

## Clinical Decision Support Standards Worldwide (in Health Level Seven)

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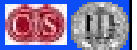
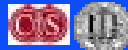
## Overview: Clinical Decision Support Standards

- HL7: Role of the SDO in KR
- Rationale for Guidelines: Knowledge dissemination
- Shareable components of computable guidelines
- Guideline models
- Convergence & the future



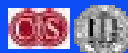
## I. Work on KR: HL7

- Growing international organization
  - 20+ international affiliates
  - participation by wide range of stakeholders: academia, vendors, government, consultants
- Moving beyond the core messaging standard
  - CDA, CCOW, Arden Syntax
- Key characteristics
  - All-volunteer organization
  - Refereed consensus process



## Improving KR of Guidelines: Focus on HL7

- Main focus: Clinical Decision Support TC
  - Arden Syntax SIG
  - Clinical Guidelines SIG
  - Electronic Health Records SIG
- Related tasks elsewhere in organization
  - Modeling and Methodology TC: HDF
  - RIM



## HL7 Clinical Decision Support Activities

- Decision Support Workbook: Identifying potential decision support standards
- Arden Syntax: Procedural medical knowledge
- Infobutton: Querying knowledge sources
- Clinical guideline formalism



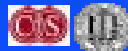
## II. Rationale for Guidelines: Evidence of Poor Performance

- **USA: Only 54.9% of adults receive recommended care for typical conditions**
  - community-acquired pneumonia: 39%
  - asthma: 53.5%
  - hypertension: 64.9%

McGlynn EA, Asch SM, Adams J et al. The quality of health care delivered to adults in the United States. *N Engl J Med* 2003;348:2635-2648.

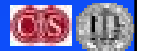
- **Delay in adoption: 10+ years for adoption of thrombolytic therapy**

Antman EM, Lau J, Kupelnick B et al. A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. Treatments for myocardial infarction. *JAMA* 1992;268(2):240-8.



## Rationale for Guidelines: What are they?

- “Systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances.” (Field MJ, Lohr KN eds. *Clinical Practice Guidelines: Directions for a New Program*. IOM, Washington, DC: NAP, 1990)
- **Guideline: Multi-step plan that unfolds over time**
  - Incorporate the latest (scientific) evidence
  - Identify a standard of care
  - Distribute to caregivers



## Rationale for Guidelines: Guideline Types

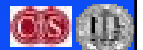
- Screening and prevention
- Diagnosis and prediagnosis management of patients
- Indications for use of surgical procedures
- Appropriate use of specific technologies and tests as part of clinical care
- Care of specific clinical conditions

Field MJ, Lohr KN eds. *Guidelines for Clinical Practice: From Development to Use*. Washington, DC: NAP, 1992.



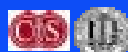
## Improving Guidelines: Incorporate in CDSS

- Use in context of systems for providing patient care
  - CPOE
  - EMR
- Use at the time decisions are being made
- Ample success for limited alerts/reminders
  - Medication prescribing practices
  - Preventive care: screening tests, immunizations
- Less demonstrated success for complex guidelines



## Challenges in Implementing Guidelines in CDSS

- Availability of data
- Identification of data: structured, controlled vocabularies
- Clinical data repositories: Data model
- Shareable knowledge representation



## Benefits of Shareable Guidelines

- Avoid duplication of effort when using common guidelines in many institutions
- Rapid dissemination of modifications
- Encourage development of tools for retrieving and using guideline information
- Encourage future guideline authors to be more rigorous (decreased ambiguity)

Ohno-Machado L, Gennari JH, Murphy SN et al. The Guideline Interchange Format: a model for representing guidelines. *JAMIA* 1998;5:357-372.



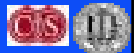
### III. Shareable Guideline Components: Challenges to Agreeing a Standard Guideline Model

- Many models: GEODE-CM, GLIF, Arden Syntax, EON, DILEMMA, PROforma, Asbru, GEM, GUIDE, PRODIGY, ...
- Many stakeholders: government, vendors, academics, professional organizations, etc
- Many types of guidelines
- Many types of (paper) guideline formats: narrative text, tables, flowcharts, graphs, maps, lists, critical pathways, if-then statements, etc



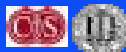
### Shareable Guideline Components: Decomposing the Problem

- Agreement on an overall standard formalism is challenging.
- Instead, first focus on shareable components:
  - Data model
  - Expression language
- Future: One or more widely implemented models with shared components
  - Shared components = ease the process of database mapping, etc



### Shareable Guideline Components: Standard Data Models

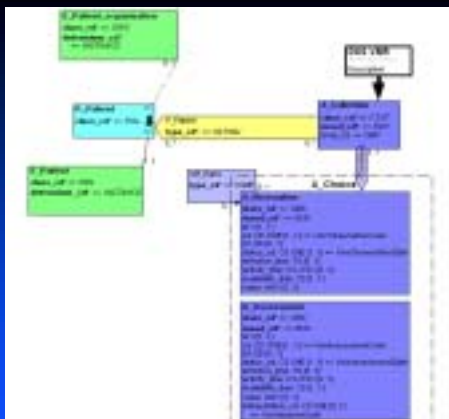
- Candidates
  - RIM = HL7 Reference Information Model
  - vMR = Virtual Medical Record
- Purpose: Standardize references to patient data
  - *Promote knowledge transfer*: One-time mapping between standard and local model, followed by automated translation at the time of transfer/execution
  - *Goal*: Avoid manual rewriting of data references



### Standard Data Model: vMR

- Problem with RIM: Too abstract
- Potential solution: Tailored version of RIM specifically for decision support
- Current work: Virtual Medical Record (SCHIN)
  - Establish distinct objects that in RIM might be high-level classes (with mood and other attributes)
- Key classes: patient, plan, procedure, medication, appointment, referral, goal and assessment

Johnson PD, Tu SW, Musen MA, Purves I. A virtual medical record for guideline-based decision support. Proc AMIA Symp 2001;:294-298.



### Standard Data Model: Not Enough

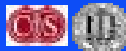
- Need standard vocabularies
- Agreement is difficult
  - Solution: Format for referring to a standard vocabulary in data references
  - Examples: SNOMED-CT, ICD-9, LOINC, CPT, etc
  - Implementation: One-time mapping between local and standard vocabularies
- Facilitation: Free licensing of SNOMED in USA as part of UMLS



## Shareable Guideline Components: Expression Language

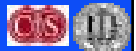
- Purposes
  - Query data (READ)
  - Logically manipulate data (IF-THEN, etc)
- Current work: GELLO (BWH) = Guideline Expression Language

Ogunyemi O, Zeng Q, Boxwala A. Object-oriented guideline expression language (GELLO) specification: Brigham and Women's Hospital, Harvard Medical School, 2002. Decision Systems Group Technical Report DSG-TR-2002-001.



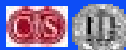
## Expression Language: GELLO

- Original goal (InterMed): Procedural component for high-level guideline format (GLIF)
- Subsequent goal: Provide similar functionality for current HL7 KR standard (Arden Syntax)
- Emphasis: Shareability of queries and expressions
- Mechanism: Reference data in OO fashion



## GELLO (continued)

- Provides basic data types
- Allows reference to underlying standard data model (vMR)
- Based on the Object Constraint Language (UML)
- Current goal: Ballot as a separate HL7 standard during the coming 12 months



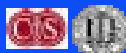
## GELLO: Examples

- Queries
  - Observation.select(coded\_concept='03245')
  - Observation.selectSorted(coded\_concept='C0428279')
- Expressions
  - The variables calcium and phosphate are not null  
calcium.notEmpty() and phosphate.notEmpty()
  - The patient has renal failure and the product of calcium and phosphate exceeds a threshold signifying osteodystrophy  
renal\_failure and calcium\_phosphate\_product > threshold\_for\_osteodystrophy



## IV. Guideline Models

- Work proceeds in parallel with shareable components
- Process: HL7 HDF
  - story board modeling process
  - work from use cases
- Candidate models
  - Arden Syntax
  - GLIF
  - GEM
  - CPGA



## Guideline Models: Arden Syntax

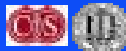
- ASTM v1 1992, HL7 v2 1999, v2.1 (ANSI) 2002
- Formalism for procedural medical knowledge
- Unit of representation = Medical Logic Module (MLM)
  - Enough logic + data to make a single decision
  - Generate alerts/reminders
- Adopted by several major vendors

Jenders RA, Dasgupta B. Challenges in implementing a knowledge editor for the Arden Syntax: knowledge base maintenance and standardization of database linkages. Proc AMIA Symp 2002;:355-359.



## Arden Syntax (continued)

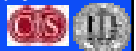
- Has been used to encode guidelines (as hierarchy of MLMs)
- Consensus: Not ideally suited for guidelines
  - Entry points and eligibility criteria (not triggers)
  - Flow of steps (not procedures)
- Ongoing work
  - Arden as a separate standard for simple alerts
  - Examine other models for guidelines
  - Standardize data mappings: Eliminate the “curly brackets”



## Guideline Model: GLIF

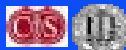
- Guideline Interchange Format
- Origin: Study collaboration in medical informatics
- Now: GLIF3
  - Very limited implementation
- Guideline = Flowchart of temporally ordered steps
  - Decision & action steps
  - Concurrency: Branch & synchronization steps

Pekg M, Ogunyemi O, Tu S et al. Using features of Arden Syntax with object-oriented medical data models for guideline modeling. Proc AMIA Symp 2001;:523-527.



## GLIF (continued): Levels of Abstraction

- Conceptual: Flowchart
- Computable: Patient data, algorithm flow, clinical actions specified
- Implementable: Executable instructions with mappings to local data



## Guideline Model: GEM

- Guideline Elements Model = Current ASTM standard
- Markup of a narrative guideline into structured format using XML
  - Not procedural programming
  - Tool = GEM Cutter
- Resulting structure might be used to translate to executable version

Shiffman RN, Agrawal A, Deshpande AM, Gershkovich P. An approach to guideline implementation with GEM. Proc Medinfo 2001;271-275.



## GEM (continued)

- Model = 100+ discrete elements in 9 major branches
  - identity and developer, purpose, intended audience, development method, target population, testing, revision plan and knowledge components
- Iterative refinement: Adds elements not present verbatim but needed for execution
- Customization: Adding meta-knowledge
  - controlled vocabulary terms, input controls, prompts for data capture



## Guideline Model: CPGA

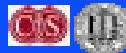
- Clinical Practice Guideline Architecture (SCHIN -> UK NHS)
- Model = Based on HL7 CDA (XML)
  - Not a programming language
  - Represents the structure of a guideline

Sowerby Centre for Health Informatics at Newcastle. Clinical practice guideline architecture, version 0.797. <http://www.schin.ncl.ac.uk/cpga> Web site accessed 24 April, 2003.



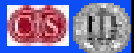
## CPGA (continued)

- **Guideline = Hierarchy of elements**
  - Header
    - Title, developer, etc
  - Body
    - Basis of evidence, recommendation, etc
- **Elements can be refined into more atomic elements**
  - Action recommendation -> recommendation ID, author, evidence, prose recommendation and structured recommendation



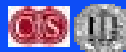
## V. Convergence and The Future

- **Ongoing work:** Use HDF to broker consensus on a computable guideline formalism
  - Proceed from real-world use cases
  - Use story board techniques
  - Resulting formalism may include elements of Arden, GLIF, GEM and CPGA
  - Ultimate result probably will include both a high-level document model and a low-level execution model



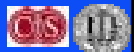
## Convergence (continued)

- **Opposing view:** A single formalism may not be possible or desirable
  - Complexity of guidelines and their purposes
  - Result: A small number of “niche” formalisms
    - Arden for simple alerts/reminders
    - Others for complex guidelines
  - A small group of formalisms would share common components (data model, vocabulary, expression language)



## The Future: Parallel Tracks

- HDF process for a guideline model
- Shareable components of a guideline model
  - Work on these components may promote consensus on an overall guideline model



## Summary

- Clinical performance is not ideal + knowledge is exploding
  - Guidelines can help
- Paper guidelines not used ideally
  - Need computable guidelines
- Knowledge sharing is fostered by standards
  - Components: Expression language, data model
  - Guideline formalism: Arden, GLIF, GEM, CPGA, etc



## Thanks!

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