



GEM As a CDS Standard

Briefing for ONC and AHRQ April 11, 2012

GLIDES PROJECT **GuideLines Into DEcision Support**

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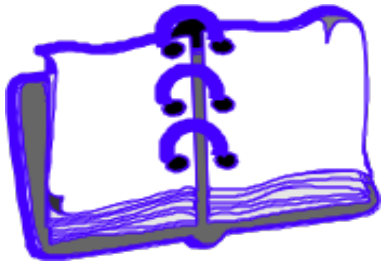


American Society of Clinical Oncology

Topics

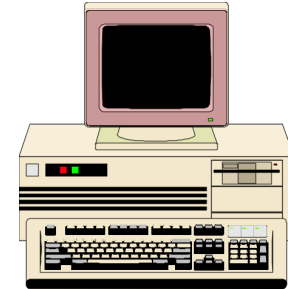
- GLIDES 4-level “stack”
 - **Narrative** guideline with quality, implementability appraisals
 - To **Semi-structured** via GEM Cutter
 - To **Semi-Formal** via EXTRACTOR, standard codes
 - To **Formal CDS** via workflow analysis, action-types design, modality selection, and local coding/linking
 - To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

Challenge of Representing Guideline Knowledge Electronically



Published Guideline

Black Box

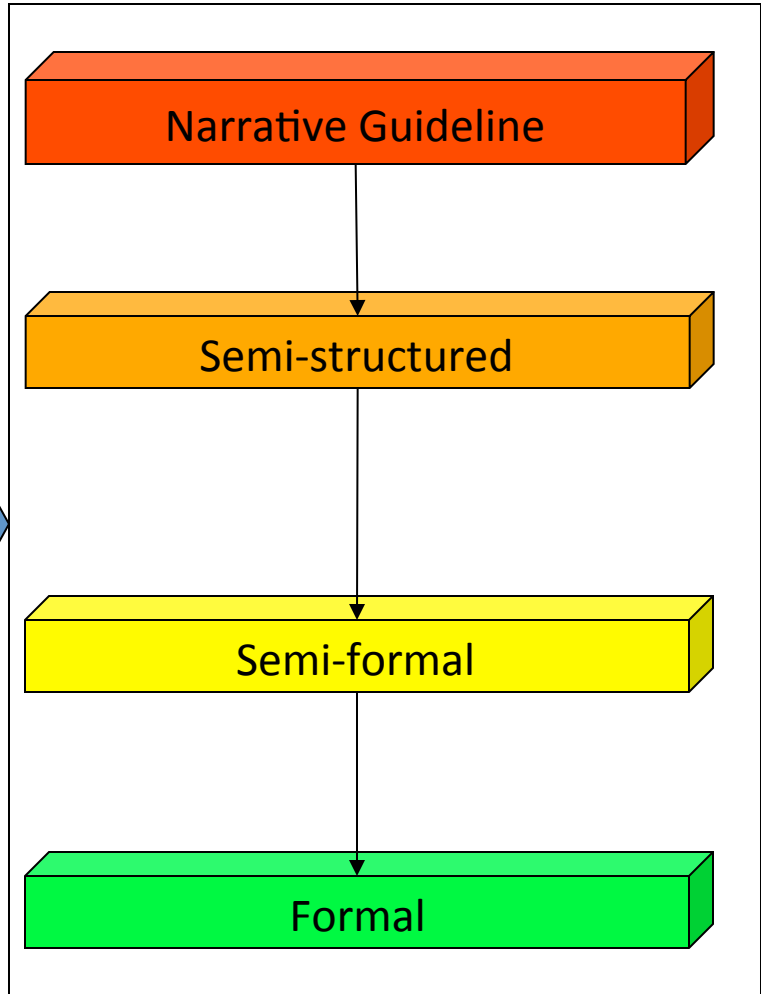
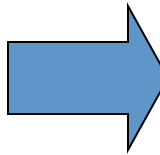


**Decision Support
Application**

Dangerous Differences: Translation of Guideline Knowledge for Decision Support

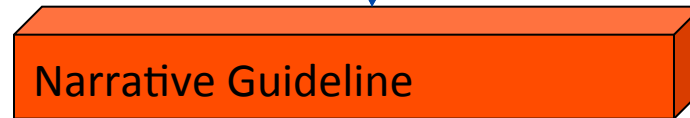
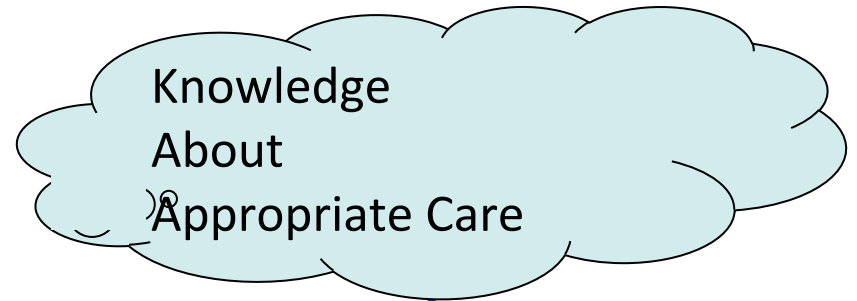
- Collaborators at Stanford, Harvard and Columbia
- **Task:** Knowledge engineers individually encoded guidelines for (1) vaccine administration and for (2) workup of breast mass into CDS
- **Test:** Submit standardized patients
- **Outcome:** Different recommendations would be given for the same patient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

Black Box

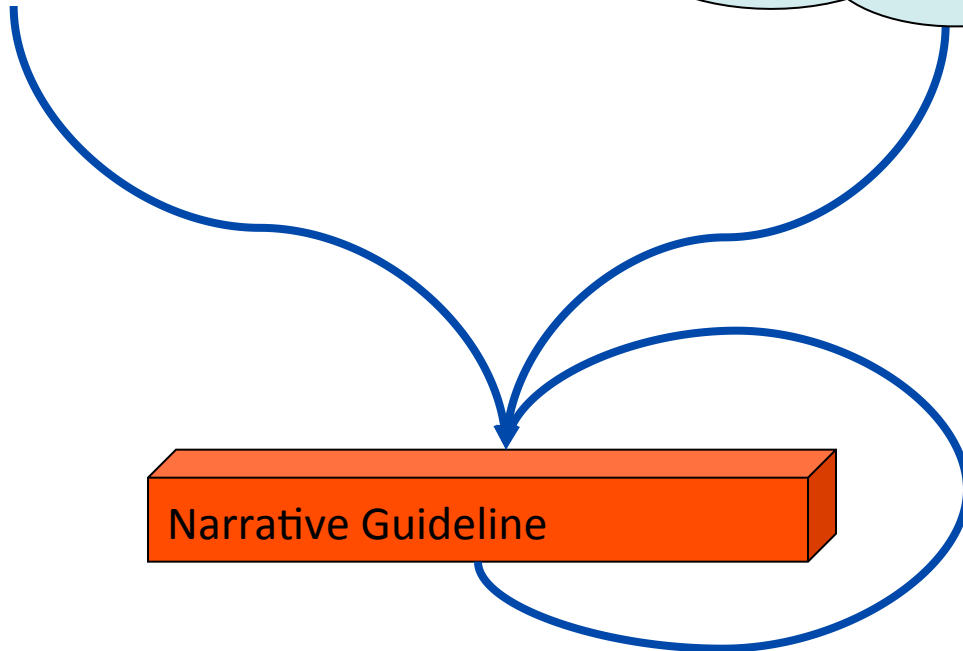


Adapted from Shahar Y, et al. 2003

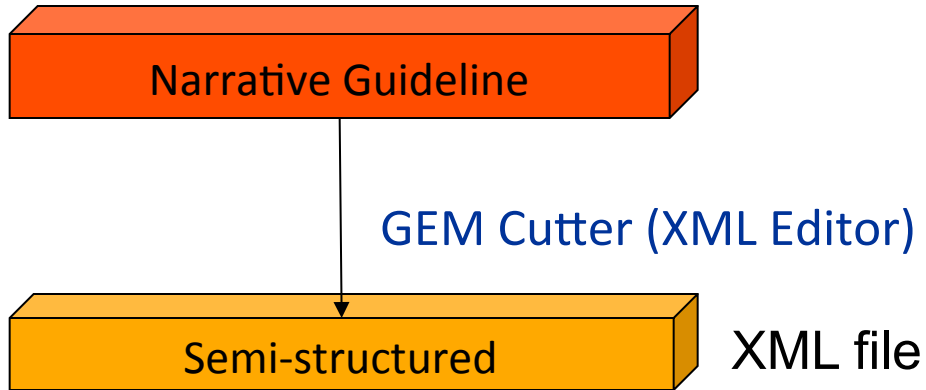
Local Clinical Objectives



AGREE, COGS
GLIA, IOM

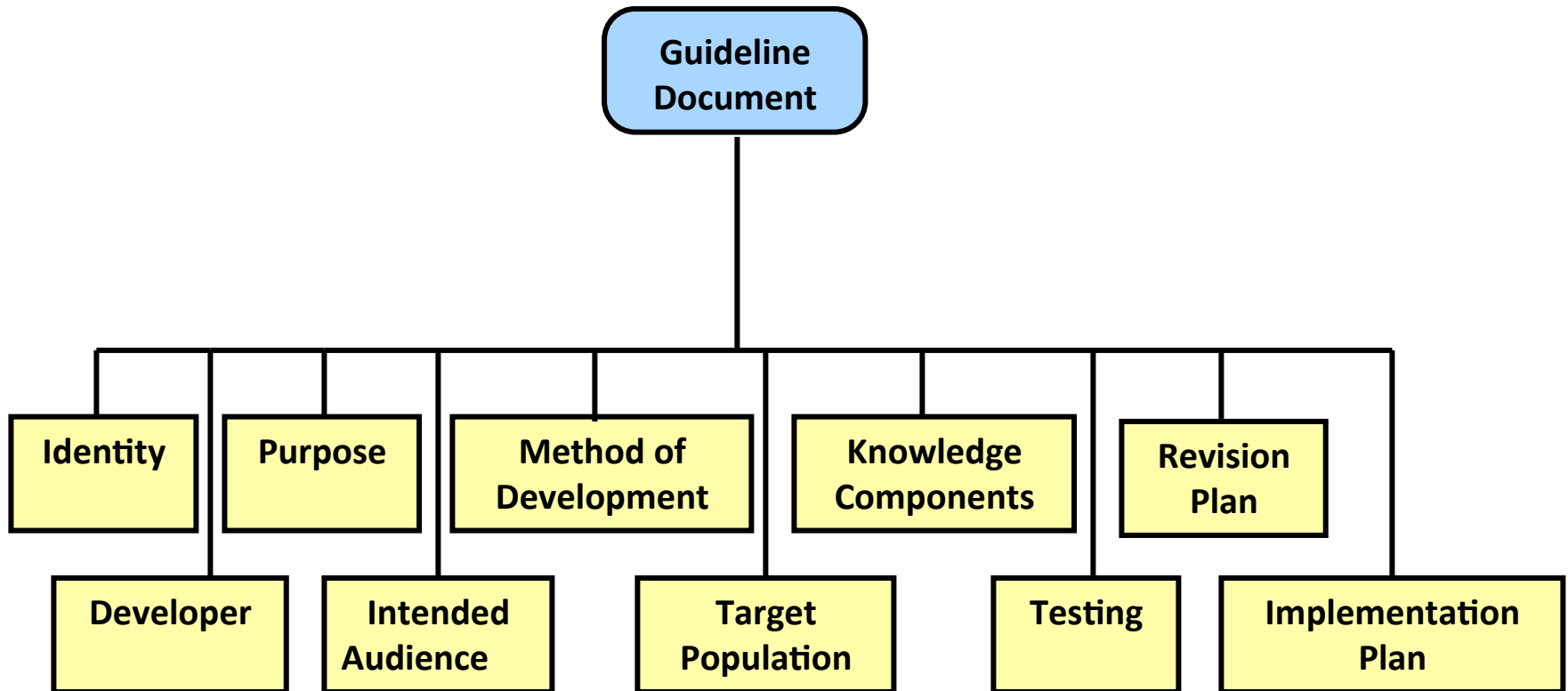


Narrative to Semi-Structured



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.

GEM Cutter (XML Editor)

GEM Cutter 2.9 Project: AromataseInhibitors

Project View Report Tree

Find All



¥ [Recommendation 5](#). 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.](#)

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        <DecisionVariable> intolerant of one AI
        <DecisionVariable> candidate for adjuvant endocrine therapy
        <Action> may be advised to consider tamoxifen
        <Action> may be advised to consider a different AI.
        <Reason> the Update Committee interprets available data as suggesting that
        <EvidenceQuality> clinical opinion of the Update Committee (rather than dire
        <RecommendationStrength> may
        <Flexibility>
        <Logic> If postmenopausal AND intolerant of one AI AND candidates for ad
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        <Certainty>
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<Reason>
test
 N/D Explicit Inferred

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

An explanation or justification for a recommendation

... XML

<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 A

<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>

</Conditional>

</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

Decidable	Vocab
Y	76498008
Y	
Y	
Executable	Vocab
?	
?	

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*

XML

<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

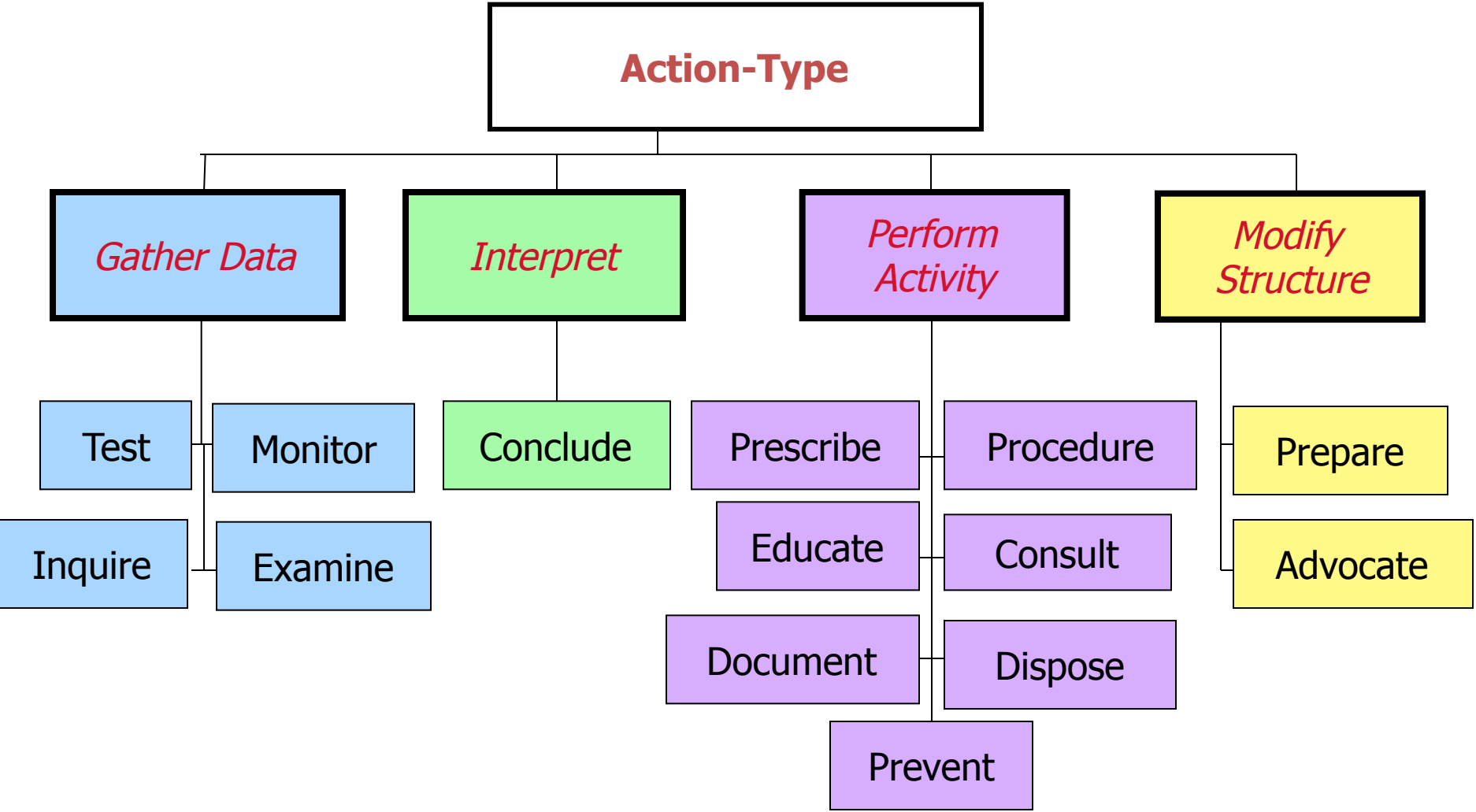
[May] Discuss another Aromatase Inhibitor (RxNorm: 105647, 199750, ...)

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

Formal

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

Local workflow & barrier analysis
Local codes
DS modality selection

Clinical Decision Support System

Prescribe

Anti-hypertensive

AI

Seizure

Present drug information			
Clinician (e.g., indications, on-formulary?)	✓	✓	
Patient (how-to-take, common side-effects)	✓	✓	
Display safety alerts			
Drug-allergy	✓	✓	✓
Drug-drug interaction	✓	✓	✓
Drug-food interaction	✓		
Dosage calculation assistance by weight/BSA		✓	✓
Corollary orders	✓	✓	✓

Palette of CDS Modalities



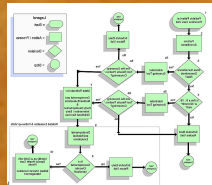
Documentation
template



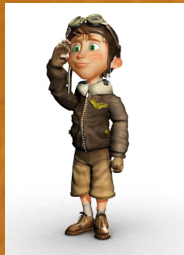
Alert



Reminder



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

FIGURE 4–3b. ASSESSING ASTHMA CONTROL AND ADJUSTING THERAPY IN CHILDREN 5–11 YEARS OF AGE

Components of Control		Classification of Asthma Control (5–11 years of age)		
		Well Controlled	Not Well Controlled	Very Poorly Controlled
Impairment	Symptoms	≤2 days/week but not more than once on each day	>2 days/week or multiple times on ≤2 days/week	Throughout the day
	Nighttime awakenings	≤1x/month	≥2x/month	≥2x/week
	Interference with normal activity	None	Some limitation	Extremely limited
	Short-acting beta ₂ -agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	Lung function • FEV ₁ or peak flow • FEV ₁ /FVC	>80% predicted/ personal best >80%	60–80% predicted/ personal best 75–80%	<60% predicted/ personal best <75%
	Exacerbations requiring oral systemic corticosteroids	0–1/year	≥2/year (see note)	
Risk	Consider severity and interval since last exacerbation			
Reduction in lung growth	Evaluation requires long-term followup.			
Treatment-related adverse effects	Medication side effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.			
Recommended Action for Treatment (See figure 4–1b for treatment steps.)	<ul style="list-style-type: none"> Maintain current step. Regular followup every 1–6 months. Consider step down if well controlled for at least 3 months. 	<ul style="list-style-type: none"> Step up at least 1 step and Reevaluate in 2–6 weeks. For side effects: consider alternative treatment options. 	<ul style="list-style-type: none"> Consider short course of oral systemic corticosteroids, Step up 1–2 steps, and Reevaluate in 2 weeks. For side effects, consider alternative treatment options. 	

Herine Flanagan

CLASSIFYING COMPONENTS OF ASTHMA SEVERITY AND INITIATING TREATMENT

Is patient currently on controller medication? yes no

Has this patients severity been classified? yes no

Assessment for: Control Severity

----- Persistent -----

Impairment ----- Intermittent ----- Mild Moderate Severe

Cough due to asthma None ≤2 days/wk >2 days/wk Daily All Day

Wheezing None ≤2 days/wk >2 days/wk Daily All Day

Chest tightness None ≤2 days/wk >2 days/wk Daily All Day

Shortness of breath None ≤2 days/wk >2 days/wk Daily All Day

Nighttime awakening None ≤2x/month 3–4x/month >1x/wk Often 7x/wk

Interference with normal activity
Reduction in school/play/work None <----- Mild Moderate Severe

SABA use (not for EB) None ≤2 days/wk >2 days/wk but not Daily Several times per

Lung Function
FEV1 or peak flow FEV>80% predict <----- <----- FEV=60-80% prec FEV<60% predict

FEV1/FVC >85% <----- >80% =75-80% <75%

Impairment Classification: Moderate

Risk

Acute/ ER visit(s) due to asthma 0 1 in last year 2 in last year 3 in last year ≥4 in last year

Hospitalizations due to asthma 0 1 in last year 2 in last year 3 in last year ≥4 in last year

Exacerbations requiring oral systemic corticosteroids 0-1/year ≥2/year

AND Risk Factors for persistent asthma

Medication Adverse Effect

Thrush

Palpitations

Jitteriness

Sleep Disturbances

Decreased Growth

Other

Comments

Risk Classification: Low

Asthma Severity Classification: Moderate Persistent

Next Form (Ctrl+PgDn) Close

Visit Type <input type="checkbox"/> Well Child <input checked="" type="checkbox"/> Asthma	Decision Support - Today Severity Class: Moderate Persistent Impairment: Moderate Risk: Low	Control Classification Control Class: Impairment: Risk: Previous Step:	Severity Classification Severity Class:
---	---	---	---

HPI Cntrl/Sev Inhaler/Env PE Asmt Tx Plan Action Plan	Provider Assessment - Today Current level of control is: <input checked="" type="radio"/> Well Controlled <input type="radio"/> Not Well Controlled <input type="radio"/> Very Poorly Controlled Inhaler Technique: <input type="radio"/> Correct <input type="radio"/> Incorrect <input checked="" type="radio"/> N/A Adherence: <input checked="" type="radio"/> N/A <input type="radio"/> Good <input type="radio"/> Fair <input type="radio"/> Poor Environmental Control: <input checked="" type="radio"/> Adequate <input type="radio"/> Inadequate <input type="radio"/> N/A
---	--

Prompts for Assessments

Display of Relevant Past Information

Severity Classification: Moderate Persistent Recommended therapy is Step 3 or 4
--- Regular follow up every 1 - 6 months ---

Intermittent Asthma	Persistent Asthma: Daily Medication			
<input type="radio"/> Step 1	<input type="radio"/> Step 2	<input checked="" type="radio"/> Step 3	<input type="radio"/> Step 4	<input type="radio"/> Step 5
Step Comments/Reason for Step Change:				

Alert

	Preferred:	Preferred: Low-dose ICS+	Preferred: Medium-dose ICS+LABA, or COMBO	Preferred: High-dose ICS+LABA, or COMBO	Preferred: High-dose ICS+LABA, or COMBO+ oral systemic corticosteroid
	Nedocromil	Medium-dose ICS	Alternative: Medium-dose ICS+LTRA	Alternative: High-dose ICS+LTRA	Alternative: High-dose ICS+ LTRA + oral systemic corticosteroid
	Consider consultation	Consult Asthma Specialist	Consult Asthma Specialist	Consult Asthma Specialist	Consult Asthma Specialist

Information Access

Narrative Guideline

Semi-structured

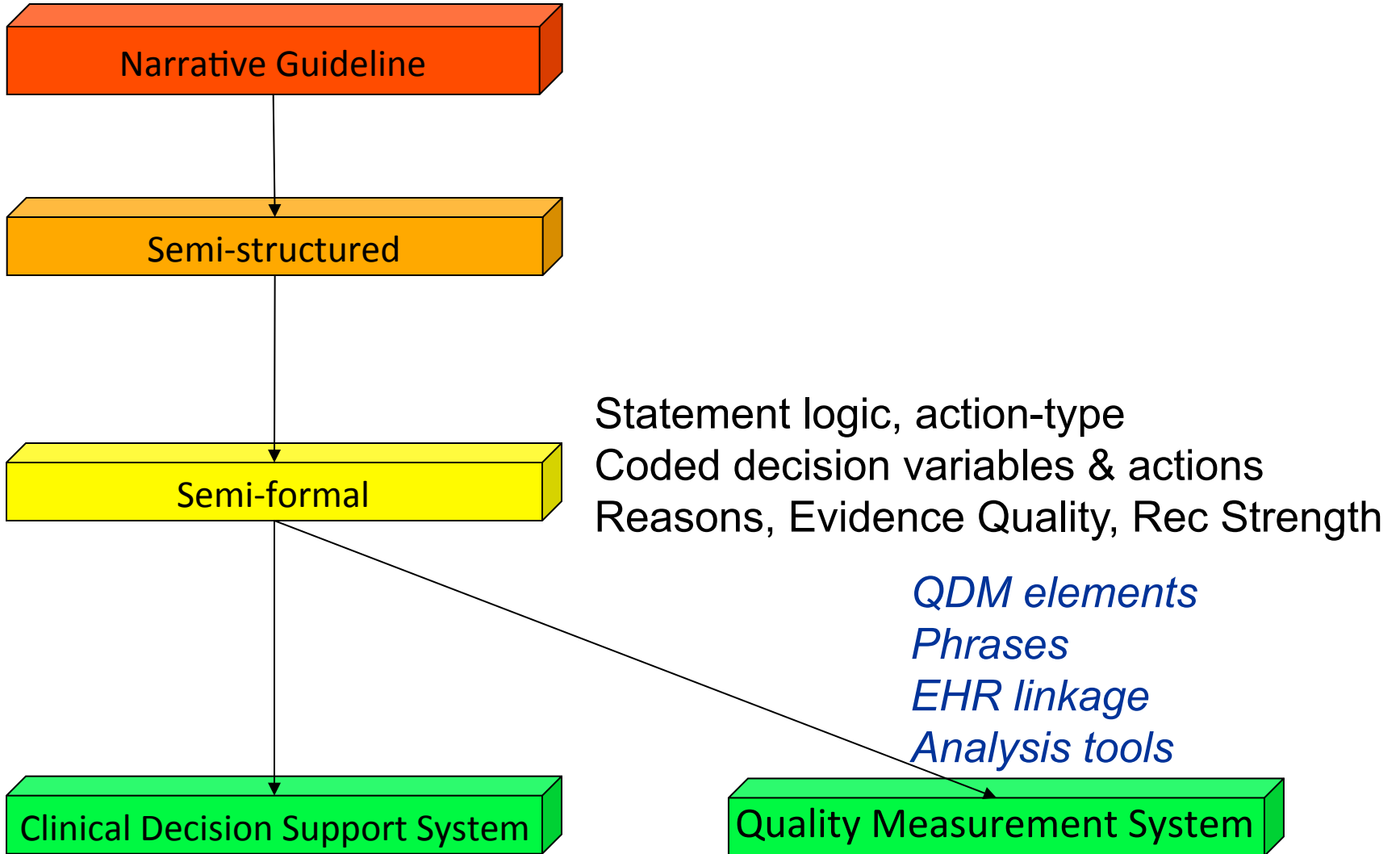
Semi-formal

Clinical Decision Support System

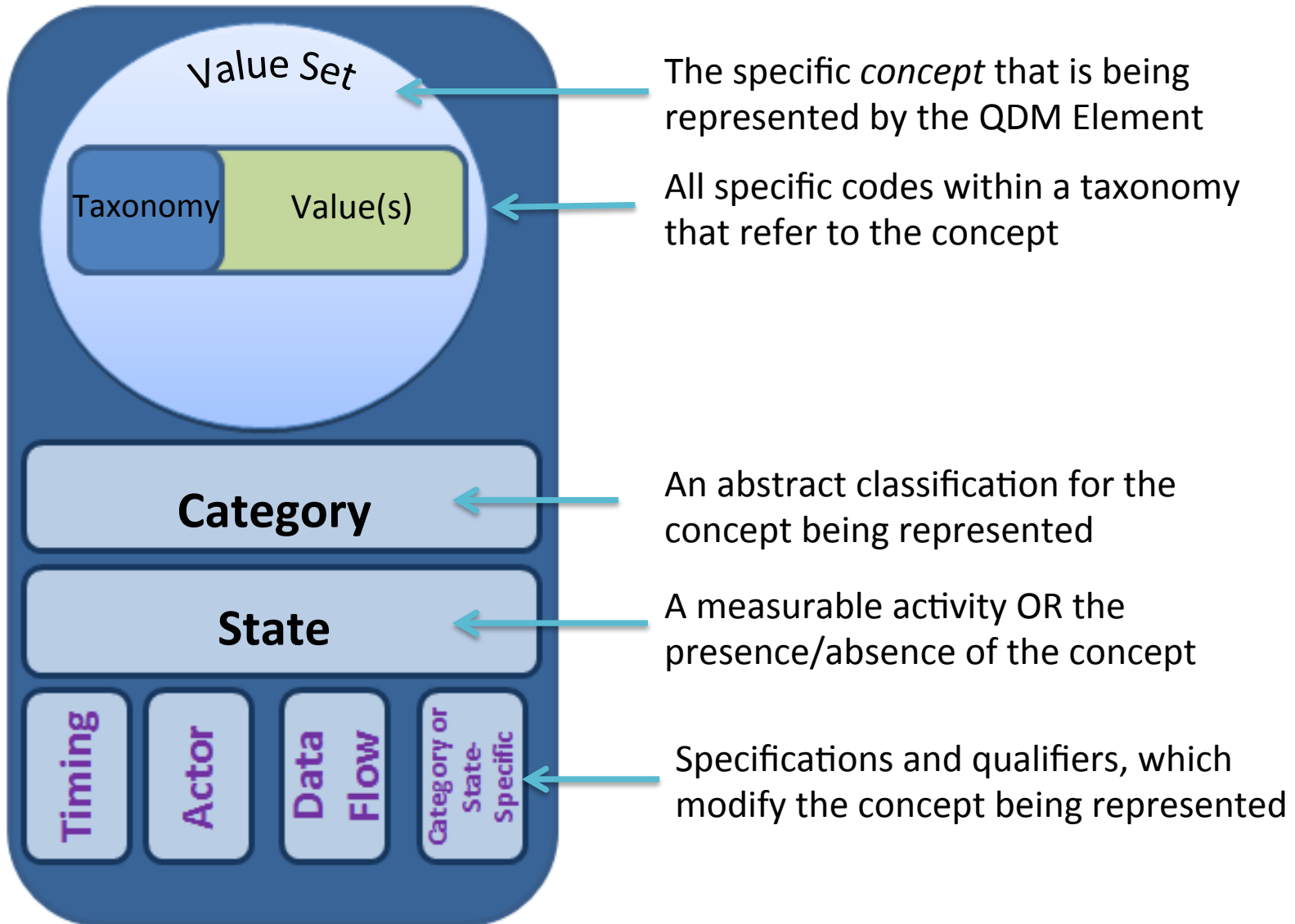
Statement logic, action-type
Coded decision variables & actions
Reasons, Evidence Quality, Rec Strength

QDM elements
Phrases
EHR linkage
Analysis tools

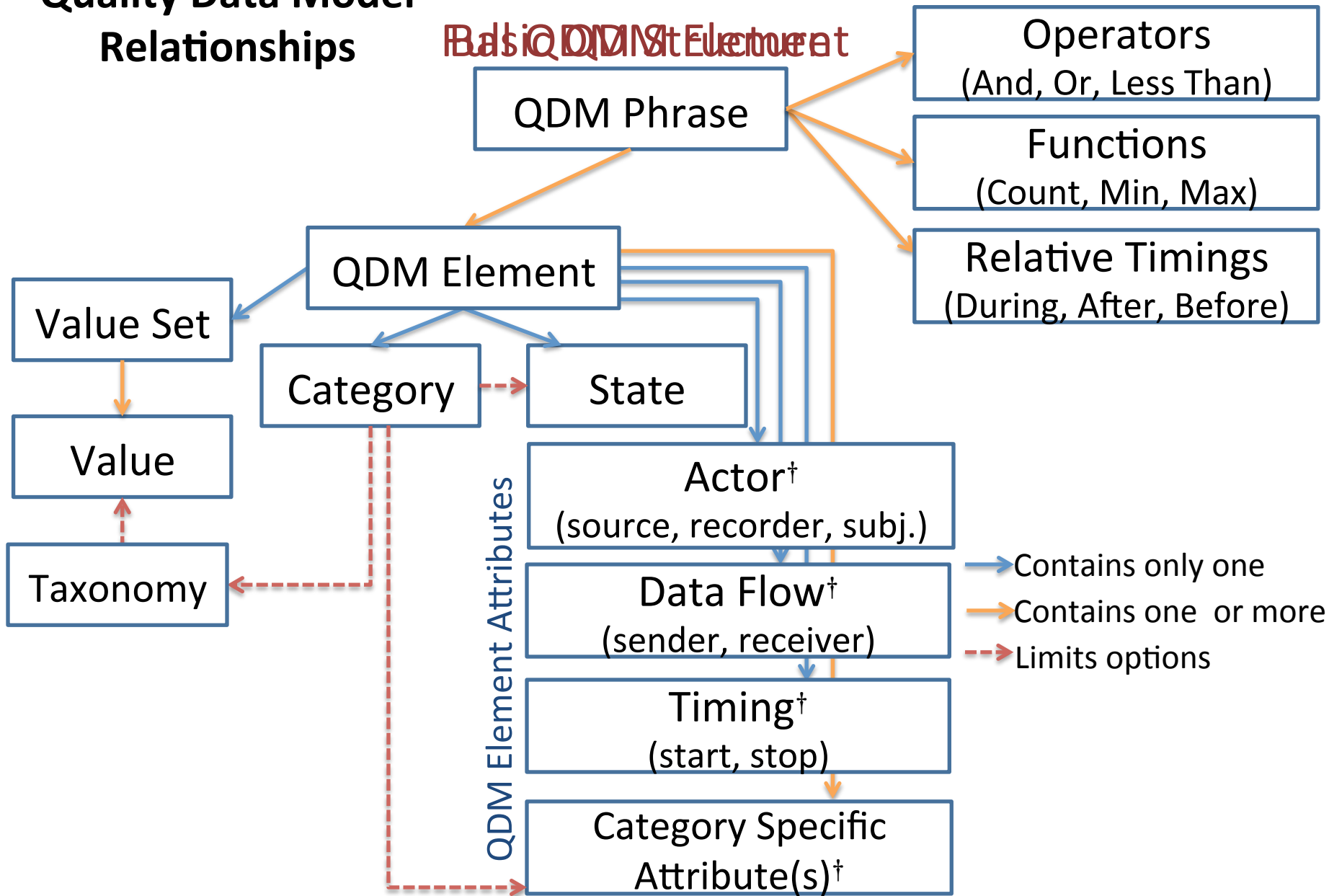
Quality Measurement System



QDM Element Overview



Quality Data Model Relationships



GEM and QDM

	Guideline Elements Model	Quality Data Model
Function	Model clinical knowledge from guidelines	Model performance measures in a facility-independent manner
Underlying Structure	XML-Based	XML-Based
Organization	Hierarchical structure	Phrases, complex interactions among components
Temporality	Present Tense ("Clinicians should do")	Past Tense ("Clinicians should have done")
Stability	Relatively stable; a standard	Continuously evolving to adapt to changing user requirements

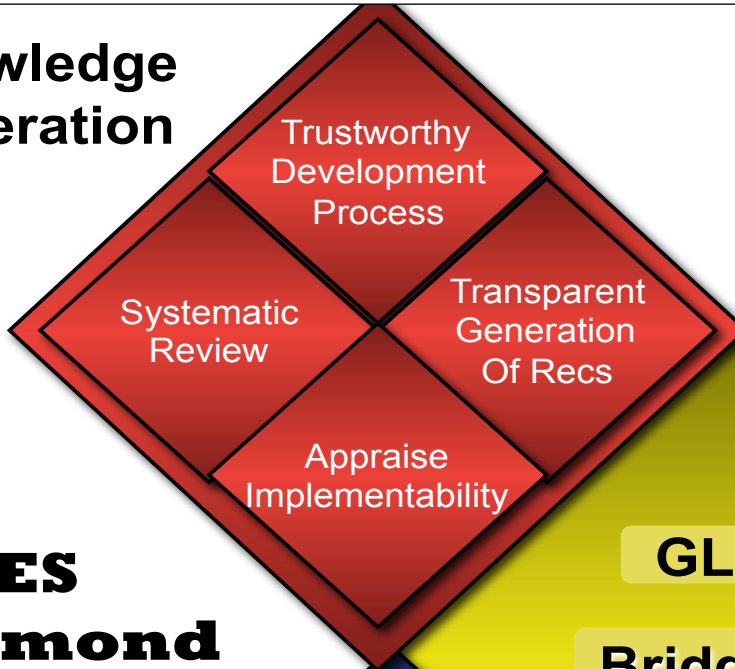
BRIDGE-Wiz



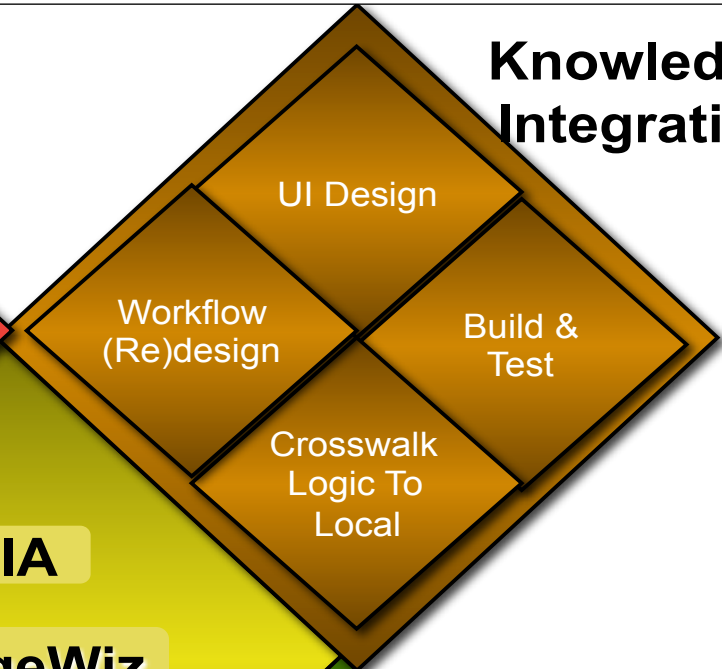
Building Recommendations in a Developer's Guideline Editor

- 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

Knowledge Generation



Knowledge Integration



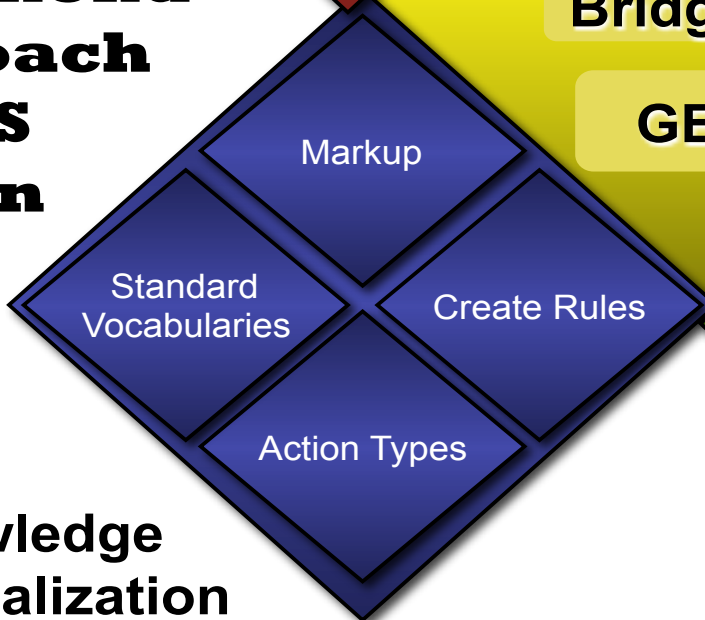
**GLIDES
4 Diamond
Approach
To CDS
Design**

GLIA

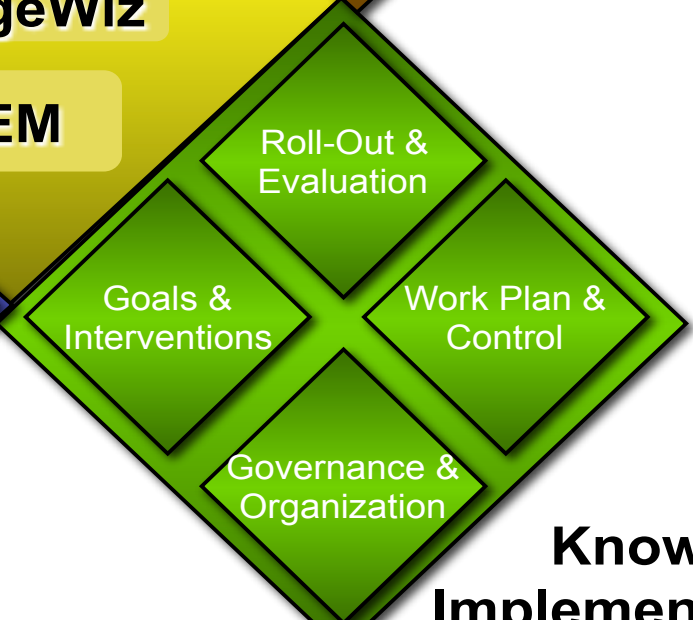
BridgeWiz

GEM

Knowledge Formalization



Knowledge Implementation



National Guideline Clearinghouse is Preparing to Distribute GEM-cut Versions of Selected Guidelines



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AHRQ Agency for Healthcare Research and Quality

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National Guideline
Clearinghouse

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Guideline Summary

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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