Applying Axiomatic Design Methodology to Create Guidelines that are Locally Adaptable

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Clinical practice guidelines that have been developed at a national level are often difficult to use in specific-settings because of contextual factors such as non-availability of resources or expertise or because of different disease prevalence. We have created a model for guideline representation that supports local adaptation of nationally developed guidelines. The latter guidelines are specified in a setting-independent manner. These guidelines can then be adapted to local settings by each practice. The guideline is represented hierarchically with the top level steps of the guideline specifying the broad objectives of the guideline. The lower level steps specify the guideline recommendations in greater detail. We use the axiomatic design framework to provide a principled method for hierarchical design. This results in guidelines which can be more easily modified. Our approach can assist in local adaptation by explicitly describing the order in which changes must be made. The approach has been implemented by incorporation in the GLIF guideline modeling environment.

INTRODUCTION

One important purpose for creating clinical practice guidelines is to improve quality of care by reducing variations in practice. However, guideline recommendations that are insensitive to the care context, or don't recognize necessary variations, can adversely affect acceptance by care providers. For example, a national guideline for a diagnostic workup might recommend an MRI examination if a screening test is equivocal. However, adherence to this guideline would be difficult if MRI equipment were not available in a particular setting. Practitioners and patients are less likely to adhere to guidelines that are not seen as applicable to their situation or context [1].

The contextual factors that can affect patient care decisions can be setting-related (e.g., urban vs. rural practice, equipment availability), practitioner-related (e.g., medical specialty, levels of expertise), and patient-related (e.g., personal preferences, co-morbidity). Guidelines that are implemented as part of computer-based decision-support systems must be further adapted to fit into the clinical information systems environment. These adaptations are made to automate the triggering of recommendations in response to entry of relevant patient data and to support delivery of recommendations to the care provider. For example, decision criteria are modified to work with the patient data that is available in the electronic medical record, and the format and vocabulary in which the data are recorded [2].

It is important that guidelines be sensitive to the context in which they will be implemented. In doing so, guidelines must balance the goals of achieving standardization of care based on scientific evidence and of maintaining consistency with local practice [3]. Thus, nationally developed guidelines should be adapted locally during their implementation.

Contextually adapted guidelines may enhance acceptance of evidence-based guidelines by making the guidelines more consistent with local practice and population variations. Guidelines adapted to reflect local practice patterns can be more readily integrated with clinical workflow. Tighter integration with workflow has been demonstrated to improve compliance with guidelines [4]. Further, the process of local adaptation may lead to a feeling of ownership by local practitioners. Ownership and local consensus opinion have been identified as important factors in acceptance of guidelines [5].

We have created a model for representing guidelines with the aim of enhancing their acceptance by (1) improving the consistency of guidelines with local practice and population variations, (2) better integrating guidelines within clinical workflow, (3) incorporating local opinions thus generating feeling of ownership, and (4) including and maintaining the scientific evidence for recommendations. The overall approach is to express setting-independent intentions for the guideline that are then contextualized to the practice setting. We apply axiomatic design theory to guideline modeling, by incorporating it in the Guideline Interchange Format (GLIF) representation [6], and have used this enhanced model to represent a cholesterol guideline.

BACKGROUND

Asbru, CAMINO, and IMM/Serve are systems which support local adaptation of guidelines. These systems use different approaches to addressing the problem.

Asbru is an intention-based language for representing skeletal plans [7]. Plans (or guidelines) in Asbru are represented hierarchically with deeper levels providing more details. Plans can be expressed at various levels of detail, thereby describing the intention of the plan while allowing for interpretation and flexibility in executing the plan at deeper levels.

The CAMINO program is a tool for adapting "generic" guidelines for local use [8]. CAMINO provides a series of operators (e.g., addition, deletion, and substitution) that are applied to a guideline step to adapt it. The program maintains the links between the corresponding steps of the generic guideline and the locally adapted guideline.

Miller et al have described a system called IMM/Serve for successfully maintaining multiple versions of a childhood immunization guideline [9]. Their approach disassociates decision rules from parameters of the rules (e.g., the parameter *age* at which the DPT vaccine is due).

AXIOMATIC DESIGN OF GUIDELINES

Our approach utilizes the strengths of the above methods. Setting-independent guidelines are created in a hierarchical manner with the outer level of the guideline specifying high-level objectives. The deeper levels of the guideline contain detailed specifications of the recommended actions and decision criteria. Authors can specify constraints that affect how particular steps can be modified during local adaptation. Authors may also provide thresholds for decision criteria, which can be modified locally.

During local adaptation, changes to one step of a guideline should ideally have no impact on other steps in the guideline at the same level of the hierarchy. This is analogous to modular development of software, wherein internal changes to the implementation of a module do not usually impact other modules. However, with respect to steps of a guideline, such modular design is often not easy or not possible. A goal for authors of setting-independent guidelines is to design steps such that changes made to it for local adaptation will have no impact on other steps. If that is not possible, the authors should identify those steps that will be impacted by a change to another step. Preferably, a procedure should be provided that the authors could follow for adapting a guideline.

Axiomatic design theory was developed in the field of mechanical engineering as a principled approach to product design [10]. The use of a set of axioms results in product designs that are flexible and can be easily modified. This theory can be applied to the design of guidelines that are easily modified in local practice settings. We have specified the National Cholesterol Education Program's (NCEP) cholesterol management guideline [11] using the axiomatic design approach. This guideline is used to illustrate the approach in the following sections.

Design

The process of axiomatic design involves mapping design elements among four domains. The *customer domain* consists of the customer's needs (CN) for the product being designed. An example of a customer need is that of reducing risk of cardiovascular disease (CHD) in patients with elevated LDL. In the *functional domain*, the customer needs are translated by the designers into a set of functional requirements (FRs). In the above example, an FR would be to reduce LDL cholesterol level. In the *physical domain*, the FRs are satisfied using certain solutions called design parameters (DPs). A DP in this case may be a CHD-risk-proportionate treatment plan. Finally, in the *process domain*, a process characterized by process variables (PVs) is created for producing the product. For the LDL guideline, a PV may be a workflow for implementing the treatment plan.

Axioms of design

The framework provides two axioms or principles to guide the design process [12]. The first axiom, known as the *Independence Axiom*, states that the independence of functional requirements must be maintained in the design. The second axiom, known as the *Information Axiom*, states that the design must contain the least information.

FRs comprise a minimum set of independent requirements that the design must satisfy. According to the Independence Axiom, when there is more than one FR, the design must be such that each of the FRs can be satisfied without affecting other FRs. Therefore, the DP for an FR must be chosen or designed such that it satisfies the requirement of its corresponding FR without affecting other FRs.

The Information Axiom aids in selecting among alternative design solutions. The axiom provides a measure of the "goodness" of a design: the design with the least information content is the best. Shannon's information theory can be used to measure a design's information content [13].

The design matrix

The relationship among the FRs and the corresponding DPs is specified by the design equation,

$$\{FR\} = [A]\{DP\}$$

where {FR} is the vector of functional requirements, {DP} is the corresponding vector of design parameters, and $[A]$ is the design matrix. The design matrix is a square matrix, the elements of which signify the mapping of a DP to an FR, and is of the form

$$[A] = \begin{bmatrix} A_{11} & A_{12} & A_{13} \\ A_{21} & A_{22} & A_{23} \\ A_{31} & A_{32} & A_{33} \end{bmatrix}$$

for a design consisting of three FRs (rows) and three DPs (columns). In order to satisfy the Independence Axiom, the design matrix must be a diagonal matrix (all elements not on the diagonal are zero) or a lower triangular matrix (all elements above but not including the diagonal are zero). A zero value of a matrix cell indicates no effect of a DP on an FR. When the design matrix is diagonal, the design is called *uncoupled* because each FR is satisfied independently by a single DP. When the design matrix is lower triangular, the design is *decoupled*. In such a case, the independence of FRs is only possible if the DPs are determined in a specific order (from top to bottom of the DP vector). In other forms of the matrix, the design is *coupled*. A coupled design is not desirable since DPs must be changed iteratively until a solution is reached.

Consider the following design for the management of metabolic syndrome:

FR_1 = Diagnose metabolic syndrome
DP_1 = Metabolic syndrome diagnostic criteria
FR_2 = Treat metabolic syndrome
DP_2 = Weight and lipid control algorithm

In this case, the design matrix is given by

$$[A] = \begin{bmatrix} X & 0 \\ 0 & X \end{bmatrix}$$

This matrix indicates that DP_1 has an effect on FR_1 only and DP_2 has an effect on FR_2. In other words, if the diagnostic criteria for metabolic syndrome change, the treatment algorithm does not have to be modified. The reverse is also true.

Design by zigzagging

A design starts by specifying CNs, FRs, DPs, and PVs at a very high level. Design then proceeds in a hierarchical manner to more detailed levels for each of these elements. Lower level elements can only be determined once their corresponding higher level element is specified. In fact, the design proceeds in a zigzag manner. That is, once the highest level FR is selected, a DP must be selected or formulated as a solution. The set of FRs at the next level is then determined based on the DP at the level above. In the preceding example, for the DP, *Risk-based treatment plan*, the next level FRs would be to *Measure risk*, *Use therapeutic life-style changes as first line treatment* and *Use drug therapy for high-risk cases* (Figure 1). The corresponding DPs would then be selected. In this manner, design proceeds top-down, adding more detailed levels of FRs and DPs until an implementable solution is reached.

Modeling guidelines using axiomatic design

Modeling setting-independent guidelines using the axiomatic design approach involves (1) specifying the setting-independent top-level objectives or intentions of the guideline; (2) partially refining the guideline through decomposition and zigzagging. For each intention identified in step 1, a DP consisting of a flowchart, a decision criterion or an atomic task is specified. For each step of the flowchart, the intentions are specified as in step 1; and (3) minimizing interactions among steps by following the Independence Axiom. This may involve restructuring of flowcharts such as splitting an algorithm into two.

During local adaptation of the setting-independent guideline, the following procedure is followed: (1) any refinements necessary to steps of the guideline are carried out by adding more levels to the FR and DP trees; (2) changes such as addition, deletion, or modification of steps (i.e., recommendations) are made; and (3) if the changes made above have an impact on other steps in the guideline, these steps must be inspected and adjusted appropriately.

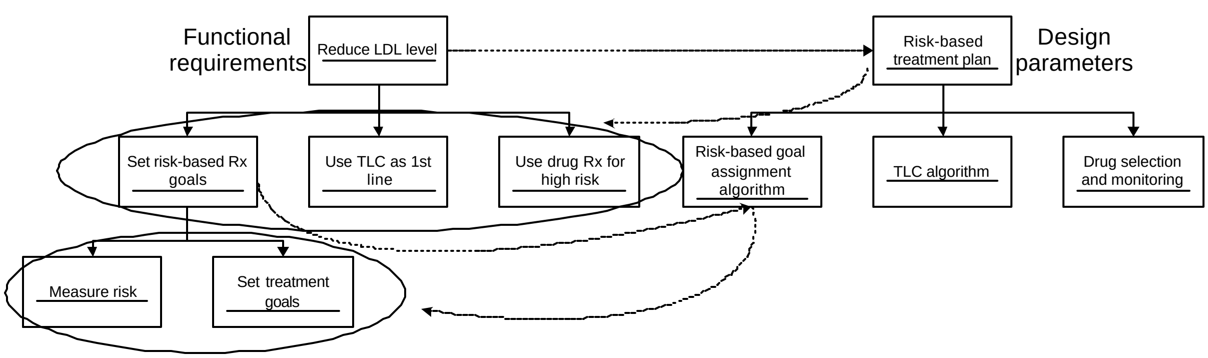

Figure 1. The FR tree (left) and the DP tree (right) for a guideline for management of elevated cholesterol illustrating the zigzagging process during guideline design. The trees show the hierarchy of the FRs and DPs respectively. The dashed arrows indicate the order of creation of FRs and DPs.

Hierarchical design facilitates local adaptation by supporting (1) selective implementation of the guideline recommendations. Those branches of the hierarchy which may not be essential or possible to implement locally can be deleted; (2) inclusion of more details for a coarsely-specified setting-independent guideline by adding more depth to a branch of a tree; and (3) modification of a recommendation by replacing a branch of the tree with a new sub-tree. Due to the top-down design, typically these changes will be made at the lower levels of the tree, thus minimizing changes to the broader intent of the setting-independent guidelines. Further, explicit specification of the FRs can assist in making local modifications that are consistent with the intent of the guideline.

The axiomatic approach is used to design a hierarchically specified guideline such that the resulting specification can be easily modified. The steps of a flowchart produced following the first axiom are uncoupled or decoupled. The steps can thus be adapted to local settings with minimal impact on other steps. The refinement process is guided by the change order process map derived from the design matrix. This map suggests the order in which the modifications must be made based on the impact of change to a step on other steps.

Mapping axiomatic design elements to GLIF

We mapped the elements of axiomatic design to elements used in specifying setting-independent guidelines in GLIF [6]. Customer needs in axiomatic design translate to health care needs as determined from research studies and expert knowledge. The didactic elements in GLIF can be used to specify these needs. The FRs and DPs are used to specify the guideline flowchart. The FRs correspond to the intentions of guideline steps. Currently, GLIF does not include a language for specifying intentions. DPs map to subguidelines, tasks, and decision criteria of steps.

Software tools

We have developed a software tool for authoring of setting-independent guidelines using the axiomatic approach. The tool provides multiple views of the guidelines (such as FR and DP trees and nested flowcharts), and the ability to specify the design matrix. The software was implemented in Java by extending libraries developed for the GLIF project. We will soon implement software for local adaptation of setting-independent guidelines.

RESULTS

We coded the NCEP's cholesterol guideline using the axiomatic framework. The document used for coding was the 40 page executive summary of the guideline since the complete text of the guideline had not been published when we started our effort. The coding was performed using Microsoft Visio™ as our software was still in development. Figure 2 illustrates the top-level flowchart of the encoded guideline showing the three high-level FRs of the guideline. Subguidelines model the implementation of these three FRs. The top three steps of the guidelines suggest implementation strategies. The LDL/Cholesterol screening is usually implemented in decision-support systems as a reminder, the elevated cholesterol treatment as a disease management program, and lifestyle advice offered through online and offline education programs.

We found the algorithmic recommendations (such as for CHD risk assessment) easier to encode using axiomatic design. The recommendations for drug treatment proved more difficult to encode. Drug recommendations were specified using tabular declarative structures in guideline document. Implementing these in flowchart structures of GLIF is very complex. These may best be implemented using a declarative ontology of the medications used for treating cholesterol, with an algorithm for selecting the drug and doses based on indications, contraindications, and other patient findings. In fact, such an algorithm may be generalizable to the treatment of other diseases such as hypertension where multiple drugs are available for treatment.

The typical types of steps which have strong interactions with each other, not surprisingly, are those that involve initiating a treatment and then following up

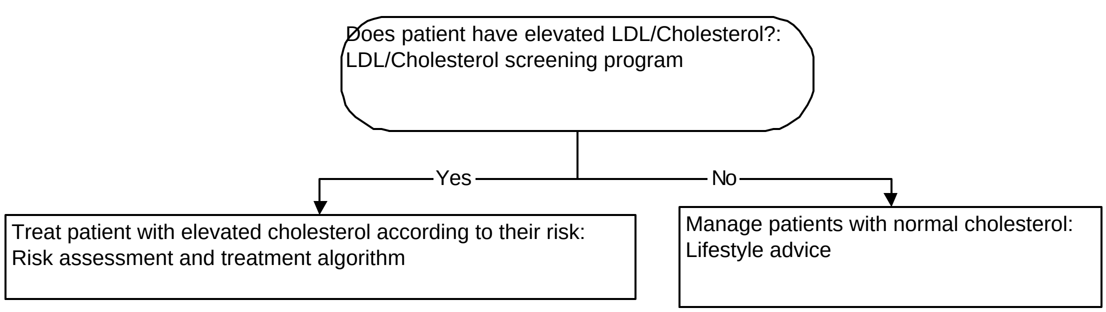

Figure 2. The top-level flowchart of the cholesterol guideline showing three steps. These steps specify the high-level objectives of the guideline. Lower level details are specified through subguidelines.

to assess its impact and adjusting treatment. In contrast, the algorithms which involve making a diagnosis and then treating the condition (e.g., metabolic syndrome) have less interaction among steps.

DISCUSSION

The method described above is a principled approach to specify guidelines that can be adapted to local settings. Existing guideline specification and dissemination methods do not explicitly support local adaptation of guidelines, a process that may enhance acceptance of guidelines.

The guidelines produced using the axiomatic approach are easy to adapt and to revise. The modular structure localizes the effect of changes to the guideline. The change order process map guides the adaptation process, identifying the impact of changes to a step on other steps.

We have investigated this approach for specifying guidelines by extending the GLIF representation. GLIF is intended as a representation for sharable guidelines. Thus, the ability to locally adapt guidelines would be essential in GLIF. However, the general axiomatic design approach can be utilized with other guideline-specification formalisms.

The axiomatic approach encourages the creation of self-documenting guidelines. The specification of needs links in the evidence from scientific literature. The functional requirements and the hierarchical design make the goal of the guideline steps explicit.

Significant effort was required upfront to produce the setting-independent cholesterol guideline. The effort is required to design DPs that maintain the independence of FRs. We believe that the time required to author guidelines using this approach will decrease with experience. Better software tools to assist with the guideline authoring process will also help reduce the time and effort. We plan to improve the design of our software through usability studies.

FUTURE WORK

The approach and the representation need to be extended in several ways. Operators need to be more completely developed for authors of setting-independent guidelines to specify local modifications permitted to guideline steps. A syntax for specifying intentions (FRs) formally needs to be included in the representation. A structured approach for marking up changes made during local adaptation and during revision of guidelines is needed so that revised setting-independent guidelines can be re-integrated easily into local environments. We would like to explore the use of the information axiom in comparing alternative algorithm designs.

We intend to conduct an evaluation study of this design approach for (1) ease of use, and (2) efficacy in producing locally adaptable guidelines. We are also designing a trial to study the impact of locally adapted guidelines on compliance by physicians.

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