Final Report

Structuring Care Recommendations for Clinical Decision Support

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Project Overview

This report summarizes the work performed under the "Structuring Care Recommendations for Clinical Decision Support" or SCRCDS project (originally named "Hardened Rules for Clinical Decision Support"[1]), which began in September 2009 and concluded in September 2011.

The project was aimed at reducing a key barrier to the use of evidence-based clinical care recommendations, namely, that there is currently no formalized process for translating narrative recommendations from prose to an unambiguous, structured and coded format that can then be adopted widely for local conversion into machine-executable clinical decision support (CDS) rules in various information systems and care settings. The hypothesis was that, if developed, a consistent method and format for translating narrative clinical care recommendations into structured, coded logic statements would facilitate the local implementation of CDS rules and, ideally, would facilitate the wider use of such rules and corresponding improvements in patient care and outcomes.

Under this contract, the Thomson Reuters-led team devised, vetted with a broad community of stakeholders, documented, and tested a formal method for transforming evidence-based clinical recommendations and performance measures into a format that can be adapted further for widespread implementation in Clinical Information Systems (CISs) and other health information technology (health IT) products. The team also developed and delivered to the Agency for Healthcare Research and Quality (AHRQ) a collection of structured recommendations in that format, referred to as eRecommendations. These are based on the 45 A and B recommendations from the U.S. Preventive Services Task Force and 12 rules relevant to Stage 1 Meaningful Use (MU) measures. In addition, two guides were created to support various stakeholders in creating and using eRecommendations. Extensive vetting with multiple stakeholders of the eRecommendation format and content—from draft to its current iteration—validated the promise of eRecommendations for improving the efficiency and effectiveness with which clinical recommendations are translated into CDS rules.

The eRecommendation project legacy extends beyond the results described above. For example, work is under way to make the eRecommendations produced under this project available on the ACDS portal. In addition, building on the eRecommendation schema, the ONC-sponsored SHARP C-2B project is creating an implementer's workbench for configuring setting specific factors (SSFs) pertinent to converting eRecommendations into locally useful CDS rules. The eRecommendations created by the SCRCDS project have been converted in the SHARP project to their enhanced XML-based schema and will be available through the Implementer's

[1] The term "hardened rules" had been intended to mean clinical recommendations that were well-grounded in evidence and accepted in clinical practice. Contrary to the purpose of the project, the title "Hardened Rules for CDS" might give a connotation of inflexible rules and "cookbook medicine." The revised title better reflects the purpose of the project as a process for developing a structure to accelerate the uptake of clinical recommendations into CDS.

Workbench repository. Finally, there is evidence that government guideline developers are pursuing contracts that extend and further tailor to public health needs the work begun with the eRecommendation project.

The result of the eRecommendation project's interplay with other related projects is that it appears to have further stimulated progress toward a "whole" (regarding CDS rule development and value) that is greater than the sum of the parts. The active engagement by a broad range of public and private stakeholders in CDS-facilitated health care performance improvement to develop and vet project deliverables is another important project by-product.

Methods

The project team was instructed by AHRQ to develop a method and format for translating clinical recommendations that went as far down the pathway to a machine-executable form as the process could be taken while still ensuring widespread value from the material. Phase 1 of the project involved gathering input from key stakeholders (gathered in a Rule Value Advisory Panel [RVAP]) who would potentially use the products from this project and designing the approach for translating care recommendations into semistructured logic statements. Background assessment and synthesis activities that informed the design of methods consisted of reviewing relevant initiatives and methods, assessing stakeholder needs, and vetting a draft format for structured recommendations.

Through these activities, it became apparent that the national push for MU of health IT, and related efforts to apply electronic health records (EHRs) to performance measurement and improvement, made it desirable for the eRecommendations project to leverage this momentum and related tools when developing methods for structuring care recommendations. Phase 2 of the project implemented the translation methods for USPSTF recommendations and a few others related to performance measures pertinent to MU.

Phase 3, conducted during the contract modification period, built on these efforts by taking steps toward widespread eRecommendation use in CDS rules, should that goal prove valuable. A key activity consisted of pilot testing the eRecommendations in two real world settings—one inpatient and one outpatient. The Memorial Hermann Health System pilot, led by Dr. Robert Murphy, CMIO, and their health IT vendor Cerner were selected for the inpatient setting because of their strong interest in the project and highly successful earlier collaboration. For the outpatient site, the pilot site team was identified through David Bergman of ONC and consisted of Bergman, staff from the Louisiana Health IT Regional Extension Center (LA REC), a small practice affiliated with Tulane led by Dr. Eboni Price-Haywood, and the practice's EHR vendor, SuccessEHS. The project team placed particular emphasis on the vendor engagement in the pilot because, in outpatient practices especially, EHR vendors play such a central role in CDS rule implementation.

Other major Phase 3 activities consisted of expanding the RVAP into a more robust "eRecommendation Stakeholder Community" spanning the CDS rule value chain to follow the pilots activities and results and to help drive eRecommendation use to scale; further fleshing out

the eRecommendation template; and developing eRecommendations for additional MU measures based on implementer need.

Lessons Learned and Suggestions

The eRecommendation project tested whether consistently structured and coded logic statements could be created in a manner that would be widely useful to those developing and implementing clinical guidance and CDS rules. The results from pilot implementation analysis and broad stakeholder feedback demonstrate that there is wide interest in the eRecommendation template and content across all stakeholder categories (such as health care provider organizations, guideline developers, EHR and CDS suppliers), and that using this material can deliver significant value. It also identified a variety of technical and related needs and opportunities to further stimulate widespread eRecommendation project deliverable value and use. Major themes of lessons learned about the process of creating eRecommendations and pursuing greater scalability that delivers on their promise are as follows:

1. **Multistakeholder community engagement.** The value of engaging multistakeholder communities (comprising diverse and interrelated constituencies) in the difficult task of producing useful CDS artifacts in this complex and dynamic informatics arena.

2. **Linkages to relevant drivers.** The importance of linking development of new CDS rule content and structures such as eRecs to powerful incentives and infrastructure relevant to stakeholders. An example is aligning the rule format and codes with corresponding elements for EHR-integrated performance assessment and reporting.

3. **Balancing universality and specificity.** The importance of ‗staying high' in the CDS rule value chain to support widespread use by not over-specifying implementation details, but at the same time considering that detailed deployment guidance is important to many implementers.

4. **Starting at guideline development.** Ideally, clinical guidance from guideline developers and others should be formulated with application to CDS rules and other intervention types in mind. The eRecommendation template offers promise of adding value in this area, but reconciliation with other current and emerging CDS rule formalisms is needed to be of greatest value to guidance suppliers.

5. **Codes as key content.** The value of structured, coded logic statements in developing CDS rules.

6. **Knowledge management.** Knowledge management issues—such as responsibility for ongoing rule/eRec maintenance—need to be addressed for scaling this work and integrating it with related CDS efforts.

II. Project Overview

This report summarizes the work performed under the "Structuring Care Recommendations for Clinical Decision Support" or SCRCDS project (originally named "Hardened Rules for Clinical Decision Support"[2]) which began in September 2009. A contract modification extended the project's conclusion from September 2010, the end of the original period of contract performance, to September 2011. More recently, the project has been informally referred to as the eRecommendations or eRec project. The term "eRecommendation" was coined during this project to refer to the structured, coded version of a clinical care recommendation that is a core deliverable. This term was chosen to emphasize the interplay with corresponding work to incorporate clinical performance measures into electronic health records as eMeasures.[3]

A. Background

The project is aimed at reducing a key barrier to the use of evidence-based clinical care recommendations, namely, that there is currently no formalized process for translating narrative recommendations from prose to an unambiguous, structured and coded format that can then be adopted widely for local conversion into machine-executable clinical decision support (CDS) rules in various information systems and care settings. The work required by local implementers to translate recommendations into CDS rules is time- and resource-intensive, whether performed by care delivery organizations or clinical information system (CIS) suppliers. Further, this effort is associated with significant and unnecessary duplication of effort.

B. Purpose

To address these challenges, the overall project goals were to (1) devise and document a consistent method for transforming evidence-based clinical recommendations into a format that can be readily adapted further for widespread implementation in CIS and other health information technology (health IT) products, (2) develop a collection of structured recommendations in that format, and (3) demonstrate, via pilot tests and Stakeholder Community feedback, how to enhance eRecommendation use in CDS. The initial focus for logic statement development in this project was the set of 45 A and B recommendations for prevention and screening from the U.S. Preventive Services Task Force (USPSTF). In addition, the format was refined and subsequently applied to 12 recommendations underlying clinical performance measures that are reportable to the Centers for Medicare & Medicaid Services (CMS) under "Meaningful Use (MU)" regulations.[4]

The SCRCDS project hypothesized that, if developed, a consistent method and format for

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[3] The eRecommendation template consists of sections aligned, to the extent possible, with the Health Quality Measures Format (HQMF). HQMF is currently an HL7 Draft Standard for Trial Use for expressing a health quality measure's structure, metadata, definition and logic in a format suitable for EHR integration, i.e., an eMeasure.

[4] http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__meaningful_use_announcement/2996

translating narrative clinical care recommendations into structured, coded logic statements would facilitate the local implementation of CDS rules and, ideally, would facilitate the wider use of such rules and corresponding improvements in patient care and outcomes. It is believed that developing a consistent method and applying it to clinical recommendations will (a) diminish the redundant —translation" work occurring across systems and care delivery organizations that are implementing widely used clinical recommendations; (b) diminish the lag time and resources expended between the time recommendations are published and implemented in clinical health IT systems; and (c) increase the uptake of broadly accepted clinical recommendations.

C. Products

Under this contract, the Thomson Reuters-led team devised, vetted with a broad community of stakeholders, documented, and tested a formal method for transforming evidence-based clinical recommendations (and performance measures that imply such recommendations) into a format that can be adapted further for widespread implementation as CDS rules in CIS and other health IT products. The team also developed and delivered to AHRQ a collection of structured recommendations in that format, referred to as eRecommendations. These are based on the 45 A and B recommendations from the USPSTF and 12 rules relevant to Stage 1 MU measures. In addition, two guides were created to support various stakeholders in using project products: (1) a Guide for eRecommendation Developers to help clinical practice guideline developers and CDS software vendors effectively use the eRecommendation template to present —if...then…" type guidance in a way that can be more easily and consistently converted into CDS rules by implementers, and (2) a Guide for eRecommendation Implementers to help health care delivery organizations, EHR vendors, and other CDS facilitators in effectively using eRecommendations to create and deploy CDS rules for improving health care quality. See the Key Deliverables section of this report for a detailed list of project deliverables.

D. Intended Audience/Stakeholders

An underlying hypothesis was that, in addition to supporting CDS implementers and suppliers/vendors, results of this project will be valuable to clinical guidance creators and disseminators (e.g., clinical guideline developers such as the USPSTF) who may desire to use the format to deliver recommendations. Furthermore, government and private sector entities that have a broader role in supporting health IT-enabled improvements in health care delivery and patient outcomes—for example, the Office of the National Coordinator for Health IT and their various pertinent projects (e.g., Health IT Regional Extension Centers, Beacon Communities), and the National Quality Forum—may be interested in leveraging the learnings and products from this project.

III. Methods

Phase 1 of the project involved gathering input from key stakeholders (gathered in a Rule Value Advisory Panel (RVAP)) who would potentially use the products from this project and designing the approach for translating care recommendations into semistructured logic statements. Background assessment and synthesis activities that informed the design of methods consisted of reviewing relevant initiatives and methods, assessing stakeholder needs, and vetting a draft format for structured recommendations. Phase 2 of the project implemented the translation methods for USPSTF recommendations and a few others related to performance measures pertinent to Meaningful Use (MU). Phase 3, conducted during the contract modification period, built on these efforts by taking steps toward widespread eRecommendation use in CDS rules. Key activities consisted of pilot testing the eRecommendations in two real world settings; expanding the RVAP into a more robust "eRecommendation Stakeholder Community" spanning the CDS rule value chain to follow pilots and help drive eRecommendation use to scale; further fleshing out the eRecommendation template; and developing eRecommendations for additional MU measures based on implementer need.

The individuals and organizations who participated in information-gathering discussions with the project team as part of the assessment and synthesis activities are listed in Figure 1 of the synthesis/methods report (see Deliverable #8 and #14, *Background Assessment, Synthesis, and Methods Report* submitted March 31, 2010). The RVAP and subsequent Stakeholder Community had strong representation from hospitals, health systems and other key sectors. The project team initially relied on information from RVAP member Dr. Reider (Allscripts [an EHR vendor serving small practices]) and the HIMSS Electronic Health Records Association (EHRA) to help identify issues facing smaller practices. In addition, the perspective of smaller practices was sought through representation by the American College of Physicians (ACP), American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP) on the RVAP and Stakeholder Community. Furthermore, eRecommendation pilot testing was conducted in a small practice (as well as a health system) and engaged a small practice vendor to further amplify the input from this important constituency. Appendix A identifies the broad cross-section of potential eRecommendation developers, users, and other relevant parties who participated in the Stakeholder Community.

A. Review of Relevant Prior Work

The review of relevant Federal initiatives and methods—formalisms, data structures, and tools -- for translating clinical recommendations into executable logic for CDS was intended to surface major relevant projects and resources, and not intended to be exhaustive. It started with guidance from the Agency for Healthcare Research and Quality (AHRQ) and Department of Health and Human Services (DHHS) on the extent and types of prior and ongoing work to be explored. In addition to projects specifically named by AHRQ and DHHS, we used the Clinical Decision Support–Federal Collaboratory's (CDS-FC) CDS Inventory. Other significant CDS initiatives, methods, and tools reviewed were identified based on the SCRCDS team's collective knowledge and expertise, and discussions with key stakeholders. Team members with technical expertise in the translation and implementation of clinical recommendations included Jerry Osheroff, M.D., of

Thomson Reuters; Robert Greenes, M.D., Ph.D., of Arizona State University; Aziz Boxwala, M.D., Ph.D., of the University of California at San Diego; Peter Haug, M.D., of Intermountain Healthcare; Edward Shortliffe, M.D., Ph.D., of the American Medical Informatics Association (AMIA); and Harold Lehmann, M.D., Ph.D., of Johns Hopkins University, among others.

We looked at materials from related AHRQ-funded projects as well as other prior and ongoing projects identified in peer-reviewed journal articles and information on Web sites. Initiatives reviewed included both collaborative activities for building tools and resources, and specific formalisms for structuring clinical care recommendations. The collaborative activities examined include the Clinical Decision Support Consortium (CDSC), Guidelines into Decision Support (GLIDES), the Institute for Medical Knowledge Implementation (IMKI), the InterMed Collaboratory, the Morningside Initiative, and the Knowledge Management Repository (KMR) project. The formalisms reviewed include Arden Syntax, GELLO, the Guideline Elements Model (GEM), Guideline Interchange Format (GLIF), the Shareable Active Guideline Environment (SAGE), and the Health Quality Measures Format (HQMF) for eMeasures. We were interested in how past and present efforts had approached the challenges of formalizing clinical recommendations, standards for data representations and structures (e.g., information models, terminology, code sets, editing and authoring tools), attempts to create shared knowledge repositories, and the applicable lessons learned from these various efforts.

In addition, the project team explored the potential implications of developments occurring around project inception in applying health IT to performance/quality measurement and improvement. Most notably, this included legislation related to MU of health IT (which requires deployment of CDS rules) that has accelerated health IT implementation and related standards development.

B. Needs Assessment

Ensuring that the proposed process for developing structured recommendations was informed by what had already been learned about this complex task—and that potential end users would value the project deliverables—were key to accomplishing project goals. To determine how best to create structured recommendations that could be easily used on a widespread basis to support CDS rule development, the SCRCDS team conducted informational meetings to evaluate organizational requirements for implementing clinical care recommendations as health IT-integrated CDS rules. The project team was particularly alert for opportunities to align with current efforts to implement clinical recommendations in health IT, as well as efforts to measure care quality using EHRs. Therefore, persons and organizations representing both activities were selected for these informational meetings to provide the project team with a broad perspective.

Discussions were held from October 2009 through February 2010 with key stakeholders known to have insights into challenges in generating a model process for translating clinical recommendations into useful logic statements. Individuals and organizations were asked to participate in these discussions primarily if (a) they were identified by the AHRQ Task Order Officer as key implementers among members of the CDS-FC or (b) they represented clinical institutions, vendors, or membership organizations focused on implementing clinical recommendations or designing products to support such implementations. Discussions focused on uncovering needs associated with expressing guidelines as CDS rules, including how organizations

are choosing, translating, and implementing these recommendations. In addition, the project team sought to identify and document major challenges in translation and implementation, and how these barriers were addressed (see Deliverable #8 and #14, *Background Assessment, Synthesis, and Methods Report* submitted March 31, 2010).

C. Template Development and Vetting

Based on early explorations and discussions, the project team determined that an HQMF-like template could serve as a foundation for project deliverables. The team was given approval to proceed by developing a modified version of the HQMF template more suited than the performance measurement function for which HQMF was created to expressing clinical recommendation logic in a manner that could support CDS rule deployment. To reinforce synergies with EHR-enabled quality measurement, the team coined the term ―eRecommendation" for a clinical recommendation that has been expressed in this logic statement template. The SCRCDS team developed a sample structured recommendation based on the HQMF template, and populated it with draft content based on the USPSTF breast cancer screening recommendation.

As a result of this accelerated content development, the purpose of first-time information-gathering discussions with technical experts and other stakeholders was modified to focus on receiving stakeholder feedback on this prototype eRecommendation and draft template. Starting in mid-December 2009, feedback was provided by previous discussants and their colleagues surrounding uptake and use of the sample eRecommendation for breast cancer screening. At the same time, the eRecommendation was vetted with members of EHRA, the president and interested members of the Association of Medical Directors of Information Systems (AMDIS), and AMIA. These individuals are EHR and CDS implementers and developers, and/or subject matter experts. Comments outside of informational meetings were collected via an electronic mailbox set up for this purpose, and by emails directly to SCRCDS team members. These comments were systematically reviewed by the entire SCRCDS project team in order to refine the structured recommendation format and related aspects of the methods for structuring recommendations.

D. Translation Methods Implementation

The project's translation activities focused on discrete care recommendations, not complex guidelines as a whole. The distinction is that ―clinical guideline" is often taken to mean a multistep process that unfolds over time, with various decision points and actions; that serves as a way to present a summary of best practices for diagnosing or managing a specific disease or condition; and that can apply to patients at various stages in the process. Guidelines can contain various recommendations at specific steps in the process. Our focus was more limited, i.e., the advice that pertains to a single patient at a particular point in time about a limited clinical issue (such as might be provided via an alert or reminder).

The essential components of the format and methods for structuring recommendations (i.e., the eRecommendation template) were developed during the initial months of the project and proposed to AHRQ in the synthesis/methods report (see Deliverable #8 and #14, *Background Assessment, Synthesis, and Methods Report* submitted March 31, 2010). These were based on the experience of

thoroughly translating one USPSTF recommendation (i.e., breast cancer screening) and three others less completely. The methods were intended to be generally aligned with those for eMeasures and included a revised eRecommendation template that reflected comments provided by a wide range of stakeholders.

Comments also were provided by the key stakeholders on the importance of producing the eRecommendations as XML output or, alternatively, the value of eRecommendations that are only available in human-readable format. The general consensus was that XML is important for many potential eRecommendation consumers, but that a human-readable format as an interim step is acceptable for most users. Based on this input—and the fact that creating an XML output would consume significant time and resources—we were instructed to proceed with translation to a human-readable format. An Excel-based version of the eRec template was developed to enable eRecommendation content to be documented and exported in a more granular fashion. In addition, the Excel file was embedded with XML tags to facilitate further processing into XML at a later date. For example, the Excel format can be converted to CSV (or similar format) and a program could be written to upload this content into the XML tool. As described below, this has actually been done in SHARP C-2B, a related CDS project from the Office of the National Coordinator for Health IT (ONC).

Excel-based draft eRecs for the 45 USPSTF recommendations Grade A and B were initially produced by applying the proposed practices for populating the eRec. As expected, the process of applying the structuring methods to the entire set of 45 USPSTF recommendations Grade A and B uncovered a few additional issues and resulted in refinements to the translation approach. For example, we chose to create separate rules—one for each subpopulation—when recommendations are intended for multiple populations with different inclusion/exclusion criteria (e.g., a pregnant adolescent female or a sexually active young adult female). Also, the eRec data model, which derives from the NQF Quality Data Set, was revised to include ―Diagnosis Family History" as an additional class. Subsequent passes through the draft USPSTF eRecs were made by the SCRCDS team to ensure that these refinements were universally implemented and to ensure consistency across the eRecs.

In the absence of standardized codes for logic statement elements from an authoritative source, these elements were presented as a clear and accurate English-like description. This is the case with the draft USPSTF eRecs, roughly half of which are not related to quality measures that are being retooled by the Centers for Medicare & Medicaid Services (CMS) for the EHR environment. The remaining eRecs that do have related eMeasures were handled in a similar manner because valid, current medical code sets and coding standards resulting from the retooling process were not yet available to the SCRCDS team.

Next, Excel-based draft eRecs were produced for a second recommendation set: two recommendations that underlie MU criteria, specifically the eMeasures for breast cancer screening and colorectal cancer screening. The eRecommendation template and method for populating it that was refined during production of the draft USPSTF eRecs served as the foundation for translating these two MU-relevant recommendations. However, rather than expressing an English-like description, the retooled eMeasures and accompanying code lists developed by NQF were used since they were then available for expressing the logic elements as codes.

Similar to the experience in producing the draft USPSTF eRecs, we uncovered a few issues that resulted in further refinements to the previously developed methods as we created the MU-related eRecs. Most central were time-related issues, e.g., how to reflect the effects of the measurement period and age limits for patient inclusion criteria from a *retrospective* performance metric when this logic is applied *concurrently* within an eRec. We took the view that the structured logic for MU criteria should be oriented toward the clinical objectives underlying the MU eMeasure and the clinical parameters contained in it (e.g., USPSTF recommendation or other), rather than the specific timeframe-related parameters of the performance measures (e.g., measurement period, measurement end date). That is, the logic would identify patients who, according to the clinical evidence, should have certain actions taken at a certain point in time based on their age at the time the rule is executed.

E. Ongoing Stakeholder Input

Developing, documenting, and validating the logic statement format and production process involved substantial vetting and refining of the logic statement format and contents. To help ensure that the work performed was supported by the full range of stakeholder perspectives, the team convened an RVAP. RVAP meetings in March and August 2010 provided input about the value of proposed project deliverables and their potential future use. RVAP participants included representatives of government and private health care providers, medical and informatics specialty societies, CIS vendors, Federal health IT committee members, ONC and other HHS representatives, guideline developers, and others. We specifically sought out potential users of structured recommendations who were interested in testing the usefulness of the eRecommendation template in the short run and possibly providing continuing feedback over the longer run.

In addition, we provided information about the SCRCDS project and its deliverables to a growing number of stakeholders via presentations at AHRQ conferences, workshops at national informatics conferences (e.g., AMIA and HIMSS), and other outreach activities. Project staff also had a growing number of discussions regarding future integration and use of SCRCDS project products by the health care community, e.g., ONC CDS contractors, the NQF CDS Expert Panel, PCPI, members of the Health IT Standards Committee, the American Thoracic Society, and the Centers for Disease Control and Prevention. We participated in quarterly meetings of the CDS-Federal Collaboratory in November 2009, February 2010, May 2010, and September 2010 to present project updates and hear feedback. As described more below, during the second project year, the RVAP was expanded into an enhanced eRecommendation Stakeholder Community.

F. Expand Usefulness of eRecommendations

Because the project cultivated synergies with other related national CDS initiatives during the first year, efforts were made during the second year to improve the format and method for populating eRecommendations by better aligning with these evolving conventions for information specification and existing standards and tools. Specifically, this involved the NQF CDS Taxonomy, the NQF Quality Data Set, and the Guideline Elements Model (GEM).

CDS taxonomy and quality data set. A variety of CDS and quality measurement developments were reviewed to determine their implications for the eRecommendation's "implementation considerations" section. This section is a list of generic setting-specific factors relating to rule triggering, user response, and other factors that need to be considered to successfully use the eRecommendation to develop a corresponding CDS rule in various settings. In January 2011, the newly released National Quality Forum (NQF) Expert Panel's Clinical Decision Support (CDS) Taxonomy was compared to the implementation considerations list to assess the extent of overlap in factors represented and to compare terms used. The team also explored with the pilot sites whether it was preferable for the implementation considerations section to be specific to each eRecommendation or to provide a generic list of issues for implementers to consider for any CDS rule. It was suggested by the pilot sites, and reaffirmed by the TOO, that a generic list would be more expedient within the scope of this work, but a subsequent effort to develop eRec implementation considerations that provide more detailed guidance on specific implementation scenarios would be desirable; this latter activity is the focus of the SHARP C-2B project. A substantially rewritten and reorganized generic implementation considerations section was drafted, leveraging the CDS Five Rights framework from the HIMSS CDS guidebook update, referencing NQF resources (including the CDS taxonomy and health IT measurement framework), and incorporating insights from the SHARP C-2B project, which is developing an Implementer's Workbench for addressing these configuration issues. This version of the implementation considerations was incorporated into additional structured statements developed in the second year. It will also be published in the 2011 update to the HIMSS CDS implementer's guidebook "Improving outcomes with clinical decision support," which is partially supported through the SCRCDS project.

Project work during the contract modification was to include synchronization of the eRecommendation data model with the NQF Quality Data Set information model. During this period, the Quality Data Set underwent further evolution and clarification and has emerged as the "Quality Data Model" (QDM). There were interactions with NQF regarding the eRecommendation team's updating of the eRecommendation data model to account for the revised eMeasure-related information model. Due in part to the significant changes and relatively early, plastic state of the QDM (version 3 comment period had not ended before the eRecommendation deliverables were due), this reconciliation was not completed. Therefore, the additional structured statements developed in the second year used the NQF's former QDS as the basis for the eRec data model.

In addition, the project team and NQF met on several occasions to discuss the implications of an eMeasure authoring tool intended to be generally available in September 2011. The tool facilitates looking up code sets that underlie specific logic statement terms. Although the timing of completion prevented the tool from being applied as an eRecommendation authoring tool for additional structured statements developed in the second year, it might be applied over the longer term, e.g., for SHARP C-2B or follow-on eRec-related work.

GEM. As noted elsewhere in this report, a crescendo of focus on health care performance improvement is creating tremendous interest in applying clinical decision support (CDS) to performance improvement at a national scale (e.g., in an effort to achieve widespread MU of EHRs and Health IT); this, in turn, creates needs for CDS-related standards to support this CDS deployment at scale. In parallel with this movement, AHRQ and ONC funded several CDS-related

demonstration projects and related tools, which each have taken related but slightly different approaches to formalisms for encoding CDS rules.[5] AHRQ also funded, together with the National Library of Medicine, the development of the Guideline Elements Model (GEM) and the GEM Cutter tool under the leadership of Dr. Richard Shiffman at Yale University. GEM is an XML-based guideline document model and GEM Cutter is an XML editor that facilitates markup of clinical practice guidelines and conversion of a guideline into the GEM format.

During the initial phase of the eRecommendation project, in order to surface and learn from major relevant projects and resources for translating clinical recommendations into structured logic for CDS, the project team reviewed these prior and ongoing Federal initiatives, including the resulting formalisms, data structures, and tools. In particular, it had been suggested by various stakeholders that the structured recommendation template be aligned with GEM, an ASTM[6] standard that has attracted significant interest by clinical guideline developers, who typically produce content in a narrative rather than structured format.

The elements and corresponding definitions in the Guideline Elements Model (GEM) were assessed for their use in informing the eRecommendation template. Based on this preliminary assessment and interactions with GEM's Rick Shiffman, the eRec team concluded that the GEM schema and tools would be of limited use for the eRec during initial rounds of eRec template and content development. Rather, the team identified a model that was more closely aligned with data structures and codes needed for EHR integration as the predominant framework for structuring care recommendations as eRecommendations. At the same time, it was acknowledged that further analysis could determine benefits and strategies for creating a closer alignment between GEM and the eRecommendation template.

As one step toward broader reconciliation between GEM and the eRecommendation, under the contract modification, AHRQ charged the eRec project team with re-examining the interplay between GEM and eRecommendations. This subtask, led by ASU (Bob Greenes), involved exploring synergies between GEM and the eRecommendation that may not have been apparent to the Technical team during the earlier review of related work, with an eye toward identifying opportunities to better align the two tools. Where feasible and with the agreement of AHRQ, steps would be taken toward implementing improvements. In brief, the exploration involved a series of telephone calls between the eRec team and Rick Shiffman, joint development of a document outlining the interplay and key issues, and a more detailed examination of whether/how GEM guideline markup could support eRec development.

More specifically, the analysis phase began in November 2010 with the project team assembling and sharing materials describing GEM and the eRecommendations, including their schema. The

[5] For pointers to these initiatives, see the following sites: Clinical Decision Support Web page at AHRQ's National Resource Center for Health Information Technology at http://healthit.ahrq.gov/portal/server.pt?open=514&objID=5554&mode=2&holderDisplayURL=http://wci-pubcontent/publish/communities/k_o/knowledge_library/key_topics__backup/health_briefing_01242006122700/clinical_decision_support.html; the Advancing CDS Project aims to support meaningful use standards to achieve widespread use of clinical decision support systems (see http://www.rand.org/health/projects/clinical-decision-support.html); the Strategic Health IT Advanced Research Projects (SHARP) Program, C-2B, Modeling of Setting-Specific Factors to Enhance Clinical Decision Support Adaptation, endeavors to incorporate patient and setting specific factors into CDS in order to optimize the effectiveness of CDS (see http://www.uthouston.edu/nccd/).

[6] ASTM International was originally known as the American Society for Testing and Materials.

Thomson Reuters team also prepared and circulated an initial mapping of elements from the eRecommendation schema to GEM. Although it appeared that GEM and eRecs were focused on somewhat different processes/targets at the time, the fact that they both aimed to support CDS rule development suggested that some tighter connection was possible. Based on this exchange, a document was drafted to summarize each tool, the analysis of the intersections and disconnections in the GEM/eRec interplay, and the group's recommendations to AHRQ for optimizing synergies between the two projects (see Appendix B).

Building on the shared framework outlined in that document, the eRec team and Rick Shiffman continued the alignment task by exploring the use of GEM tools or output for populating eRec fields. The eRec team's Knowledge Engineer (and eRec author) Sordo was guided through existing examples of GEM output for asthma and observed that it could be beneficial to the eRecommendation authoring process to start with GEM output, if possible. She also said that the GEM output didn't need to completely replace the source document, as long as the eRec author could rely on GEM consistently for what it did provide. Appendix C is a graphic diagram of the GEM and eRec contributions to implementer/vendor steps for processing rules. This appendix also provides a more detailed graphic of GLIDES and an explanation of how it relates, via rule development, to eRecs.

To further explore the hypothesis that GEM output could be a useful starting point for eRec development, the eRec template was marked up by highlighting 28 fields that are populated using information from the source document for the USPSTF guidelines. It was later determined that seven of these did not *directly* use information in the source document, e.g., values that describe data elements based on standardized code sets. Next, Shiffman reviewed the list of fields and indicated that 16 most likely could be populated using GEM output, GEM output could be helpful but probably not sufficient for populating 1 field, and 4 fields could not be populated with GEM output because they were metadata not represented in the current GEM document model. See Appendix D for more details about the specific eRec fields that are informed by the source document and the likely corresponding GEM elements.

To test the actual usefulness of the GEM output for eRec authoring, it is necessary for an eRec Knowledge Engineer with a yet-to-be-determined threshold familiarity with GEM output to view this output and reassess its value to the eRec process. The expectation is that such an exercise would confirm that marking up and extracting elements (from the clinical recommendation's source document) that relate to decision variables, eligibility, inclusion/exclusion criteria, actions, etc., does help an eRec author to identify necessary eRec elements and to begin the process of refining them. eRecommendation-optimized GEM output was not available to the project team during the contract period so this analysis was not done. Therefore, we cannot comment on the extent to which the GEMified elements are sufficient information for populating the eRec fields that are informed by the source document and, ultimately, for creating the logic statement for executing the recommendation. A CDS Metaconsortium convened by AHRQ and ONC is exploring interplay more broadly between the CDS projects mentioned above—including eRecs and GEM output—so there may be future opportunities to address this issue in a broader context.

G. Additional Review of eRecommendations

By the end of the first year of the project, multiple stakeholders had validated that initial deliverables held promise for improving the efficiency and effectiveness with which clinical recommendations can be structured and coded for subsequent CDS rule implementation. However, the project had also identified important issues that must be addressed to fully realize this promise. To enhance the usefulness of the eRecommendations and explore how they might be brought to scale, a pilot implementation analysis was conducted and a Stakeholder Community was built to observe these pilots.

Pilot test. The project team selected two providers—one inpatient and one outpatient—to ―pilot test" the implementation of two eRecommendations in their organizations. This process started in November 2010, when the project team recruited candidate pilot inpatient sites by contacting institutional providers who had participated in the RVAP calls during the original period of performance or were entrained in the eRecommendation project through other mechanisms. The nominees were discussed with AHRQ and Memorial Hermann Health System—represented by their CMIO (Dr. Robert Murphy) and their health IT vendor Cerner—were selected for the inpatient setting because of their strong interest in the project and highly successful earlier collaboration (e.g., copresenting a workshop on eRecommendations at the AMIA 2010 Spring Conference). For the outpatient site, the pilot site team was identified through David Bergman of ONC and consisted of Bergman, staff from the Louisiana Health IT Regional Extension Center (LA REC), a small practice affiliated with Tulane led by Dr. Eboni Price-Haywood, and the practice's EHR vendor SuccessEHS. The project team placed particular emphasis on vendor engagement in the pilot because, in outpatient practices especially, EHR vendors play such a central role in CDS rule implementation.

Candidates who expressed interest but were not selected as one of the two pilot sites were invited to ―swim along" with the pilot sites by using the eRec materials prepared for the pilot sites to conduct implementation reviews within their own organizations and then share their experiences through the Stakeholder Community. See below for more information on these swim along pilot sites.

After being selected as pilot sites, Memorial Hermann and the LA REC team were asked to prepare for the implementation review by (1) identifying individuals within their team who should be part of evaluating eRecommendation implementation details and issues; (2) thinking about clinical priorities for MU CDS rule implementation in preparation for selecting a specific eRecommendation for implementation review in their site (i.e., for use in a CDS rule that has been, or will be, implemented for MU); and (3) providing basic information characterizing their practices, CIS and CDS systems, and environment/workflow where their eRecommendation is envisioned to be used. A kickoff teleconference call was held in the first week of December 2010, during which pilot sites received the eRecommendation for their identified MU or CDS clinical priority. The inpatient site selected an eRecommendation corresponding to the MU eMeasure for antithrombotic therapy by hospital day 2, while the outpatient site selected one for HbA1c >9 percent. These two eRecommendations were prepared by the project Knowledge Engineer for this evaluation.

From mid-December 2010 through early February 2011, three pilot site teleconferences were conducted with the provider organizations and their vendors to receive feedback from their implementation review of their chosen eRecs. Pilot sites were asked to describe their rule implementation process, the actual or expected impact of the eRecommendation on this process, and the changes that would be needed to the eRecommendation template in order for the eRecommendation to be more useful in the local implementation process. The pilot sites were also asked to comment on the usefulness of the substantially rewritten implementation considerations section and to prioritize the Stage 1 MU measures for which additional eRecs would be most valued. This feedback from the pilot site implementation review was recorded in a variety of documents, including a rule implementation process document that was later shared with the Stakeholder Community. Finally, the pilot sites were asked to review the draft *Guide for eRecommendation Implementers* to help ensure that this resource is useful to a broad range of eRecommendation users.

Stakeholder community. As mentioned above, an eRecommendation Stakeholder Community was convened to enhance the prior RVAP and represent the full value chain for CDS rules—from clinical guidance synthesis through CDS rule development and implementation. The purpose of this community was to follow the pilot site experience and help support eRec scalability by making observations about the pilot site findings as well as offering insights and experiences based on their individual and organizational perspectives on the CDS rule value chain. Invitees to this Stakeholder Community consisted of a growing list of individuals who had interactions with the eRecommendation project, particularly participants in the two previous teleconferences with the RVAP and others felt to be critical to scaling eRecommendation value and use. Over 150 individuals were on the Stakeholder Community mailing list, and scores attended each of the 3 Stakeholder Community meetings. Categories of Stakeholder Community participants include the following:

- Federal stakeholders (health IT/CDS research/development and guideline developers, e.g., CDC, NHLBI, USPSTF, and ONC)
- Federal care delivery sites (e.g., HIS and DOD)
- eRecommendation ~~"s~~wim alongs" (with pilot activities) – University of Pennsylvania, Texas Health Resources, the Veterans Administration, and Kaiser Permanente
- Non-Federal guideline developers and specialty societies (e.g., ACP, AAFP, AAP, ATS, and ACCP)
- CIS vendors other than pilot participants
- Policy/standard setting community (e.g., Health IT Standards/Policy Committee members)
- Quality/performance measure community (e.g., NQF and NCQA)
- Informatics projects/experts (e.g., from AMIA, AMDIS, and HIMSS)

Significant effort was focused on the engagement of the stakeholders necessary for the success of the project. Specific objectives of the Stakeholder Community were to create an opportunity for open-ended feedback and discussion on eRecommendation use/barriers/opportunities, refinements to the eRecommendation template and content, eRecommendations to be developed for additional MU measures, and scaling eRecommendation use and value. In addition to further discussing implications of the pilot site results, meetings aimed to develop stakeholder action steps to achieve this scale. The learnings and other results from the Stakeholder Community also were applied in

developing the project's Guide for eRecommendation Implementers and the Guide for eRecommendation Developers. See the Lessons Learned section of this report for highlights. A key activity related to the Stakeholder Community was the engagement of individual guideline developers in conversations regarding specific needs and opportunities regarding their potential use of eRec deliverables. A separate phone meeting was held in January 2011 with a large number of CDC staff and contractors/grantees. In addition, the Project Director and the AHRQ Task Order Officer participated in a USPSTF meeting in March 2011; the Task Force suggested that their dissemination workgroup might be the appropriate body to give eRecs further consideration. Finally, representatives from nine guideline developer organizations (e.g., NHLBI, ATS, ACCP, and VA) were invited to a separate teleconference at the end of March to explore their needs and interests with regard to using the eRecommendations.

To ensure that the unfolding eRec work is mutually supportive of related Federal CDS activities, the eRecommendation team participated in the "CDS Metaconsortium" convened by ONC and AHRQ and consisting of their contractors and grantees involved in developing information and tools for improved CDS implementation. The Project Director worked closely with the Metaconsortium leadership to align and leverage eRec project work in support of Federal efforts to get useful CDS products to users—especially via other related Federal initiatives such as Beacon Communities—and to cultivate pertinent synergies among these key national projects. The Metaconsortium is one forum where future eRecommendation-related work is expected to be discussed. It may be beneficial for the CDS Metaconsortium to tap back into the eRecommendation Stakeholder Community as part of its efforts to support widely used and useful standards-based CDS tools.

H. Translate eRecs for Meaningful Use

The development of 12 eRecommendations (including two drafted for the pilot implementation review) for additional MU measures was based on implementer need and incorporated improvements identified through the pilot test, Stakeholder Community, and other activities. These eMeasure-based eRecommendations are intended to help providers meet the Stage 1 Meaningful Use requirement of implementing one CDS rule, or to go beyond this minimal requirement by implementing additional related rules.

Improving the template and process. This Phase 3 activity continued the iterative refinement of the process for translating recommendations into structured logic statements but with a focus on applying the template and process to Meaningful Use measures. Input about possible changes to the template or process for populating eRecs came primarily from (1) issues identified by the project team's work on technical tasks, including the eRecommendation author's experience drafting the initial two MU eRecommendations for pilot sites and (2) feedback from pilot sites—and, to a lesser extent, the Stakeholder Community—in the course of their implementation review of the selected eRecommendations. The revised template and process were applied when creating the additional eRecommendations. Appendix E of the *Guide for eRecommendation Developers* describes the elements in the eRecommendation template for each of the four major sections (i.e., header, data definitions, logic specification, and implementation considerations). Due to the developmental and demonstration nature of this project, the draft eRecommendations are not considered "industrial

strength‘. Given the dynamic nature of the health IT and clinical environments, further clinical, editorial and informatics review and updating of the submitted deliverables is desirable. Mechanisms for addressing these knowledge management issues are not currently in place, but might potentially be considered in the context of the broader CDS ecosystem in forums such as the CDS Metaconsortium.

A key issue warranting further attention is that the MU-related eRecommendation is a ―special case" that deviates in subtle but important ways from the eRecommendations that are based on a clinical recommendation and that served as the starting point for this project. The basis for the MU eRecommendation is a performance measure. As a result, the intended purpose of these initial MU eRecommendations is to contribute to performance improvement by identifying patients that would be at risk of failing the measure. For this initial exploration and demonstration work on eMeasure-based eRecommendations, the action in the ―then" portion of the ―if… then…" eRecommendation logic statement was chosen to be to ―notify appropriate person(s) and/or system that this patient meets the health or process of care criteria that the eMeasure will consider undesirable," e.g., is a candidate for intensified management of poorly controlled diabetes, or is a candidate to receive appropriate discharge instructions. It is important to note that this focus often occurs very late in the care process, and proactive CDS would generally seek to provide recommendations for appropriate care at the earliest stage feasible, not when the patient is about to fail a measure.

Other issues relate to the fact that the current source document for MU eRecommendations is the eMeasure specification. As a result, there may not be explicit guidance for an eRecommendation field necessary for creating a CDS rule, such as an intervention interval indicating how far back in time to look for a specific test or the interval during which the most recent test is considered relevant. Developers of clinical guidance—especially when working in collaboration with measure developers—can remedy this situation by identifying the appropriately detailed clinical recommendation to correspond to the measure. This way, eRecommendations engineered from quality measures can better support CDS aimed at improving clinical performance on the measure. The narrative that accompanied the *Additional Structured Statements* (Del. 26 submitted on May 13, 2011) and Appendix E provides additional examples of the eMeasure-related eRec issues as well as their recommended resolution.

Selecting eRecommendations for development. The final MU regulation identified 46 Stage 1 clinical quality measures (eMeasures) for eligible professionals (EPs) and 15 for eligible hospitals (EHs). As noted earlier, the first two eRecommendations developed during Phase 3 were selected based on the priorities of the pilot sites and related to the MU measures ―percent of diabetic patients with HbA1c >9 percent‘ and ―antithrombotic therapy administered by hospital day 2.‘ The remaining 8 MU measures translated during Phase 3 were selected based on project team review of eMeasure suitability for eRecommendations as well as the input of pilot site teams and the broader eRec Stakeholder Community, including ONC. See *Additional Structured Statements* (Del. 26, submitted May 13, 2011) for the final list of 10 eMeasures developed in project Phase 3, intentionally divided equally between those pertinent to eligible providers (EPs) and eligible hospitals (EHs) seeking Meaningful Use incentive payments.

The *Additional Structured Statements* deliverable also provides more information on how the project team used their clinical and CDS knowledge to separate the 61 eMeasure candidates into

three groups: good candidates for eRecommendation, possible fit, and probably not appropriate. This grouping was based on the team's assessment of access to structured information needed, practicality for addressing with a CDS rule, number of patients affected, implementer priorities, and the gap between evidence and practice. A shorter list of 10 candidates was developed based on Stakeholder Community feeback such as (1) among topics from the EH list, stroke was overrepresented, (2) it is desirable to align choice with topics being used in other programs, e.g., HRSA, PQRI, CHIPRA, ACOs, etc, (3) importance of CDS for smoking cession and weight screening/counseling, and (4) desire for rules on newborn screens and adult immunization (e.g., postpartum women and pertussis), and (5) need to address all three core Stage 1 eMeasures for EPs.

I. Dissemination

An important goal of this project was to engage public and private stakeholders and disseminate findings and products to these groups. In addition to accomplishing this through the eRecommendation RVAP and Stakeholder Community interactions described above, key dissemination activities included the following:

- Presentations and workshops about the eRecommendation project at professional meetings (e.g., AMIA 2010 Spring and Fall conferences, HIMSS 2010 and 2011 conferences) as well as AHRQ-sponsored meetings (e.g., the 2010 AHRQ health IT contractor/grantee and annual meetings) and other seminar series (e.g., a 2011 Scottsdale Institute Webinar).
- Working in various venues, particularly large scale collaborative initiatives, on developing and disseminating best practices for measurably improving care outcomes (e.g., quality, safety, cost, efficiency) through CDS. A component of this involves contributing to the second edition of the HIMSS CDS guidebook, *Improving Outcomes with CDS: An Implementer's Guide*. The guidebook is helping to leverage and disseminate work on the eRecommendations, e.g., referring to the eRecommendation project and deliverables, and presenting the eRec Implementation Considerations to help with CDS rule implementation.
- A package of draft project deliverables that could be sent directly to persons who are interested in more information about the project and its products than what was available on the AHRQ Web site in the short term. (Because AHRQ project deliverables are not typically disseminated via the Web site until products are final, the project team prepared and shared this package (with the AHRQ TOO's approval) as requested).
- Working with the AHRQ National Resource Center for Health IT and the AHRQ health IT portfolio dissemination team regarding a separate Web page design and content related to the eRecommendations project.[7]

The eRecommendation project legacy extends beyond the results described above. For example, work is underway to make the eRecommendations produced under this project available on the ACDS portal. In addition, building on the eRecommendation schema, the ONC-sponsored SHARP C-2B project is creating an implementer's workbench for configuring setting specific factors (SSFs) pertinent to converting eRecommendations into locally useful CDS rules. The eRecommendations

[7] http://healthit.ahrq.gov/structuring_care_recommendations_for_CDS

created by the SCRCDS project have been converted in the SHARP project to their enhanced XML-based schema, and will be available through the Implementer's Workbench repository. Finally, there is evidence that government guideline developers are pursuing contracts that extend and further tailor to public health needs the work begun with the eRecommendation project.

The result of the eRecommendation project's interplay with other related projects is that it appears to have further stimulated progress toward a "whole" (regarding CDS rule development and value) that is greater than the sum of the parts. Nonetheless, as evidence by the feedback from HITSC members during the third eRecommendation Stakeholder Community meeting and from the GEM-eRec interplay analysis, much work remains to be done to fully realize this whole. It appears that the ONC/AHRQ CDS Metaconsortium is currently the most active and promising forum for this.

The active engagement by a broad range of public and private stakeholders in CDS-facilitated health care performance improvement to develop and vet project deliverables is another important project by-product.

IV. Key Deliverables

The following deliverables under this project were submitted during the September 22, 2009, through September 30, 2011 period of performance**:**

- *Work Breakdown Structure (WBS)* – Deliverable 2. Submitted October 15, 2009.
- *Project Plan, Revised Project Plan, and Updated Project Plan* – Deliverables 3 through 3.2. Submitted October 28, 2010, January 28, 2010, and April 7, 2011.
- *Quarterly Progress Reports* – Deliverables 4.1 through 4.5. Submitted January 26, 2010 for Fourth Quarter 2009; April 20, 2010 for First Quarter 2010; July 7, 2010 for Second Quarter 2010; March 31, 2011 for Fourth Quarter 2010; and June 6, 2011 for First Quarter 2011. Third Quarter 2010 was subsumed by the Draft Final Report for the original contract period and Second Quarter 2011 was subsumed by the Draft Updated Final Report.
- *Monthly Meeting Minutes* -- Deliverables 5.1 through 5.21. Submitted October 26, 2009; November 16, 2009, December 23, 2009; February 1, 2010; February 25, 2010; March 24, 2010; April 20, 2010; May 21, 2010; June 21, 2010, August 9, 2010; September 9, 2010; October 28, 2010; December 15, 2010; February 7, 2011; February 28, 2011; March 23, 2011; April 19, 2011; May 20, 2011; and June 22, 2011.
- *Draft 508 Compliance Plan* and *Final 508 Compliance Plan* – Deliverables 6 and 7. Submitted October 26, 2009 and July 30, 2010.
- *Draft Background Assessment, Synthesis and Methods Report* – Deliverables 8 and 14. Submitted March 31, 2010.
- *CDS Federal Collaboratory Meeting Feedback Summary* – Deliverables 11.2 through 11.4. Submitted November 20, 2009; March 1, 2010; May 21, 2010; and September 21, 2010.
- *Rule Value Advisory Panel Meetings* – Deliverables 12 and 13. Conducted March 8, 2010 and August 31, 2010.
- *Draft Structured Statements* (for USPSTF Recommendations) – Deliverables 15, 17, and 19. Submitted June 11, 2010.
- *Draft Structured Statements Underlying Meaningful Use Criteria* – Deliverables 15, 17 and 19 (Part 2). Submitted August 20, 2010.
- *Additional Structured Statements* – Deliverable 26. Submitted May 13, 2011.
- *Standard Operating Procedures* -- Deliverable 23.1. Submitted September 17, 2010 as draft to be completed during period of contract modification.
- *Guide for eRecommendation Developers (formerly Updated Standard Operating Procedures)* **–** Deliverable 23.2. Submitted June 17, 2011.
- *Guide for eRecommendation Implementers (formerly User Guide)* – Deliverable 28. Submitted May 16, 2011.
- *Draft Final Report, Draft Updated Final Report, and Updated Final Report* -- Deliverables 24.1 through 24.2. Submitted September 17, 2010, and June 30, 2011. This document, the *Updated Final Report* (Del. 25), was submitted in September 2011.

V. Lessons Learned and Suggestions

The eRecommendation project tested whether consistently structured and coded logic statements could be created in a manner that would be widely useful to those developing and implementing clinical guidance and CDS rules. The results from pilot implementation analysis and broad stakeholder feedback demonstrate that there is wide interest in the eRecommendation template and content across all stakeholder categories (such as healthcare provider organizations, guideline developers, EHR and CDS suppliers), and that using this material can deliver significant value. It also identified a variety of technical and related needs and opportunities to further stimulate widespread eRecommendation project deliverable value and use.

This section provides lessons about the process of creating the eRecommendations and pursuing greater scalability that delivers on their promise. These themes were reinforced by participants in the final meeting of the Stakeholder Community (see Appendix F). Major themes are as follows:

1. **Multistakeholder community engagement.** The value of engaging multistakeholder communities (comprising diverse and interrelated constituencies) in the difficult task of producing useful CDS artifacts in this complex and dynamic informatics arena.
2. **Linkages to relevant drivers.** The importance of linking development of new CDS rule content and structures such as eRecs to powerful incentives and infrastructure relevant to stakeholders. For example, aligning the rule format and codes with corresponding elements for EHR-integrated performance assessment and reporting.
3. **Balancing universality and specificity.** The importance of ‗staying high' in the CDS rule value chain to support widespread use by not over-specifying implementation details, but at the same time considering that detailed deployment guidance is important to many implementers.
4. **Starting at guideline development.** Ideally, clinical guidance from guideline developers and others should be formulated with application to CDS rules and other intervention types in mind. The eRecommendation template offers promise of adding value in this area, but reconciliation with other current and emerging CDS rule formalisms is needed to be of greatest value to guidance suppliers.
5. **Codes as key content.** The value of structured, coded logic statements in developing CDS rules.
6. **Knowledge management.** Knowledge management issues—such as responsibility for ongoing rule/eRec maintenance—need to be addressed for scaling this work and integrating it with related CDS efforts.

Multistakeholder community engagement. Facilitating CDS rule development and implementation has important technical, workflow and social/political components. The critical role that technical factors play was demonstrated—among other ways -- by the priority that implementers place on having coding specifications, and the ongoing challenge of developing rules that can be shared across sites. The significance of the less tangible yet possibly equally complex social factors was evidenced by the breadth of stakeholder interests and needs relevant

to the eRec project, and the many diverse workflows into which deliverables could be incorporated.

Given that the ultimate goal for project deliverables is widespread uptake, the team focused as much attention on collaboration building as on the technical solution details. That is, we ensured that key stakeholders in this dissemination—e.g., CDS implementers, EHR suppliers, Federal health IT policy stakeholders, and among many others—were aware of and had the opportunity to provide input into deliverable development from the very beginning. This started with the RVAP and related stakeholder activities in the early phases of the project. The depth and breadth of engagement substantially increased with the Stakeholder Community that was cultivated during the third project phase. Although other related projects have sought stakeholder input, in this case we (again, based on TOO requirements) maintained a strong and persistent emphasis on widespread use of project deliverables in reaching out to, and using feedback from, pertinent stakeholders.

Because the eRecommendation Stakeholder Community was such a large, diverse and engaged group, we the project team believes it is a powerful forum that could be further developed and leveraged to address a variety of important CDS-related issues, either pertaining to eRecommendations or beyond. Such a group could help inform and support execution on the other recommendations below.

Linkages to relevant drivers. The consumers for project deliverables (e.g., CIS vendors, CIS/CDS implementers, guideline developers) function in a highly pressured business environment with many significant challenges to survival. Any effort to change behavior of these groups—for example, to understand and use deliverables from a health IT project such as this one—must carry a compelling ~~"b~~usiness case" for such attention and action. Recent legislation -- and related action by health care payers, accreditors, and others – has made delivering measurable improvements in health care quality, safety, and cost an imperative for these stakeholders. eMeasures and the HQMF format now play in important role in addressing these imperatives for performance management and reporting. By linking the eRecommendation structure and codes to these imperatives and formalisms (including the requirement to implement a CDS rule to achieve Meaningful Use [MU]), we have increased the relevance of our output to key business drivers for those who are intended consumers for our deliverables.

Nevertheless, given the ambitious agenda for MU, providers are increasingly leaning on vendors and other implementation facilitators to provide the products needed to meet business requirements. The eRecommendation format and content produced in this project could be an important communication vehicle for these collaborations.

In light of the linkage to performance measurement, the context of eRec availability was an important factor in potential users' sentiments toward the eRec. Specifically, it made a difference to implementers we spoke to whether AHRQ's development of the eRecs was to facilitate a voluntary use or whether this was part of a Federal initiative where eRec use would be mandatory. (The project team clarified verbally and in its deliverables that the deliverables are part of a demonstration project and their use is voluntary.)

Dynamics in health care delivery beyond the rule development process limit the reach of structured CDS logic, such as eRecs. For example, the historical lack of coordination and data sharing within the U.S. health care system may limit the effectiveness of CDS rules in supporting appropriate screening, diagnostic and management interventions. This can occur because data pertinent to such rules isn't readily available or communication channels to ensure the rule's intent is carried out aren't in place.

Balancing universality and specificity. The TOO strongly emphasized from the outset of this project—and at every stage throughout—that we should make the clinical logic as specific and as implementable as possible, up to and until this specificity begins to limit the ability of stakeholders to adopt and use the deliverables. This focus (combined with substantial stakeholder engagement efforts mentioned above) helped ensure that the structure and coding details of the eRec formalism didn't contain obstacles of the sort that has vexed prior efforts (e.g., the Arden Syntax "curly braces problem").

Substantial tension exists between users who value structured recommendations that address implementation/workflow issues more comprehensively and in more detail (e.g., implementers) vs. those who prefer doing so with less implementation specificity (e.g., CIS vendors). In the short term, less specificity in the structured recommendations increases portability and would enable clinical information system (CIS) implementers and vendors to tailor deployment details to suit their needs and constraints. In the long term, a continued high priority for development is the ability to share rules—or precursors to implementable rules - across settings. If a guideline developer intends that a clinical recommendation apply to certain common and/or high priority implementation scenarios, observations from this project lead us to believe that it would be valuable for the guideline developer to provide guidance within the Implementation Considerations section of the eRecommendation for the scenarios of interest. Alternatively, to support the development of implementation considerations specific to different topics, research may be needed on whether a limited number of triggers/scenarios can address a significant fraction of deployment needs.

Exploration could be done into how to make the implementation considerations more executable, e.g., with XML tags for key pieces of information as opposed to presenting this section en bloc as a link to another spreadsheet page. The SHARP C-2B project is explicitly concerned with such a "Level 3" (see Appendix C) adaptation of an eRecommendation to a particular implementation scenario through the modeling of Setting-Specific Factors (SSF), which formalize the transformation of the rule representation based on implementation considerations.

Starting at guideline development. The eRecommendation template can be a tool for guideline developers and specialty societies in addressing their dissemination goals. Clinical recommendation developers can potentially help those who consume their content to more efficiently achieve better care in areas targeted for performance improvement if the developers seed CDS rule development by structuring and coding the guidance as eRecommendations. The eRecommendation provides a vehicle for guideline developers to impact how their guidance is translated and implemented in clinical settings. Thus, it presents an opportunity to ensure that guidelines are translated by implementers as intended by developers. It also offers guideline developers a practical starting point for discussions with EHR vendors about how the clinical

recommendation logic might be made executable, a topic with which guideline developers might not yet have substantial experience.

Within the private sector, there are also efforts to create formats that facilitate the application of clinical information and practice guidelines for use in decision support. Examples include the American Academy of Pediatrics' Partnership for Policy Implementation and their Child Health Informatics Center. To the extent that these organizations are familiar with the eRecommendation template, the tool may be useful in supporting their guideline implementation activities.

Guideline developers had advice for how to improve the project's Guide for eRecommendation Developers. These included adding a glossary of IT terms and providing training on how to use the eRecommendation template. Suggestions were also made for developing and testing a quality assurance process to ensure that guidelines being populated correctly in the template, as well as testing the conversion of non-USPSTF recommendations into the eRecommendation template.

Going forward, guideline developers and others who wish to develop eRecs might consider using GEM output as a starting point. There is a belief that this could potentially save time in eRec creation, and increase the quality, reliability, and verifiability of these eRec fields. However, the overall conclusion of the GEM/eRec alignment task is that further analysis and, possibly, development work would be needed before the full value of guideline GEMification in eRec development is fully apparent and realized. First, GEM output should be optimized for the specific purpose of authoring eRecs; a forthcoming GEM 3 may provide additional capabilities relevant to this handoff. Furthermore, the eRec author's requisite level of familiarity with the GEMified documents and how they relate to the eRec template should be identified; an improved GEM tutorial may help aid eRec authors.

As reinforced by the eRec Stakeholder Community input, there is an important need to reconcile the various CDS rule (and other CDS-related) formalisms produced by AHRQ- and ONC-funded projects and others. The GEM/eRec alignment analysis was an important first step on this agenda, and the recently convened ONC/AHRQ CDS Metaconsortium is a promising venue for continuing and expanding this reconciliation.

Codes as key content. Care delivery organizations—and EHR developers that support them - typically apply substantial resources to the process of translating clinical recommendations for implementation in CDS. Therefore, assistance with the knowledge translation process is highly desired. In particular, implementers want clearly defined and coded data elements for logic statements. It is therefore a problem when codes are not found in source documents and related references. Ideally, clinical guidance developers should unambiguously and thoroughly define terms used to specify populations and actions in their recommendations. This would facilitate eRecommendation development, and CDS rule development more broadly. Tools to facilitate assigning appropriate codes to these terms should emerge over time.

The potential creation of a ~~"d~~efinition variable" for items such as ~~"d~~iabetes present" used in the logic statements would avoid the complex strings of code/value sets directly in the eRecommendation logic statement. The project team considers central maintenance and reuse of

such key terms as important not only to enhance eRecommendation readability but also to facilitate their development and maintenance. Again, this is an extension being done under the SHARP C-2B project.

Some code-related rule development issues were beyond our ability to resolve. Key among these is clinical ambiguity in the narrative version of the care recommendations and lack of easily obtainable coding specifications from authoritative sources of the care recommendations. Even the eMeasure coding specifications were difficult to use when no label (descriptor or name) accompanied the individual code. For example, the eMeasure coding specifications indicate that the code list for the concept "breast cancer screening—diagnostic study performed" is N_c72, N_c73, N_c74, N_c81, and N_c82. Furthermore, it indicates that N_c72 refers to codes 76090, 76091, 76092, 77055, 77056, and 77057 from the CPT taxonomy, while N_c73 refers to codes G0202, G0204, etc. from the HPCCS taxonomy. However, the eMeasure specifications do not indicate what specific diagnostic procedure for breast cancer screening is represented by each code.

Knowledge management. Existing CDS-related standards do not fully capture the needs of this project, and the lack of consensus on various pertinent standards was particularly problematic in initially developing the eRec format. Perhaps our work will spur efforts aimed at refining existing standards or adopting new standards for representing clinical recommendations as logic statements to underpin CDS rules or standards for the clinical practice guidelines themselves. For example, links to certification standards for clinical information systems may be necessary to incentivize vendors to incorporate eRecs or related formalisms into their products. There were some inquiries from those in policy and standard setting organizations as to whether the eRecommendation had the potential to be a standard for rules knowledge sharing/dissemination. Further consideration of the results from this project—in the context of related CDS initiatives—can inform efforts toward the needed standards. Again, the CDS Metaconsortium may be one forum for these deliberations.

Key elements of a continued effort to bring eRecommendations to scale include iteratively increasing the number of CDS implementers and recommendation developers using the eRec template and artifacts. Along the way, the value proposition for this material should be evaluated and refined. Second, eRecommendations for more MU topics, driven by implementer need, would be needed. Finally, stakeholders asked about what entities would function as "owners" to support the development, maintenance and use of eRecommendations artifacts. For example, over the longer term, it may be possible for the authoritative source(s) of the clinical recommendations or eMeasures represented in the eRecommendations to create, maintain, own and distribute additional eRecommendations.

The template version created and used in the eRecommendation project represents eRecommendations as an Excel spreadsheet with XML tags and details; some readers find it a challenge to digest this quickly. A more English-like, human-readable presentation or a more streamlined presentation will be important for some users, such as clinical reviewers. Other government-funded projects, such as the ONC-funded SHARP C-2B project noted above, are now developing authoring tools that should make it easier to produce future eRecommendations in alternative formats, including XML-based output for those who desire it. An XML authoring

tool could use XSLT style sheets to generate separate output optimized for machine uptake and for human readability. The current spreadsheet format with XML tags was chosen for this project to facilitate subsequent conversion to the more versatile output, and has been used in SHARP for this purpose.

Authors of future iterations of MU eRecommendations could build on project work by providing ―if. . . then…" statements for actions to be taken earlier or in a more proactive manner so as to optimize care assessed by the measure (rather than just notifying about the impending measure failure). This would require identifying the appropriate clinical recommendation underlying the eMeasure, which is not consistently clear in the current eMeasure specifications. Quality measure developers are in a good position—perhaps in collaboration with guideline developers—to specify the proactive clinical guidance that should correspond to the measure. It is also important that eMeasures reference and be in sync with the appropriate version of a clinical recommendation.

Other MU eRec issues relate to the fact that the current source document for MU eRecommendations is the eMeasure specification. As a result, there may not be explicit guidance for an eRecommendation field necessary for creating a CDS rule, such as an intervention interval indicating how far back in time to look for a specific test or the interval during which the most recent test is considered relevant. Developers of clinical guidance—especially when working in collaboration with measure developers—can remedy this situation by identifying the appropriately detailed clinical recommendation to correspond to the measure. This way, eRecommendations engineered from quality measures can better support CDS aimed at improving clinical performance on the measure.

Similarly, the header information could be further optimized to account for source documents that are performance measures rather than clinical recommendations. The project team made many refinements to this section based on more in-depth work on eMeasure-based eRecommendations during the contract modification. Nonetheless, the header section could be further developed, subject to clear identification of source documents as well as additional eRec developer and user input. The goal would be for the header to optimally reflect key information pertinent to the source document (especially when this is an eMeasure), the clinical recommendations underlying the eMeasure, and the pertinent metadata pertaining to the eRecommendation itself.

Appendix A: Participants in eRecommendations Stakeholder Community

Stakeholder Group Type and Name of Individual	Attended Meeting #1 Thursday, 1/27/11	Attended Meeting #2 Friday, 2/25/11	Attended Meeting #3 Friday, 4/15/11
FEDERAL GUIDELINE DEVELOPERS AND HEALTH IT/CDS RESEARCH/DEVELOPMENT			
Eduardo Ortiz, NHLBI	✓	✓	
Nedra Garrett, CDC		✓	
Abigail Viall, CDC/OID/NCHHSTP	✓	✓	✓
Ninad Mishra, CDC		✓	✓
Gail R. Janes, CDC		✓	
Rebecca Morgan, CDC			
Peter Kilmarx, CDC			
Raul Romaguera, CDC			
Jessie Wing,CDC	✓	✓	
Geoff Beckett, CDC			
Stuart Berman, CDC/OID/NCHHSTP			✓
Daniel Pollock, CDC			
Clifford McDonald, CDC			
John Jernigan, CDC			
Michael Bell, CDC		✓	
Jeff Hageman, CDC			
Tom Sukalac, CDC			
Amrita Patel, CDC	✓	✓	
Nikolay Likskiy, CDC			
David Bergman, ONC			✓
Greg Downing, ONC			
Minyoung Kim, ONC		✓	
Alicia Morton, HHS/ONC			
Farzad Mostashari, ONC			
Rachel Nelson, ONC			
Ted Smith, ONC	✓	✓	
Jonathan Teich, ONC			
Janhavi Kirtane, ONC Beacon community program		✓	
Shaline Rao, ONC Beacon Community program	✓	✓	
Leah Marcotte, REC program			
Janice Genevro, AHRQ (USPSTF staff)	✓		✓
Claire Weschler, AHRQ	✓		✓

Stakeholder Group Type and Name of Individual	Attended Meeting #1 Thursday, 1/27/11	Attended Meeting #2 Friday, 2/25/11	Attended Meeting #3 Friday, 4/15/11
Chuck Friedman, HHS	✓	✓	✓
Clem McDonald, NLM			
Kyle Nicholls, HHS			
FEDERAL CARE DELIVERY SITE			
Veterans Administration (see also Swim Alongs)			
Steve Brown			
Mary Goldstein, Stanford			
Jonathan Nebeker, Utah	✓		
Indian Health Service			
Theresa Cullen			
Chris Lamer	✓		
Aneel Advani	✓	✓	
Department of Defense			
Steve Steffensen, DoD			
Emory Fry, DoD	✓	✓	
Peter Park, DoD (emergency room setting)			
Hon Pak, DoD		✓	
PILOT SITES			
Tulane/LA REC (LHCQF)/SuccessEHS		✓	
Dr. Eboni Price-Haywood, Tulane	✓	✓	✓
Brenda Ikerd, LHCQF			
Nadine Robin, LHCQF	✓	✓	✓
Adele Allison, EHS		✓	✓
Erin Gipson, EHS			✓
Karen Handley, EHS		✓	
Lori Hines, EHS	✓		
Elizabeth Pharo, EHS	✓	✓	✓
Sam Seetaram, EHS		✓	
David Turner, EHS	✓		
Memorial Hermann/Cerner			
Bob Murphy, Memorial Hermann	✓	✓	✓
Anwar Sirajuddin, Memorial Hermann			
Lynn Baldwin, Cerner			✓
Kim Hlobik, Cerner			
Chad Ruoff, Cerner	✓	✓	✓
SWIM ALONGS			

Stakeholder Group Type and Name of Individual	Attended Meeting #1 Thursday, 1/27/11	Attended Meeting #2 Friday, 2/25/11	Attended Meeting #3 Friday, 4/15/11
Michael Krall, Kaiser Permanente			
Wiley Chan, Kaiser Permanente			
Dan Zisook, Kaiser Permanente	✓	✓	
Yang Huang, Kaiser Permanente	✓	✓	
Erin Stone, Kaiser Permanente	✓		
Richard Loomis, Kaiser Permanente		✓	
John Mattison, Kaiser Permanente	✓		✓
Craig Robbins, Kaiser Permanente	✓	✓	✓
Ferdinand Velasco, Texas Health		✓	
Karen Adams, Texas Health	✓	✓	
Luis Saldana, Texas Health	✓	✓	✓
Cheryl Skinner, Texas Health	✓	✓	
Craig Umscheid, UPENN		✓	✓
Patrick Redington, VA		✓	✓
Caroline L. Goldzweig, VA	✓	✓	
Michelle Lucatorto, VA	✓	✓	
Terri Murphy, VA, VHA National Center for Health Promotion and Disease Prevention (NCP)	✓	✓	✓
PRIVATE CARE DELIVERY SITE			
Gil Kuperman, NYP			
Joel Shoolin, Advocate Health			
David Trachtenenbarg, MMCI			
William Bria, Shriners Hospital			✓
George Hripcsak, Columbia	✓		
Harold Lehmann, Johns Hopkins			
Peter Greene, JHU		✓	✓
Judy Murphy, Aurora		✓	
Peter Haug, Intermountain Healthcare		✓	
Milisa Rizer, OSUMC (Ohio)			
GUIDELINE DEVELOPERS AND SPECIALTY SOCIETIES			
David Kibbe, AAFP			
Steve Waldren, AAFP	✓		
Jennifer Mansour, AAP	✓	✓	
Caryn Davidson, AAP			✓
Christopher Lehmann, AAP			
Kevin Johnson, AAP			
Sandy Lewis, ACCP			✓
John Tooker, ACP			

Stakeholder Group Type and Name of Individual	Attended Meeting #1 Thursday, 1/27/11	Attended Meeting #2 Friday, 2/25/11	Attended Meeting #3 Friday, 4/15/11
Thomson Kuhn, ACP	✓	✓	✓
Karen Kmetik, AMA	✓	✓	✓
Marjorie Rallins, AMA	✓	✓	✓
Steve Crane, American Thoracic Society	✓	✓	
Tom Stibolt, American Thoracic Society			✓
CIS VENDORS			
Cerner Team - see pilot sites above			
Jacob Reider, Allscripts and EHRA	✓	✓	✓
Matt Stitz, Microsoft			
David Bordewyk, Thomson Reuters		✓	✓
Katie Carls, Provation/Wolters Kluwer	✓	✓	✓
Patrick Yoder, ProVation		✓	✓
ePocrates Team			
Michelle Snyder			
Tom Giannulli	✓	✓	
Kent Westervelt			
Applied Pathways			
Mark Rangell			✓
John Feldman			
Nelson Rosenbaum			✓
Jim Woodburn			✓
Woody Barela			
POLICY/STANDARD SETTING COMMUNITY, E.G. HEALTH IT STANDARDS COMMITTEE			
Chris Chute, Mayo			
Mark Overhage, Regenstrief			
Jim Walker, Geisinger	✓	✓	✓
Paul Tang, Stanford David McCallie, Cerner		✓	✓
QUALITY/PERFORMANCE MEASURE COMMUNITY			
Rick Moore, NCQA		✓	✓
Greg Pawlson, NCQA			
Floyd Eisenberg, Quality Forum	✓	✓	
INFORMATICS PROJECTS/EXPERTS			
Rob Kolodner	✓		✓
Glen Moy, California Healthcare Foundation		✓	
Alexis Elward, Washington University in St. Louis		✓	

Stakeholder Group Type and Name of Individual	Attended Meeting #1 Thursday, 1/27/11	Attended Meeting #2 Friday, 2/25/11	Attended Meeting #3 Friday, 4/15/11
David Collins, HIMSS		✓	✓
Pat Johnson, HIMSS		✓	✓
Deborah Even, LPHI (Cresent City Beacon)		✓	✓
Eric Baumgartner, LPHI (Crescent City Beacon)		✓	
Maria Ludwick, LPHI (Crescent City Beacon)			
Saira N. Haque, RTI International			
Shelli Williamson, Scottsdale Institute			✓
Douglas Bell, RAND			✓
Justin Starren, Northwestern			
David Lobach, Duke			✓
Partners/ACDS/CDSC:			
Tonya Hongsermeier (ACDS project)	✓	✓	✓
Janet Lewis		✓	✓
Blackford Middleton	✓		
Saverio Maviglia			
Roberto Rocha			
GLIDES:			
Rick Shiffman, Yale			
AMIA			
Ted Shortliffe		✓	
Meryl Bloomrosen			
PROJECT TEAM/TOO			
Jon White, AHRQ	✓	✓	✓
Aziz Boxwala, UCSD	✓	✓	
Bob Greenes, ASU	✓		✓
Margarita Sordo, Harvard			
Rosanna Coffey, Thomson Reuters			
Jerry Osheroff, Thomson Reuters	✓	✓	✓
Susan Raetzman, Thomson Reuters	✓	✓	✓
Andriana Hohlbauch, Thomson Reuters	✓	✓	✓
Lynne Schabert, Thomson Reuters	✓	✓	
TOTAL ATTENDEES	**54**	**70**	**53**

Appendix B: Analysis and Recommendations to AHRQ Regarding Interplay between GEM and eRecs to Support CDS Rule Implementation (3/2/11 draft)

Background on Each Project

GEM

(a) GEM starts with narrative guideline statement
- uses formal/standardized method for markup according to a standardized schema
- uses systematic methods to generate a semiformal representation, including decomposing conditional expressions and action statements, and determining code lists
- represents a standard for guideline document representation (ASTM E2210-06)
- tools exist for markup and knowledge transformation
- capable of expressing the heterogeneous knowledge contained in guideline (i.e., comprehensive)
- expressively adequate to convey the complexities and nuances of clinical medicine while remaining informationally equivalent to the original guideline
- able to deal with the variety and complexity of guidelines (i.e., flexible). The representation permits modeling at high and low levels of granularity, so that guidelines can be interpreted at different levels of abstraction.
- reusable across all phases of the guideline lifecycle

(b) QDS has been applied to marked up rules, i.e., the GEM-ified document was put through EXTRACTOR to identify decision variables and actions that were subsequently modeled in QDS (See forthcoming AAP type 2 diabetes guideline)

(c) Other characteristics of GEM
- the model matches the stakeholders‘ normal problem-solving language and allows domain experts to describe their knowledge with little effort (i.e., comprehensible)
- shareable across institutions
- the main focus is on what the eRecommendations project refers to as a Level-1 (structured header, unstructured text) representation
    - the markup process does not include conversion to a standard data model or terminologies
    - there is no formal syntax for logic expressions

eRecommendation

(a) eRecommendations often start with a narrative guideline statement
- aimed at single-step rule codification, not full guideline
- uses an explicit method for identifying eligibility criteria, conditional logic, and actions
- could use GEM markup from above process as starting point for populating the Level 1 template, if marked-up version exists

- for Level 2, progressively refines the above into data elements and code sets, formal logic expression, and specific action recommendation

(b) eRecommendations sometimes begin with a performance measure standard
- obtains eligibility criteria from the performance measure
- because eMeasure doesn‘t necessarily specify underlying guideline/action, default action for eRec is to notify someone about potential for performance failure or need for compliance on the measure
  - Note that this is a very intermediate step, in that proactive CDS would need to anticipate actions that should be done before potential for failure could occur. However, to go beyond the default, would need to identify appropriate guideline dealing with this situation as in (a)

(c) eRecommendation uses QDS data model (NQF now calls this the Quality Data Model or QDM) developed for performance measures

(d) Other characteristics of eRecommendations
- Tags the rule components according to an XML schema, and assembles the information into an eRec template (definitions of elements are currently contained in draft Standard Operating Procedures document). This XML schema and template are still evolving as richer sets of eRecs are being produced and feedback is obtained, and are being augmented by SHARP-C 2B project
- Incorporates a set of workflow and setting-specific ~~–i~~mplementation considerations” as suggestions to implementers
- Template, data elements, and implementation considerations continue to be developed/refined with broad stakeholder input and information sharing from other projects (i.e., SHARP-C 2B)

Reconciliation Progress to Date

1. During first eRec phase looked at GEM, spoke to R. Shiffman and preliminary conclusion was that purposes were sufficiently different from eMeasures and goals of eRec project that GEM schema would not have much relevance

2. Contract modification called for revisiting this issue; did eRec/GEM mapping, email exchanges, call with Rick. High-level upshots to date:
   - GEM and eRec are focusing on somewhat different process/targets right now
   - Still, the fact that both GEM and eREC are developing rules calls for some level of standardization of rule components
   - As eRecs dive deeper into guideline-based recommendations underlying eMeasures (as opposed to just notifying about potential patients at risk of measure failure) there might be better synergies

More Indepth Analysis of GEM-eRec Interplay—Disconnects and Opportunities

- eRec process of going from published EBM statement to structured template could start with GEM-marked-up version once generated. Guideline developers could do this, as GEM Cutter is simple to use, particularly if the focus is just on the recommendation statement.

- Header info in eRec does match up with GEM in a few places, particularly in terms of reference to purpose and source material

- GEM –polishing" has been described, as has the eRec process of going from Level 1 to 2, i.e. refining of all data elements and definitions and specification of logic in terms of those data elements (again, see the draft Standard Operating Procedures document for more in-depth description). Level 3, beyond the scope of eRec (but being refined by SHARP-C 2B), involves a systematic process of transforming a rule module based on selection of Setting-Specific Factors (SSFs).

- Synergies are thus potentially bidirectional
  - GEM process for transforming a Level 0 EBM statement to a marked-up document that can be used in the creation of the eRec Level 1 document
  - eRec process for formalizing data elements, definitions, and logical expressions
  - eRec/future SHARP-C 2B process for incorporating SSFs.

- Some minor adjustments will also be beneficial
  - For example, elaboration of decision variables in GEM differs from eRecs. The eRec decomposes conditional clauses into triples (data element, logical operator, target value) while GEM decomposes into pairs (data element, value range/limit). Despite the difference in number of elements, mapping could be relatively straightforward.
  - Also, eRec seeks to create a template-based foundation for an executable rule (in terms of fields rather than a visual flowchart, but essentially seeking to define the process flow for execution), whereas GEM decomposes the elements, but leaves the process flow or algorithm as somewhat separate. GEM incorporates a <link> element in each conditional or imperative that can be used to describe flow between statements. In addition, GEM includes <action step>, <conditional step>, <branch step>, and <synch step> derived from the GLIF model.

- Current lack of significant overlap of formal GEM-encoded guidelines and eRec content. eRecs to date are focused on A and B USPSTF recommendations and notification associated with impending failure on an eMeasure. ECRI has independently used GEM to markup guidelines from more than 10 professional organizations and Rick's team has not been constrained by any age range (or guideline type) in their work. The Yale team views USPSTF guidelines as more amenable to GEM-ification than many other guidelines.

Recommendations to AHRQ

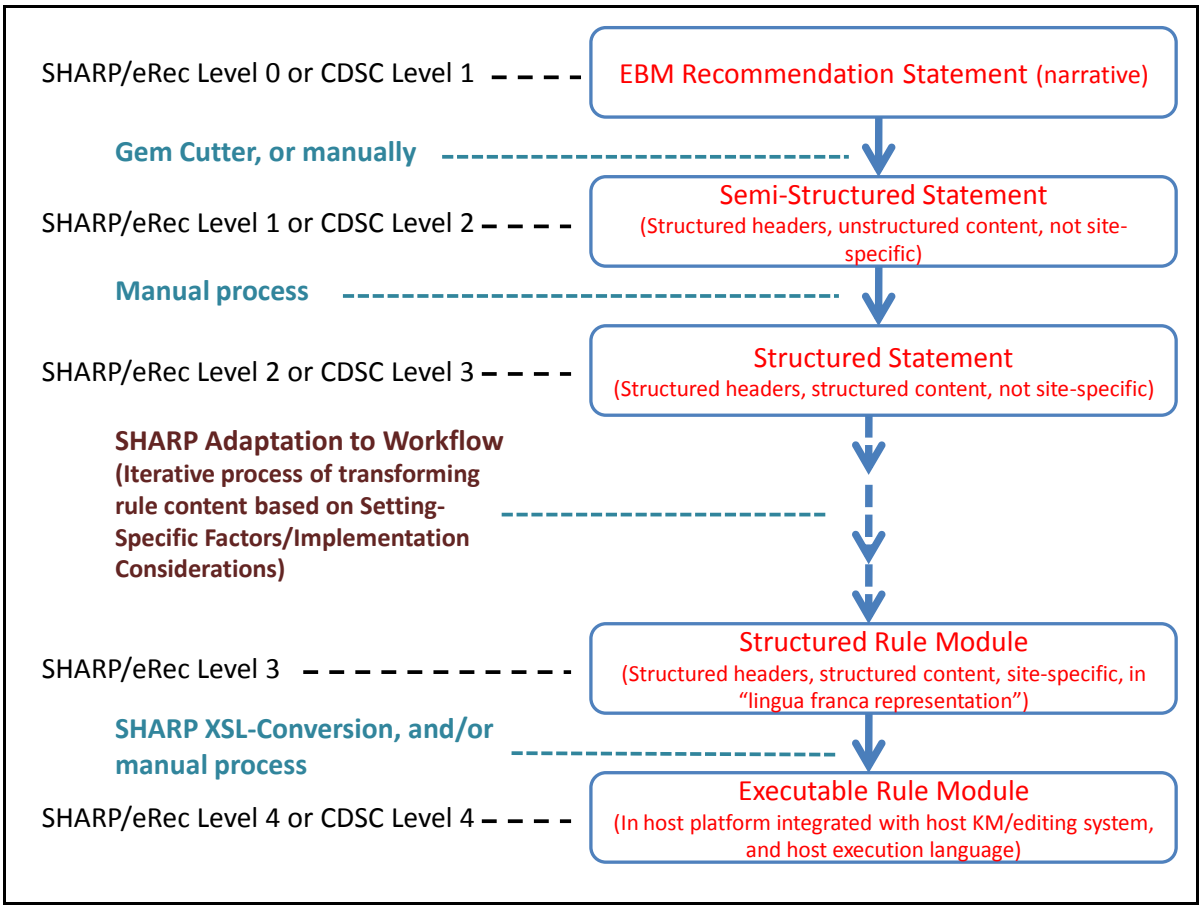
1. Use GEM output (XML schema) as Level 1 input into populating eRec fields. Use GEM to mark up published EBM statements and to annotate them with quality, strength of evidence, etc. Parsing a statement into standardized bins, defining logical connectors, choosing an appropriate level of abstraction, and chunking text into semantically identifiable concepts all have value. This would be a theoretically better starting point for eRec template construction, if feasible. Even better would be to provide a structured authoring template directly to guideline authors/developers, so that the fields needed can be explicitly defined by them. This work is underway with the GLIDES team's BRIDGE-Wiz application that leads guideline authors through a systematic process for defining actionable recommendations and linking the recommendations to supporting evidence and judgments about anticipated benefits and harms.

    - Therefore, the following specific course of action is recommended: Apply GEM Cutter to a guideline that underpins one of the MU eMeasures that's high on the eRec team's target list for development. The eRec team would then create this eRec using the output from GEM. The process and the results could be compared to creating an eRec for the same MU-related guideline without the aid of GEM Cutter.

2. Engage in broader discussion about approaches for managing (and ideally harmonizing) the 3 different AHRQ-funded formalisms for expressing logic statements from clinical guidelines in a manner suitable for use in CDS rules (i.e., GLIDES/GEM, CDSC, eRecommendations).

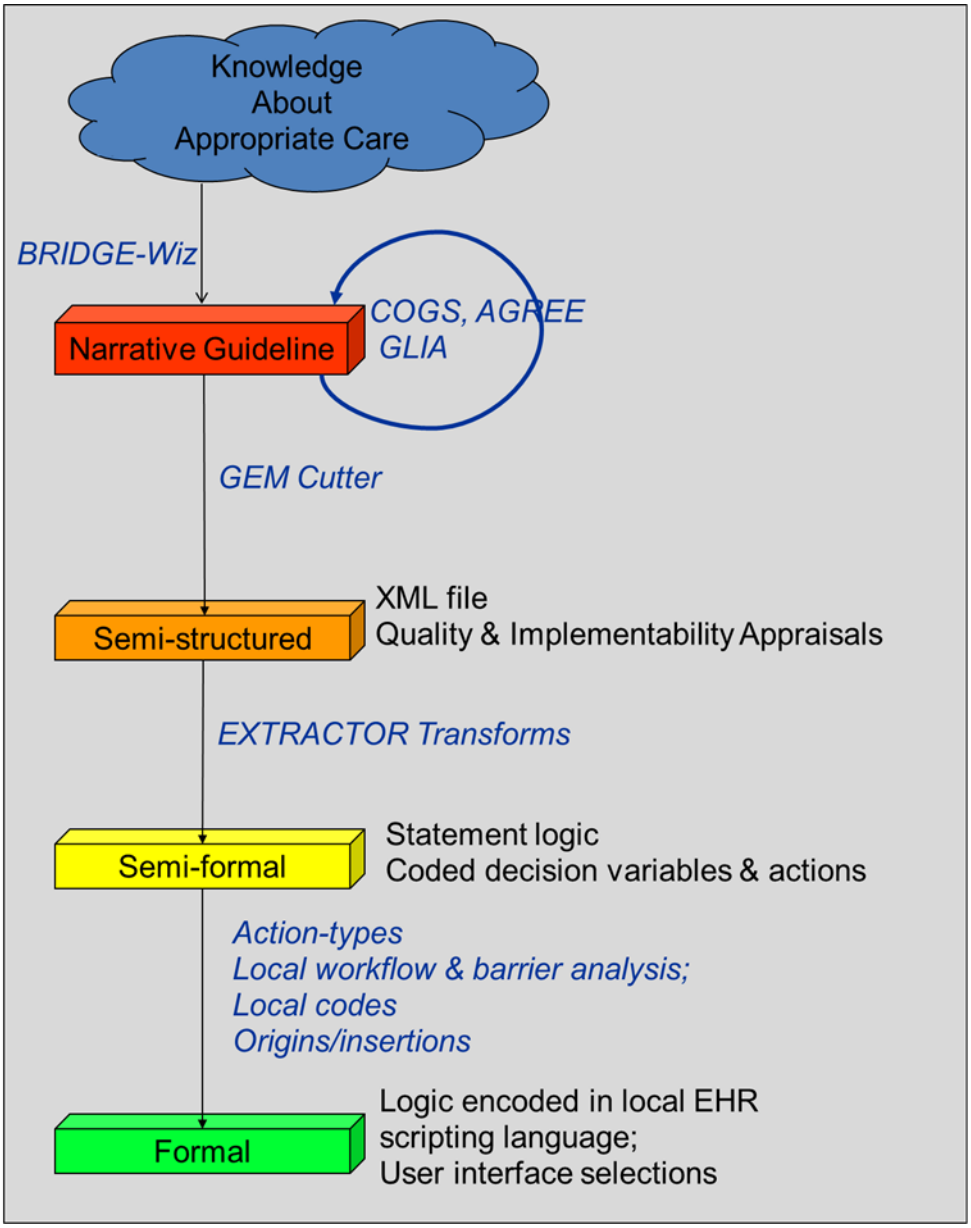
Appendix C: Model Alignment Within Stages of Rule Development

Figure C1: eRec and GEM Model Alignment within Stages of Rule Development



The more detailed diagram of GLIDES levels below also fits with the models in the diagram above. The red rectangle (narrative guideline) corresponds to the EBM Recommendation Statement stage. The orange rectangle (semistructured) corresponds to the semistructured statement stage. The green rectangle (formal) corresponds to the executable rule module stage. Finally, the intermediate yellow rectangle (semiformal) straddles the structured statement and structured rule module stages.

Figure C2: Details of GLIDES Model



Source: GLIDES (GuideLines Into DEecision Support) Web site at http://gem.med.yale.edu/glides

Appendix D: Mapping of GEM Elements and eRecommendation Fields to Source Documents for Clinical Recommendations

Gray-shaded rows indicate the 28 fields from the eRecommendation template that are populated using information from the source document for the USPSTF guidelines. It was later determined that 7 of these did not directly use information in the source document, e.g., values that describe data elements based on standardized code sets. These fields are denoted by red cells at the end of the row. The 16 fields judged by Rick Shiffman to be capable of being populated using GEM output are denoted by green cells at the end of the row and the one field where GEM output could be helpful but probably not sufficient for populating is denoted by yellow cells at the end of the row. In addition, the four fields that could not be populated with GEM output because they were metadata not represented in the current GEM document model also are denoted by red cells at the end of the row.

Level	XML Tag	Value	Definition	Relevant data from USPSTF	GEM OUTPUT MATCH TO eREC (Output fully populates eRec field; Output is helpful but not sufficient for populating eRec field; Output is not helpful in populating eRec field)	OTHER COMMENTS RE: MATCH
0	<Header>	HEADER	The Header section of the template contains general information about the underlying care recommendation, as well as information to support eRecommendation editorial processes including content creation and structuring, version management, and ownership.			
1	<eRecommendationInformation>	eRecommendationInformation	This section contains information related to the eRecommendation			
2	<eRecommendationName>	eRecommendation Name	Short, descriptive name assigned to populated template. Name indicates the recommendation category and rule classification, e.g., USPSTF SCREENING FOR COLORECTAL CANCER (A, B Recommendation on Screening only).	Title of clinical guideline indicating the USPSTF as recommending entity. Also, include target population and recommendation type. E.g. USPSTF SCREENING FOR BREAST CANCER IN THE GENERAL POPULATION (B Recommendation on mammography only)	Output is not helpful in populating eRec field	Would not find words together to make title (so this is meta data). Closest is called "Guideline title" in GEM but covers more than one recommendation. No name for the Gemified document.
2	<eRecommendationID>	eRecommendation ID	Unique, descriptive identifier assigned to document.	Include recommending entity (USPSTF), and abreviation of the type of action, purpose of the guideline (Mammography -> MAMMO) and the type of recommendation (A or B recommendation) E.g. USPSTF-MAMMO-B-REC		
2	<eRecommendationTargetPopulation>	eRecommendation Target Population	Population targeted by the recommendation, i.e., general population	This information can be identified from the RATIONALE section of the clinical guideline or in any other section of the guideline where the target populations are identified. For example, the breast cancer screening focuses only on the general population so, this field should be encoded as: General Population. If a recommendation targets more than one population, as in the case of breastfeeding, then this field should indicate the population being targeted. In the case of breast feeding, this field should be:Pregnant women and new mothers, and newborns.	Could fully populate eRec field using GEM output	Have target population elements, as specific as possible. Depends on how deeply you go down tree, e.g.,use "eligibility," "inclusion criteria," "exclusion criteria."
2	<eRecommendationPart>	eRecommendation Part	A recommendation can address more than one target population. This field indicates the population the eRecommendation is targeting, as well as whether it is part of a multi-population recommendation. I.e., 1 of 1.	This information can be identified from the RATIONALE section of the clinical guideline or in any other section of the guideline where the target populations are identified. For example, the breast cancer screening focuses only on the general population so, this field should be encoded as: 1 of 1 If a recommendation targets more than one population, as in the case of breastfeeding, then this field should indicate the population being targeted and the number of populations the recommendation addresses. In the case of breast feeding, this field should be: 1 of 2, and 2 of 2.	Output is not helpful in populating eRec field	This refers to different chapters of guideline. Publication parts are not covered by GEM. Metadata.
2	<eRecommendationVersion>	eRecommendation Version Date/Number	Document version number and date of creation. As well as revision date(s)	Date of the current version of the eRecommendations for the USPSTF Clinical Recommendations. E.g. 05/31/10		
2	<TemplateVerDateNum>	eRecommendation Template Version Date/Number	Version and date of template format used in creating the eRecommendation.	03/27/2011 / V.3.2		
2	<AuthorshipeRec>	Authorship of eRecommendation				
3	<eRecAuthorName>	eRecommendationAuthorName	Name of person who encoded the eRecommendation	E.g. For Screening for Breast Cancer Clinical Recommendation, Margarita Sordo		
3	<eRecAuthorOrganization>	eRecommendation AuthorOrganization	Name of eRecommendation author's organization	I.e., Thomson Reuters		
2	<VerifiedBy>	eRecommendation Verified by	Name of person or institution who verified the eRecommendation, otherwise assign unverified	Agency for Healthcare Research and Quality (AHRQ) and United States Preventive Services Task Force (USPSTF)		
2	<MaintainedBy>	eRecommendation Maintained by	Name of person or institution responsible for maintaining the eRecommendation content.			
1	<SourceDocumentInformation>	SourceDocumentInformation	This section contains information related to the USPSTF source document used to create this eRecommendation			
2	<SourceDocumentName>	Source Document Name	Name of the source document USPSTF used to create this eRecommendation	I.e., Clinical Guidelines: Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. U.S. Preventive Services Task Force	Could fully populate eRec field using GEM output	Use "Guideline Title"
2	<RecommendationGrade>		One of USPSTF grades: A or B	A- and B-grade sections of the Recommendation	Could fully populate eRec field using GEM output	GEM has rating schema and rating. Use "Evidence Quality" and "Recommendation Strength"
2	<AuthorshipSourceDocument>		Information about authorsip of source recommendation statement	I.e., Clinical Guidelines: Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. U.S. Preventive Services Task Force	Could fully populate eRec field using GEM output	??? Use "Committee Name."
3	<SourceAuthorName>		USPSTF	USPSTF	Could fully populate eRec field using GEM output	Use "Committee name." GEM also has committee member and committee expertise etc.
3	<SourceAuthorOrganization>		USPSTF	USPSTF	Could fully populate eRec field using GEM output	Use "Developer name."
2	<RecommendationOrEmeasureSet>	Recommendation or eMeasure Set	Group of recommendations to which this recommendation belongs, according to the source, e.g., USPSTF Grade A recommendations.	USPSTF A and B Recommendations	Output is not helpful in populating eRec field	Meta data
2	<SetID>	Recommendation Set ID	If applicable, identifying label for group of recommendations to which this recommendation belongs.	USPSTF-A-B-RECS	Output is not helpful in populating eRec field	Meta data
2	<RecOrEMeasureVersionDateNumber>	Recommendation or eMeasure Version Date/Number	Version number and revision date of the care recommendation from the source. Note that this field does not indicate whether the current recommendation is the latest version. It is the user's responsibility to determine whether the eRecommendation reflects the latest care recommendation update and to select the latest version if desired.	For example, from Screening for Breast Cancer, this field should be: 2 (revision of 2002 guidelines)		
2	<RelatedeMeasure>	Related eMeasure(s)	NQF retooled measure ID that is related to USPSTF recommendation, when available.	For Screening for Breast Cancer Clinical Recommendation: PQRI112:Preventive Care and Screening: Screening Mammography [PQRI age range40 69]		
2	<DescriptionPurpose>	Recommendation Description/Purpose	Brief overview of the source document recommendation.	E.g. Screening for Breast Cancer: U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for breast cancer in the general population.	Could fully populate eRec field using GEM output	Use "Objective."
2	<RecOrEMeasureTextSummary>	Recommendation or eMeasureText from Source: Summary Statement	Summary description of the care recommendation as it appears in the narrative source document.	Summary of recommendation: E.g. Screening for Breast Cancer: The USPSTF recommends biennial screening mammography for women between the ages of 50 and 74 years.	Could fully populate eRec field using GEM output	Use "Conditional" or "Imperative." All conditionals and imperatives would provide bold faced statement of what recommendation intended to do.

Level	XML Tag	Value	Definition	Relevant data from USPSTF	GEM OUTPUT MATCH TO eREC (Output fully populates eRec field; Output is helpful but not sufficient for populating eRec field; Output is not helpful in populating eRec field)	OTHER COMMENTS RE: MATCH
2	<RecTextIncExc>	Recommendation Text from Source: Additional Inclusion/Exclusion Criteria	For USPSTF recommendations, this is text as it appears in Clinical Considerations, Patient Population under Consideration section of narrative source document. It indicates additional considerations for inclusion/exclusion criteria.	This recommendation statement applies to women 40 years or older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation.	Could fully populate eRec field using GEM output	Gemified output calls this "decision variables." Plus target population/eligibility population description?
1	<Setting>	Setting (if specified by Source)	Clinical setting (e.g., doctor's office) where the recommendation applies, if specified in the narrative source document. Also indicate if additional information might be added in implementation considerations section.	Not specified. See implementation considerations.	Could fully populate eRec field using GEM output	Use "Care Setting" under Intended Audience
2	<RecommendationOrEMeasureFocus>	Recommendation or eMeasure focus	Purpose of the recommendation (e.g., screening, prevention, diagnosis).	E.g. for Breast Cancer Screening: Preventive Services: Screening	Could fully populate eRec field using GEM output	Use "Main focus." This is the primary condition or health practice or intervention.
2	<Rationale>	Rationale	For USPSTF recommendations, this is stated in the Rationale section of the narrative source document and includes Importance, Detection and Benefits of Detection, and Early Intervention. If this section is not available, include narrative from Clinical Considerations. For Meaninful Use, include information from Rationale section.	For USPSTF recommendations, this is stated in the Rationale section of the narrative source document and includes Importance, Detection and Benefits of Detection, and Early Intervention. If this section is not available, include narrative from Clinical Considerations.	Could fully populate eRec field using GEM output	Use "Rationale" (why guideline needed) and "Objective."
2	<SourceReferenceDocument>	Source Reference Document	For USPSTF recommendations, use full citation of the source's recommendation statement. For Meaningful Use, use references from References section	For USPSTF recommendations, use full citation of the source's recommendation statement.	Could fully populate eRec field using GEM output	Use "Citation"
2	<SourceReferenceURL>	Source Reference URL	URL for the online version of the care recommendation from the source.	Link to USPSTF source document		
0	**<DataDefinitions>**	**DATA DEFINITIONS**				
1	**<EligibilityInclusionData>**	**Eligibility/Inclusion-related data**				
2	<InclusionData>	Inclusion data	Identify all applicable data properties the target population should meet in order to be included. E.g. gender, age range, smoking status.	For Screening for Breast Cancer: Target gender: F Target age low limit: 50 Target age high limit: 74	Could fully populate eRec field using GEM output	Use "Decision variable" (e.g., gender) and "Decision variable value" (e.g., female). Located in different place than inclusion/exclusion because only relevant for specific recommendation statement.
2	<InclusionComments>	Comments Relating Inclusion Criteria	Include any comments relevant to inclusion criteria in relation to the Clinical Guideline itself or in relation to variations to MU inclusion data/values.	For Screening for Breast Cancer: Note that for PQRI 112 to which this logic statement is related, age high limit = 69		
1	**<InclusionCriteriaData>**	**Inclusion criteria-related data**	These four slots should be repeated as needed for each property of the target population.		N/A	N/A
2	<InclCrieriaValueSetName>	Value set name	Data element attribute relevant to inclusion criteria	E.g. Patient Gender	Field contents don't come directly from source document	GEM 3 will have this but not there now.
2	<InclCrieriaQualityDataType>	Quality data type	Data type(s) from Data model relevant to inclusion critera	E.g Patient Characteristic	Field contents don't come directly from source document	GEM 3 will have this but not there now.
2	<InclCrieriaCodeSet>	Code set	Applicable code set definition	E.g. HL7 CDA AdministrativeGenderCode	Field contents don't come directly from source document	GEM 3 will have this but not there now.
2	<InclCrieriaCodeList>	Code list	List of codes for the selected code set definition	E.g. target gender	Field contents don't come directly from source document	GEM 3 will have this but not there now.
1	**<InterventionInterval>**	**Intervention interval**				
2	<InterventionIntervalValue>	Intervention interval	Intervention interval as defined in the recommendation or MU. If not specified in document. Implementers should consider defining an appropriate intervention interval.	E.g. 2 years	Could fully populate eRec field using GEM output	Use "Action" or "action description," if described in source document.
1	**<ExclusionCriteriaData>**	**Exclusion criteria-related data**	All patient or clinical data that may exclude a patient from the targte population. E.g. Prior tests, procedures indicating the presence of the disease being screened; genetic mutations, family history that will put the patient at a higher risk and hence will exclude them from the protocol; screening test performed within the screening interval. The following four slots should be repeated for each relevant data item considered for exclusion purposes.			
2	<ExclCrieriaValueSetName>	Value set name	Data item that will exclude patient	E.g. History of chest radiation	Field contents don't come directly from source document	GEM 3 will have this but not there now.
2	<ExclCrieriaQualityDataType>	Quality data type	Data type(s) from Data Model relevant to exclusion criteria	E.g. Procedure		
2	<ExclCrieriaCodeSet>	Code set	Applicable code set definitions	E.g. (CPT 4, ICD9, SNOMED)		
2	<ExclCrieriaCodeList>	Code list	List of codes for the selected code set definition. If specific codes are not available, then describe them in an English-like short sentence.	E.g. {list of relevant codes relating to Hx of chest radiation}.		

Level	XML Tag	Value	Definition	Relevant data from USPSTF	GEM OUTPUT MATCH TO eREC (Output fully populates eRec field; Output is helpful but not sufficient for populating eRec field; Output is not helpful in populating eRec field)	OTHER COMMENTS RE: MATCH
2	<ExclusionCriteriaNotes>	Exclusion criteria-related data notes	Narrative-ike description of other factors that should be taken ito consideration when excluding patients from current protcol and/or assigning them to another protocol if available.	E.g. For Breast Cancer Screening: High risk patients may require a different screening protocol. The USPSTF recommendation states that a known genetic mutation or a history of chest radiation puts a woman at an increased risk for breast cancer and excludes this group from the screening recommendation. The recommendation implies that a different screening/ treatment recommendation/ protocol applies to this high risk group, although it does not make explicit such a recommendation/ protocol. Therefore, it might be appropriate for implementers to consider if there is a recommendation/protocol for the screening/treatment of the given high risk group in place in the system: • If there is a protocol, and if there is evidence that a high risk patient is already on such a protocol, exclude this patient from the recommendation. • If there is a protocol, and a high risk patient is not on it, recommend that the patient be put on the protocol • If there is no protocol, or if there is evidence that the patient is on such a protocol elsewhere, exclude this patient. • Otherwise, do not exclude this high risk patient.	Helpful but not sufficient for populating eRec field	Included in "Action description" or "Decision variable description," depending on whether related to condition being talked about or action to be performed. Or use action benefit, action risk/harm, action cost (modifiers of an action that might be relevant).
2	<OperationalExclusionCriteriaData>	Operational exclusion criteria-related data	Operational inclusion criteria may be used to define criteria pertinent to local needs and constraints.	Optional element: implementer may define and use operational exclusion criteria pertinent to local needs and constraints. For example, if the intervention recommended is addressed/ pending, or if patient has condition being screened and is already undergoing treatment, etc. then implementers may wish to suppress the intervention recommendation to minimize false positive notifications. See Implementation Consideration section for further details and examples.		
1	**<ActionRelatedData>**	**Action related data**	Screening action(s) to be performed on target patients. The following four slots should be repeated for each relevant action to be performed.			
2	<ActionRelatedValueSetName>	Value set name	Screening action to be performed	Bilateral mammogram	Field contents don't come directly from source document	GEM 3 will have this but not there now.
2	<ActionRelatedQualityDataType>	Quality data type	Data type(s) from Data Model relevant to action	Diagnostic Study Order		
2	<ActionRelatedCodeSet>	Code set	Applicable code set definitions	(CPT, LOINC, SNOMED)		
2	<ActionRelatedCodeList>	Code list	List of codes for the selected code set definition. If specific codes are not available, then describe them in an English-like short sentence.	{list of relevant codes for screening mammography tests}		
0	**<LogicStatement>**	**LOGIC STATEMENT**	This section contains the encoded antecedents for elegibility criteria. The basic element of the antecedent decision rule is a triplet of the form *<Object.attribute> <operator><value>* where the *Object.attribute* is an instance of a Class in the Data Model which is compared, through an *operator* , against a *value* . Decision rules for inclusion/exclusion criteria are constructed by combining these triplets by means of Boolean operators i.e. *OR, AND, NOT* . In this cell include a summary list of the conditions for inclusion and exclusion criteria and the action to be performed if the conditions in the antecedent are met: *IF* [patient meets inclusion criteria:] *AND DOES NOT* [have these exclusion criteria:] *THEN* [action:]	*IF* [patient meets inclusion criteria: Gender = target gender AND Age between 50 and 74] *AND DOES NOT* [have these exclusion criteria: Patient has a history of chest radiation OR Patient has a known genetic mutation OR There is evidence of mammogram results documented within 2 years] *THEN* [action: Recommend bilateral mammogram]		
1	**<EligibilityInclusionCriteria>**	**<Eligibility/inclusion criteria>**	This section pertains to encoding the antecedents that apply to the inclusion criteria			
2	<EligibilityInclusionCriteriaText>	EligibilityInclusionCriteriaText	*Encode in English-like representation the inclusion criteria using <Object.attribute> <operator><value>* triplets combined with Boolean operators *Also, Arden operators may be used to calculate values (e.g. current date)*	If Patient Characteristic.Gender = target gender AND (*current date* - Patient Characteristic. Person Date of Birth) is between target age low limit and target age high limit		
2	<EligibilityInclusionCriteriaComments>	EligibilityInclusionCriteriaComments	This field should include any information pertinent to the inclusion criteria, including target values, and information that might not be encoded in the rule but should be considered for future implementations. Also, information about assumptions or decision made while encoding the rules should be described in this field.	target age low limit = 50 target age high limit = 74 target gender = female		
			Breakdown the English-like representation of the inclusion criteria into simple conditions and/or subclauses. *Nested conditions should be encoded as subclauses. Conditions in a subclause should also be encoded as triplets of the form <Object.attribute> <operator><value> combined with Boolean operators.* *All simple conditions and subclauses should be grouped with Boolean operators to represent the whole inclusion criteria.*			
2	<EligibilitySubclause1>	Subclause	*If encoding nested conditions, provide a label for the subclause. This label should be used as a condition in the main logic.* *If there are no nested conditions, leave this row empty.*			

Level	XML Tag	Value	Definition	Relevant data from USPSTF	GEM OUTPUT MATCH TO eREC (Output fully populates eRec field; Output is helpful but not sufficient for populating eRec field; Output is not helpful in populating eRec field)	OTHER COMMENTS RE: MATCH
2	<EligibilityCondition1a>	Condition	write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model	(current date - Patient Characteristic. Person Date of Birth) is between target age low limit and target age high limit		
2	<EligibilityBooleanOp1>	Boolean operator	add Boolean operator (AND, OR, NOT) if needed	AND		
2	<EligibilityCondition1b>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model	Patient Characteristic.Gender = Target gender		
2	<EligibilityBooleanOp2>	Boolean operator	add Boolean operator (AND, OR, NOT) if needed			
2	<EligibilityCondition1c>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model			
2	<EligibilityEndSubclause1>	EndSubclause				
2	<EligibilitySubclause2>	Subclause	Same as above - use as needed			
2	<EligibilityCondition2a>	Condition				
2	<EligibilityBooleanOp2>	Boolean operator				
2	<EligibilityCondition2b>	Condition				
2	<EligibilityEndSubclause2>	EndSubclause				
2	<EligibilitySubclause3>	Subclause	Same as above - use as needed			
2	<EligibilityCondition3a>	Condition				
2	<EligibilityBooleanOp3>	Boolean operator				
2	<EligibilityCondition3b>	Condition				
2	<EligibilityEndSubclause3>	EndSubclause				
2	<EligibilitySubclause4>	Subclause	Same as above - use as needed			
2	<EligibilityCondition4a>	Condition				
2	<EligibilityBooleanOp4>	Boolean operator				
2	<EligibilityCondition4b>	Condition				
2	<EligibilityEndSubclause4>	EndSubclause				
2	<EligibilitySubclause5>	Subclause	Same as above - use as needed			
2	<EligibilityCondition5a>	Condition				
2	<EligibilityBooleanOp5a>	Boolean operator				
2	<EligibilityCondition5b>	Condition				
2	<EligibilityBooleanOp5b>	Boolean operator				
2	<EligibilityCondition5c>	Condition				
2	<EligibilityBooleanOp5c>	Boolean operator				
2	<EligibilityCondition5d>	Condition				
2	<EligibilityEndSubclause5>	EndSubclause				
1	**<ExclusionCriteria>**	**<Exclusion criteria>**	This section pertains to encoding those antecedents that apply to the exclusion criteria. E.g. prior diagnosis of a disease; procedures and/or treatments that indicate the existence of a disease; existence of genetic risk factors, family history that would exclude the patient from the current screening protocol. In this cell include a summary of exclusion criteria: *exclusion criteria* : [Patient has XX] OR ...	*Exclusion criteria:* [Patient has a history of chest radiation] OR [Patient has a known genetic mutation] OR [There is evidence of mammogram results documented within 2 years]		
2	<ExclusionCriteriaOtherProtocol>	**<Patients for whom a different intervention protocol may be warranted>**	*All logic conditions should be encoded separately and as triplets of the form <Object.attribute> <operator><value>. Nested conditions should be encoded as subclauses. Conditions in a subclause should also be encoded as triplets of the form <Object.attribute> <operator><value> combined with Boolean operators. All logic conditions should be joined with Boolean operators to represent the whole exclusion criteria.* *Subclauses with as many conditions, and operators should be added as needed to represent all exclusion logic conditions.*			
3	<ExcCrOtherPrtclSubclause>	Subclause	*If encoding nested conditions, provide a label for the subclause. This label should be used as a condition in the main logic.* *If there are no nested conditions, leave this row empty.*			
3	<ExcCrOtherPrtclCond>	Condition	*write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model*	"History of chest radiation = non-null" --> Exist(Procedure.Type = {list of CPT, ICD9 and SNOMED CT codes for chest radiation procedures} AND Procedure.Tense = NULL AND Procedure.Procedure date/Time < *current date*)		
3	<ExcCrOtherPrtclBooleanOp>	Boolean operator	*add Boolean operator (AND, OR, NOT) if needed*	OR		
3	<ExcCrOtherPrtclCond1a>	Condition	*if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model*	"Known genetic mutation = non-null" --> Exist(Laboratory Test Result.Result Type = {LOINC, SNOMED list of codes for genetic test} AND Laboratory Test Result.Status = complete AND (Laboratory Test Result.Interpretation = abnormal OR Laboratory Test Result. Value = *value indicating there is a mutation*))		
3	<ExcCrOtherPrtclBooleanOp>	Boolean operator	*add Boolean operator (AND, OR, NOT) if needed*			

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3	<ExcCrOtherPrtclCond1b>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model			
3	<ExcCrOtherPrtclBooleanOp>	Boolean operator	add Boolean operator (AND, OR, NOT) if needed			
3	<ExcCrOtherPrtclCond>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model			
3	<ExcCrOtherPrtclEndSubclause>	EndSubclause				
3	<ExcCrOtherPrtclSubclause2>	Subclause	Same as above - use as needed			
3	<ExcCrOtherPrtclCond2a>	Condition				
3	<ExcCrOtherPrtclBooleanOp2>	Boolean operator				
3	<ExcCrOtherPrtclCond2a>	Condition				
3	<ExcCrOtherPrtclEndSubclause2>	EndSubclause				
3	<ExcCrOtherPrtclSubclause3>	Subclause	Same as above - use as needed			
3	<ExcCrOtherPrtclCond3a>	Condition				
3	<ExcCrOtherPrtclBooleanOp3>	Boolean operator				
3	<ExcCrOtherPrtclCond3a>	Condition				
3	<ExcCrOtherPrtclEndSubclause3>	EndSubclause				
2	<ExcCrInterventionRcvd>	**<Patients that have already received intervention within recommended interval>**	This section should include logic conditions checking whether any prior screening actions have been performed within the screening interval. If true, the patients should be excluded from the screening protocol. All logic conditions should be encoded separately and as triplets of the form <Object.attribute> <operator><value>. Nested conditions should be encoded as subclauses. Conditions in a subclause should also be encoded as triplets of the form <Object.attribute> <operator><value> combined with Boolean operators. All logic conditions should be joined with Boolean operators to represent the whole exclusion criteria. Subclauses with as many conditions, and operators should be added as needed to represent all exclusion logic conditions			
3	<ExcCrInterventionRcvdSubclause1>	Subclause	If encoding nested conditions, provide a label for the subclause. This label should be used as a condition in the main logic. If there are no nested conditions, leave this row empty.			
3	<ExcCrInterventionRcvdCond1a>	Condition	write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model	"Mammogram results documented within 2 years = non-null" --> Exist(Diagnostic Study.Procedure Type = {ICD9, CPT and SNOMED CT code list for mammograms} AND Diagnostic Study.Tense = NULL AND *current date* - Diagnositic Study.Procedure Date/Time between 0 and 2 years) OR **Exist(** **Diagnostic Study.Procedure Type = {eMeasure #112 Numerator Inclusion codes} AND** **Diagnostic Study Tense = NULL AND** **current date - Diagnostic Study.Procedure Date/Time between 0 and 2 years** **)**		
3	<ExcCrInterventionRcvdBooleanOp1>	Boolean operator	add Boolean operator (AND, OR, NOT) if needed			
3	<ExcCrInterventionRcvdCond1b>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model			
3	<ExcCrInterventionRcvdBooleanOp2>	Boolean operator	add Boolean operator (AND, OR, NOT) if needed			
3	<ExcCrInterventionRcvdCond1c>	Condition	if needed, write single condition as <Object.attribute> <operator><value> where Object.attribute is an instance of a Class.attribute from the data model			
3	<ExcCrInterventionRcvdEndSubclause1>	EndSubclause				
3	<ExcCrInterventionRcvdSubclause2>	Subclause	Same as above - use as needed			
3	<ExcCrInterventionRcvdCond2a>	Condition				
3	<ExcCrInterventionRcvdBooleanOp2>	Boolean operator				
3	<ExcCrInterventionRcvdCond2b>	Condition				
3	<ExcCrInterventionRcvdEndSubclause2>	EndSubclause				
3	<ExcCrInterventionRcvdSubclause3>	Subclause	Same as above - use as needed			
3	<ExcCrInterventionRcvdCond3a>	Condition				
3	<ExcCrInterventionRcvdBooleanOp3>	Boolean operator				
3	<ExcCrInterventionRcvdCond3b>	Condition				
3	<ExcCrInterventionRcvdEndSubclause3>	EndSubclause				

Level	XML Tag	Value	Definition	Relevant data from USPSTF	GEM OUTPUT MATCH TO eREC (Output fully populates eRec field; Output is helpful but not sufficient for populating eRec field; Output is not helpful in populating eRec field)	OTHER COMMENTS RE: MATCH
1	**<OperationaExclCriteria>**	**<Operational exclusion criteria>**		Will depend on implementation considerations/choices: See Section 3, Implementation Considerations for examples		
1	**<Action>**	<Action>				
2	<RecommendedAction>	Recommended action	Action to be performed on those patients that satisfy the inclusion criteria	Bilateral mammogram	Could fully populate eRec field using GEM output	Use "Action" (i.e., name for an action when the recommendation is conditional) or "directive" (i.e., name for an action when the recommendation is imperitive)
1	**<ImplementationConsiderations>**	**IMPLEMENTATION CONSIDERATIONS**	This section should contain all additional rule development and deployment details, as well as issues necessary for implementing generic logic statemets useful for CDS. These implementations refer to many possible settings, based on differences in clinical policies, information systems capabilities, availability of electronic/coded data, workflow considerations and the like.	Link to template for implementation considerations tab		

Appendix E: Examples of Issues in Adapting eRecommendation Template for MU Measures

Column 1 of this table lists a sampling of the issues identified by stakeholders and project team members. Column 2 describes the core project team's comments and suggested actions in response to issues raised. Column 3 documents the actual action taken to date after project team discussion and Column 4 provides the justification for such action(s).

Issue	Comments / Suggested Action(s)	Action Taken	Justification
GENERAL			
Need for human-readable nice formatting version and removal of extra rows and columns and hiding of internal geek fields	No comment/suggested action	We'll use the most complete template and from this we'll select relevant rows/information to create 'views' suitable to users	We need to keep the richest template from which we can select information targeted to specific users.
Should have two versions: one for human reader, hiding code sets and translation of logic, and one with latter.	No comment/suggested action	Same as above.	Same as above.
HEADER			
Need to group eRec fields together and separate from fields pertaining to underlying guideline.	There may not be a single source but a set of references or material from which derived. Suggested Action: Rename this or have a separate field for explicit source document if there is one and another for other references.	Reorganize the header section into 2 subcategories, one for the source guideline document and another for the eRec.	By separating the header into sections we will clearly indicate the source of information used to populate template, ownership of information, etc.

Issue	Comments / Suggested Action(s)	Action Taken	Justification
How much EBM ref and grading, authority source, etc., to include in header?	A and B only mean something for USPSTF Clinical Guidelines. There are other guideline rating criteria as in GLIA. This again raises the question of whether there is an explicit source for the eRec. If there is, then its rating can be cited (including link to explanation of rating system) but encoders should opt to do rating as a comment rather than have an explicit rating scheme.	There should be explicit reference about the level of evidence as specified in the source documents. Clearly state if the source is an A or B Recommendation—we'll add a field (row) in template for this. **No action taken:** Evidence rating for non-USPSTF recommendations	Clearly state source of information for KM purposes.
RecommendationSetID field—This is mostly a placeholder for future—is it needed? For example, if there are recommendations for teenagers that differ from that for adults, for same problem, should they be part of a set	This will be needed but see comments below about eRec ID	For the time being we'll use Recommendation Set: Meaningful Use Stage 1 CMS Measures with an arbitrary sequential numbering. In SOP we will indicate that a hierarchy/structure is required with some sort of tracking for numbering, particularly when multiple people develop/populate templates.	Currently we are the only implementers of eRecs so we are keeping track of this. However, we need to implement a repository and a tracking system for ID-ing sets.

Issue	Comments / Suggested Action(s)	Action Taken	Justification
Setting field—Placeholder—e.g., for inpatient vs. outpatient, home vs. office, emergency vs. not, etc.	Again, same issue: there are many potential KM axes TBD	We'll keep this with a note indicating that the information in this field is from the source document indicating the setting where this eRec is applicable, However, it would be up to the author/implementer to decide if this eRec could be applied in any other setting besides the specified in the source document. If the source document does not specify a setting, this field should say 'not specified'	For Knowledge Management purposes it is important that we include the setting where this guideline was intended to be used. However, implementers should be free to decide if this eRec applies to settings other than those specified in the source document.
Comments about removing author, verifier, and maintenance should not be followed—need to keep this info, but may want to hide it in some distribution versions.	Removing these fields may lead to some ambiguity about author—source document or encoder of eRec. Suggested Action: Keep fields	We'll keep these fields for Knowledge Management purposes.	Information in these fields contains audit data required to keep track of source documents, authorship, etc.
Author field	Keep author field and populate with identifiable information from source document. Author might be a committee, not a person.	We'll incorporate two categories, each with two fields: author and organization to the template to indicate authorship of the source document and authorship of the eRec (who captured/entered data into the template)	To keep more accurate track of authorship, we'll have two categories: source document authors (with author and institution) and eRecommendation author (with author name and institution)

Issue	Comments / Suggested Action(s)	Action Taken	Justification
Row 22 Reference (and row 23 Ref URL) are not specific enough – are we giving general references, or is there a particular EBM recommendation that we are translating? It would be good to, wherever possible, have a specific set of source recommendation(s), cited here, and then another row for other related references.	See earlier comment about whether an identifiable source exists.	We'll keep primary document source and include an URL to users can access source document. We will remove clinical references that appear in source document so users are not distracted by too much information.	Users will have a link to source document if available. If the want to further check references included in source document, they'll have a link they can navigate to.
eRecommendation ID field	A master, sequential ID field should exists for every new artifact. Some of these IDs will be versions of older eRecs, some will be for Prev/Screen, some for MU, etc., but the ID field shouldn't be where this is coded. Also, we should have a classification field for purpose/intent separately, another field for version, another field indicating how recommendations may relate to each other, e.g., siblings of each other or derived from another (see RecSetID field above). These nuances may be beyond our scope right now but will be important in any KM effort.	**No action taken:** This is a pending issue. We need to establish a registry process for giving a unique ID to each eRec. eRecs would get a revision number tied to the ID but separate from that. Should begin with E00001 for example. Any subsequent classifications, e.g., for purpose, domain, source (eMeas or USPSTF), can be added as separate fields.	We need to establish a central repository where we can keep track of versioning, etc.
eRecommendationPart field -- should be renamed to eRecommendationPopulation.	No comment/suggested action	We'll rename this field "eRecommendation Population."	This field will indicate the target population the eRec is addressing. If this eRec is part of a broader guideline, this field should indicate how this eRec was derived, and the source it comes from.

Issue	Comments / Suggested Action(s)	Action Taken	Justification
eRecommendationPart field	It would be desirable to have definition rules – not yet created.	This field will reflect whether a guideline targets 2 separate populations. The underlying logic will be specific to the target population.	The idea of eRecs dealing with 2 separate subpopulations should be handled by a definition rule that defines each and then including them in the logic. Same as above.
RecClassification field – This is largely a placeholder for future.	No comment/suggested action	We will rename this field as "Recommendation Focus" This field indicates whether the source guideline targets things like medication management, interaction check, prevention/screening. For the time being, we will populate this field with available information from the source document. Currently, we do not have a list of available options to populate this field.	The value assigned to this field is mainly determined by the type of action defined by the source document.

Issue	Comments / Suggested Action(s)	Action Taken	Justification
A few header fields are tentatively populated with information from the eMeasure (e.g., NQF or PQRI numbers, title to identify the eMeasure, rationale).	No comment/suggested action	**No action taken.** We need a true handbook or template with constraints for how to enter all possible fields.	These methods are considered tentative because we are awaiting feedback about how best to express specific pointers to eMeasures within the eRecommendation. So far we do not have clear links to.
DATA DEFINITIONS			
Diagnosis Family History in data model – In some instances these data points [relationship of family member to patient or other family member] are tied back to specific relationships, in other instances the data is tied back broadly to the patient's family (e.g., 'family history of early CAD') It may be helpful to accommodate for a generic 'family member' type of relationship for these types of entries.	This requires further analysis so a long-term solution can be put in place. For the purposes of this project, we will keep field/template as it is.	**No action taken.** The person populating the template should decide how to disambiguate this based on the available information in the source document.	The HITSP_V1.0_2010_C154_-_Data_Dictionary-1 document does not specify if the field can be left empty to indicate a "generic" family member. At the same time, it does not say it cannot be done, so it is up to the implementers how to populate this field.
Element entitled Data Definitions/ActionRelatedData should be redefined so that it doesn't say: Screening action(s) to be performed on target patients.	Extend the logic structure to include an ELSE part so alternative actions can be specified if the logic fails.	**No action taken.** For the time being we will keep things simple: The logic structure will remain as an "if…then… and the rule will trigger only when all conditions matching the logic are true. If the conditions are satisfied a single action will be executed. The action may contain more than one 'sub-actions' but these are left to the implementer to define. For example, 'screening for…' may require several tests/diagnostic procedures, but specifying these is beyond the scope of this project.	The rule will only trigger when all conditions in the logic are satisfied. The action to be executed may contain more than one 'sub-actions' but these are left to the implementer to define. For example, 'screening for…' may require several tests/diagnostic procedures, but specifying these is beyond the scope of this project.
Row 28, Eligibility/inclusion data – not clear what comment means: "EMR vendor's CEM is a powerful	Should clearly mention that the final user/implementer is responsible for addressing	We expanded the implementation consideration sections to specify, as clearly as possible, issues that a final	Detailed implementation considerations are beyond the scope of this project. It is up to the final

Issue	Comments / Suggested Action(s)	Action Taken	Justification
tool to meet MU eMeasures. Can see how system operationalizes inclusion criteria."	implementation considerations based on their environment and source data.	user/implementer may consider addressing.	user/implementer how to address eligibility based on their source data.
Row 37 Quality data type – not clear what is meant here. Comment that it is not useful.	No comment/suggested action	**No action taken.** This refers to the class.attribute in the QDS data model to which this element refers to	This refers to the element of the QDS model that it uses.
Rows 38-41: May need not just code set and value sets, but possibly constraint logic. Ultimately may need to define complex entities like diabetes through logic statements that are rules, where action is assert diabetes = T or F. Not clear why comment made that code set is not useful.	This refers to issue that some concepts require definition logic, not just lists of code/value sets. Again it is an argument for being able to include definitional rules.	**No action taken.** These refer to the vocabulary source(s) (code set) and the actual codes (code list) used to build the decision criteria	These are the target values in a triplet *<variable><comparison_operator><threshold value>* used to build up the decision criteria. These codes come from NQF.
Row 57, intervention interval: Interval specifications (in data/logic or operational) that are directly referenced in MU measure or EBM statement should be called out here, differently from implementation considerations, i.e., distinguish between what measure or recommendation says and what's discretionary	The intervention interval is defined by the source document. If such interval is not defined, it is at the discretion of the implementer to adjust this to local needs.	The intervention interval is defined by the source document. It is at the discretion of the implementer to adjust this to their local needs.	Refer to implementation considerations. Implementer should be able to tweak the intervention interval to their needs. This is encoded in the eRec to reflect the information in the source document. Provide degrees of freedom around what's specified as ICs. Here is also where a field on indicating whether this is a repeating interval or a one time after a prior event. What to do if missed, what to do if succeed (repeat or not).
Row 64, exclusion criteria-related notes – may go into ICs more effectively.	Exclusion criteria if specified in the source document should be included, otherwise, it is at the discretion of the encoder and such information could be included as well in the implementation considerations section.	Exclusion criteria are encoded as described in source document.	It is at the discretion of implementers to adapt/expand these criteria to meet their needs. This could be addressed in the implementation considerations section.

Issue	Comments / Suggested Action(s)	Action Taken	Justification
It was difficult to use the eMeasure coding specifications to create the eRec when no label (descriptor or name) accompanied the individual code, even though the group of codes listed was given a general.	No comment/suggested action	**No action taken.** Currently we do not have specific descriptions for listed codes. They are grouped in broad categories.	At this stage it is up to the implementer to check specific codes if required. However, unless required for a specific purpose, the current grouping of codes should suffice for executing logic.
What is the action?	Actions are not just screening or monitoring. Can use the whole range of CDS Action taxonomy.	The action is indicated by the action related data. For example, it could be a screening, monitoring action.	See row 161, and rows 89-94 for data types relating to the action. The listed action may be a broad single action, e.g. 'screening for…' This may require several 'sub-actions' like lab tests or diagnostic procedures. This is left to the implementer to decide.
LOGIC SPECIFICATION			
Row 89 col K raises an interesting issue. I think 'interval' is how often the 'intervention' gets repeated. In this case, the intervention (tell someone patient isn't on anticoagulants and should be) is something that happens *once* on hospital day 2 – and thus is not repeated so there is no repeat interval.	The intervention indicates a point in time when the rule should fire to evaluate the conditions in the rule. A separate issue is, if the conditions in the rule are not satisfied at the given point in time, should there be a repeat interval so the rule can get triggered at a later point in time?	**No action taken.**	Whether the rule should fire more than once if it fails to fire at the first opportunity is an implementation consideration and it is outside of the scope of the description of the logic, i.e., this is left to implementers to adapt to their environment.
Do we need an *if then else* and a *repeat until* type of modifier?	It would be desirable to include an ELSE action. (See above). This could in fact be the firing of another rule.	**No action taken.** Rules are encoded to fire at a point in time. If a rule does not fire within its specified interval, there should be no other action.	If implementers want the rule to fire at a later time as if it were embedded in a monitoring loop, they should take this up as an implementation consideration.
EligibilitySubclause1 – inclusion of numbers in the tag names and subclause names is an artifact of how the excel 'template' was defined.	No comment/suggested action	Current structure of template is an artifact of using an excel template.	When we move to an XML template all these issues will be hidden from the user and only populated fields will be displayed. Only populated subclauses will be generated and displayed.
ExCrOtherPrtclSubclause1 field	No comment/suggested action	Same comment as above	Same comment as above

Issue	Comments / Suggested Action(s)	Action Taken	Justification
ExcCrOtherPrtclEndSubclause3 field	No comment/suggested action	Same comment as above	Same comment as above
OperationalExclCriteria field – Escalation is an important option. Should be listed as to be addressed in ICs? Why is this comment in Operational Excl field note?	No comment/suggested action	**No action taken.** This relates to specific implementation issues and/or preferences of implementers for excluding patients.	If any exclusion criteria other than the listed in the source document are to be included, implementation considerations should be addressed in the corresponding section—this is left to implementers.
OpExclCrLogicCondition1 field—nested condition expressions will be needed in the future. A more BNF-oriented expression syntax is needed	This will be addressed with the XML team in SHARP 2B project.	**No action taken.** Current logic structure is simple. More complex structure might be needed in the future.	So far, we have been able to represent the logic of rules with simple structure. However, it is desirable to have a more robust BNF-oriented expression syntax to encode more complex expressions, should the situation arises.
Issues relating logic encoding of exclusion criteria, operational exclusion criteria, eligibility/inclusion criteria, inclusion-related criteria	No comment/suggested action	**No action taken.**	Template has the required slots to hold this information. It would be just a matter of adding extra logic and codes to represent these criteria if needed.
Specific issues about rows nor being useful	No comment/suggested action	**No action taken.**	These were comments made by physicians who were more interested in the whole recommendation rather than encoding each part of it.
IMPLEMENTATION CONSIDERATIONS			
Make sure rule aligns with local clinical flow, user privileges, local policy	No comment/suggested action	Include slots in Implementation considerations to hold: - Allowable Range of test value limits - Medication dose limits - Range of time limits And: - Mechanisms to ensure rule content is monitored for ongoing appropriateness	Issues reviewed in reorganized implementation considerations V2 311 – rem edits.
Handling rule triggering: - Patient Specific	No comment/suggested action	Template will be modified to include these.	Issues reviewed in reorganized implementation considerations V2 311

Issue	Comments / Suggested Action(s)	Action Taken	Justification
- Batch - Timing considerations			– rem edits.
Provide data to trigger a rule - by specific system: data already available - By person who provides data/ how system enables them to provide it	No comment/suggested action	Template will be modified to include these.	Issues reviewed in reorganized implementation considerations V2 311 – rem edits.
Ensure rule triggers for the right patient - Additional inclusions/exclusions for greater patent specificity - Exclude exceptions already documented in the system	No comment/suggested action	Template will be modified to include these.	Issues reviewed in reorganized implementation considerations V2 311 – rem edits.
Results affect the care delivery process - Setting where notification is delivered, rule output recipient and delivery channel. - User interaction with rule output, including rule actions and modifications. - Rule results disposition (e.g., processing user response)	No comment/suggested action	Template will be modified to include these. Some of them may be already included in template. Will revise and modify as needed.	Issues reviewed in reorganized implementation considerations V2 311 – rem edits.
How will rule behavior and effects be monitored: - Rule availability in the system - Rule firing - Recipient response - Workflow impact - Effects of outcome - Intended/unintended effects	No comment/suggested action	Template will be modified to include these.	Issues reviewed in reorganized implementation considerations V2 311 – rem edits.

Appendix F: Summary of Key Points from eRecommendation Stakeholder Community Call #3

Lessons Learned

1. Template provides predictable way to specify recommendations; encourages consistency
   - eRec reduces vendor time to extract inclusion/exclusion criteria, etc.
   - Standard logic format, source citation, and implementation considerations ‗checklist' in eRecs can serve as helpful foundation for the iterative CDS configuration communications between rule implementers and information system vendors.
   - Already developed eRecs will be knowledge resources shared through other projects.

2. eRec content is of greatest value, so codes must be current, complete, accurate

3. Template signals to guideline developers the type of information needed to implement, including technical support documentation
   - Guideline developers using eRec can support how recommendations are translated (i.e., further helping translate expertise and intent from evidence analysis into action-oriented guidance).
   - Abbreviated form of eRec might support more timely implementation of new recommendations (or action on public health emergencies).

4. Coordinating CDS (eRec) with quality/performance improvement environment is critical (e.g., rules themselves don't make clinical policies or change purposeful practices).

5. Stakeholder Community process is example of an effective activity in leveraging health IT to measurably improve health care delivery, i.e., engagement of and dialog among broad stakeholders to inform health IT design/build and scalable value.

Implications

1. Role for standardization
   - Value in converging on practical CDS standards, including definition of terms (e.g., rule logic inclusion and exclusion criteria and actions/order catalog), ontology and language to improve specificity/sensitivity.
   - Ability of project products (e.g., from CDS Metaconsortium) to integrate with each other will be key signal to vendors.
   - Likewise for guideline developers have choices in approach to formalizing logic expression; desire convergence on standard.

2. Opportunities for further development/refinement
   - Streamlined content is less overwhelming, e.g., less cluttered and simplified expression of logic statement for purposes such as clinical validity check.

- Expand topics for which eRecs developed, e.g., cover more MU eMeasures, other opportunities for population health improvement.
- Consider extensions to the eRec approach to accommodate multiple recommendations or more CDS modalities (beyond alerts/reminders).
- Consider degree to which eRecs need data not native to the local EHR system, and whether/how eRecs can be tuned to operate on data that's available in an HIE.
- Consider further fleshing out eRec-specific implementation considerations for common implementation scenarios.

3. Need for ongoing development and maintenance of ~~"l~~evel 2" artifacts, e.g., eRecommendations for USPSTF guidelines and MU eMeasures that have already been produced.

4. Opportunities for implementation
   - Need for broader vendor engagement on CDS to support eRecommendations and other tools for addressing eMeasures, especially for small practices.
   - Consider broader support for process redesign needed to make optimal use of eRec artifacts for CDS rule development [note, 2011 update to HIMSS CDS guidebook series, which is partially funded through the AHRQ eRec contract, provides extensive guidance on this context of CDS program and intervention development].
   - Current eRec template and tools are useful; should continue to build on and learn from the current approach, since the learning and development will take time and MU creates urgency for getting CDS rules right. RECs are a potentially powerful vehicle for this work. However, HHS should be cautious not to push eRec dissemination too hard until there is more information about their benefits and risks from credible studies and until the interplay with related CDS standards is sorted out.