GLIDES PROJECT
GuideLines Into DECision Support

sponsored by
The Agency for Healthcare Research and Quality

GEM As a CDS Standard
Briefing for ONC and AHRQ April 11, 2012
Topics

• GLIDES 4-level “stack”
  – **Narrative** guideline with quality, implementability appraisals
  – To **Semi-structured** via GEM Cutter
  – To **Semi-Formal** via EXTRACTOR, standard codes
  – To **Formal CDS** via workflow analysis, action-types design, modality selection, and local coding/linking
  – To **Formal Quality Measure** via QDM, eMeasure

• BRIDGE-Wiz, GLIDES Repository, NGC
Challenge of Representing Guideline Knowledge Electronically

Published Guideline

Black Box

Decision Support Application
Dangerous Differences: Translation of Guideline Knowledge for Decision Support

- Collaborators at Stanford, Harvard and Columbia
- **Task:** Knowledge engineers individually encoded guidelines for (1) vaccine administration and for (2) workup of breast mass into CDS
- **Test:** Submit standardized patients
- **Outcome:** Different recommendations would be given for the same patient because of different interpretations

Patel VL. JAMIA 1998
Black Box

Adapted from Shahar Y, et al. 2003
Local Clinical Objectives

Knowledge About Appropriate Care

Narrative Guideline

AGREE, COGS GLIA, IOM
Narrative to Semi-Structured

Narrative Guideline → GEM Cutter (XML Editor) → Semi-structured XML file
GEM is:

- A hierarchical model of guideline-related concepts
- Concepts have been carefully defined and standardized by an international standards development organization
Guideline CommitteeSpeak

• *Recommendation 5*...In the clinical opinion of the Update Committee (rather than direct evidence from randomized trials), postmenopausal patients intolerant of one AI but who are still candidates for adjuvant endocrine therapy may be advised to consider tamoxifen or a different AI.
In the absence of direct comparisons, the Update Committee interprets available data as suggesting that benefits of AI therapy represent a "class effect." Meaningful clinical differences between the commercially available third-generation AIs have not been demonstrated to date. In the clinical opinion of the Update Committee (rather than direct evidence from randomized trials), postmenopausal patients intolerant of one AI but who are still candidates for adjuvant endocrine therapy may be advised to consider tamoxifen or a different AI.
<Recommendation>
  <Conditional>
    In the clinical opinion of the Update Committee (rather than direct evidence from randomized trials), postmenopausal patients intolerant of one AI but who are still candidates for adjuvant endocrine therapy may be advised to consider tamoxifen or a different AI.
  </Conditional>
  <Decision.variable>postmenopausal</Decision.variable>
  <Decision.variable>intolerant of one AI</Decision.variable>
  <Decision.variable>still a candidate for adjuvant endocrine therapy</Decision.variable>
  <Action>patients may be advised to consider tamoxifen</Action>
  <Action>patients may be advised to consider another AI</Action>
  <Reason>
    the Update Committee interprets available data as suggesting that benefits of AI therapy represent a “class effect.” Meaningful clinical differences between the commercially available third-generation AIs have not been demonstrated to date.
  </Reason>
  <Evidence.Quality>clinical opinion of the Update Committee</Evidence.Quality>
</Recommendation>
Narrative Guideline

Semi-structured

EXTRACTOR Transform, Coding

Semi-formal

- Statement logic
- Coded decision variables & actions
- Reason, Evidence Quality, Rec Strength
- Action-type
A Natural Language Rule

RECOMMENDATIONS

Recommendation
Recommendation 5

Conditional:

In the clinical opinion of the Update Committee (rather than direct evidence from randomized trials), postmenopausal patients intolerant of one AI but who are still candidates for adjuvant endocrine therapy may be advised to consider tamoxifen or a different AI.

IF

postmenopausal

intolerant of one AI

candidate for adjuvant endocrine therapy

THEN

Patients may be advised to consider tamoxifen

Patients may be advised to consider a different AI
Evidence Quality: clinical opinion of the Update Committee (rather than direct evidence from randomized trials),

Strength of Recommendation: may

Reason: the Update Committee interprets available data as suggesting that benefits of AI therapy represent a “class effect.” Meaningful clinical differences between the commercially available third-generation AIs have not been demonstrated to date

Logic: If postmenopausal AND intolerant of one AI AND candidates for adjuvant endocrine therapy Then may be advised to consider tamoxifen OR may be advised to consider a different AI.
SNOMED-CT and ICD-9 Codes

- **SnoMED CT**
- Available
- 76498008 Postmenopausal state (finding) Clinical findings
- **Proxies**
- 76742009 Postmenopausal bleeding (finding) Clinical findings
- 403389006 Postmenopausal flushing (disorder) Clinical findings
- 403574001 Postmenopausal pruritus (disorder) Clinical findings
- 102447009 Postmenopausal osteoporosis (disorder) Clinical findings
- 21237001 Postmenopausal urethral atrophy (disorder) Clinical findings
- 415149004 Postmenopausal postcoital bleeding (finding) Clinical findings
- 403319002 Postmenopausal androgenetic alopecia (disorder) Clinical findings
- 232449005 Postmenopausal atrophy of vocal cord (disorder) Clinical findings
- 266677000 Menopausal and postmenopausal disorders (disorder) Clinical findings
- 403325003 Postmenopausal frontal fibrosing alopecia (disorder) Clinical findings
- 203453001 Postmenopausal osteoporosis with pathological fracture (disorder) Clinical findings
- 161788002 History of - postmenopausal bleeding (situation) Context Dependent categories
- **ICD-9**
- Available
- V49.81 asymptomatic age-related (natural) postmenopausal status
- **Proxies**
- V07.5 Prophylactic use of agents affecting estrogen receptors and estrogen levels
- V07.4 Hormone replacement therapy (postmenopausal)
- 627 Menopausal and postmenopausal disorders
- 627.1 Postmenopausal bleeding
- 627.2 Symptomatic menopausal or female climacteric states
- 627.8 Other specified menopausal and postmenopausal disorders
- 627.9 Unspecified menopausal and postmenopausal disorder
ICD-10

• No Direct Code
• Suggested Proxies
  – Osteoporosis, Postmenopausal M81.0*
  – Postmenopausal bleeding N95.0*
  – Hormone Replacement Therapy, postmenopausal Z79.80*
  – Postmenopausal atrophic vaginitis N95.2*
  – ? Unspecified menopausal and perimenopausal disorder N95.8*
  – ? Unspecified menopausal and perimenopausal disorder N95.9*
<Logic>
  IF
  
  postmenopausal is [True] (SnoMED CT: 76498008,... ; ICD-9: V49.81,...)
  
  AND
  
  Intolerance [Adverse Effect, Side Effects] (AI or Tamoxifen on Medication List with discontinue reason intolerance or side effect) to one Aromatase Inhibitor [RxNorm AI code list] (RxNorm: 105647, 199750, ...)

  THEN
  
  [May] Discuss Tamoxifen (RxNorm: 198240, 105630, ...)
  
  OR
  
  [May] Prescribe Tamoxifen (RxNorm: 198240, 105630, ...)
  
  OR
  
  [May] Discuss another Aromatase Inhibitor (RxNorm: 105647, 199750, ...)
  
  OR
  
  [May] Prescribe another Aromatase Inhibitor (RxNorm: 105647, 199750, ...)
</Logic>
Actions can be categorized reliably into 14 action-types.
Narrative Guideline

Semi-structured

Semi-formal

Statement logic
Coded decision variables & actions
Reasons, Evidence Quality, Rec Strength
Local workflow & barrier analysis
Local codes
DS modality selection

Formal
Clinical Decision Support System
<table>
<thead>
<tr>
<th>Present drug information</th>
<th>Anti-hypertensive</th>
<th>AI</th>
<th>Seizure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician (e.g., indications, on-formulary?)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Patient (how-to-take, common side-effects)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Display safety alerts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug-allergy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Drug-drug interaction</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Drug-food interaction</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Dosage calculation assistance by weight/BSA</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Corollary orders</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Palette of CDS Modalities

- Alert
- Reminder
- Documentation template
- Algorithm
- Order Facilitator
- Infobutton
- Calculator
- Flowsheet
Selected Guideline

- Asthma
  - EPR3 *Diagnosis and Management of Asthma* from the NHLBI (2007)
  - Demonstrates challenges involved in implementation of recommendations for chronic management of complex disease
### Components of Control

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Classification of Asthma Control (5–11 years of age)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well Controlled</td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤2 days/week but not more than once on each day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>≤1x/month</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>None</td>
</tr>
<tr>
<td>Short-acting beta-agonist use for symptom control (not prevention of EIB)</td>
<td>≤2 days/week</td>
</tr>
</tbody>
</table>

### Risk

<table>
<thead>
<tr>
<th>Exacerbations requiring oral systemic corticosteroids</th>
<th>0–1/year</th>
<th>&gt;2/year (see note)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in lung growth</td>
<td>Evaluation requires long-term followup.</td>
<td></td>
</tr>
</tbody>
</table>

### Harm

Recommended Action for Treatment

(See figure 4–1b for treatment steps.)

- **Regular followup every 1–6 months.**
- **Consider step down if well controlled at least 3 months.**
- **Consider short course of oral systemic corticosteroids.**
- **Step up 1–2 steps, and reevaluate in 2–3 weeks.**
- **For side effects, consider alternative treatment options.**

### Classifying Components of Asthma Severity and Initiating Treatment

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Intermittent</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough due to asthma</td>
<td>None</td>
<td>&lt;=2 days/week</td>
<td>&gt;2 days/week</td>
<td>Daily</td>
</tr>
<tr>
<td>Wheezing</td>
<td>None</td>
<td>&lt;=2 days/week</td>
<td>&gt;2 days/week</td>
<td>Daily</td>
</tr>
<tr>
<td>chest tightness</td>
<td>None</td>
<td>&lt;=2 days/week</td>
<td>&gt;2 days/week</td>
<td>Daily</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>None</td>
<td>&lt;=2 days/week</td>
<td>&gt;2 days/week</td>
<td>Daily</td>
</tr>
<tr>
<td>Nighttime awakening</td>
<td>None</td>
<td>&lt;=2x/month</td>
<td>&gt;2x/month</td>
<td>Daily</td>
</tr>
<tr>
<td>Difficulties with normal activity</td>
<td>None</td>
<td>&lt;=2x/month</td>
<td>&gt;2x/month</td>
<td>Daily</td>
</tr>
<tr>
<td>Activity limitation due to EIB</td>
<td>None</td>
<td>&lt;=2x/month</td>
<td>&gt;2x/month</td>
<td>Daily</td>
</tr>
<tr>
<td>SABA use (not for EIB)</td>
<td>None</td>
<td>&lt;=2 days/week</td>
<td>&gt;2 days/week</td>
<td>Daily</td>
</tr>
<tr>
<td>Lung function</td>
<td>FEV1 or peak flow</td>
<td>FEV1 &gt; 50% of predicted</td>
<td>FEV1 = 50–80% of predicted</td>
<td>FEV1 = 30–50% of predicted</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>&lt;75%</td>
<td>&lt;75%</td>
<td>&lt;75%</td>
<td></td>
</tr>
</tbody>
</table>

**Impairment Classification: Moderate**

<table>
<thead>
<tr>
<th>Risk</th>
<th>Acute (1 visit) due to asthma</th>
<th>1 in last year</th>
<th>2 in last year</th>
<th>3 or more in last year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehospitalization due to asthma</td>
<td>0</td>
<td>1 in last year</td>
<td>2 in last year</td>
<td>3 or more in last year</td>
</tr>
</tbody>
</table>

### Treatment-Related Adverse Effects

<table>
<thead>
<tr>
<th>Medication Adverse Effect</th>
<th>Communities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throat</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td></td>
</tr>
<tr>
<td>Sleep Disturbances</td>
<td></td>
</tr>
<tr>
<td>Decreased Appetite</td>
<td></td>
</tr>
</tbody>
</table>

**Risk Classification: Low, Asthma Severity Classification: Moderate Persistent**
Prompts for documentation

Real-time calculation and display
Information Access

Prompts for Assessments

Display of Relevant Past Information

Alert

Severity Classification: Moderate Persistent  Recommended therapy is Step 3 or 4

... Regular follow up every 1 - 6 months ...
**Quick-Relief**
Short acting B-2 agonist

<table>
<thead>
<tr>
<th>Medication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALBUTEROL NEBS 0.083% Q4 hrs PRN</td>
<td>NEW ORDER</td>
</tr>
</tbody>
</table>

**Long Term Control**
Preferred

1. Low-dose inhaled steroid
   - PULMICORT 0.25 MG BID

2. LTRA

3. COMBO

Added: Albuterol sulfate 0.083% nebu 2.5 mg .5cc with 3cc NS nebulized every 4 hours
Added: Pulmicort 0.25 mg/2ml susp 0.25 MG/ML nebulized twice a day
Narrative Guideline

Semi-structured

Semi-formal

Clinical Decision Support System

Quality Measurement System

Statement logic, action-type
Coded decision variables & actions
Reasons, Evidence Quality, Rec Strength

QDM elements
Phrases
EHR linkage
Analysis tools
The specific concept that is being represented by the QDM Element

All specific codes within a taxonomy that refer to the concept

An abstract classification for the concept being represented

A measurable activity OR the presence/absence of the concept

Specifications and qualifiers, which modify the concept being represented

Adapted from Quality Data Model – Draft October 2011
## GEM and QDM

<table>
<thead>
<tr>
<th>Guideline Elements Model</th>
<th>Quality Data Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Function</strong></td>
<td>Model clinical knowledge from guidelines</td>
</tr>
<tr>
<td><strong>Underlying Structure</strong></td>
<td>XML-Based</td>
</tr>
<tr>
<td><strong>Organization</strong></td>
<td>Hierarchical structure</td>
</tr>
<tr>
<td><strong>Temporality</strong></td>
<td>Present Tense (&quot;Clinicians should do&quot;)</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Relatively stable; a standard</td>
</tr>
</tbody>
</table>
BRIDGE-Wiz
Building Recommendations in a Developer’s Guideline Editor

• Formalizes a process for writing implementable recommendations
• Focuses discussion
• Incorporates prompts based on COGS to improve guideline quality
• Controlled natural language
  – Offers verb choices based on action-type
  – Traps and disallows use of “consider”
  – Discourages “statement of fact” masquerading as recommendation
  – Limits boolean connectors to all ANDs or ORs in a statement
• Incorporates decidability and executability checks
• Requires systematic appraisal of evidence quality and benefit-harms
  – Suggests appropriate obligation term (deontic modal)
• Output includes a high-level “rule” and an evidence profile
National Guideline Clearinghouse is Preparing to Distribute GEM-cut Versions of Selected Guidelines
GEM Was Not Designed to be Directly Executable

- GEM parses and represents natural language and its transformation into encodable concepts
- Integration of CDS with local workflow is essential
  - Technical capabilities and limitations of each EHR system will constrain the ways in which the CDS can be integrated into the workflow and delivered to clinicians
- There is a balance between the CDS design decisions that can be made centrally and those that are made locally during each implementation effort within individual practice settings.
Why GEM?

- Delivers what vendors want
  - Coded rules that can be branded and integrated
- Track record of stability and utility
- ANSI Standard
- Tools exist
- Available NOW