Designation: E 2210 – 02

An American National Standard

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

This standard is issued under the fixed designation E 2210; 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 covers a document type definition (DTD) that specifies 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 DTD*—This specification defines a standard DTD for clinical practice guidelines. The DTD 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 *ASTM Standards:*

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems[3]

E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)[3]

E 1633 Specification for Coded Values Used in the Electronic Health Record[3]

E 2182 Specification for Clinical XML DTDs in Healthcare[3]

E 2183 Guide for XML DTD Design, Architecture and Implementation[3]

2.2 *W3C World Wide Web Consortium:*

XML 1.0 Recommendation [4]

XHTML Basic Recommendation [5]

XLINK [6]

Namespaces Recommendation [7]

XSL/XSLT [8]

Schemas [9]

2.3 *HL7 Standards:*[10]

Informative Document: Using XML as an Alternative Message Syntax for HL7, Version 2.3.x

Clinical Document Architecture

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

[1] This specification is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.28 on Electronic Health Records.

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

[3] *Annual Book of ASTM Standards*, Vol 14.01.

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

[5] http://www.w3.org/TR/2000/REC-xhtml-basic-20001219

[6] http://www.w3.org/XML/Linking

[7] http://www.w3.org/TR/REC-xml-names/

[8] http://www.w3.org/Style/XSL/

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

[10] http://www.HL7.org

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 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 *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. Schema is a W3C term for the next generation of DTDs.

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.[11]

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.[12]

3.2.3 *guidelines interchange format (GLIF)*—a proposed representation for guideline logic created by the INTERMED Collaboratory.[13]

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.[14]

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 E 2210 DTD is based on the GEM knowledge representation. It is intended to be:

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

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

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

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

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 E 2210 DTD store the actual language of the guideline, thereby remaining true to the original. Moreover, this DTD does not require recommendation knowledge to be structured in a temporal sequence, an often artificial transformation necessary for algorithmic representations.

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 E 2210 DTD 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 E 2210 DTD 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.[15] 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 DTD specified in this specification in order to conform to this specification.

5. Procedure

5.1 *GEM Document Structure*—The architecture of the clinical document is described in another ASTM standard, Guide E 2183. Each clinical document has a header and a body. The structure of the guideline header is specific to the GEM DTD defined in this specification. The structure of the body is unique to each document type. Elements of the body may contain content or serve as XLinks to external content. Additionally the DTD may make use of namespaces to resolve conflicts with other XML standards and XHTML tags.

5.2 *GEM Architecture*—The root level of this Specification E 2210 DTD is the guideline document. At the next tier, the model defines header and body elements. The <guideline-.header> includes identity and developer elements. The <guideline.body> includes purpose, <intended.audience>, <method.of.development>, <target.population>, <knowledge-.components>, testing, and revision elements. Each of these elements comprises one or more additional levels of guideline constructs.

5.3 *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. A small number of metalevel tags provide information about the guideline that has been interpreted, for example, <developer-.type>. To distinguish whether an element's content is explicitly stated within the guideline document or was inferred by the person who performed the markup, each element has an attribute called "source." The source attribute can take values of "explicit," "inferred," or in some cases "NGC" (to indicate that the National Guidelines Clearinghouse structured vocabulary is used).

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 <release.date>, 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 patient education materials, foreign language versions, quick reference guides, and technical reports, a construct for <companion-.document> is included. An entry stored in the adaptation element identifies whether the guideline has been adapted from another publication.

5.5 *Developer*—The organization responsible for development of the guideline is identified and described. A <developer.type> element (for example, medical specialty society, federal government agency, managed care organization) provides a structured description of the guideline's sponsor. The formal name of the committee within the developing organization, as well as its members' names and individual or committee expertise, are represented. In addition, sources of financial support for the guideline's development, 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 elements describe the main health practices, services, or technologies addressed by the guideline and the reasons for the guideline's development. Guideline category classifies the major focus of the guideline, for example, diagnosis, treatment, or prevention. The rationale for guideline development (for example, evidence of inappropriate practice or wide practice variation) is subtly different from the

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

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 <health.outcomes> element stores the specific health outcomes or performance measures that the guideline is intended to affect. The <available.options> 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. Strategies, performance measures, and plans for implementing the recommendations may be stored in the <implementation-.strategies> element.

5.7 *Intended Audience*—The <intended.audience> for a guideline refers to the healthcare providers whose behavior the guideline is intended to influence. It includes constructs for both the clinician and the <care.setting> in which a guideline recommendation may be applicable, for example, office, intensive care unit, or a particular health maintenance organization. The <clinical.specialty> element applies the NGC structured vocabulary to categorize the intended users.

5.8 *Method of Development*:

5.8.1 The validity of a guideline's recommendations is closely tied to concepts incorporated in <method.of.development>. 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 <description.evidence.collection> element refers to approaches taken by the guideline developers to identify and retrieve scientific evidence. The <method.evidence.collection> stores an NGC structured construct; <number.source.documents> refers to the number of documents identified during evidence collection. The <evidence.time.period> refers to the publication dates of the evidence. The <method.evidence.grading> stores criteria used to gauge the quality of information from different sources and may include a formal <rating-.scheme>. The <method.evidence.combination> 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 <specification.harm.benefit> describes qualitatively the anticipated benefits, potential risks, or adverse consequences associated with implementing the guideline recommendations, while <quantification.harm.benefit> provides an element for storing mathematical models and numeric estimates.

5.8.4 The <role.value.judgment> 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 <role.patient.preference> in determining policies is explicitly declared and stored within this element.

5.9 *Target Populations*—The <target.population> refers to the group of individuals who are the subject of the guideline recommendations. Eligibility criteria includes <inclusion.criterion> and <exclusion.criterion> that determine the specific portion of the target population for which recommendations are applicable. The NGC specifies gender and age ranges for categorization of the target population.

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

5.11 *Revision Plan*—The date of "Scheduled Review and Expiration Date" for the guideline recommendations store data that help to determine the validity of the recommendations in light of new evidence.

5.12 *Knowledge Components*—The <knowledge.components> store and categorize the expert knowledge that is the salient feature of clinical practice guidelines. Knowledge components are classified into three high-level classes, recommendation, definition, and algorithm, because the subelements of each of these call for different approaches to processing. Each of the knowledge components and its subtree in the Specification E 2210 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 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 <decision.variable> 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 actions. Reason elements explain why the action has been triggered. The <evidence.quality> that led the guideline developers to call for a particular recommendation and the <recommendation.strength> that they attach to a particular recommendation are tagged in appropriately named elements. 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. 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.

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 <test.parameters> for individual decision variables (sensitivity, specificity, <predictive.value>) and benefits and risks or harms associated with individual actions. In contrast to conditional recommendations, imperative recommendations present broadly applicable directives (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. With the exception of <decision.variable> 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.

5.12.2 *Definition*—A definition element stores important guideline terminology, as well as the meaning of the terms.

5.13 *Algorithm*:

5.13.1 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.

5.13.2 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*) <action.step>, which specifies a clinical action that is to be performed in the patient-care process, (*2*) <conditional.step>, which directs flow from one guideline step to another based on the evaluation of a criterion, (*3*) <branch-.step>, which directs flow in alternate directions, and (*4*) <synchronization.step>, which represents a convergence of other steps.

6. Precision and Bias

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

6.2 *Testing*:

6.2.1 The DTDs have been tested against several validators. An online XML document validator produced by the Brown University Scholarly Technology Group (STG) is available.[16]

6.2.2 *Other Online Validators Include*:

6.2.2.1 The Language Technology Group at The University of Edinburgh (Scotland).[17]

6.2.2.2 The W3C web validator.[18]

6.3 *Facilitation of Validation*—In order to facilitate such online testing, the DTDs and sample documents have been placed in a directory.[19] This directory will contain links software demonstrating use of the Guide E 2183 DTDs and schemata as they are developed.

6.4 *XML Tools*—There is a good deal of inconsistency in parsing and validating against the W3C XHTML Basic 1.0 recommendation. In particular, XML Authority 2.0 reports many warnings as errors (for example, undefined elements). Many warnings are generated from the XHTML Basic DTDs, for example, regarding DTD defaulted namespace declarations. These are actually warnings, not errors, and do not affect document validity.

6.5 *XML Browsers*—Microsoft's IE5 frequently hangs when attempting to parse XML files with external DTD subsets. The solution is to remove the <!DOCTYPE> declaration when browsing XML files using IE5 and use the MSXML as a nonvalidating parser. For this reason, compliant documents must not depend on DTD attribute defaulting and must explicitly include attribute values for #FIXED attributes.

6.6 *Guideline Tools*:

6.6.1 A wide variety of published practice guidelines has been marked up using the GEM DTD. Committee E31 has devised a GEM editor (GEM Cutter) that facilitates encoding guideline content.

6.6.2 In addition, Committee E31 has devised several XSL stylesheets that promote comparison of guideline quality, when guidelines have been encoded in GEM.

7. Keywords

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

[16] http://www.stg.brown.edu/service/xmlvalid/

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

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

[19] http://www.openhealth.org/ASTM/ (for example, operative.report.example.xml)

ANNEX

(Mandatory Information)

A1. GEM DTD

```
<!--
American Society for Testing and Materials (ASTM) E2210, main-
tained by E31.28 Guideline 1.0 DTD last revised 1/30/2002

PUBLIC IDENTIFIER ″-//ASTM//DTD Guideline 1.0//EN″
XML Namespace ″http://www.openhealth.org/ASTM/guideline″
-->
<!-- the default is not to prefix namespace qualified elements -->
<!ENTITY % NS.prefixed ″IGNORE″>
<!-- prefix xlink attributes -->
<!ENTITY % XLINK.namespace.prefixed ″INCLUDE″>
<!-- base module for E31.28 XML DTDs -->
<!ENTITY % ASTM.base.module PUBLIC ″-//ASTM//DTD E2182
Base 1.0//EN″ ″ASTM.E2182.dtd″>

%ASTM.base.module;
<!-- GEM namespace -->
<!ENTITY % GEM.xmlns.attrib ″xmlns CDATA #FIXED 'http://
www.openhealth.org/ASTM/guideline'″>
<!-- common attributes -->
<!ENTITY % guideline.attrib ″
   id ID #IMPLIED
   xml:lang NMTOKEN #IMPLIED
   %xlink.simple.attrib;
″>

<!ELEMENT guideline.document (guideline.header , guideline.body
)>
<!ATTLIST guideline.document %GEM.xmlns.attrib; %astm.docu-
ment.attrib;>

<!ELEMENT guideline.header (identity | developer )*>
<!ATTLIST guideline.header %guideline.attrib; >

<!ELEMENT identity (guideline.title | citation | release.date | avail-
ability | status | companion.document | adaptation )*>
<!ATTLIST identity %guideline.attrib; >
<!ELEMENT guideline.title %astm.content;>
<!ATTLIST guideline.title %guideline.attrib; >
<!ELEMENT citation (#PCDATA | %ASTM.Mix; | guideline.length )*>
<!ATTLIST citation %guideline.attrib; >
<!ELEMENT guideline.length %astm.content;>
<!ATTLIST guideline.length %guideline.attrib; >
<!ELEMENT release.date %astm.content;>
<!ATTLIST release.date %guideline.attrib; >
<!ELEMENT availability (#PCDATA | %ASTM.Mix; | electronic | print
| contact )*>
<!ATTLIST availability %guideline.attrib; >
<!ELEMENT electronic %astm.content;>
<!ATTLIST electronic %guideline.attrib; >
<!ELEMENT print %astm.content;>
<!ATTLIST print %guideline.attrib; >
<!ELEMENT contact %astm.content;>
<!ATTLIST contact %guideline.attrib; >
<!ELEMENT status %astm.content;>
<!ATTLIST status %guideline.attrib; >
<!ELEMENT companion.document (#PCDATA | %ASTM.Mix; | pa-
tient.resource )*>
<!ATTLIST companion.document %guideline.attrib; >
<!ELEMENT patient.resource %astm.content;>
<!ATTLIST patient.resource %guideline.attrib; >
<!ELEMENT adaptation %astm.content;>
<!ATTLIST adaptation %guideline.attrib; >


<!ELEMENT developer (developer.name | committee.name | funding
| endorser | comparable.guideline )*>
```

```
<!ATTLIST developer %guideline.attrib; >
<!ELEMENT developer.name (#PCDATA | %ASTM.Mix; | developer-
.type )*>
<!ATTLIST developer.name %guideline.attrib; >
<!ELEMENT developer.type %astm.content;>
<!ATTLIST developer.type source (ngc) ″ngc″>
<!ATTLIST developer.type id ID #IMPLIED>
<!ATTLIST developer.type Options CDATA #IMPLIED>
<!ELEMENT committee.name (#PCDATA | %ASTM.Mix; | commit-
tee.expertise | committee.member )*>
<!ATTLIST committee.name %guideline.attrib; >
<!ELEMENT committee.expertise %astm.content;>
<!ATTLIST committee.expertise %guideline.attrib; >
<!ELEMENT committee.member (#PCDATA | %ASTM.Mix; | mem-
ber.expertise )*>
<!ATTLIST committee.member %guideline.attrib; >
<!ELEMENT member.expertise %astm.content;>
<!ATTLIST member.expertise %guideline.attrib; >
<!ELEMENT funding %astm.content;>
<!ATTLIST funding %guideline.attrib; >
<!ELEMENT endorser %astm.content;>
<!ATTLIST endorser %guideline.attrib; >
<!ELEMENT comparable.guideline %astm.content;>
<!ATTLIST comparable.guideline %guideline.attrib; >

<!ELEMENT guideline.body (purpose | intended.audience | develop-
ment.method | target.population | knowledge.components | testing |
revision.plan )*>
<!ATTLIST guideline.body %guideline.attrib; >

<!ELEMENT purpose (main.focus | category | rationale | objective |
available.option | implementation.strategy | health.outcome | excep-
tion )*>
<!ATTLIST purpose %guideline.attrib; >
<!ELEMENT main.focus %astm.content;>
<!ATTLIST main.focus %guideline.attrib; >
<!ELEMENT category %astm.content;>
<!ATTLIST category source (ngc) ″ngc″>
<!ATTLIST category id ID #IMPLIED>
<!ATTLIST category Options CDATA #IMPLIED>
<!ELEMENT rationale %astm.content;>
<!ATTLIST rationale %guideline.attrib; >
<!ELEMENT objective %astm.content;>
<!ATTLIST objective %guideline.attrib; >
<!ELEMENT available.option %astm.content;>
<!ATTLIST available.option %guideline.attrib; >
<!ELEMENT implementation.strategy %astm.content;>
<!ATTLIST implementation.strategy %guideline.attrib; >
<!ELEMENT health.outcome %astm.content;>
<!ATTLIST health.outcome %guideline.attrib; >
<!ELEMENT exception %astm.content;>
<!ATTLIST exception %guideline.attrib; >

<!ELEMENT intended.audience (users | care.setting )*>
<!ATTLIST intended.audience %guideline.attrib; >
<!ELEMENT users (#PCDATA | %ASTM.Mix; | clinical.specialty |
professional.group )*>
<!ATTLIST users %guideline.attrib; >
<!ELEMENT clinical.specialty %astm.content;>
<!ATTLIST clinical.specialty source (ngc ) 'ngc'
                                id ID #IMPLIED
                                Options CDATA #IMPLIED >
<!ELEMENT professional.group %astm.content;>
<!ATTLIST professional.group source (ngc ) 'ngc'
                                id ID #IMPLIED
                                Options CDATA #IMPLIED >
<!ELEMENT care.setting %astm.content;>
<!ATTLIST care.setting %guideline.attrib; >

<!ELEMENT development.method (description.evidence.collection |
evidence.time.period | method.evidence.grading | description.evi-
dence.combination | cost.analysis | specification.harm.benefit |
quantification.harm.benefit | role.value.judgment | role.patient.prefer-
ence | qualifying.statement )*>
<!ATTLIST development.method %guideline.attrib; >
<!ELEMENT description.evidence.collection (#PCDATA |%ASTM-
.Mix; | method.evidence.collection | number.source.documents )*>
<!ATTLIST description.evidence.collection %guideline.attrib; >
```

```
<!ELEMENT method.evidence.collection %astm.content;>
<!ATTLIST method.evidence.collection source (ngc ) 'ngc'
                                    id ID #IMPLIED
                                    Options CDATA #IMPLIED >
<!ELEMENT number.source.documents %astm.content;>
<!ATTLIST number.source.documents %guideline.attrib; >
<!ELEMENT evidence.time.period %astm.content;>
<!ATTLIST evidence.time.period %guideline.attrib; >
<!ELEMENT method.evidence.grading (#PCDATA | %ASTM.Mix; |
rating.scheme )*>
<!ATTLIST method.evidence.grading source (ngc ) 'ngc'
                                    id ID #IMPLIED
                                    Options CDATA #IMPLIED >
<!ELEMENT rating.scheme %astm.content;>
<!ATTLIST rating.scheme %guideline.attrib; >
<!ELEMENT description.evidence.combination (#PCDATA | %AST-
M.Mix; | method.evidence.combination )*>
<!ATTLIST description.evidence.combination %guideline.attrib; >
<!ELEMENT method.evidence.combination %astm.content;>
<!ATTLIST method.evidence.combination source (ngc ) 'ngc'
                                    id ID #IMPLIED
                                    Options CDATA #IMPLIED >
<!ELEMENT cost.analysis %astm.content;>
<!ATTLIST cost.analysis %guideline.attrib; >
<!ELEMENT specification.harm.benefit %astm.content;>
<!ATTLIST specification.harm.benefit %guideline.attrib; >
<!ELEMENT quantification.harm.benefit %astm.content;>
<!ATTLIST quantification.harm.benefit %guideline.attrib; >
<!ELEMENT role.value.judgment %astm.content;>
<!ATTLIST role.value.judgment %guideline.attrib; >
<!ELEMENT role.patient.preference %astm.content;>
<!ATTLIST role.patient.preference %guideline.attrib; >
<!ELEMENT qualifying.statement %astm.content;>
<!ATTLIST qualifying.statement %guideline.attrib; >

<!ELEMENT target.population (eligibility | age | sex )*>
<!ATTLIST target.population %guideline.attrib; >
<!ELEMENT eligibility (#PCDATA | %ASTM.Mix; | inclusion.criterion
| exclusion.criterion )*>
<!ATTLIST eligibility %guideline.attrib; >
<!ELEMENT inclusion.criterion %astm.content;>
<!ATTLIST inclusion.criterion %guideline.attrib; >
<!ELEMENT exclusion.criterion %astm.content;>
<!ATTLIST exclusion.criterion %guideline.attrib; >
<!ELEMENT age %astm.content;>
<!ATTLIST age source (ngc ) 'ngc'
                                    id ID #IMPLIED
                                    Options CDATA #IMPLIED >
<!ELEMENT sex %astm.content;>
<!ATTLIST sex source (ngc ) 'ngc' id ID #IMPLIED Options CDATA
#IMPLIED >
<!ELEMENT knowledge.components (recommendation | definition |
algorithm )*>
<!ATTLIST knowledge.components %guideline.attrib; >
<!ELEMENT recommendation (#PCDATA | %ASTM.Mix; | condi-
tional | imperative )*>
<!ATTLIST recommendation %guideline.attrib; >
<!ELEMENT conditional (#PCDATA | %ASTM.Mix; | decision.vari-
able | action | reason | evidence.quality | recommendation.strength |
flexibility | logic | cost | link | reference | certainty )*>
<!ATTLIST conditional %guideline.attrib; >
<!ELEMENT decision.variable (#PCDATA | %ASTM.Mix; | value |
decision.variable.description | test.parameter | decision.variable.cost
)*>
<!ATTLIST decision.variable source CDATA #IMPLIED id ID #IM-
PLIED
decision.variable.id CDATA #IMPLIED >
<!ELEMENT value %astm.content;>
<!ATTLIST value %guideline.attrib; >
<!ELEMENT decision.variable.description %astm.content;>
<!ATTLIST decision.variable.description %guideline.attrib; >
<!ELEMENT test.parameter (#PCDATA | %ASTM.Mix; | sensitivity |
specificity | predictive.value )*>
<!ATTLIST test.parameter %guideline.attrib; >
<!ELEMENT sensitivity %astm.content;>
<!ATTLIST sensitivity %guideline.attrib; >
<!ELEMENT specificity %astm.content;>
<!ATTLIST specificity %guideline.attrib; >
```

```
<!ELEMENT predictive.value %astm.content;>
<!ATTLIST predictive.value %guideline.attrib; >
<!ELEMENT decision.variable.cost %astm.content;>
<!ATTLIST decision.variable.cost source CDATA #IMPLIED id ID
#IMPLIED >
<!ELEMENT action (#PCDATA | %ASTM.Mix; | action.benefit | ac-
tion.risk.harm | action.description | action.cost )*>
<!ATTLIST action source CDATA #IMPLIED id ID #IMPLIED
   action.id CDATA #IMPLIED >
<!ELEMENT action.benefit %astm.content;>
<!ATTLIST action.benefit %guideline.attrib; >
<!ELEMENT action.risk.harm %astm.content;>
<!ATTLIST action.risk.harm %guideline.attrib; >
<!ELEMENT action.description %astm.content;>
<!ATTLIST action.description %guideline.attrib; >
<!ELEMENT action.cost %astm.content;>
<!ATTLIST action.cost %guideline.attrib; >
<!ELEMENT reason %astm.content;>
<!ATTLIST reason %guideline.attrib; >
<!ELEMENT evidence.quality %astm.content;>
<!ATTLIST evidence.quality %guideline.attrib; >
<!ELEMENT recommendation.strength %astm.content;>
<!ATTLIST recommendation.strength %guideline.attrib; >
<!ELEMENT flexibility %astm.content;>
<!ATTLIST flexibility %guideline.attrib; >
<!ELEMENT logic %astm.content;>
<!ATTLIST logic %guideline.attrib; >
<!ELEMENT cost %astm.content;>
<!ATTLIST cost %guideline.attrib; >
<!ELEMENT link %astm.content;>
<!ATTLIST link %guideline.attrib; >
<!ELEMENT reference %astm.content;>
<!ATTLIST reference %guideline.attrib; >
<!ELEMENT certainty %astm.content;>
<!ATTLIST certainty %guideline.attrib; >

<!ELEMENT imperative (#PCDATA | %ASTM.Mix; |directive | reason
| evidence.quality | recommendation.strength | flexibility | logic | cost
| link | reference | certainty )*>
<!ATTLIST imperative %guideline.attrib; >
<!ELEMENT directive (#PCDATA | %ASTM.Mix; |directive.benefit |
directive.risk.harm | directive.description | directive.cost )*>
<!ATTLIST directive source CDATA #IMPLIED id ID #IMPLIED
   directive.id CDATA #IMPLIED >
<!ELEMENT directive.benefit %astm.content;>
<!ATTLIST directive.benefit %guideline.attrib; >
<!ELEMENT directive.risk.harm %astm.content;>
<!ATTLIST directive.risk.harm %guideline.attrib; >
<!ELEMENT directive.description %astm.content;>
<!ATTLIST directive.description %guideline.attrib; >
<!ELEMENT directive.cost %astm.content;>
<!ATTLIST directive.cost %guideline.attrib; >
<!ELEMENT definition (#PCDATA | %ASTM.Mix; | term )*>
<!ATTLIST definition %guideline.attrib; >
<!ELEMENT term (#PCDATA | %ASTM.Mix; | term.meaning )*>
<!ATTLIST term %guideline.attrib; >
<!ELEMENT term.meaning %astm.content;>
<!ATTLIST term.meaning %guideline.attrib; >
<!ELEMENT algorithm (#PCDATA | %ASTM.Mix; |action.step | con-
ditional.step | branch.step | synchronization.step )*>
<!ATTLIST algorithm %guideline.attrib; >
<!ELEMENT action.step %astm.content;>
<!ATTLIST action.step %guideline.attrib; >
<!ELEMENT conditional.step %astm.content;>
<!ATTLIST conditional.step %guideline.attrib; >
<!ELEMENT branch.step %astm.content;>
<!ATTLIST branch.step %guideline.attrib; >
<!ELEMENT synchronization.step %astm.content;>
<!ATTLIST synchronization.step %guideline.attrib; >
<!ELEMENT testing (external.review | pilot.testing )*>
<!ATTLIST testing %guideline.attrib; >
<!ELEMENT external.review (#PCDATA | %ASTM.Mix; | review-
.method )*>
<!ATTLIST external.review %guideline.attrib; >
<!ELEMENT review.method %astm.content;>
<!ATTLIST review.method source (ngc ) 'ngc'
                                    id ID #IMPLIED
                                    Options CDATA #IMPLIED >
```

```
<!ELEMENT pilot.testing %astm.content;>
<!ATTLIST pilot.testing %guideline.attrib; >
<!ELEMENT revision.plan (expiration | scheduled.review )*>
<!ATTLIST revision.plan %guideline.attrib; >
<!ELEMENT expiration %astm.content;>
<!ATTLIST expiration %guideline.attrib; >
<!ELEMENT scheduled.review %astm.content;>
<!ATTLIST scheduled.review %guideline.attrib; >
```

TABLE A1.1 GEM Definitions

Element	Definition
<identity>	
<guideline.title>	Complete title of the guideline
<citation>	Bibliographic citation
<guideline.length>	Number of pages in printed document
<release date>	Date on which the guideline was released to public
<electronic>	Information regarding sources of guideline in electronic format
<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 a revised or updated version of a previously issued document
<companion.document>	Other documents (including technical reports, consumer guidelines, quick reference guidelines) produced by the guideline developer relevant to the guideline
<patient.resource>	Patient resources that are directly related, that is, derived and/or prepared from the guideline
<adaptation>	Indication that the guideline has been adapted from another guideline
<developer>	
<developer.name>	Organization(s) responsible for developing the guideline
<developer.type>	Classification of organization type of developer (NGC)
<committee.name>	Formal name of committee within developer organization responsible for developing guideline
<committee.expertise>	Group composition or expertise, or both, present within the group that authored guideline
<committee.member>	Name(s) of developer committee member(s)
<member.expertise>	Background or expertise of an individual guideline committee member
<funding>	Source of financial support for guideline development
<endorser>	Organization that has endorsed the guideline
<comparable.guideline>	Another guideline on the same or similar topic cited in the document
<purpose>	
<main.focus>	Primary disease/condition, health practice, service, or technology addressed in the guideline
<category>	Classification of major focus of the guideline (NGC)
<rationale>	Reasons for developing recommendations including why the guideline was developed/needed, for example, evidence of practice variation or inappropriate practice
<objective>	Goals and objectives that implementation of the guideline is intended to bring about
<available.option>	Main management options considered; principal alternative preventive, diagnostic, or therapeutic strategies available
<implementation.strategy>	Specific strategies, aims, performance measures, or plans for implementing the recommendations and expected barriers
<health.outcome>	The most important specific outcomes or performance measures considered in the guideline; includes pt outcomes and diagnostic test performance characteristics
<exception>	Situations in which socially relevant factors permit an exception to be made in applying the guidelines; include home and family situation, constraints on healthcare delivery system (IOM)
<intended.audience>	
<users>	Intended users of guideline information
<clinical.specialty>	Classification of the clinical specialties that might use the guideline professionally (NGC)
<professional.group>	Classifies the groups intended to use the guideline (NGC)
<care.setting>	The settings in which guideline is intended for use
<method.of.development>	
<description.evidence.collection>	Methods used to collect, identify, and retrieve scientific evidence on which recommendations are based, including details on computer searches and use of personal files and bibliographies
<method.evidence.collection>	Classification of methods used to collect evidence (NGC)
<number.source.documents>	Number of source documents identified by methods described above
<evidence.time.period>	Publication date of earliest and most recent evidence considered
<method.evidence.grading>	Criteria used to gauge the quality of information collected (NGC)

TABLE A1.1 *Continued*

Element	Definition
<rating.scheme>	Criteria for rating quality of evidence and/or strength of recommendation
<description.evidence.combination>	Formal method of synthesis used to combine the scientific evidence quantitatively or otherwise; formal expert or group judgment techniques used to reach professional consensus
<method.evidence.combination>	Classification of methods used by developer to synthesize the evidence (NGC)
<cost analysis>	Describes any formal cost analysis performed
<specification.harm.benefit>	Qualitative description of anticipated benefits and potential risks associated with implementation of guideline
<quantification.harm.benefit>	Quantification of benefits or risks associated with implementation of guideline
<role.value.judgment>	Implicit or explicit process for judging relative desirability of health, economic, and process outcomes associated with alternative practices
<role.patient.preference>	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
<qualifying.statement>	Important caveat relating to a major recommendation. Identifies an area of uncertainty; disclaimer
<target.population>	
<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
<inclusion.criterion>	Criterion whose presence is necessary for the guideline recommendations to be applicable
<exclusion.criterion>	Criterion whose presence excludes the applicability of the recommendations
<age>	Classification of a population subgroup by age to whom recommendations are applicable (NGC)
<sex>	Classification of a population subgroup by gender to whom recommendations are applicable (NGC)
<knowledge.components>	
<recommendation>	Statement of appropriate practice that is intended to influence practitioners' behavior. A number or brief title for a specific recommendation should be stored in this element
<conditional>	Recommendation applicable under circumstances specified by an if-then statement. The complete text of the conditional statement should be stored in this element
<decision.variable>	Condition that must be tested to indicate the appropriateness of a conditional recommendation. Store only a single variable in each decision variable element
<value>	Specified state of a decision variable
<decision.variable.description>	Text that provides and amplifies information about a decision variable
<test.parameter>	Information about the quality of a decision variable
<sensitivity>	Indication of the probability of the decision variable being present under specific clinical circumstances
<specificity>	Indication of the probability of the decision variable being absent under specific clinical circumstances
<predictive.value>	Indication of the probability of an outcome occurring when a particular value of the decision variable is present
<decision.variable.cost>	Cost of testing a decision variable
<action>	Appropriate activity to be carried out given the specific circumstances defined by values of decision variables. Store only a single action each action element
<action.benefit>	Improvement in status of some measured outcome that may occur as a result of following a recommendation
<action.risk.harm>	Risk or adverse outcome associated with a specified action
<action.description>	Text that provides and amplifies information about an action
<action.cost>	Cost of performing a specific action
<reason>	Explanation or justification for a recommendation
<evidence.quality>	Indication of methodologic rigor of the studies that support the specified recommendation
<recommendation.strength>	ndication of the guideline developers' level of support for a given recommendation
<flexibility>	Indication of optional actions
<logic>	Boolean operators that indicate how the decision variables and actions in a given conditional are to be combined
<cost>	Overall cost of performing a specific conditional recommendation
<linkage>	Indicator of a relationship between this conditional 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
<directive>	An appropriate activity for the eligible population. Store only a single activity in each directive element
<directive.benefit>	An improvement in status that may occur as a result of following a directive
<directive.risk.harm>	Risk or adverse outcome associated with implementation of a directive
<directive.description>	Text that provides and amplifies information about a directive
<directive.cost>	Cost of performing a specific directive
<reason>	An explanation or justification for a recommendation
<evidence.quality>	An indication of methodologic rigor of the studies that support a recommendation
<recommendation.strength>	An indication of the guideline developers' level of support for a given recommendation
<flexibility>	Indication of options in performing imperative
<logic>	Boolean operators that indicate how directives are to be combined
<cost>	Overall cost of performing an imperative recommendation
<linkage>	Indicator of a relationship between this imperative 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
<term.meaning>	The precise definition of the term for guideline purposes

TABLE A1.1 *Continued*

Element	Definition
<algorithm>	A sequential representation (often graphic) of stages in health management described by a guideline
<action.step>	Specifies clinical actions that are to be performed in the patient-care process (GLIF)
<conditional.step>	Directs flow from one guideline step to another based on the evaluation of a criterion (GLIF)
<branch.step>	Directs flow in alternate directions (GLIF)
<synchronization.step>	Synchronization step represents a convergence of other steps (GLIF)
<testing>	
<external.review>	Findings of individuals and groups outside the sponsoring organization regarding the recommendations of the guideline
<review.method>	Classification of methods used to review or validate the guideline (NGC)
<pilot.testing>	Preliminary validation testing
<revision.plan>	
<expiration>	Time (or date) when recommendations cease to be valid
<scheduled.review>	Future time (or date) planned to review continued appropriateness of recommendations

TABLE A1.2 XML Element Tags

<guideline.document>	Definition
<identity>	
<guideline.title>	Complete title of the guideline
<citation>	Bibliographic citation
<guideline.length>	Number of pages in printed document
<release.date>	Date on which the guideline was released to public
<availability>	
<electronic>	Information regarding sources of guideline in electronic format
<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 a revised or updated version of a previously issued document
<companion.document>	Other documents (including Technical Reports, Consumer Guidelines, Quick Reference Guidelines) produced by the guideline developer relevant to the guideline
<patient.resource>	Patient resources that are directly related, i.e., derived and/or prepared from the guideline
<adaptation>	Indication that the guideline has been adapted from another guideline
<developer>	
<developer.name>	Organization(s) responsible for developing the guideline
<developer.type>	Classification of organization type of developer(NGC)
<committee.name>	Formal name of committee within developer organization responsible for developing guideline
<committee.expertise>	Group composition and/ or expertise present within the group that authored guideline
<committee.member>	Name(s) of developer committee member(s)
<member.expertise>	Background or expertise of an individual guideline committee member
<funding>	Source of financial support for guideline development
<endorser>	Organization that has endorsed the guideline
<comparable.guideline>	Another guideline on the same or similar topic cited in the document
<purpose>	
<main.focus>	Primary disease/condition, health practice, service, or technology addressed in the guideline
<category>	Classification of major focus of the guideline (NGC)
<rationale>	Reasons for developing recommendations including why the guideline was developed/needed, for example, evidence of practice variation or inappropriate practice

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