Making Generic Guidelines Site-Specific

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Health care providers are more likely to follow a clinical guideline if the guideline's recommendations are consistent with the way in which their organization does its work. Unfortunately, developing guidelines that are specific to an organization is expensive, and limits the ability to share guidelines among different institutions. We describe a methodology that separates the site-independent information of guidelines from site-specific information, and that facilitates the development of site-specific guidelines from generic guidelines. We have used this methodology in a prototype system that assists developers in creating generic guidelines that are sharable across different sites. When combined with site information, generic guidelines can be used to generate site-specific guidelines that are responsive to organizational change and that can be implemented at a level of detail that makes site-specific computer-based workflow management and simulation possible.

INTRODUCTION

Modern medical care is a collaborative activity among physicians, nurses, and other health care providers working within large, complex organizations. In the United States, managed care and market pressures are driving medical organizations to increase productivity and to reduce costs, all without adversely affecting patient care. One method that has been used to achieve these goals is to adopt standard practice guidelines. There has been significant effort at both national and institutional levels to create standard care plans, critical pathways, and protocols to reduce practice variability and to improve the quality of patient care.[1] When properly followed, guidelines do have the desired effect of improving patient care while reducing patient care costs.[2]

Because of the substantial time and effort needed to create good guidelines, there is an incentive to make guidelines sufficiently general to be shared among different institutions. Site-independent guidelines are difficult to use, however, without modifications to reflect the way in which medical care is delivered within a particular organization.[3,4,5] Most guidelines undergo changes to make them acceptable to health care providers within a particular setting.[6] These changes may be as simple as specifying the preferred formulary drugs available at an institution, indicating which referral forms are required to order a particular laboratory test, or designating who can schedule a procedure. More radical customizations include changing the order of guideline activities to streamline scheduling of patients in the clinic. Many institutions recognize the importance of creating guidelines that are specific to their organization, and have a medical director or committees of health care providers to create these specialized guidelines. These administrators transform the generic guideline into a site-specific guideline more acceptable to the practitioners in the institution and more capable of effecting change in medical practice.[6]

Customizing a guideline for a particular organization may be helpful in improving guideline acceptance and compliance, but presents its own series of problems. How do we know if these changes are valid? Customizations of guidelines are necessary to affect clinical behavior, but at present, the steps from site-independent guideline to site-dependent guideline are not well specified. The danger is that a well formulated site-independent guideline will be changed in ways that the guideline builder never intended, and this will bias the guideline's recommendations. When a generic guideline is adapted for a particular site, these changes must be valid and consistent with the original guideline. In addition to validating site-specific guidelines, it is necessary to alter guidelines as both the institutions and medical knowledge change. A treatment recommended by a guideline, may be supplanted by changes in the organization (e.g., moving services from the inpatient to the outpatient setting) or by changes in medical knowledge. Maintaining accurate, valid guidelines in the face of these changes can be difficult. A richer description of guidelines is needed for valid customization and guideline maintenance, and for a better understanding of the methods used to make a site-independent guideline more specific. In this paper, we present a framework to formalize site-specific customization, a first step to computer-based support for site-specific guideline development.

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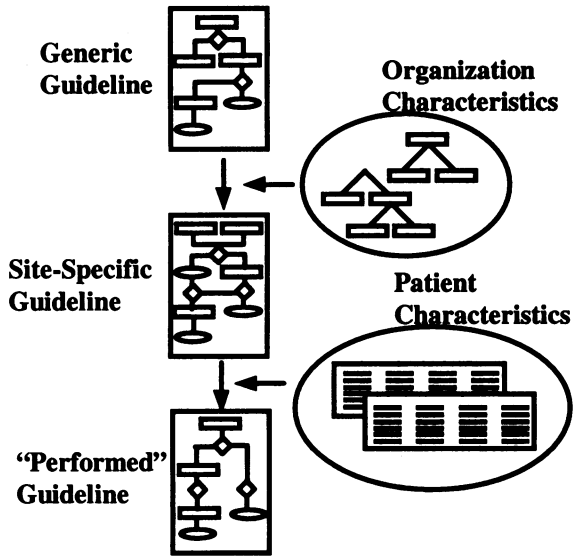

Figure 1. The process of guideline specialization

GENERIC TO SITE-SPECIFIC GUIDELINES

To make a generic guideline site-specific, a medical director needs three components: (1) A generic guideline annotated with additional information that makes explicit the assumptions the authors used in constructing their guideline, (2) a model of organization activities, with information about organizational resources, policies and preferences, and (3) rules that define allowed transformations that make a generic guideline site-specific. We have developed a prototype tool, CAMINO, that provides support for the process of specializing a guideline for a specific organizational setting (Figure 1).

Site-independent Guidelines

We define site-independent or generic guidelines as guidelines meant to be used in more than one clinic or organization. AHCPR guidelines on urinary incontinence or acute postoperative pain, for example, are well-known examples of such guidelines[7,8]. Such generic guidelines are not always explicit about the guideline's intentions, about how each of the activities in the guideline assist in achieving an intention, or about the relative importance of a particular activity versus other activities. Is the guideline descriptive of patient states (and ways to achieve those states) or prescriptive in the actions that are necessary to provide good medical care? To achieve the guideline's intentions, is it necessary to follow the guideline exactly, or are some activities more important than others? Does this guideline emphasize cost containment over timely diagnosis? To answer these questions, site-independent guidelines must make explicit:

- the intentions of the guideline authors in specifying the activities that the guideline comprises
- a measure of the value or utility of the activities that support the guideline's intention (since not all activities within a guideline provide equivalent support for the guideline's intentions).
- a measure of activity cost assumed in the guideline
- constraints on the temporal ordering of the activities

With this information, site-specific guidelines can be created that follow the intentions of the guideline, but that may substitute different ways of achieving those intentions. For example, one hospital may find it better to use an intravenous pyelogram than to refer the patient to a distant hospital for an ultrasound in the diagnosis of kidney stones. At another site, because of local expertise, it may be more desirable to get an ultrasound prior to surgery in a patient with suspected appendicitis than it is to perform surgical exploration. If the site-independent guideline is annotated with information about the assumptions and intentions of the guideline author, it is easier to make changes that remain true to the guideline, while remaining consistent with the characteristics of the organization that is u sing the guideline.

Creating Site-specific Guidelines

Site-specific guidelines are guidelines that have been adapted for use within a particular organization. Guidelines that are created specifically for a particular clinic are by definition site-specific, but many other guidelines are based on guidelines developed by governmental or professional organizations. To create a site-specific guideline, a series of transformations must occur. These include:

Addition New activities are added to the guideline when the additional activities satisfy an organizational requirement (checking insurance status), or an implicit requirement of the guideline (additional testing to determine eligibility).

Deletion In the process of specialization, this would mean the removal of activities that cannot be done in that organiz ation, or that are redundant.

Aggregation The guideline may indicate two different activities that the organization always treats as a unit. For example, a guideline may indicate to check a patient's blood pressure and then his pulse. The clinic protocol may only be concerned that vital signs are taken, which include a blood pressure and pulse. Here, the generic guideline has more detail

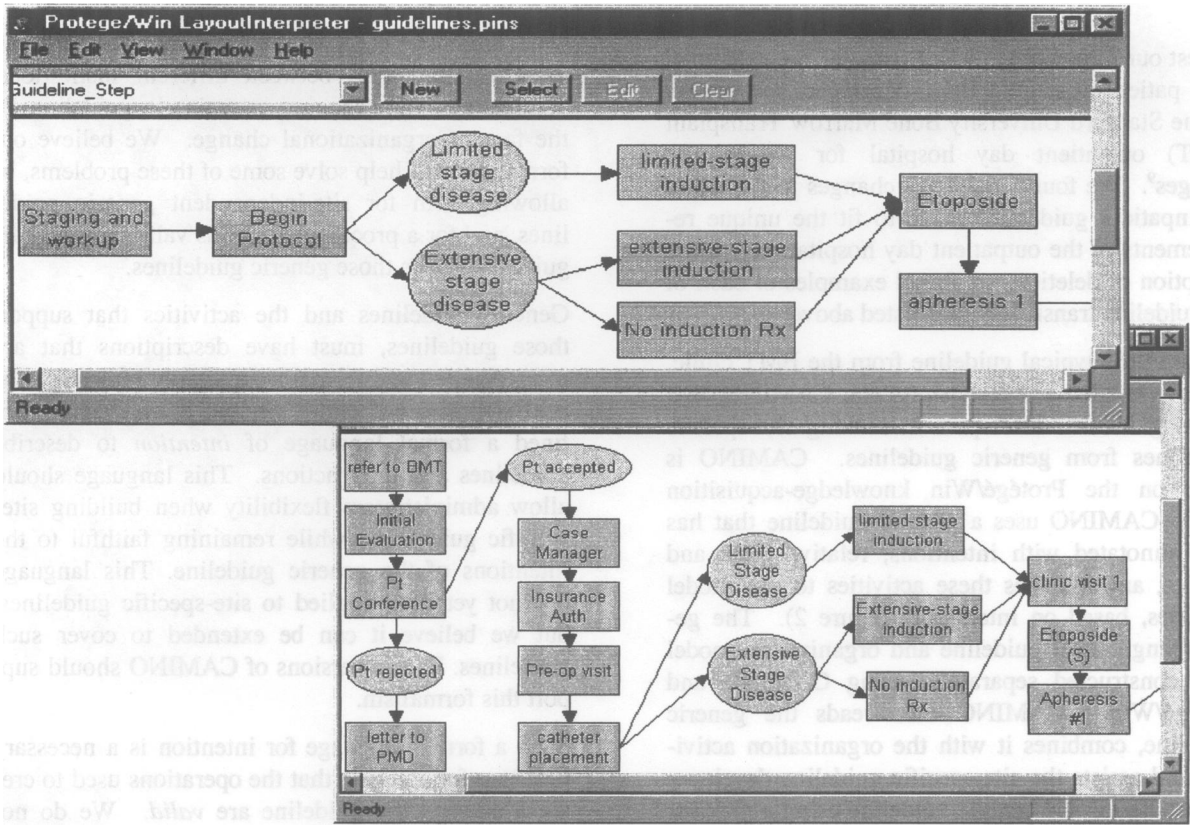

Figure 2. The CAMINO editing environment.

than is necessary for doing the tasks within the organization.

Expansion A site-specific protocol may require more detail than that specified in the generic protocol. For example, the protocol may indicate that chemotherapy should be given; the site-specific guideline, however, may specify prehydration requirements, monitoring tasks, and follow-up visits as part of the process of giving the chemotherapy.

Substitution Substitution is a combination of addition and deletion. The original activity is deleted, and one or more activities are added to the guideline. These activities would have the same underlying intention or goal.

Temporal reordering It should be possible to reorder activities that do not have explicit temporal constraints to be consistent with the organization's procedures. For example, if the guideline indicates that one test should be done and a second done based on the results of the first, it may be more efficient for the organization (and convenient for the patient) to do these tests at the same time and then to evaluate them both simultaneously.

The Site Model

In addition to these operators, we need a model of clinical activities that are carried out by a particular organization. This site model contains the activities the institution carries out, their relationship to other activities, the resources that are available to support those activities, and the people responsible for those activities and resources. The site model also contains information about the organization's preferences for different activities that support a similar intention, based on cost metrics and organizational utility.

The separation of the site model from the generic guideline has significant benefits. If there are changes within the organization, only the site model requires updating—the generic guideline would not change, and a new site-specific guideline could be generated using this new site model. Conversely, if the generic guideline were to change, a new site-specific guideline could be generated using the new intentions and sites within the organization that support those intentions. In this framework, the authors of the generic guideline maintain separately their guideline from those activities in the site model.

CAMINO

To test our model of guideline changes, we examined nine patient-care guidelines developed specifically for the Stanford University Bone Marrow Transplant (BMT) outpatient day hospital for site-specific changes[9]. We found extensive changes to the existing inpatient guidelines made to fit the unique requirements of the outpatient day hospital. With the exception of deletion, we found examples of each of the guideline transformations listed above.

Using a prototypical guideline from the BMT clinic, we have created a prototype system, CAMINO, that assists guideline developers in making site-specific guidelines from generic guidelines. CAMINO is based on the Protégé/Win knowledge-acquisition tool[10]. CAMINO uses a generic guideline that has been annotated with intentions, relative costs and utilities, and matches these activities to site model activities, based on intentions (Figure 2). The generic lung cancer guideline and organization model were constructed separately, using CAMINO and Protégé/Win. CAMINO then reads the generic guideline, combines it with the organization activities, and assists the site-specific guideline developer in specializing the generic guideline using a pick list of possible organizational tasks.

In Figure 2, we show a portion of a generic guideline and a site-specific guideline in the CAMINO tool. The generic activity "Staging and Workup" in the upper left-hand window is expanded into a series of site-specific tasks in the site-specific guideline. Additional activities that satisfy insurance verification requirements of the organization have been added after the "Begin Protocol" step. These new guideline activities are an example of an addition step.

The output from CAMINO is an ASCII, object-centered representation, capable of translation into a number of different storage formats. We expect a workflow management system can use information from a site-specific guideline to support the coordination of patient care by specifying the responsible providers, the required resources, and the preference information.

DISCUSSION

Patient care guidelines are not new to medicine, but it has only been recently that interest in guideline-based care has increased, in part due to economic and social factors to improve standardization of care and maintain high quality care. Guidelines are most effective at altering provider behavior when they are customized for the institution that will use them.[3] Unfortunately, this customization makes it difficult to share guidelines between different institutions, validate guideline changes or maintain guidelines in the face of organizational change. We believe our formalism will help solve some of these problems, by allowing both for site-independent generic guidelines, and for a process that builds valid, site-specific guidelines from those generic guidelines.

Generic guidelines and the activities that support those guidelines, must have descriptions that are more detailed and formal than simply indicating the next step in a guideline. Shahar et al.[11,12], have defined a formal language of *intention* to describe guidelines and their actions. This language should allow administrators flexibility when building site-specific guidelines, while remaining faithful to the intentions of the generic guideline. This language has not yet been applied to site-specific guidelines, but we believe it can be extended to cover such guidelines. Future versions of CAMINO should support this formalism.

Such a formal language for intention is a necessary first step for assuring that the operations used to create a site-specific guideline are *valid*. We do not anticipate that the process of making generic guidelines site-specific will be completely automated, but that a more formal description of operators will allow computers to provide better support during guideline customization. These operators depend on a rich description of temporal constraints to limit valid modifications of guidelines. In the planning literature, these constraints can be thought of as *protections* that prevent modifications of the guideline that invalidate the intentions of the generic guideline author. How to best represent these protections to provide adequate computer-support will be important to both validation and maintaining the site-specific guideline.

In our methodology, we emphasize the importance of a site model as a source of information about the organization in which the guideline is to be used. What features will be important to encode in the site model will, in part, depend on the application for which the guideline will be used. For example, if the generic guideline is to be specialized for use in a clinical information system or workflow environment, the site model would need a detailed description of resources and resource constraints that that particular site and application required. A different institution might use the same guideline for education and training, but their site model would contain

information about supporting reference material. It is an active research issue to define the features of a site model that would facilitate these customizations.

Finally, we believe the best opportunity to improve the efficiency, the cost and the quality of patient care is by including organizational factors in guideline development. Once we have assured that the site-specific guidelines are valid and consistent with respect to the intentions and goals of the guideline authors, we can focus on the process of care and ways in which it might be changed to improve patient care quality. There has been significant effort in the business community to improve organization performance through business process reengineering, computational organization models, and discrete event simulations[13]. We believe we can apply this work to medical care by using site-specific guidelines as a model of the organizational processes in health care. Computational models of organizations provide a "wind-tunnel" for testing and simulating organizational processes[14]. Such simulations can be used to gain insight into how organizational makeup hinders or helps patient care.

With additional knowledge of what the organization does most efficiently, we can make modifications to the generic guideline in ways that remain true to the intention of the original site-independent guideline, and provide a guidelines that reflects accurately the best medical knowledge, the best patient knowledge and the best organizational knowledge relevant to the care of patients.

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