Managing Revisions of Rules and Guidelines Used in Clinical Information Systems:
Exploring a Hierarchical Knowledge Representation Model

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ABSTRACT

One important purpose for creating clinical practice guidelines is to improve quality of care by reducing variations in practice. In the current healthcare environment, guidelines are being advocated as a means to disseminate research findings, standardize care, improve quality of care, and increase the cost-effectiveness of health care services. Unfortunately, compliance with text-based clinical practice guidelines is unsatisfactory. On the other hand, adherence to guideline recommendations is increased when providers receive patient-specific recommendations during the patient-provider consultation.

Guideline-based point of care decision support systems have been shown to increase provider adherence to guideline recommendations. Computer-interpretable formats for clinical practice guidelines are a prerequisite for decision support systems. The development process of a text-based clinical practice guideline is long and arduous and in most cases this process is repeated when text-based guidelines are revised to include new medical knowledge. Clearly, once text-based guideline knowledge is translated into a computer-interpretable format, the computer-interpretable guideline would also require periodic revisions to maintain the integrity of its evidence-base. Therefore, representation formalisms for encoding guideline knowledge into computer-interpretable formats should enable easy revisions of the encoded guidelines.

This thesis describes a study I conducted to demonstrate that modular knowledge representation of clinical practice guidelines facilitates easy guideline revisions. To test the hypothesis, I used a methodology for modular representation of guidelines, HieroGLIF, developed by Decision Systems Group, Brigham and Women’s Hospital, Boston Massachusetts. HieroGLIF uses Axiomatic Design theory to encode "guideline knowledge modules" into a hierarchical tree structure. Axiomatic Design theory was developed in the field of engineering as a principled approach to product design.

I applied HieroGLIF to encode parts of three outdated guidelines. I revised these designs to model updated guideline releases. Quantitative metrics assessed the adequacy of the tool to encode generic setting-independent guidelines and to facilitate revisions in encoded guidelines without complete recoding of the model. This work explores the use of HieroGLIF and Axiomatic Design theory to facilitate revisions of computer-interpretable guidelines.

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I. Introduction

1.1 Background

Clinical practice guidelines are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific medical circumstances". Clinical guidelines are designed to compile the best medical knowledge in order to provide physicians with a practical decisional aid. Therefore, guidelines usage may reduce clinician errors by minimizing variability in the clinical practice of medicine. In the current healthcare environment, guidelines are being advocated as a primary means to disseminate research findings, standardize care, improve quality of care, and increase the cost-effectiveness of health care services.2,3

Guidelines are usually issued in a textual format as long electronic narratives (i.e. static documents). Currently, the National Guideline Clearinghouse (http://www.guideline.gov) has aggregated and makes publicly available almost 1000 guidelines published by various organizations.4 Recommendations from guidelines developed at the national level are based on information from extensive literature searches combined with the clinical experience of medical experts. Because of the substantial time and effort needed to create good guidelines, there is an incentive to make nationally-developed guidelines sufficiently general to be shared among institutions with diverse patient populations, medical expertise, and institutional equipment. These all-purpose guidelines may be called "setting-independent guidelines".
One study has shown that guideline medical knowledge generally becomes outdated every six years\(^5\). Therefore as medical knowledge evolves every "setting-independent" guideline once released will likely undergo periodic reviews, revisions and re-releases to maintain the integrity of its evidence-based recommendations.

Several studies have shown that adherence to clinical practice guidelines is improved if the generic setting-independent guideline is adapted to a provider's local clinical contexts.\(^6\)\(^7\)\(^8\)\(^9\) Thus, the setting-independent guideline may also need to be revised before implementation at the institutional level to adapt it to the specific needs of local practices.

Clearly, text-based setting-independent guidelines should be amenable to revisions to include new medical knowledge and to revisions to adapt the guideline to local clinical contexts. Currently, the process of revising a text-based setting-independent clinical practice guideline is just as time and labor intensive as the process used to create the original guideline.

Disseminating clinical practice guidelines in a textual format in addition to making the revisioning of the guideline difficult has proven inefficient in other ways. The practitioner would have to read several pages of a guideline's text before finding the appropriate recommendation for a specific clinical situation. Guidelines would prove much more efficient if made available during patient-provider consultations and integrated into the institutional information system. Minimizing the time a provider spends consulting clinical practice guidelines is crucial if clinical practice guideline usage
is to improve. Guideline-based point-of-care decision support embedded within electronic medical record systems has been shown to increase provider acceptance of clinical practice guidelines. However, decision support systems require guideline knowledge to be represented in a computer-interpretable format.

Great effort is expended developing high-quality text-based guidelines. In like fashion, great effort will be expended to encode published text-based guideline knowledge into a computer-interpretable format; it is, therefore, highly desirable that the formalism used to represent computer-interpretable guidelines also facilitate easy revisions of guidelines. Several representation formalisms have been developed to facilitate the sharing of guideline knowledge in a form executable by decision support. Revision of text-based setting-independent guidelines to include new medical knowledge or to adapt the generic setting-independent guideline to local clinical contexts is poorly supported by current representation formalisms.

If a guideline knowledge representation schema is to effectively support revisions of encoded guidelines: 1) a change to one part of the encoded guideline --to update medical knowledge-- should have minimal impact on other parts; 2) when a change to one part does have wider impact, the tools should direct the user to review only those parts of the encoded guideline affected; and 3) the tools must assist with the adaptation of generic setting-independent guidelines into more practical guideline versions for use in actual practice settings.
To enable easy revisions of guidelines while maintaining guideline integrity, the Decision System Group, Brigham and Women's Hospital (BWH), Boston, MA developed a method for modular representation of guidelines. The approach, HieroGLIF, can be used to encode setting-independent guidelines released in a text-based format into a computer-interpretable format. This computer-interpretable format can enhance adherence to clinical practice guidelines by facilitating (1) better integration of encoded guidelines into clinical workflow, (2) encoding and incorporation of characteristics of local clinical contexts into encoded setting-independent guidelines, and (3) encoding and inclusion of new medical knowledge into encoded setting-independent or locally adapted guidelines.

HieroGLIF facilitates the development of "modules" in a hierarchical tree structure. HieroGLIF applies Axiomatic Design theory to guideline modeling. Axiomatic Design theory (AD) was developed in the field of mechanical engineering as a principled approach to product design. AD facilitates easy guideline revisions. Two axioms guide the AD process:

Axiom 1: Independence Axiom – the independence of "modules" or "functional requirements" must be maintained in the design.

Axiom 2: Information Axiom – the design must contain the least information.

These two axioms are at the core of what axiomatic design is. These axioms allow a designer to create feasible designs and then to discern objectively the "best" from a series of designs.
For clinical practice guideline modeling, modules can be composed of bits of guideline knowledge, tabular information, algorithms, recommendations, and etc. in a computer-interpretable format. The Independence Axiom holds that "modules" or guideline intentions or goals or "functional requirements" must be as independent of each other as possible. This means that if one alters the parameters used to satisfy one module, it is best if doing so does not affect other parameters of other modules. Thus, creating designs with independent modules significantly reduces the likelihood that a direct change to one module --to include new medical knowledge-- will impact or force changes in other modules. There is an important corollary to Axiom 2 -- the information axiom: If one has two designs, and one design has a lower level of interdependence among modules, than that design is necessarily the best design.

When construction of all-independent modules is not possible, and that is often the case (in my experience) in guideline knowledge modeling, AD matrices capture and map dependencies among modules. Thus, when encoded knowledge needs revising, design matrices direct the author to only those other modules in the model secondarily impacted by direct changes or "primary changes".

1.2 Objectives

I propose to use HieroGLIF authoring tools to translate text-based setting-independent guidelines into computer-interpretable formats. I propose to test the hypothesis that
HieroGLIF and Axiomatic Design modeling allow easy revisions of these computer-interpretable guidelines. I will look for answers to the following questions:

Will HieroGLIF and Axiomatic Design modeling theory be adequate to represent (encode) setting-independent guidelines?

What measures can be used to assess the ease of revising encoded setting-independent guidelines?

Do axiomatic design matrices effectively capture dependencies among modular components?

1.3 Significance of the Study

Adherence to clinical practice guidelines is enhanced when computer-interpretable guideline knowledge are embedded into an electronic medical record as a decisional support aid. HieroGLIF reflects an innovation and potentially an improvement over current representation languages for clinical practice guideline knowledge. Unlike other representation formalisms developed for sharing computer-interpretable guidelines, HieroGLIF supports revisions of encoded guidelines to include new medical knowledge or to adapt the guideline to local clinical contexts, and, therefore, has the potential to become a standard for representing computer-interpretable guidelines.

1.4 Scope of the Study
This study will be limited to one person (me) encoding and revising parts of three nationally developed text-based setting-independent guidelines. Evaluation criteria in the form of quantitative endpoints will be created to test for ease of "revisibility" of the original encoded designs. For each design, statistical significance testing will be used to assess the degree to which modules were independent from each other, the degree to which revisions occurred in independent versus dependent modules and the degree to which Axiomatic Design matrices were able to map dependent relationships among modules and facilitate revisions by identifying only those modules secondarily affected by changes to update the guideline.

Before applying metrics, I will consult with other physicians in the study group and with practicing physicians outside of the study group. Consultants will decide when my encoded guidelines acceptably maintain the trueness and integrity of the text-based guidelines from which they will be modeled. I will use a software tool known as SIGTool to model guidelines in HieroGLIF.

1.5 Limitations of the Study

Because this proposed research is of a non-experimental study design, results from this study will be considered exploratory and should be confirmed in a controlled trial. In addition, since my skill with using HieroGLIF is still improving and since HieroGLIF is still being developed and refined, the designs I create may not be the "best" designs possible.
The Information Axiom can be used to choose the "best" design from among other designs. This axiom will not be applied in this study since I alone will be modeling guidelines and "other techniques" to modeling guideline knowledge into modules will not be compared to my technique.

1.6 Summary

The Decision Systems Group, Brigham and Women's Hospital, Boston, MA, has developed a representation scheme known as HieroGLIF which facilitates development and implementation of computer-interpretable guidelines. Using Axiomatic Design matrices, the encoded guidelines can be revised without a complete re-coding of the guideline design.

The schema represents setting-independent guideline knowledge as independent modules in a hierarchical tree structure. This representation is implemented by extending the Guideline Interchange Format (GLIF) language, a frame-based ontology that has been previously developed for representation of guidelines.

I will apply HieroGLIF to encode parts of three outdated guidelines released during 2000-2001, and I will revise these designs to model updated releases of the guidelines. Quantitative metrics will be developed to assess the types of changes made to the encoded guidelines. From my work, I hope to glean information about the guideline revision process that may be important for ongoing and future work exploring the uses of HieroGLIF for creating and revising computer-interpretable guidelines.
II. Clinical Practice Guidelines

2.1 Definition

Clinical Practice Guidelines are “recommendations for patient management that identify one or more strategies for treatment”. Guidelines have been developed and used for all aspects of patient care: disease management, risk-assessment, utilization review and preventive care. The objective of clinical practice guidelines is to decrease physician practice variation, slow the rise of healthcare costs, monitor inappropriate care, assist clinicians to stay abreast of new clinical information, set research priorities and thereby, promote better healthcare outcomes. Evidence-based medicine focuses on the use of best available clinical evidence to reach informed decisions in patient care. The development of clinical practice guidelines uses evidence-based methods to ensure that guidelines provide valid and appropriate recommendations.

2.2 Setting-Independent Guideline Content Development

The initial step in guideline development typically involves identifying a problem where something valuable, such as lives saved, reduced morbidity, or cost savings, may be gained from arriving at ideal recommendations. According to Woolf et al, a clinical practice guideline should use clear language, define terms precisely, be logical, employ a multidisciplinary approach, and have a scheduled review process. It should include a statement about who funded, developed, and endorses it.
The guideline development process begins with identification of domain experts. An exhaustive search and review for pertinent information in the scientific literature is conducted. The development of a setting-independent guideline draws on a variety of data obtained from different sources. Informal consensus is formulated through a process in which the medical experience of participants is summarized using general decision-making criteria. Formal consensus is then obtained by medical experts who reach agreement in a structured conference and support their opinion with selected evidence-based studies that have been validated with outcomes research.\textsuperscript{30, 31}

2.3 Maintaining Evidence-Base Integrity of Setting-Independent Guideline Content

As medical knowledge evolves, the need exists for clinical practice guidelines to be periodically reviewed and subsequently revised and re-released if needed. There is no formal process or timetable for maintenance of the validity and integrity of published guideline knowledge. The AMA, most medical specialty groups, IOM, and AHRQ believe the best methodology for maintaining the validity of a guideline’s knowledge-base mandates prospective data collection and amendment of guidelines based on observed outcomes. Maintaining, reviewing, and revising clinical practice guidelines can be costly, and the actual revision process of text-based clinical practice guidelines can be just as arduous and labor intensive as the initial development process.

III. Adherence to Clinical Practice guidelines

3.1 Factors Influencing Guideline Acceptance
Studies have found that compliance with guidelines in actual clinical practice has not been satisfactory.\textsuperscript{32} 33 34 For a guideline to be successfully used, the provider must have knowledge of the guideline, must accept the guideline, and the provider's environment must not prevent the use of the guideline. Thus, factors that affect adherence to guideline can be categorized along the following spectrum\textsuperscript{35}:

1. Knowledge of guidelines
   a. Lack of awareness of guidelines
   b. Lack of familiarity with guidelines
2. Provider attitude towards guidelines
   a. Lack of agreement with specific guidelines
   b. Lack of agreement with guidelines in general
   c. Lack of expectancy of desired outcomes
   d. Lack of self-efficacy, i.e., the belief that one cannot render the recommended care because of lack of skills, experience, or training.
   e. Inertia of previous practice
3. Factors affecting practitioner behavior
   a. Patient-related factors such as the inability to reconcile patient preferences with recommendations
   b. Guideline-related factors such as the presence of contradictory guidelines, convenience of use, and ambiguities in decision criteria and recommendations
   c. Environmental factors such as lack of resources, lack of time, reimbursement issues, and perceived malpractice liability
d. Workflow-related issues such as incorporation of guidelines into clinical activities
and non-availability of a reminder system

3.2 Rule-Based Approaches for Increasing Guideline Adherence

Most working implementations of computer-based clinical practice guidelines have been
relatively simple "if–then" rules triggered off electronic medical record (EMR) data. The
resultant messages can be synchronous and interactive, such as alerts linked to computer-
based physician charting or order entry, or asynchronous, such as alphanumerical pages,
phone calls, electronic or paper mail, or printed documents. The messages are usually reminders or recommendations, but they may also be performance reviews or feedback. They may be directed at nurses, pharmacists, clerical staff, or patients in addition to physicians. In general, the beneficial effect of these systems has been on the order of 10–20% absolute improvement in process measures, and most studies have not evaluated patient outcomes.

At BWH, we have an extensive history of implementing single-step rule-based guidelines
and reminders. I will describe the rule-based outpatient reminder system now functioning at BWH at length in the next Section.

IV. Knowledge Bases used for Clinical Decision-Support at BWH

4.1 BWH Guideline-Based Decision Support Systems: General Overview

An inventory of knowledge bases used at the BWH was conducted to assess the role of knowledge in BWH clinical information system, in terms of current processes that use it,
how it is created, maintained, updated, and executed. BWH is a 700-bed tertiary care academic medical center in Boston.

The BWH clinical information system environment has several features that can support the implementation of computer-based guidelines. Primary care physicians at BWH use an EMR that, in addition to coded laboratory and visit data, contains physician-maintained allergy records, medications prescribed, and coded problem lists. BWH also has an inpatient physician order entry application with built-in drug-dosing calculators and synchronous, interactive alerts and reminders about drug-allergy and drug-drug interactions. In addition, an event monitor, coupled with an active provider coverage database, automatically can notify clinicians asynchronously based on data added to the clinical data repository.

Finally, BWH’s ambulatory reminders application can compute short messages using if-then rules and print them on the bottom of encounter sheets produced for every scheduled outpatient visit. (Recently, BWH has completely replaced printing paper reminders with showing onscreen reminders.)

4.2 BWH Guideline-Based Decision Support Systems: Outpatient Reminders Overview

I participated in an inventory of the BWH outpatient knowledge-bases used for decision support. In the BWH outpatient clinics, patient-specific reminders are generated based on knowledge expressed in rules and using data in the BWH ambulatory electronic medical record. The outpatient reminder application identifies:
• patients due for health maintenance screenings,

• patients due for laboratory procedures,

• patients receiving more expensive medications when cheaper medicines of the same class are available on formulary, and

• patients who might benefit from the initiation of well established therapeutic interventions (i.e., patient has coronary artery disease and is not on aspirin).

Providers are alerted to upcoming annual health maintenance visits (i.e., diabetics due for yearly ophthalmology exams) beginning two months before the actual one year anniversary date. Almost due reminders for every three year health maintenance visits (i.e., women due for routine Pap smear) begin at visits six months before the overdue notice, and almost due reminders for every six month health maintenance visits (i.e., diabetics monitored with HbA1C laboratory work) begin a month before the overdue notice.

4.2.1 Description of BWH Outpatient Knowledge-Base

The knowledge-base consists of a set of 73 rules. Twenty-five outpatient reminder rules are presently active in the system. The remainder represents discontinued and old versions of rules. A synopsis of four of the rule categories with examples are shown below in Table 1. Titles of the twenty-five active rules are shown in Table 2.

<table>
<thead>
<tr>
<th>Rule Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Maintenance</td>
<td>Remind for cholesterol every 5 years; pneumovax once for patients over 65; mammogram and pap smears annually in eligible women</td>
</tr>
<tr>
<td>Expensive medication reminders</td>
<td>Inform if there is a less expensive H2 blocker, HMG CoA reductase inhibitor, ACE inhibitor,</td>
</tr>
<tr>
<td>Rule title</td>
<td>Rule category</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Diabetic overdue for HbA1C</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diabetic almost due for HbA1C</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diabetic overdue for ophtho exam</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diabetic almost due for ophtho exam</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diabetic overdue for total cholesterol</td>
<td>Diabetes</td>
</tr>
<tr>
<td>Diabetic almost due for total cholesterol</td>
<td>Diabetes</td>
</tr>
<tr>
<td>CAD and no beta blocker</td>
<td>Drug disease</td>
</tr>
<tr>
<td>CAD and no ASA</td>
<td>Drug disease</td>
</tr>
<tr>
<td>CAD and LDL&gt;130 and no statin</td>
<td>Drug disease</td>
</tr>
<tr>
<td>DM+HTN and no ACEI</td>
<td>Drug disease</td>
</tr>
<tr>
<td>DM and LDL &gt; 130 and no statin</td>
<td>Drug Disease</td>
</tr>
<tr>
<td>Patient on Troglitazone</td>
<td>Drug Disease</td>
</tr>
<tr>
<td>CAD overdue for total cholesterol</td>
<td>Drug Disease</td>
</tr>
<tr>
<td>CAD almost due for total cholesterol</td>
<td>Drug Disease</td>
</tr>
<tr>
<td>Non-diabetic, non CAD, almost due for total cholesterol</td>
<td>Health maintenance</td>
</tr>
<tr>
<td>Needs Influenza Vaccination 18-64</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Non-diabetic, non CAD, overdue for total cholesterol</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Overdue for mammography</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Needs Influenza Vaccination Older Than 65</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Needs pneumovax</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Almost due for pap smear</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Overdue for pap smear</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Almost due for mammography</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Patient on statin and frequency is QAM</td>
<td>Med</td>
</tr>
</tbody>
</table>

Table 2. The twenty-five rules currently active in the LMR reminders system.
4.2.2 Outpatient Knowledge-Base Development and Maintenance Process

The initial rules were submitted by a BWH General Medicine faculty member, and then critiqued and refined by a panel of experts including: sub-specialist consultants, a medical informatics trained knowledge engineer, the Ambulatory Care Improvement Team (ACIT) at BWH, the Information Systems (IS) Department at Partner’s HealthCare System, a programmer, and a person in charge of evidence-based consensus building. To maintain the quality of the clinical decision support application, rules are evaluated periodically and are changed or discontinued as necessary by the above team.

A database developed using Microsoft Access has been used as a tool for documenting rules, keeping track of the status and versions of rules, and communication among clinical experts, knowledge engineers, and programmers. The database stores the rule in a textual format though each rule is segmented into its components using database fields. The rule is implemented in the LMR using procedural MUMPS code.

Figure 1. Components of a knowledge base engineering process
4.2.3 Use and Impact of BWH Outpatient Reminder Decision Support System

In a one-year study, involving about 200 physicians from BWH, approximately 30,000 patients, and a knowledge base consisting of 16 reminder rules, more than 55000 reminders were generated. The reminders in this study were printed on the patient’s encounter sheet. There was significant impact on physicians’ actions of reminders for health maintenance, diabetes management, and expensive medications. The coronary artery disease related recommendations were less accepted by the physicians.

Reasons for varied compliance by rule needs further study. Compliance may be related to the rule logic or to workflow circumstances in the clinic which inhibit carrying out the reminder. Once the rule’s suggestion is carried out by the physician, data to determine the appropriateness of the provider’s subsequent interventions is also lacking. More specific
rule logic, methodologies to insure suitability of secondary interventions once reminders are accomplished, and more targeted evaluations of the effectiveness of the BWH outpatient reminder system may improve the use and impact of the knowledge base.

The LMR system has only recently been rolled-out. Data on reminders provided using the workstation screen (rather than the paper chart) are still not available.

4.3 Summary

Brigham and Women's Hospital has a robust platform for implementation of rule-based outpatient decision support. Currently, work is ongoing to add automated algorithms for treatment of chronic disease.\textsuperscript{62} The next sections describe representation of such algorithms in computer-interpretable formats.

V. Computer-interpretable Clinical Practice Guidelines

5.1 Development of Computer-Interpretable Clinical Practice Guidelines

As noted earlier, access to a digital but still narrative-text version of a printed document is now widely available to an entire practice or institution via an intranet or more globally on the Internet. However, simply displaying guidelines on a computer monitor does not make them computer-interpretable and will not increase guideline adherence.\textsuperscript{63}

These major steps describe the typical current practice of development to actual implementation and integration of clinical practice guidelines into clinical information systems. These are: (1) developing a setting-independent clinical practice guideline in
text form, (2) encoding the knowledge in the text-based setting-independent guideline into computer-interpretable format, (3) integrating the encoded rules or algorithms into the clinical system, and (4) examining the impact of the decision support on processes and outcomes with subsequent refinement as necessary. It is important to note that while the current practice involves creating a guideline in a narrative text format and later encoding it into a structured format, one can imagine that in the future, guidelines will be created directly in a structured format.

5.2 Sharable Computer-Interpretable Format

The work done at BWH and elsewhere has shown that computer-generated, patient-specific reminders can positively influence practice. As computers become standard tools of clinical practice and as electronic medical records (EMRs) become more prevalent and robust, computer-based rules, algorithms and guidelines increasingly can be integrated into routine workflow. In order for the computer to make use of the patient’s clinical data, follow its own algorithm internally, and present only the information relevant to the current state to the provider, the language of the text-based guidelines must be translated into a computer-interpretable format. However, the process of translating guideline statements into equivalent ones that use available coded data is arduous and also carries the risk of distorting the spirit and intent of the original guideline.

There is a clear interest, then, in developing a standardized consensus guideline representation language. Several factors should be considered in creating a format for
sharable computer-interpretive guidelines: (1) the scope of guidelines and their intended applications; (2) the method of delivery of the recommendations; and (3) the environment, consisting of the practice setting and the information system in which the guidelines will be applied. Several investigators have proposed solutions that improve the sharability of computer-interpretive guidelines and, more generally, of medical knowledge.\textsuperscript{13}

VI. Selected Guideline Representation Models

6.1 Models and Tools for Extracting and Organizing Guideline Knowledge

To address the issue of sharable computer-interpretive guidelines, several models and tools for extracting and organizing knowledge, representation models for publishing and sharing guidelines, and computational models for implementing guidelines have been developed.\textsuperscript{46} Descriptions of three related efforts in guideline representation follow:

Asbru\textsuperscript{18} is an intention-based language for representing skeletal plans. 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. However, the Asbru language does not support operations that may be applied to plan components in order to revise guideline for adaptation to different clinical contexts.

Fridsma et al have developed a program known as CAMINO for adapting “generic” guidelines for local use.\textsuperscript{68} The CAMINO program provides a series of operators (e.g.,
addition, deletion, and substitution) that are applied to a guideline step to adapt it for local use. The program maintains the links between the corresponding steps of the generic guideline and the locally adapted guideline. However, the authors have not described a formal method to create generic guidelines that are easily adaptable. Further, this approach does not provide mechanisms that enforce maintenance of the integrity of the generic guideline.

Miller et al have described an approach for successfully maintaining multiple versions of a childhood immunization guideline. They utilize an approach that disassociates decision rules from parameters of the rules (e.g., the parameter age at which the DPT vaccine is due). The authors recognize that their technique may have narrow applicability, i.e., primarily for use in childhood immunization guidelines.

6.2 HieroGLIF

The Guideline Interchange Format (GLIF) is a language for structured algorithmic representation of guidelines. HieroGLIF is an extension of GLIF that supports the representation of hierarchical modular guidelines. HieroGLIF extends the GLIF ontology by explicitly supporting representation of guideline intentions or “functional requirements”.

A software tool known as SIGTool was developed to support authoring of guidelines in HieroGLIF. The software tool was implemented in Java by extending libraries developed for the GLIF project. During guideline creation the tool facilitates the creation of the
hierarchical structure and allows the user to specify the design matrix. In the guideline modification mode (used during revision or local adaptation), when a guideline module is changed, the tool uses the principles from axiomatic design (i.e., the dependency information contained in the design matrix) to identify other steps affected by the change.

6.3 Axiomatic Design

Axiomatic Design (AD) theory was developed in the field of mechanical engineering as a principled approach to product design. AD methodology allows designers to be more creative and minimizes the iterative trial-and-error process traditionally used in design. The use of two axioms results in product designs that are flexible and easily modified. The Independence Axiom states that the independence of intentions or functional requirements should be maintained throughout the design. The Information Axiom states that the best design contains the least information. This latter axiom is important in comparing designs and is beyond the scope of this paper.

AD involves the interaction between “what we want to achieve” and “how we achieve it” or “how to satisfy the needs.” In AD, four domains create demarcation lines between various design activities: customer, functional, physical, and process. The functional and physical domains are the most relevant to guideline modeling and will be our focus.

6.3.1 Axiomatic Design Applied to Guideline Modeling

AD guideline modeling constructs two design trees: a functional requirement (FR) tree and a design parameter (DP) tree. The designer may begin by specifying an overall
guideline intention or FR1 and placing it at the highest level of the FR tree. (Actually
guideline modeling may begin with one or many FRs at the topmost level). At the top of
the DP tree is placed an action or DP1 that is used to carry out FR1. The second level of
FRs is built by the decomposition of FR1 based on the constraint of DP1. In our example,
DP1 decomposes FR1 into the sibling group: FR11, FR12, and FR13. Ideally, a sibling
group should be composed of mutually exclusive and exhaustive components of its
parent. Second-level DPs -- DP11, DP12, and DP13 -- are specified to carry out the
intention of each of the second-level FRs. Continuing with our example, DP11
decomposes FR11 into the mutually independent FRs, FR111 and FR112. Each of the
other second-level DPs will decompose its own FR and in this way contribute to the
building of the third level of the FR tree, and so forth.

To summarize, guideline modeling creates an FR and a DP tree. Designing begins by
specifying one FR or a sibling group of more than one FR at level one of the FR tree. A
DP is chosen for each FR. DPs are used to decompose their own FRs. FR decomposition
should optimally result in independent FRs in a sibling group or a single child at the next
lower-level. Leaf FRs are not further decomposed because their corresponding DPs are
concrete and detailed enough to be deployed. This building method is called zigzagging"
Figure 3: “Zigzagging” process of building Axiomatic Design trees

6.3.2 The Design Matrix

The relationship or interaction among FRs and DPs within a sibling group is specified by the design equation: \{FRs\}=[A] \{DPs\}. [A] is the design matrix. Thus, for three FRs:

\[
\begin{bmatrix}
FR \ 1 \\
FR \ 2 \\
FR \ 3 \\
\end{bmatrix} = \begin{bmatrix}
A_{11} & A_{12} & A_{13} \\
A_{21} & A_{22} & A_{23} \\
A_{31} & A_{32} & A_{33}
\end{bmatrix} \begin{bmatrix}
DP \ 1 \\
DP \ 2 \\
DP \ 3 \\
\end{bmatrix}
\]

Linear algebra equations for three FRs can be written:

FR1 = A11 DP1 + A12 DP2 + A13 DP3
FR2 = A21 DP1 + A22 DP2 + A23 DP3
FR3 = A31 DP1 + A32 DP2 + A33 DP3
We see that a functional requirement can be expressed as a linear combination of each of the design parameters in its sibling group. This linear combination is called a module. Submodules specifically refer to modules that are not at the highest level of the guideline. In designing guidelines, the numerals 1 and 0 are the most appropriate entries for DPs within the design matrix because it is important only to know that a DP either interacts with an FR or not. Three types of design matrices are important in guideline modeling:

1. A diagonal matrix represents an uncoupled design, in which each FR is independently satisfied by only its own DP.

\[
\begin{align*}
\{ FR 1 \} &= \begin{bmatrix} 1 & 0 & 0 \end{bmatrix} \{ DP 1 \} \\
\{ FR 2 \} &= \begin{bmatrix} 0 & 1 & 0 \end{bmatrix} \{ DP 2 \} \\
\{ FR 3 \} &= \begin{bmatrix} 0 & 0 & 1 \end{bmatrix} \{ DP 3 \}
\end{align*}
\]

This is the optimal design because altering one functional requirement only requires the altering of its own design parameter. Thus, the FRs fully satisfy the independence axiom.

2. A triangular matrix represents a decoupled design. The matrix here is an off-diagonal lower triangular matrix; the elements of the lower triangle are A21=A31=A32=1; an upper triangular matrix would have the same effect. Since decoupled designs with upper triangular matrices can be converted to decoupled designs with lower triangular matrices, we used the lower triangular matrix as our standard. In this sibling group, FR3 is dependent on DP3, DP2 and DP1; FR2 is dependent on DP2 and DP1, and FR1 is
dependent only on DP1. This sibling group of three FRs has three out of a possible three
off-diagonal lower triangle dependencies or dependencies.

\[
\begin{bmatrix}
FR 1 \\
FR 2 \\
FR 3 \\
\end{bmatrix} = 
\begin{bmatrix}
1 & 0 & 0 \\
1 & 1 & 0 \\
1 & 1 & 1 \\
\end{bmatrix} \begin{bmatrix}
DP 1 \\
DP 2 \\
DP 3 \\
\end{bmatrix}
\]

In this case, we can satisfy the functional requirements by specifying the DPs in a
particular order. For example, let’s define high-level FRs for hormone replacement
therapy guidelines for a perimenopausal woman complaining of hot flushes and
decreased libido:

FR1: Obtain clinical assessment

FR2: Hormone replacement therapy?

We would first specify DP1: History, physical, etc to satisfy FR1 since it alone
determines FR1. The FR1 module is then completely decomposed by DP1 to leaf
submodules before DP2 can be specified. Then, based on the information derived from
the clinical assessment module, we can specify DP2, which might be DP2: Collaborative
decision making and management with patient to satisfy FR2. The 2x2 design matrix for
this example would have one out of a possible one dependency because FR2 is dependent
on DP2 and DP1.
When an uncoupled design is impossible, it becomes incumbent upon the designer to construct a decoupled design. This process involves creating a design matrix and then ordering the FRs in such a way that the matrix becomes triangular.

3. Any other kind of matrix represents a coupled design.

\[
\begin{align*}
FR 1 & : [1 \ 0 \ 1] \\
FR 2 & : [1 \ 1 \ 0] \\
FR 3 & : [1 \ 1 \ 1]
\end{align*}
\begin{align*}
DP 1 & : [1] \\
DP 2 & : [1] \\
DP 3 & : [1]
\end{align*}
\]

In the above coupled design, where A21=A31=A32=A13=1, the procedures used in the decoupled design for specifying DPs and FRs are not possible. There is no one algorithm that can be used to satisfy any DP without reversing and changing the other DPs. None of the encodings that were produced in this study resulted in a coupled design.

VII. Study Design and Results

7.1 Study Objective

My study objective was to demonstrate that modular knowledge representation of clinical practice guidelines using HieroGLIF and Axiomatic Design modeling methodology facilitates easy guideline revisions. Using HieroGLIF and axiomatic design authoring tools, the text-based guidelines were translated into an encoded model which was revised to build a new encoded setting-independent guideline updated with the new medical knowledge. These endpoints (endpoints described in later section) were used to test my hypothesis on each of three setting-independent clinical practice guidelines:
1. Most FRs will maintain the independence axiom.

2. Most non-independent FRs will occur at higher-levels of the design tree.

3. Revisions to encoded guidelines are more likely to occur at the lower more detailed levels of the design tree.

7.2 Study Guidelines Encoded and then Revised to Include New Medical Knowledge

With SIGTool, three text-based guidelines were encoded and revised in HieroGLIF:

1. Lipid Screening in Adults, developed by the Institute for Clinical Systems Improvement (ICSI), Bloomington, MN, released Jan. 2000. Revised and re-released Dec. 2002,


These guidelines were chosen because they each addressed clinically important problems. The guidelines were modeled and revised by one informatics fellow who is board certified in both internal medicine and preventive medicine and public health. The author is involved in the development of HieroGLIF and is experienced in using SIGTool. The author consulted with other physicians in the study group and with a practicing internist-
endocrinologist outside of the study group. Consultants agreed that the encoded
guidelines maintained the integrity of the recommendations in the text-based guidelines.

7.2.1 Defining Types of Revisions to Encoded Guideline Models

We gave the name "Primary Change" to any change made to an encoded guideline as a
direct consequence of a revision in the text-based guideline. Every revision to an encoded
guideline involved adding/deleting module(s), changing the information detailed in a
module, or a combination of these revisions.

Primary Insertion (Deletion): A new module is added (deleted) because of changes
specified in the most recently published guideline.

Inspection: A module (let us call it FRx) must be inspected for a possible change when it
is dependent on at least one other module’s design parameter and the design parameter(s)
upon which FRx is dependent underwent a change. Also, changing FRx requires
inspection of FRx’s children.

Secondary Deletion: A module is removed from the guideline because of a change or
deletion elsewhere in the design. For example, a sibling group was deleted if its parent
was deleted.
Secondary Change: A module is changed because a change elsewhere indicated that the author inspect the module -- and upon inspection, it is determined that changes are required.

7.2.2 Defining Design Dependencies in Encoded Guideline Models

For decoupled guideline designs, the numerals 1 and 0 are the most appropriate entries for DPs within the design matrix because it is important to know only that a DP either interacts with an FR or does not. For any sibling group, we defined off-diagonal dependencies as the number of numeral 1s in the lower triangle of the design matrix. To compute the total number of possible dependencies per sibling group of n FRs with an nxn design matrix, we used this equation:

Possible dependencies per sibling group of n FRs = n(n-1)/2

7.3 Study Endpoints

Our study objective, that modular knowledge representation of guidelines with AD facilitates easy guideline revision, was tested using these three endpoints on each design’s FR tree:

1. Most functional requirements will maintain the independence axiom. This was determined by finding the ratio of actual lower triangular dependencies per total number of possible lower triangular dependencies.
2. Most non-independent functional requirements will occur at higher-levels of the design tree. This was determined by comparing the number of dependencies in the higher-level versus (vs.) the lower-level of the design tree.

3. Revisions to encoded guidelines are more likely to occur at the lower, more detailed levels of the design tree. This was determined by comparing the actual number of changes and inspections in the higher vs. the lower level of the design tree.

For an even number of levels in an FR tree, we considered higher-level dependencies to be those in the top half of the tree; the rest of the tree was the lower-level. For an FR tree with an odd number of levels, the higher-level included the extra level. For dependency counts only, a single top-level FR was not counted as a level.

7.3.1 Statistical Analyses

We calculated relative risk (RR) at a 95% confidence interval (CI) using Fisher's exact test one-tailed p-value. EpiInfo version 6 Statcalc was used for all calculations.\textsuperscript{74}

7.4 Study Results

7.4.1 Lipid Screening in Adults Guideline Modeling and Revision Results

The FR design tree of the original LSA guideline had 45 modules in a six-level hierarchy; the design had a single top-level FR. Most modules were independent -- 77%. The design matrices contained 15 dependencies of 64 total possible dependencies. All 15 of these dependencies were in the higher-level of the hierarchy (15 higher-level dependencies of
23 possible higher-level dependencies). There were no dependencies in the lower-level (0 lower-level dependencies of 41 possible lower-level dependencies). We calculated the relative risk for higher-level versus lower-level dependencies to be [RR 2.54, CI 1.80, 3.57, p<.003]. This represents significantly more higher-level than lower-level dependencies.

The revision of the LSA guideline included the elimination of initial non-fasting screening blood tests for both total and HDL cholesterol. Also removed were risk factor assessments that were part of the decision criteria to perform fasting cholesterol fractionation. LDL, HDL, and triglyceride threshold values, all used for decision criteria for lipid management referral, were removed and replaced with only elevated total cholesterol. These revisions required:

1. A primary deletion of the “initial blood test” module at level 4 with secondary deletions of both its children (assessment of HDL and total cholesterol results)
2. A primary deletion of the “assess risk factors” module with secondary deletions of all its children (the specific risk factors) at levels 4 and 5, respectively
3. Six primary changes to threshold values at level 6
4. One primary addition at level 5 and two at level 6. These were needed to include “results of total cholesterol blood test” as a criterion for lipid management.

The design matrices identified the need for seven inspections (four at level 4 and three at level 5); one of these inspections led to twelve module deletions (modules that
categorized patients after initial blood testing and modules that assessed the number of risk factors).

Table 3. Frequency of primary and secondary changes made in the LSA guideline according to the level of the design tree

<table>
<thead>
<tr>
<th>Level (numbered from root)</th>
<th>1-3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Add</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Primary Delete</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Primary Change</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Secondary Delete</td>
<td>0</td>
<td>3</td>
<td>11</td>
<td>6</td>
<td>20</td>
</tr>
</tbody>
</table>

A total of 39 changes and inspections were performed to revise the guideline -- 11 primary and 21 secondary changes and 7 inspections. All 39 changes were made among the 40 modules of the lower-level (Table 1) of the hierarchy. There were significantly
more changes made to lower-level modules than higher-level modules [RR 1.13, 95% CI 1.01 - 1.25, p<.04].

7.4.2 Hormone Replacement Therapy Guideline Modeling and Revision Results

The design tree of the original HRT guideline had 32 modules on five levels. Most modules were independent -- 58%. There were significantly more higher-level dependencies: 81% (13 of 16 possible higher-level dependencies) in the top 3 levels versus 10% (2 of 20) in the lower-level [Risk Ratio 4.93, 95% CI 1.24 - 19.63, p<.02].

This guideline was revised to remove cardiovascular indications for initiation of HRT therapy and to recommend discontinuation of HRT for women on HRT solely for cardiovascular indications. The revised guideline also included the possible addition of androgen therapy for women with decreased libido not improved on estrogen/progesterone therapy if both the patient and provider agreed this was appropriate.

A primary deletion of the cardiovascular indications module was performed with no ensuing secondary changes. The patient education module underwent a primary change without secondary changes to include the new medical knowledge responsible for the guideline revisions. Under the module entitled “management of women on HRT”, the “drug adjustment” sub-module underwent primary changes for two distinct reasons: (1) An addition of a sub-module to discontinue HRT for women on HRT for cardiovascular reasons alone and (2) Changing the drug adjustment algorithm to include consideration of
androgen therapy for reasons previously noted. Four other inspections were required due to these changes, but no secondary changes were necessary. In total, to revise this guideline, eight changes including inspections were made all at higher-levels (six at level 5 and two at level 4) and all occurring on leaf nodes. There were three primary changes, no secondary changes, and five inspections. Statistical analyses were not performed because of a small sample size.

7.4.3 Initiation of Antiretroviral Therapy Guideline Modeling and Revision Results

The design tree of the original HIVRX guideline (Figure 4) had 16 modules on four levels. Most modules were independent -- 77%. The design matrices identified dependencies on level 1 of the guideline structure only. There were 3 dependencies from a total of 13 possible dependencies. This guideline was revised to replace threshold values obtained from the bDNA assay of HIV RNA v. 2.0 with threshold values for the newer v. 3.0 of the assay. Only primary changes to the detail of the two children of the bDNA module were required. No inspections were indicated. Statistical analyses were not possible due to a very small sample size.
7.5 Summary of Results: Ease of Guideline Revision Using HieroGLIF Approach

The results of this study suggest that modular knowledge representation of guidelines using AD facilitates easy guideline revision. Although each of our designs was a decoupled design, most modules maintained the Independence Axiom. A change to an independent FR only required changing its DP and inspecting its children; thus, revisions to one part of our encoded guidelines had minimal impact on more distant parts.

In our FR trees, most non-independent modules occurred at upper-levels. Upper-level modules contained general intentions and less directed actions and required decomposition to more concrete and detailed lower-level components before actions could actually be deployed. Our designs had significantly fewer dependencies at the lower levels and revisions to our guidelines occurred significantly more often at these
more detailed lower-levels of the design tree. Although decoupled designs are less than optimal designs, AD was still able to facilitate easy revision of our guidelines because the designer was able to minimize dependencies at lower tree levels where changes were most likely to occur and thus minimize the impact of primary changes on other modules. Using SIGTool, the author created design matrices that supported the revision process.

VIII. Discussion of Results and Conclusions

8.1 Hypothesis and Overall Results

I used HieroGlif and axiomatic design authoring tools to translate text-based setting-independent guidelines released at the national level into computer-interpretable formats. I tested the hypothesis that HieroGLIF and axiomatic design modeling allow easy modifications of computer-interpretable guidelines when revising encoded guidelines to include updated medical knowledge:

I earlier proposed the questions:

1. Will HieroGLIF and Axiomatic Design modeling theory be adequate to represent (encode) setting-independent guidelines?

2. What measures can be used to assess the ease of revising encoded setting-independent guidelines?

3. Do axiomatic design matrices effectively capture dependencies among modular components?
My answers:

1. HieroGLIF adequately enabled encoding of segments of three guidelines. However, dependent relationships which occurred in only a minority of modules may be minimized with more experience in diverse modeling techniques. Also, the process of translating guideline knowledge into a computer-interpretable format was very time intensive.

2. For each design, statistical significance testing was used to assess the degree to which modules were independent from each other, and the degree to which revisions occurred in independent versus dependent modules. Qualitative measures described the types of changes made to the original encoded guidelines. (See sections 7.2.1 and 7.2.2 for specific measures used.)

3. For the three cases I used, Axiomatic Design matrices assisted in guideline revision by capturing dependencies among modules. Expert consultants verified that my modeling of text-based setting-independent guidelines followed by the revision of the encoded guideline to update it resulted in "correct" or "accurate" models of the actual revised text-based guideline knowledge. So in this way, because the resultant revised models were a true depiction of the actual revised text-based guideline knowledge, design matrices appropriately enabled the author to inspect and/or change only those modules in the original design affected by a primary change in the original design. Clearly, further work is required to say
that design matrices in every instance will identify only other modules affected by primary changes.

8.2 Importance and Contributions of Study

The goal of enhancing quality of health care is a primary motivation for development of clinical guidelines. Yet there is no evidence that the large investment in guideline development has achieved this goal to date.

Many problems with guideline adherence can be addressed by computer-based implementation of guidelines. A huge corpus of guidelines has been developed but only a few of these have been encoded in computer-based format other than for simple dissemination as CD-ROM or Web documents. As a result, most guidelines have had little impact on practice at the point of care and are, rather, simply consulted occasionally as references. The effort required to create medically valid, evidence-based, robust guidelines is enormous, as attested to by the experience of various study groups and professional organizations that have undertaken the task. Considerable further effort is required to encode guidelines in computer-based form using any of the existing guideline-authoring environments. Still additional effort is required to maintain the guidelines over time as medical knowledge evolves, or to adapt the guidelines to local constraints, preferences, and idiosyncrasies, and to integrate guidelines into actual applications that practitioners will find useful and desirable.
To deliver on the promise of guidelines to increase quality healthcare, computer-based representations of guideline knowledge are required. Sharability of computer-based clinical practice guidelines is also essential if the best guidelines are to be able to be used soon in multiple experimental and test-bed systems, and eventually routinely throughout the healthcare environment.\(^5\) A common format for representation and sharing of guidelines must have the ability to operate in diverse settings for a variety of applications.

The work of the Decision Systems Group at Brigham on development of HieroGLIF has been motivated by the desire to create a sharable format for guidelines. HieroGLIF is an innovation because it facilitates easy revisions of encoded guidelines.

My study represents early work done to gain experience with HieroGLIF and guideline modeling and revising using Axiomatic Design theory. AD is a powerful tool that models guideline knowledge into independent modules. Independent "guideline knowledge modules" can be revised independently of other modules much like modularization of computer programs has aided software development.

### 8.3 Future Directions

At Decision Systems Group work is ongoing using HieroGLIF to encode conventional national guidelines in the setting-independent format into models adapted to local clinical settings.
A randomized controlled trial will be conducted to test the potential impact of the local adaptation methodology on adherence to guidelines. For each recommendation, primary care physicians (PCP) will respond to a questionnaire that will measure whether PCPs will be more likely to follow the generic recommendations or the adapted recommendations. Data will also be analyzed to look for attributes of recommendations that are important for their acceptance by PCPs.
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