Structuring Care Recommendations for Clinical Decision Support: Background Assessment, Synthesis, and Methods Report

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Contents

Figures

Appendixes

Executive Summary

Introduction

This assessment, synthesis, and methods report informs the "Structuring Care Recommendations for Clinical Decision Support" or SCRCDS project (originally named "Hardened Rules for Clinical Decision Support") which began in September 2009 and concludes in September 2010. The project aims to improve the speed, efficiency, and effectiveness with which broadly accepted care guidelines are deployed in electronic health record (EHR) systems by system suppliers and clinical decision support (CDS) implementers. An additional goal is providing insights and tools to clinical guideline developers that might be useful in their efforts to produce care recommendations in a format that can be more easily incorporated into CDS rules.

To support these changes, this project is to produce the following:

- A consistent method for transforming evidence-based clinical recommendations into a format that can be readily adapted further for deployment by CDS implementers, and
- Structured, coded logic statements for the 45 A and B recommendations from the U.S. Preventive Services Task Force (USPSTF), and for a second guideline set.

This report describes the proposed methods for producing the structured recommendations. The development of these methods was informed by a review of relevant initiatives and methods, an assessment of the needs of multiple stakeholders, and development and extensive vetting of a draft format for the structured recommendations (which we call "eRecommendations").

Stakeholders providing input included Federal and private care delivery organizations, large health care systems, primary care specialty societies (representing the small-practice perspective), leaders in quality infrastructure, and others.

Report Findings

The key findings regarding the format and process for structuring recommendations under this project are:

1. Given that care delivery organizations typically apply substantial resources to the process of translating clinical recommendations for implementation in CDS, assistance with the knowledge translation process is desirable.
2. Substantial tension exists between potential users of project products who would most 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., vendors). Less specificity in the structured recommendations would increase portability and would enable clinical information system (CIS) implementers and vendors to tailor deployment details to suit their needs and constraints.
3. Implementers want clearly defined and coded data elements for logic statements.

4. The national push for Meaningful Use (MU) of health information technology (health IT) and related efforts to apply EHRs to performance measurement and improvement make it desirable for the SCRCDS project to leverage this momentum and related tools when developing methods for structuring care recommendations.
5. There is broad consensus about the value of the draft eRecommendation template. Several care delivery organizations expressed interest in consuming the eRecommendation format and/or eRecommendations for specific clinical guidelines.

Proposed Approach to Structuring Recommendations

Based on the findings outlined above, the essential components of the proposed format and method for structuring recommendations are listed next. Some of these items go beyond the scope of this contract (e.g., keeping the data model aligned with Quality Data Set (QDS) evolutions after September 2010, creating the User Guide).

- Achieve a semistructured format (Stage 2 in the four-stage model of rule development shown in Figure 2) for representing the clinical recommendations.
- Align the format of the eRecommendation with the Health Quality Measures Format (HQMF) for eMeasures to the extent possible. Major sections common to both formats are the header, data specification, and logic specification.
- Restrict the logic statement content to the clinical recommendation as articulated by the source.
- Do not specify local implementation issues (e.g., policies, systems, constraints) in the logic statement or code such details that may be needed for CDS rules. Instead, to help with this critical challenge, include an additional section in the eRecommendation that starts to identify types of implementation considerations that need to be addressed. Align terminology used in discussing implementation considerations with the taxonomy under development by the National Quality Forum (NQF) CDS Expert Panel.
- Employ a data model for representing eRecommendations that is adopted from the QDS and the related Healthcare Information Technology Standards Panel (HITSP) Data Dictionary (C154). The seven main classes adopted are Patient Characteristics; Diagnosis; Diagnostic Study; Laboratory Test; Procedure; Physical Finding (Vital Signs as a specialization of Results); and Medication. As the underlying QDS model evolves with use, so too will the adopted data model for eRecommendations. Their attributes can be conveyed with a .dot notation.
- To define data in eRecommendations, when available, use valid, current medical code sets and coding standards resulting from the process of retooling measures for the EHR environment by the Centers for Medicare & Medicaid Services (CMS). Because access to coded data needed for rule logic will be problematic in many cases, the alternative will be a clear and accurate Englishlike description.
- To represent the conditional logic in eRecommendations, select the most relevant Boolean, temporal, mathematical operators and features from Arden Syntax and HQMF

eMeasure logic constructs.

- Produce each eRecommendation as both Englishlike, human-readable logic statements and XML-based output.
- To help ensure that care recommendations are translated in a consistent manner, a User Guide should be developed based on the Standard Operating Procedures document. The User Guide and other packaging for the eRecommendations would clearly indicate that the eRecommendations and the format are not proprietary and their use is voluntary.

The second set of guidelines for which structured recommendations will be produced under this project are those that correspond to up to five clinical measures that must be reported to achieve MU.

Introduction

Project Background

This assessment, synthesis, and methods report informs 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 concludes in September 2010. 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, 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. As discussed in this report, 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.

To address these challenges, the overall project goals are 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 and (2) to develop a collection of structured recommendations in that format. The primary focus for logic statement development in this project is the set of 45 A and B recommendations for prevention and screening from the U.S. Preventive Services Task Force (USPSTF) (see Appendix A). In addition, at least one other recommendation/guideline will be selected for adaptation to the selected format.

It is believed that developing a consistent method and applying it to an initial set of 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. The expectation is that, in addition to supporting CDS implementers and vendors, results of this project will be valuable to clinical guidance creators and disseminators (e.g., Evidence-based Practice Centers, USPSTF) who may desire to use the format to deliver recommendations.

Purpose of Report

The SCRCDS project hypothesizes that a single, 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. The purpose of this report is to (a) provide a fact-based rationale for the proposed approach to translating recommendations and

[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.

(b) to describe the proposed methods for producing structured recommendations. The project team was instructed to draw on public and private sector needs and experiences in translating clinical care recommendations. This is to ensure that the proposed process for developing structured recommendations is informed by what has already been learned about this complex task, and that potential end users would value the project deliverables. In particular, the team was to find out (a) how far down the pathway to a machine-executable format this process can be taken while still ensuring widespread value from the converted material and (b) to identify the reasons why it was not possible to go further. It is envisioned that follow-on efforts will refine and extend this process, and the findings documented in this report can likewise inform those efforts as well.

Note that we use the terms "consistent" and "formalized" rather than "sandardized," given that existing international standards do not fully capture the needs of this project; furthermore, the immediate deliverables from this project will not themselves constitute a standard. A formal process through international standard-setting organizations would be required in the future for such designation. Nonetheless, we hope that the results of our work will lead to efforts aimed at refining existing standards or adopting new standards for representing clinical recommendations as logic statements to underpin CDS rules. Structures for representing information, whether or not they are standards, are referred to as formalisms in this report.

In addition, this project focuses 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 is 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).

Report Methods

This assessment, synthesis, and methods report draws upon the many interrelated types of prior and ongoing activities, formalisms, data structures, and tools that have implications for producing the structured recommendations under this project. It also provided an opportunity to investigate pertinent developments in applying health IT to performance/quality measurement and improvement and its relation to Meaningful Use (MU) of health IT (which includes deploying CDS rules). The process of learning more about these activities shed light on the requirements for and constraints in implementing clinical care recommendations as CDS rules.

The general assessment and synthesis activities that informed the design of methods presented in this report—a review of relevant initiatives and methods, an assessment of stakeholder needs, and a vetting of a draft format for structured recommendations—are described beginning in the next section. Figure 1 identifies the individuals and organizations who participated in information-gathering discussions with the project team as part of the assessment and synthesis activities.

Unfortunately, it was not feasible to conduct an extensive inquiry into the workings of small group practices and solo providers. The project team initially relied on information from 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 is being 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 project's Rule Value Advisory Panel (RVAP), which first convened on March 8, 2010.

Figure 1: Information-Gathering Discussions, October 2009–February 2010

Date	Organization	Individuals
10/14/2009	Agency for Healthcare Research and Quality (AHRQ)	Jan Genevro and Claire Kendrick
11/3/2009	Association of Medical Directors of Information Systems (AMDIS)	William Bria
11/6/2009	HIMSS Electronic Health Records Association (EHRA)	Jacob Reider
11/13/2009	American Medical Association (AMA)	Kendra Hanley and Delane Heldt
11/23/2009	Indian Health Service (IHS)	Chris Lamer
11/23/2009	U.S. Department of Defense (DoD)	Steve Steffensen
11/24/2009	National Library of Medicine	Clem McDonald
12/7/2009	Intermountain Healthcare	Peter Haug
12/8/2009	U.S. Department of Veterans Affairs (VA)	Steve Brown
12/15/2009	U.S. Navy and Department of Defense (DoD)	Peter Park
12/23/2009	Partners Healthcare	Deb Goldman, Blackford Middleton, Saverio Maviglia, and Beatrice Rocha
1/6/2010	National Quality Forum (NQF)	Danny Rosenthal and Floyd Eisenberg
1/6/2010	U.S. Army and Department of Defense (DoD)	Hon Pak
1/8/2010	U.S. Navy and Department of Defense (DoD)	Emory Fry
1/8/2010	Kaiser Permanente	Craig Robbins, John Mattison, and Michael Krall
1/12/2010	U.S. Department of Veterans Affairs (VA) and Department of Defense (DoD)	Syed Tirmizi, Linda Kinsinger, Daryl Larnsbry, Joe Francis, Patricia Ripley, Rick Downs, Marlon Cassidy, Erica Barger, and Jon Cookler
1/25/2010	Microsoft® and the Mayo Clinic	Carol Olson (Mayo), Laurie Nelson (Mayo), and Matt Stitz (Microsoft)[2]
1/27/2010	Yale University	Richard Shiffman
2/4/2010	Association of Medical Directors of Information Systems (AMDIS)	William Bria, Robert Murphy, Milisa Rizer, Joel Shoolin, and Dave Trachtenbarg
2/10/2010	Kaiser Permanente	John Mattison and Erin Stone

[2] According to analysts, Microsoft® is considered a key market mover in the personal health record space. They say that Dossia and Google™ Health are in danger of becoming irrelevant unless they take decisive action to expand their personal health record platforms and compete with product offerings similar to Microsoft HealthVault. See **Analyst: Dossia, Google Health Should Ramp Up PHR Platform Offerings** in *Healthcare IT News*. We therefore focused our attention for a limited foray into the PHR space on the Microsoft/Mayo PHR joint venture.

The full RVAP that met in March also provided input about the value of proposed project deliverables and their potential future use. Participants included nearly 20 individuals representing government and private health care providers, medical and informatics specialty societies, and others.

Review of Relevant Initiatives and Methods

The review of relevant Federal initiatives and methods 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.[3] Other significant CDS initiatives, methods, and tools to be 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 include Jerry Osheroff, M.D. of Thomson Reuters; Robert Greenes, M.D., Ph.D. of Arizona State University; Aziz Boxwala M.D., Ph.D. of 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,[4] 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. See Appendix B for brief descriptions of key initiatives.

The SCRCDS project team was also instructed to look for information and lessons applicable from other select initiatives. Although AHRQ specifically identified the CDS Roadmap,[5] the ePreventive Services Selector,[6] and the Family Health History Tool,[7] we concluded that their direct usefulness to project deliverables is relatively low. However, each is discussed briefly.

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[3] Clinical Decision Support Government Collaboratory, Clinical Decision Support Inventory, Draft Interim Report, August 3, 2009.
[4] Sordo M, Ogunyemi O, Boxwala AA, Greenes RA. GELLO: an object-oriented query and expression language for clinical decision support. AMIA Annu Symp Proc. 2003;:1012
[5] Osheroff J, Teich J, Middleton B, et al. A roadmap for national action on clinical decision support. JAMIA 2007; 14:141-5.
[6] http://epss.ahrq.gov/
[7] https://familyhistory hhs.gov/

The goals of the CDS Roadmap are to improve development, implementation, and use of CDS to enable measureable improvements in health care quality and outcomes. The CDS Roadmap spoke strongly to the need for standardized guideline translation: to "represent knowledge and CDS interventions in standardized formats" and to "collect, organize and distribute clinical knowledge and CDS interventions."

The ePreventive Services Selector (ePSS) is a CDS application, developed by AHRQ, which provides clinicians with patient-relevant USPSTF recommendations based on patient demographic information entered by users via a personal digital assistant (PDA) or mobile device. Based on input received to date, there do not appear to be specific tools or approaches related to ePSS that would influence SCRCDS methods or deliverables.

The Family Health History Tool (also known as the Surgeon General's My Family Health Portrait) aids patients in documenting their health history, as well as pertinent family members' health information, so that it can be shared with providers. To the extent that patients benefit from targeted alerts, it might be desirable for the Family Health History Tool or personal health records to integrate structured recommendations. Currently, these types of tools are not typically tied to an electronic health record (EHR) environment, although this is expected to change in the future as vendors and organizations develop the capability to access and use information in personal health records for risk assessment and decision support.

In addition, the project team chose to further explore the potential implications of recent health IT and health care quality developments—most notably the legislation related to MU of health IT—which have accelerated health IT-related standards development. A particularly pertinent example is work to standardize and integrate performance measurement and reporting into EHRs (e.g., using HQMF). The close synergies between these measurement and reporting components of the performance improvement cycle—and the care enhancement components, including CDS rules—suggested that there may be opportunities to explicitly link our efforts to these developments on the measurement side of the performance improvement cycle and thereby accelerate SCRCDS deliverable uptake.

Needs Assessment

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 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 (see Figure 1 above). 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.

Conversations held early in the process covered a broader range of topics, including guideline structure, clarity, and level of detail, as well as processes for deploying recommendations as CDS rules. The later conversations focused more narrowly on specific issues identified in the earlier meetings with direct implications for project deliverables. In particular, during the early discussions and review of relevant initiatives, the team noted that there was a strong movement toward incorporating quality measurement into EHR implementations. This involves using the HQMF formalism to express quality measures as structured, coded eMeasures which are suitable for EHR integration. Therefore, the project team spoke with several discussants about the implications of using an HQMF-like template for rule encoding.

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 to expressing clinical recommendation logic in a manner that could support CDS rule deployment than the performance measurement function for which HQMF was created. To reinforce synergies with EHR-enabled quality measurement, the team coined the term "eRecommendation" for clinical recommendations that have been expressed in this logic statement template. Likewise, a potential future title for the logic statement template is "Structured Care Recommendation Format" or SCRF. The SCRCDS team developed a sample structured recommendation template (i.e., a prototype SCRF) based on the HQMF template, and populated it with draft content based on the USPSTF breast cancer screening recommendation.

As a result, 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 also solicited from 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 Association of Medical Directors of Information Systems (AMDIS), and AMIA using organizational Listservs. These individuals are EHR and CDS implementers and developers, and/or subject matter experts. Comments outside of informational meetings were collected via an eRec_comments@thomsonreuters.com mailbox and by e-mails directly to SCRCDS team members. To date, about 20 stakeholders have sent roughly 95 written comments regarding the eRecommendations template. 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.

Most recently, the project's RVAP that met in March provided additional insights about the value of the proposed eRecommendation template.

Organization of Remainder of Report

The second part of the report, Key Findings: Structuring Recommendations, presents key findings from the assessment and synthesis activities, focusing on the implications for standardizing guideline translation across care delivery organizations and clinical information systems. The third part, Proposed Methods: Structuring Recommendations, describes the project team‘s proposal for a formal, consistent approach to creating the structured care recommendations. It also discusses the selection of a second guideline set for translation and proposes an approach to sequencing recommendations to be structured. Appendixes referred to throughout the report are found at the end of this document.

Key Findings: Structuring Recommendations

The assessment and synthesis revealed the challenges associated with formalizing the process by which clinical care recommendations are translated from narrative form to machine-executable code. Particularly problematic are lack of consensus on various pertinent standards, and implementation differences that limit wide scalability. Regarding a successful format for structuring recommendations under this project, we extracted the following key findings, which are more fully discussed further below.

1. Given that care delivery organizations typically apply substantial resources to the process of translating clinical recommendations for implementation in CDS, assistance with the knowledge translation process is desirable.
2. Substantial tension exists between potential users of project products who would most 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., vendors). Less specificity in the structured recommendations would increase portability and would enable clinical information system (CIS) implementers and vendors to tailor deployment details to suit their needs and constraints.
3. Implementers want clearly defined and coded data elements for logic statements.
4. The national push for MU of health IT and related efforts to apply EHRs to performance measurement and improvement make it desirable for the SCRCDS project to leverage this momentum and related tools when developing methods for structuring care recommendations.
5. There is broad consensus about the value of the draft eRecommendation template. Several care delivery organizations expressed interest in consuming the eRecommendation format and/or eRecommendations for specific clinical guidelines.

Opportunities to Facilitate Knowledge Translation Process

The SCRCDS team sought insights into how various care delivery organizations select and implement clinical recommendations. This information is needed to build on their experiences and to ensure that project deliverables will support these processes. The large health systems and others inside and outside the Federal Government that we spoke with have done pioneering work in the area of translating clinical recommendations into CDS rules. What we heard helped us better understand implementer challenges and surfaced examples of the scenarios and circumstances in which similar organizations might consume project deliverables.

Though the specific steps involved in implementing CDS rules differ from one organization to another or one delivery site to another, translating clinical recommendations into structured, coded logic statements expressed as machine-executable language within a CIS typically follows a multistep process[8]:

- **Select focus areas for CDS rules.** Factors by which topics may be prioritized include cost of condition, volume of patients affected, feasibility of implementing, reason for gap in practice, and relationship to performance measurement reporting and reimbursement. Some delivery organizations conduct an extensive evidence-gathering activity as part of the process. Rule topics for systems overlapped with the USPSTF A and B recommendations, but most were not implementing the entire set.

- **Agree on discrete clinical rule elements.** Workgroups of subject matter experts typically interpret the recommendation and related evidence, and make decisions that determine the logic that goes into CDS rules. One of the most challenging and critical aspects of creating specific, clear, structured logic is defining eligible patients, indicating who should be included and excluded from the clinical recommendation.[9]

- **Consider workflow and available system capabilities.** Technical staff address the integration of recommendations into the provider's CDS. The extent and sophistication with which health IT systems are available and used in a particular care setting strongly affects the manner and degree to which CDS rules are integrated into workflow. Likewise, local clinical policies and data availability affect rule development and deployment. As a result, workflow isn't easily scripted across implementations, even in the same organization (e.g., for an entity with different delivery sites, or a national insurer with local plans). These system- and setting-specific issues are typically configured on a local basis.

- **Create and program encoded logic statements based on clinical, workflow, technological, and other specifications received.** This requires assigning values from the appropriate code sets for rule elements, which organizations reported is a major, time-consuming challenge. Organizational ability to transform information from one code set (i.e., that used in information source) to another (i.e., that used by their systems) varies greatly.

- **Deploy rule.** This step typically happens independently for different sites in large organizations where the rule is deployed. In certain Federal sites, the National Health Information Network (NHIN) will be an important delivery mechanism and service-oriented architecture (SOA) an important approach.

- **Evaluate the CDS rule implementation effects**. An evaluation environment with a multidisciplinary team that understands workflow and process redesign can help ensure that rules are ultimately presented to the right person at the right time. Some systems

[8] It is not unusual for rule development in national organizations to occur at regional or local levels.

[9] SCRCDS team members also raised concerns about false positive alerts due to EHR documentation that is insufficient to identify patients that should be excluded from the clinical recommendation. For example, the negative effects of false positive alerting are illustrated by the situation where a patient who has had a bilateral mastectomy receives an alert in her PHR that a screening mammography is needed. This can happen if pertinent data about her prior diagnosis and surgery isn't available to the CDS system so that the rule can be suppressed in this case. Even when such false positive alerts don't occur frequently (which they often do) the results can have strong negative implications.

monitor overall patient outcomes in addition to process variables, such as when alerts are triggered and how users respond.

- **Keep rule up to date.** Care delivery organizations that begin the guideline implementation process by evaluating the evidence, find it particularly challenging to keep up with frequent changes to the recommendations. This often results in a longer implementation process. Very large or sophisticated organizations may have knowledge repositories that store rules in the organization‘s format.

Some large health care systems have dozens of staff developing and deploying CDS rules, and in some cases, the evidence-based clinical guidance on which the rules are based. By contrast, providers in solo and small group practices are typically far more constrained by time, resources and pertinent skills. In these settings, providers largely rely on their EHR vendor to ensure that the clinical recommendations are translated and updated and the rules work well when implemented for varied processes and workflows.

Challenge of Workflow Issues

Whether the structured recommendations should include information specific to local implementation within a given organization‘s workflow was a frequent topic of discussion and comments. Because proper placement of the rule in workflow is an important determinant of rule success, many participants expressed a desire for rules that address implementation issues specific to their care processes and health IT systems. Such local factors include triggering events, thresholds for sending alerts, recipients of the alerts, and how alerts would be transmitted (e.g., pager, EHR-based messaging tool). At the same time, once participants understood the SCRCDS project goal of broad adaptability of the structured recommendations, most observed that specifying too much workflow detail in the structured recommendation would limit widespread usefulness.

Other participants preferred in any case to specify their own workflow during implementation, especially because it might not be possible for the source of clinical recommendations to identify and incorporate all important issues affecting workflow in a given organization. The availability of data to determine if rule criteria have been met is one such source of workflow differences identified by discussants. For example, data elements that typically come from billing information are not available to providers that do not charge for services (such as Shriners Hospitals for Children), so system features dependent on information from the bill cannot be implemented. In addition, organizations that attempt to adapt existing systems to a new purpose rather than develop/implement new systems can encounter incomplete data or data that are in an inaccessible format. Such use of “legacy” systems is widespread.

EHR vendors expressed a strong desire to address rule workflow and other implementation issues with their development teams and clients and not have this information included at all in the structured recommendation. For example, vendors may wish to do something different with a rule and apply it to different records or at different points in the workflow; such workflow integration features might be used as a market differentiator in vendor systems. The view was that only at the point when a workflow attribute becomes a best practice or standard should it be incorporated into the eRecommendation for broad use.

Similar conclusions are suggested by collaborative efforts to develop and use shared repositories of medical knowledge that is executable or near-executable, such as that contained in guidelines, rules, and order sets. Recent projects such as the Morningside Initiative[10] and the AHRQ-funded CDSC and GLIDES[11] projects aim to develop organizational and technical structures to facilitate CDS content sharing among diverse organizations and provider sites. Generalizing the process whereby rules are integrated into clinical workflow has been a major challenge.[12] The more workflow issues are added into the rules, the less able they are to be shared across entities. However, Morningside Initiative experts emphasized the importance of including implementation considerations in any formalism, asserting that failing to "document the approach, timing, and context of the delivery of a CDS intervention would leave a site that wishes to import these rules with documentation inadequate to do so successfully."[13] Morningside Initiative members have sought to develop an ontology of workflow/site-specific factors that may be used to modify core medical knowledge to create workflow-specific rule sets.

These experiences reinforce the value of an "intermediate" approach to this project's eRecommendation format, i.e., one that captures the medical knowledge unambiguously in a formal, well-structured, and coded manner, but without site-specific workflow and related features to promote widespread sharing. See Figure 2 for the steps involved in transforming clinical recommendations from a narrative format to a machine-executable format. Although the stage 3 or stage 4 form of the rule may not be sharable due to local differences, the stage 2 form of the rule is broadly applicable. Other projects are focused on later stages of this process. For example, the Morningside Initiative aims to formalize stages 2 and stage 3. The Knowledge Management Repository (KMR) project of the DoD seeks to generate a stage 4 representation of rules through a service-oriented architecture (SOA) interface that integrates CDS with EHRs and uses a shared knowledge repository as the source of the CDS knowledge.

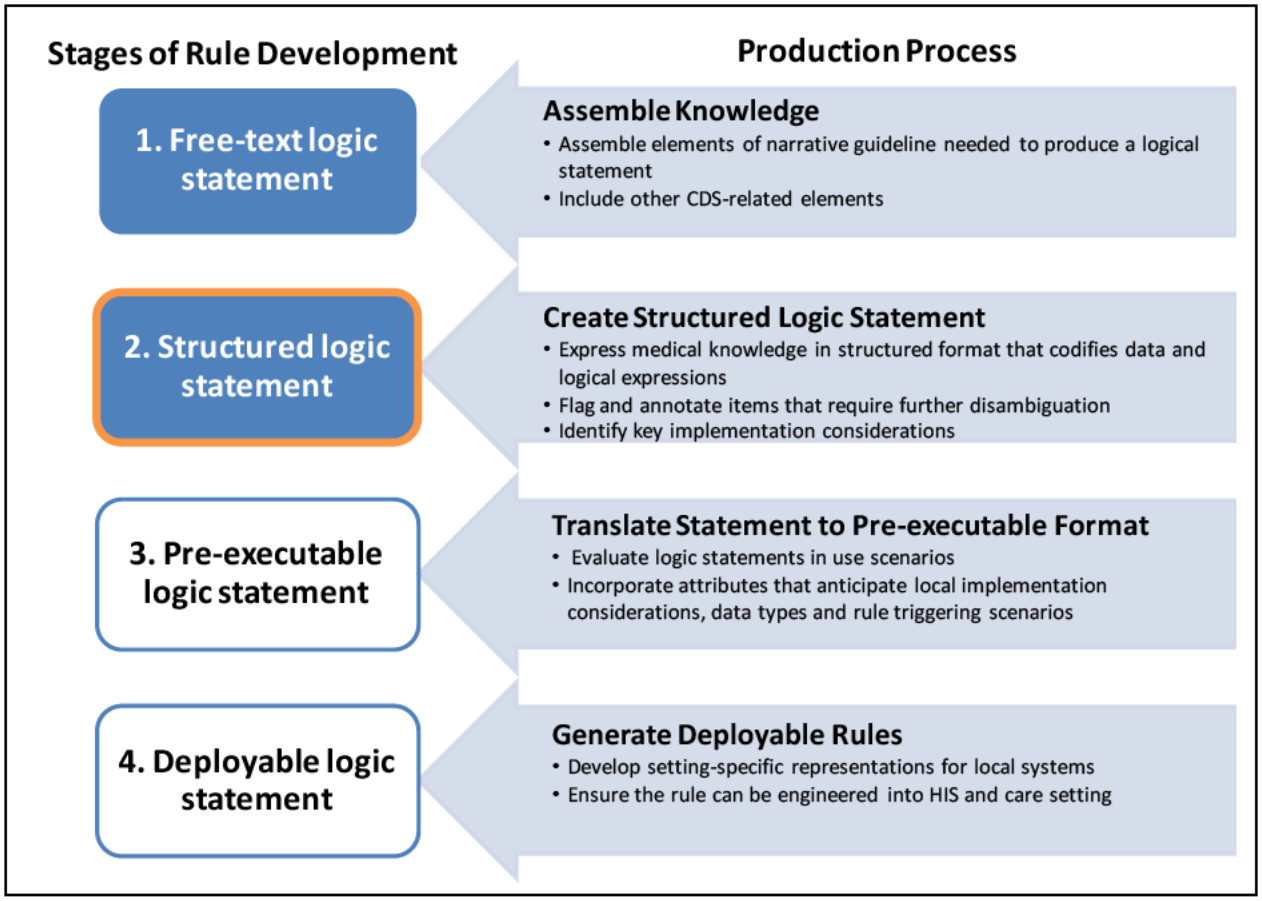
[10] The Morningside Initiative is an ongoing collaboration, begun in 2007, of participants from the U.S. Department of Defense, the U.S. Department of Veterans Affairs, Partners Healthcare, Kaiser Permanente, Intermountain Healthcare, Henry Ford Health System, Arizona State University, and the American Medical Informatics Association. It aims to develop an approach to sharing across multiple provider systems the best available knowledge for clinical decision support, in a format that is as close as possible to being executable.

[11] CDSC and GLIDES are AHRQ-sponsored demonstrations that focus on the "development, adoption, implementation, and evaluation of best practices using clinical decision support (CDS)." http://healthit.ahrq.gov/portal/server.pt?open=512&objID=654&&PageID=13665&mode=2&in_hi_userid=3882&cached=true.

[12] Communication with Rick Shiffman, January 27, 2010.

[13] Greenes RA, et al. The Morningside initiative: collaborative development of a knowledge repository to accelerate adoption of clinical decision support. Submitted for publication.

Figure 2: Four-Stage Model of Rule Development



To further inform its approach to balancing these views, the SCRCDS project sought stakeholder input on the extent to which implementation considerations should be incorporated into the developing eRecommendation formalism and the impact that has on its ultimate use. Discussants provided the following workflow-oriented suggestions for the design of the structured recommendations:

- Elaborate further on the issues in the workflow that the implementer should consider. For example, if the action trigger depends on data that are not always present, the implementer should be aware that this could be a problem and affect how often the rule fires. Several discussants indicated that implementers would benefit from the project team‘s (or others‘) thoughts about what is relevant to implementation of specific recommendations, particularly if issues that would not otherwise surface were identified.
- Make assumptions about the implementation issues explicit in the recommendation so that implementers can easily identify where local decisions are needed.
- Put information regarding implementation of the recommendation (e.g., workflow, data type, location) into the metadata.

A compromise that does not specify implementation issues in the logic statement or code details—but instead includes a section on implementation considerations—appears to best accommodate stakeholders‘ divergent opinions and needs.

Importance of Clear Logic and Data Specifications

As described above, each time a provider organization implements a clinical recommendation, resources must be devoted to identifying and resolving the ambiguities in prose recommendations and to crafting a logic statement with clearly defined data elements that are available in the local health information system. Discussants uniformly emphasized the need for structured recommendations to have unambiguous and clearly-written logic statements that reduce interpretation required by users (e.g., implementers, vendors) to make the statement computable. Discussants also expressed the need for well-specified logic and data elements that reduce false positive alerting and missed opportunities for helpful alerting. Essential logic statement ingredients that should be clearly designated include: target population for the recommendation, the specific recommended action, and intervention timing. At the same time, flexibility to adapt data requirements to local constraints is also considered necessary.

Discussants indicated that having standardized code sets and values for data elements specified would be particularly important to streamlining their translation processes (i.e., logic statements that are not specific with respect to definitions or code sets and values are much less useful). The project team heard numerous examples of common conditions, such as diabetes and asthma, or events that could be defined in a variety of ways. In addition, definitional ambiguities may arise because issues are not addressed in the narrative recommendation. Examples stemming from the breast cancer screening guideline or related literature include the impact on rule eligibility of a previous diagnostic mammogram for one breast or even a breast cancer diagnosis, as well as the significance of newer screening modalities, such as ultrasound, MRI, tomomammography, and digital mammography. Standard terminologies and code lists would also foster more consistent recommendation implementation across various sites in an organization. One discussant warned that inclusion/exclusion criteria that are defined too rigidly could require the availability of extensive data in order to trigger the rule, and problems with data availability could limit rule usefulness.

For implementers using a rules engine, the engine needs to be able to match patient facts to a data structure.[14] Discussants requested the use, where possible, of existing, defined data structures rather than creating new structures for the project output. One specific recommendation was that data elements be related to HL7 data types or structures from the HL7 Clinical Document Architecture (CDA). CDA is an XML-based standard that specifies the semantics and structure of clinical documents for the purpose of vendor-independent and inter-enterprise information exchange.[15] The CDA standard specifies that the document content consists of a mandatory textual part, which ensures human interpretation of the document contents, and optional structured parts for software processing. The structured parts rely on coding systems such as SNOMED and LOINC to represent concepts. Emerging quality measure

[14] SCRCDS team members experienced in guideline translation also raised concerns about the availability of patient data to populate the structured recommendation, as recommendations may require data that only comes from non-structured, non-coded sources, e.g., follow-up observations pertaining to adherence to a non-smoking program, which normally are documented only in free-text visit notes. Over time, it is expected that data essential to CDS/measurement (e.g., for measurable performance improvement in high priority target areas) will be made available in a structured/coded way through the introduction of regulations. For example, the proposed 2011 Meaningful Use requirements move toward gathering data about smoking status in this way. As EHRs begin including more key data that has not been available for use in CDS rules, more context-sensitive alerting will be possible.

[15] CDA Release 2 received ANSI approval in May 2005 and is published by the HL7 organization.

formalisms (discussed below) are using the CDA as a framework for viewing clinical data and define data elements in terms of their access from a CDA document.

Specifying a structure, terminologies, and definitions for the data elements are formidable technical challenges that apply to translating narrative clinical recommendations into a consistent format.[16] The CDSC and GLIDES demonstrations also identified the mapping of data elements in the recommendation to the appropriate locally available data elements as a key challenge.[17] However, standardization of terminologies and code lists for knowledge representation has not been accomplished to date because it requires a defined data model (i.e., a structure for categorizing and defining data elements); currently, there is no universal standard for data elements and data definitions that has been fully adopted by health information systems.

Despite the lack of standards, given stakeholder needs, we sought to specify a schema for data elements which will readily map to data elements in existing EHRs. The HL7 Reference Information Model (RIM) v.3.0 and GELLO surface as candidates. HL7 is devoting significant effort to developing the RIM as an object-oriented standard data model, and the GELLO expression language is based on the RIM. Yet the HL7 v.3.0 is used by a very small fraction of clinical information systems, and thus GELLO is not widely used either.[18] An alternative, the HITSP C154 document, specifies a minimal set of patient-level and clinically relevant data elements needed for quality measurement—and thus also for CDS. Less complex than the HL7 v.3.0 RIM, HITSP C154 uses a simple, shallow Object.Attribute data model (i.e., a model for describing clinical data that relies on classes or objects that are further delineated by attributes).

Based on stakeholder needs, the SCRCDS project team also sought a data structure that reduces site-specific features and can therefore be used more widely, yet enables local implementers to incorporate site-specific features as needed. Arden Syntax, an HL7 and ANSI standard for encoding recommendations into medical logic modules (MLMs), has local EHR data mapping dependencies and contains rule triggering (evoking) and notification details that limit the MLM portability to environments that differ in those respects. Though it does not provide a data model or mapping, Arden provides a standard syntax for logical operators, relations, and functions. The latest version of Arden Syntax also supports the class.attribute syntax for representing data elements, which is an appropriate match with the level of specificity required for structuring recommendations.

Finally, we sought a formalism that provides a consistent data model and which can be adapted to and used in many different information systems. There are various such formalisms for computer-interpretable guidelines and recommendations, although most have not been widely implemented.[19] The HL7 CDS Workgroup explored guideline representation standards in the early 2000s but could not achieve consensus. This workgroup determined that further work toward a standard guideline formalism should focus on the formalism components, such as the information language, the expression language, and a workflow representation model.

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[16] Tu S, et al. The SAGE guideline model: achievements and overview; and Peleg/Boxwala. 2001 PowerPoint

[17] CDSC project staff, unpublished summary of challenges identified by TEP to CDSC and GLIDES, November 2009.

[18] Neotool. The HL7 Evolution: Comparing HL7 Version 2 to Version 3, Including a History of Version 2 http://www neotool.com/pdf/HL7-Version-3-with-HL7-Version-2-History.pdf.

[19] Tu S, et al. The structure of guideline recommendations: a synthesis. AMIA 2003 Symposium Proceedings.

Furthermore, there are a host of initiatives (e.g., EON3, PRODIGY,[20] Athena,[21,22] and ProForma[23]) devoted to developing formalisms for the translation of complex, multiple-step guidelines, the actions of which may take place over a period of time, rather than at a single point in time. For the most part, however, USPSTF recommendations are discrete and involve single action steps. Nonetheless, some are more complex than others.

It has been recommended by various stakeholders that the structured recommendation template be aligned with the Guideline Elements Model (GEM). GEM is an XML-based schema and an ASTM[24] standard for marking up and organizing the type of statements contained within a narrative clinical recommendation. The GEM schema has attracted significant interest by narrative guideline developers, and its role in this project is further addressed in the Proposed Methods section.

Synergies with Performance Measurement Agenda

Early stakeholder discussions reinforced that the health care policy environment is driving considerable movement toward incorporating quality measurement in EHRs which, in turn, is driving changes in the health IT marketplace. Providers using EHRs have strong incentives to incorporate into these systems measures on which their performance will be evaluated, such as criteria for MU and pay-for-performance programs. For example, the Indian Health Service (IHS) is giving priority to addressing items that are of national significance and tied to reimbursement, such as MU measures. Vendors of EHRs also view integrating these measures into their products as a high priority. Several contacts suggested that the project could benefit from finding synergy with these efforts. Further discussions backed up the approach of tying eRecommendations closely to performance measurement structures, logic, and codes. One discussant advised that the project team focus on recommendations that are tied to pay-for-performance or MU measures because vendors and providers will view these as high value. The project team also noted that, in its previous deliberations, the CDSC and GLIDES technical expert panel raised the question of how to engage the quality measurement community.

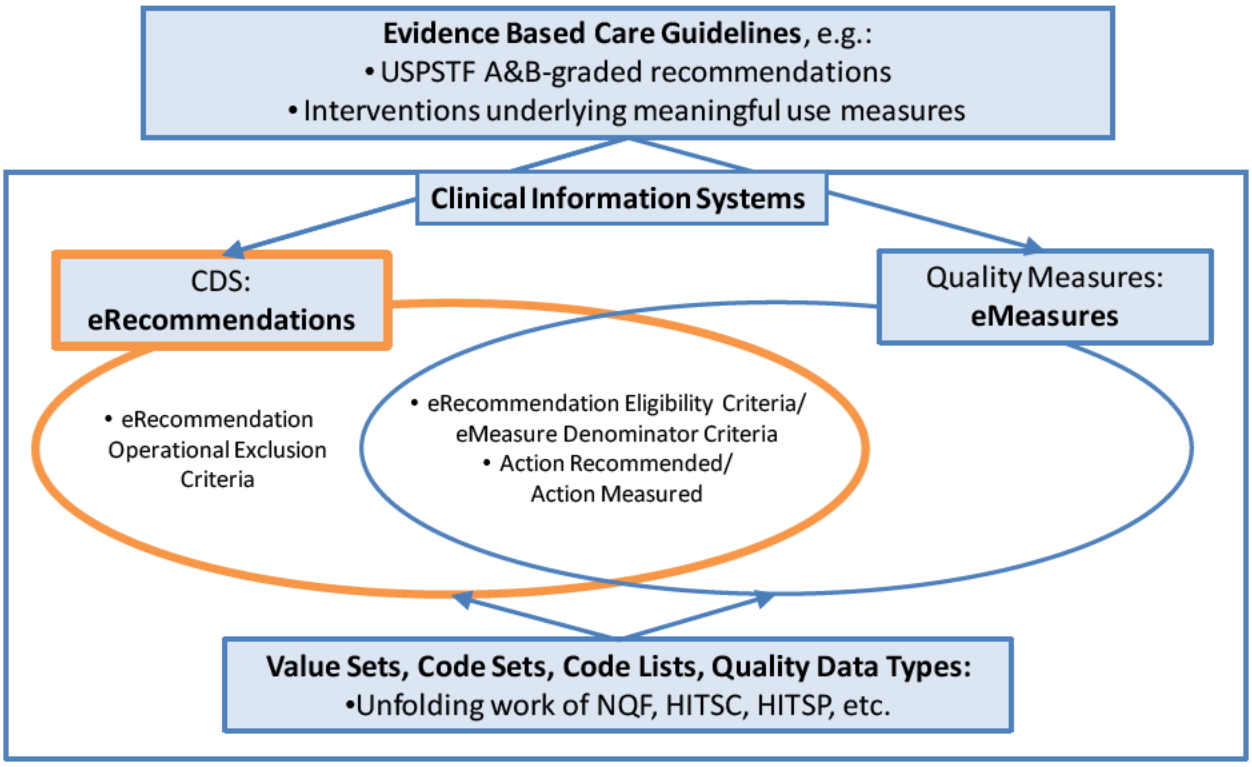
The project team reviewed pertinent measurement related initiatives including Health Quality Measures Format (HQMF).[25] HQMF is an HL7 Draft Standard for Trial Use for expressing a health quality measure‘s structure, metadata, definition and logic in a format suitable for EHR integration. An eMeasure is the result of populating the HQMF template with information pertinent to a specific quality measure. The project team learned that considerable groundwork had already been laid in the vendor community for standardization efforts that are closely related

[20] Johnson PD, Tu S, Booth N, et al. Using scenarios in chronic disease management guidelines for primary care. Proc AMIA Symp 2000:389-93.
[21] Goldstein MK, Hoffman BB, Coleman RW, et al. Implementing clinical practice guidelines while taking account of changing evidence: ATHENA DSS, an easily modifiable decision-support system for managing hypertension in primary care. Proc AMIA Symp 2000:300-4.
[22] This project is being conducted at the Palo Alto VA Medical Center in collaboration with Stanford. It maintains physical and logical data independence from the host VA VistA system, so it can be potentially integrated into a variety of electronic medical record systems. Applications are primarily in hypertension and, more recently, diabetes management. Because evidence for best management of hypertension evolves continually, ATHENA DSS is designed to allow clinical experts to customize the knowledge base to incorporate new evidence or to reflect local interpretations of guideline ambiguities.
[23] Fox J, Johns N, Rahmanzadeh A. Disseminating medical knowledge-the PROforma approach. Artif Intell Med 1998 Sep-Oct;14(1-2):157-81.
[24] ASTM International was originally known as the American Society for Testing and Materials.
[25] Dolin, et al. eMeasure: Representation of the Health Quality Measures Format (HQMF). January 10, 2010. Draft document.

to what will be required for widespread uptake of structured logic statements to underpin CDS rules. In addition, because CMS has recently proposed requiring that Medicare and Medicaid clinical quality measures eligible for incentive payments be submitted through EHR technology by 2012,[26] HQMF is likely to be quickly and widely adopted by providers and information systems vendors engaged in performance measurement associated with MU and other major health IT-related health care drivers.

Figure 3 illustrates the conceptual and operational similarities between expressing quality measures and clinical recommendations in formats that are more readily digested by electronic systems. In addition to being derived from the same evidence basis (box at top of Figure 3), both clinical recommendations and performance measures can be expressed by similar data structures and coded data (box at the bottom of Figure 3). Although performance measurement is closely related to providing decision support, important differences also exist. For example, the individual patient must fit into the inclusion criteria to make him or her eligible for the intervention conveyed in the CDS rule, while measure specification and the needed standardized data definitions focus on populations. Information about factors that are critical to a real CDS implementation, such as a pre-existing diagnosis of the condition or data reflecting that a clinical recommendation has already been acted upon, are not included in the measures' logic statements because performance measures don't need to make these distinctions.

Figure 3: Leveraging quality measure standards and EHR integration to support structured recommendations that underpin CDS rules



[26] Available at: Centers for Medicare & Medicaid Services. CMS Office of Public Affairs. CMS Proposes Definition of Meaningful Use of Certified Electronic Health Records (EHR) Technology, Fact Sheet, December 30, 2009. https://www.cms hhs.gov/apps/media/press/factsheet.asp?Counter=3564&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date. Accessed December 2010.

Because the challenge of data mapping and defining data structures is significant for quality measurement, other developments in standardizing EHR-enabled quality measurement and reporting have occurred. First, the U.S. Department of Health and Human Services supported the National Quality Forum (NQF) in developing a Quality Data Set (QDS), which establishes a common language to describe the information within quality measures and maps to the HL7 Clinical Document Architecture (CDA). Specifically, the framework provides standard elements or a code list for a specific condition, quality data elements or information describing the context of use, and data flow attributes or the care setting providing the information. NQF's CDS Expert Panel Taxonomy workgroup subsequently determined that the QDS data model is relevant to CDS, representing the input data and triggers required.[27] Second, an authoring tool for implementing the QDS was developed after examining 500 NQF-endorsed quality measures. The tool, which utilizes an Access database, allows the user to specify QDS elements corresponding to each component of an HQMF-expressed eMeasure. Third, NQF is currently retooling a set of quality measures into the HL7 HQMF format (represented in XML).[28] Some of the measures slated for retooling are preventive care measures (e.g., influenza vaccination, colorectal cancer screenings, screening mammography, smoking cessation counseling). Depending on the timing schedule for these retooled measures, the SCRCDS project could benefit from using the retooled measures as a base for defining eligibility and exclusion criteria for corresponding structured CDS recommendations.

Value of Draft eRecommendation Template

To one degree or another, each conversation and stakeholder affirmed that the general SCRCDS approach to building eRecommendations on performance measurement constructs, tools, and codes is valuable. Most also indicated that they will consider using the draft template in their CDS rule efforts. Some stakeholders pointed out that there may be greater challenges in producing eRecommendations beyond breast cancer screening, e.g., in cases where multiple decision variables are involved, or the recommendation is to not perform an action under specific circumstances. See Appendix C for highlights of stakeholder comments on specific draft eRecommendation features. The Methods section of this report explains how this feedback shaped the eRecommendation template and process for populating it, as well as ensuring that the structured recommendations are useful to as many potential adopters as possible.

Comments about related aspects of the template, but not the format itself, included a recommendation that hard copy distribution vehicles, such as journals, be considered for the final structured care recommendations. Another point regarding dissemination came from telephone conversations in which stakeholders identified the need for packaging structured care recommendations to carefully communicate how they are intended to be used, i.e., as a helpful starting point for further local adaptation and not a Federal mandate; as a public good rather than a proprietary product.

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[27] http://www.qualityforum.org/Projects/Clinical_Decision_Support.aspx. SCRCDS project staff are represented on NQF's CDS Expert Panel.

[28] Previously, the Iowa Foundation for Medical Care (IFMC) assigned value sets (lists of codes) to a number of the data elements for the 2010 versions of select PQRI measures; the project did not assign contexts of where the information would be found within an electronic record. The current retooling project is _retooling' these same measures in the context of the Quality Data Set (QDS) and new codes are being identified based on that work. Therefore, the work being performed this year to take effect after 2011 will develop similar but different value sets than what is published for 2010 reporting and the 2011 program.

In addition to producing feedback on the draft eRecommendation template for structured recommendations, we used the vetting process to identify stakeholders who are potentially interested in using/consuming the project output. Although pursuing this interest in detail is outside the current contract scope, the potential users and their next steps related to this project are briefly described below. Some care delivery organizations envision using the project results as the starting point for their guideline translation process, eliminating a lot of upfront work. Others believe the eRecommendation format itself could be a useful structure when developing their own structured logic statements and CDS rules. We will seek opportunities to incorporate this interest into pertinent activities during this project. Furthermore, these organizations may serve as good starting points for future AHRQ efforts related to Structuring Care Recommendations.

Federal Government

- **IHS** observed that using the eRecommendations and their template to structure and populate care recommendations would decrease redundant efforts by various Federal care delivery organizations. Such agencies could decrease rule development resources by starting with a completely documented set of care recommendations, such as will be provided by this project. That information could populate its CDS rule requirements document, with modifications as needed to address the agency‘s unique circumstances. To the extent that the eRecommendations are in harmony with pertinent reporting mandates, this approach would also make it easier to comply. It is expected that eRecommendations could be consumed by the IHS if each element is defined and adequately documented (e.g., standard codes used to define labs, procedures, screenings, and so on).

- The **Office of Patient Care Services, National Center for Health Promotion and Disease Prevention (NCP) at the Department of Veterans Affairs (VA)** recently established a process for developing Clinical Preventive Services (CPS) Guidance Statements. The CPS Guidance Statements are used in developing the VA‘s national clinical reminders. For all of the screening, counseling, and preventive medication recommendations, the process starts with the USPSTF recommendations, which are adapted for the VA based on patient population characteristics, clinical settings, and so on. The VA sees the SCRCDS eRecommendations as a useful alternative to the written USPSTF recommendations as a starting point in their process for developing CPS Guidance Statements.

- **The VA** also provided input from other staff directly involved in CDS rule deployment. They observed that a fair number of the proposed eRecommendation data elements and logic specifications have a direct connection with the data and logic used in their reminder definitions. The VA would like to use the SCRCDS templates as starting points for developing national VA clinical reminders, and believes it could automate the process of taking data and logic from a template to initiate reminder development.

- **The Department of Defense (DoD)** expressed interest in running one completed eRecommendation through their clinical information system for emergency department services.

- The **U.S. Navy** is interested in mapping KMR constraints to the draft template for structured recommendations to see if they are relevant and useful.
- The **Centers for Disease Control and Prevention (CDC) Division of HIV/AIDS Prevention** has expressed interest in potentially using this project's outputs to advance its efforts to devise and encourage the uptake of clinical quality measures and decision rules for EHRs. The agency is already exploring proposals to CMS regarding Stage 2 MU criteria, and the agency suspects that products from the SCRCDS project could eventually feed into these as well. The agency would specifically like to directly encourage major EHR vendors to enable their systems and software to include diagnostic testing prompts around HIV. Other CDC units have likewise expressed interest in using project outputs in their effort to leverage EHRs to improve public health in priority areas.

Private Sector

- **AMDIS** members volunteered to give feedback through a small self-identified group, several of whom indicated that the draft eRecommendation and template appeared to be helpful for their CDS rule deployments. Organizations indicating potential interest in consuming SCRCDS eRecommendations include Ohio State, Methodist Medical Center (IL), Advocate Healthcare, and Memorial Hermann. One AMDIS member CMIO explained that selecting codes has been the most time-consuming part of rule implementation for his organization, so having this information in the eRecommendation is what would make it most valuable.
- The Southern California region of **Kaiser Permanente (KP)** looked at the draft template with an eye toward what would need to be done to enable it to support their process for implementing clinical recommendations as CDS rules. Because they are beginning to adopt Yale's GLIA tool for assessing guideline implementability (e.g., decidability, executability, computability criteria), KP determined that the draft template was fairly compatible with GLIA and that they could potentially use it. The template would likely be used to validate that the KP logic reflects the clinical recommendation intended by its source; this would be especially valued for the more complex recommendations.
- **Mayo Clinic –** The Mayo Clinic Health Manager[29] (MCHM), a Microsoft® HealthVault-based consumer product, is a personal health record that delivers evidence-based personalized guidance to the user. This team structures the guidance around wellness, prevention, and certain health conditions like pregnancy, asthma, high blood pressure, high cholesterol, and diabetes (future). They noted synergies with their approach to translating care recommendations into their system, and were optimistic about the potential value of the eRecommendations template and content adding value to their PHR.

[29] www healthmanager mayoclinic.com

Proposed Methods: Structuring Recommendations

Based on the analysis outlined above, the SCRCDS project team concludes that the most useful approach for structuring and encoding clinical recommendations in this project is to fully address the elements in Stage 2 of Figure 2, and leave work at Stages 3 and 4 to local implementers. These final products—recommendations written in a semistructured format—will dovetail with the intermediate stages outlined in the Morningside Initiative's life cycle of rule refinement, CDSC's multilayered model, and GLIDES guideline transformation process.

This report section describes the proposed methods for expressing narrative care recommendations as formally structured and coded statements, or eRecommendations. To help ensure that care recommendations are translated in a consistent manner, we recommend that a User Guide be developed based on the Standard Operating Procedures document created as part of this project. The User Guide and other packaging for the eRecommendations should clearly indicate that the information is not proprietary and their use is voluntary.

Setting Up Structured Recommendations

This section describes the proposed template for capturing, representing, and encoding key patient and clinical information from a clinical recommendation into a logic statement to underpin CDS rule development. In general, the technical challenge of defining the necessary data elements motivated the SCRCDS project team to align with corresponding performance measurement and reporting efforts (e.g., QDS, HQMF, and "retooling" performance measures for EHR integration), so as to leverage those standards to address value sets, codes, and other logic elements needed for implementing related recommendations as CDS. These formalisms are being adopted by EHR suppliers as well as by the quality-measurement community.

Overall Structure of eRecommendation Template

HQMF was used as a starting point for creating this project's structured recommendation template. As explained in the Findings section, quality measures, performance measures, or quality indicators—designed to determine whether appropriate care has been given based on predefined clinical criteria—are often derived from clinical guidelines. Many quality measures are currently being structured for the health IT environment using HQMF with its clearly defined sections, metadata (e.g., author, verifier), definitions (e.g., "numerator," "initial patient population"), and logic. This formatting makes it possible to achieve at least minimal consistency and readability of encoded eMeasures, even if these are not fully able to be machine processed.

The elements and corresponding definitions in the Guideline Elements Model (GEM) were also assessed for their use in informing the eRecommendation template. The GEM document markup model is an abstraction of a guideline document. It allows guideline developers, implementers, and end users to highlight relevant guideline concepts, concept attributes, and relationships among concepts through predefined constructs. These constructs generally do not deal with implementation details. GEM markup can be used to translate paper-based narrative clinical guidelines into formatted templates that can be processed electronically, though not necessarily

for direct rule implementation. HQMF is currently more closely aligned with data structures and codes needed for EHR integration, so is used as the predominant framework for structuring recommendations as eRecommendations. Further analysis could determine benefits and strategies for creating a closer alignment between GEM and the eRecommendation template.

To test whether and how HQMF might underpin an eRecommendation template, an eMeasure was obtained, all information in the populated fields was deleted, and the resulting HQMF template was repopulated with key patient-level and clinically related data extracted from the USPSTF Grade B recommendation for breast cancer screening. The purpose of this step was to ensure that (a) the HQMF structure and granularity is grossly adequate for eRecommendations and (b) the template could be expanded or modified to accommodate needs specific to encoding clinical recommendations. To further evaluate HQMF usefulness as a foundation for the eRecommendation template, the SCRCDS team also translated three additional USPSTF recommendations into the modified template. In addition, the team surveyed the remaining A- and B-graded USPSTF recommendations to identify commonalities among the entire recommendation set that should be reflected in the eRecommendation template. Likewise, we reviewed a limited set of clinical measures proposed by the Health IT Policy Committee in August 2009 for meaningful use reporting in 2011 to get a general sense of whether the evolving approach would likely accommodate the types of recommendations underlying those measures.

The team iterated through successive refinements to the original HQMF-derived draft template, incorporating insights from SCRCDS team members and other stakeholders as outlined in the Findings section. The resulting eRecommendation template proposed in this report (see Appendix D) contains three main sections:

1. Header Information (similar to HQMF header, with some additional and modified fields)
2. Data Specification and Logic Specification (similar to HQMF data criteria and measure specification sections)
3. Implementation Considerations (added)

Header Information

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. The current descriptions of Header fields assume the clinical recommendations are from the USPSTF; these descriptions will likely become more generic when the project structures recommendations from the second guideline set. The Header fields are:

- **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).
- **eRecommendation ID:** Unique, descriptive identifier assigned to document.
- **eRecommendation Version Date/Number:** Document version number and date of creation.

- **Recommendation Set:** Group of recommendations to which this recommendation belongs, according to the source, e.g., USPSTF Grade A recommendations.
- **Set ID:** If applicable, identifying label for group of recommendations to which this recommendation belongs.
- **Recommendation 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.
- **Template Version Date/Number:** Version and date of template format used in creating the eRecommendation.
- **Related eMeasure(s):** NQF retooled measure ID that is related to USPSTF recommendation, when available.
- **Author:** Name of person or institution who encoded the eRecommendation.
- **Verified by:** Name of person or institution who verified the eRecommendation.
- **Maintained by:** Name of person or institution responsible for maintaining the eRecommendation content.
- **Description/Purpose of eRecommendation:** Brief overview of the USPSTF recommendation.
- **Recommendation Text from Source – Summary Statement:** Summary description of the care recommendation as it appears in the narrative source document.
- **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.
- **Setting:** Clinical setting (e.g., doctor's office) where the recommendation applies, if specified in the narrative source document.
- **Recommendation Classification:** Purpose of the recommendation (e.g., screening, prevention, diagnosis).
- **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.
- **Reference:** Full citation of the source's recommendation statement.
- **Reference URL:** URL for the online version of the care recommendation from the source.

The SCRCDS team proposes that each individual USPSTF A and B recommendation be encoded separately even if they are presented together in the same "guideline," e.g., journal article that might list several related recommendations on the same clinical topic. However, if it is

determined that the criteria and/or actions of one of these recommendations has an effect on the other recommendation(s), they would be encoded as part of the same eRecommendation to preserve this interrelationship.

Data Specification

Specifying the data in a consistent manner for structured recommendations hinges on defining a data model. This section describes (a) the key patient-level and clinically related elements in USPSTF recommendations that the data model must address; b) the review of existing data models in order to select, modify, or develop one model for encoding recommendations; and (c) the relevant code sets.

Key Data Elements. In many deployments, getting key data—even the most basic elements—needed for proper rule functioning could be problematic. Therefore, we identified the key patient-level and clinically related information from several USPSTF recommendations in order to ensure that the data model would capture all such information necessary for encoding eRecommendations and supporting CDS rule development. These initial data elements, which may be extended or modified based on further experience in structuring the required recommendation set, include patient demographic information, medications, procedures, and diagnoses. They were converted into classes and attributes (e.g., classes includee "Patient Characteristics" and attributes include "gender") and used to select a simple data model.

Data Model. The HL7 v3.0 RIM, an object-oriented reference information model, was examined because it is the basis for the information content of all HL7 v3 protocol standards. Despite all its advantages, the RIM relies on a complex class structure where a subclass inherits attributes from multiple classes. This, combined with the lack of widespread use of HL7 V3, makes the HL7 RIM too complex as a data model for SCRCDS purposes. As described in the Findings section above, relative simplicity is required to optimize widespread logic statement uptake.

Another potential data model source comes from the Healthcare Information Technology Standards Panel (HITSP). In evaluating the Quality Use Case, HITSP and the American Health Information Community (AHIC) identified a need for a quality dataset. NQF, a consensus-based organization with transparent processes, convened—with sponsorship from AHRQ—the Health Information Technology Expert Panel (HITEP) to address this need for a quality measurement data framework. HITEP produced the initial Quality Data Set (QDS) as an evolving source for such standardized clinical data elements needed to measure patient care quality and performance. The data types used to categorize these elements capture patient information components, bound to the context of use. For example, medications figure prominently in patient care delivery and assessment, and for the medication data element, the QDS captures contexts of use including medication administered, medication allergy, and medication ordered. Such concept specificity helps enable key information to be located in a variety of electronic patient information sources including electronic health records (EHRs), personal health records (PHRs), registries, and health information exchanges (HIEs). Furthermore, this core dataset is generally the same as is needed to characterize content in clinical guidelines and CDS rules. HITSP also has been using HITEP as the ongoing source for the quality data requirements to inform the HITSP Quality Interoperability Specification.

Based on the QDS, the HITSP Quality Data Dictionary[30] provides a usable data model with classes and attributes that are simple to understand and can be easily extended to accommodate SCRCDS needs and findings. The QDS is mapped to the Clinical Document Architecture (CDA)—which is, in turn, based on the HL7 RIM—and provides a more practical approach to applying the RIM. Representations are defined in terms of code set standards and constraints. The HITSP Quality Data Dictionary provides a simple, comprehensive, and flexible source for defining a data model, given that it (a) characterizes patient-related information in multiple contexts; (b) characterizes information as it is expressed in various health IT sources; and (c) overlaps with data needs for clinical recommendations and CDS.

The proposed data model adopts seven main classes and their attributes from the HITSP Quality Data Dictionary to underpin eRecommendations representation: (1) Patient Characteristics; (2) Diagnosis; (3) Diagnostic Study; (4) Laboratory Test; (5) Procedure; (6) Physical Finding (Vital Signs as a specialization of Results); and (7) Medication. These data elements suffice to represent the classes and attributes identified in the SCRCDS team's preliminary analysis of USPSTF A and B recommendations. The attribute "Tense" is used to express time as it relates to a data element. For example, an event has occurred in the past or will occur in the future. It should be noted that, because the underlying QDS model is intended to evolve with use,[31] the data classes and attributes used for eRecommendations might evolve in parallel. The current SCRCDS data model classes, selected from HITSP C154, are defined as follows:

- **Patient Characteristics** mainly contains specific information about a patient, including demographics.
- **Diagnosis, problem, or condition** is defined as a scientific interpretation of result, assessment and treatment response data that persists over time and tends to require intervention or management. It is used to guide planning, implementation, treatment, and evaluation. A problem or condition includes, but is not limited to chronic conditions, diagnoses, or symptoms, functional limitations, or visit or stay-specific conditions.
- **Diagnostic study** is used to define a test not performed in a clinical diagnostic laboratory. Examples include, but are not limited to, imaging procedures (radiology, ultrasound, radionuclide scans, and so on), cardiology studies (EKG, treadmill stress test with or without isotope), pulmonary function testing, vascular laboratory testing, and so on. Hence, diagnostic test order, diagnostic test performed, diagnostic test result, diagnostic test declined, and so on, all provide context for diagnostic tests. Context is identified by the assigned value in the Tense attribute.
- **Laboratory test** (order, declined, performed, and so on) and laboratory result relate to studies performed in a clinical diagnostic laboratory (traditionally chemistry, hematology, microbiology, serology, urinalysis, blood bank). Contexts of use are identified by the value assigned to Tense.
- **Procedure** includes both (a) intervention reimbursable procedures (e.g., surgical procedures, colonoscopy, insertion of extended-use catheters, physical therapy, and so on) and (b) intervention nonreimbursable procedures (e.g., dressing change, placement of

[30] HITSP Data Dictionary Component. HITSP/C154 at http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=154.
[31] The new Health IT Advisory Committee (HITAC) which will be seated in April or May 2010 will help review such changes.

venous thromboembolism prevention devices, assisting the patient with walking).[32] Both require a physical interaction with the patient and are therefore different than communication. Procedure has various contexts of use such as procedure ordered, procedure performed, procedure result, procedure declined, procedure adverse event, and so on. The context can be identified by the Tense attribute.

- **Physical Finding** is the result from evaluating the patient's body to determine their state of health. The techniques of inspection include palpation (feeling with the hands and/or fingers), percussion (tapping with the fingers), auscultation (listening), and smell. Measurements may include vital signs (blood pressure, pulse, respirations) as well as other clinical measures (such as expiratory flow rate, size of lesion, and so on.)
- **Medications** provided routinely are found in the medication list or medication administration record (depending on setting and information desired). Medications provided in the context of procedures are generally recorded in the procedure documentation, e.g., perioperative medications are often recorded on the anesthesia record or operating room record, and conscious sedation is often recorded on the procedure note.

The quality measure retooling process that NQF is engaged in has developed rules for determining the class to which an intervention belongs (the "parent"). The proposed process for generating structured recommendations would use the same criteria. Examples including the following:

- An imaging procedure classifies the intervention as a diagnostic study even if a biopsy was included.
- A laboratory study that includes injection of a substance (e.g., glucagon or glucose given prior to a series of serum specimens over time) classifies the intervention as a laboratory study.
- There can be some confusion whether a procedure that does not require an operating room is a diagnostic test or procedure. For example, there can be therapeutic bronchoscopy to remove an aspirated peanut, as compared with diagnostic bronchoscopy. Currently, the QDS model classifies all such procedures (whether performed at bedside or in the operating room) as diagnostic studies.

Appendix E presents in detail the proposed eRecommendation data model. The first column presents the definition for each class as mapped to a Quality Data Element. For each Quality Data Element, a definition is provided in the second column. The third column presents a list of the attributes for each main element, while column four defines the attribute, the context where it is used, and, when applicable, the preferred vocabulary (as defined in the HITSP Quality Data Dictionary). The last column provides additional information.

[32] In the initial Quality Data Dictionary, Procedures were separated into two data element classes distinguished by reimbursement. HITSP felt that reimbursement rules should not define procedures given that reimbursement policies change, so they were merged into one category.

Code Sets. To clearly and unambiguously represent data elements that describe a patient and health care services delivered, careful attention must be paid to selecting pertinent code sets and data element values. Ideally, code sets and approaches to value selection should be standardized and widely used, yet there are currently few such widely adopted standards. However, NQF is playing a leadership role in national work to rapidly change this situation as part of efforts to drive meaningful use of health IT. The SCRCDS team proposes, therefore, to either (a) use medical code sets and value sets selected by NQF when available to construct the data definitions for eRecommendation logic statements or (b) provide a clear and accurate Englishlike description of the health care concept as a placeholder until more authoritative codes and values are available. This approach is considered preferable to an ad hoc approach to coding specifications for the clinical recommendations.

Logic Specification

Encoding Language. Logic specification requires three types of information: (a) information from the recommendation section in the narrative form of the clinical guideline, (b) relevant data elements from the defined data model, and (c) threshold values to build decision rules for inclusion/exclusion criteria. The aim—and the challenge—is to represent these logic statements in a consistent, well-defined manner that is simple to understand and can be ultimately rendered into code in a specific computer language used in a particular site.

Experts we consulted confirmed that there are two leading approaches for logic encoding: Arden Syntax[33] and HQMF[34] logic constructs—but no "gold standard." Both approaches have advantages and limitations. For example, the Arden Syntax procedural language is structured, well-defined, and has many relevant operators and built-in functions. These can be used, for example, to express temporal dimensions often needed in logic statements and CDS rules. It fully supports the "dot" notation (i.e., class and attribute expressed with a period in between) and aligns with the SCRCDS proposed data model. Despite its advantages, Arden Syntax has not been widely adopted by vendors and members of the health care community. The alternative HQMF logic constructs have been defined as a way to express performance measures while preserving the clinical intent of the measure itself. Although not a query language, HQMF supports formal, unambiguous criteria—through the HL7 RIM Act Class and its various moods[35]—by expressing these criteria as HL7 RIM patterns coupled with vocabularies. The two main limitations of the HQMF are its somewhat more complicated notation and that it relies on the HL7 V3 RIM, which has experienced limited adoption.

The SCRCDS project team proposes to select the most relevant Boolean, temporal, mathematical operators and features from Arden Syntax and HQMF eMeasure logic constructs to build structured, consistent, easy-to-understand Englishlike expressions with a .dot notation that accurately represent the conditional logic in the recommendations. In the future, as the HQMF

[33] ANSI/HL7 Arden V2.7-2008, HL7 at http://www hl7.org/implement/standards/ardensyntax.cfm.
[34] HITSP Clinical Document and Message Terminology Component. HITSP/C80 Part III Department of Health and Human Services. 45 CFR Part 170. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule http://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf.
[35] The class describes the type of Act, such as an observation, an encounter, or the administration of a drug. Mood is analogous to the tense of a verb. Mood code indicates whether an Act has happened (an event), is a request for something to happen, or is a goal or even a criterion. For example, "weight = 200 pounds" is an observation event; "measure weight daily" is a request; "reduce weight to 180 pounds is a goal, and "if weight is greater than 180 pounds" is a criterion.

eMeasure specification evolves and adapts, the SCRCDS approach can be reharmonized so it remains fully aligned with what will likely become a foundational health IT standard.

Logic Structure. In its basic form, a decision rule consists of two elements: an antecedent (condition part) and a consequent (action part). If all of the conditions in the antecedent are true, then the specified actions will be executed.

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, as in the expression: Patient Characteristic.Gender = female. Decision rules for inclusion/exclusion criteria are constructed by combining these triplets by means of Boolean operators, e.g., OR, AND, NOT. As an example, for the clinical recommendation that clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography in women 40-49 years of age,[36] the Englishlike representation is:

If Patient Characteristic.Gender = female AND (current date – Patient Characteristic.Person Date of Birth) is between 40 and 49 years	Antecedent (conditions)
then perform individualized assessment of risk for breast cancer	Consequent (action)

Implementation Considerations

The Implementation Considerations section serves as a placeholder for documenting rule development and deployment issues beyond the structured, coded logic statement itself. In other words, these are issues among those that implementers should consider as they adapt the Stage 2 SCRCDS output into locally useful and executable Stage 4 CDS rules. This section is a compromise that allows limited thoughts on the topic to be shared by eRecommendation authors; it also provides a foundation for potential subsequent refinement based on eRecommendation user feedback. For now though, the variation in local considerations makes it infeasible to uniformly specify these considerations in detail in the current eRecommendation. As a result, the implementation considerations section will not contain all the guidance some implementers seek. Although the approach leaves substantial translation work in the hands of the implementer, it is believed to represent the best approach to achieving widespread eRecommendation usefulness.

The SCRCDS team proposes a generic checklist in each eRecommendation to help implementers consider implementation issues that may be pertinent to successful CDS rule development. Key implementation consideration categories to be included are outlined below. These implementation categories will be refined by the SCRCDS team during eRecommendation creation and populated in a preliminary fashion with some specific considerations for each eRecommendation.

- Clinical policies
- Rule specificity optimization (i.e., operational exclusion criteria)

[36] Ann Intern Med. 2007;146:511-5.

- Obtaining key data
- Notification approaches
- Rule triggering
- Additional workflow issues
- Other considerations

When possible, we will align terminology used in the implementation considerations section with the taxonomy under development by the NQF CDS Expert Panel. At the highest level, this taxonomy refers to input data, trigger, intervention and realization options (i.e., offered choices for local workflow consideration).

Filling in the eRecommendation Template

Methods may evolve somewhat as eRecommendations are created; the final process for populating the eRecommendation template will be described in a Standard Operating Procedures document submitted near project completion. As noted above, we recommend that a User Guide be developed from the SOP document to guide users in how to populate fields in the template. The User Guide should include a worksheet to stimulate recommendation-specific implementation considerations that help implementers translate the eRecommendation into CDS rules optimized for specific systems and settings. Below is a high-level description of the initial plan for producing eRecommendations.

Populating the Template

The first step involves matching excerpts from the narrative form of a clinical recommendation with fields in the template. Figure 4 below shows how each element in the Header Section and Data and Logic Specification maps to the narrative clinical recommendations available from the USPSTF. For elements not available from the narrative, the eRecommendation author will provide the pertinent information or placeholder content.

Figure 4: Mapping template fields to the clinical recommendation narrative (for USPSTF recommendations published in a medical journal)

Template Data Element	Equivalent in Clinical Recommendation Narrative
1. Header Information	
eRecommendation Name	Recommendation Title
eRecommendation ID	
eRecommendation version date/number	
Recommendation set	
Set ID	
Recommendation version date/number	Recommendation date
Template version date/number	
Related eMeasure	

Template Data Element	Equivalent in Clinical Recommendation Narrative
Author	
Verified by	
Maintained by	
Description/ Purpose	Description
Summary statement from source	Recommendation statement in abstract
Additional inclusion/exclusion criteria from source	Clinical considerations, Patient population in recommendation
setting	
Rule classification	Keyword(s) in abstract
Rationale	Rationale section in recommendation
References	Recommendation citation
Reference URL	
2. Data and Logic Specification	
2.a Data definitions	
Eligibility/Inclusion-related data	Identify key data element involved in the recommendation
Patient data Target age lower limit Target age upper limit Target gender Target race/ethnicity	Identify classes and attributes in data model that correspond to identified elements in recommendations and clinical considerations
Intervention interval	Recommendation(s)
Exclusion criteria-related data	Recommendation(s)
Operational exclusion criteria-related data	
2.b Logic Statement	
<Eligibility/inclusion Criteria>	Using all identified data for inclusion
	Construct triplets of the form: Class.Attribute <operator> <value> for each key data element identified in the data definition
	Concatenate triplets with Boolean operators
<Exclusion Criteria>	Using all identified data for exclusion
	Construct triplets of the form: Class.Attribute <operator> <value> for each key data element identified in the data definition
<Operational exclusion criteria>	
<Action>	Identified recommended actions in Recommendations/ clinical consideration sections

The second step involves populating the Data and Logic Specification section of the template. This template section contains three columns (see Figure 5 for example). The first column captures the category being encoded, e.g., eligibility/inclusion-related data. The second column describes the data elements for a given category. The third column lists relevant notes, issues, clarifications, and observations for the current category. For example, this column would be used to identify important differences between data definitions based on the narrative USPSTF recommendation and those in the related eMeasure. In the example below, the third column indicates that, although one of the key data elements for building the inclusion criteria (target age) as identified in the USPSTF recommendation for breast cancer screening[37] has a high limit of 74 years, the value for this data element when expressing the quality measure PQRI 112 to which this logic statement is related is 69 years.

Figure 5: Example of three-column eRecommendation section for data definitions

2.a Data definitions		
Category	Data Elements	Relevant Notes
Eligibility/Inclusion-related data	Demographic • Target Gender: F • Target Age low limit: 50 • Target Age high limit: 74 Condition • [not relevant to mammography example] Risk • [not relevant to mammography example]	For PQRI 112 to which this logic statement is related, Age Limit High = 69

The general process of populating the three columns requires identifying key patient data and clinical information as defined in the A or B Recommendation and matching those elements with the classes and attributes in our data model. Then a simple logic statement is built in the form <Object.Attribute> <operator> <value>; where <operator> is an operator selected from relevant Boolean, temporal, mathematical operators and features from either Arden Syntax or HQMF eMeasure logic constructs; and <value> is the comparator value as defined in the narrative recommendation. Finally, all of these simple logic statements are connected with Boolean operators. Currently, we propose using diagnostic codes when inclusion/exclusion criteria mentions a prior diagnosis and inserting placeholders for inferred diagnoses based on laboratory test results, or procedures, e.g., where there aren‘t diagnosis codes to suggest a patient has diabetes but available laboratory results suggest the patient has this disease.

Appendix F uses the USPSTF recommendation for Screening for Type 2 Diabetes Mellitus in Adults[38] to illustrate how to populate the data and logic specifications section of a template.

[37] Ann Intern Med November 17, 2009 151:716-26.
[38] Ann Intern Med. 2008;148:846-54.

Output Format

Significant differences across consumers of SCRCDS project deliverables suggest that eRecommendations should be adaptable to and implementable in different environments by staff with different skill sets. Although not all consumers may be able to use eRecommendations encoded in XML, this format has several important uses. It will enable eRecommendation content to be transformed into additional formats that users may need, allow for eRecommendation searching within a growing knowledge repository, give the user greater flexibility in how eRecommendation content is organized for their systems, and bring the eRecommendation one step closer to being machine- executable. For these and other reasons, the goal is for structured recommendation output to include both an Englishlike, human readable logic statement and XML-based output (from which the human readable format can be derived).

If funding becomes available to perform this activity, we propose to use an XML form tool to generate both the XML output for the eRecommendation and an Excel file of the human-readable text in the eRecommendation format. The XML schema that is aligned with the eRecommendation template would be a closely related, yet simpler, version of the eMeasures schema. The simplified schema would initially capture key eRecommendation sections, subsections, and references to encoded data elements. The schema could be extended in the future to capture more logic structure and/or specify more data model details. An XML authoring tool based on the schema would be used to manage the schema components in a systematic way and to produce the desired representations.

Clinical Recommendations To Be Structured

Selection of Second Set

This project calls for the translation of all 45 USPSTF recommendations that are graded A or B. The SCRCDS team will revisit which version of the breast cancer screening recommendation to translate for use, given that the 2002 breast cancer recommendation—not the recently updated and more controversial version—was used for vetting the draft eRecommendation template. In any case, we envision populating and presenting the eRecommendations in a manner that leaves implementers the flexibility to fine-tune such key parameters as they see fit.

The SCRCDS team is to propose a second set of guideline recommendations to be translated into logic statements.[39] Key criteria for selecting this second guideline set were previously proposed and refined during the kickoff meeting: (1) extent of "hardening" (e.g., based on strong evidence base, widely accepted, and unlikely to change dramatically); (2) opportunity to drive significantly improved care for many individuals; (3) suitability of the guideline recommendations for translating and implementing; and (4) interest by implementers in deploying corresponding rules.

With the January 13, 2010 release of the Federal Notice of Proposed Rulemaking that included MU criteria related to health IT, it became clear that the clinically relevant measures that must be reported to achieve MU would be an important focus for the "second guideline" to be translated. First, the measures represent national priorities for performance improvement. Second, financial

[39] As previously described, "recommendation" refers to single-step rules that describe one clinical action to be taken at a specific point in a patient's care or a clinical action to be triggered by an event that determines whether an action should be taken.

incentives and penalties for providers are tied to deploying CDS rules to help ensure that the corresponding care recommendations are followed. During the needs assessment phase of this project, various stakeholders confirmed that eRecommendations focusing on MU clinical measures would be valuable. Because there is such clear and strong consensus on this direction, the project team did not pursue other research originally planned to identify the "second recommendation set."

The project team will be populating the structured recommendations template with up to five eRecommendations that correspond to clinical measures that must underpin the 5 CDS rules required for MU. After translating the USPSTF recommendations, attention will turn to selecting specific single-action clinical recommendations related to the MU measures. By that time, the final MU regulation will have been issued and the universe of clinical measures that are reported to CMS will likely have been narrowed down and further refined. The SCRCDS team will identify candidates for the five additional eRecommendations based on the final regulation.

Key criteria for selecting up to five recommendations that correspond to clinically relevant MU measures include those identified above (i.e., extent of hardening, ability to significantly improve care for a population, suitability for CDS translation/implementation, implementer interest) that were considered for the broader decision about a second guideline set. Of particular importance when selecting the most appropriate MU clinical measures to translate are those of high interest to implementers as one of five CDS rules needed to meet MU requirements. If all other factors are equal in selecting a MU measure for translation, one other criterion to be applied will be whether the measure introduces variety into the mix of translated recommendations. For example, if the MU recommendations to be translated apply primarily to outpatient settings, it may be desirable to produce a structured recommendation that applies to a hospital inpatient measure. Note that the USPSTF recommendations for breast cancer screening and colorectal cancer screening are also represented among MU measures.

Processing Sequence

The proposed approach to translating the selected clinical recommendations (USPSTF Grade A and B recommendations and up to five related to MU) is to completely populate the template for each one before moving on to the next. However, experience translating each additional recommendation might uncover the need for slight adjustments to the eRecommendation template. Therefore, after 5 to 10 recommendations are translated, the SCRCDS team will determine whether there have been frequently encountered issues with the process or template that require slight modifications. In that case, adjustments will be made to the previously translated recommendations before moving on to recommendations that have not yet been translated. This complete-and-reassess process will be performed for every 5 to 10 additional recommendations that are translated, as needed, until all have been translated. We envision a final review of all eRecommendations to ensure consistency across the full set.

In general, we propose that the sequence in which clinical recommendations are translated be based on the availability of quality measures that have been retooled for the EHR environment. See Appendix G for the relationship between USPSTF A and B recommendations and priorities for NQF retooling of quality measures. USPSTF recommendations with no related quality measure could be translated first, if NQF retooled measures are not yet available when eRecommendation production begins. NQF quality measures with "high" priority will be

available before others; related recommendations would be translated as soon as these retooled measures are available. Clinical recommendations related to NQF quality measures with "medium" and "low" priority would follow. Recommendations related to MU measures will likely be translated last due to anticipated timing of the final MU regulation. We plan to remain flexible and consider sequencing modifications that would be beneficial to accommodate opportunities or needs that arise in the process, e.g., insights from recommendations already translated, actual availability of retooled measures, or other external developments.

We recommend that the USPSTF or other authoritative source be engaged concerning recommendations for which we are unable to resolve definitional issues or where we believe further review is required.

Appendix A: U.S. Preventive Services Task Force Recommendations, Grades A and B (as of 3/15/10)

Grade A Recommendations

Aspirin to Prevent CVD: Men age 45 to 79 to prevent myocardial infarctions
Aspirin to Prevent CVD: Women age 55 to 79 to prevent ischemic strokes
Asymptomatic Bacteriuria: Screening -- Pregnant Women
Cervical Cancer: Screening -- Women who are sexually active
Chlamydia: Screening -- Women Ages 24 and Younger OR Women Ages 25 and Older at ncreased Risk
Colorectal Cancer: Screening -- Adults, beginning at age 50 years and continuing until age 75 years
Congenital Hypothyroidism: Screening -- Newborns
Folic Acid: Supplementation -- All Women Planning or Capable of Pregnancy
Gonorrhea: Preventive Medication -- Newborns
HIV: Screening -- Adults and Adolescents at Increased Risk
HIV: Screening -- Pregnant Women
Hepatitis B Virus: Screening -- Pregnant Women
High Blood Pressure: Screening -- Adults 18 and Over
Lipid Disorders in Adults: Screening -- Men 35 and Older
Lipid Disorders in Adults: Screening -- Women 45 and Older, Increased risk for CHD
Phenylketonuria (PKU): Screening -- Newborns
Rh(D) Blood Typing: Screening -- Pregnant Women, First Pregnancy- Related Visit
Sickle Cell Disease: Screening -- Newborns
Syphilis: Screening - Pregnant Women
Syphilis: Screening -- Men and Women at Increased Risk
Tobacco Use: Counseling and Interventions for Adults
Tobacco Use: Counseling and Interventions for Pregnant Women

Grade B Recommendations

Abdominal Aortic Aneurysm: Screening -- Men 65-75, Smoker
Alcohol Misuse: Screening and Behavioral Counseling -- Men, Women, and Pregnant Women
BRCA Mutation Testing for Breast and Ovarian Cancer: Women, Increased Risk
Breast Cancer: Preventive Medication Discussion -- Women, Increased Risk
Breast Cancer: Screening Mammography -- Women 50 and Older
Breastfeeding: Primary Care Interventions to Promote -- All Pregnant Women and New Mothers
Chlamydia: Screening -- Pregnant Women Ages 24 and Younger OR Pregnant Women Ages 25 and Older at Increased Risk
Dental Caries: Oral Fluoride Supplementation -- Preschool Children 6 Months and Older
Depression: Screening -- Adolescents, 12-18 years of age, in Clinical Practices with Systems of Care
Depression: Screening – Adults age 18 and over – When staff-assisted depression care supports are in place
Gonorrhea: Screening -- Pregnant Women and Women at Increased Risk
Healthy Diet: Counseling -- Adults with Hyperlipidemia and Other Risk Factors for CVD
Hearing Loss in Newborns: Universal Screening -- Newborns
ron Deficiency Anemia: Iron Supplementation -- Asymptomatic Children 6-12 Months,
ron Deficiency Anemia: Screening -- Asymptomatic Pregnant Women
Lipid Disorders in Adults: Screening -- Men 20-34, Increased risk for CHD
Lipid Disorders in Adults: Screening -- Women 20-44, Increased risk for CHD
Obesity: Screening and Intensive Counseling -- Obese Men and Women
Osteoporosis: Screening -- Postmenopausal Women 65 Years and Older with No Risk Factors, or 60 Years and Older with Risk Factors
Rh (D) Blood Typing: Screening -- Antibody Testing Unsensitized Rh (D)-Negative Pregnant Women
Sexually Transmitted Infections: Behavioral Counseling -- Sexually Active Adolescents and Adults at Increased Risk
Type 2 Diabetes Mellitus: Screening Men and Women -- Sustained BP 135/80+
Visual Impairment: Screening -- Children Younger than 5 Years

Appendix B: Brief Descriptions of Relevant Initiatives

Formalisms

Arden Syntax (HL7 and ANSI Standard)

Overview: Arden Syntax is an HL7 and ANSI standard for encoding recommendations into discrete Medical Logic Modules (MLMs), which are structured ASCII files that organize and store a recommendation‘s metadata and logic statements. In the MLM, local references to clinical data are isolated in “curly braces,” that is, no data structure or standardized definitions are provided. Arden MLMs are thus agnostic to an EHR‘s underlying data storage model and terminology in that curly braces are designed to allow adaptation to any EHR‘s data.

Arden MLMs support a modest amount of syntax that can be used to implement workflow. The "Evoke" slot provides a general-purpose tool that supports several aspects of workflow implementation, while the “Destination” statements and messaging model provide some control over how alerts and suggestions are delivered. In all of these cases, the contents of the curly braces would need to be modified to reflect local capabilities. MLMs are thus designed to have a general intended workflow or mode of use in terms of triggering conditions (Evoke), mode of interaction, and how their actions are to be carried out.

Considerations: Arden Syntax is used in active clinical systems by a modest number of EHR vendors. A model expressing Arden MLMs in XML format has been developed, but is not widely used. Arden Syntax was an initial candidate for the output of the SCRCDS project given its successful use in existing systems. However, since Arden also requires specification of triggering conditions (in its Evoke slot), and makes assumptions about data availability, interactivity with a user, and notification processes, a rule in that format is already too specific for multiple possible workflows and modes of use. Additionally, the “curly braces” mean data structures and definitions are expected to be specified locally, reducing portability. The lack of independent or open-source Arden engines also limits the use of Arden rules to systems with proprietary Arden implementations, and there are other business logic rules engines available. Because it encodes single step rules (MLMs), it is not a true guideline model.

Key References:

The Arden Syntax for Medical Logic Systems, version 2.7. ANSI/HL7 standards document; 2008.

Hripcsak G. The Arden Syntax for medical logic modules; introduction. Comput Biol Med 1994;24(5):329-30.

Kim S, Haug P, Rocha R, Choi I. Modeling the Arden Syntax for medical decisions in XML. Int J Med Inform 2008 Oct; 77 (10):650-6.

GELLO (HL7 and ANSI Standard)

Overview: GELLO is an HL7 standard for encoding the logical expression and data reference components of guidelines into an object-oriented language. GELLO provides a flexible, object-oriented data structure for referencing data elements that is compatible with the HL7 v.3.0 RIM.

Considerations: GELLO's object-oriented language allows for construction of expressions for retrieving or doing logical and computational operations on clinical data. GELLO is designed to be embedded in a rules system or in other applications where expressions and data access are required. It is not a procedural language itself. The advantages of this language for clinical rules are that the model enables the mapping of data references to host systems to be done globally, through the v3 RIM, so that individual rules do not need to be customized by individual data mappings, and that rules using GELLO have the robustness of expressivity of an object-oriented data model. Despite these benefits of the GELLO data structure, it is incompatible with most clinical information systems, as most developers and vendors continue to be more comfortable with HL7 v.2.X than with v.3.0. This has inhibited the uptake of GELLO to date, and therefore reduces the attractiveness of GELLO as a format to produce widely consumable deliverables in the SCRCDS project.

Key References:

Sordo M, Boxwala AA, Ogunyemi O, Greenes RA. Description and status update on GELLO: a proposed standardized object-oriented expression language for clinical decision support. Medinfo. 2004;164-8.

Sordo M, Ogunyemi O, Boxwala AA, Greenes RA. GELLO: an object-oriented query and expression language for clinical decision support. AMIA Annu Symp Proc 2003;1012

Available at: http://www.openclinical.org/gmm_gello.html

Guideline Interchange Format (GLIF)

Overview: GLIF is a guideline model designed to be readable by both human experts and by machines, developed by the InterMed Collaboratory during the late 1990s and early 2000s. In GLIF, a flow chart is used to model the clinical actions and decisions in the guideline. GLIF2 does not include data element mappings. GLIF3 is object-oriented and the data structures are aligned with standards such as the HL7 RIM and standard terminologies.

Considerations: GLIF3 has been considered as an HL7 standard, but the HL7 CDS Work Group was unable to reconcile competing guideline models, and to date no executable guideline model has been proposed as a standard. The work is not currently funded for further development.

Key References:

Boxwala AA, Peleg M, Tu S, et al. GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines. J Biomed Inform 2004 Jun;37(3):147-61.

Greenes RA, Boxwala A, Sloan WN, et al. A framework and tools for authoring, editing, documenting, sharing, searching, navigating, and executing computer-based clinical guidelines. Proc AMIA Symp 1999;261-5.

Greenes RA, Peleg M, Boxwala A, et al. Sharable computer-based clinical practice guidelines: rationale, obstacles, approaches, and prospects. Stud Health Technol Inform 2001;84(Pt 1):201-5.

Ohno-Machado L, Gennari JH, Murphy SN, et al. The guideline interchange format: a model for representing guidelines. J Am Med Inform Assoc 1998 Jul-Aug;5(4):357-72.

Patel VL, Kaufman DR, Allen VG, et al. Toward a framework for computer-mediated collaborative design in medical informatics. Methods Inf Med 1999 Sep;38(3):158-76.

Wang D, Peleg M, Tu SW, et al. Design and implementation of the GLIF3 guideline execution engine. J Biomed Inform 2004 Oct;37(5):305-18.

Guideline Elements Model (GEM)

Overview: GEM is an ASTM and HL7 standard for marking up and organizing the various types of statements contained within a narrative clinical guideline. It is an XML-based schema designed to facilitate the translation of a guideline from narrative to machine-executable form. The GEM schema includes headers and subheaders under which aspects of the narrative relating to such factors as source, eligibility, data needs and implementation plans pertinent to guideline specification may be tagged. The GEM Cutter tool allows for the extraction of information needed to form an XML representation of the content. This is useful for guideline searching and for evaluating aspects of a guideline‘s quality and computability.

Considerations: The GEM schema has attracted significant interest by narrative guideline developers. The SCRCDS project crosswalked its draft template for structuring recommendations with GEM and found interplay at only the most general level of data element description, e.g., header elements.

Key Reference:

Available at: http://gem.med.yale.edu/

Shareable Active Guideline Environment (SAGE)

Overview: SAGE is a formalism for encoding clinical guidelines to enable integration into existing EHR systems through service-oriented architecture (SOA)-based interfaces. It was intended to (a) utilize information model and terminology standards, (b) incorporate simple flow-of-control models, (c) include workflow awareness, and (d) support exchange of data and action recommendations with host EHR systems.

Considerations: The SAGE project used an early version of the virtual Medical Record (vMR) an information model view of the HL7 RIM tailored for CDS purposes, and points out the value of a vMR.

SAGE is designed for encoding multistep guidelines, while the SRCDS project is largely focused on encoding one-step reminders. After demonstrating integration with one vendor system, the project is currently dormant.

Key Reference:

Tu SW, Campbell JR, Glasgow J, et al. The SAGE guideline model: achievements and overview. J Am Med Inform Assoc 2007 September-October;14(5):589-98. Available at: http://sage.wherever.org/

Health Quality Measures Format (HQMF)

Overview: HQMF is 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. An

eMeasure is the result of populating the HQMF template with information pertinent to a specific measure. The HQMF approach to the data mapping issue was the development of the Quality Data Set (QDS) which maps to the HL7 CDA.

Considerations: Because HQMF was designed for the retrospective collection of data, its measures for prevention and screening compliance contain no specifications for workflow integration or for prospectively delimiting eligibility based on prior diagnosis or prior instance of procedure to be recommended during a screening interval. However, considerable groundwork had already been laid in the vendor community for standardization efforts that are closely related to what will be required for widespread uptake of structured logic statements to underpin CDS rules. In addition, because CMS has recently proposed requiring that Medicare and Medicaid clinical quality measures eligible for incentive payments be submitted through EHR technology by 2012, HQMF is likely to be quickly and widely adopted by providers and information systems vendors engaged in performance measurement and participating in the meaningful use of health information technology.

Key Reference:

Availabe at: http://www.hl7.org/v3ballot/html/domains/uvqm/UVQM.htm

Collaboratives and Other Initiatives

Clinical Decision Support Consortium (CDSC)

Overview: The CDSC is a collaborative of academic institutions, health care organizations, and health care IT vendors led by Brigham and Women‘s Hospital and funded by AHRQ. The goal of the CDSC is to assess, define, demonstrate, and evaluate best practices for knowledge management for clinical decision support in health care information technology at scale—across multiple ambulatory care settings and EHR technology platforms. In practice, this consortium is conducting knowledge management life-cycle assessments, and developing a multilevel knowledge representation format, CDS Web services, and knowledge management tools. The scope of activities includes demonstration projects that integrate the Web services into commercially available and institutionally developed ambulatory EMRs.

Implications: This project uses a multilevel knowledge representation format that progressively transforms recommendations from free-text to executable knowledge. This methodology addresses the need to disseminate knowledge for execution in heterogeneous CDS environments. Guidelines are represented as collections of recommendations that support decisions at a point-in-time. This approach allowed CDSC to rapidly integrate knowledge into the CDSC Web service using a commercial rules engine. At Partners Healthcare, the Web service in turn has been integrated with the LMR, the EMR system to deliver reminders.

Key Reference:

Available at: http://www.partners.org/cird/cdsc/default.asp.

Guidelines into Decision Support (GLIDES)

Overview: The objective of the AHRQ-funded GLIDES project is the development, implementation and evaluation of demonstration sub-projects that advance understanding of how best to incorporate CDS into the delivery of health care. The project explores how the translation of clinical knowledge into CDS can be routinized in practice, and taken to scale, to improve the quality of health care delivery in the United States. The GLIDES project team is developing, conducting and evaluating the implementation of clinical guidelines for Asthma and Pediatric Obesity in a total of six clinical sites. The Guideline Elements Model (GEM) and the GEM Cutter II tool have been used to transform the knowledge contained in the guidelines into a computable format.

Implications: It remains unclear whether a representation model for executable guidelines or recommendations will emerge from this project.

Key References:

Available at: http://gem.med.yale.edu/glides/

Institute for Medical Knowledge Implementation (IMKI)

Overview: IMKI was a nonprofit collaborative of health IT systems vendors, publishers, and professional societies (as publishers of guidelines) set up with seed funding from Eclipsys Corporation and a grant from the Robert Wood Johnson Foundation. The organization‘s objective was to develop and maintain a library of executable medical knowledge for use in clinical information systems—with an initial focus on chronic disease management in the ambulatory setting. IMKI created knowledge in a format consistent with Arden Syntax. The institute closed operations in 2003 (before its products were incorporated in any EMR system) when funding became problematic due to lack of a compelling business model for competitors to support this enterprise.

Implications: Collaboration among all stakeholders is key to successful development of shared knowledge. Since vendors are not being asked to contribute financially to develop or maintain the output from the SCRCDS project, obstacles similar to those that IMKI experienced should not be an issue for this project. To the contrary, the strong participation by EHRA in early project stages bodes well for ongoing vendor engagement. Nonetheless, the unwillingness of individual organizations and vendors to contribute knowledge content that they had developed to IMKI raises caution that this might impede the sharing of successful experiences.

Key Reference:

Crum R. Tool to create clinical decision support rules gains some acceptance. (Prepared by the Institute for Medical Knowledge Implementation, Ltd.). Princeton, NJ: Robert Wood Johnson Foundation; October 2003. Available at: http://www.rwjf.org/reports/grr/044737.htm.

InterMed Collaboratory

Overview: The InterMed Collaboratory was an NLM/AHRQ/TATRC cofunded project aimed at developing shared tools and resources for academic collaboration in health informatics. The later

years of the project were devoted to guideline modeling and resulted in the development of the Guideline Interchange Format (GLIF) model for clinical practice guideline representation.

Implications: The InterMed experience involved multisite collaboration on the development of a model, and taught many lessons about project management in such settings, one of which was the need for frequent teleconferences as well as periodic face-to-face meetings, and another of which was to be sure that the participants had a shared vision of the purpose, goals, and milestones. The GLIF project has also informed several of the participants of the SCRCDS project about the complexities of guideline representation.

Key References: See GLIF references

Knowledge Management Repository (KMR)

Overview: The KMR project is aimed at demonstrating that CDS material can be retrieved from a central, shared repository and executed within military and civilian health information systems. It seeks to create an open source infrastructure, based on the FHA NHIN-Connect open source release, for sharing domain knowledge and executing CDS. The uniqueness of this approach is that it will not only result in an open standards platform with standardized APIs and services, but it will also contribute to the growth of a collaborative academic community. To support ongoing, iterative improvement in functional and technical capabilities, the system is being designed to collect performance and usability metrics.

Implications: The KMR project represents one or more of the end users of the results of the SCRCDS project—its test bed delivery environments include AHLTA and the IHS clinical systems. KMR has adopted a formalized approach to knowledge management with which the SCRCDS project might interface.

Key Reference:

Available at: www.socraticgrid.org.

Morningside Initiative

Overview: The Morningside Initiative is an ongoing collaboration, begun in 2007, of participants of the Department of Defense, the Veterans Health Administration, Partners Healthcare, Kaiser Permanente, Intermountain Healthcare, Henry Ford Health System, Arizona State University, and the American Medical Informatics Association aimed at developing an approach to sharing best available knowledge for clinical decision support, in as close to executable form as possible. The aim is to adopt and drive standards, to make the knowledge broadly available, and to use open source tools for knowledge acquisition, representation, management, and localization wherever possible. Initial focus is on exploring ways to share and reuse already implemented CDS knowledge from one organization in others, and has been primarily examining diabetes-related CDS to date. Another focus has been on the development of bylaws and governance processes suitable for public–private collaboration such as the Morningside Initiative.

Implications: The Morningside Initiative is tackling the content and knowledge management issues related to sharing knowledge with the aim of facilitating reuse.

Key Reference:

Greenes RA, et al. The Morningside Initiative: collaborative development of a knowledge repository to accelerate adoption of clinical decision support. Open Med Inform J, in revision, 2010.

The Virtual Medical Record (vMR)

Overview: The Virtual Medical Record (vMR) project sets out to create a standard that facilitates unambiguous communication between decision support systems and electronic health records. It aims to do so by defining standard models of record classes, with standardized names and attributes. In addition, it aims to detail a standardized set of messages and/or functions, a process by which to mediate terminology integration, and performance and/or quality of service (QoS) guarantees.

Implications: The vMR could be used for defining elements of the medical record—the data elements of decision support rules—in a standardized way. Given that the vMR is a view of the HL7 V.3 RIM, as long as EHR systems are able to provide a mapping of their data to the RIM, reference to data in terms of vMR names and attributes will be able to access them from the EHRs However, the vMR is still in formative stages in the HL7 standards group and early implementations have focused only on specific concept domains.

Key References:

Johnson PD, Tu SW, Musen MA, Purves I. A virtual medical record for guideline-based decision support. Proc AMIA Symp 2001; 294–8.

Virtual medical record for clinical decision support. recent ballots and materials. Available at: HL7.org.

Digital Electronic Guideline Library (DeGeL)

Overview: DeGeL is a project being conducted at Ben Gurion University in Israel by Yuval Shahar and colleagues. This group has created what they refer to as a hybrid, multiple-format representation of clinical guidelines that facilitates conversion of guidelines from free text to a formal representation. Guidelines are represented in four increasingly structured and formal models: Free text (one or more original sources); semistructured text (labeled by the target guideline-ontology semantic labels); semiformal text (which includes some control specification); and a formal, machine-executable representation. There are a set of tools developed around this representation to create, disseminate, and execute the knowledge.

Implications: The representation structure has similarities to the approach being proposed for this project. The key differences are that the ontologies used within DeGeL represent guidelines as a time-oriented graph or protocols. The approach in the SCRCDS project is to focus on single-step recommendations or decisions to be made at a point in time.

Key References:

Hatsek A, Young O, Shalom E, Shahar Y. DeGeL: A clinical-guidelines library and automated guideline-support tools. Stud Health Technol Inform 2008;139:203-12.

Shahar Y, Young O, Shalom E, et al. A framework for a distributed, hybrid, multiple-ontology clinical-guideline library, and automated guideline-support tools. J Biomed Inform 2004 Oct;37(5):325-44.

Appendix C: Highlights of Stakeholder Comments on eRecommendation Template, 1/6/2010 Version

Header Section

Great care must be taken in ensuring that the text in the eRecommendation follows the narrative recommendation precisely, unless there is an explanation for changing it.

Providing a URL link to the narrative recommendation and/or underlying evidence in header information would be very helpful.

More careful thought is needed in populating the "setting" and "class" fields which inform implementers about circumstances when the recommendation should be applied.

Separate fields are needed for template version and date as well as recommendation version and date. Also, minor adjustments in how ages ("as of" a date) and time intervals (days) were recommended. The reference times for intervals upon which alerts are based need to be expressed better.

Data Elements/Logic Section

Data elements (e.g., age, gender, evidence of condition/risk) needed for eligibility inclusion and exclusion criteria in logic may not be comprehensive enough for all USPSTF recommendations. More than one commenter raised concern about the thoroughness or specificity of exclusion criteria. Screening history or other current/historical reasons why a CDS rule that implements a recommendation should not be fired is essential to effective longitudinal primary care practice.

Exclusion and inclusion criteria with ICD-9 codes now and SNOMED/ICD-10 codes in the future would be very helpful. These code sets and value lists also need to be flexible to handle missing data without resulting in a "hard stop" when there are not definitive answers to questions, e.g., family history of disease for person adopted. Exclusion criteria need to accommodate many possibilities, including the absence of coded data.

It is important to consider information other than diagnosis (e.g., surgical history, biopsies, other treatments) in identifying patients who should be excluded because of a medical condition. Also, information from breast biopsies for identified abnormalities would be relevant to future mammographic screening.

Similarly, there may be multiple risk factors other than chest radiation that should be taken into account for screening mammogram beginning at age under 50. Consider the Gail model?

Implementation Considerations Section

As many of the implementation considerations as possible should be structured and coded because the ideal format should include all of the best information available. Implementers can still decide which parts they can actually use. Implementation considerations that are vital to all

local sites should be included in the core logic statements. Similarly, some critical information resides in footnotes and may be overlooked unless relocated to the body of the template.

Should consider whether to present "generic" implementation considerations that do not vary much from recommendation to recommendation in a different location from those "specific" to the recommendation.

It would be very valuable to have a taxonomy/ontology behind the implementation considerations section, particularly if it came from practitioners.

General/Other Comments

Template should be compared and contrasted to rule templates for a few leading primary care EHRs to assess whether presentation is too cumbersome or not.

An XML form of the recommendation is needed to make the template more helpful than the narrative guideline. It will also keep the logic statement, with complete inclusion and exclusion criteria, from becoming very complex.

A section of the template should address measures for monitoring and reporting on rule firing. Similarly, at the individual patient level, it is helpful in measuring outcomes of recommendation implementation to be able to capture the outcome of rule firing, including both provider and patient adherence.

An element that lists related recommendations and describes the relationship could be useful. A library of rules from all major guideline makers would provide benefit.

Appendix D: Breast Cancer Screening–Example of eRecommendation Using 3/19/2010 Version of Template

1. Header Information

eRecommendation Name	USPSTF SCREENING FOR BREAST CANCER (B Recommendation on mammography only)	**Recommendation Set**	USPSTF A and B Recommendations
eRecommendation ID	USPSTF-MAMMO-B-REC	**Set ID**	USPSTF-A-B-RECS
eRecommendation Version Date/Number		**Recommendation Version Date/Number**	2 (revision of 2002 guidelines)
Template Version Date/Number			
Related eMeasure(s)	PQRI112:Preventive Care and Screening: Screening Mammography [PQRI age range 40–69]		
Author			
Verified by			
Maintained by	Agency for Healthcare Research and Quality (AHRQ) and U.S. Preventive Services Task Force (USPSTF)		
Description/Purpose	U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for breast cancer in the general population.		
Recommendation Text from Source	**Summary Statement**	The USPSTF recommends biennial screening mammography for women between the ages of 50 and 74 years.	
	Additional 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.	
Setting (if specified by Source)	Not specified. See implementation considerations.		
Recommendation classification	Screening: primary prevention		
Rationale	**Importance** Breast cancer is the second-leading cause of cancer death among women in the United States. Widespread use of screening, along with treatment advances in recent years, has been credited with significant reductions in breast cancer mortality. **Detection** Mammography, as well as physical examination of the breasts (CBE and BSE), can detect presymptomatic breast cancer. Because of its demonstrated effectiveness in randomized, controlled trials of screening, film mammography is the standard for detecting breast cancer; in 2002, the USPSTF found convincing evidence of its adequate sensitivity and specificity. **Benefits of Detection and Early Intervention:** There is convincing evidence that screening with film mammography reduces breast cancer mortality, with a greater absolute reduction for women aged 50 to 74 years than for women aged 40 to 49 years. The strongest evidence for the greatest benefit is among women aged 60 to 69 years.		
Reference	Clinical Guidelines: Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. U.S. Preventive Services Task Force		

	Ann Intern Med November 17, 2009 151:716-726
Reference URL	http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm

2. Data and Logic Specification

These data definitions and logic statement elements are a generalized first approximation to consider in implementing a CDS rule for the purpose outlined above based on this eRecommendation statement. They are based where pertinent on a corresponding performance measure specification to assist in using the rule to support local performance excellence on the measure. In some cases, the data elements may not be readily accessible electronically for automated rule processing and will have to be adapted to local needs, workflows and data availability (i.e., in the absence of pre-existing data, a site may choose to accept lower notification specificity, query the user for needed data, or reconfigure the information system to gather needed data).

2.a Data definitions		
Category	**Data Elements**	**Relevant Notes**
Eligibility/Inclusion-related data	**Demographic** • Target gender: F • Target age low limit: 50 • Target age high limit: 74 **Condition** • [*not relevant to mammography example*] **Risk** • [*not relevant to mammography example*]	For PQRI 112 to which this logic statement is related, age high limit = 69
Intervention interval	Screening interval: 2 years *[See Section 3. Implementation Considerations below for details on operational exclusion criteria and related logic where screening interval is used]*	
Exclusion criteria-related data	**High risk patients** <Value set: History of chest radiation > • Quality data type: Procedure Result • Code set: (CPT 4, ICD9, SNOMED) • Code list: {list of relevant codes relating to Hx of chest radiation}. <Value set: Known genetic mutation, BRCA1, BRCA2, [possibly others]> • Quality data type: Laboratory test result • Code set: (LOINC, SNOMED) • Code list: {list of relevant codes for genetic tests} <Value set: mammogram results documented within 2 years >	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:

	• Quality data type: Diagnostic study result • Code set: (CPT,LOINC, SNOMED) • Code list: {list of relevant codes} **Other exclusion-related data** • [*not relevant to mammography example*]	• 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 (e.g., having had BRCA1/2 testing), **exclude** this patient. • Otherwise, **do not exclude** this high risk patient.
Operational exclusion criteria-related data	[*Will depend on implementation considerations/choices: See Section 3, Implementation Considerations for examples*]	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, then implementers may wish to suppress the intervention recommendation to minimize false positive notifications. See **Implementation Consideration** section for further details and examples.
Action related data	<Value set: Bilateral mammogram> • Quality data type: Diagnostic Study Order • Code set: (CPT,LOINC, SNOMED) • Code list: {list of relevant codes for screening mammography tests}	

2.b Logic Statement	**If** <Eligibility/inclusion criteria> **AND NOT** (<Exclusion criteria> OR <Operational exclusion criteria>) **THEN** <Action>	
Category	**Logic Elements**	**Relevant Note**
<Eligibility/inclusion criteria>	Patient gender = Target gender AND: <Patient age >= Target age low limit> AND <Patient age <= Target age high limit> *AND:* *<Evidence of condition/risk = non-null]>*	<Evidence of condition/risk> statement is a template placeholder for other rule types: not pertinent to this breast cancer screening sample
<Exclusion criteria>	**<Patients for whom a different intervention protocol may be warranted>** • <Value set: History of chest radiation > = non-null • OR: <Value set: Known genetic mutation > = non-null **<Patients that have already received intervention within recommended interval>** <Value set: mammogram results documented within 2	See section 3, subsection on Optimizing Rule Specificity for further details on operational exclusion criteria, e.g., related to pertinent pending interventions

	years > = non-null	
<Operational exclusion criteria>	[*Will depend on implementation considerations/choices: See Section 3, Implementation Considerations for examples*]	

<Action>	**<Recommended action: perform Intervention: procedure/test/medication/counseling/etc.>**
	• <Bilateral mammogram>
	  ○ Quality data type: Diagnostic Study Order>
	  ○ <Code set: (CPT,LOINC, SNOMED)
	  ○ Code list: {list of relevant codes for screening mammography tests}	

3. Implementation Considerations

Successfully implementing the logic statement above as a useful CDS rule also will require careful attention to additional rule development and deployment details. These are typically specific to local circumstances and relate to clinical policies, information system capabilities, availability of electronic/coded data, workflow considerations and the like. To stimulate implementers' thinking about how to further adapt the eRecommendation logic statement for their CDS environments, several types of implementation considerations are listed below. It is expected that users will identify others. Therefore, this list is not intended to be exhaustive; rather, it should serve as a starting point in the process. For additional information about implementation issues that should be considered for all eRecommendations, please refer to the Users' Guide.

OPTIMIZING RULE SPECIFICITY:

Operational data

- Notification fired
  - Provider, date
- Acknowledgment
  - Provider, date, type (to be done, refused by provider, refused by patient, already done, etc.)
- Screening interval
  - 2 years
- Alerting interval
  - 2 months

Operational exclusion criteria data

- Tests for diagnosis or problem in process or done within specified screening interval

  Mammogram completed within past 2 years: Record of the patient having received a mammogram in the previous 2 years (by history or by stored data)

  - By history
    - Mammogram externally as per patient history or need for such request to be asked in CDS
  - By data
    - Completed mammography encounter: Notation of previous encounter in a mammography setting, billing for mammography procedure/interpretation
    - Mammogram completed: Mammogram noted in patient record

- Mammogram already ordered or scheduled but not yet completed
- MRI, ultrasound or other procedure of breast done or ordered (e.g., women with dense breasts by mammogram may be followed subsequently by these means instead of mammogram)
- <Value Set: evidence of the screening procedure or related procedures having been done>: <Bilateral mammogram>
  - Quality data type: Diagnostic Study Result
  - Code set: (CPT, LOINC, SNOMED)
  - Code list: {list of relevant codes for screening mammography tests} >

- Pre-existing condition diagnosis or problem

  - Patient has condition being screened (thus being managed, not in primary prevention mode)
    - Problem list or diagnosis of breast cancer or premalignant lesion, e.g., in one breast
      - <Value set: Diagnosis of breast cancer> e.g., ...
      - Quality data type: Diagnosis Performed
      - Code set: SNOMED CT
      - Code list: {List of relevant codes for personal history of malignant neoplasm, breast}>
  - Indirect evidence of diagnosis or problem already made
    - Recurrent tests or procedures implying diagnosis
      - <Value set: Pathology diagnoses, cytology, etc.
      - Quality data type: Diagnostic Procedure result, laboratory test result
      - Code set: CPT, ICD9, SNOMED CT
      - Code list: {List of codes indicating diagnostic procedures, laboratory test results relevant to breast cancer}>
    - Treatments implying diagnosis or problem
      - <Value set: Radiation, chemotherapy, surgery etc, e.g.,
      - Quality data type: Procedure performed
      - Code set: { List of relevant codes indicating chest radiation, chemotherapy, surgery, or any procedure relating to the breast} >
    - Related or derivative diagnoses or problems
      - <Value set: Post radiation or chemo illnesses without other primary disease explanation – need to alert
      - Quality data type: Diagnosis Performed
      - Code set: : SNOMED CT
      - Code list: { List of codes indicating any post radiation or chemo illnesses without other primary disease explanation} >

- Rule having fired within specified alerting interval
  - Intervention recommended has been acknowledged, action pending
    - Notification indication of rule having been triggered within past XX interval (e.g., past 2 months)

- Reason noted for not following rule recorded within specified alerting interval
  - Patient or clinician declined recommendation
    - Acknowledgment having been made of reason for refusal or deferral within past XX interval (e.g., past 2 months)
    - Was declining of recommendation on temporary or permanent basis?

<u>Operational exclusion criteria logic</u>

- AND NOT: Tests for diagnosis or problem in process
AND NOT: Pre-existing condition diagnosis or problem
- ELSE AND NOT: Rule having fired within specified alerting interval
OR NOT: Reason noted for not following rule recorded within specified alerting interval

DETERMINING RULE TRIGGERING:

- Is operation interactive/real time?
- Batch mode, e.g., through clinic/practice administration?
- Can information be obtained from patient at time of rule firing?
- Where you might get the data from (e.g., ask the patient if the data is not available in the EMR)
- Is rule fired by visit, by elapsed time interval, as result of a search finding eligible patients, or by query initiated by provider or patient? Potential Rule Forms to consider:
  - Alert on data trigger
  - Reminder on time trigger
  - Interactive recommendation on user request
  - Search evaluation list

- Scenarios might include:
  - Encounter with potentially eligible patient
  - Reminder of due date for test for patient already having been identified (e.g., in a registry or based on previous test)
  - Search for eligible patients (e.g., those to be seen, or periodically for those in a panel or database)
  - Inquiry by provider
  - Inquiry by patient

DEFINING NOTIFICATION APPROACH:

- User notification: Is it desirable to set an indicator that a notification has been delivered, e.g., to avoid redundant firing?
- Notification Acknowledgment: Is it desirable to document notification response, e.g., for rejection of recommended action?

OBTAINING KEY DATA:

- What minimum data are needed to fire a useful rule for this recommendation in your organization?
- Are these minimum data available in your system?

ACCOMMODATING LOCAL CLINICAL POLICIES:

- Target age high limit
- Target age low limit
- Screening interval

ADDITIONAL WORKFLOW/OTHER CONSIDERATIONS: [placeholder for other issues TBD]

- …

Appendix E: Detailed Description of Proposed Data Model for eRecommendations

HITEP II Quality Data Element (Class)	HITEP II Definition	HITSP Data Element (Attribute)	Definition	Comments/ Additional Information
Patient characteristics	Specific information about the patient, including demographics	Gender	HL7 CDA AdministrativeGenderCode is used to refer to administrative sex rather than biological sex so it should be easily classified into female and male	
		Person Date of Birth	Date and time of birth of the patient	
		Race	Race as defined by the CDC and the Census Bureau.	
		Ethnicity	Extends the concept of race. It should be aligned with Federal reporting standards of the CDC and the Census Bureau	
Diagnosis	A problem, diagnosis, or condition that is currently monitored, tracked, or is a factor that must be considered as part of the treatment plan in progress	Problem Date	Date when the condition was diagnosed	NOTE: Does not include Family History
		Problem Code	SNOMED CT code indicating the diagnosed problem	
		Age (at Onset)		
		Problem Status	The status of the problem (active, inactive, resolved)	
Diagnostic study - Offered (see Tense) - Order (see Tense) - Performed (see Tense)	Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others	Procedure Type	This is a coded value describing the type of Procedure	NOTE: Diagnostic study performed is available in the resulted test as well as in the list of procedures performed
	Offered: An offer or suggestion to a patient for a diagnostic study. **Order:** A request by a physician or appropriately licensed care provider to an appropriate provider or facility to perform a diagnostic on a patient. The request may be in the form of a consultation or a direct order to the facility or organization that performs	Tense	**Offered:** HL7 ActMood = INT Where INT(intent) = 10199 **Order**: HL7 ActMood = RQO Where INT(intent)= RQO (request) 19973 **Performed:** NULL	Tense is a modifier to a data element used to express time as it relates to a data element. For example, an event has occurred in the past or will occur in the future

	the diagnostic study. **Performed:** A diagnostic study has been completed.			
		Procedure Date/Time	The date and time of the procedure, including duration if pertinent	
		Body Site	The anatomical site where a procedure is performed using SNOMED CT	
		Result ID	Result unique identifier	NOTE: Resulted procedure is part of the results entry NOTE: Result elements apply only to diagnostic order and diagnostic performed
		Result Date/Time	The biologically relevant date/time for the observation	
		Result Type	Coded representation of the observation performed. Result Type SHOULD be selected from LOINC or SNOMED CT.	
		Result Status	Status for this observation, e.g., complete, preliminary	
		Result Value	The value of the result, including units of measure if applicable	
		Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc. from Health Level Seven (HL7) Version 3.0 Vocabulary	
		Result Reference Range	Reference range(s) for the observation	
Diagnostic study **result**	The result, described in concepts or numerical values of a diagnostic on a patient. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others	Result ID	Result unique identifier	NOTE: Diagnostic study performed is available in the resulted test as well as in the list of procedures performed
		Result Date/Time	The biologically relevant date/time for the observation	
		Result Type	Coded representation of the observation performed. Result Type SHOULD be selected from LOINC or SNOMED CT.	
		Result Status	Status for this observation, e.g., complete, preliminary	
		Result Value	The value of the result, including units of measure if	

			applicable	
		Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc. from Health Level Seven (HL7) Version 3.0 Vocabulary	
		Result Reference Range	Reference range(s) for the observation	
Laboratory test - offered (see Tense) - order (see Tense) - Performed (see Tense)	A study in the clinical laboratory (traditionally chemistry, hematology, microbiology, serology, urinalysis, blood bank) has been ordered. Depending on the point in the clinical workflow desired by the measure, various options are provided - **offered**, **declined**, **ordered**, **performed,** and **resulted**	Procedure Type	This is a coded value describing the type of the Procedure	
		Tense	**Offered:** HL7 ActMood = INT Where INT(intent) = 10199 **Order**: HL7 ActMood = RQO Where INT(intent)= RQO (request) 19973 **Performed:** NULL	
		Procedure Date/Time	The date and time of the procedure, including duration if pertinent	
		Body Site	The anatomical site where a procedure is performed using SNOMED CT	
		Result ID	Result unique identifier	NOTE: Result elements apply only to laboratory test order and laboratory test performed
		Result Date/Time	The biologically relevant date/time for the observation	
		Result Type	The value set is defined as being the set of LOINC values which represent laboratory results. These are defined as LOINC codes with CLASSTYPE=1 and (ORDER_OBS=Both or ORDER_OBS=Observation)	
		Result Status	Status for this observation, e.g., complete, preliminary	
		Result Value	The value of the result, including units of measure if applicable	
		Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc. from Health Level Seven (HL7) Version 3.0 Vocabulary	
		Result Reference Range	Reference range(s) for the observation	
Laboratory test **result**	The result of a study in the clinical	Result ID	Result unique identifier	

	laboratory (traditionally chemistry, hematology, microbiology, serology, urinalysis, blood bank). Depending on the point in the clinical workflow desired by the measure, various options are provided - offered, declined, ordered, performed, and resulted			
		Result Date/Time	The biologically relevant date/time for the observation	
		Result Type	The value set is defined as being the set of LOINC values which represent laboratory results. These are defined as LOINC codes with CLASSTYPE=1 and (ORDER_OBS=Both or ORDER_OBS=Observation)	
		Result Status	Status for this observation, e.g., complete, preliminary	
		Result Value	The value of the result, including units of measure if applicable	
		Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc. from Health Level Seven (HL7) Version 3.0 Vocabulary	
		Result Reference Range	Reference range(s) for the observation	
Procedure - **Offered (see Tense)** - **Order (see Tense)** - **Performed (see Tense)**	Procedures also include patient care processes provided directly to a patient by a care provider to assist or direct a patient with activity or to apply single use or durable medical equipment. Examples include assisted ambulation, behavioral interventions (e.g., counseling provided), dressing changes, placement of antithrombotic devices, insertion or removal of intravascular access.	Procedure Type	This is a coded value describing the type of the Procedure CPT, ICD9, SNOMED CT	NOTE: Medications are included because they may be bound to the procedure or surgical event (e.g., Anesthesia – section in operative note of a surgical procedure, or a procedure note of procedures that do not enter the body cavity such as colonoscopy)
	Offered: A procedure is suggested or recommended to a patient **Order**: A request by a physician or appropriately licensed care provider to an appropriate provider or facility to perform a procedure **Performed:** A procedure has been completed.	Procedure Date/Time	The date and time of the procedure, including duration if pertinent	
		Body Site	The anatomical site where a procedure is performed	

			using SNOMED CT	
		Tense	**Offered:** HL7 ActMood = INT Where INT(intent) = 10199 **Order**: HL7 ActMood = RQO Where INT(intent)= RQO (request) 19973 **Performed:** NULL	
		MEDICATION ENTRY	See Medication, active for complete list of relevant HITSP Data Elements for medications	
Procedure Result	Procedure results are the findings identified as a result of the procedure. The result of a surgical procedure documents the actual procedure performed and the findings of the procedure. The procedure result is distinct from the pathology report which is a laboratory result.	Result ID	Result unique identifier	
		Result Date/Time	The biologically relevant date/time for the observation	
		Result Type	The value set is defined as being the set of LOINC values which represent laboratory results	
		Result Status	Status for this observation, e.g., complete, preliminary	
		Result Value	The value of the result, including units of measure if applicable	
		Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc. from Health Level Seven (HL7) Version 3.0 Vocabulary	
		Result Reference Range	Reference range(s) for the observation	
		Procedure Type	This is a coded value describing the type of the Procedure CPT, ICD9, SNOMED CT	
		Procedure Date/Time	The date and time of the Procedure, including duration if pertinent	
		Body Site	The anatomical site where a procedure is performed using SNOMED CT	
		MEDICATION ENTRY	See Medication, active for complete list of relevant HITSP Data Elements for medications	
Medication - Active - Administered - Dispensed - History - Offered (see Tense)	**Active:** Medications currently taken by a patient **Administered:** A record by the care provider that a medication actually was administered and whether or not	Indicate Medication Stopped	Used to express a "hard stop," such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.	NOTE: Does not include Mediation Allergy, Medication Intolerance, Medication Adverse Reaction.

- Order (see Tense)	this fact conforms to the order. Appropriate time stamps for all medication administration are generated **Dispensed:** A medication prescription is filled by a pharmacy; the medication has been provided to the patient or patient proxy. In the ambulatory setting, medications are primarily taken directly by patients and not directly observed. Hence, dispensed is the closest health provider documentation of medication compliance. In settings where patients attest, in electronic format, to taking medications (perhaps a Personal Health Record) patient attestation of 'medication taken' may be available **History:** Medications taken by a patient in the past **Offered:** A specific medication has been offered to the patient or patient proxy **Order:** A request by a physician or appropriately licensed care provider to a pharmacy to provide medication to a patient. The request is in the form of prescriptions or other medication orders with detail adequate for correct filling and administration			
		Tense	**Offered:** HL7 ActMood = INT Where INT(intent) = 10199 **Order**: HL7 ActMood = RQO Where INT(intent)= RQO (request) 19973	
		Administration Timing	Defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time	
		Frequency	Defines how often the medication is to be administered as events per unit of time. Often	

			expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)	
		Interval	Defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)	
		Duration	For non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes	
		Route	Indicates how the medication is received by the patient (e.g., by mouth, intravenously, topically, etc.)	
		Dose	Indicates the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)	
		Site	The anatomic site where the medication is administered. Usually applicable to injected or topical products	
		Delivery Method	A description of how the product is administered/consumed	
		Coded Product Name	A code describing the product from a controlled vocabulary: National Library of Medicine – RxNorm, NDF-RT	NOTE: Prefer RxNorm, NDF-RT
		Product Concentration	The amount of active ingredient, or substance of interest, in a specified product dosage unit, mass or volume. For example 250 mg per 5 ml.	
		Type of Medication	A classification based on how the medication is marketed (e.g., prescription, over the counter drug)	
		Status of Medication	If the medication is Active, Discharged, Chronic, Acute, etc.	
		Order Number	The order identifier from the perspective of the ordering clinician. Also known as the 'placer number' versus the pharmacy's prescription number (or 'filler number')	
		Fills	The number of times that the ordering provider has authorized the pharmacy to dispense this medication	
		Quantity Ordered	The amount of product indicated by the ordering	

			provider to be dispensed. For example, number of dosage units or volume of a liquid substance. Note: this is comprised of both a numeric value and a unit of measure	
		Order Expiration Date/Time	The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance	
		Order Date/Time	The date, including time if available, when the ordering provider wrote the order/prescription	
	IMMUNIZATION ENTRY	Refusal	A flag that the immunization event did not occur. The nature of the refusal (e.g., patient or patient caregiver refused, adverse reaction)	
		Administered Date	The date and time of substance was administered or refused, i.e., when the immunization was administered to the patient, or refused by the patient or patient caregiver	
		Medication Series Number	Indicate which in a series of administrations a particular administration represents (e.g., "hepatitis B vaccine number 2")	
		Coded Product Name	A code describing the product from the CDC Codes for Vaccine Administered (CVX code) vocabulary	
		Reaction		
Physical exam finding	A physical examination is the evaluation of the patient's body to determine its state of health. The techniques of inspection include palpation (feeling with the hands and/or fingers), percussion (tapping with the fingers), auscultation (listening), and smell. Measurements may include vital signs (blood pressure, pulse, respirations) as well as other clinical measures (such as expiratory flow rate, size of lesion, etc.)	Vital Sign Result ID	An identifier for this specific vital sign observation	
		Vital Sign Result Date/Time	The biologically relevant date/time for the vital sign observation	
		Vital Sign Result Type	A coded representation of the vital sign observation performed based on LOINC or SNOMED	Interim Recommendation: Clinical procedure use LOINC; whereas for the "result" of procedures use SNOMED
		Vital Sign Result Status	Status for this vital sign observation, e.g., complete, preliminary	
		Vital Sign Result Value	The value of the result, including units of measure if	

			applicable	
		Vital Sign Result Interpretation	An abbreviated interpretation of the vital sign observation, e.g., normal, abnormal, high, etc.	
		Vital Sign Result Reference	Reference range(s) for the vital sign observation	

Appendix F: Method for Populating Data and Logic Specifications Section in Template—an Example[40]

METHOD FOR POPULATING SECTION

From recommendation section in USPSTF statement, identify key classes and attributes:

EXAMPLE:
Screen for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg (B recommendation)

Breakdown identified classes and attributes, and key elements:

- Adults: age >= *min_age_value*
- Sustained: at least 3 measurements over past 6 months[41]
- Blood pressure > 135/80 mm Hg

Map identified classes and attributes to data model
Build simple logic statements of the form <*Object.Attribute*> <*operator*> <*value*>
Identify relevant NQF code sets or provide an accurate English-like description of the health care service

EXAMPLE:

- Adults: (current date - Patient Characteristic.Person Date of Birth) > = *min_age_value*
- Blood pressure: Physical Exam Finding.Vital Sign Result type = {NQF 0061 – PQRI 3 – Diabetes: Blood Pressure Management code set}
- Identify relevant NQF code sets or provide an accurate English-like description of the health care service
- Blood pressure greater than 135/80 mm Hg: Physical Exam Finding. Vital Sign Result value > 135/80 mm Hg

Construct logic as Boolean combination of conditions:

[1] Age is calculated as the difference between today's date and the date of birth of the patient. *Current date* is an Arden operator that returns today's date.
[2] This condition gets all the vital sign exams form blood pressure by selecting those with a result type with a code equal to those codes listed in the NQF Blood Pressure Management code set}
[3] For those conditions selected by [2], get those with a result value greater than 135/80 mm Hg
[4] These blood pressure values have been 'sustained' (there are at least 3 measurements with value >= 135/80 within the past 6 months)
[5] *count* and *within past* are Arden Syntax operators

Adults is defined by [1]
Sustained blood pressure > 135/80 mm Hg is defined by [2-4]

EXAMPLE:
IF
(*current date* - Patient Characteristic.Person Date of Birth) > = *min_age_value* [1]
AND
(Physical Exam Finding.Vital Sign Result type = {**NQF 0061–PQRI 3–Diabetes: Blood Pressure Management code set**} [2]
AND
Physical Exam Finding.Vital Sign Result value > 135/80 mm Hg [3]
AND
count(Physical Exam Finding.Vital Sign Result date/time *within past* 6 months) >= 3 [4][5]
)
THEN
Recommended Action: Screen for type 2 Diabetes
ENDIF

[40] Example based on Screening for Type 2 Diabetes Mellitus in Adults, USPSTF Recommendation Statement from Annals of Internal Medicine 2008;148:846-854
[41] Definition of "sustained" is not official but for illustrative purposes only

Appendix G: Relationship between USPSTF Recommendations and Quality Measures for Retooling

High Priority Under Quality Measure Retooling

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Aspirin to Prevent CVD: Women age 55 to 79 to prevent ischemic strokes	NQF 0068 – PQRI #204 Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic – **HIGH**
A	Colorectal Cancer: Screening -- Adults, beginning at age 50 and continuing until age 75	NQF 0034 – PQRI #113 Colorectal Screening – **HIGH**
B	Healthy Diet: Counseling -- Adults with Hyperlipidemia and Other Risk Factors for CVD	No retooled measures – some elements may be available from: NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH**
B	Obesity: Screening and Intensive Counseling -- Obese Men and Women	NQF 0421 – PQRI 128 – Adult weight screening and follow-up – **HIGH**
B	Type 2 Diabetes Mellitus: Screening Men and Women -- Sustained BP 135/80+	Related: NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH**

Medium Priority Under Quality Measure Retooling

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Asymptomatic Bacteriuria: Screening -- Pregnant Women	NQF 0138 – Urinary Catheter-Associated Urinary Tract Infection for Intensive Care Unit (ICU) Patients – **MEDIUM**
A	Cervical Cancer: Screening -- Women who are sexually active	NQF 0032 – Cervical Cancer Screening – **MEDIUM**
A	Chlamydia: Screening -- Women Age 24 and Younger OR Women Ages 25 and Older at Increased Risk	NQF 0033 – Chlamydia Screening in Women – **MEDIUM**
A	HIV: Screening -- Pregnant Women	NQF 0012 Prenatal Screening for Human Immunodeficiency Virus (HIV) – **MEDIUM**

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Hepatitis B Virus: Screening -- Pregnant Women	No Hepatitis B, the following 4 are present for Hepatitis C: NQF 0397 – PQRI 86 – Hepatitis C: Antiviral Treatment Prescribed – **MEDIUM** NQF 0399 – PQRI 183 – Hepatitis C: Hepatitis A Vaccination in Patients with HCV – **MEDIUM** NQF 0400 – PQRI 184 – Hepatitis C: Hepatitis B Vaccination in Patients with HCV – **MEDIUM** NQF 0401 – PQRI 89 – Hepatitis C: Counseling Regarding Risk of Alcohol Consumption – **MEDIUM**
B	Alcohol Misuse: Screening and Behavioral Counseling -- Men, Women, and Pregnant Women	NQF 0110 – Bipolar Disorder for Major Depression: Appraisal for Alcohol or Chemical Substance Use – **MEDIUM** NQF 0401 – PQRI 89 – Hepatitis C: Counseling Regarding Risk of Alcohol Consumption – **MEDIUM** NQF 004 – Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: a. initiation, b. engagement – **MEDIUM**
B	Chlamydia: Screening -- Pregnant Women Ages 24 and Younger OR Pregnant Women Ages 25 and Older at Increased Risk	NQF 0033 – Chlamydia screening in women – **MEDIUM**
B	Depression: Screening -- Adolescents, 12–18 years of age, in Clinical Practices with Systems of Care	NQF 0103 – PQRI 106 Major Depressive Disorder (MDD): Diagnostic Evaluation – **MEDIUM** NQF 0104 – PQRI 107 Major Depressive Disorder (MDD): Suicide Risk Assessment – **MEDIUM** NQF 105 – PQRI (TBD) – New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management – **MEDIUM** NQF 0110 – Bipolar Disorder for Major Depression: Appraisal for Alcohol or Chemical Substance Use – **MEDIUM**

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
B	Depression: Screening -- Adults age 18 and over – When staff-assisted depression care supports are in place	NQF 0103 – PQRI 106 Major Depressive Disorder (MDD): Diagnostic Evaluation – **MEDIUM** NQF 0104 – PQRI 107 Major Depressive Disorder (MDD): Suicide Risk Assessment – **MEDIUM** NQF 105 – PQRI (TBD) – New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management – **MEDIUM** NQF 0110 – Bipolar Disorder for Major Depression: Appraisal for Alcohol or Chemical Substance Use – **MEDIUM**

Mixed Priority Under Quality Measure Retooling

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Aspirin to Prevent CVD: Men age 45 to 79 to prevent myocardial infarctions	NQF 0142 – AMI-2 Inpatient – Aspirin prescribed at discharge for AMI – **MEDIUM** NQF 0068 – PQRI #204 Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic – **HIGH**
A	Tobacco Use: Counseling and Interventions for Adults	NQF 0026 – Measure pair: 1) Tobacco use prevention for infants, children and adolescents, 2) Tobacco use cessation for infants, children and adolescents – **LOW LOW** NQF 0027 – PQRI 115 Smoking Cessation, Medical Assistance: a. advising smokers to quit, b. discussing smoking cessation medications, c. discussing smoking cessation strategies – **HIGH** NQF 0028 – PQRI 114 Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention – **HIGH**
A	High Blood Pressure: Screening -- Adults 18 and Over	NQF 0013 Blood Pressure Management – **MEDIUM** NQF 0061 – PQRI 3 – Diabetes: Blood Pressure Management – **HIGH** NQF 0073 – PQRI 201 – Ischemic Vascular Disease (IVD): Blood Pressure Management Control – **HIGH** PQRI 122 (Not NQF endorsed) – **LOW LOW**
A	Lipid Disorders in Adults: Screening -- Men 35 and Older	NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH** NQF 0075 – PQRI 202/203 – IVD: Complete Lipid Profile and LDL Control <100 – **LOW LOW** PQRI 121 (Not NQF endorsed) – Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH), and Lipid Profile) – **LOW LOW**

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Lipid Disorders in Adults: Screening -- Women 45 and Older, Increased risk for CHD	NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH** NQF 0075 – PQRI 202/203 – IVD: Complete Lipid Profile and LDL Control <100 – **LOW LOW** PQRI 121 (Not NQF endorsed) – Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH), and Lipid Profile) – **LOW LOW**
B	BRCA Mutation Testing for Breast and Ovarian Cancer: Women, Increased Risk	NQF 0387 – PQRI 71 – Breast Cancer: Hormonal Therapy for Stage IC-IIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer – **MEDIUM** NQF 0031 – PQRI 112 – Breast Cancer Screening – **HIGH**
B	Breast Cancer: Preventive Medication Discussion -- Women, Increased Risk	NQF 0387 – PQRI 71 – Breast Cancer: Hormonal Therapy for Stage IC-IIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer – **MEDIUM** NQF 0031 – PQRI 112 – Breast Cancer Screening – **HIGH**
B	Breast Cancer: Screening Mammography -- Women 50 and Older	NQF 0387 – PQRI 71 – Breast Cancer: Hormonal Therapy for Stage IC-IIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer – **MEDIUM** NQF 0031 – PQRI 112 – Breast Cancer Screening – **HIGH**
B	Lipid Disorders in Adults: Screening -- Men 20-34, Increased risk for CHD	NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH** NQF 0075 – PQRI 202/203 – IVD: Complete Lipid Profile and LDL Control <100 – **LOW LOW** PQRI 121 (Not NQF endorsed) – Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH), and Lipid Profile) – **LOW LOW**
B	Lipid Disorders in Adults: Screening -- Women 20-44, Increased risk for CHD	NQF 0064 – PQRI 2 – Diabetes Measure Pair: A. Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B. Lipid management: LDL-C <100 – **HIGH** NQF 0075 – PQRI 202/203 – IVD: Complete Lipid Profile and LDL Control <100 – **LOW LOW** PQRI 121 (Not NQF endorsed) – Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorous, Intact Parathyroid Hormone (iPTH), and Lipid Profile) – **LOW LOW**

Not Addressed Under Quality Measure Retooling

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
A	Congenital Hypothyroidism: Screening -- Newborns	No comparable measure for retooling
A	Folic Acid: Supplementation -- All Women Planning or Capable of Pregnancy	No comparable measure for retooling
A	Gonorrhea: Preventive Medication -- Newborns	No comparable measure for retooling
A	HIV: Screening -- Adults and Adolescents at Increased Risk	No retooled measure (???)
A	Phenylketonuria (PKU): Screening -- Newborns	No retooled measure
A	Rh(D) Blood Typing: Screening -- Pregnant Women, First Pregnancy-Related Visit	Original measure has been retired – removed from the retooling list
A	Sickle Cell Disease: Screening -- Newborns	No retooled measure
A	Syphilis: Screening - Pregnant Women	No retooled measure
A	Syphilis: Screening -- Men and Women at Increased Risk	No retooled measure
A	Tobacco Use: Counseling and Interventions for Pregnant Women	No specific pregnancy tobacco intervention measure
B	Abdominal Aortic Aneurysm: Screening -- Men 65–75, Smoker	No retooled measure
B	Breastfeeding: Primary Care Interventions to Promote -- All Pregnant Women and New Mothers	No retooled measure
B	Dental Caries: Oral Fluoride Supplementation -- Preschool Children 6 Months and Older	No retooled measure
B	Gonorrhea: Screening -- Pregnant Women and Women at Increased Risk	No retooled measure
B	Hearing Loss in Newborns: Universal Screening -- Newborns	No retooled measure
B	Iron Deficiency Anemia: Iron Supplementation -- Asymptomatic Children 6–12 Months, Increased Risk	No retooled measure

Grade	USPSTF Recommendation	Closest alignment to measures being retooled
B	Iron Deficiency Anemia: Screening -- Asymptomatic Pregnant Women	No retooled measure
B	Osteoporosis: Screening -- Postmenopausal Women 65 Years and Older with No Risk Factors, or 60 Years and Older with Risk Factors	No retooled measure
B	Rh(D) Blood Typing: Screening -- Antibody Testing Unsensitized Rh (D)-Negative Pregnant Women	Original measure has been retired – removed from the retooling list
B	Sexually Transmitted Infections: Behavioral Counseling -- Sexually Active Adolescents and Adults at Increased Risk	No retooled measure
B	Visual Impairment: Screening -- Children Younger than 5 Years	No retooled measure