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Toward Improved Guideline Quality: Using the COGS Statement with GEM

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Abstract

The Conference on Guideline Standardization (COGS) was convened to create a standardized documentation checklist for clinical practice guidelines in an effort to promote guideline quality and facilitate implementation. The statement was created by a multidisciplinary panel using a rigorous consensus development methodology. The Guideline Elements Model (GEM) provides a standardized approach to representing guideline documents using XML. In this work, we demonstrate the sufficiency of GEM for describing COGS components. Using the mapping between COGS and GEM elements we built an XSLT application to examine a guideline's adherence (or non-adherence) to the COGS checklist. Once a guideline has been marked up according to the GEM hierarchy, its knowledge content can be reused in multiple ways.

Keywords:

clinical practice guidelines, implementation, standards, Guideline Elements Model

Introduction

In an ideal world, clinical practice guidelines would embody a clear statement of the most appropriate practice according to best scientific evidence. The validity of each proposed policy would be clear. Implementation of guideline recommendations would be straightforward and the intended audience of clinicians would gratefully integrate the recommendations into their daily practice. As a consequence, measurably improved health benefits would be demonstrated. Worldwide, enormous resources have been dedicated toward achieving these goals by government agencies, specialty societies, disease-related institutions, managed care organizations, and individual practices.

Yet, guideline quality, implementability, and effectiveness have all been called into question. Following an evaluation of 279 guidelines, Shaneyfelt and colleagues found that guidelines published in the peer-reviewed medical literature do not adhere well to established methodological standards [1]. They concluded that "published guidelines are falling considerably short of standards and that much more attention is needed by those involved in both guideline creation and in guideline review and publication". Likewise, Cluzeau and colleagues—working in the United Kingdom—found that there was considerable variation in the 60 guidelines they appraised with most failing to fulfill quality criteria [2]. Lack of confidence in the validity of guideline recommendations may ultimately limit end-user adherence [3].

Encoding of guideline recommendations into formats that can be processed by computer has been marked by considerable inconsistency [5, 6]. The result may be a serious misinterpretation of guideline recommendations by those charged with implementation.

Often guideline documents are written in ways that interfere with their own implementation. In implementing national guidelines for management of heart failure in a computer-based format, Tierney and colleagues were challenged by the fact that the guideline lacked explicit definitions, focused more on errors of omission than on errors of commission and did not account for co-morbid conditions, concurrent treatments, or the timing of interventions and follow-up [4]. The authors recommended that all guideline recommendations should be written in a simple if-then-else format with all of the parameters strictly defined using routinely collected clinical data. Yet this recommendation, which appeared prominently in the informatics literature, has been ignored by guideline developers who are, by and large, unfamiliar with implementation issues.

The Conference on Guideline Standardization (COGS) was convened to create a standardized reporting system for clinical practice guidelines intended "to promote guideline quality and facilitate implementation" [7]. The COGS statement provides a checklist of necessary guideline content intended to be used prospectively by guideline authors to enhance the validity and usability of their work products.

In this work we briefly describe the development of the COGS statement, discuss elements considered to be necessary components for implementation, demonstrate that the COGS checklist maps to the GEM guideline document model, and describe an XSLT application that can assist those concerned with guideline quality and implementability to assess conformance with COGS.

Development of the COGS Statement

A multidisciplinary panel of experts in guideline development, dissemination, and implementation was assembled to identify and define guideline components that they considered necessary to demonstrate guideline validity and to facilitate application of guideline knowledge. The method has been described in detail in [7]. An initial set of candidate elements was extracted from published models. Panel members evaluated the necessity for in-

cluding each candidate element in guidelines on a 9-point scale via an internet-enabled rating system. The results of this first round of ratings were summarized in reports for each panelist that compared their individual ratings with those of the group as a whole.

The group convened in New Haven, Connecticut in April 2002. Each candidate item was discussed and potential new items were suggested. Panelists decided to rate separately the necessity of guideline components to establish validity and the necessity for practical application in the second round. Each panelist then rated each candidate item privately and the responses were tabulated. Those items that attained median ratings of 7 or greater with low disagreement indices were retained.

To establish the face validity of these items, the list of 44 elements was distributed to 23 organizations that were active in evidence-based guideline development. A large majority of these organizations responded positively.

The 44 items were consolidated into 18 topics (the COGS checklist) that collectively comprise necessary content for clinical practice guidelines. Guideline developers are urged to ensure that each of these topics is considered in their publications.

Which elements are key to implementation?

Informaticians are most often involved in dissemination and implementation phases of the guideline lifecycle. As such, they are most concerned with guideline components necessary for practical application. The 24 items rated by the panel as necessary for practical application are shown in table 1.

GEM Mapping

The Guideline Elements Model is a hierarchical, XML-based document model for clinical practice guidelines [8] that has been standardized as ASTM E2210-02. It has been used to facilitate guideline development, quality appraisal, and implementation [9-11]. One purpose of GEM is to facilitate reuse of guideline content in a variety of contexts [12].

Since COGS encapsulates necessary guideline content as determined by a multidisciplinary panel, we sought to demonstrate the adequacy of the Guideline Elements Model to represent COGS concepts. We carefully reviewed COGS topic names and descriptions and attempted to map each concept to GEM elements and their definitions. Since each COGS topic contains a number of underlying constructs we made an effort to assure that each would be represented by one or more GEM elements. Because of variations in markup [6], we were liberal in selecting all elements that might contain relevant content.

GEM to COGS Transformation

To determine whether a given guideline fulfills the COGS checklist, we created software that applies the mapping to display relevant guideline content for each COGS element (see Figure 1). Such a report would most likely be valuable to guideline authors in preparing final manuscript drafts before a guideline is published.

The application employs an XSLT stylesheet to access the text content of relevant elements from within the nested hierarchy of a GEM-ified document and to display them for effective analysis. When present, relevant text is displayed adjacent to COGS checklist topic names and descriptions. If a relevant element contains no text, the word "empty" is displayed.

Item	Necessity for Practical Application (Median Score)
main focus	9
eligibility	9
recommendation	9
reason	9
recommendation strength	9
users	8
care setting	8
definitions	8
objectives	8
availability of guideline	8
updating plan	8
structured abstract	7
patient resource	7
expected barriers	7
quality measures	7
pilot testing	7
outcomes	7
quick reference guide	7
alternative strategies	7
strength of recommendation rating scheme	7
algorithm	7
linkage between recommendation and evidence	7

Table 1: Guideline components rated necessary for practical application by the COGS panelists.

GEM Mapping

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We found that each COGS topic was represented by one or more GEM elements. The full mapping is presented in Table 2.

COGS Topic	Relevant GEM Elements
1) Overview material	<citation>,<release date>, <status>, <electronic>, <print>, <adaptation>, <contact>
2) Focus	<main.focus>, <category>, <available.option>, <comparable.guideline>
3) Goal	<objective>, <rationale>, <health.outcome>
4) Users/ setting	<users>, <clinical specialty>, <professional group>, <care setting>
5) Target population	<target.population>, <eligibility>, <inclusion.criterion>, <exclusion.criterion>, <age>, <sex>
6) Developer	<developer name>, <developer type>, <committee name>, <committee expertise>, <committee member>, <member expertise>
7) Funding source/ sponsor	<funding>, <developer name>
8) Evidence collection	<description evidence collection>, <method evidence collection>, <number source documents>, <evidence time period>
9) Recommendation grading criteria	<method evidence grading>, <rating scheme>
10) Method for synthesizing evidence	<description evidence combination>, <method evidence combination>
11) Pre-release review	<external review>, <review method>, <pilot testing>
12) Update plan	<expiration>, <scheduled review>
13) Definitions	<definition>, < term>, <term meaning>
14) Recommendations and rationale	<recommendation>, <conditional>, <imperative>, <decision variable>, <action>, <reason>, <evidence quality>, <recommendation strength>, <reference>, ...
15) Potential benefits and harms	<health outcome>, <cost analysis>, <specification harm benefit>, <quantification harm benefit>, <decision variable cost>, <action benefit>, <action risk harm>, <action cost>...
16. Patient preferences	<role patient preference>
17) Algorithm	<algorithm>, <action step>, <conditional step>, <branch step>, <synchronization step>
18) Implementation considerations	<implementation strategy>, <companion document>, <patient resource>

Table 2: Mapping of GEM elements to COGS topics.

GEM to COGS Transformation

To determine whether a given guideline fulfills the COGS checklist, we created software that applies the mapping to display relevant guideline content for each COGS element (see Figure 1). Such a report would most likely be valuable to guideline authors in preparing final manuscript drafts before a guideline is published.

The application employs an XSLT stylesheet to access the text content of relevant elements from within the nested hierarchy of a GEM-ified document and to display them for effective analysis. When present, relevant text is displayed adjacent to COGS checklist topic names and descriptions. If a relevant element contains no text, the word "empty" is displayed.To extract relevant text from a GEM-ified guideline, we searched the GEM hierarchy recursively and applied logic rules within the search. For many COGS topics, a single occurrence of text within an element is expected to satisfy the topic requirement, e.g., availability in print and electronic formats. Other topics might require accessing multiple child elements within the GEM hierarchy. Moreover, each recommendation within the guideline must be scanned individually to assess adherence to the COGS checklist. For example, guideline recommendations can be stated by guideline authors as conditional statements (IF decision variable THEN action) or as imperatives (Do directive). Each <conditional> element might contain any number of <action> elements, and each action may or may not contain one or more <action.cost> elements .

To simplify the report display, if an action daughter-element existed but it did not contain a text component, we elected not to display the element as empty, nor to display the parent element's content. If there were multiple action-daughter elements, we first determined whether any of the elements contained text and if so, displayed only those that did, while if none of the action-daughter elements, if they existed, contained text, we did not display this branch for this recommendation.

The GEM-COGS transformation stylesheet will be made available online at http://ycmi.med.yale.edu/GEM.

Discussion

The COGS checklist was created by a panel of guideline developers, disseminators, and implementers to define necessary content to be documented in clinical practice guidelines. The multidisciplinary membership of the panel (including a substantial number of individuals with skills in computer-mediated guideline implementation), the rigorous method for ascertaining consensus, and the COGS focus on a checklist to be used *during* guideline development distinguish this effort from that of other groups active in guideline appraisal.

One factor that contributes to the variation of guideline quality and implementability is the fact that guideline expert panels are most often composed of individuals who are inexperienced in guideline authoring. New committees of experts are assembled to address each clinical problem. The COGS checklist is intended to serve as a common starting point to ensure comprehensive documentation of information necessary to establish guideline

(1) Overview material	*Provide a structured abstract that includes the guideline's release date, status (original, revised, updated), and print and electronic sources.*
Release Date	JULY 1997
Status	revised
Available in Electronic Format	http://www.nhlbi.nih.gov/nhlbi/nhlbi.htm
Available in Print Format	National Heart, Lung, and Blood Institute Information Center, P.O. Box 30105, Bethesda,
Bibliographic citation	Guidelines for the Diagnosis and Management of Asthma. NIH PUBLICATION NO. 97-4051 JULY 1997
Contact Information	Claude Lenfant, M.D., Director National Heart, Lung, and Blood Institute Chair, National Asthma Education and Prevention Program Coordinating Committee
Adapted From Another Guideline	Empty
(2) Focus	*Describe the primary disease/condition and intervention/ service/ technology that the guideline addresses. Indicate any alternative preventive, diagnostic or therapeutic interventions that were considered during development.*
Primary disease or condition	This report presents basic recommendations for the diagnosis and management of asthma that will help clinicians and patients make appropriate decisions about asthma care.
NGC classification	Management
Alternative Strategies Available	Empty
Comparable Guideline	Empty
(3) Goal	*Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.*
Goal	The goal of the Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma is to serve as a comprehensive guide to diagnosing and managing asthma.
Rationale	In 1995, the Science Base Committee recommended to the NAEPP Coordinating Committee that sufficient new information had been published since 1991 to convene a panel of experts to update the first Expert Panel Report.
Outcomes or Performance Measures Considered	Asthma diagnosis and management are expected to improve, which should reduce the numbers of lost school and work days, hospitalizations and emergency department visits, and deaths due to asthma. A net reduction in total health care costs should result.

Figure 1 - A portion of the GEM to COGS transformation. The 3 horizontal bars represent COGS topics. Below each is shown the relevant GEM elements and their content from a GEM-ified asthma guideline developed by the US NHLBI

validity and to promote creation of guideline statements that can be implemented.

Despite the best efforts of guideline developers and disseminators, a disconnect often occurs when the guideline documents are delivered to implementers to put into practice. Multiple modalities for implementation—including continuing education, academic detailing, administrative incentives and disincentives, and feedback systems—have been applied in an effort to change clinicians' behavior [13]. None has been more successful than the use of computer-generated reminders. Computer-mediated decision support systems based on high-quality guideline knowledge show considerable promise for improving physician performance and patient outcomes [14]. Likewise, information technology will be a necessary part of the infrastructure to promote patient safety by minimizing clinical errors [15].

The successful mapping of COGS to GEM in effect serves as a use-case that demonstrates the sufficiency of the Guideline Elements Model to represent critical components of practice guidelines. According to its original design specification, GEM was intended for use during all phases of the guideline lifecycle and this work validates its value during the guideline authoring phase. Once marked up, guideline content can be reused in many ways [9-12].

The transformation application that operates on GEM-ified guidelines described in this work can facilitate adherence to the COGS checklist by demonstrating areas where additional and/or clearer documentation is necessary. Because the checklist has only recently been published, it is not yet known whether it will achieve that goal. Ongoing activities include collecting comments and suggestions from COGS users and incorporating this pragmatic experience in future versions of the checklist.

Additional current work in our laboratory is directed toward the development of an Implementability Rating Profile. This instrument focuses on factors intrinsic to a guideline that facilitate implementation or serve as barriers that can be anticipated and addressed. This tool and the COGS checklist should help to improve the product of guideline authoring group.

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