how a guideline-based DSS should behave in the scenario. Figure 5 shows part of an activity graph as encoded in the SAGE Guideline Model using Protégé-2000, a knowledge-engineering tool developed at Stanford University [10]). It shows a context that is triggered by a patient checking into a primary care clinic. If the patient is enrolled in this guideline and the precondition defining the relevant patient states evaluate to true, the system should invoke a subguideline to check immunizations that may be due. If any immunization is due, it should then request a clinic nurse to document any outside immunizations. Data entry by a nurse triggers another context, which causes the system to update the set of expected immunizations and to request additional documentation before these immunizations are ordered.

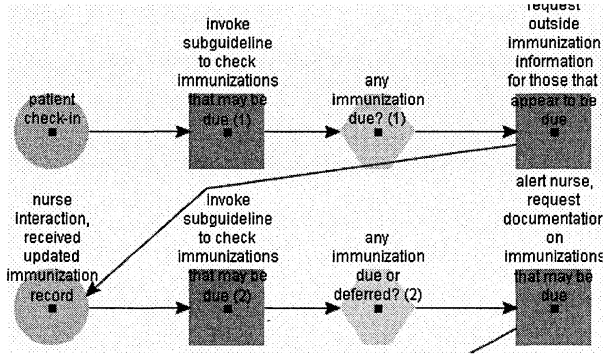

Figure 5 - The top-level process specification in the SAGE immunization guideline using the Protégé-2000 tool. It defines how a guideline DSS should react to the events in the care process

Modeling usage scenarios of a guideline in the SAGE guideline model requires that clinical settings, provider roles, resources used, triggering events, and notification mechanisms be made explicit. These entities are represented in an organizational ontology that is one component of the models required in the SAGE methodology.

Most of the guideline logic used to determine when an immunization is due is purely declarative. To model such declarative knowledge, we use the SAGE *decision-map* formalism [9]. A decision map consists of a collection of *decisions*, each of which contains a context similar to those in an activity graph, a collection of action choices, and a decision model to determine the appropriate choice in alternative circumstances. Thus, the decision logic such as that shown in Figure 2 is decomposed into a context (children age < 19 years), actions that make assertions about the status of hepatitis B immunization (due, deferred, not due or contraindicated), and a decision model that allows precise specification of the circumstances in which a particular immunization status is recommended.

We applied the SAGE methodology to the encoding of the Institute for Clinical Systems Improvement's immunization guideline [11]. The four usage scenarios defined by SAGE clinicians were modeled as four activity graphs similar to the one show in Figure 5. Decisions about administration of Diphtheria toxoid-Tetanus toxoid-acellular Pertusis (DTaP), Tetanus-diphtheria (Td), polio, pneumoccoccus, influenza, Measles-mumps-rubella (MMR), varicella, hepatitis A and B, and hemophilus influenza vaccines were organized as a single decision map (Subguideline A). The administration of DT vaccine, because of its dependency on the status of DTaP vaccination, is modeled in a separate activity graph (Subguideline B) that includes an action that calls Subguideline A and a subsequent decision on the administration of DT vaccine. Each top-level activity graph calls Subguideline B repeatedly to determine the immunization status of the vaccines. We tested the resulting knowledge base using a prototype simulation test bed that is integrated with the IDX clinical infor-

mation system. Engineers at IDX Systems Corporation developed a SAGE guideline execution engine that can interpret a guideline encoded using the SAGE guideline model. The execution engine retrieves patient data specified in the guideline knowledge base and, based on these data and the clinical context, presents recommendations for guideline-based care. Access to patient data is provided by a set of vMR web services that insulate the guideline execution engine from details of the IDX clinical data repository. A preliminary integration of the SAGE execution engine into the IDX's clinical information system allowed simulation of each usage scenario as a series of interactions between a user and the guideline-enhanced IDX clinical information system.

To further test the generality of the methodology, we analyzed retrospectively the way ATHENA[5], a hypertension guideline DSS deployed at some Department of Veteran Affairs clinics, was constructed and situated in workflow of VA clinics.

Results

The results of executing the immunization guideline and the experience of applying the steps outlined in the Methods section served as the basis for our analysis of this process. Not surprisingly, instead of moving sequentially through the steps, we iterated through them.

We found that the "deployment-driven" approach to guideline modeling required us to clarify the assumptions we made about the capabilities of the CIS. Our incomplete understanding of the CIS features at the time of the initial encoding forced us to revise the knowledge base subsequently. While the decision maps that capture the logic for determining when vaccinations are due are largely independent of CIS capabilities, the activity graphs that model how users, through the CIS, receive immunization recommendations depend on available modes of interactions between the DSS and the CIS. Thus, for example, if order-entry and synchronous request-and-response capabilities are not available in the CIS and the DSS can only use asynchronous on-screen messaging and inbox notification to communicate with a user, the activity graphs have to be formulated to support these types of interactions.

We found that the steps of extracting and distilling the guideline logic in semi-structured "if-then" form and of specifying guideline concepts in terms of standard terminologies were enormously useful for identifying the relevant guideline knowledge and for communication between clinicians and informaticians on the project. For the immunization guideline, we used approximately 180 clinical concepts, out of which 30 were not directly available in SNOMED CT or LOINC. Thus, the ability to extend standard terminologies through the mechanisms described in the Methods section is crucial.

The retrospective analysis of ATHENA verified that the six steps described in the Methods section were present in either the development stage or the deployment architecture of the system. ATHENA has a well-defined usage scenario: the DSS gives recommendations to physicians on the use of anti-hypertensive agents in primary-care outpatient setting. As such, ATHENA client software is installed only in primary-care outpatient clinics. The ATHENA client pops a window offering drug recommendations only to a controlled list of physicians. A national guideline on the management of hypertension was the primary source of the guideline knowledge in ATHENA. However, clinicians on the project consulted primary medical literature to make extensive modifications and additions. They maintain the specification for the knowledge base in a "golden rule book" document.

ATHENA uses the vMR of the EON system [7] as the patient data model and it uses VA terminologies as its standard vocabulary. High-level concepts in the guideline knowledge base are either mapped to VA codes or defined using expression languages available in the EON system. Recommendations for use of anti-hypertensive agents are organized into the equivalent of a decision map in the EON guideline model [12].

Discussion

Current multi-step guideline modeling formalisms either have no explicit representation for clinical care processes or assume that the guideline system is in control of workflow management. In contrast, the SAGE approach models a guideline DSS as a reactive system that is triggered by clinical or administrative events in the care process. We characterize the SAGE methodology for guideline knowledge-base development as "deployment-driven" because usage scenarios, based on the guideline to be implemented, form the basis for both (1) the top-level activity graphs that define how a guideline DSS reacts to specific clinical scenarios and (2) the distillation of the guideline knowledge to be encoded in the knowledge base. While not performing ethnographic studies of actual workflow may be a shortcoming in the methodology, the usability laboratory at the Mayo Clinic provides a vehicle for investigating properties of simulated human-machine interactions. Actual implementations, such as ATHENA, require careful observation and analysis of actual care processes in clinical settings.

Evaluation of the SAGE methodology is necessarily incomplete at this stage. Limitations of the current experiment include the fact that, even though the SAGE guideline model is rich enough to model complex medical and workflow processes that span multiple encounters and that require management of concurrent processes, we have not yet tested these capabilities. Furthermore, the current methodology assumes a flow of work that is unique to each guideline. If multiple guidelines are implemented, a DSS's responses to workflow events would need to be coordinated across guidelines.

The SAGE methodology raises questions about how computer-interpretable guidelines may be shared. In contrast to InterMed's GLIF [13] approach, which assumes that guidelines will be encoded using a top-down approach, starting with high-level medical logic and progressively refined to computer-interpretable and implementation-specific layers, the top-level activity graphs in the SAGE approach are dependent on details of workflow processes. We hypothesize that institution-specific workflow knowledge can be separated from reusable medical logic, as we did with workflow-specific activity graphs and the decision-map subguideline. Furthermore, we believe that the activity graphs, if created using only very basic functions of CISs, may be adapt-

able at different sites. However, these hypotheses remain to be tested with additional experiments.

A second question addressed by the SAGE methodology, is how standardized clinical vocabularies with reference terminology features can be used to encode computer-interpretable guidelines. Whereas previous guideline encoding efforts have made use of standard terminologies, our approach highlights the importance of reference terminologies with extensible post-coordination features and the interrelationship between terminologies and standard data models. We assert that commitment to reference vocabulary standards is a necessary step towards true interoperability of decision-support technology.

Conclusion

The SAGE project explores a novel guideline modeling methodology that makes analysis of clinic workflow and opportunities for delivering decision support the basis for selecting and formalizing medical decision-making knowledge. This methodology promises to produce DSSs that better match the requirements for clinical deployment. At the same time it raises questions about and proposes an alternative approach toward the sharability of computerized guidelines.

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