Designation: E2210 – 12

An American National Standard

Standard Specification for Guideline Elements Model version 3 (GEM III)—Document Model for Clinical Practice Guidelines[1]

This standard is issued under the fixed designation E2210; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification updates a standard representation for storing and organizing the heterogeneous information contained in clinical practice guidelines. This specification is intended to facilitate translation of natural-language guideline documents into a format that can be processed by computers. It can be used to represent document content throughout the entire guideline life cycle. Information at both high and low levels of abstraction can be accommodated. This specification is based on the guideline elements model (GEM) created at the Yale Center for Medical Informatics and designed to serve as a comprehensive XML-based guideline document representation.

1.2 This specification refers to and makes use of recommendations from the World Wide Web consortium, the W3C.[2]

1.3 *Standard Guideline Schema*—This specification defines a standard Schema for clinical practice guidelines. The Schema is included in Annex A1.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.*

2. Referenced Documents

2.1 *W3C World Wide Web Consortium:*
XML 1.0 Recommendation[3]
XML Schema 1.0[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *document type definition (DTD)*—the formal definition of the elements, structures, and rules for enabling platform-independent data access via XML, or for marking up a given type of SGML document.

3.1.2 *extensible markup language (XML)*—standard from the World Wide Web Consortium (W3C) that provides for tagging of information content within documents, offering a means of representation of content in a format that is both human and machine readable. Through the use of customizable style sheets and schemas, information can be represented in a uniform way, allowing for interchange of both content (data) and format (metadata).

3.1.3 *health level 7 (HL7)*—a standards organization traditionally focused on standards for healthcare information interchange. HL7 messages are the dominant standard for peer-to-peer exchange of clinical text-based information. More recently, HL7 has developed a comprehensive object model of the healthcare enterprise and the first level of an XML clinical document architecture.

3.1.4 *HL7 clinical document architecture (CDA)*—a document markup standard for the structure and semantics of exchanged clinical documents. A clinical document is a documentation of observations and other services with the following characteristics: persistence, stewardship, potential for authentication, wholeness, and human readability. A CDA document is a defined and complete information object that can exist outside of a message and can include text, sounds, and other multimedia content.

3.1.5 *hypertext markup language (HTML)*—the language used in creating a web page. Its origin is an implementation of SGML DTD. It provides tags regarding the way a document should be displayed in the text of an HTML document, which act as commands that a browser interprets when downloading an HTML file.

3.1.6 *namespaces*—provide a simple method for qualifying element and attribute names used in XML documents. This is accomplished by associating a particular tag set by associating a prefix with a URI reference. XML namespaces provides a mechanism for authoring compound documents (documents consisting of elements and attributes from multiple DTDs or

[1] This specification is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.35 on Healthcare Data Analysis.

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[2] http://www.w3.org

[3] http://www.w3.org/XML/

[4] http://www.w3.org/XML/Schema

schemas) in such a way that will provide global identification without collisions of names that are the same but are used differently.

3.1.7 *parser*—a specialized software program that recognizes markup in a document and differentiates the content from the markup. A parser that reads a DTD and checks and reports on markup errors is a validating XML parser. A parser can be built into an XML editor to prevent incorrect tagging and to check whether a document contains all the required elements.

3.1.8 *XML Schema*—provides a means for defining the detailed structure, content and semantics of XML documents. XML Schema was approved as a W3C Recommendation approved on 2 May 2001 and with a second edition incorporating many errata was published on 28 October 2004 that provides a means for defining the detailed structure, content and semantics of XML documents. XML Schema defines the elements that can appear within the document and the attributes that can be associated with an element. It also defines the structure of the document: which elements are child elements of others, the sequence in which the child elements can appear, and the number of child elements. It defines whether an element is empty or can include text. The schema can also define default values for attributes.

3.1.9 *stylesheet*—the XSL transformations (XSLT) describes a vocabulary recognized by an XSLT processor to transform information from an organization in the source file into a different organization suitable for continued downstream processing. The extensible stylesheet language (XSL) describes a vocabulary recognized by a rendering agent to reify abstract expressions of format into a particular medium of presentation.

3.1.10 *valid XML document*—a document that is well-formed, with internal or DOCTYPE reference to element definition of tags within the document.

3.1.11 *well-formed XML document*—an XML document that conforms to the syntax as specified by the W3C XML 1.0 recommendation.

3.1.12 *World Wide Web Consortium (W3C)*—develops interoperable technologies (specifications, guidelines, software, and tools) to lead the Web to its full potential as a forum for information, commerce, communication, and collective understanding.

3.1.13 *XHTML*—HTML documents that are well formed and can be processed by an XML parser.

3.1.14 *XLL/XLINK/XPOINTER*—XLL, the extensible linking language, is divided into two parts, XLinks and XPointers. XLink, the XML linking language, defines how one document links to another document. XPointer, the XML pointer language, defines how individual parts of a document are addressed. XLinks point to a URI (in practice, a URL) that specifies a particular resource. The URL may include an XPointer part that more specifically identifies the desired part or section of the targeted resource or document. XPointer, the XML pointer language, defines an addressing scheme for individual parts of an XML document. XLinks point to a URI (in practice, a URL) that specifies a particular resource. The URI may include an XPointer part that more specifically identifies the desired part or element of the targeted resource or document. XPointers use the same XPath syntax as XSL transformations to identify the parts of the document they point to, along with a few additional pieces.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *clinical practice guidelines*—systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.[5]

3.2.2 *guideline elements model (GEM)*—an XML-based guideline document model that promotes translation of natural language guideline documents into a format that can be processed by computers. Developed at the Yale Center for Medical Informatics, GEM serves as the basis for this specification.[6]

3.2.3 *guidelines interchange format (GLIF)*—a proposed representation for guideline logic created by the INTERMED Collaboratory.[7]

3.2.4 *national guidelines clearinghouse (NGC)*—a website sponsored by the U.S. Agency for Healthcare Quality and Research that disseminates information about qualifying guidelines. It includes a structured vocabulary for describing several aspects of guidelines.[8]

3.3 *GEM Definitions:*

3.3.1 See Table A1.1 in Annex A1.

4. Significance and Use

4.1 *GEM Representation*—The guideline elements model (GEM) was created to unify representations created by health services researchers and by informatics specialists. Specification E2210 Schema is based on the GEM knowledge representation. It is intended to be:

4.1.1 *Comprehensive*, that is, capable of expressing all the knowledge contained in a guideline. Existing health services models of guidelines are inadequate for expressing the complexity of knowledge components in sufficient detail to facilitate electronic translations. On the other hand, existing informatics models are insufficient to model constructs that express and support guideline validity. Lack of confidence in the validity of guideline recommendations may ultimately limit end user adherence.

4.1.2 *Expressively adequate* to express the complexities and nuances of clinical medicine while remaining *informationally equivalent* to the original guideline. Most tagged elements in the Specification E2210 Schema store the actual language of the guideline, thereby remaining true to the original. Moreover, this Schema does not require recommendation knowledge to be structured in a temporal sequence, an often artificial transformation necessary for algorithmic representations.

[5] *Guidelines for Clinical Practice: From Development to Use*, Institute of Medicine, National Academy Press, Washington, DC, 1992.

[6] http://ycmi.med.yale.edu

[7] http://www.glif.org.

[8] http://www.guideline.gov

4.1.3 *Flexible*, that is, a useful model must be able to deal with the variety and complexity of guidelines. The representation should permit modeling at high and low levels of granularity so that guidelines can be interpreted at different levels of abstraction. The Specification E2210 Schema allows markup using high-level tags or deeper analysis using elements from lower levels in the hierarchy. In addition, the open XML document model can be modified easily if necessary to accommodate missing semantic constructs.

4.1.4 *Comprehensible*, that is, it should match the stakeholders' normal problem-solving language and allow domain experts to describe their knowledge with little effort. The Specification E2210 Schema markup does not require knowledge of programming. The markup process parallels physical highlighting of a document and should be learned easily by nonprogrammers.

4.1.5 *Shareable across institutions*. The use of XML for knowledge representation and markup provides unparalleled cross-platform compatibility.

4.1.6 *Reusable* across all phases of the guideline life cycle.

4.2 *Conformance*—A document is tested for conformance to this specification by a validating XML parser according to the W3C XML 1.0 recommendation.[9] A conformant document must validate without either well-formedness or validity errors, according to XML 1.0. A conformant document must also conform to constraints expressed within the prose of this specification; however, this specification does not express a formal means of testing conformance to such additional constraints. A document must be valid according to the Schema specified in this specification in order to conform to this specification.

4.3 *Use*—The Guideline Elements Model has been the subject of considerable interest and application and has become the leading exemplar of document-centered guideline knowledge representation. It has been applied by national specialty societies in the U.S. for guideline development. Shahar in Israel has employed GEM within the DeGeL architecture to create a digital guideline library.[10] In Paris, Georg and colleagues found the GEM representation to be superior to their then current guideline system (ASTI) for encoding therapeutic guidelines.GEM has been incorporated within the GUIDE architecture in Pavia, Italy; it has been used to teach informatics students about guidelines by Rector in the UK; it was incorporated within the CPGA architecture by Purves in the UK; and it is being used in New Zealand for referral guideline dissemination. In Canada, Jones has used GEM to generate tailored patient education materials and Kershaw has applied the system to create a web-enabled best-evidence retrieval system. GEM is featured and linked on the Open Clinical website in the UK.

4.3.1 Workers at Yale have found that parsing guideline recommendations into decision variables (and values), actions, and directives facilitates their encoding in controlled vocabularies such as SNOMED and LOINC and promotes the creation of rules based on the recommendations.

5. Procedure

5.1 *GEM Architecture*—As shown in Fig. 1, the root <schema> element contains three components: <GuidelineDocument>, <GemBasicType>, and <GemCodeType>.. The next tier of the <GuidelineDocument> hierarchy defines a series of high-level elements that include <Identity>, <Developer>. <Purpose>, <IntendedAudience>, <MethodOfDevelopment>, <TargetPopulation>, <KnowledgeComponents>, <Testing>, <RevisionPlan>, and <ImplementationPlan> elements. Each of these elements comprises one or more additional levels of guideline constructs.

5.1.1 The named global complex data type <GemBasicType> defines the "source," "version," "id," and "lang" attributes. The "source" attribute distinguishes whether an element's content is explicitly stated within the guideline document or was inferred by the person who performed the markup and takes values of "explicit," "inferred," or "not_defined." The "version" attribute defines the specific version of the element.The "id" attribute defines a unique identifier for each element. The "lang" attribute indicates the language of the text content.

5.1.2 The named global complex data type <GemCodeType> defines the"source," "version," "codeset," "id," and "lang" attributes. The "source" attribute distinguishes whether an element's content is explicitly stated within the guideline document or was inferred by the person who performed the markup and takes values of "explicit," "inferred," or "not_defined." The "version" attribute defines the specific version of the element. The "codeset" attribute identifies the name of the dataset o f concept identifiers for each element. The "id" attribute defines a unique identifier for each element. The "lang" attribute indicates the language of the text content.

5.2 *Components:*

5.2.1 *Elements*—Elements can appear as often as required. Most elements store information that is literally presented in the guideline text itself, for example, release date, name of sponsoring organization, and recommendation text. Element definitions are provided in Table A1.1.

5.2.2 *Data Types*—Elements are of type GemBasicType or GemCodeType or contain the GemBasicType or GemCodeType attributes.

5.2.3 *Annotations*—Annotations contain definitions of elements.

5.2.4 Codes—The elements DecisionVariableCode, ActionCode, DirectiveCode, RecommendationStrengthCode, InclusionCriterionCode, ExclusionCriterionCode, and ScopeCode contain letters or digits that are used for identification or selection purposes. The system from which the code originates isspecified in the "codeset" attribute.

[9] http://www.w3.org/TR/2000/REC-xml-20001006

[10] Shahar, Y., Shalom, E., Mayaffit, A., Young, O., Galperin, M., Martins, S., et al, "A Distributed, Collabaorative, Structuring Model for a Clinical-Guideline Digital-Library," Musen, M. A., editor, *AMIA 2003 Symposium*, Washington, DC, 2003, pp. 589-593.

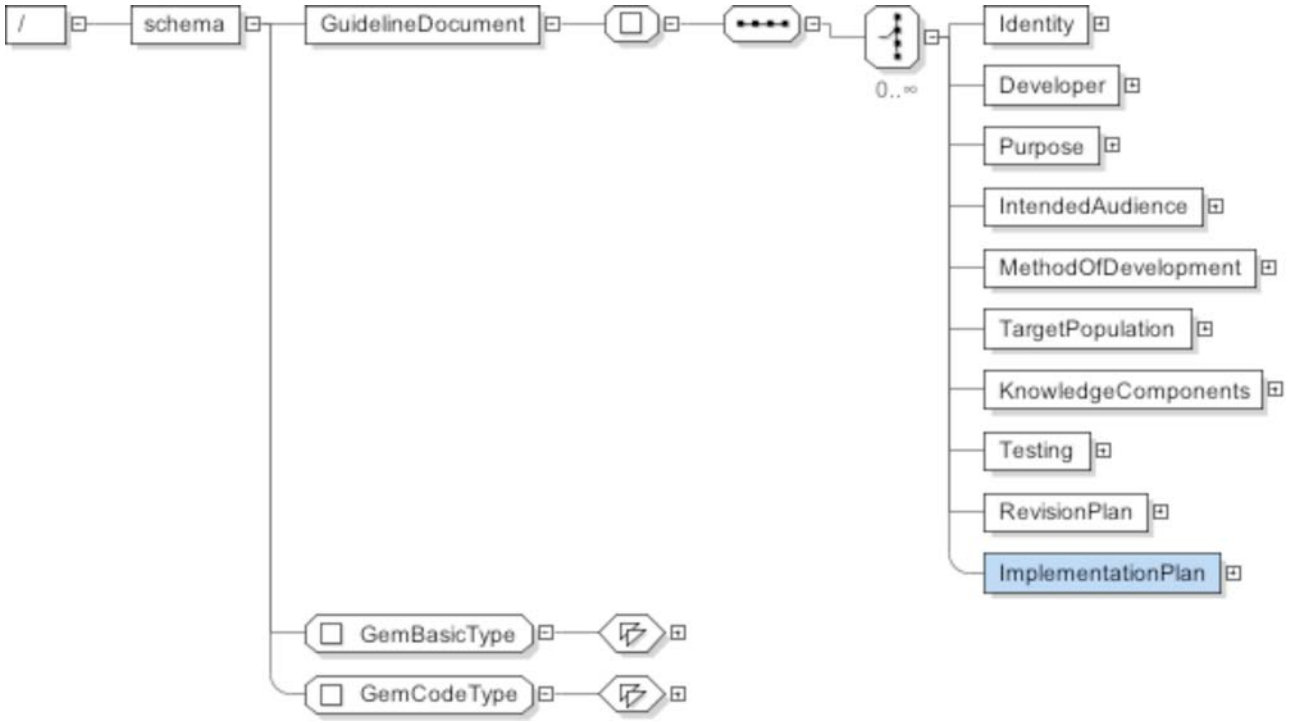

FIG. 1 Top Level of the GEM III Schema

5.3 *Namespace*—The target and default namespace declarations are "http://gem.yale.edu." The prefix for the XML Namespace "http://www.w3.org/2001/XMLSchema" is "xs."

5.4 *Identity*—Information that identifies a particular guideline document and describes it in general terms is clustered within this construct. The <Identity> element includes the guideline's complete <Title>, a <Citation> that references its publication, its <ReleaseDate>, its <Availability> (in <Electronic> and <Print> formats) and a person or organization to be contacted for further information. The <Status> element indicates whether the guideline has been updated or revised. Since many current guidelines are released as packages that may include <PatientResource>, foreign language versions, <QuickReferenceGuide>, and <TechnicalReport>, a construct for <CompanionDocument> is included. An entry stored in the <Adaptation> element identifies whether the guideline has been adapted from another publication. A <StructuredAbstract> element contains a high-level description of the guideline. <GEMCutHistory> contains a record of GEM file creation. It has a single subelement of <GEMCutVersion> that identifies when the GEM file was created and this element contains two subelements <GEMCutAuthor> and <GEMCutDate> which identify the individual responsible for creating the version of the GEM file and the date when the file was created.

5.5 *Developer*—The organization responsible for development of the guideline is identified and described. The formal name of the committee within the developing organization, as well as its members' names and individual or committee expertise, are represented. Potential sources of bias of a panel member, for example, financial or intellectual, that could influence the development process are captured.In addition, sources of financial support for the guideline's development, the role of the sponsor in guideline authoring activities and potential conflict of interest are accommodated. Principles and strategies to address potential conflicts and disclosure of real conflicts and how they are addressed are included. In addition, the names of organizations that have endorsed the guideline, and reference to other organizations' guidelines on the same topic are included.

5.6 *Purpose*— <Purpose> sub-elements describe the main health practices, services, or technologies addressed by the guideline and the reasons for the guideline's development. The <Rationale> for guideline development (for example, evidence of inappropriate practice or wide practice variation) is subtly different from the <Objective> of the guideline (for example, to increase use of a particular test, to diminish inappropriate use of a therapy) and either (or both) may be described. The <HealthOutcomes> element stores the specific health outcomes or performance measures that the guideline is intended to affect. The <AvailableOptions> describe the principal alternative preventive, diagnostic, or therapeutic interventions that are available. Exception refers to factors that may permit an exception to be made in applying the guidelines, including home and family situation and constraints on the healthcare delivery system.

5.7 *Intended Audience*—The <IntendedAudience> for a guideline refers both to the healthcare provider <User> whose behavior the guideline is intended to influence and the <CareSetting> in which a guideline recommendation may be applicable, for example, office, intensive care unit, or a particular health maintenance organization.

5.8 *Method of Development:*

5.8.1 The validity of a guideline's recommendations is closely tied to concepts incorporated in <MethodOfDevelopment>. Evidence-based guideline development processes relate recommendations directly to the scientific evidence that supports them. Such constructs are clearly important to developers and implementers, and to end users of guideline recommendations, as they decide whether the recommendations should influence their behavior.

5.8.2 The <DescriptionEvidenceCollection> element refers to approaches taken by the guideline developers to identify and retrieve scientific evidence. The <NumberSourceDocuments> refers to the number of documents identified during evidence collection. Criteria for filtering of retrieved literature is stored within <EvidenceSelectionCriteria>. The <EvidenceTimePeriod> refers to the publication dates of the evidence. The <RatingScheme> and its subelements <EvidenceQualityRatingScheme> and <RecommendationStrengthRatingScheme> store criteria used to gauge the quality of information from different sources. The <MethodEvidenceCombination> refers to formal methods of synthesis used to develop summary measures that reflect the strength of scientific evidence, for example, meta-analysis, decision analysis, or formal group judgment techniques.

5.8.3 The <SpecificationHarmBenefit> describes qualitatively the anticipated benefits, potential risks, or adverse consequences associated with implementing the guideline recommendations, while <QuantificationHarmBenefit> provides an element for storing mathematical models and numeric estimates.

5.8.4 The <RoleValueJudgment> stores information related to whose values were applied in determining the relative desirability of a health practice. For example, guidelines that optimize healthcare from the point of view of the individual patient, the payor, and society may well differ. Likewise, the specific <RolePatientPreference> in determining policies is explicitly declared and stored within this element.

5.8.5 The <PatientAndPublicInvolvement> addresses the role of patients, advocates, consumer organizations in guideline development and review.

5.9 *Target Populations*—The <TargetPopulation> refers to the group of individuals who are the subject of the guideline recommendations. <Eligibility> criteria includes <InclusionCriterion> and <ExclusionCriterion> that determine the specific portion of the target population for which recommendations are applicable.

5.10 *Testing*—The <ExternalReview> refers to the findings of individuals and groups outside the sponsoring organization that have reviewed recommendations. The <PilotTesting> refers to testing of the guideline's recommendations in clinical settings.

5.11 *Revision Plan*—The date of <ScheduledReview> and <Expiration> elements store data that help to determine the validity of the recommendations in light of new evidence.

5.12 *Knowledge Components*—Elements in the <KnowledgeComponents> subtree store and categorize the expert knowledge that is the salient feature of clinical practice guidelines. Knowledge components are classified into five high-level elements, <Recommendation>, <Definition>, <Algorithm>, <BackgroundInformation>, <ResearchAgenda>, and <StatementOfFact>. Each of these knowledge components and its subtree in the Specification E2210 hierarchy is discussed in the following paragraphs:

5.12.1 *Recommendations:*

5.12.1.1 Recommendations are the unique components that distinguish guidelines from other clinical publications; recommendations are intended to influence practitioners' behavior. When recommendations are analyzed into atomic concepts (and perhaps encoded in a structured vocabulary) they can be executed by a computer's logic.

5.12.1.2 Recommendations can be categorized as <Conditional> or <Imperative> statements. While conditional statements clearly delineate the situations in which they apply, imperatives are broadly applicable to the entire target population and do not impose constraints on their pertinence.

5.12.1.3 Conditional recommendations can be described in rules that take the form:

If CONDITION then ACTION(S) {because REASON(S)}

5.12.1.4 A condition, in turn, is specified by one or more combinations of a <DecisionVariable> and its <Value> linked by comparison operators, for example, platelet count less than 50 000. In many cases, the value of a decision variable is not explicitly stated in guideline text but is implied to be true or present.

5.12.1.5 Fulfillment of the condition triggers one or more guideline-specified <Action>. <Reason> elements explain why the action has been triggered. The <EvidenceQuality> that led the guideline developers to call for a particular recommendation and the <RecommendationStrength> that they attach to a particular recommendation are tagged in appropriately named elements. <EvidenceQualityDescription> of the applicability, quantity, and consistency of the available evidence is addressed. Any <Disagreement> or differences of opinion regarding the recommendationis captured in this element.The <Flexibility> element describes optional conditions or actions that relate to a particular rule and are often recognizable by the presence of "or" statements in the guideline text. Defining a condition and executing an action often entail an economic burden that can be described in <Cost> elements associated with individual decision variables or actions or with the higher level conditional. In some cases, a recommendation relates to attaining an explicit <Goal>, for example, diastolic blood pressure or blood glucose level. Information about the relationships between recommendations is stored in the <Link> element. Such links might define a temporal sequence or a part-whole relationship or relate one part of the hierarchy to another. A <Reference> slot can be used to store citations to specific evidence that supports a particular recommendation. The <Logic> element summarily stores the boolean connectives that link component decision variables and actions. <BenefitHarmAssessment> contains the outcome of weighing the benefits against risks, harms, and costs that expresses imbalance or equilibrium.

5.12.1.6 At deeper levels of the conditional tree, elements store information that describes in detail individual decision variables and actions. Specific elements define quantitative

<TestParameters> for individual decision variables (<Sensitivity>, <Specificity>, <PredictiveValue>) and benefits and risks or harms associated with individual actions. Some users have found it valuable to separate <Action> as a predicate from <ActionValue>. <ActionType> refers to one of 14 categories of action that can be useful for the design of guideline implementation strategies; each action-type can be associated with a menu of reusable services that can be selected by an implementation planner. The 14 defined action types are Test, Monitor, Inquire, Examine, Conclude, Prescribe, Procedure, Educate/Counsel, Consult/Refer, Document, Advocate, Prevent, Prepare, and Dispose.

5.12.1.7 In contrast to conditional recommendations, imperative recommendations present broadly applicable <Directive>s (that parallel the actions in a conditional recommendation). Imperatives often include terms such as "require," "must," and "should," but do not contain conditional text (for example, "if," "when," "whenever") that would limit their applicability to specified circumstances. In some cases, however, guideline authors limit the <Scope> of specific imperatives to a subgroup of the eligible population, e.g., in a guideline about congestive failure, one chapter's imperatives may refer to those with congestive failure after a myocardial infarction. With the exception of <DecisionVariable> elements (which only exist in the conditional tree), most of the deeper level elements of the knowledge components hierarchy are similarly applicable to both imperative and conditional statements.

5.12.1.8 *Definition*—A <Definition> element stores important guideline terminology, as well as the meaning of the terms.

5.12.1.9 *Algorithm:*

(1) Many (though not all) guidelines include algorithms that are graphically represented in flowcharts. These describe temporal sequences of activities and the branching decision logic that implement the guideline's recommendations. In GEM, a flowchart can be included *en bloc* as an <Algorithm> element or it can be broken down into its component parts.

(2) The GLIF specification consists of a collection of guideline steps that are linked in a directed graph. The GEM Algorithm hierarchy includes elements derived from the GLIF steps model: *(1)* <ActionStep>, which specifies a clinical action that is to be performed in the patient-care process, *(2)* <ConditionalStep>, which directs flow from one guideline step to another based on the evaluation of a criterion, *(3)* <BranchStep>, which directs flow in alternate directions, and *(4)* <SynchronizationStep>, which represents a convergence of other steps.

5.12.1.10 *Background information* contains information relevant to the guideline's topic but not related to other Knowledge Components.

5.12.1.11 *Research agenda* is a proposal for further scientific investigation to correct identified deficiencies in the evidence base for this guideline topic.

5.13 *Implementation Plan:*

5.13.1 <ImplementationStrategy>, <PerformanceMeasure>, and <ImplementationMode> may be stored in the <ImplementationPlan> hierarchy, along with <AnticipatedBarrier> and <AnticipatedEnabler> of implementation success.

5.14 *Statement of Fact,*

5.14.1 <StatementOfFact> is a non-executable statement intended by the author to describe appropriate care. This category includes US Preventive Services Task Force "I Statements", that is, the authors conclude that there is insufficient evidence to support a recommendation for or against such an action.

6. Precision and Bias

6.1 *Architecture*—Precision to the schema architecture is determined by XML validating parsers and conformance to this specification.

6.2 *Testing:*

6.2.1 The schema has been tested against several validators.

6.2.2 *Other Online Validators Include:*

6.2.2.1 The Language Technology Group at The University of Edinburgh (Scotland).[11]

6.2.2.2 The W3C web validator.[12]

6.3 *Guideline Tools:*

6.3.1 A wide variety of published practice guidelines has been marked up using the GEM W3C Schema. The Yale Center for Medical Informatics (YCMI) has devised a GEM editor (GEM Cutter) that facilitates encoding guideline content.

6.3.2 In addition, YCMI has devised several XSLT stylesheets that promote transformation of guideline content into a semiformal representation that is more amenable to computer processing.

7. Keywords

7.1 clinical decision support; clinical practice guideline; health care; healthcare quality assurance; namespaces; schema; XHTML; XML

[11] http://www.ltg.ed.ac.uk/~richard/xml-check.html

[12] http://validator.w3.org

ANNEX

(Mandatory Information)

A1. GEM III SCHEMA

```
< xs:schema targetNamespace=″http://gem.yale.edu″ xmlns=″http://
gem.yale.edu″ xmlns:xs=″http://www.w3.org/2001/
XMLSchema″elementFormDefault=″qualified″
attributeFormDefault=″unqualified″version=″3.0″>< xs:schema
targetNamespace=″http://gem.yale.edu″ xmlns=″http:// gem.yale.edu″
xmlns:xs=″http://www.w3.org/2001/XMLSchema″
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  < xs:complexType>
   < xs:sequence>
    < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
    < xs:element name=″Identity″>
     < xs:complexType mixed=″true″>
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        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
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         < xs:element name=″GEMCutVersion″>
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instance ofthe GEM file
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versionof the GEM file
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             < /xs:annotation>
            < /xs:element>
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wascreated
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             < /xs:annotation>
```

```
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          < /xs:choice>
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          < xs:attribute name=″version″ type=″< xs:string″/>
          < xs:attribute name=″id″ type=″< xs:ID″/>
          < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
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        < /xs:element>
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       < xs:attribute name=″version″ type=″< xs:string″/>
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     < /xs:element>
     < xs:element name=″ReleaseDate″ type=″GemBasicType″>
      < xs:annotation>
       < xs:documentation>Date on which the guideline was released
tothe public
       < /xs:documentation>
      < /xs:annotation>
     < /xs:element>
     < xs:element name=″Availability″>
      < xs:annotation>
       < xs:documentation>Information regarding sources of a
guidelineand associated documentation
       < /xs:documentation>
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       < xs:complexType mixed=″true″>
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        < xs:element name=″Electronic″ type=″GemBasicType″>
         < xs:annotation>
          < xs:documentation>Information regarding sources of
guideline inelectronic format
         < /xs:documentation>
         < /xs:annotation>
        < /xs:element>
        < xs:element name=″Print″ type=″GemBasicType″>
         < xs:annotation>
          < xs:documentation>Information regarding sources of
guideline inprint format
         < /xs:documentation>
         < /xs:annotation>
        < /xs:element>
        < xs:element name=″Contact″ type=″GemBasicType″>
         < xs:annotation>
          < xs:documentation>Person or organization to contact for
additionalinformation about a guideline
         < /xs:documentation>
         < /xs:annotation>
        < /xs:element>
       < /xs:choice>
       < xs:attribute name=″source″ type=″< xs:string″/>
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       < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
      < /xs:complexType>
     < /xs:element>
     < xs:element name=″Status″ type=″GemBasicType″>
      < xs:annotation>
       < xs:documentation>Statement of whether the guideline is
originalor a revised orupdated version of a previously issued
document
       < /xs:documentation>
      < /xs:annotation>
     < /xs:element>
     < xs:element name=″CompanionDocument″>
      < xs:annotation>
       < xs:documentation>Refers to other documents (including
TechnicalReports,Consumer Guidelines, Quick Reference
Guidelines) produced bythe guidelinedeveloper relevant to the
guideline
       < /xs:documentation>
      < /xs:annotation>
       < xs:complexType mixed=″true″>
        < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
        < xs:element name=″PatientResource″ type=″GemBasicType″>
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```

< xs:documentation>A patienta resource intended to assist patients with guidelineapplication.
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″QuickReferenceGuide″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>A concise document that summarizes guidelinerecommendations for clinicians
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″TechnicalReport″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>A document or document component that describesindetail the method of guideline development
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
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< /xs:element>
< xs:element name=″Adaptation″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Indicates that the guideline has been adaptedfrom anotherguideline
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″StructuredAbstract″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>A summary statement that describes a guidelineusingstructured headings
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
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< xs:element name=″DeveloperName″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Organization(s) responsible for developing theguideline
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″CommitteeName″>
< xs:annotation>
< xs:documentation>Formal name of committee within developerorganizationresponsible for developing guideline
< /xs:documentation>
< /xs:annotation>
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< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
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< xs:annotation>
< xs:documentation>Expertise present within the group that authoredguideline
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″CommitteeMember″>
< xs:annotation>
< xs:documentation>Name of member of guideline developmentcommittee

```
      < /xs:documentation>
     < /xs:annotation>
      < xs:complexType mixed="true">
       < xs:choice minOccurs="0" maxOccurs="unbounded">
       < xs:element name="MemberExpertise"
type="GemBasicType">
        < xs:annotation>
         < xs:documentation>Professional expertise of
individualguideline committee member
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
       < xs:element name="MemberConflict" type="GemBasicType">
        < xs:annotation>
         < xs:documentation>A potential source of bias (e.g., financial
orintellectual) related to a panelist or potential panelist that
couldinfluence process
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
       < xs:element name="MemberRole" type="GemBasicType">
        < xs:annotation>
         < xs:documentation>Expected function of a committee
member,e.g,, chair, epidemiologist, or implementation specialist
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
      < /xs:choice>
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      < xs:attribute name="version" type="< xs:string"/>
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  < xs:annotation>
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guidelinedevelopment
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  < /xs:annotation>
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 < xs:element name="Endorser" type="GemBasicType">
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   < xs:documentation>Organization that has endorsed theguideline
   < /xs:documentation>
  < /xs:annotation>
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Type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Another guideline on the same or
similartopic
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="RoleOfSponsor" type="GemBasicType">
  < xs:annotation>
   < xs:documentation>The sponsor's part in developing,
modifying,and reporting theguideline
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="ConflictOfInterest">
  < xs:annotation>
   < xs:documentation>Potential situations in which financial or
otherconsiderations may compromise, or have the appearance of
compromising,adeveloper's professional judgment
   < /xs:documentation>
  < /xs:annotation>
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< /xs:documentation>
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< /xs:element>
< xs:element name=″COIDisclosure″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Report of potential and real conflicts of interestand how they are addressed
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
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< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
< xs:element name=″MainFocus″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Primary disease/condition, treatment/ intervention, healthpractice, service, or technology addressed in the guideline mainfocus
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Rationale″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Reasons for developing recommendations includingwhy theguideline was developed/needed, e.g., evidence of practice variationorinappropriate practice
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Objective″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>General goals that implementation of theguideline is intendedto bring about
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″AvailableOption″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Principal alternative preventive, diagnostic, ortherapeuticstrategies considered
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″HealthOutcome″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The most important specific outcomes (health,economic, etc)considered in the guideline
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Exception″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Situations in which socially relevant factorspermit anexception to be made in applying the guidelines; including homeand familysituation, constraints on health care delivery system
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>

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< xs:complexType mixed=″true″>
< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
< xs:element name=″Users″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Intended users of guideline information
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″CareSetting″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The settings in which the guideline is
intendedforuse
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
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< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
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< xs:annotation>
< xs:documentation>A description of methods used to
collect,identify, andretrieve scientific evidence on each question on
which recommendationsbased, including details on computer
searches (including dates)personal files and bibliographies
< /xs:documentation>
< /xs:annotation>
< xs:complexType mixed=″true″>
< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
< xs:element name=″EvidenceTimePeriod″
type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Publication date of earliest and most
recentevidence considered
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″NumberSourceDocuments″
Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Number of source documents identified
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″EvidenceSelectionCriteria″
Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Methods used to choose the evidence
thatinformsguideline development, including inclusion and
exclusioncriteria for specific studies
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
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< xs:attribute name=″id″ type=″< xs:ID″/>
< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
< /xs:complexType>
< /xs:element>
< xs:element name=″DescriptionEvidenceCombination″>
< xs:annotation>
< xs:documentation>Method of synthesis used to combine the
scientificevidencequantitatively or otherwise
< /xs:documentation>

```
  < /xs:annotation>
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  < /xs:complexType>
 < /xs:element>
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  < xs:annotation>
   < xs:documentation>Describes any formal cost analysisperformed
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="SpecificationHarmBenefit"
Type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Qualitative description of anticipated
benefitsand potentialrisks associated with implementation of
guideline
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="QuantificationHarmBenefit"
Type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Quantification of benefits or risks
associatedwithimplementation of guideline
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="RoleValueJudgment" type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Implicit or explicit process for judging
relativedesirabilityof health, economic, and process outcomes
associated with alternativepractices
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="RolePatientPreference"
Type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Role of patient preferences for possible
outcomesof care whenthe appropriateness of a clinical intervention
involves a substantialelement of personal choice or values
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="QualifyingStatement" type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Important caveat relating to a major
recommendation.Identifies an area of uncertainty
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="MethodsToReachJudgment"
Type="GemBasicType">
  < xs:annotation>
   < xs:documentation>Group judgment techniques used to
reachjudgment onrecommendations; a description of how the
developer made thetransition fromevidence to recommendation
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
 < xs:element name="RatingScheme">
  < xs:annotation>
   < xs:documentation>Criteria for rating quality of evidence and/
orstrength ofrecommendation
   < /xs:documentation>
  < /xs:annotation>
   < xs:complexType mixed="true">
    < xs:choice minOccurs="0" maxOccurs="unbounded">
    < xs:element name="EvidenceQualityRatingScheme"
Type="GemBasicType">
     < xs:annotation>
      < xs:documentation>Criteria for rating quality ofevidence
      < /xs:documentation>
     < /xs:annotation>
```

```
    < /xs:element>
    < xs:element name=″RecommendationStrengthRatingScheme″
Type=″GemBasicType″>
     < xs:annotation>
      < xs:documentation>Criteria for rating strength
ofrecommendation
      < /xs:documentation>
     < /xs:annotation>
    < /xs:element>
   < /xs:choice>
   < xs:attribute name=″source″ type=″< xs:string″/>
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   < xs:attribute name=″id″ type=″< xs:ID″/>
   < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
  < /xs:complexType>
 < /xs:element>
 < xs:element name=″PatientAndPublicInvolvement″
Type=″GemBasicType″>
  < xs:annotation>
   < xs:documentation>Role of patients, advocates, consumer
organizationsin guideline development and review
   < /xs:documentation>
  < /xs:annotation>
 < /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
< xs:attribute name=″version″ type=″< xs:string″/>
< xs:attribute name=″id″ type=″< xs:ID″/>
< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
0< /xs:complexType>
- < /xs:element>
- < xs:element name=″TargetPopulation″>
0< xs:complexType mixed=″true″>
 < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
 < xs:element name=″Eligibility″>
  < xs:annotation>
   < xs:documentation>Describes population that the
recommendationsare intended toaffect; identifies restrictions on
guideline use such as within amanagedcare organization or
geographic region
   < /xs:documentation>
  < /xs:annotation>
   < xs:complexType mixed=″true″>
    < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
    < xs:element name=″InclusionCriterion″ >
     < xs:annotation>
      < xs:documentation>A criterion whose presence is necessary
fortheguideline recommendations to be applicable
      < /xs:documentation>
     < /xs:annotation>
      < xs:complexType>
       < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
       < xs:element name=″InclusionCriterionCode″
Type=″GemCodeType″ >
        < xs:annotation>
         < xs:documentation>Identifier selected from a standard
terminologythat describes an inclusion criterion
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
      < /xs:choice>
      < xs:attribute name=″source″ type=″< xs:string″/>
      < xs:attribute name=″version″ type=″< xs:string″/>
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      < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
     < /xs:complexType>
    < /xs:element>
    < xs:element name=″ExclusionCriterion″ >
     < xs:annotation>
      < xs:documentation>A criterion whose presence excludes
theapplicability of the recommendations
      < /xs:documentation>
     < /xs:annotation>
      < xs:complexType>
       < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
       < xs:element name=″ExclusionCriterionCode″
Type=″GemCodeType″ >
        < xs:annotation>
```

```
        < xs:documentation>Identifier selected from a standard
terminologythat describes an exclusion criterion
        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
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     < xs:attribute name=″source″ type=″< xs:string″/>
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< /xs:element>
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0< xs:element name=″KnowledgeComponents″>
 < xs:complexType mixed=″true″>
  < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
  < xs:element name=″Recommendation″>
   < xs:annotation>
    < xs:documentation>Statement of appropriate practice and the
conditionsunderwhich it is to be undertaken. The statement is
intended to influencepractitioners' behavior and/or patient outcomes.
A number or brieftitle fora specific recommendation should be stored
in thiselement.
    < /xs:documentation>
   < /xs:annotation>
    < xs:complexType mixed=″true″>
     < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
      < xs:element maxOccurs=″unbounded″ minOccurs=″0″
Type=″GemBasicType″name=″StatementOfFact″>
       < xs:annotation>
        < xs:documentation>A non
       < /xs:annotation>
      < /xs:element>
      < xs:element name=″Conditional″>
       < xs:annotation>
        < xs:documentation>A recommendation applicable under
circumstancesspecified by an ifconditional statement should be
stored in thiselement
        < /xs:documentation>
       < /xs:annotation>
        < xs:complexType mixed=″true″>
         < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
         < xs:element name=″BenefitHarmAssessment″
Type=″GemBasicType″>
          < xs:annotation>
           < xs:documentation>The outcome of weighing benefits
againstrisks, harms, and costs that expresses equilibrium or
imbalance.
          < /xs:documentation>
          < /xs:annotation>
         < /xs:element>
         < xs:element name=″DecisionVariable″>
          < xs:annotation>
           < xs:documentation>A condition that must be tested
toindicate the appropriateness of a conditionalrecommendation.
Store only a single variable in eachdecision variable element
          < /xs:documentation>
         < /xs:annotation>
          < xs:complexType mixed=″true″>
           < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
           < xs:element name=″Value″ type=″GemBasicType″>
            < xs:annotation>
             < xs:documentation>A specified state of adecision variable
             < /xs:documentation>
            < /xs:annotation>
```

```
< /xs:element>
< xs:element name=″DecisionVariableCode″
Type=″GemCodeType″>
< xs:annotation>
< xs:documentation>Identifier selected from a standard
terminologythat describes a decision variable
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″DecisionVariableDescription″
Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Text that provides andamplifies
information about a decision variable < /xs:documentation>
< /xs:annotation>
<xs:complexType>
<xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
<xs:element name=″IntentionalVagueness″
type=″GemBasicType″>
<xs:annotation>
<xs:documentation>An indication of the reason for
deliberate underspecification of a recommendation's conditions or
actions.</xs:documentation>
</xs:annotation>
</xs:element>
</xs:choice>
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< xs:element name=″TestParameter″>
< xs:annotation>
< xs:documentation>Information about thequality of a
decisionvariable
< /xs:documentation>
< /xs:annotation>
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< xs:choice minOccurs=″0″maxOccurs=″unbounded″>
< xs:element name=″Sensitivity″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>An indication of the probability of the
decisionvariable being present under specific clinical circumstances
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Specificity″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>An indicationof the probability of
thedecision variable beingabsent under specificclinicalcircumstances
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″PredictiveValue″
Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>An indicationof the probability of
anoutcome occurring when aparticular value of thedecision variable
ispresent
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
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< /xs:complexType>
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Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The cost of testing adecision variable
< /xs:documentation>
< /xs:annotation>
< /xs:element>
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```

< /xs:complexType>
< /xs:element>
< xs:element name=″Action″>
< xs:annotation>
< xs:documentation>Appropriate activity to be carried outgiven the specific circumstances defined by valuesof decision variables. Store only a single actioneach Action element
< /xs:documentation>
< /xs:annotation>
< xs:complexType mixed=″true″>
< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
< xs:element name=″ActionActor″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The person(s) or role intended to carry out therecommended activity.
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionCode″ type=″GemCodeType″>
< xs:annotation>
< xs:documentation> Identifier selected from a standard terminologythat describes an action
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionVerb″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The word or phrase in a recommendation thatexpresses action, state, or relationship
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionDeonticTerm″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The word of phrase that defines the level ofobligation or permission of a recommendation.
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionVerbComplement″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Word or phrase that completes the sense of averb and includes direct and indirect objects
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionBenefit″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>An improvement in statusof some measured outcome that may occuras a result of following arecommendation
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionRiskHarm″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Risk or adverse outcomeassociated with a specifiedaction
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″ActionDescription″>
< xs:annotation>
< xs:documentation>Text that provides andamplifies information about anaction
< /xs:documentation>
< /xs:annotation>
< xs:complexType>
< xs:choice minOccurs=″0″maxOccurs=″unbounded″>
< xs:element name=″IntentionalVagueness″ Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>An indication of the reason for deliberate underspecificationof a recommendation’s conditions or actions.

```
            < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
         < /xs:choice>
        < /xs:complexType>
       < /xs:element>
       < xs:element name=″ActionCost″ type=″GemBasicType″>
        < xs:annotation>
         < xs:documentation>Cost of performing aspecific action
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
       < xs:element name=″ActionValue″ type=″GemBasicType″>
        < xs:annotation>
         < xs:documentation>A specified state of anaction
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
       < xs:element name=″ActionType″>
        < xs:annotation>
         < xs:documentation>A categorization ofactivity directed by
aconditional
         < /xs:documentation>
        < /xs:annotation>
        < xs:simpleType>
         < xs:restriction base=″< xs:string″>
         < xs:enumeration value=″test″/>
         < xs:enumeration value=″inquire″/>
         < xs:enumeration value=″examine″/>
         < xs:enumeration value=″prescribe″/>
         < xs:enumeration value=″procedure″/>
         < xs:enumeration value=″educate/counsel″/>
         < xs:enumeration value=″dispose″/>
         < xs:enumeration value=″consult/refer″/>
         < xs:enumeration value=″conclude″/>
         < xs:enumeration value=″monitor″/>
         < xs:enumeration value=″document″/>
         < xs:enumeration value=″advocate″/>
         < xs:enumeration value=″prevent″/>
         < xs:enumeration value=″prepare″/>
        < /xs:restriction>
       < /xs:simpleType>
      < /xs:element>
     < /xs:choice>
     < xs:attribute name=″source″ type=″< xs:string″/>
     < xs:attribute name=″version″ type=″< xs:string″/>
     < xs:attribute name=″id″ type=″< xs:ID″/>
     < xs:attribute name=″action.id″ type=″< xs:string″/>
    < /xs:complexType>
   < /xs:element>
   < xs:element name=″Reason″ type=″GemBasicType″>
    < xs:annotation>
     < xs:documentation>An explanation or justification for
arecommendation
     < /xs:documentation>
    < /xs:annotation>
   < /xs:element>
   < xs:element name=″EvidenceQuality″ >
    < xs:annotation>
     < xs:documentation>An indication of methodologic rigor of
thestudies that support the specified recommendation
     < /xs:documentation>
    < /xs:annotation>
    < xs:complexType>
     < xs:choice>
     < xs:element name=″EvidenceQualityDescription″
Type=″GemBasicType″>
      < xs:annotation>
       < xs:documentation>Description of the applicability, quantity
(includingcompleteness) and consistency of the aggregate
availableevidence. explanation of the part played by values, opinion,
theory,and clinical experience in deriving the recommendation
       < /xs:documentation>
      < /xs:annotation>
     < /xs:element>
     < xs:element name=″Disagreement″ type=″GemBasicType″>
      < xs:annotation>
```

< xs:documentation>Description and explanation of any differencesof opinion regarding the recommendation, including minorityreport
< /xs:
< /xs:element>
< /xs:choice>
< xs:attribute name="source" type="< xs:string"/>
< xs:attribute name="version" type="< xs:string"/>
< xs:attribute name="id" type="< xs:ID"/>
< xs:attribute name="action.id" type="< xs:string"/>
< /xs:complexType>
< /xs:element>
< xs:element name="RecommendationStrength">
< xs:annotation>
< xs:documentation>An indication of the guidelinedevelopers' level of support for a givenrecommendation
< /xs:documentation>
< /xs:annotation>
< xs:complexType>
< xs:choice>
< xs:element name="RecommendationStrengthCode" Type="GemCodeType">
< xs:annotation>
< xs:documentation> Identifier selected from a standard terminologythat describes recommendation strength
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< /xs:complexType>
< /xs:element>
< xs:element name="Flexibility" type="GemBasicType">
< xs:annotation>
< xs:documentation>Indication of options in performingconditinal
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Logic" type="GemBasicType">
< xs:annotation>
< xs:documentation>Boolean operators that indicate howdirectives are to be combined
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Cost" type="GemBasicType">
< xs:annotation>
< xs:documentation>Overall cost of performing thisrecommendation
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Linkage" type="GemBasicType">
< xs:annotation>
< xs:documentation>Indicator of a relationship betweenthis recommendation and other knowledgecomponent(s)
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Reference" type="GemBasicType">
< xs:annotation>
< xs:documentation>Specific citation relevant to thisconditional recommendation
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Certainty" type="GemBasicType">
< xs:annotation>
< xs:documentation>Indication of the likelihood that thisrecommendation will lead to specifiedoutcomes
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name="Goal" type="GemBasicType">
< xs:annotation>
< xs:documentation>The state that a recommendation isintended to achieve, maintain, oravoid
< /xs:documentation>

```
        < /xs:annotation>
       < /xs:element>
      < /xs:choice>
      < xs:attribute name=″source″ type=″< xs:string″/>
      < xs:attribute name=″version″ type=″< xs:string″/>
      < xs:attribute name=″id″ type=″< xs:ID″/>
      < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
     < /xs:complexType>
    < /xs:element>
    < xs:element name=″Imperative″>
     < xs:annotation>
      < xs:documentation>Recommendation directed at the entire
targetpopulation without limitation. The complete text of
theimperative statement should be stored in thiselement
      < /xs:documentation>
     < /xs:annotation>
      < xs:complexType mixed=″true″>
       < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
       < xs:element name=″BenefitHarmAssessment″
Type=″GemBasicType″>
        < xs:annotation>
         < xs:documentation>The outcome of weighing benefits
againstrisks, harms, and costs that expresses equilibrium or
imbalance.
         < /xs:documentation>
        < /xs:annotation>
       < /xs:element>
       < xs:element name=″Scope″>
        < xs:annotation>
         < xs:documentation>Implicit eligibility criteria for animperative
statement
         < /xs:documentation>
        < /xs:annotation>
         < xs:complexType>
          < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
          < xs:element name=″ScopeCode″ type=″GemCodeType″ >
           < xs:annotation>
            < xs:documentation>Identifier selected from a standard
terminologythat describes the scope
             < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
         < /xs:choice>
         < xs:attribute name=″source″ type=″< xs:string″/>
         < xs:attribute name=″version″ type=″< xs:string″/>
         < xs:attribute name=″id″ type=″< xs:ID″/>
         < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
        < /xs:complexType>
       < /xs:element>
       < xs:element name=″Directive″>
        < xs:annotation>
         < xs:documentation>An appropriate activity for theeligible
population. Store only a single activity ineach Directive element
         < /xs:documentation>
        < /xs:annotation>
         < xs:complexType mixed=″true″>
          < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
          < xs:element name=″DirectiveActor″ type=″GemBasicType″>
           < xs:annotation>
            < xs:documentation>The person(s) or role intended to carry
out therecommended activity.
             < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
          < xs:element name=″DirectiveCode″ type=″GemCodeType″>
           < xs:annotation>
            < xs:documentation> Identifier selected from a standard
terminologythat describes a directive
             < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
          < xs:element name=″DirectiveVerb″ type=″GemBasicType″>
           < xs:annotation>
            < xs:documentation>The word or phrase in a
recommendation thatexpresses action, state, or relationship
             < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
```

```
< xs:element name=″DirectiveDeonticTerm″
type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>The word of phrase that defines the
level ofobligation or permission of a recommendation.
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveVerbComplement″
Type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>Word or phrase that completes the
sense of averb and includes direct and indirect objects
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveBenefit″
Type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>An improvement in statusthat may
occur as a result of followinga directive
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveRiskHarm″
Type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>Risk or adverse outcomeassociated
with implementation of adirective
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveDescription″>
 < xs:annotation>
  < xs:documentation>Text that provides andamplifies
information about adirective
  < /xs:documentation>
 < /xs:annotation>
  < xs:complexType>
   < xs:choice minOccurs=″0″maxOccurs=″unbounded″>
   < xs:element name=″IntentionalVagueness″
Type=″GemBasicType″>
    < xs:annotation>
     < xs:documentation>An indication of the reason for
deliberate underspecificationof a recommendation's conditions or
actions.
     < /xs:documentation>
    < /xs:annotation>
   < /xs:element>
  < /xs:choice>
 < /xs:complexType>
< /xs:element>
< xs:element name=″DirectiveCost″ type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>Cost of performing aspecific directive
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveValue″ Type=″GemBasicType″>
 < xs:annotation>
  < xs:documentation>The specified state of adirective
  < /xs:documentation>
 < /xs:annotation>
< /xs:element>
< xs:element name=″DirectiveType″>
 < xs:annotation>
  < xs:documentation>A categorization ofactivity directed by
animperative
  < /xs:documentation>
 < /xs:annotation>
  < xs:simpleType>
   < xs:restriction base=″< xs:string″>
   < xs:enumeration value=″test″/>
   < xs:enumeration value=″inquire″/>
   < xs:enumeration value=″examine″/>
   < xs:enumeration value=″prescribe″/>
   < xs:enumeration value=″procedure″/>
   < xs:enumeration value=″educate/counsel″/>
```

```
            < xs:enumeration value=″dispose″/>
            < xs:enumeration value=″consult/refer″/>
            < xs:enumeration value=″conclude″/>
            < xs:enumeration value=″monitor″/>
            < xs:enumeration value=″document″/>
            < xs:enumeration value=″advocate″/>
            < xs:enumeration value=″prevent″/>
            < xs:enumeration value=″prepare″/>
           < /xs:restriction>
          < /xs:simpleType>
         < /xs:element>
        < /xs:choice>
        < xs:attribute name=″source″ type=″< xs:string″/>
        < xs:attribute name=″version″ type=″< xs:string″/>
        < xs:attribute name=″id″ type=″< xs:ID″/>
        < xs:attribute name=″directive.id″ type=″< xs:string″/>
       < /xs:complexType>
      < /xs:element>
      < xs:element name=″Reason″ type=″GemBasicType″>
       < xs:annotation>
        < xs:documentation>An explanation or justification for a
recommendation
        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
      < xs:element name=″EvidenceQuality″ >
       < xs:annotation>
        < xs:documentation>An indication of methodologic rigor of
thestudies that support the specified recommendation and the level
ofconfidence evidence underpinning the recommendation
        < /xs:documentation>
       < /xs:annotation>
        < xs:complexType>
         < xs:choice>
         < xs:element name=″EvidenceQualityDescription″
Type=″GemBasicType″>
          < xs:annotation>
           < xs:documentation>Description of the applicability, quantity
(includingcompleteness) and consistency of the aggregate
availableevidence. explanation of the part played by values, opinion,
theory,and clinical experience in deriving the recommendation
           < /xs:documentation>
          < /xs:annotation>
         < /xs:element>
         < xs:element name=″Disagreement″ type=″GemBasicType″>
          < xs:annotation>
           < xs:documentation>Description and explanation of any
differencesof opinion regarding the recommendation, including
minorityreport
          < /xs:element>
         < /xs:choice>
         < xs:attribute name=″source″ type=″< xs:string″/>
         < xs:attribute name=″version″ type=″< xs:string″/>
         < xs:attribute name=″id″ type=″< xs:ID″/>
         < xs:attribute name=″action.id″ type=″< xs:string″/>
        < /xs:complexType>
       < /xs:element>
       < xs:element name=″RecommendationStrength″>
        < xs:annotation>
         < xs:documentation>An indication of the guideline
developers'level of support for a given recommendation
         < /xs:documentation>
        < /xs:annotation>
         < xs:complexType>
          < xs:choice>
          < xs:element name=″RecommendationStrengthCode″
Type=″GemCodeType″>
           < xs:annotation>
            < xs:documentation>Identifier selected from a standard
terminologythat describes recommendation strength
            < /xs:documentation>
           < /xs:annotation>
          < /xs:element>
         < /xs:choice>
        < /xs:complexType>
       < /xs:element>
       < xs:element name=″Flexibility″ type=″GemBasicType″>
        < xs:annotation>
```

```
< xs:documentation>Indication of options in
performingimperative
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Logic″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Boolean operators that indicate
howdirectives are to be combined
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Cost″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Overall cost of performing
thisrecommendation
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Linkage″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Indicator of a relationship betweenthis
recommendation and other knowledgecomponent(s)
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Reference″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Specific citation relevant to
thisimperative recommendation
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Certainty″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Indication of the likelihood that
thisrecommendation will lead to specifiedoutcomes
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< xs:element name=″Goal″ type=″GemBasicType″>
< xs:annotation>
< xs:documentation>The state that a recommendation
isintended to achieve, maintain, oravoid
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
< xs:attribute name=″version″ type=″< xs:string″/>
< xs:attribute name=″id″ type=″< xs:ID″/>
< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
< /xs:complexType>
< /xs:element>
< xs:element name=″RecommendationNotes″
Type=″GemBasicType″>
< xs:annotation>
< xs:documentation>Additional comments related to the
developmentof the recommendation.
< /xs:documentation>
< /xs:annotation>
< /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
< xs:attribute name=″version″ type=″< xs:string″/>
< xs:attribute name=″id″ type=″< xs:ID″/>
< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
< /xs:complexType>
< /xs:element>
< xs:element name=″Definition″>
< xs:annotation>
< xs:documentation>Concise description of terminology relevant
totheguideline
< /xs:documentation>
< /xs:annotation>
< xs:complexType mixed=″true″>
< xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
< xs:element name=″Term″>
```

```
      < xs:annotation>
       < xs:documentation>A word or phrase defined in theguideline
       < /xs:documentation>
      < /xs:annotation>
       < xs:complexType mixed="true">
        < xs:choice minOccurs="0" maxOccurs="unbounded">
        < xs:element name="TermMeaning" type="GemBasicType">
         < xs:annotation>
          < xs:documentation>Precise meaning of words and
phrasesthat may be unfamiliar to guideline readers; termsare
defined as used in this guidelinecontext
          < /xs:documentation>
         < /xs:annotation>
        < /xs:element>
       < /xs:choice>
       < xs:attribute name="source" type="< xs:string"/>
       < xs:attribute name="version" type="< xs:string"/>
       < xs:attribute name="id" type="< xs:ID"/>
       < xs:attribute name="lang" type="< xs:NMTOKEN"/>
      < /xs:complexType>
     < /xs:element>
    < /xs:choice>
    < xs:attribute name="source" type="< xs:string"/>
    < xs:attribute name="version" type="< xs:string"/>
    < xs:attribute name="id" type="< xs:ID"/>
    < xs:attribute name="lang" type="< xs:NMTOKEN"/>
   < /xs:complexType>
  < /xs:element>
  < xs:element name="Algorithm">
   < xs:annotation>
    < xs:documentation>A flowchart representation of the stages
andactivities inhealth management described by the guideline
    < /xs:documentation>
   < /xs:annotation>
    < xs:complexType mixed="true">
     < xs:choice minOccurs="0" maxOccurs="unbounded">
     < xs:element name="ActionStep" type="GemBasicType">
      < xs:annotation>
       < xs:documentation>Specifies clinical actions that are to
beperformed in the patient
       < /xs:annotation>
      < /xs:element>
      < xs:element name="ConditionalStep" type="GemBasicType">
       < xs:annotation>
        < xs:documentation>Directs flow from one guideline step to
anotherbased on the evaluation of a criterion (GLIF)
        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
      < xs:element name="BranchStep" type="GemBasicType">
       < xs:annotation>
        < xs:documentation>Directs flow in alternate directions(GLIF)
        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
      < xs:element name="SynchronizationStep"
type="GemBasicType">
       < xs:annotation>
        < xs:documentation>Synchronization Step represents a
convergenceofother steps (GLIF)
        < /xs:documentation>
       < /xs:annotation>
      < /xs:element>
     < /xs:choice>
     < xs:attribute name="source" type="< xs:string"/>
     < xs:attribute name="version" type="< xs:string"/>
     < xs:attribute name="id" type="< xs:ID"/>
     < xs:attribute name="lang" type="< xs:NMTOKEN"/>
    < /xs:complexType>
   < /xs:element>
   < xs:element name="ResearchAgenda" type="GemBasicType">
    < xs:annotation>
     < xs:documentation>Proposal for further scientific investigation
tocorrectidentified deficiencies in the evidence base for this
guidelinetopic
     < /xs:documentation>
    < /xs:annotation>
   < /xs:element>
```

```
< xs:element name=″BackgroundInformation″>
 < xs:annotation>
  < xs:documentation>Information relevant to the guideline's
topicbut not relatedto other Knowledge Components
  < /xs:documentation>
 < /xs:annotation>
 < /xs:element>
< /xs:choice>
< xs:attribute name=″source″ type=″< xs:string″/>
< xs:attribute name=″version″ type=″< xs:string″/>
< xs:attribute name=″id″ type=″< xs:ID″/>
< xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
< /xs:complexType>
< /xs:element>
< xs:element name=″Testing″>
 < xs:complexType mixed=″true″>
  < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
  < xs:element name=″ExternalReview″ type=″GemBasicType″>
   < xs:annotation>
    < xs:documentation>Methods of eliciting peer review
commentsand vettingguideline draft
    < /xs:documentation>
   < /xs:annotation>
  < /xs:element>
  < xs:element name=″PilotTesting″ type=″GemBasicType″>
   < xs:annotation>
    < xs:documentation>Preliminary validation
testingxs:documentation>
   < /xs:annotation>
  < /xs:element>
  < xs:element name=″FormalAppraisal″>
   < xs:annotation>
    < xs:documentation>Evaluation of the guideline draft to
appraise itsvalidity andusability (e.g., COGS), quality (e.g., AGREE)
and implementability(e.g.,GLIA)
    < /xs:documentation>
   < /xs:annotation>
  < /xs:element>
 < /xs:choice>
 < xs:attribute name=″source″ type=″< xs:string″/>
 < xs:attribute name=″version″ type=″< xs:string″/>
 < xs:attribute name=″id″ type=″< xs:ID″/>
 < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
 < /xs:complexType>
< /xs:element>
< xs:element name=″RevisionPlan″>
 < xs:complexType mixed=″true″>
  < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
  < xs:element name=″Expiration″ type=″GemBasicType″>
   < xs:annotation>
    < xs:documentation>Time (or date) that recommendations
cease tobevalid
    < /xs:documentation>
   < /xs:annotation>
  < /xs:element>
  < xs:element name=″ScheduledReview″ type=″GemBasicType″>
   < xs:annotation>
    < xs:documentation>Future time (or date) planned to review
continuedappropriateness of recommendations
    < /xs:documentation>
   < /xs:annotation>
  < /xs:element>
 < /xs:choice>
 < xs:attribute name=″source″ type=″< xs:string″/>
 < xs:attribute name=″version″ type=″< xs:string″/>
 < xs:attribute name=″id″ type=″< xs:ID″/>
 < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
< /xs:complexType>
< /xs:element>
< xs:element name=″ImplementationPlan″>
 < xs:complexType mixed=″true″>
  < xs:choice minOccurs=″0″ maxOccurs=″unbounded″>
  < xs:element name=″ImplementationStrategy″
Type=″GemBasicType″>
   < xs:annotation>
    < xs:documentation>Specific plans for implementing
therecommendations
    < /xs:documentation>
```

```
      < /xs:annotation>
     < /xs:element>
     < xs:element name=″AnticipatedBarrier″ type=″GemBasicType″>
      < xs:annotation>
       < xs:documentation>A factor that might be expected to
impedeoperationalizationof the guideline
       < /xs:documentation>
      < /xs:annotation>
     < /xs:element>
     < xs:element name=″AnticipatedEnabler″ type=″GemBasicType″>
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promoteoperationalizationof the guideline
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      < /xs:annotation>
     < /xs:element>
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type=″GemBasicType″>
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measurable elements
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      < /xs:annotation>
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    < /xs:choice>
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    < xs:attribute name=″id″ type=″< xs:ID″/>
    < xs:attribute name=″lang″ type=″< xs:NMTOKEN″/>
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     < /xs:documentation>
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TABLE A1.1 GEM Definitions

Element	Definition
<Identity>	
<GuidelineTitle>	Complete title of the guideline
<Citation>	Bibliographic citation
<GuidelineLength>	Number of pages in printed document
<ReleaseDate>	Date on which the guideline was released to the public
<Electronic>	Information regarding sources of guideline in electronic format
<Availability>	Information regarding sources of a guideline and associated documentation
<Print>	Information regarding sources of guideline in print format
<Contact>	Person or organization to contact for additional information
<Status>	Statement of whether the guideline is original or a revised or updated version of a previously issued document
<CompanionDocument>	Refers to other documents (including Technical Reports, Consumer Guidelines, Quick Reference Guidelines) produced by the guideline developer relevant to the guideline
<QuickReferenceGuide>	A concise document that summarizes guideline recommendations for clinicians.
<TechnicalReport>	A document or document component that describes in detail the method of guideline development.
<PatientResource>	A patient-oriented summary of guideline content or a resource intended to assist patients with guideline application.
<Adaptation>	Indicates that the guideline has been adapted from another guideline
<StructuredAbstract>	A summary statement that describes a guideline using structured headings.
<GEMCutHistory>	Record of GEM file creation
<GEMCutVersion>	Identification details of the current instance of the GEM file
<GEMCutAuthor>	Individual responsible for creating this version of the GEM file
<GEMCutDate>	Date when this version of the GEM file was created
<Developer>	
<DeveloperName>	Organization(s) responsible for developing the guideline
<CommitteeName>	Formal name of committee within developer organization responsible for developing guideline
<CommitteeExpertise>	Expertise present within the group that authored guideline
<CommitteeMember>	Name of member of guideline development committee
<MemberExpertise>	Professional expertise of individual guideline committee member
<MemberConflict>	A potential source of bias (e.g., financial or intellectual) related to a panelist or potential panelist that could influence the CPG development process
<MemberRole>	Professional expertise of individual guideline committee member
<Funding>	Expected function of a committee member, for example, chair, epidemiologist, or implementation specialist
<RoleOfSponsor>	The sponsor's part in developing, modifying, and reporting the guideline.
<ConflictOfInterest>	Potential situations in which financial or other considerations may compromise, or have the appearance of compromising, a developer's professional judgment
<COIPolicy>	Principles and strategies adopted by developer to address potential conflicts
<COIDisclosure>	
<Endorser>	Organization that has endorsed the guideline
<ComparableGuideline>	Another guideline on the same or similar topic
<Purpose>	Report of potential and real conflicts of interest and how they are addressed
<MainFocus>	Primary disease/condition, treatment/intervention, health practice, service, or technology addressed in the guideline main focus
<Rationale>	Reasons for developing recommendations including why the guideline was developed/needed, e.g., evidence of practice variation or inappropriate practice
<Objective>	General goals that implementation of the guideline is intended to bring about
<AvailableOption>	Principal alternative preventive, diagnostic, or therapeutic strategies considered
<HealthOutcome>	The most important specific outcomes (health, economic, etc.) considered in the guideline.
<Exception>	Situations in which socially relevant factors permit an exception to be made in applying the guidelines; including home and family situation, constraints on health care delivery system
<IntendedAudience>	
<Users>	Intended users of guideline information
<CareSetting>	The settings in which the guideline is intended for use
<MethodOfDevelopment>	
<DescriptionEvidenceCollection>	A description of methods used to collect, identify, and retrieve scientific evidence on each question on which recommendations are based, including details on computer searches (including dates) and use of personal files and bibliographies
<NumberSourceDocuments>	Number of source documents identified
<EvidenceTimePeriod>	Publication date of earliest and most recent evidence considered
<EvidenceSelectionCriteria>	Methods used to choose the evidence that informs guideline development, including inclusion and exclusion criteria for specific studies
<RatingScheme>	Criteria for rating quality of evidence and/or strength of recommendation
<EvidenceQualityRatingScheme>	Criteria for rating quality of evidence
	Criteria for rating strength of recommendation
<RecommendationStrengthRatingScheme>	
<DescriptionEvidenceCombination>	Method of synthesis used to combine the scientific evidence quantitatively or otherwise
<CostAnalysis>	Describes any formal cost analysis performed
<SpecificationHarmBenefit>	Qualitative description of anticipated benefits and potential risks associated with implementation of guideline
<QuantificationHarmBenefit>	Quantification of benefits or risks associated with implementation of guideline
<RoleValueJudgment>	Implicit or explicit process for judging relative desirability of health, economic, and process outcomes associated with alternative practices
<RolePatientPreference>	Role of patient preferences for possible outcomes of care when the appropriateness of a clinical intervention involves a substantial element of personal choice or values
<QualifyingStatement>	Important caveat relating to a major recommendation. Identifies an area of uncertainty
<TargetPopulation>	

TABLE A1.1 *Continued*

Element	Definition
<Eligibility>	Describes population that the recommendations are intended to affect; identifies restrictions on guideline use such as within a managed care organization or geographic region
<InclusionCriterion>	A criterion whose presence is necessary for the guideline recommendations to be applicable
<InclusionCriterionCode>	Identifier selected from a standard terminology that describesan inclusion criterion
<ExclusionCriterion>	A criterion whose presence excludes the applicability of the recommendations
<ExclusionCriterionCode>	Identifier selected from a standard terminology that describes an exclusion criterion
<KnowledgeComponents>	
<StatementOfFact>	A non-executable statement intended by the author to describe appropriate care. This category includes US Preventive Services Task Force “I Statements”, that is., the authors conclude that there is insufficient evidence to support a recommendation for or against such an action
<Recommendation>	Statement of appropriate practice and the conditions under which it is to be undertaken. The statement is intended to influence practitioners’ behavior and/or patient outcomes. A number or brief title for a specific recommendation should be stored in this element
<RecommendationNotes>	Additional comments related to the development of the recommendation
<Conditional>	A recommendation applicable under circumstances specified by an if-then statement. The complete text of the conditional statement should be stored in this element
<BenefitHarmAssessment>	The outcome of weighing benefits against risks, harms and costs that expresses equilibrium or imbalance
<DecisionVariable>	A condition that must be tested to indicate the appropriateness of a conditional recommendation. Store only a single variable in each decision variable element
<DecisionVariableCode>	Identifier selected from a standard terminology that describes a decision variable
<Value>	A specified state of a decision variable
<DecisionVariableDescription>	Text that provides and amplifies information about a decision variable
<TestParameter>	Information about the quality of a decision variable
<Sensitivity>	An indication of the probability of the decision variable being present under specific clinical circumstances
<Specificity>	An indication of the probability of the decision variable being absent under specific clinical circumstances
<PredictiveValue>	An indication of the probability of an outcome occurring when a particular value of the decision variable is present
<DecisionVariableCost>	The cost of testing a decision variable
<Action>	Appropriate activity to be carried out given the specific circumstances defined by values of decision variables
<ActionValue>	A specified state of an action
<ActionType>	A categorization of activity directed by a conditional
<ActionBenefit>	An improvement in status of some measured outcome that may occur as a result of following a recommendation
<ActionRiskHarm>	Risk or adverse outcome associated with a specified action
<ActionDescription>	Text that provides and amplifies information about an action
<IntentionalVagueness>	An indication of the reason for deliberate underspecification of a recommendation’s conditions or actions
<ActionCost>	Cost of performing a specific action
<ActionActor>	The person(s) or role intended to carry out the recommended activity
<ActionVerb>	The word or phrase in a recommendation that expresses action, state, or relationship
<ActionVerbComplement>	Word or phrase that completes the sense of a verb and includes direct and indirect objects
<ActionDeonticTerm>	The word or phrase that defines the level of obligation or permission of an action
<ActionCode>	Identifier selected from a standard terminology that describes an action
<Reason>	An explanation or justification for a recommendation
<EvidenceQuality>	An indication of methodologic rigor of the studies that support the specified recommendation
<EvidenceQualityDescription>	Description of the applicability, quantity (including completeness) and consistency of the aggregate available evidence. It may include an explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation
< Disagreement >	Description and explanation of any differences of opinion regarding the recommendation, including minority report
<RecommendationStrength>	An indication of the guideline developers’ level of support for a given recommendation based on their confidence in the balance of anticipated benefits and costs, harms, and risks
<RecommendationStrengthCode>	Identifier selected from a standard terminology that describes recommendation strength
<Flexibility>	Indication of options in performing imperative
<Logic>	Boolean operators that indicate how the decision variables and actions in a given conditional are to be combined
<Cost>	Overall cost of performing this recommendation
<Goal>	The state that a recommendation is intended to achieve, maintain, or avoid
<Linkage>	Indicator of a relationship between this recommendation and other knowledge component(s)
<Reference>	Specific literature citation relevant to this conditional a recommendation
<Certainty>	Indication of the likelihood that this recommendation will lead to specified outcomes
<Imperative>	Recommendation directed at the entire target population without limitation. The complete text of the imperative statement should be stored in this element
<BenefitHarmAssessment>	The outcome of weighing benefits against risks, harms and costs that expresses equilibrium or imbalance
<Scope>	Implicit eligibility criteria for an imperative statement
<ScopeCode>	Identifier selected from a standard terminology that describes the scope
<Directive>	An appropriate activity for the eligible population. Store only a single activity in each Directive element
<DirectiveBenefit>	An improvement in status that may occur as a result of following a directive
<DirectiveRiskHarm>	Risk or adverse outcome associated with implementation of a directive
<DirectiveDescription>	Text that provides and amplifies information about a directive
<IntentionalVagueness>	An indication of the reason for deliberate underspecification of a recommendation’s conditions or actions
<DirectiveCost>	Cost of performing a specific directive
<DirectiveActor>	The person(s) or role intended to carry out the recommended activity
<DirectiveVerb>	The word or phrase in a recommendation that expresses action, state, or relationship
<DirectiveVerbComplement>	Word or phrase that completes the sense of a verb and includes direct and indirect objects
<DirectiveDeonticTerm>	The word or phrase that defines the level of obligation or permission of a directive
<DirectiveCode>	Identifier selected from a standard terminology that describes a directive

TABLE A1.1 *Continued*

Element	Definition
<Reason>	An explanation or justification for a recommendation
<EvidenceQuality>	An indication of methodologic rigor of the studies that support a recommendation
< EvidenceQualityDescription >	Description of the applicability, quantity (including completeness) and consistency of the aggregate available evidence. It may include an explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation
<Disagreement>	Description and explanation of any differences of opinion regarding the recommendation, including minority report
<RecommendationStrength>	An indication of the guideline developers' level of support for a given recommendation based on their confidence in the balance of anticipated benefits and costs, harms, and risks
<RecommendationStrengthCode>	Identifier selected from a standard terminology that describes recommendation strength
<Flexibility>	Indication of options in performing imperative
<Logic>	Boolean operators that indicate how directives are to be combined
<DirectiveValue>	The specified state of a directive
<Directive Type>	A categorization of activity directed by an imperative
<Cost>	Overall cost of performing an imperative recommendation
<Goal>	The state that a recommendation is intended to achieve, maintain, or avoid
<Linkage>	Indicator of a relationship between this recommendation and other knowledge component(s)
<Reference>	Specific citation relevant to this imperative recommendation
<Certainty>	Indication of the likelihood that this recommendation will lead to specified outcomes
<Term>	A word or phrase defined in the guideline
<TermMeaning>	Precise meaning of words and phrases that may be unfamiliar to guideline readers; terms are defined as used in this guideline context
<BackgroundInformation>	Information relevant to the guideline's topic but not related to other Knowledge Components
<ResearchAgenda>	Proposal for further scientific investigation to correct identified deficiencies in the evidence base for this guideline topic
<Algorithm>	A flowchart representation of the stages and activities in health management described by the guideline
<ActionStep>	Specifies clinical actions that are to be performed in the patient-care process (GLIF)
<ConditionalStep>	Directs flow from one guideline step to another based on the evaluation of a criterion (GLIF)
<BranchStep>	Directs flow in alternate directions (GLIF)
<SynchronizationStep>	Synchronization Step represents a convergence of other steps (GLIF)
<Testing>	
<ExternalReview>	Methods of eliciting peer review comments and vetting of guideline draft
<FormalAppraisal>	Evaluation of the guideline draft to appraise its validity and usability (e.g., COGS), quality (e.g., AGREE) and implementability (e.g., GLIA)
<PilotTesting>	Preliminary validation testing
<RevisionPlan>	A statement indicating whether or not there is a plan to update the guideline
<Expiration>	Time (or date) that recommendations cease to be valid
<ScheduledReview>	Future time (or date) planned to review continued appropriateness of recommendations
<ImplementationPlan>	
<ImplementationStrategy>	Specific plans for implementing the recommendations
<AnticipatedBarrier>	A factor that might be expected to impede operationalization of the guideline
<AnticipatedEnabler>	A factor that might be expected to promote operationalization of the guideline
<PerformanceMeasure>	Guideline-derived tool to measure the quality of care they provide by defining specific, measurable elements