CDS Connect Pilot Report

Patient-Centered Outcomes Research Clinical Decision Support Prototype Development and Dissemination

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

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**Contents**

[Executive Summary vi](#_Toc492381417)

[Overview 7](#_Toc492381418)

[Background 7](#_Toc492381419)

[Project Context 8](#_Toc492381420)

[Pilot Scope 8](#_Toc492381421)

[Pilot Partnership 10](#_Toc492381422)

[Pilot Partner Requirements 10](#_Toc492381423)

[Pilot Partner Selection 10](#_Toc492381424)

[Outcomes and Measurement 12](#_Toc492381425)

[Outcome Domains 12](#_Toc492381426)

[Outcomes Measurement 13](#_Toc492381427)

[Pilot Approach 14](#_Toc492381428)

[Communication and Collaboration 14](#_Toc492381429)

[Data Management 14](#_Toc492381430)

[Pilot CDS Representation 15](#_Toc492381431)

[Placement and Trigger 15](#_Toc492381432)

[Disease Management Advisory (DMA) Tool Updates to Support the Pilot 15](#_Toc492381433)

[Clinical Pilot Site Selection and Onboarding 17](#_Toc492381434)

[Clinical Pilot Site Selection 17](#_Toc492381435)

[Onboarding and Training 17](#_Toc492381436)

[Artifact Validation and Enhancement 17](#_Toc492381437)

[Artifact Validation 18](#_Toc492381438)

[Artifact Enhancement 18](#_Toc492381439)

[Enhancements Made During Initial Discussions with Alliance 18](#_Toc492381440)

[Enhancements Made During Integration Development and Testing 19](#_Toc492381441)

[Enhancements Made During Implementation Testing and the Live Pilot 19](#_Toc492381442)

[Technical Integration 20](#_Toc492381443)

[Development of a RESTful Web Service for CQL Execution 20](#_Toc492381444)

[Integration of CQL Execution into Clinical Workflow 22](#_Toc492381445)

[Technical Integration Project Management 24](#_Toc492381446)

[Technical Integration Testing 24](#_Toc492381447)

[Pilot Findings and Lessons Learned 25](#_Toc492381448)

[Pilot Outcomes 25](#_Toc492381449)

[Focus Group Findings 25](#_Toc492381450)

[Reduced Clinician Burden 25](#_Toc492381451)

[Data Sharing 26](#_Toc492381452)

[Efficacy of CDS Results 26](#_Toc492381453)

[Reconciling Guidance Conflicts 27](#_Toc492381454)

[Alterations to Clincial Workflow 27](#_Toc492381455)

[Role of the Patient in CDS 27](#_Toc492381456)

[Future of CDS 28](#_Toc492381457)

[EHR Data Findings 28](#_Toc492381458)

[Key Lessons Learned and Future Recommendations 29](#_Toc492381459)

[Conclusion 31](#_Toc492381460)

**Figures**

[Figure 1: Logo and Branding for CDS Connect 7](#_Toc492381461)

[Figure 2: CDS Connect Concept of Operations (CONOPS) 8](#_Toc492381462)

[Figure 3: CDS Connect Project Feedback Model 9](#_Toc492381463)

[Figure 4: Pilot CDS Implementation Sequence 22](#_Toc492381464)

[Figure 5: Pilot CDS Recommendations by Encounter 29](#_Toc492381465)

**Tables**

[Table 1: Outcome Domains 12](#_Toc492371524)

# Executive Summary

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable. AHRQ works within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ’s primary area of focus is improving healthcare quality by accelerating implementation of patient-centered outcomes research (PCOR). Further, AHRQ is focused on making healthcare safer; increasing accessibility to healthcare; and improving healthcare affordability, efficiency, and cost transparency.

The Patient Protection and Affordable Care Act (ACA) of 2010 directs AHRQ to disseminate and to build capacity in PCOR. Working with relevant medical and clinical associations, AHRQ is assisting users of health information technology (IT) focused on clinical decision support (CDS) to incorporate findings into clinical practice and to promote the ease-of-use of such incorporation. AHRQ supports processes for receiving feedback about the value of information and the assistance provided from stakeholders including physicians, providers, patients, and commercial vendors of health IT focused on CDS.

Through this project (named “CDS Connect”), the CMS Alliance to Modernize Healthcare (CAMH) is piloting a process that accounts for the agile nature of CDS development. CAMH is a Federally Funded Research and Development Center (FFRDC) operated by the MITRE Corporation. The CDS Connect project has included clinical and technical translation of guidelines into computable CDS, testing and monitoring, implementation protocols, and feedback loops. Initial work is grounded in the domain of cholesterol management and designed to promote the transformation of findings into actionable, relevant, and interoperable clinical capabilities.

This report outlines the design, clinical, and technical work efforts, and findings of the CDS Connect pilot of a newly developed CDS artifact, Statin Use for the Primary Prevention of CVD in Adults. In both design and execution, the pilot focused on collaboration with the project’s clinical partner to ensure a balance of development rigor and real-world considerations. Through this report, one can review the process used for piloting the MITRE-developed CDS, including the development and refinements of the piloted CDS, technical integration with the pilot site electronic health record (EHR), evaluation of the pilot CDS’s performance, and lessons learned through evaluation of the pilot testing experience, which includes direct clinical user feedback. The piloted artifact described in this report is free and openly available on the CDS Connect Repository, and can be accessed at <https://cds.ahrq.gov/>.

The CDS Connect project has resulted in a proof-of-concept that will lead to the increased use of evidence-based clinical findings in healthcare practice. Furthermore, this work provides the foundation for improved healthcare outcomes via CDS creation, discovery, integration, and implementation using interoperable data standards to express the logic of the CDS for use by health IT software systems.

# Overview

## Background

The Agency for Healthcare Research and Quality (AHRQ) has requested the CMS Alliance to Modernize Healthcare’s (CAMH) Federally Funded Research and Development Center (FFRDC) operated by The MITRE Corporation (MITRE) to conduct a Patient-Centered Outcomes Research (PCOR) Clinical Decision Support (CDS) Prototype Development and Dissemination project. The overall objective of the work is to generate a systematic and replicable process of transforming PCOR findings into shareable, health IT standards-based, and publicly available CDS, including developing, implementing, and evaluating the prototype tools that would facilitate such a process of transformation.

AHRQ tasked MITRE with the development and dissemination of a project, “CDS Connect” that is focused on supporting the rapid translation of evidence-based, patient-centered outcomes research into clinical practice through interoperable CDS artifacts. This tasking led to the development of two prototype web-based software tools in the CDS space. The first service is a Repository for storing, sharing, iterating, and discussing CDS. Another complimentary service is an Authoring Tool that can generate CDS in an internationally recognized data standard, the HL7 Clinical Quality Language (CQL). The project was named “CDS Connect” (Figure 1), to underscore AHRQ’s goal of this work to connect the CDS community and evidence-based research to clinicians and the patients in their care.

Figure 1: Logo and Branding for CDS Connect



Clinical organizations endeavor to support patients, providers, and their organizations through increased quality improvement efforts, of which several rely on technology. One such example is the use of CDS and its integration with electronic health record (EHR) systems and clinical workflows.

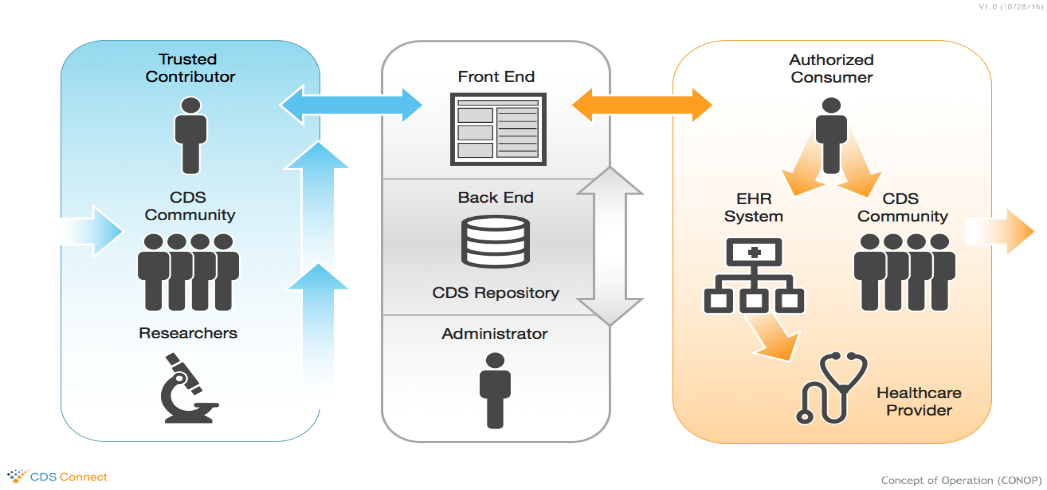
Through CDS, organizations can leverage the combined value of clinical insight and multiple data sources to improve patient-centered outcomes and clinician engagement while maintaining awareness of the evolving evidence-based guidelines for care. The ‘real-world’ work of implementing evidence-based CDS within a clinical organization is subject to barriers and facilitators across multiple areas, including: 1) determining if a particular CDS is the right tool given organizational goals, 2) identifying suitable and verified CDS artifacts, 3) technical creation and integration with a commercial EHR system through interoperable health IT standards, 4) clinician and clinical staff training, 5) workflow changes across staff roles, 6) how CDS artifacts results will be shared with the patient and incorporated into treatment plans, and ultimately 7) measuring whether or not the CDS tool has achieved the intended goal.

## Project Context

The CDS Connect project includes seven tasks or key work areas, each designed to support the goals of the project. In addition to project and task leadership, work focused on the development of the CDS Connect Repository as well as Authoring Tool (and their hosting and maintenance), the establishment of Work Groups in the both clinical and technical domains, the development of PCOR CDS Artifacts, and ultimately, the activity of piloting a MITRE-developed PCOR CDS artifact in a live clinical setting.

The CDS Connect project developed a simple, visual Concept of Operations (CONOPS) to underscore the collaborative and iterative nature of the PCOR CDS artifact development process (Figure 2). Through the lens of the CONOPS, the pilot tasking outlines activities related to the “Authorized Consumer” role, which includes both connectivity to an EHR and the clinicians who use it, as well as individuals with clinical, technical, and/or informatics resources that align with the broader CDS community. As illustrated in the CONOPS through the final orange arrow to the right of the visual, outputs from the “Authorized Consumers” (e.g., our pilot collaborator) are meant to provide feedback to both the broader CDS community, including those responsible for validating evidence-based sources for CDS, and the prototype CDS Connect Repository tool with regard to desired features and functions to promote usability and a positive user experience.

Figure 2: CDS Connect Concept of Operations (CONOPS)



## Pilot Scope

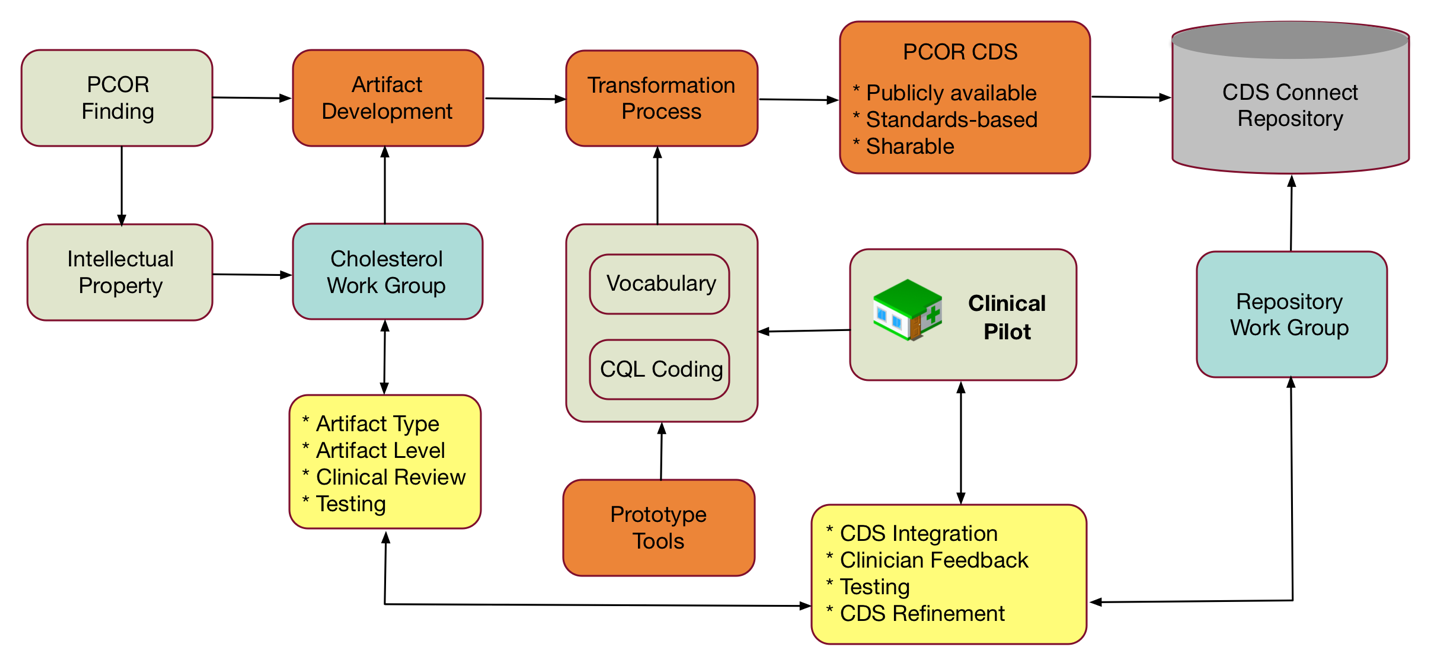
The primary goal of this feasibility pilot was to ensure that the piloted CDS artifact, which is posted on the CDS Connect Repository, performs as expected. The term “artifacts” has been deliberately embraced by the CDS Connect project to provide the ability to support a variety of CDS that are not exclusively limited to the space of clinical alerts (which is commonly attributed with “CDS”). The term “artifacts” can apply to a variety of CDS domains including alerts, order sets, textual reports, citations, etc. This provides flexibility in inviting participation in the CDS Connect project with a broader set of stakeholders in the CDS space.

As part of this goal, the pilot had three main activities:

1. Engage a CDS “Consumer” in the work of the CDS Connect Repository, and gain their understanding of the project as the pilot runs. Consumers can be healthcare providers, EHR vendors, or potentially even patients. Consumers are those users who benefit from the accurate and timely execution of CDS artifacts.
2. Utilize the pilot organization’s technical, clinical, and operational expertise to enhance the project’s CONOPS and in-development CQL-based CDS artifacts.
3. Technically and clinically validate the MITRE-developed artifact in a live clinical environment, and provide feedback to inform both the artifact and the overall work of the CDS Connect project.

As shown in Figure 3, the pilot was one connected component in a larger body of work and was designed with the ability to evolve based on a continuous feedback loop amongst the multidisciplinary pilot team and the project’s stakeholders, spanning clinicians, technologists, informaticists, and provider leadership.

Figure 3: CDS Connect Project Feedback Model



# Pilot Partnership

## Pilot Partner Requirements

For the pilot, MITRE sought a collaborator with both technical readiness and a suitable clinical environment for piloting the MITRE-developed CDS. There were several key factors influencing the selection of the pilot site, as noted below. A principal factor was the pilot site’s representatives being aware, and understanding the requirements, of participation in the pilot and representing their organization’s clinical, operational, and technical staff. This multidisciplinary perspective was deemed critical, as a focus area for the pilot was to tailor its implementation to meet the capabilities and needs of the pilot partner and clinical pilot environment.

This focus existed based on the pilot’s aim to use the pilot partner’s experiences to refine the CDS artifacts and inform the CDS Connect project’s software development (i.e., the CDS Connect Repository). MITRE reviewed partnership options that met the minimum criteria outlined below:

1. Care delivery through an ambulatory practice, with preference for a community health center or like provider.
2. Focus on or access to an appropriate medical specialty for the pilot CDS’s clinical domain of cholesterol management (e.g., Internal or Family Medicine, Cardiology).
3. Identification and support of clinical, operational, and technical staff.
4. The ability for the partner to identify leaders with the technical capability to implement the pilot CDS in collaboration with MITRE and the use of a mature and robust health IT system.
5. Organizational commitment and operational resources to meet pilot needs pre, during, and post implementation, including:
   1. Provision of clinical workflow materials and/or guidance on interpretation.
   2. Consultation on the pilot CDS and its placement into the clinical workflow.
   3. Ability to perform site-based and other training as needed.
   4. IRB coordination and support in identifying and reporting any adverse events.
   5. Commitment of designated site-based point(s) of contact.

## Pilot Partner Selection

While the work of this project is meant to provide a real-world approach to the development and implementation of CDS, it was critical to select a pilot partner capable of maintaining standard operations while engaging in the feasibility pilot. To meet this need, MITRE aimed to secure an established pilot partner that could provide strong support to the technical (i.e., implementing the pilot CDS in their EHR, which was planned as an iterative process) and clinical implementation (i.e., ensuring the CDS was clinically accurate, that clinicians were trained, and that the pilot CDS entered the clinical workflow appropriately in terms of both EHR placement and clinician trigger).

After evaluating several potential partners, AllianceChicago (Alliance) was chosen in collaboration and with the approval of AHRQ. Alliance is a healthcare IT service provider for a national network of Federally Qualified Health Centers.

In addition to serving as an exemplar health IT organization, Alliance and their clinical network met the pilot partner criteria noted above; brought a well-vetted, systematic approach to developing, testing, and implementing CDS to the work; and could offer infrastructure and lessons learned from having successfully operationalized a CDS tool similar to that of the pilot CDS. Alliance was awarded a subcontract through the MITRE Corporation for the March 2017 to September 2017 period.

# Outcomes and Measurement

## Outcome Domains

There were several outcomes the CDS Connect project established for this feasibility pilot. At a high level, the pilot is considered successful if it achieves the following:

1. The pilot site can incorporate the pilot CDS artifact into their EHR system (i.e., technical integration).
2. The pilot CDS artifact launches when appropriate and captures and shares information as designed (i.e., artifact development).
3. Clinicians utilize the pilot CDS artifact when appropriate.
4. The pilot site maintains the pilot CDS after the pilot, in whole or part.
5. The project gains information from the pilot partner and clinical site needed to support the CDS Connect project CONOPS and enhance and validate the pilot CDS.

In addition to these desired high-level pilot outcomes, there are three main domains representing additional outcome areas (i.e., people, process, and technology) that were addressed through several validation questions in the monitoring and evaluation processes associated with the pilot.

Table 1: Outcome Domains

|  |  |
| --- | --- |
| **Domains** | **Validation Questions** |
| People | Do clinicians gain greater insight into a patient’s health when using the pilot CDS, and does this influence the care plan? |
| People | Are clinicians and patients receptive to and ready to use CDS/the pilot CDS?  Do clinicians experience greater patient engagement when using the pilot CDS? |
| People | Is the pilot CDS user-friendly and easy to incorporate into the workflow?  Do clinicians, staff, or patients value the pilot CDS?  Does the pilot CDS reduce cognitive burden for clinicians? |
| Process | Do clinicians require training to use the pilot CDS?  If yes, how much and what kind? What is the cost to the organization? |
| Process | Does the clinical workflow require adjustment, given the pilot CDS?  If yes, what and how extensive are the adjustments?  Do the adjustments outweigh the value of the pilot CDS? |
| Process | Did the pilot CDS improve the quality of patient care (e.g., increases in screening, avoidance of unnecessary or duplicate testing)? |
| Technology | Can the pilot partner maintain the pilot CDS after the study period? |
| Technology | Does the pilot partner identify a component of patient care that could have been missed or a subset of a previously undetected population in need? |
| Technology | Are the resource requirements needed to implement CDS (e.g., staff number and skill mix, hours of labor, new equipment, training) feasible? |

## Outcomes Measurement

The CDS Connect project approach is grounded in ‘agile development,’ which, for the purposes of outcome measurement, translates into an ongoing, iterative, ‘as-needed’ model for discussing findings and ways to enhance the work to ensure outcomes, to the extent possible, are met. This approach also supports the collection of both formal and informal information and data that can be both qualitative and quantitative, and incorporates these “lessons learned” into a feedback loop that improves the CDS artifact and benefits the broader community of users.

Throughout the pilot period, MITRE and Alliance engaged in collaborative discussions concerning all aspects of the pilot. In regard to clinical details, discussions focused on the pilot CDS (e.g., value set refinement for exclusion criteria and appropriate wording for the pilot CDS recommendation statements to support clinical utility).

To support software engineering and technical activities, the MITRE and Alliance teams met weekly via conference call to ensure the pilot CDS was undergoing successful installation and testing in Alliance’s EHR. Through these informal interactions with Alliance, MITRE worked toward assessing progress toward outcomes, while considering the ‘voices’ of clinical, operations, and IT teams.

In terms of formal, qualitative outcomes measurement, a member of the CDS Connect project team led a structured, virtual focus group with the pilot site clinicians. Statements captured during the focus group provide answers to many of the proposed outcome domains and related validation questions, and are described in more detail in the Findings section of this report.

The quantitative measurement for the pilot occurred through informal, ongoing monitoring of the pilot CDS artifact as well as formal data extraction from the Alliance EHR. Within 10 days of the pilot starting the ‘go live’ phase, Alliance began generating weekly reports as informal deliverables that were sent to the CDS Connect project team throughout the 4-week pilot. Each report documented the number of calls to the pilot CDS artifact and the resulting recommendation provided at the de-identified patient level.

After each report was generated, an Alliance clinician leader would review the output to validate that the pilot CDS was performing as expected. During weekly technical team calls between MITRE and Alliance, any questions regarding the weekly report were addressed. Formally, upon the pilot’s conclusion, Alliance extracted data that MITRE had requested through Alliance’s formal process utilizing a unique Alliance Data Request Form (DRF). Initially, MITRE requested a variety of relevant data to evaluate the use and impact of the pilot CDS on the patient. Ultimately, the sample size of patients who experienced the pilot CDS was insufficient to conduct meaningful analysis, resulting in this aspect of the pilot to be unreported.

# Pilot Approach

## Communication and Collaboration

Upon securing the sub-contract with Alliance, CDS Connect project leadership attended a 2-day onsite meeting in March 2017 at the Alliance headquarters in Chicago, IL. During this onsite ‘kick-off,’ MITRE and Alliance established the timeline and implementation details for the pilot activities. The main outcome from this meeting was the development of a Pilot Plan that was submitted to AHRQ as a formal project deliverable.

To maintain ongoing situational awareness and communication, CDS Connect project leadership stood up a bi-weekly operational call with Alliance leadership that ran from March through August. Additionally, once the pilot artifact and required software to operate the artifact was sufficiently developed, a weekly technical call was introduced, where both organizations’ operational, clinical, and technical leadership could address technical questions and their implication on clinical execution and, ultimately, pilot outcomes and goals. Throughout Alliance’s period of performance, both Alliance and MITRE made leadership and key resources readily available to address questions or issues as needed. Toward the end of the subcontract, a 2-day virtual ‘wrap-up’ meeting was scheduled to review pilot activities and outputs.

## Data Management

Agreement was reached that Alliance would have exclusive access to all patient-level data and would furnish a de-identified dataset to MITRE via a secure transmission after the live clinical pilot. MITRE agreed to submit a formal request for database elements using Alliance’s DRF.

Given the research and evaluation nature of the work and the project’s goal to provide both specific and generalizable knowledge to a broad community of stakeholders, the CDS Connect project team engaged in the Institutional Review Board (IRB) process, securing IRB approval letters and ensuring compliance with applicable human subjects protection policies. MITRE worked with Alliance to identify data elements that could provide insight into the patient population in which the CDS was employed (e.g., Patient Demographics, Lifestyle Goals, and Clinician Referrals). Alliance provided MITRE with a de-identified data to support ongoing research and development work as part of the artifact development process.

To allow for live clinical testing and the potential publication of both the pilot process and resulting artifact validation, both MITRE and Alliance secured IRB approval. To achieve IRB approval, all parties involved were required to complete or provide evidence of Collaborative Institutional Training Initiative (CITI) training and comply with all required IRB processes for both the MITRE IRB and the Chicago Department of Public Health (CDPH) IRB. MITRE’s IRB and CDPH’s IRB were granted approval on May 17, 2017, and May 24, 2017, respectively.

## Pilot CDS Representation

### Placement and Trigger

Given the structure of the Alliance EHR, the placement of and triggers for the pilot CDS were straightforward. Alliance and the pilot site utilized a Disease Management Advisor (DMA) form that was part of an existing workflow and contained two unique tools for providing a recommendation concerning statin initiation. The Alliance’s existing tools were included in a modular form in the EHR that was visible when an adult visit was in view.

The DMA form and the associated CDS was triggered by clinician action only. Within that form, clinicians could click the Calculate 10-year ASCVD (atherosclerotic cardiovascular disease) Risk Score button to perform a risk score calculation using the American College of Cardiology (ACC)/American Heart Association (AHA) risk algorithm,[[1]](#footnote-1) and receive the ACC/AHA recommendation or CDS generated from guidance underlying the Framingham Heart Study (FHS). Within the specific clinical pilot site, and the Alliance network more broadly, the FHS option was rarely utilized. Therefore, during the kick-off meeting, Alliance elected to decommission the FHS section of the DMA, and replace it with the U.S. Preventive Services Task Force (USPSTF) CDS artifact.

The complete DMA allowed for several visual “tabs” on the user interface: a main tab that highlighted the patient’s medications and problem list, as well as the ASCVD CDS score and recommendations, and two calculator-specific tabs that provided either context for the CDS or a live calculator in which the clinician could enter different or missing algorithmic components and receive a risk score.

The Alliance team modified the behavior of the main tab’s button to *also* invoke the USPSTF-based CDS artifact so that the USPSTF recommendation could be provided. Thus, the Calculate 10-year ASCVD Risk Score served as the trigger for the risk score calculation *and* the USPSTF-based CDS artifact.

It is important to note that the USPSTF-based CDS did *not* perform the 10-ASCVD risk score calculation itself, but rather re-used the score already calculated by the ACC/AHA calculator. While the USPSTF-based CDS could be invoked via the main DMA form, Alliance also developed a specific USPSTF Risk Estimator tab within the form that provided additional details about the USPSTF CDS along with the current recommendation and rationale. In addition, clinicians could perform *what-if* scenarios, tweaking individual patient data elements (such as HDL) to see how it would affect the risk score and, ultimately, the recommendation.

### Disease Management Advisory Tool Updates to Support the Pilot

The original DMA Tool used by the pilot site contained three tabs. The first tab was the DMA and included a Problems list and a Medications list, as well as patient age and alerts on any chronic conditions the patient had. The second tab featured the ACC/AHA ASCVD Risk Estimator, and the third tab featured the Framingham Risk calculator. The latter tabs included sections on information and a Patient Education Tool. For this pilot, as noted, the Framingham Heart Study calculator functionality was replaced by the CDS developed based on the USPSTF recommendation statement.

MITRE performed a human-factors review of the existing DMA tool and provided several design recommendations to improve the usability of the tool for the pilot. The changes primarily focused on consolidating information that was originally distributed across multiple tabs and improving consistency of the displays across both risk estimators. All new design recommendations were made to be consistent with the Alliance Clinical Content Standards for designing EHR components.

Since both the ACC/AHA and USPSTF risk estimators are based on the same pooled cohort equations for 10-year CVD risk, both recommendations were consolidated with the presentation of the score on the main DMA display, rather than separating the recommendations on different tabs. In this way, the initial DMA screen became an overview dashboard, where the score is computed only once for both tests, with options for the user to click on one estimator or the other to drill deeper into the ACC/AHA or USPSTF risk estimators as needed.

The two screens specific to the ACC/AHA and USPSTF were designed to be as consistent as possible with respect to displaying the parameters used as inputs by the risk estimators, supplemental information about the parameters and risk scores, and information on interpreting the risk scores. Originally, there was a lack of consistency in both the ordering and labeling of parameters used by the risk estimators.

For example, the list of input parameters included an entry for “Current Smoker (1 year),” while the adjacent Resources tab providing definitions of each parameter referred instead to “Smoking Status.” The order of the input parameters was different than the order of the list of definitions of the parameters. Such inconsistencies increase the effort to find needed information, leading to frustration and potential errors.

Preserved in the design was functionality for shared decision making (SDM) between the clinician and patient, contained in the Patient Education Tool section of the interface. This tool facilitates a forward-looking conversation between clinician and patient by calculating hypothetical risk scores should the patient make certain changes (e.g., quitting smoking, reducing cholesterol by 30 points, etc.). However, there again were inconsistencies between the displays of the risk estimator parameters and the Patient Education Tool. Consistency was achieved by duplicating the display of the risk estimator input parameters (which are automatically populated from the EHR), but making the Patient Education Tool table editable.

The live CDS implemented by Alliance incorporated these ideas in the final interface used in the pilot, with some additional changes to wording and layout.

# Clinical Pilot Site Selection and Onboarding

## Clinical Pilot Site Selection

Alliance facilitated collaboration with one of their Rural Community Health Center Networks (Health Network) in the Western U.S. to pilot the CDS in their facility. The Health Network, referred throughout this report as the pilot site, has three clinical locations, of which two are approximately 40 miles apart. Alliance selected this pilot site due to the number of patients the site serves that could meet the inclusion criteria for the pilot CDS, the anticipated population that would access an adult visit during the pilot, and the sites’ interest in pilot participation.

## Onboarding and Training

AHRQ, MITRE, and Alliance visited the pilot sites in June 2017 in preparation for the pilot’s July 2017 go-live. During a day-long visit, MITRE and Alliance leadership provided an overview of the CDS Connect project, an orientation to the pilot, and the clinical provider consent process to the site’s physicians and advance practice clinicians. The clinicians provided positive feedback regarding the features and functions of the pilot CDS artifact (i.e., USPSTF; namely the more conservative statin initiation guidance) and the ability to stay within their EHR vs. going to an external, web-based calculator (which they had been doing to access USPSTF guidance in this domain). MITRE reviewed the IRB-approved clinician consent form, which all 10 pilot site clinicians and MITRE leadership signed, and returned the consent forms to the clinicians.

MITRE, in conjunction with an Alliance clinician leader, delivered training on the new CDS user interface, the underlying differences between the USPSTF and ACC/AHA recommendation statements, and any potential workflow considerations. CDS Connect leadership also had the opportunity to interview clinicians regarding their workflow related to patient assessment in consideration of statin initiation.

The trip concluded with visits to the three clinical sites where the pilot would take place. At the start of the go-live period for the pilot, Alliance prepared and delivered a brief audio webinar on the pilot CDS for the study clinicians. Additionally, Alliance prepared and delivered a Frequently Asked Questions document that outlined pertinent information on the pilot and specifics related to the pilot CDS.

## Artifact Validation and Enhancement

As noted—based on the availability of secured intellectual property and value-add to Alliance—MITRE, AHRQ, and Alliance elected to pilot the MITRE-developed artifact Statin Use for the Primary Prevention of CVD in Adults (USPSTF artifact),[[2]](#footnote-2) based on a USPSTF guideline,[[3]](#footnote-3) in a live clinical setting.

## Artifact Validation

The CDS Connect team worked with Alliance throughout the pilot CDS development period to elicit their inputs as a proxy CDS Connect Repository “Consumer.” Through this early and open dialogue, Alliance provided insight and feedback that led to enhancements and versioning of the MITRE-developed pilot CDS artifact. Throughout the artifact development process, Alliance provided critical feedback to the value sets utilized in the CDS elements, specific aspects of real-world inclusion and exclusion criteria refinements, and appropriate ways to message recommendation statements.

As the USPSTF artifact was being finalized, Alliance utilized test patients from within their EHR environment, coupled with manual record review by an experienced clinician, to validate the logic of the CDS. Once the pilot went live, the Alliance team also provided a weekly clinical review of patient encounters on which the USPSTF artifact had been run. This review ensured that the artifact performed as expected and clinicians were utilizing the CDS correctly. Findings that arose during development, testing, and implementation informed and enhanced artifact specifications, leading to a richer expression of the clinical intent and underlying logic for the final pilot CDS used for go-live.

One component of the pilot CDS validation involved working with Alliance to assess the artifact usability and clinician acceptance of pilot CDS. This validation occurred through a focus group activity with clinicians at the pilot site upon the pilot’s conclusion. Main areas of inquiry included:

1. In what ways did the clinician use the artifact during the patient encounter?
2. How user-friendly was the artifact to the clinician?
3. What were the costs and benefits to the clinician of using the artifact?
4. What was the impact to the healthcare organization of setting up and using the Repository?

MITRE worked with Alliance to identify data elements needed to support the validation of the pilot CDS. MITRE documented data elements specific to the pilot CDS, as well as upstream and downstream data elements related to the pilot CDS and the patients who were eligible for its use. These data elements were documented through the Alliance DRF, and included categories such as pilot CDS Inclusion and Exclusion Criteria, Patient Demographics, Medication Orders, Social Determinants of Health, Self-Management Goals, and Referrals.

## Artifact Enhancement

Through the artifact validation process, which involved collaborative work sessions with Alliance, multiple enhancements were made to the pilot CDS generally, and to support the implementation of the CDS at Alliance. MITRE delivered a detailed “Enhanced Artifacts” report to AHRQ, of which a summary is provided below.

### Enhancements Made During Initial Discussions with Alliance

The primary enhancement made during initial discussions with Alliance involved determining which aspects of the USPSTF recommendation statement to pilot. More specifically, USPSTF issues varies “grades” of recommendation based on the level of clinical evidence found in support of the recommendation (e.g., high certainty of substantial net benefit from the recommended service results in an “A” grade). In regard to the USPSTF Statin Use recommendation statement related to statin therapy for the treatment and prevention of CVD that was the clinical underpinning of the pilot CDS artifact, the USPSTF issued “B,” “C,” and “I (insufficient evidence)” grade recommendations for various populations in 2016.

The MITRE-developed pilot CDS artifact was specified to include the expression logic for both the “B” and “C” grade recommendation. However, organizational policy at Alliance allows only for implementation of Grade A and Grade B recommendations. To accommodate organizational preference, MITRE included a parameter to the pilot CDS artifact to “disable” logic associated with a graded recommendation (i.e., the Grade C recommendation), enabling Alliance to select the Grade B recommendation for inclusion in their EHR for the purposes of the pilot. Because of this organizational input, grade parameters will likely be included, when relevant, for any additional MITRE-developed CDS to allow organizations flexibility.

### Enhancements Made During Integration Development and Testing

During integration development to align the organization’s coded data and the CDS specifications, several “disconnects” were identified between how data was captured in Alliance’s EHR and how the data concepts were expressed in the Statin Use artifact. Based on these findings and in collaboration with Alliance, the CDS Connect team implemented several enhancements to the piloted artifact across four high-level data categories:

1. Conditions (i.e., Pregnancy, Breastfeeding, Familial Hypercholesterolemia, and Hypertension).
2. Medications (i.e., Low, Moderate, and High Intensity Statins).
3. Laboratory tests (i.e., LDL-C and HDL-C results).
4. Procedures (i.e., Dialysis).

The enhancements ultimately ensured robust data evaluation and the delivery of accurate CDS interventions.

### Enhancements Made During Implementation Testing and the Live Pilot

End-to-end implementation testing of the Statin Use artifact occurred over the course of 13 days (i.e., from June 23, 2017, to July 5, 2017). Due to the enhancements listed above, testing demonstrated consistently valid and reliable CDS execution. Furthermore, no additional enhancements were required during the live pilot of the CDS artifact.

# Technical Integration

Integrating specific CDS capabilities or artifacts into an existing system often requires custom development and configuration. CDS implementation direction that exists only as narrative or a flow chart requires the most effort, while CDS guidelines that use standard formats reduce integration burden. The current landscape of health IT is such that sufficient CDS standards exist, and many vendors plan to support them, but most have not yet implemented full support. To provide the Alliance EHR with the pilot CDS, both organizations’ technical teams developed or customized software.

The CDS Connect pilot CDS, Statin Use for the Primary Prevention of CVD in Adults, based on a USPSTF guideline, was authored using the Health Level 7 (HL7) Clinical Quality Language (CQL)[[4]](#footnote-4) to represent logic, and HL7 Fast Healthcare Interoperability Resources (FHIR)[[5]](#footnote-5) to represent clinical data. The EHR in use at Alliance, GE Centricity™ (Centricity), supported neither CQL nor FHIR in its current version, so the integration effort required solutions to bridge these gaps in a seamless manner, with a goal of minimizing custom development within the EHR.

The custom code developed was a piece of software designed to translate Alliance EHR outputs into a format the pilot CDS could understand, and then return to the EHR CDS-generated output. This effort involved identifying the application programming interface (API) to access the EHR data, determining the method of converting data or API to FHIR, writing CQL, and accessing Alliance’s build environment. Throughout the course of development and planning of the pilot integration, the CDS Connect and Alliance operational and technical teams met on a weekly basis to discuss requirements, architecture, technical approach, and outstanding issues.

## Development of a RESTful Web Service for CQL Execution

To support CQL in a minimally invasive way, a RESTful web service was developed to accept requests for CQL execution and to respond with the calculated results. This service supports simple registration of CQL artifacts by placing CQL files in a predetermined file location on the server. In this way, artifact updates can be easily applied by simply overwriting older CQL files with updated versions. The RESTful web service reads CQL files and automatically exposes endpoints corresponding to the CQL library names and versions. For example, an execution request for the piloted artifact can be invoked via an HTTP POST to the endpoint:

/api/library/USPSTF\_Statin\_Use\_for\_Primary\_Prevention\_of\_CVD\_in\_Adults\_FHIRv102/version/1.

Execution requests are required to consist of a valid JSON document, containing the following properties:

* data: an array of FHIR 1.0.2 (DSTU2) resources representing all of the data needed to execute the CDS for a single given patient.
* parameters: an *optional* set of parameter names and values to use during CQL execution.
* returnExpressions: an *optional* set of expression names to identify a subset of expression results to include in the response (otherwise all results are returned).

Responses to execution requests return a JSON document containing the following properties:

* library: the name and version of the library that was executed.
* parameters: the parameter values used during execution.
* returnExpressions: the names of the expressions requested for return.
* timestamp: the timestamp representing when the CQL was executed.
* patientID: the patient identifier corresponding to the patient in the incoming data.
* results: the computed CQL expression results.

The CQL execution service was implemented by the CDS Connect team using the popular cross-platform server-side JavaScript framework, Node.js.[[6]](#footnote-6) At the heart of the CQL execution service is the open source JavaScript CQL execution library.[[7]](#footnote-7) This Apache-licensed library was integrated into the service along with several enhancements needed to fully support the pilot effort. The first enhancement consisted of a FHIR 1.0.2 (DSTU2) data source to allow the execution engine to operate on instances of FHIR data. The second enhancement allowed for value sets to be dynamically resolved via the Value Set Authority Center (VSAC) public APIs.[[8]](#footnote-8)

The CQL execution service’s implementation on Node.js allows for flexible deployment options, supporting Windows, Mac, and Linux environments. For the pilot at Alliance, the execution service was deployed on a Windows 2012 Server platform using PM2[[9]](#footnote-9) as a service-wrapper. This Windows 2012 Server instance also hosted the software components that invoked the CQL execution service, allowing for requests to be performed efficiently over unencrypted HTTP with no threat of exposing data. This single server supported all three Alliance pilot sites.

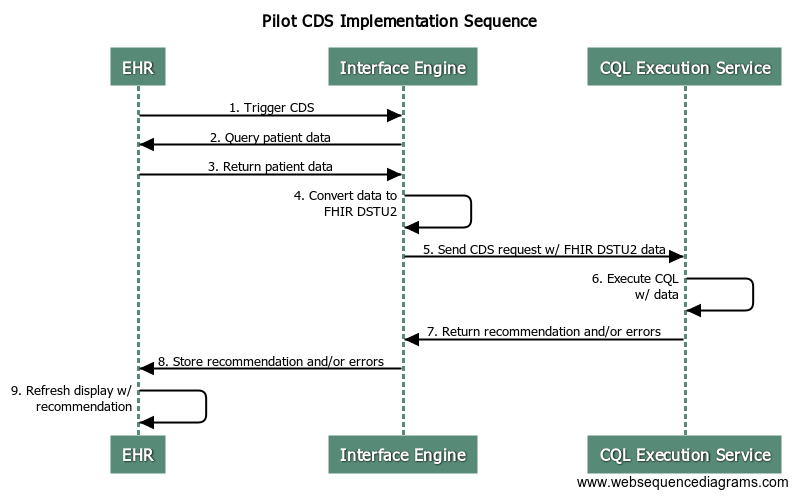
As the CDS Connect team developed the CQL execution service and refined the CDS artifact, it provided the Alliance team documentation updates regarding the software and the artifact. The RESTful service API was described in terms of necessary HTTP parameters, incoming request formats, and the expected response formats. In addition, each data element required by the artifact was listed along with its expected FHIR resource representation, including properties of interest. For example, the documentation indicated that LDL-C should be sent as a FHIR Observation, containing a code from a specific LDL value set; a status set to “final” or “amended;” a valueQuantity with “mg/dL” or “mmol/L” units; and a timestamp via an effectiveDateTime, effectivePeriod, or issued property. Alliance used this documentation to assess feasibility and begin development of the integration within their environment.

While the CDS Connect team was responsible for developing the CDS artifact and the CQL execution service that executes the CDS logic, the Alliance team was responsible for invoking the CDS with the correctly formatted data and displaying the results in the EHR user interface. This included several steps: triggering the CDS, retrieving and transforming the patient data, sending the HTTP request to the CQL execution service, parsing and storing the response, and displaying the results to the clinician in the EHR.

## Integration of CQL Execution into Clinical Workflow

The integration of the CDS by Alliance into their EHR served as a case study of the CDS implementation process by a healthcare institution. Alliance’s existing EHR already provided a DMA form, used for interacting with supported CDS components. Within that form, clinicians could click the Calculate 10-year ASCVD Risk Score or Framingham Risk Score button to perform a risk score calculation using the ACC/AHA[[10]](#footnote-10) or Framingham[[11]](#footnote-11) risk algorithms, and receive the correlated recommendation. As noted, the Alliance team modified the behavior of that button to remove the Framingham risk tool and instead invoke the USPSTF-based CDS artifact so that the more conservative USPSTF recommendation could also be provided. Thus, the Calculate 10-year ASCVD Risk Score served as the trigger for the risk score calculation *and* the USPSTF-based CDS artifact. It’s important to note that the USPSTF-based CDS did *not* perform the 10-year ASCVD risk score calculation itself, but rather, re-used the score already calculated by the ACC/AHA calculator.

Figure 4: Pilot CDS Implementation Sequence



Alliance implemented the primary interactions between the EHR and the CQL execution service using a commercial interface engine. The interface engine was necessary to support the exchange of FHIR DSTU2 formatted data, since the EHR did not support it natively. While many EHRs are actively working on FHIR support, this capability is often only available as a beta and/or at limited sites. As EHRs support FHIR natively in production environments, the use of an integration engine can be minimized or eliminated, resulting in increased accuracy of data and improved performance.

When Alliance’s EHR’s DMA form triggered a CDS request, it issued a web service call to the interface engine. This web service message contained basic patient information from the current clinical visit. Upon receiving the message from the EHR, the interface engine constructed JSON-formatted FHIR DSTU2 resources, as required by the USPSTF-based CDS, using custom JSON templates developed by Alliance. The interface engine populated these templates with the clinical visit data transmitted by the EHR, then queried the EHR database for additional data to populate the remaining fields. During the course of development and testing, these JSON templates were updated as bugs were discovered or new data requirements emerged.

Once the patient data was transformed to the required format, the interface engine built the request for CDS logic execution and sent it via an HTTP POST to the CDS execution service. This request contained all of the necessary data and parameters to execute the CDS for the given patient. Since Alliance does not allow Grade C recommendations in clinical practice, the CDS request also set the “GradeCRecommendationEnabled” parameter to *false*. This ensured that only the Grade B recommendation or higher would be considered for the response. In addition, the request specified that only a few expression results should be returned: “Recommendation,” “Rationale,” and “Errors.” These were the only expression values needed for the purposes of the integration, so all other expression values were purposely suppressed to simplify parsing and reduce storage requirements.

When the response was received by the integration engine, it segregated the unique data elements and posted them back to the EHR database, tying the results to the current office visit document. This allowed for the history of the CDS interaction to be maintained for further analysis or display, but was also necessary as part of the workflow to display the results in the user interface. Once the results were posted to the EHR, the form was refreshed, causing the new results to be displayed to the clinician. Due to a bug in the EHR software, however, clinicians sometimes experienced a lag between when the CDS was triggered and when the form was refreshed to display the results. One documented workaround for this lag was to switch to another tab in the EHR or toggle outside of the EHR and then go back to the original form, which would then show the data more quickly.

While the USPSTF-based CDS could be invoked via the main DMA form, Alliance also developed a specific USPSTF Risk Estimator tab within the form that provided additional details about the USPSTF CDS along with the current recommendation, rationale for selected risk score and recommendation, and educational tools for the patient. From a technical standpoint, this worked in the same fashion as described above. In addition, clinicians could perform *what-if* scenarios, tweaking individual patient data elements (such as HDL) to see how it would affect the risk score and, ultimately, the recommendation. Again, this worked in much the same way as described above, except that the temporary/notional data would be sent to the CDS execution service rather than the *real* data extracted from the patient record.

## Technical Integration Project Management

Throughout the course of development and planning of the pilot integration, the CDS Connect and Alliance technical teams met on a weekly basis to discuss requirements, architecture, technical approach, and outstanding issues. In addition, early versions of the CQL execution service software and CDS artifact were provided to Alliance for deployment in their test environment. Alliance reported that the CQL execution service software and CQL logic files were easy to install and update as needed. In this way, integration issues could be identified and resolved early, allowing for a smoother testing experience as the pilot launch date approached.

## Technical Integration Testing

The CDS service and the pilot CDS artifact were tested by the CDS Connect team throughout the development cycle. A comprehensive set of test cases and synthetic test patients was developed to exercise all data elements and branches of the CDS logic, including inclusions, exclusions, errors, and all potential recommendations. These tests provided assurance that the logic of the CDS was sound before beginning the formal pilot implementation and testing in the Alliance environment. An original plan involved Alliance downloading the pilot CDS directly from the CDS Connect Repository. Ultimately, the Repository development cycle was not able to support this. Therefore, the CDS Connect team shared the software code directly with Alliance, rather than pushing it through the CDS Connect Repository.

In the weeks prior to launch, the primary integration components were completed and a formal testing period ensued at Alliance. This testing effort was mainly manual, leveraging existing Alliance test data as a starting point. Synthetic test patients were loaded into the EHR and testers interacted with the system as a clinician would. When the CDS results were received, they were manually checked against the patient data to ensure correctness. In some cases, testers modified the test patient data to exercise edge cases or other situations that had not yet been tested. This testing period uncovered a few minor data transformation issues that were easily resolved. At the end of the test period, all cases were performing as expected and the pilot was formally activated and launched at the three pilot sites.

# Pilot Findings and Lessons Learned

## Pilot Outcomes

Through the pilot activities, the outcomes the CDS Connect project established were met. Through collaborative work with Alliance, the EHR utilized by the clinical pilot site was able to incorporate the pilot CDS into their system, achieving a successful technical integration. Through both artifact development and validation, and technical testing activities, MITRE confirmed that the pilot CDS launched when appropriate and both captured and shared information as designed by the artifact logic.

Through both the weekly EHR-based reports and clinician focus group, Alliance and the CDS Connect team learned that clinicians were using the CDS when appropriate and found that, as a pilot piece of CDS, there was sufficient merit to justify additional investment in maintaining and enhancing CDS built with the underlying USPSTF guidance on statin initiation. To that end, Alliance plans to keep the pilot CDS in production through, at a minimum, March 2018.

Finally, through the pilot work at large, the CDS Connect project gained information from Alliance and the clinical site to support the CDS Connect project CONOPS and enhance and validate the pilot CDS moving forward. Alliance leadership and technical team members engaged on the work of the CDS Connect Repository through direct participation in the Repository Work Group; providing input on meta-data fields, operational constructs, and design perspective from both a CDS “Consumer” and “Contributor” perspective.

## Focus Group Findings

MITRE conducted a one-hour virtual focus group on August 30, 2017. In attendance were fivePCP/APCs from the pilot sites that had regularly used the pilot CDS, as well as members of the Alliance leadership team. The virtual focus group was selected largely to accommodate the rural and geographically dispersed clinicians and their respective sites, and the project’s goal of being sensitive to the clinicians’ time and patient demand. The same CDS Connect team member that attended the pilot site visit in June served as the focus group facilitator. The facilitator utilized a question guide, while allowing for a naturalistic, conversation-based approach to obtain clinician feedback. Overall, the clinicians shared similar feedback and consensus regarding responses. While more detailed questions were asked of the clinicians, the nature of their feedback provided the information needed to address the pilot’s validation questions across the three domains of people, process, and technology.

### Reduced Clinician Burden

When asked if the pilot CDS reduced clinician burden, clinicians said that it did to some extent, but felt that ultimately, CDS, and the pilot CDS specifically, was best thought of as a helpful tool, especially as a conversation starter with patients, that still allowed them to decide if they would leave their EHR to visit a web-based risk score calculator of a like ASCD tool. While the goal of the pilot CDS was to remove the need for clinicians to leave their EHR for the calculator resource, some clinicians, at least some of the time, still engaged in this practice.

When asked about pilot CDS use, and the use of an outside ASCVD risk calculator, clinicians reported that the prior DMA was easier to use because it had a more transparent way of showing the conditions and other data elements that factored into the ASCVD risk score.

### Data Sharing

When asked for thoughts as to what conditions and data elements needed to be better shared, it was discovered that at least one clinician was unaware of the underlying reference material used for the pilot CDS (i.e., the USPSTF recommendation). Some clinicians seemed unclear on the differences between the recommendation criteria between the USPSTF and AHA/ACC guidelines (i.e., both consider diabetes, but the pilot CDS, per the USPSTF recommendations, does not automatically recommend a high intensity statin for all patients with diabetes).

Several important lessons came from this dialogue. One lesson learned is that clinicians may need customized, or at least repeated, trainings on both new CDS and the underlying rationale or clinical evidence supporting them, as part of the implementation process and before using them in a clinical encounter.

An additional lesson is that clinicians may need an opportunity to ask questions, or be presented with an opportunity to share their understanding of new CDS tools prior to, and during the early stages of, implementation of new CDS.

Finally, there was a lesson specific to the user interface for the pilot CDS; namely, that clinicians wanted more information on the standards, CDS, and their underlying basis in a quickly digestible format. While the pilot team worked to provide a robust level and nature of background information on the pilot CDS, we learned that more detail to allow for greater transparency into the logic of the CDS, could be of value.

An additional reason clinicians shared for augmenting or ignoring the pilot CDS was the lack of reliability concerning its execution (i.e., the time to produce a recommendation for statin initiation, not receiving a recommendation at all, or receiving recommendations that were different than an external, web-based calculator).

### Efficacy of CDS Results

In terms of the time to return a result, or the inability for the system to return a result, Alliance had shared a work-around. When the clinicians were asked about the work-around, some had not been aware of it, and some had tried it with inconsistent results. In terms of the varied results between the pilot CDS and external, like CDS tools, the clinicians did not have specific names of tools they could share, but agreed that the pilot CDS and the online tools may not be based on the same underlying logic (i.e., the calculator algorithm and the underlying filters and logic that yield a USPSTF-based recommendation statement).

Lessons learned from this exchange include the need for a consistent feedback loop between clinical management, clinicians, and health IT providers when new CDS is being proposed, when it is implemented, and again at regular, frequent intervals, to ensure any technical, clinical, or operational questions or issues are addressed.

It is important to note that in addition to an initial onsite training in June, led by an Alliance clinician leader and supplemented by training materials, including detailed information on the USPSTF recommendation statement, Alliance also provided a brief audio-only webinar that walked through the pilot CDS, an emailed FAQ, and the emailed work-around. Given the various trainings and guidance provided to the pilot site, and the resulting issues raised during the focus group, it is a valid lesson learned that additional touchpoints, including ones at the actual location of the clinicians vs. email or other digital formats, with practicing clinicians is needed for CDS to have a successful implementation. This lesson could be challenging to act on given the increasing demands on clinician time.

### Reconciling Guidance Conflicts

In the DMA’s user interface, both the ACC/AHA and USPSTF recommendations were made available to the clinician. When asked if, in cases of conflicting clinical recommendations, how did clinicians reconcile the guidance, the clinicians shared that they were comfortable with conflicting recommendations in part because of their ability to separate their own clinical expertise from the advice provided by the CDS (i.e., they knew it was a tool, rather than a substitute for clinical judgment). However, they would prefer more transparency into the reasons for the different recommendations to aid their reconciliation process or decide on a course of action.

### Alterations to Clincial Workflow

When asked if the pilot CDS altered their workflow, the clinicians responded that no changes to their workflow had occurred. This was a positive finding, as the pilot CDS was intentionally placed in the EHR in a location some clinicians had been using regularly, and for the same type of clinician decision support. When asked if the inclusion of the pilot CDS increases, decreases, or keeps consistent the amount of time you normally spend on the DMA module, clinicians felt they didn’t spend more time; but that if they did it was because they derived value from the use of the tool in that instance and were comfortable using their and their patients time in this way.

Additionally, clinicians shared that in some cases, they would run the pilot CDS more than once, and, in cases such as this, not during the patient’s in-person encounter. For example, the pilot CDS was occasionally run before or after the patient’s visit, for example, before a visit to determine priorities, or when new lab results come in and the ASCVD risk score or recommendation for statin initiation could change.

### Role of the Patient in CDS

The original pilot CDS development plan included a tool for shared decision-making, between clinicians and patients (or their caregivers), to be included in the pilot CDS to allow for clinicians to easily share the ASCVD risk score, recommendation, and rationale (i.e., the data elements that contribute to the risk). When the clinicians were asked about the role of the patient in the pilot CDS (e.g., did they share the screen view of the pilot CDS with the patient?) some clinicians shared that they do show the pilot CDS as well as the original Alliance CDS that addressed the ACC/AHA recommendation to their patients, as a way to start a conversation around modifiable risk factors for a non-fatal cardiovascular event in the next 10 years (e.g., blood pressure, smoking status). Other clinicians said that user interface of the EHR and the pilot CDS was not sufficient for clinician-patient interaction (e.g., there is too much detail, limited non-text visual representation, and no built-in ‘take-away’ for the patient). The clinicians shared that they would value a live connection to a printed handout (i.e., ‘take-way’) for the patient or caregiver that listed the recommendation(s) and underlying information, especially for areas the patient can change (e.g., quitting smoking, losing weight).

### Future of CDS

Finally, when the clinicians were asked if they wanted to keep the pilot CDS as is, keep it and invest more resources into improvements, or decommission it, the clinicians unanimously agreed to keep the CDS and invest in improvements. The clinicians shared that they appreciated the added information and felt it is valuable to them. The main areas in which they recommended improvements include ensuring the CDS works and the time to generate a recommendation is faster, that greater transparency into the underlying logic and clinical reasoning behind the CDS be made more prominent in the design, and that a patient-friendly ‘take-away’ resource be made available. Throughout the pilot, Alliance listened and noted areas where the pilot site clinicians felt improvements could be made to the pilot CDS. Through the MITRE collaboration, Alliance has the ability to maintain the pilot CDS in their EHR into March 2018.

## EHR Data Findings

During the 4-week live clinical pilot, 34 patient encounters (32 unique patients) employed the new CDS artifact. Alliance sent the CDS Connect team weekly reports of the encounters, including the output of the CDS, concluding with a final report of all recorded patient encounters using the CDS. Alliance verified that the CDS correctly fired for all patients based on the applicable inclusion and exclusion criteria.

It is important to note that the correct firing of the CDS meant that not every patient would receive a recommendation statement based on USPSTF guidance on statin initiation. Given the comparatively more conservative guidance from USPSTF, compared to ACC/AHA, many pilot site patients did not meet the inclusion or exclusion criteria to trigger guidance to initiate a statin.

Through the clinician focus group, it was identified that clinicians recognized this feature of the pilot CDS; however, they would have valued more clear reasoning as to why the particularpatient was not receiving a recommendation statement (e.g., patient does not meet the inclusion criteria of a risk score equal to or greater to 10 or blood pressure value does not meet the inclusion criteria). Figure 4 shows the number of encounters resulting in the three possible outputs of the CDS artifact.

It is interesting to identify that the majority of the times the clinicians utilized the pilot CDS to ascertain the USPSTF guidance on statin initiation for their patient, there was no recommendation provided. While the lack of a recommendation was not indicative of the pilot CDS not performing, it does show that not all CDS will be applicable to every patient.

Figure 5: Pilot CDS Recommendations by Encounter

Pilot CDS Recommendations by Encounter

## Key Lessons Learned and Future Recommendations

Many of the lessons learned throughout the pilot work were either already incorporated into the CDS Connect project or are included throughout sections of this report. However, there are some additional lessons learned that are worth noting.

The clinicians’ initial reactions to the CDS were positive. Not only did they learn about functionality of the DMA Tool they were not previously aware of, they also noted that they had looked up the same risk assessment tools on the internet and looked forward to having the USPSTF CDS embedded in their EHR. Through the pilot, we learned that having the tool in the EHR is not sufficient long-term. The clinicians, through the focus group, provided areas for future enhancement specific to the representation of the EHR in their system (i.e., clear and transparent logic). Additionally, clinicians liked the more conservative USPSTF approach and found it to be aligned with their clinical philosophy and patient needs. They also had other USPSTF guidelines they followed in their practice. For future work, the CDS Connect project and Repository could explore thematic groupings of like-CDS (e.g., source of evidence, so that “consumers” can download and monitor a “suite” of artifacts).

While the clinicians participating in the pilot valued the pilot CDS, they were more interested in how the information feeding into and coming out of the CDS could be displayed on screen or shared with the patient. While the pilot CDS and DMA user interface did allow for onscreen support for clinician and patient shared decision making, the pilot CDS interfaces and logic were complex. For example, clinicians had multiple tabs, two sets of guidance, and several EHR-based data elements to navigate on screen. This volume of data forced the interface to be largely textual and compact. The clinicians would have preferred a patient-facing view with imagery, or a handout with a subset of relevant information to walk through with the patient. In earlier designs of the pilot CDS a shared decision making visual was developed. However, due to limitations of the pilot site’s EHR, namely its ability to house robust graphics, this feature was paused in the CDS Connect project’s first year. The CDS Connect project and Repository could focus efforts on identifying not just CDS, but the wrap-around tools and resources that facilitate their use, for example, a re-imagined clinical visit summary that is graphical and comprehensible, as well as tailored to the patient.

The number of patients exposed to the pilot CDS was lower than anticipated. Reasons for this include the population in the pilot sites catchment area that utilizes a community health center, as well as some concerns with the pilot CDS (e.g., time lag, uncertainty of recommendations). Weekly checks on the number of patients exposed to the CDS were performed, and there was consideration to employ a proactive patient “recruitment” effort. Ultimately, MITRE and Alliance agreed to keep the pilot naturalistic, maintaining the real-world pilot CDS validation. Future pilot work would benefit from ensuring a larger sample size can be obtained for both clinician exposure and any desired research and evaluation work.

In discussions around the USPSTF-based pilot CDS, the idea to use it as a pre-visit or population health management activity was addressed. While not done for this pilot specifically, other clinical practices interested in the pilot or similar CDS could make modifications to the pilot CDS and test the tool across these additional use cases. The CDS Connect Repository could evaluate how best to provide artifacts that support this type of work and use of CDS in the future.

# Conclusion

This feasibility pilot achieved its goal in that it developed, refined, and verified that the MITRE-developed pilot CDS performed as expected in a live clinical setting, and the piloted USPSTF CDS was made publicly available on the beta version of the AHRQ CDS Connect Repository in August 2017.

There is substantial value in clinical, operational, and technical validation of newly developed CDS in the design, development, and piloting stages that occur prior to its public release. Due in part to the work of this pilot, Contributors to the AHRQ CDS Connect Repository will have the opportunity to share if their CDS has been validated or is in an experimental state; this provides potential “consumers” of the Repository with critical information when deciding how best to implement and test the CDS in their EHR.

Additionally, the three main objectives of the pilot were achieved through the work of the overall pilot team. Namely, MITRE engaged with Alliance and their Rural Community Health Center Networks to support the project and gain greater understanding of how the CDS Connect Repository could be utilized in clinical environments and the organizations that support them.

Through collaboration with Alliance, MITRE benefitted from Alliance’s technical, clinical, and operational expertise to enhance the project CONOPS and CQL-based CDS artifacts, making the pilot CDS a better reflection of the environment in which it was piloted. Finally, the objective to ultimately technically and clinically validate the pilot CDS in a live clinical environment was realized through the 4-week pilot period; direct clinician feedback was received through the pilot’s concluding focus group. Collectively, the goals and objectives of the pilot were well met and added value to the artifact development process and overall work of the CDS Connect project.

1. <http://tools.acc.org/ascvd-risk-estimator/#page_about> [↑](#footnote-ref-1)
2. <https://cds.ahrq.gov/cds/artifact/statin-use-primary-prevention-cvd-adults> [↑](#footnote-ref-2)
3. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/statin-use-in-adults-preventive-medication1> [↑](#footnote-ref-3)
4. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=400> [↑](#footnote-ref-4)
5. <http://hl7.org/fhir/DSTU2/index.html> [↑](#footnote-ref-5)
6. <https://nodejs.org/> [↑](#footnote-ref-6)
7. <https://github.com/cqframework/clinical_quality_language/tree/master/Src/coffeescript/cql-execution> [↑](#footnote-ref-7)
8. <https://www.nlm.nih.gov/vsac/support/usingvsac/vsacsvsapiv2.html> [↑](#footnote-ref-8)
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11. <https://www.framinghamheartstudy.org/risk-functions/cardiovascular-disease/10-year-risk.php> [↑](#footnote-ref-11)