

GUIDES Project: CDS Implementation Methodology

Knowledge Transformation Activities

Apply the GuideLine Elements Model (GEM) and its related tools to transform the knowledge contained in the selected evidence-based clinical practice guidelines into a standardized format—i.e., XML based on the GEM Schema Standard (ASTM E2210-06) [34].

Performed For Each Guideline Selected For Implementation:

Phase / Task / Milestone	Description	Performed By	Potential Milestones/ Measurements
Appraise GuideLine Implementability (GLIA)	Prepare the implementation teams for challenges intrinsic to the selected guideline recommendations and contribute to the documentation in support of the implementation.	Transformation Team (including clinical experts)	GLIA highlights obstacles that may be anticipated when the guideline and recommendation are operationalized, including problems in <ul style="list-style-type: none"> - Decidability - Executability - Effect on process of care - Presentation and formatting - Measurable outcomes - Apparent validity - Novelty/innovation - Flexibility - Computability
Select and Classify Each Recommendation By Clinical Objective	Select recommendations for implementation. Classify each recommendation by clinical objective, describing the goals to be targeted.	Transformation Team (including clinical experts)	Osheroff and colleagues have noted that the objective class is useful in choosing specific types of clinical decision support interventions.
Mark up Selected Recommendations Using GEM Cutter II	GEM Cutter II accepts as input a guideline text file. Users mark up the file, classifying guideline text into appropriate elements of the standardized GEM II hierarchy	Transformation Team (including clinical experts)	Output is a standard XML file that comprises information critical for implementation: <ul style="list-style-type: none"> - The guideline’s intended audience - The target population of patients - The recommendations themselves including decision variables - The reason(s) for making the recommendation
Submit Guideline’s GEM file to GEM-COGS Transform	Facilitate an appraisal of the guideline’s quality. The Transform displays the Conference on Guideline Standardization checklist accompanied by pertinent text from the marked up-guideline (if present).	Transformation Team (including clinical experts)	Users can judge how well the guideline text meets COGS criteria for quality and usability (see Appendix for sample report).

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Phase / Task / Milestone	Description	Performed By	Potential Milestones/ Measurements
Apply EXTRACTOR transforms to the GEM files	EXTRACTOR is a set of Web-based XSLT transforms that are designed to automate the process of extracting this implementation-critical information from marked up guidelines.	Transformation Team (including clinical experts)	The EXTRACTOR transforms create a list of decision variables and actions for each recommendation. When “extracted” from context, it often becomes clearer which decision variables are vague, underspecified, or ambiguous. EXTRACTOR also highlights missing information that must be filled in locally by Clinical Experts. By cataloging and documenting these circumstances, we will provide feedback to guideline development teams about content that is critical for implementation but missing from the published guideline.
Adjust Level of Abstraction	Improve the decidability and executability of the recommendation statements. Clinical experts on the team will help to assure that the original intended meaning of the terms is not distorted	Transformation Team (including clinical experts)	A careful record of modifications will be logged and reviewed by an independent team of clinical experts to assure that the meaning of the implemented recommendation is consonant with the published text.
Restate in Human-Readable Statement Logic	Each recommendation will be restated in human-readable statement logic that can be translated readily into computable statements	Transformation Team (including clinical experts)	A limited number of logical operators (AND, OR, NOT, IF...THEN, GREATER/LESS/EQUAL, and parentheses) has proven sufficient to express individual guideline recommendations.
Categorize Action-Types	Help select replicable patterns for implementation. Recommendations call for a relatively small set of recurring activities (action-types).	Transformation Team (including clinical experts)	The activities associated with each of these action-types involve patterns that are useful in routinizing the translation of guideline recommendations into computer-based decision support tools. Importantly, recommendations NOT to perform any of these action-types call for different patterns of activities.
Map Concept Codes	Map concept codes for each eligibility criterion, decision variable, and action in relevant controlled vocabularies, e.g., SNOMED, LOINC and RxNORM.	Transformation Team (including clinical experts)	Terminology used by authors in the guideline document often does not match concept codes in controlled vocabularies. We will document and submit unmatched concepts to the curators of each vocabulary for future inclusion.
Add Critical Terms To Recommendation Glossary	Critical terms will be added to a recommendation glossary with precise definitions supplied by the clinical experts.	Transformation Team (including clinical experts)	We have noted a need for precise definitions of both domain-specific terms as well as common words (e.g., “routine,” “severe”) as applied in a particular guideline context if accurate

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CDSS Design and Build Activities

Phase / Task / Milestone	Description	Lead/Resources	Potential Milestones/ Measurements
Define Local Workflow (for each recommendation)	Specifically characterize when—in the course of longitudinal health care—values for the decision variables become available and when—in the course of clinical interactions—it is appropriate for the guideline-prescribed actions to occur.	Design/Build Team Implementation Team	There is a need for principled methods to overcome the disconnect between the EHR representation of time-oriented clinical data and corresponding knowledge of domain-relevant concept. For ambulatory care, Osheroff et al. have proposed temporal categories: pre-visit, arrival check-in, start of visit, results arrival, documentation, ordering, medication administration, and post visit. We will evaluate the usefulness of this classification system in our demonstrations and augment as necessary.
Define Intervention Triggers	ii. Define how the intervention is to be triggered. When in the course of longitudinal health care at a particular site are <i>all</i> the decision variables likely to be satisfied? What will be the source of the data (e.g., online registration information or laboratory reports, patient-entered history, clinical data recorded in the electronic health record, clinician documented findings)? What <i>event(s)</i> will trigger the decision support intervention?	Design/Build Team Implementation Team	
Map Guideline-Related Concepts to Local Codes	Concepts that were previously defined in the glossary and translated to standardized vocabulary concepts will next be matched to the specific vocabularies used by the GE and Epic systems.	Design/Build Team Implementation Team	Document and compare the applicability and accuracy of the controlled vocabulary terms vis-à-vis the original guideline language in mapping to local codes.
Choose Appropriate Decision Support Interventions	Interventions include (but are not limited to): Documentation templates; assessment forms for completion by patients, paraprofessionals, clinicians; Data flowsheets (combination of data display and data form entry); Presentation of relevant data for documentation or ordering; Choice lists; Order sets; Tools for complex ordering including guided dose algorithms, calculators; Context sensitive links to	Design/Build Team Implementation Team	Each of these decision support interventions differs in its appropriateness for use in a specific circumstance, ease of development, acceptability to the intended user population, and anticipated impact on health care. Selection of an appropriate intervention for a given recommendation must take these factors into account. We will document the selection process.

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	knowledge sources (infobuttons); Encounter-linked reminders; Dynamically-generated alerts		
Document Intervention Specifications	Document an Intervention Specification Form to summarize relevant considerations. We will modify a worksheet form, partially pre-populated by an EXTRACTOR Transform developed for that purpose.	Design/Build Team Implementation Team	Additional details will be added by local teams to document: (1) Clinical objective; (2) Desired action; (3) Baseline performance; (4) Desired outcome; (5) Origin of data necessary for performance (workflow step); (6) Selected decision support intervention; (7) Approach; (8) Target population; (9) User interface; (10) Primary stakeholders; (11) Clinical champion; (12) Potential adverse consequences, and other relevant documentation.
Programming	Using the documentation provided and EHR-specific programming tools, the teams will create a variety of decision support interventions appropriate to the information being delivered and the assessed workflow patterns.	Design/Build Team Implementation Team	Local Information Systems Teams at each site have accumulated considerable expertise in programming and incorporating decision support into their respective EHR systems. The systems have been widely deployed for at least 7 years at both Yale and Nemours.
Testing Should we break this out into various phases of testing?	Each proposed intervention will undergo unit testing of each software module and integration testing to highlight potential defects in the interfaces and interactions between modules to assure conformance with the specification.	Design/Build Team Implementation Team	The accuracy of the decision support interventions will be verified using test scripts that exercise the software, particularly at extremes of decision variable content. Members of each user community will participate as testers to judge the usability and acceptability of each intervention. An iterative process of programming refinement is anticipated.
Rollout	Identify clinical users (physicians and nurses) at each site who are regarded as leaders by their peers. Presentations will be made to staff members at each site that describe the importance and “mechanics” of each intervention. We will make documentation available before training sessions and train “trainers” who practice at each site. Information Systems personnel will work collaboratively with the users during rollout. Feedback channels will be incorporated to assure that users can communicate effectively with both the Implementation Group and the Decision Support Council.	Design/Build Team Implementation Team	Implementation teams at each site have extensive experience in training and response to their users’ needs. Upper level management will endorse the proposed interventions.

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Monitoring and maintenance	Each implementation Group will maintain close contact with their user communities to determine needs for corrective, perfective, or adaptive maintenance and to identify any unintended consequences of these interventions.	Design/Build Team Implementation Team	
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