CDS Connect

Contract Year 1
Final Report

Final Contract Report

CDS Connect

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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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Acknowledgments

Executive Summary

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to produce evidence to make health care 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 priority areas of focus are for improving health care quality by accelerating implementation of patient-centered outcomes research (PCOR). Further, AHRQ is focused on making health care safer, increasing accessibility to health care, and improving health care 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 from stakeholders, including physicians, providers, patients, and commercial vendors of health IT focused on CDS about the value of the information and the assistance provided.

CDS provides patient-specific information and knowledge, enabled by health IT, to clinicians, patients, or other individuals to enhance health and health care. CDS includes processes and mechanisms that aim to deliver the right information, to the right person, using the right format, in the right channel, and at the right time during workflow (often referred to as the "5 Rights" framework). Well-implemented CDS can improve health care processes. AHRQ has launched an initiative that fulfills its ACA requirements related to PCOR and CDS.

The goals of the initiative are to advance evidence into practice through CDS and to make CDS more shareable, health IT standards-based, and publicly available. This effort includes the following components:

1. Engaging stakeholders to catalyze the development and use of PCOR-based CDS throughout the health care system and provide CDS developers and stakeholders with constructive advice and feedback.
2. Developing prototype infrastructure to develop and share CDS, including coded clinical knowledge, implementation guides, and a publicly accessible repository of CDS resources or "artifacts."
3. Advancing CDS research through demonstration and dissemination grant funding opportunities.
4. Evaluating the overall initiative.

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. As part of this work, this 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.

The CDS Repository is a web-based software service that offers structured data, aggregated resources, and the ability to leverage the international standard Clinical Quality Language (CQL). Through the CDS Repository, CDS contributors and CDS consumers have equal access to knowledge driven by cutting-edge research in CDS, as well as clinical and regulatory standards. Additionally, organizations that work to balance limited resources are able leverage advanced technical resources and secure information critical to the CDS implementation process.

The CDS Connect Project has convened two advisory Work Groups (Cholesterol Management and CDS Repository) consisting of CDS subject matter experts from across government, industry, academia, clinical settings, and non-profits. These Work Groups guide the development, implementation, and inclusion of cholesterol management CDS artifacts while providing ongoing collaboration in support of AHRQ's commitment to developing a repository with the features and functions critical to the CDS community.

The CDS Connect project also supported the design and development of a prototype CDS Authoring Tool that leverages interoperable standards so that CDS can be written to common specifications. This capability was designed to be intuitive and easy to use, with the purposes of reducing provider burden. By making it easier to compose and express CDS artifacts, this software improves the quality of CDS design, accelerates the velocity of CDS development, ensures open access to supporting CDS resources, and enables integrated software systems for interoperable CDS.

This CDS Connect project has resulted in a proof-of-concept that will lead to the increased use of findings in clinical healthcare practice. This work is providing 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.

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Introduction

The Agency for Healthcare Research and Quality (AHRQ) is charged with producing evidence to make health care safer, better, and 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 produced is understood and, most importantly, utilized. One AHRQ priority is to improve health care quality by accelerating the real-world clinical implementation of patient-centered outcomes research (PCOR).

AHRQ has requirements related to disseminating PCOR findings and clinical decision support (CDS). CDS provides patient-specific information and knowledge to clinicians and others using health information technology (IT). AHRQ support users of health IT and CDS by incorporating PCOR findings into clinical practice. In addition, AHRQ helps to establish a process for receiving feedback from stakeholders, including providers, patients, and vendors about the value of the information and the assistance provided.

AHRQ asked the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC) to help launch a new initiative to promote the dissemination and implementation of PCOR findings. Specifically, AHRQ tasked CAMH to generate a systematic and replicable process for transforming PCOR findings into shareable, health IT standards-based, and publicly available CDS, and to develop prototype tools to facilitate this transformation process.

The MITRE Corporation (MITRE), as the operator of the CAMH FFRDC, supported AHRQ with this project, which includes the development, implementation, and integration of health information tools, products, and systems. This project, named "CDS Connect," aims to improve the quality of CDS design, accelerate the velocity of CDS development, ensure open access to supporting CDS resources, and enable integrated software systems for interoperable CDS "artifacts" to support the dissemination of PCOR CDS artifacts to U.S. healthcare practices and associated health IT developers.

Figure 1: CDS Connect Project Logo

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.

The specific aspects of the CDS Connect project are outlined in the seven tasks enumerated below. These tasks were selected as they share an opportunity to leverage the team's knowledge of standards, software, and processes in the health IT domain relating to clinical decision support.

1. Task Management
2. Develop a PCOR CDS "Repository"
3. Develop PCOR CDS Artifacts
4. Pilot PCOR CDS Artifacts
5. Establish Stakeholder Work Groups
6. Host and Maintain Prototype Tools
7. Develop a Prototype CDS "Authoring Tool"

Table 1: Key Project Activities and Work Products

Task	Key Activities	Key Work Products
1	• Leadership Meetings • Administered Sprint Planning and Burndown Meetings • Led Sponsor Engagement, Staff Management, and Deliverable Management • Conduct meetings and calls with Stakeholders to share the CDS Connect project; Tracked Stakeholder Engagements for knowledge management and strategic outreach • Developed a Concept of Operations (CONOPs) to orient stakeholders to the work	• Leadership Meeting Agendas and Briefings Sprint Planning and Burndown Meeting Minutes • CDS Connect Briefings and Conference Presentations • Stakeholder Engagement Logs • CONOPs visualization

Task	Key Activities	Key Work Products
2	• Formed a multi-disciplinary Task team of developers, requirements analysts, governance experts, and design specialists • Investigated the USHIK Platform and compared to Drupal (versions 7 and 8) to determine how each tool addressed several categories of requirements (browse, search, review, edit, help, user management, reporting) • Completed Iterative Development of Repository Metadata • Completed Iterative Design of Custom Drupal Theme • Completed Configuration of Drupal, including the configuration and deployment of a RESTful application programmers interface (API)	• Live web-based Beta CDS Connect Repository https://cds.ahrq.gov/ • CDS Connect Repository code base (Drupal configurations, custom Drupal theme, Custom seed scripts, and Build automation scripts) • USHIK and Drupal Analysis • CDS Connect Systems Document • CDS Connect Service Level Agreement • CDS Connect Draft Repository Governance Documentation
3	• Formed a multi-disciplinary Task team including a clinician, a value set expert, and a group of developers who could create and formally test CQL • Conducted and documented an Environmental Scan on CDS in Cholesterol Management • Secured Intellectual Property approval for artifacts published on the CDS Connect Repository • Determined appropriate clinical guidelines and their related value sets to inform development • Developed semi-structured CDS artifacts (e.g., de-abstraction and disambiguating statement to create human-readable logic) • Documented artifact work via a series of Decision Logs (and annotated code) and Implementation Guides • Developed CQL logic including the development and execution of an automated CQL testing framework in addition to manual, line-by-line quality review	• Environmental Scan • Intellectual Property Report • 6 Semi-Structured and Structured Artifacts for publication on the CDS Connect Repository • Artifact Decision Logs • Artifact Implementation Guides • Enhanced Artifact Report

Task	Key Activities	Key Work Products
4	• Facilitated AllianceChicago subcontract planning and management • Led Kick-off work shaping meeting, onsite at AllianceChicago • Held Operational and Technical calls at weekly and bi-weekly intervals at key points in the project • Completed CAMH and Chicago Department of Public Health Institutional Review Board Process • Created Data Request Form • Conducted Pilot site visits and project briefing; clinician consenting • Completed development of pilot technical integration, as outlined in the Pilot Report deliverable	• Signed AllianceChicago contract and associated Statement of Work • IRB applications, participant consent forms, and subsequent approvals • De-identified study database • Focus Group Questions and Responses • Signed clinician consent forms • Designs and clinical content for the Disease Management Advisor
5	• Recruited Work Group members • Developed and shared respective Work Group Charters • Identified a Chairperson for each Work Group • Determined availability of Work Group members and cadence for the meetings • Developed and disseminated monthly agendas and meeting summaries • Collaborated via email and offline conversations to further project objectives	• Work Group charters • Work Group agendas • Work Group meeting minutes • Public Release Approval for meeting summaries, published on the CDS Connect Repository • List of Work Group members and their organizations
6	• Code review and evaluation of the USHIK codebase • Hosting infrastructure	• Development plan using the open-source Drupal content management system

Task	Key Activities	Key Work Products
7	• Conducted Sprint Planning and Burndown Meetings • Completed Authoring Tool Development and Testing • Hosted Authoring Tool Demos • Developed Authoring Tool API to the CDS Connect Repository	• CQL Authoring Tool code base (alpha release) • Post-Alpha Design Concepts • Post-Alpha Plan for Moving to Beta • Export to Repository API Documentation • Service Level Agreement • User Guide • 508 Compliance Report • Exported CDS Artifact for USPSTF guideline: Statin Use for the Primary Prevention of CVD in Adults, and Test Report • Exported CDS Artifact for Statin Therapy for Prevention and Treatment of Cardiovascular Disease Electronic Clinical Quality Measure and Test Report

Task Reports

Task 1. Task Management

1.1. Operational Leadership

The CDS Connect project's tasks were managed through the establishment of a Leadership Team that included a Project Leader (PL), Associate Project Leader (APL), Technical Lead, Clinical Lead, and respective Task Leads. The Leadership Team met throughout the period of performance to ensure work objectives were met and that emerging opportunities were discussed, prioritized, and integrated when appropriate. As warranted, the CDS Connect team worked with AHRQ to schedule and conduct both virtual and in-person site meetings at AHRQ; in-person meetings included formal agendas, which served as formal deliverables. This project was aided by several subcontractors, including Dr. Blackford Middleton, AllianceChicago, and Involution Studios.

In addition to Leadership Team meetings, the CDS Connect Project was managed through bi-weekly agile "Sprints." Sprints were planned and reported on at the beginning and end of a 2-week sprint interval. Sprint meetings included AHRQ government leadership team, the CDS Project team, and MITRE's subcontractors. One of the project's formal deliverables was the documentation of Sprint meetings and the submission of meeting notes to AHRQ. All Sprint activities were tracked using Jira. Jira is AHRQ's web-based planning and execution tool that provides support for implementing agile software development processes, and transparency around the development of new features and functionality of the CDS Connect project.

All CDS Connect project members were provided with the ability to access and edit tasking in Jira. The CDS Connect PL or APL would review and assign work in the Jira project board in advance of meetings to ensure status updates and add, remove, or modify tasks to manage project scope and execution. This agile approach and these tools provided value for AHRQ for ensuring high-quality work. Further, this approach allowed for better planning and management of the competing prioritization of new capabilities with the CDS Connect software systems.

1.2. Stakeholder Engagement

Significant outreach took place across the CDS Connect project and influenced the development and refinement of CDS artifacts, the CDS Repository, and the Authoring Tool. The CDS Connect project utilized both formal and informal stakeholder engagement. Formal stakeholder engagement occurred through the standup of two Work Groups that are detailed further in this report. Informal Stakeholder Engagement occurred throughout the project through in-person and virtual outreach and dissemination efforts (e.g., webinars, conference calls, conferences, presentations). These informal communications were tracked throughout the project and have been shared as an informal deliverable.

For external-facing efforts, the CDS Connect project team engaged with both existing and potential supporters and sponsors of the CDS Connect Repository and CDS Authoring tool. These engagements were tracked through two informal deliverables: a stakeholder engagement log in Microsoft Word, and an abbreviated 'quick sort' version in Microsoft Excel. A standard point of entry in discussing the work was the review of the CONOPs (Concept of Operations). The CDS Connect team uses a CONOPS as a visual to illustrate the key role and the flow of information with the system. The CDS Connect project also engaged in several information dissemination activities, including conferences and related presentations.

The CDS Connect project team used both formal and informal external-facing stakeholder engagement strategies to pursue relationships with both existing and potential supporters and sponsors of the CDS Connect Repository and Authoring Tool. Formal stakeholder engagement occurred through the establishment and operation of two Work Groups: one focused on Cholesterol Management, and another focused on the CDS Repository. Various members of the two Work Groups made informal suggestions and referrals on additional organizations to pursue relationships with about the CDS Connect Repository and Authoring Tool.

The type of outreach conducted to these organizations included introductory calls about the AHRQ CDS Connect Project and live demonstrations of the CDS Connect Repository's and Authoring Tool's capabilities throughout their various stages of development via web-sharing platforms, and in-person meetings and conferences, such as the 2016 National Academy of Medicine Annual Meeting and the 2017 Health Information Management Systems Society (HIMSS) Conference.

Ongoing relationships were developed and maintained with a variety of stakeholder groups, including Federal agencies (i.e., Health Resources and Services Administration [HRSA], Center for Medicare & Medicaid Services [CMS] Center for Medicare and Medicaid Innovation [CMMI], and Veterans Health Administration [VHA]); academic institutions (i.e., Arizona State University, University of Michigan, and Yale University); clinical decision support vendor organizations (i.e., LogicNets and Practice Fusion); healthcare provider organizations (i.e., Boston Children's Hospital, and Children's Hospital of Philadelphia; a quality improvement organization (i.e., Quality Insights of Pennsylvania); and a patient advocate (e-Patient Dave). These engagements were tracked through two informal deliverables: a Stakeholder Engagement log in Microsoft Word, and an abbreviated 'quick sort' version in Microsoft Excel.

An additional stakeholder relationship that has both formal and informal elements is that with the PCCDS-LN, which is a 'sister' project to CDS Connect and also funded by AHRQ. This engagement occurred throughout the project through in-person and virtual outreach and dissemination efforts by AHRQ and CAMH (e.g., webinars, conference calls, conferences, presentations). These informal communications were tracked throughout the project and have been shared as an informal deliverable.

A standard point of entry in discussing the work with various stakeholders was the review of the CDS Connect project's CONOPs that used visuals to outline key CDS Connect roles and the flow of information.
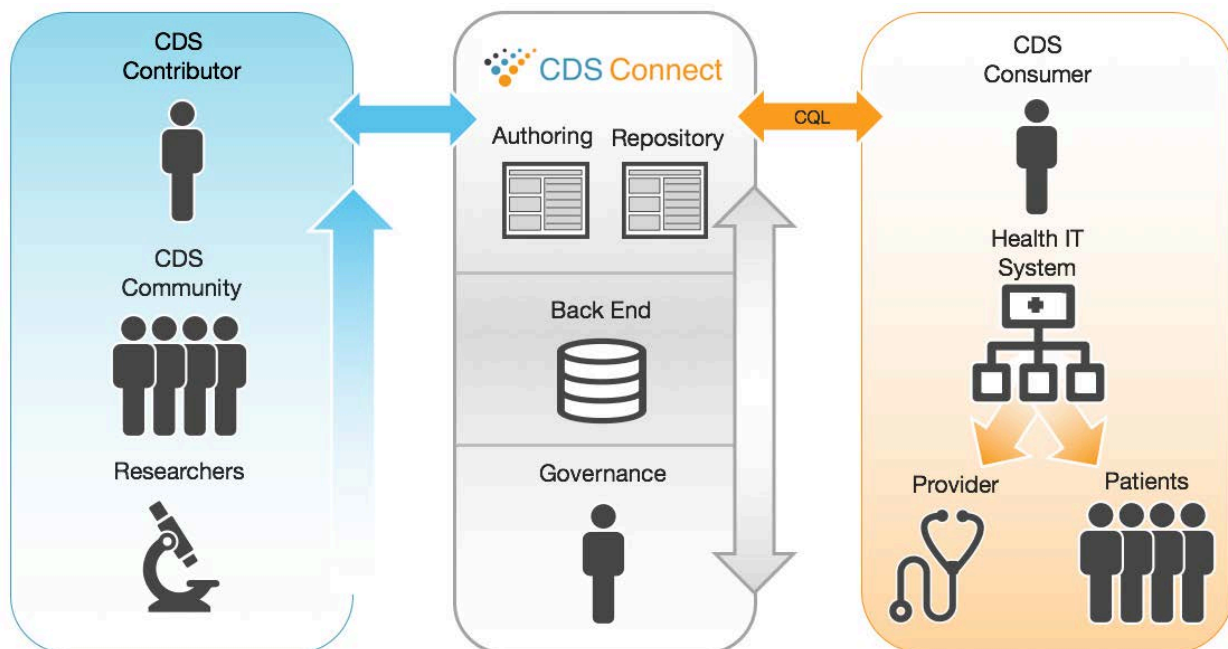
Figure 2: CDS Connect Repository Concept of Operations

Task 2. Develop a PCOR CDS Repository

The centerpiece to the CDS Connect project is a web-based "CDS Repository" for hosting, discovering, commenting on, and integrating CDS artifacts with software systems. CDS artifacts themselves will be described in greater detail in Task 3. The unique advantage and approach that this CDS Repository brings is an interoperable way to express and integrate the logical details of the CDS artifacts. Interoperability was recognized as important based upon past lessons learned and is supported via the Health Level 7 (HL7) Clinical Quality Language (CQL) standard. It provides a more "plug-and-play" approach to integrating CDS logic with commercial products.

To support this CDS Repository, MITRE designed and developed a web-based service that allows users to identify, curate and integrate CDS artifacts. This service is designed to speed the time between the availability of clinical evidence and its implementation in clinical practice. By mandating that the CDS Repository be both publicly available and available without cost to users, this project aims to support providers and provider organizations across the resource spectrum in utilizing evidenced-based CDS.

In addition to the publication of CDS artifacts, the CDS Repository provides resources and a structure that not only supports the provision of computer-interpretable CDS "artifacts," but a broader dissemination and sharing of CDS, and the processes required to develop and implement it (e.g., development, implementation, results of testing, feedback about use, decisions, and assumptions).
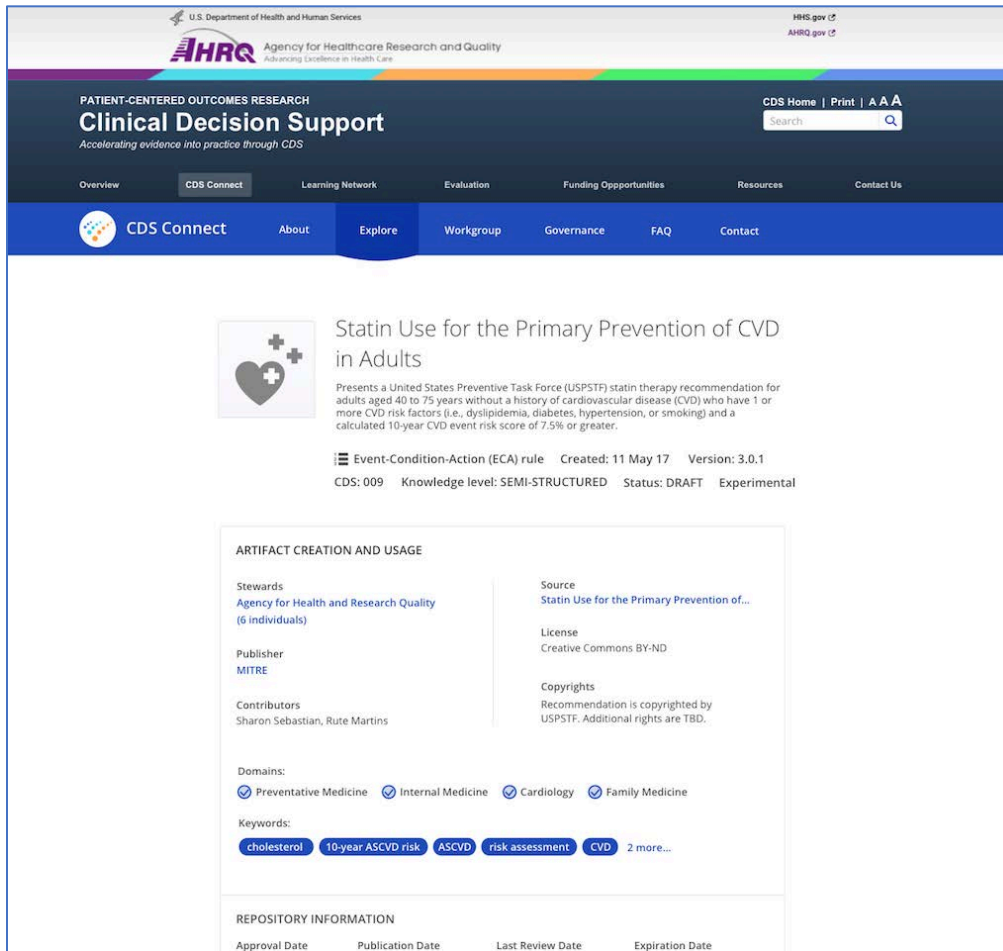
Figure 3: CDS Repository Beta Artifact View

The CDS Repository embraces an agile and iterative software development process. This approach reinforces a collaborative, responsive, and user-friendly experience. The CDS Connect project team researched a range of software development tools, which led to a final recommendation to use the Drupal content management platform. Through a detailed and collaborative analysis, AHRQ agreed to MITRE's recommendation to utilize Drupal v.7 due to its built-in functionality as a content management system and then transitioned to Drupal v.8 to take advantage of v.8's enhanced collaboration tools to support versioning of changes of CDS artifacts over time. To improve visibility and reinforce brand identity, a custom Drupal theme was designed and implemented, which is the only custom code developed for the Repository.

Repository development focused on determining the key features and functions needed to achieve AHRQ and larger CDS community stakeholder goals. Through interviews, research, and a range of stakeholder discussions, as well as iterative design development to meet the needs of multiple users, MITRE developed and implemented a series of features and functions that are live on the Beta version of the Repository. Key features of the CDS Repository include: 1)

versioning, 2) uploading of CDS artifacts produced by external stakeholders, 3) viewing and downloading various tracked versions of those artifacts.

As illustrated in the CONOPs, the CDS Repository is designed to serve as the meeting and collaboration place for both contributors and consumers of CDS. To enable both the processes and digital spaces to achieve this, MITRE identified and developed a preliminary Governance framework that will support key roles or permissions for the CDS Repository that are detailed below:
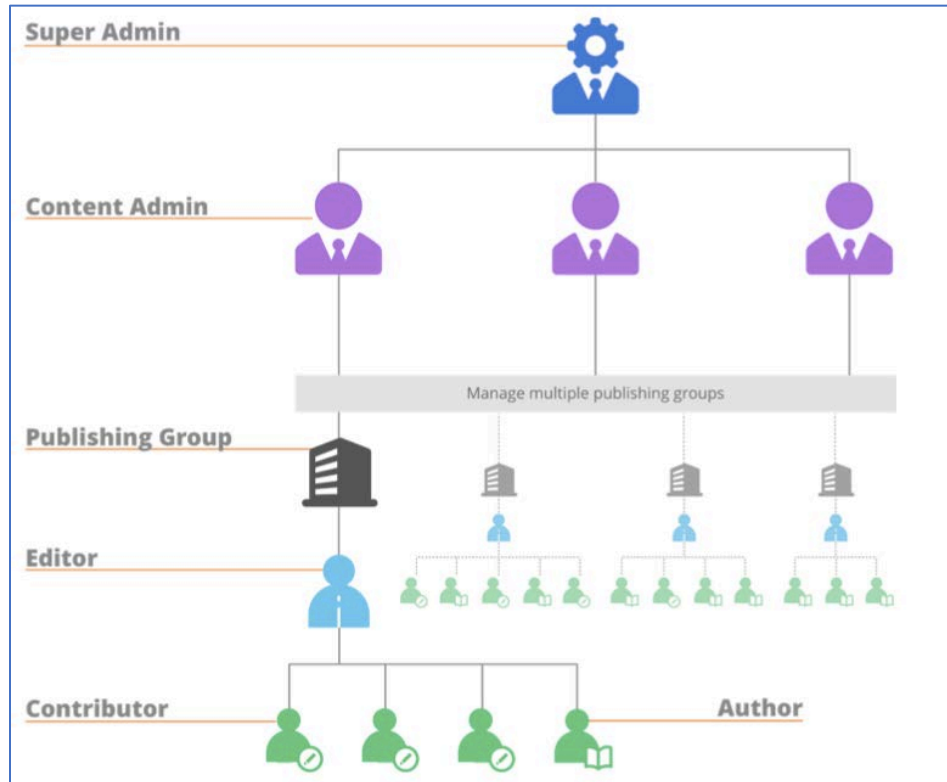
Figure 4: CDS Connect Governance Framework

Each task in this project has inputs and outputs to the others; for example, the CDS Repository was shaped early on by the artifact development process. Through MITRE developing CDS, starting with a guideline and working through the transformation logic-driven, computable, and implementable CDS, the Repository was built to support real-world use cases and corresponding meta-data fields. Through frequent feedback with Work Group members and the broader team, the organization and grouping of meta-data fields were iteratively enhanced.

A RESTful Application Programmers Interface (API) for the CDS Repository was developed, configured, and deployed in the Beta release of the CDS Repository to allow for ease of interoperability with other services and systems. Lastly, the CDS Repository has been developed in accordance with the AHRQ publishing and communications guidelines.

Task 3. Develop PCOR CDS Artifacts

Key goals of the CDS Connect project include ensuring that the Repository creates the right space for CDS contributions, and information required for a potential Repository user to determine if they will view and download a piece of CDS. To achieve these goals, MITRE worked through the artifact development process several times, starting with clinical guidelines and quality measures, and transforming them to computable CDS. Through these repeated processes, which included soliciting guidance and feedback from the project's Work Groups and pilot partner, MITRE developed several semi-structured and structured CDS artifacts in the domain of cholesterol management. The cholesterol management domain was selected based largely on results from a MITRE-conducted environmental scan of CDS related to cholesterol management, and the finding that there were several underlying evidence-based knowledge sources in which to build out CDS.

Another key goal of the project is to support data interoperability. To achieve this, MITRE utilized an emerging HL7 standard for trial use, the CQL standard, as the basis of the coded CDS artifacts. CQL artifacts are electronic health record (EHR)-agnostic and thus interoperable on an international level. Additional data standards were considered in the artifact development process, and were presented to AHRQ leadership in the form of a CDS Connect Standards briefing, which was submitted as an informal deliverable.

Significant effort was made by MITRE to align standards and making the CDS interoperable to re-purpose previous investments from HHS programs with EHR systems. Other standards and interfaces were considered, such as CDS Hooks, SMART on the Fast Healthcare Interoperable Resources (FHIR), and other procedural languages for expressing logic such as Drools. MITRE felt that the CDS Connect focus on the CQL standard compliments these other efforts, and does not exclude other efforts to integrating CDS with health IT systems. Further, the selection to emphasize the CQL standard was deliberately made to compliment CMS' efforts to pivot to the CQL standard for expressing Clinical Quality Measure logic as part of programs CMS oversees.

This alignment and harmonization with the CQL standards and the Clinical Quality Measures should reduce the software developer requirements for commercial vendors. This should benefit healthcare providers and reduce their burden by focusing on a consolidated number of standards harmonized for provider use cases and their clinical workflow.

In addition to the inherent utility of the completed artifacts, MITRE's experience during the development process is being documented and shared via the CDS Connect Repository to provide procedural insight to CDS developers and related stakeholders. The artifact development process yielded several documents that are housed on the CDS Repository and demonstrate the process by which clinical guidelines can be successfully transitioned to interoperable, computable CDS artifacts and shared using the CDS Repository (and provide an example to potential contributors to the Repository).

During MITRE's environmental scan, two major sources of clinical guidance for cholesterol management and statin were identified. This included clinical guidance from the American College of Cardiology (ACC) and the American Heart Association (AHA), and another source from the U.S. Preventive Services Task Force (USPSTF). Further, MITRE identified adoption of work that built upon the ACC/AHA infrastructure for the Million Hearts program. Both sets of guidance were pursued by MITRE for artifact development. Further, the USPSTF had recommendations on aspirin use.

Throughout this process, MITRE leveraged the input of both CDS Connect Work Groups, but particularly the cholesterol management Work Group. At the end of the base year of this contract, MITRE published six CDS artifacts. These are detailed later in Table 2.

Because of timing issues resolving intellectual property around the use of the ACC/AHA work that was built into the Million Hearts program, involvement of the ACC/AHA algorithms could not be supported in MITRE's pilot. Instead, the pilot activity involved the use of just the USPSTF CDS and their recommendations for thresholds around statin use due to considerations to Arteriosclerotic Cardiovascular Disease (ASCVD) risk.

The USPSTF Statin Recommendation Grade B[1] artifact was pilot tested in a live clinical environment. In partnership with the AllianceChicago, MITRE was able to establish a process by which an experienced CDS team with the clinical, process, and technical knowledge required could identify where the behavior of a CDS artifact needs to be changed, enhanced, or addressed. Targeted feedback was used to update the statin artifact based on the USPSTF recommendation and broader feedback was incorporated into Implementation Guides to support future artifact developers.

3.1. Clinical Content Selection and CDS Development Approach

MITRE was tasked with the creation of several semi-structured and structured CDS artifacts in the domain of cholesterol management to demonstrate the process by which clinical guidelines can be successfully transitioned to interoperable, computable CDS artifacts and shared using the Repository. An Environmental Scan of cholesterol management clinical guidelines and relevant CDS efforts was conducted and delivered by MITRE to inform this activity. The scan identified two major sources of clinical guidance for the prevention and treatment of cardiovascular disease (CVD) and cholesterol management:

- ACC/AHA statin therapy recommendation statements
- USPSTF statin therapy and aspirin therapy recommendation statements

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[1] Grade B indicates that the USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. Additional details available: https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions.

In addition, two unique and important clinical items were identified to serve as source content for artifact development:

- Million Hearts Longitudinal Arteriosclerotic Cardiovascular Disease Risk Tool (created through a joint effort of the ACC/AHA, Million Hearts Initiative and the CMS
- CMS347v1: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease electronic Clinical Quality Measure (eCQM)

The Cholesterol Management Work Group validated each PCOR source as high-value content that would enhance provider decision making as CDS and prioritized the development of several artifacts based on their potential to support key clinical decisions.

Next, each concept or statement was "atomized" by extracting single concepts from the narrative text and de-abstracted or disambiguated to translate the clinical intent of the text in to a clear, specific statement that could be coded (i.e., ages "40-75" became "≥40 and ≤75," and "dyslipidemia" became an "LDL-C lab result >190 mg/dL").[2]

Once each concept was more clearly defined, a semi-structured representation of the source material was created to outline inclusion criteria, recommended interventions and actions, and exclusion criteria (if provided in the source content). When necessary, additional clinical concepts (e.g., diagnosis, lab values) were added as CDS exclusions by the MITRE Team (based on Work Group feedback) to ensure recommendations were provided only when clinically appropriate and safe.

For example, pregnant and breastfeeding women were excluded from receiving statin recommendations. This activity was indicated if/when source clinical content did not provide comprehensive details to evaluate complex patient scenarios and comorbidities. Decisions made throughout the development of the semi-structured representations were catalogued to provide insight and transparency to viewers and are included in the Implementation Guide (IG) that accompanies each artifact.

Implementation Guides were created for clinicians, quality leaders, and health IT leaders from healthcare institutions and delivery networks who wish to browse, download, and implement the artifact. They are also available to patients, family caregivers, and health IT application developers making similar use of the artifact. The IG is a companion to the artifact files, and provides guidance and clarification as the artifact is configured and implemented in diverse computing and healthcare environments.

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[2] Tso GJ, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. AMIA Annu Symp Proc. 2016; 2016: 1189–98.

Each IG describes the clinical purpose of the artifact; a summary of the original clinical statement or source content; details of how that statement was converted into semi-structured and structured form, including clinical decisions that make the statements unambiguous and computable; a description of key primary and alternate use cases, describing in detail how the artifact might be triggered and presented in various scenarios; a description of the artifact-related files found in the Repository; and an overview of testing, implementation steps, and potential for reuse of the artifact in other contexts.

A multidisciplinary MITRE team collaborated to transform semi-structured artifact representations into structured code. The team included individuals with clinical expertise to ensure the intent of the recommendation statement was expressed, individuals with terminology and value set expertise, and several developers who authored the structured code and corresponding automated tests.

3.2. Structured Definition of CDS Connect Artifacts

Two CDS Connect artifacts are expressed as structured representations (i.e., code that is interpretable by a computer, including data elements, value sets, and logic). These artifacts were authored using: 1) HL7 CQL, which enables point-to-point sharing of executable clinical knowledge as human-readable language; and 2) the FHIR Draft Standard for Trial Use 2 (DSTU2) data model, which is built on ubiquitous proven web technologies and is supported by many vendor systems.

Value sets posted in the Value Set Authority Center (VSAC) were assessed by clinical subject matter experts (SMEs) to determine if the listed codes met the clinical intent of the logic. When necessary, new value sets were created to properly convey the concept, and the new expression was validated by the Cholesterol Management Work Group. Ultimately, specific codes or value sets were selected to represent each data element referenced in the logic. The declaration of value sets, codes, and concepts in the CQL code complies with [CQL Specifications](#) and standards. The URL for each value set in VSAC is provided in a comment above each value set declaration to ensure accessibility to the component codes.

A CQL Library was created to capitalize on capabilities of the CQL standard after numerous CDS logic patterns were identified. The library (i.e., CDS_Connect_Commons_for_FHIRv102) enabled developers to reuse common functions, reducing repetitiveness and improving consistency across the artifact itself, as well as across different artifacts entirely. The library utilizes the FHIR DSTU2 data model and implements common functions using attributes available in the stated version. In addition, the CDS Connect team developed a library for unit conversions of CQL elements *(*i.e., the CDS_Connect_Conversions Library*),* which implements common functions used when converting units of a value. Both libraries can be added to future artifacts and expanded to include additional functions.

Artifact logic was broken into three sections for organizational purposes. The first two sections calculate the population of patients who meet the inclusion and exclusion criteria for the CDS artifact. MITRE-developed libraries perform most of the required filtering, sorting, and conversion of data elements. CQL logic in these sections closely reflects the logic described in the "Inclusion" and "Exclusion" sections of the semi-structured representation.

The final section of CQL logic defines the interventions outlined in the CDS artifact. This section utilizes the population determined by the Inclusion and Exclusion logic and creates new logic for any subpopulations. When applicable, the recommendation and rationale for each subpopulation was defined. In addition, errors were specified for instances when missing or old data are identified to provide relevant information to the clinical user. These errors are defined separately from each recommendation so they can be handled differently when implemented in an EHR.

To provide additional transparency to individuals considering implementation, the CQL code was annotated to provide contextual decisions and highlight parameters that might be adjusted by each unique end user.

3.3. Artifact Testing and Quality Review

Unit tests using Mocha and Chai test frameworks were written alongside each CDS artifact to ensure CQL code correctly calculated the intended population, logic, and recommendations. The tests utilized synthetic patient data to validate the reliability and validity of CQL code based on how each test case evaluated against defined logic. Tests were performed automatically, each time a change was made to CQL specifications, to ensure the updated code performed as expected.

Prior to public release, a quality review of each artifact was performed by the Artifact Development Team to ensure that the semi-structured and structured CDS representations aligned with the intent of the recommendation statement or source content. Reviews included evaluation of value set selections, clinical and verification status definitions, lookback periods, parameters, lab values, and alternative expressions of a clinical concept (i.e., pregnancy as an active Condition *and* an Observation within the past 42 weeks). Items put forward by the Cholesterol Management Work Group (i.e., specific wording of notification messages) were double checked along with each item that made the CDS expression deterministic and computable. CQL code annotations were added, when indicated, to ensure contextual decisions were provided in key sections of CQL code. Items identified for revision were re-reviewed by the full multi-disciplinary team. Once validated by all, the artifact was approved for upload to the Repository.

3.4. Artifact Enhancements, Constraints and Status

The USPSTF Statin Use for the Primary Prevention of CVD artifact was further enhanced beyond its initial structured representation during integration testing for the pilot implementation of the artifact. Results of the testing highlighted data elements and clinical scenarios where the CQL code did not evaluate relevant data captured in patient charts. Collaboration with pilot site clinicians and data analysts, along with insight provided by the Cholesterol Management Work Group, led to enhanced specifications that reliably evaluated patient records and generated appropriate notifications. The full list of enhancements is outlined in the Enhanced CDS Artifact Based on Pilot Experience formal deliverable.

Of note, securing intellectual property (IP) clearance to express and post the source content as CDS was identified as a significant barrier to artifact development and sharing. Despite early and ongoing engagement with organizations that authored the source content, MITRE and AHRQ legal counsel encountered significant delays in realizing approvals. In some cases, approval is still pending (i.e., source content authored by the ACC/AHA). Thus, development of artifacts derived from ACC/AHA recommendation statements were placed on hold and work products are not posted on the Repository.

The complexity of the IP process and resultant impact on the nine artifacts that MITRE intended to develop is outlined in the formal AHRQ CDS Connect Artifact Intellectual Property Resolution Plan deliverable. Lessons learned regarding IP constraints are included in the associated section below.

According to the framework for transforming clinical guidelines into CDS artifacts by Boxwala, et al.[3], there are four levels of expression:

1. **Narrative** text created by a guideline or CQM developer (i.e., the recommendation statement described as a sentence).
2. **Semi-structured** text that describes the recommendations for implementation as CDS, often created by clinical subject matter experts. It serves as a common understanding of the clinical intent as the artifact is translated in to a fully structured format by software engineers.
3. **Structured** code that is interpretable by a computer and includes data elements, value sets, and coded logic.
4. **Executable** code that is interpretable by a CDS system at a local level. This code will vary for each site.

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[3] Boxwala AA, Rocha HB, Maviglia S, et al. (2011) A Multi-Layered Framework for Disseminating Knowledge for Computer-based Decision Support. J Am Med Inform Assoc 2011;18:i132ei139. doi:10.1136/amiajnl-2011-000334.

The status of each CDS artifact developed during the initial period of performance for the CDS Connect project in the cholesterol management clinical domain is outlined in Table 2: "CDS Artifacts" as detailed below.

Table 2: CDS Artifacts

Author of PCOR Source Content	Name of Each Artifact Derived from the Source Content	Level of Expression	IP Approval
USPSTF	Statin Use for Primary Prevention of CVD in Adults	Structured	Yes
USPSTF	Aspirin Therapy for the Prevention of CVD and Colorectal Cancer	Semi-structured	Yes
Million Hearts® (in conjunction with ACC/AHA and CMS)	Longitudinal ASCVD Risk Assessment Tool for Baseline Risk Assessment	Semi-structured	Yes
Million Hearts® (in conjunction with ACC/AHA and CMS)	Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making	Semi-structured	Yes
Million Hearts® (in conjunction with ACC/AHA and CMS)	Longitudinal ASCVD Risk Assessment Tool for Updated Risk Assessment	Semi-structured	Yes
CMS (based on ACC/AHA recommendations)	Statin Therapy for the Prevention and Treatment of CVD via an electronic Clinical Quality Measure	Structured	Yes
ACC/AHA	Statin Therapy for Primary Prevention Based on 10-Year ASCVD Risk with Diabetes	N/A	Pending
ACC/AHA	Statin Therapy for Primary Prevention Based on 10-Year ASCVD Risk without Diabetes	N/A	Pending

Key Challenge Area 1: Selecting, Using, and Reconciling Sources for CDS Artifact Development

1.1. Selection of clinical recommendations for development of CDS artifacts intended for broad dissemination and use can be impaired IP restrictions. Verifying and appropriately addressing IP restrictions on guidelines that are copyrighted or licensed can be very resource-intensive and IP restrictions may not be overcome. IP then becomes an important consideration for the selection of clinical recommendations that can be used to develop and publicly post CDS artifacts. Early engagement with organizations that hold IP restrictions on CDS source content is imperative. When possible, use of public domain, creative commons, or open source licensing agreements should be utilized. Guideline developers should consider eliminating or streamlining licensing restrictions for open CDS artifacts to facilitate guideline adoption.

1.2. The development of comprehensive, meaningful, and easily consumable CDS artifacts is impaired by overlapping and sometimes conflicting or incompatible clinical recommendations provided by different organizations. Published clinical recommendations can target overlapping populations and provide conflicting and/or incompatible advice. For example, in the cholesterol management domain, ACC/AHA and the USPSTF define different cardiovascular risk thresholds for the use of statin therapy. A long-standing challenge in the CDS space is that different clinical recommendations from different sources and user preferences resulted in the creation of more fragmented, source-specific artifacts. Ultimately, the choice of which artifact to use, and whether to provide the option to use different recommendations, are implementation decisions that lie beyond the specification of an individual CDS artifact. Additional work is needed to determine how single-source artifacts can be more easily integrated and parameterized to meet individual organizational needs (e.g., allowing for an organization to set the cardiovascular risk threshold to align with ACC/AHA or USPSTF).

1.3. Guidelines are often missing critical information required for the development of complete and accurate CDS artifacts. Future-oriented guidelines should strive for a comprehensive characterization of target (and excluded) populations and, where possible, precisely define clinical concepts to avoid down-stream misinterpretation.

1.4. Operationalization of clinical recommendations in CDS artifacts requires extending the original guideline or recommendation with the input of domain experts. The development of CDS artifacts requires heavy parsing of the narrative, and extension of explicit guideline content. According to a 2011 IOM report[4], trustworthy clinical practice guidelines should (among other things) "be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups." This recommendation addresses a specific, pervasive issue in implementing clinical practice guidelines in a production setting; the existing narrative form of

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[4] https://www.ncbi.nlm.nih.gov/books/NBK209538/.

many clinical guidelines does not contain the entirety of medical and technical knowledge necessary to make the clinical guidelines immediately usable by established health IT systems.

While it is understandable that not all clinical concepts lend themselves to precise, quantitative definitions, computable CDS artifacts must extend guideline content and create operating definitions based on the interpretation of the guidelines. Filling in these gaps and resolving ambiguities can require domain-specific clinical judgment, as well as technical knowledge of knowledge representation standards, including vocabulary standards.

Key Challenge Area 2: CDS Artifact Specification

2.1. Defining the scope and focus of individual artifacts is a user-driven exercise. Some users might want to use a cardiovascular risk calculator alone, while others may want to see recommendations based on risk calculation from different guideline developers reconciled and unified under a single artifact. The varied user needs must be weighed against the complexity of artifacts, which affects both understanding and ease of implementation.

2.2. Artifact development is a non-linear, iterative process, where atomization, de-abstraction, and disambiguation of clinical recommendations intertwines with clinical workflow integration, and the representation of recommendations using encoded variables and computable logic. Despite comprehensive efforts to atomize, de-abstract, and disambiguate clinical recommendations prior to building logical statements, the process of encoding variables and developing logic statements uncovered gaps that required additional disambiguation and de-abstraction of clinical concepts (e.g., missing timeframes for patient's HDL laboratory test, or whether the most recent blood pressure measurement is most appropriate to take into consideration). The specific representation of clinical variables in standard vocabularies, such as SNOMED-CT, also pose clinical questions, for instance (e.g., which Fredrickson classification of primary hyperlipidemias represents familial hypercholesterolemia?).

2.3. Developing usable CDS artifacts requires tradeoffs between completeness and simplicity. Attempting to explicitly model every clinical scenario can exponentially increase the number of variables and complexity of artifacts, raising the effort to embed artifacts in a production environment. Lowering the implementation burden requires adjusting weighing the value of the CDS intervention for a broader target population vs. the effort required to identify that population, as well as the potential unintended consequences of missed intervention opportunities and misdirected recommendations. For instance, patients in the target population for statin therapy may have comorbidities that impact the decision to use statins. A CDS artifact that removes these patients from the target population may miss the opportunity for a clinician to consider statin therapy, whereas including these patients in the target population can present a recommendation that might be contraindicated in a specific patient scenario. Ultimately, these considerations can be a matter of user preference, and it is possible that a CDS artifact developed for broad use does not serve the individual needs of an organization. Therefore, it is important

that all decisions must be carefully documented, and the artifact behavior must be justified to the users, and provide flexibility for easy modification at the point of implementation.

2.4. Documentation of decisions during artifact development is paramount. One of the most difficult aspects of developing CDS artifacts is to interpret the information provided by guideline developers. Similarly, CDS implementers look for the reasoning behind CDS artifact specifications, especially when they extend guideline recommendations, or consider scenarios not accounted for in the original recommendations. Including this information in a contextual way, for example, as comments in CQL code, can lower the effort of interpretation and increase implementer confidence in the CDS artifacts. In addition, implementation guides can be useful to convey higher-level information on the relationship between artifacts, or artifact-wide decisions and guidance.

2.5. CDS artifact integration with clinical workflow and EHRs must be considered throughout the development process. When parsing clinical recommendations for representation in a computable format, it is possible that not all atoms and disambiguated statements are available in EHR implementations today. The use of clinical variables or elements that are not readily available in EHR systems can create gaps that are difficult to address in implementation. To mitigate these downstream issues, artifacts must consider not just the clinical evidence, but also ease of implementation. This may involve identifying proxy variables for variables that are not readily available in EHRs, or keeping variables that would be too difficult to obtain from structured fields out of CDS artifact specifications.

Key Challenge Area 3: Considerations for Standards-Based, Reusable CDS Artifacts

3.1. Standards-based CDS artifacts designed for broad use must account for variations in implementation and workflows. For this reason, standards-based CDS artifacts can be more complex than custom-developed CDS artifacts targeted for specific implementation environments, because they account for several options in representing clinical concepts and scenarios, not all of which may be used at a single clinical site.

3.2. Alignment across artifacts requires active vigilance. A modular approach to artifact development with the use of tooling can sustain alignment. It is exceedingly easy for related artifacts to drift from each other, depending on the sources used for artifact development and the individuals developing the artifact logic. When artifacts encode the same logic or concepts in different ways it adds to the maintenance effort. It also causes confusion and added burden for implementers. Using a "building-block" approach to artifact development required additional effort in the beginning to identify and specify overlapping logic to suit multiple purposes, but can eliminate downstream errors and burden. The principles of modularity and reusability can be extended to unrelated artifacts, as well as value sets used to represent clinical elements. By using the CDS authoring tool, developers can ensure consistency across CDS artifacts with relatively low effort.

3.3. The CQL standard lends itself well to the representation of target populations and logic statements, but additional standards are needed to comprehensively represent CDS artifacts. CQL is an emerging standard developed to support the needs of the clinical quality improvement community (including clinical decision support and quality measurement). CQL excels in the representation of logic statements to identify target populations and to represent complex calculations, such as the Million Hearts cardiovascular risk calculator. However, other aspects of CDS artifacts can be better represented in standards specifically designed to represent knowledge artifacts, including aspects such as metadata and usage information, as well as specific interventions. The FHIR Clinical Reasoning Module is an example of an emerging standard designed to accommodate the definition of CDS triggers, actions, and metadata in a structured, concerted way. Future work should explore the integration of CQL artifacts with knowledge artifact standards such as the FHIR Clinical Reasoning Module.

3.4. When CDS and eCQM artifacts address the same clinical concern, consider reusing concepts and logic. However, the differing nature of these artifacts may prevent reuse. Because the applications of these artifacts have different purposes, it may not be appropriate to completely mirror the clinical variables and logic statements from one to the other. For instance, the statin eCQM focused on events happening over the course of a long period of time, whereas a CDS artifact is concerned with point-in-time events. Similarly, because the eCQM can be used to hold providers accountable, portions of the target population for an intervention are removed from the measure population, but in some cases, it may still be valuable to present the clinical recommendation for these patients.

3.5. Identifying appropriate existing value sets available in the VSAC to encode clinical variables is a challenging and resource-intensive process. This is due to several issues associated with published content and available tooling:

- There is no mechanism to determine which value sets are deprecated and should no longer be used, or those that are under development and should be used with caution; this adds to the burden of identifying appropriate value sets.
- There can be an array of value sets representing the same or very similar concepts; VSAC content is managed in silos by individual users or organizations, with some coordination for certain programs, but no overall governance or curation process.
- Many value sets are missing metadata, requiring reverse engineering of the content to understand appropriateness for reuse.
- There is no tooling available to compare and reconcile value set content; VSAC provides some metrics of similarity, but these do not provide sufficient information to make an informed decision about which value set is most appropriate.
- VSAC does not provide contact information for value set stewards, which can limit collaboration and clarifications about value set status and intent.

3.6. Despite the availability of numerous value sets to represent clinical concepts, some gaps continue to exist that require the creation of additional value set content. Due to lack of clarity on whether value sets are actively maintained, or inappropriateness or incompleteness of existing value set content, it may be necessary to create additional value sets. These can be used to complement existing content, and should be created as a measure of last resort.

3.5. Artifact Development Summary

The present work on artifacts has demonstrated that simple and complex clinical guidance can be transformed into computable, precise, understandable, flexible artifacts at the L2 and L3 levels. Further work on CDS artifact development, coding, and documentation can enhance the power of CDS Connect for both content suppliers and content consumers. Recommendations for further work include increasing the range of CDS content covered, providing for greater specification of CDS presentation and operation, helping with porting artifacts to EHRs and other health IT tools, and making the process for new submissions as simple and efficient as possible.

Regarding range of content, artifact development has currently focused on clinical guidelines and guidance statements, primarily expressed to end users as Event-Condition-Action artifacts (typically shown as alerts), and complex clinical formulas, expressed as relevant data summaries with calculated summary values. These are two of at least 10 CDS presentation types[5]; among the other types most commonly in use are order sets, filtered reference information (infobuttons), and parameter guidance. Further work could include reviewing and refining the artifact development process to ensure that it covers these additional types of CDS.

In addition, currently developed artifacts have focused on ambulatory care-oriented quality measures and guidance, particularly proactive disease-prevention guidance that is normally processed at the start of a patient encounter. Another large source of CDS worthy of sharing is reactive CDS, used in both the ambulatory and acute care setting to guard against prescribing errors and to respond quickly to critical test results. Further work could include exploration to ensure that these situations are handled by the methods already developed, or to adjust as needed.

CDS presentation and operation often makes the difference between successful and unsuccessful implementation of a CDS artifact. This includes best practices for when in the clinical workflow a given artifact should be triggered; what information should be displayed for the user; what suggested actions, such as recommended orders or documentation elements, should be offered; and what structured and unstructured responses a user could enter, including coded and efficient ways to document exceptions. Some of these are already included to some extent in the current artifact specification, but enhancement and expansion of this capability will make it much more

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[5] Osheroff JA, Teich JM, Levick DA et. al., Improving Outcomes with Clinical Decision Support: An Implementer's Guide. Chicago: HIMSS Press, 2012. 323pp.

likely that an artifact that has been successful at one clinical site will succeed at others. A National Quality Forum report specified some of these elements, and could conceivably be used as source material for such an enhancement[6].

Any artifact supported by CDS Connect will have its ultimate clinical expression by being embedded within a clinical EHR using that EHR's standard toolset, or by being embedded in other health IT tools accessible to clinicians and patients, such as self-assessment applications, or by being expressed as a web service that can be accessed from other health IT through a standard interface. Even though artifacts are written in the flexible and general CQL, additional specification of the artifact may be important to facilitate the practical transfer of the artifact to some of these destinations. A standard API for importing CQL into local CDS modules is not yet common in commercial EHRs; further work to understand the API elements is necessary, and to specify them in artifacts could encourage EHR suppliers to support such a common API.

Additionally, CDS Connect artifact development to date has been meticulously crafted by clinical, content, and technology experts who are very familiar with the available tools, value sets, and specification languages. Further work could be devoted to streamlining these tools, including developing templates and wizards and other aids to ensure that content contributions can be submitted by many different CDS submitters as easily and accurately as possible.

Finally, spirited collaboration should continue with government, public, and private groups who have existing CDS content that they are willing to share, and work should continue to enable Repository contributions in varied CDS formats to expand the array of clinical domains and artifact types.

Task 4. Pilot PCOR CDS Artifacts

The work of this project was meant to provide a real-world approach to the development and implementation of clinical decision support. As part of this work, MIITRE contracted with AllianceChicago, a health IT service provider for a national network of Federally Qualified Health Centers. A key aspect of this contract was the multidisciplinary approach and inclusion of clinical leaders, operational and research leadership, and a diverse team of software engineers, clinical informaticists, and data analysts, in addition to the ultimate users of the MITRE CDS: the clinicians at the pilot site.

AllianceChicago identified a community health center within their network of Federally Qualified Health Centers (FQHCs) with three clinical locations in the rural, western region of the U.S. to serve as its pilot site. AllianceChicago selected this FQHC system due to the number of patients the site serves that meet the inclusion criteria for the CDS and the anticipated population

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[6] National Quality Forum, Driving Quality and Performance Measurement – a Foundation for Clinical Decision Support: A Consensus Report. Washington DC: NQF, 2010.

that would access an adult visit during the pilot. AHRQ, MITRE, and AllianceChicago visited the pilot sites in June 2017 in preparation for the pilot's July 2017 launch. CDS Connect and AllianceChicago leadership provided an overview of the CDS Connect project, pilot goals, and the clinical provider consent process to all physicians and advance practice clinicians. In addition, they delivered training on the new CDS user interface and underlying difference between the USPSTF and ACC/AHA recommendation statements and corresponding CDS. The trip concluded with visits to the three clinical sites where the pilot would take place.

The pilot had three main objectives: 1) engage a CDS consumer in the work of the CDS Connect Repository; 2) utilize the pilot organization's technical, clinical, and operational expertise to enhance the project's CONOPS and in-development CDS artifacts; and 3) technically and clinically validate the MITRE-developed CDS artifact in a live clinical environment and provide feedback to inform both the artifact and the overall project. Based on the availability of secured intellectual property and added value to AllianceChicago, MITRE, AHRQ, and AllianceChicago elected to pilot the MITRE-developed artifact *Statin Use for the Primary Prevention of CVD in Adults* (USPSTF artifact)[7], based on a USPSTF guideline[8], to pilot in a live clinical setting.

To allow for live, clinical testing and the potential publication of both the pilot process and resulting artifact validation, both MITRE and AllianceChicago secured Institutional Review Board (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 IRB's granted approval on May 17, 2017, and May 24, 2017, respectively.

4.1. CDS Connect Repository Engagement

AllianceChicago leadership and technical team members engaged in 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. While an initial goal was to leverage the pilot site to utilize the Repository to download and version a MITRE-developed artifact, significant delays related to intellectual property surrounding source material for the artifact prevented this level of involvement.

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[7] https://cds.ahrq.gov/cds/artifact/statin-use-primary-prevention-cvd-adults.
[8] https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/statin-use-in-adults-preventive-medication1.

4.2. The Role of the Pilot Site in Development

Technical Development

To provide the AllianceChicago EHR with the USPSTF artifact, both organizations' technical teams developed or customized software. The USPSTF artifact was authored using the HL7 CQL[9] to represent logic, and HL7 FHIR[10] to represent clinical data. The EHR in use at AllianceChicago 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.

Pilot efforts included developing custom code to successfully integrate the MITRE-developed CDS with GE Centricity, the EHR used by AllianceChicago's sites. This custom code was a piece of software designed to translate AllianceChicago EHR outputs into a format the MITRE-developed CDS could understand, and then return to the EHR CDS-generated output. This effort involved identifying the API to access the EHR data, determining the method of converting data or API to FHIR, writing CQL, and accessing AllianceChicago's build environment. Throughout the course of development and planning of the pilot integration, the CDS Connect and AllianceChicago operational and technical teams met on a weekly basis to discuss requirements, architecture, technical approach, and outstanding issues.

Clinical Development

The underlying utility of the USPSTF artifact (i.e., providing a 10-year ASCVD risk score and evidence-based recommendation to the clinician concerning statin initiation) was already employed in the AllianceChicago EHR through the inclusion of two, similar CDS tools. The AllianceChicago's existing tools were included in a modular form in the EHR that was visible when an adult visit was in view. This form, the Disease Management Advisor (DMA) Form, and the associated CDS, was triggered by clinician action only. Within that form, clinicians could click the Calculate 10-year ASCVD Risk Score button to perform a risk score calculation using the ACC/AHA risk algorithm[11], 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 AllianceChicago network more broadly, the FHS option was rarely utilized. Therefore, AllianceChicago elected to decommission the FHS section of the DMA, and replace it with the USPSTF artifact.

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[9] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=400.
[10] http://hl7.org/fhir/DSTU2/index.html.
[11] http://tools.acc.org/ascvd-risk-estimator/#page_about.

The complete DMA allowed for several tabs (i.e., 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 AllianceChicago 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'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. While the USPSTF-based CDS could be invoked via the main Disease Management Advisor Form, AllianceChicago 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.

4.3. Validation of MITRE-Developed CDS

Throughout the artifact development process, AllianceChicago 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, AllianceChicago 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 AllianceChicago team also provided a weekly clinical review of patient encounters that the USPSTF artifact had been run on through clinician action. This review ensured that the artifact performed as expected and clinicians were utilizing the CDS correctly.

After the pilot, MITRE, AHRQ, and AllianceChicago team members conducted a virtual focus group with the AllianceChicago clinicians that consented to participate in the pilot. Focus group questions focused on the clinician experience with the CDS, their thoughts on the clinical and patient utility of the CDS, and insight into the incentives and barriers that the clinicians faced regarding the CDS.

MITRE also identified research and evaluation questions to be answered during the pilot. MITRE worked with AllianceChicago 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). AllianceChicago provided MITRE with de-identified data to support ongoing research and development work as part of the artifact development process.

Task 5. Establish Stakeholder Working Groups

A key task for this project was the establishment and operation of two distinct Work Groups; one that focused on the clinical domain for this project (i.e., the Cholesterol Management Work Group) and another that leveraged expertise in the technical and informatics space (i.e., the Repository Work Group). Work Group members were identified through MITRE and AHRQ contacts, and members were permitted to join at any time.

MITRE was successful in standing up both Work Groups at the beginning of the project, which included the establishment of a charter that detailed the workgroup goals, objectives, governance structure, and operational procedures and maintained active participation in the Work Groups through the end of the period of performance. Both Work Groups were asked to self-select a Chairperson to work alongside a MITRE leader-facilitator. The Chairperson was responsible for co-creating a monthly agenda with MITRE leadership and co-facilitating Work Group meetings.
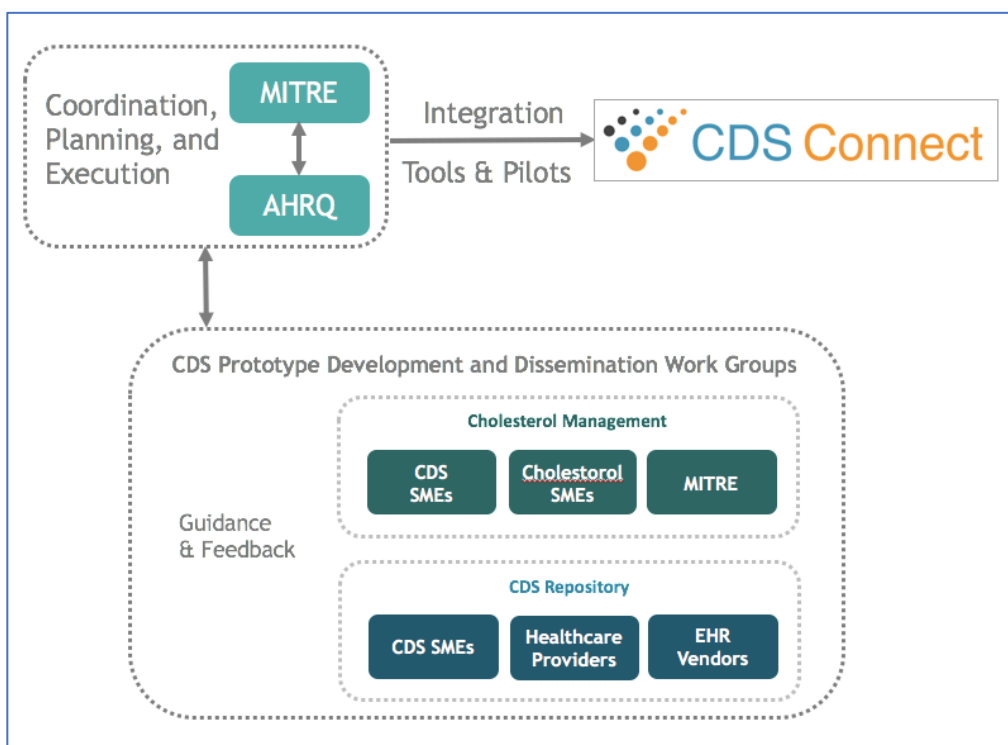

Figure 5: Work Group Governance Structure

MITRE convened these Work Groups to solicit expert feedback and properly ground the other work products. The Cholesterol Management Work Group was formed to support MITRE in developing a deeper understanding of the available, relevant clinical guidelines and how best to interpret and operationalize them. This Work Group provided recommendations for several topic areas associated with CDS artifact development such as documentation requirements; appropriate use cases and scenarios; clinical quality measurement and artifact alignment;

inclusion, exclusion, and trigger criteria for various artifacts; and future clinical domains for artifact development. The Repository Work Group was formed to understand the needs of artifact developers and end users in the context of an open, web-based CDS tool. This group provided recommendations for several topic areas associated with the CDS Connect Repository such as approaches for illustrating various domains of a CDS artifact (e.g., level of efficacy, implementation in a clinical setting, and level of popularity amongst end-users), display and versioning of metadata, governance structure, and design specifications (e.g., information landing pages and page navigation capabilities). The group also provided considerations and recommendations for the Authoring Tool such as design concepts for downloading CQL, and various work space tabs (e.g., inclusions, exclusions, recommendations, and errors). Work Group agendas and meeting summaries are located on the [CDS Connect Repository.](#)

Work Group meetings were held to drive decisions to consensus, but assertions of opposing views were encouraged to ensure that all parties were properly heard and to strengthen the consensus view through subsequent discussion. Both the Repository and Cholesterol Management Work Groups held virtual, 1.5-hour monthly meetings with additional feedback provided through follow-up emails and calls where necessary. Collaboration between both groups occurred via periodic sharing of both Work Group's activities to all the Work Group members via both Work Group meetings and at the 2017 HIMMS Conference CDS Connect Work Group Summit.

Clinical and technical Work Group members acknowledged the difficulty of developing a CDS artifact. This validated the time and skill demands that the Repository seeks to reduce. Furthermore, the Cholesterol Work Group acknowledged the challenge of defining a logic expression that can evaluate patient data captured in diverse formats across EHR systems and clinical settings. This challenge confirmed the need for rigorous integration testing prior to implementation. In addition, Work Group insight expanded the demonstration of how each artifact could be used to serve alternative use cases (i.e., population health, management of patient panels) with minor adjustments to the expression logic. These suggestions were incorporated into each Implementation Guide.

Both Work Groups provided valuable insight that informed work efforts across all CDS Connect tasks. Discussions did not always lead to consensus across attending members, but the varied opinions prompted thoughtful consideration of each alternative, which enriched decisions made throughout the project. Decisions related to artifact development are catalogued in the Appendix of each Implementation Guide to provide transparency of the rationale behind each decision.

Task 6. Hosting and Maintaining Prototype Tools

This task supports the PCOR CDS Repository task by making it accessible through AHRQ-provided IT infrastructure. It establishes MITRE's responsibilities with regard to hosting and managing the CDS Repository, maintenance of code, and required updates to the Repository.

The key goal of this task was to establish an operational version of the PCOR CDS Repository hosted on AHRQ provided IT infrastructure. This includes a review of the existing AHRQ USHIK system to determine the feasibility of code and capabilities to support the PCOR CDS Repository, and an evaluation of the open source options for creating the CDS Repository. Training and technical assistance to users of the PCOR CDS Repository is another goal for MITRE. CDS artifacts created by MITRE were to be made available in nationally recognized and interoperable data standards.

At the start of the task, MITRE conducted a thorough code review and evaluation of the USHIK codebase, and proposed a development plan using the open-source Drupal content management system. This proposal was accepted, and development of the CDS Repository took place using the Drupal CMS. Initial alpha release of the CDS Repository was made using the Drupal 7.x release, and this was upgraded to Drupal 8.x for the Beta deliverable.

MITRE was granted access to the AHRQ-provided IT hosting infrastructure through Acquia Cloud, a cloud-based server to support Drupal-based websites. All instances of the PCOR CDS Repository were hosted and made available through this hosting environment. All code deployed to the hosting servers was committed to the AHRQ Bitbucket Repository.

MITRE has maintained, updated, and patched the software for the PCOR CDS Repository, and all and patches have been committed to the AHRQ Bitbucket Repository. MITRE has documented in the Service Level Agreement (SLA) the technical support needed for the CDS Repository, and the description of updating and maintaining the code developed for the CDS Repository. MITRE has created and posted CDS artifacts using the CQL (Clinical Quality Language) standard. These have been uploaded to the CDS Repository as attachments with all necessary support files bundled into a .zip file for downloading.

Task 7. Prototype CDS Authoring Tool

MITRE was tasked with building a prototype CDS Authoring Tool to allow a user to compose CDS artifacts based on one or more PCOR findings, including interfaces with the NLM Value Set Authority Center (VSAC) and the CDS Connect Repository. Ultimately, the intent of the Authoring Tool is to allow people unfamiliar with CQL to develop structured, well-formatted CQL artifacts with a friendly user interface and to facilitate sharing of consistently developed, standards-based CDS for reuse across organizations.

Much like the rest of the project, the CDS Authoring Tool team relied on conventional Agile processes for project management, including regular project planning and burndown meetings (separate from the CDS Connect project planning and burndown meetings). As part of the Agile framework, the CDS Authoring team practiced rapid prototyping, building a minimally usable product as quickly as possible to gain end-user feedback and learn valuable lessons about the tool's fitness for purpose.

The CDS Authoring tool is currently open access. It does not support user accounts, authorization, or roles. In both Beta and production versions, user accounts will be required. This will allow users to construct artifacts that are only available to their account and prevent users from editing or removing artifacts that they don't own. The Authoring Tool has been used to construct the CAMH CDS logic for the USPSTF guideline: Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication and the CAMH CDS logic for the Statin Therapy for Prevention and Treatment of Cardiovascular Disease (CVD) eCQM. As the tool moves to Beta, other artifacts will need to be evaluated to determine if there are additional capabilities that are required to support a variety of artifacts.

The CDS Authoring Tool and the CDS Repository are both involved in the development, authoring, and publishing of a CDS artifact. The alpha version of the Authoring Tool provides basic integration with the Repository. As the Authoring Tool and Repository move into production, a more seamless integration will need to be developed. The integration will provide a coherent and consistent workflow between the two tools to fully construct and publish an artifact. This may require single sign on between the two tools and a consistent look and feel between the tools. Additionally, being able to navigate to the Authoring Tool from within the context of creating an artifact in the Repository may be required.

The CDS Authoring Tool also integrates with the National Library of Medicine (NLM) Value Set Authority Center (VSAC) services. For the Alpha version of the CDS Authoring Tool, integration with the VSAC service is through the inclusion of value set identifiers in the CQL generated for an Artifact. The value set identifiers included in the CQL are identifiers defined and managed by VSAC.

The VSAC service provides endpoints that allow the value set identifiers to be expanded to the set of clinical codes defined by that identifier. For the Alpha version of the CDS Authoring Tool, the expansion of value sets using the VSAC service occurs during the execution of the authored artifact. The use of the VSAC service in coordination with the Authoring Tool was done through testing of artifacts.

To ensure the artifacts produced by the CDS Authoring Tool are complete and accurate, a set of automated tests were developed. Artifacts were constructed using the CDS Authoring tool for the MITRE CDS logic for the USPSTF guideline: "Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication" and the Statin eCQM guideline: "Statin Therapy for the Prevention and Treatment of Cardiovascular Disease" artifacts (CVD). MITRE manually constructed the CDS logic for these artifacts in Task 3 and developed a suite of unit tests to validate the accuracy of the manually developed logic.

This set of automated tests developed for the manually constructed versions of the artifacts were run against the CDS logic exported from the CDS Authoring tool. This testing demonstrated that the construction and export of the artifact from the CDS Authoring tool is complete, accurate,

and consistent with the manually constructed version. It also showed that the value set identifiers defined in the CDS artifacts constructed by the CDS Authoring tool can be used with the VSAC service to effectively expand the associated value sets and execute the artifacts.

Future versions of the Authoring Tool will provide a user interface for creating new data elements and choosing from value sets defined in VSAC. This will extend the integration of the CDS Authoring tool and the VSAC service.

Lessons Learned

Through the CDS Connect project's base year, several valuable lessons were learned that both impacted the work of the base year, and provided critical information with which to plan for the project's second, optional year.

1. The CDS Community is exploring the full life cycle of CDS (i.e., from source material through validated CDS). In part, this means the inclusion of detailed artifact development resources will support early stage CDS developers as well as end-stage CDS implementers and evaluators. Of note, several Federal Government agencies expressed continued interest in leveraging the project work for Federal clinical decision support initiatives.
2. MITRE demonstrated the CDS Connect tools and received demos of CDS from a wide variety of stakeholders. The MITRE-developed CDS was on par with that being used in leading academic medical centers. The lesson learned is that there are likely many clinical organizations that lack sufficient CDS, so the MITRE-developed CDS, even if it is at a Level 2 or early 3 stage, could be a significant support to others.
3. Utilizing a web-development tool (i.e., Drupal) that could quickly adapt to iterative design and development was a good decision. As the audience for CDS Connect grows, the ability to reflect the needs and wants of users will be high-value.
4. The CDS Connect Repository is one of many types of CDS tools. Through various interactions with multidisciplinary stakeholders, we've learned how critical it will be for greater stakeholder involvement.
5. The CDS Connect project elected to choose Cholesterol Management as its domain of focus, despite it being a complex and potentially controversial clinical topic with myriad CDS options. This was a good decision, as the complexities of this topic enabled a deeper understanding and enhanced work product. Given AHRQ's focus on evidence-based findings and the project's resources (e.g., diverse stakeholders, Work Group members) we recommend this project continue to take on complex domains if appropriate to project goals.
6. The intellectual property challenges encountered in this project were substantial. IP in the CDS space is complex and requires patience and education with different stakeholders. Further, the CDS space includes contributors that are incentivized to support their

research from different funding sources, ranging from public/Federal programs to commercial entities. Due to these different sources for developing their work, there will be a revised strategy to accommodate the needs of these organizations as it relates to publicize and manage their intellectual property. MITRE originally felt that a fully open approach for managing access to the CDS artifacts would be embraced by the CDS community. However, there is now a stronger appreciation for a need to address organizations that support free and open access to CDS artifacts, along with organizations that consider licensed and proprietary models for access and integration of their CDS artifacts.

7. The varied, real-world touch points the Work Group members provided, in addition to their technical skill, was of high value to the first year of the CDS Connect project. Both clinical and technical resources acknowledged the difficulty in building a CDS artifact, which validated the time and skill demands the CDS Repository seeks to reduce. There is a tangible desire from stakeholders for tools that are demonstrable and shareable. As the Repository and Authoring tools matured, Work Group members began serving the work as Champions, sharing the initiative within healthcare, health informatics, and related communities. This eagerness to champion CDS Connect work was appreciated and fostered.

8. With wider adoption of the CQL standard, a richer set of CDS artifacts, and a more interoperable way of expressing and extracting the patient-level data that drives CDS calculations, the CDS calculation could be processes via secondary services: "*CDS-as-a-Service*." This service could use the CQL definitions of the CDS for a rich library of knowledge. This approach could potentially support a transformation in the application of CDS in health IT systems by de-coupling the patient data stored in EHR systems and the execution of CDS logic. An illustration of this notional concept of operations follows.
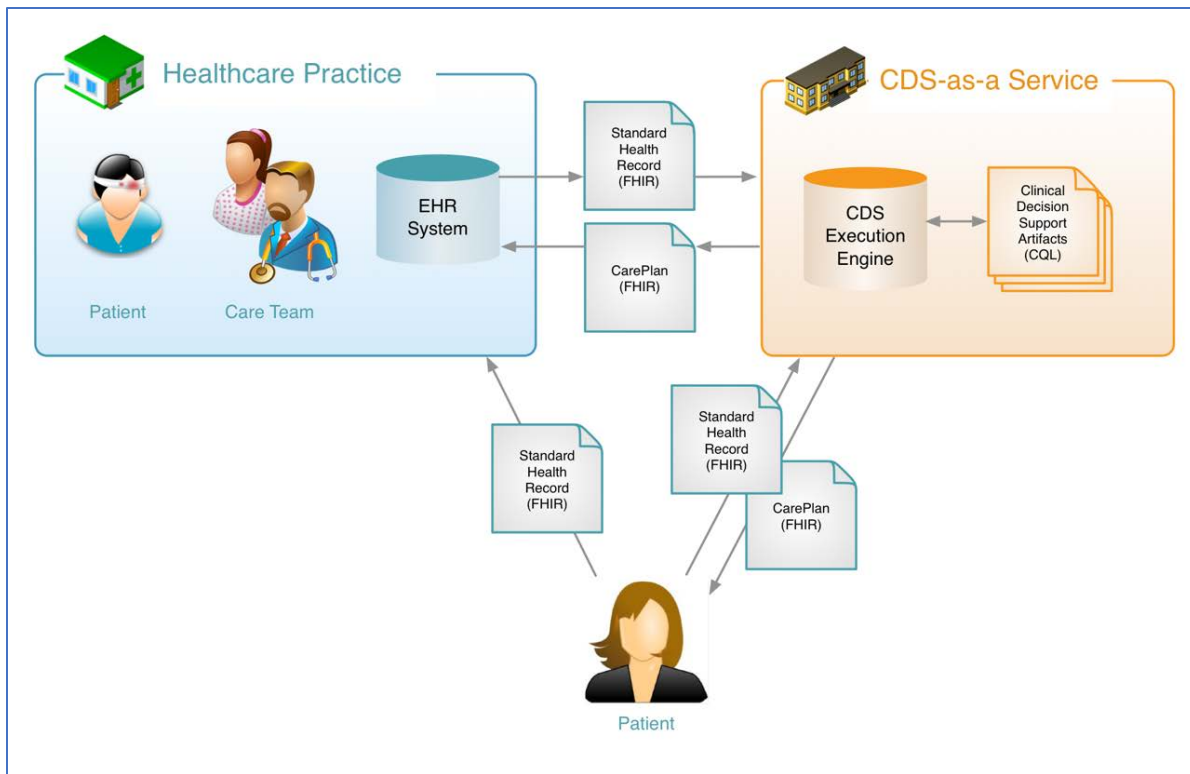
Figure 6: Notional Concept for "CDS-as-a-Service"

Recommendations

1. Future work should include the development of a scalable system to support a wide range of potential CDS Connect Repository contributors in developing and publishing their CDS artifacts through the Authoring Tool and other formats. Stakeholder engagement, through a multi-start process that can be shepherded by AHRQ, MITRE, or a to-be-determined Steering or Governance Committee would be well-positioned to work with the CDS Community as they look to engage with the Repository.
2. As the project's second year advances, the development of a strong communications plan will be of value. The project would benefit from continued presence, and demonstration, at conferences and events. Additionally, web-based information sessions and trainings on the Repository and authoring tool could be employed to both share the tooling and provide an initial round of education.
3. Ensure sufficient resources are allocated to the build-out of the CDS Connect Repository's features and functions to be responsive to known best practices, the goals of the overall work, and the evolving needs of users. Create or support the creation and upload of many types of CDS on the Repository.
4. The project could benefit from building stronger ties with EHR vendors to allow for integration of CQL artifacts.

5. Given AHRQ's focus on evidence-based findings, and the project's resources (e.g., diverse stakeholders, Work Group members) we recommend this project continue to take on complex domains if appropriate to project goals.
6. Copyright status of artifacts should be worked out in advance of broader public access. CDS contributors are responsible for securing and communicating IP status; AHRQ should ensure adequate protections are in place before posting any CDS to a public Repository.
7. Any future pilots should ensure that technical requirements are enumerated before a commitment is made to pilot with an organization (i.e., Will middleware be required to operationalize Repository or project CDS?).
8. The underlying data structure and processes for authoring tools should be optimized for a wide range of potential build processes from the outset, rather than specially targeted at a subset of authoring functionality.

Recommendations for Open Source

Several software components developed on CDS Connect would benefit greatly from an open-source release. First and foremost, an open-source release of software demonstrates full transparency for the actions taken and decisions made during a software development project. Binary releases of finished software products can be accompanied by user guides that explain current functionality and the development process, but no level of documentation can replicate insights into the breadth and depth of a project provided by the release of source code.

The increased transparency afforded by open-source release also helps to foster the creation of a community that can contribute additional code fixes and/or end-user feedback like bug reports, feature requests, and usability information. This review by a wide number of developers and users (which is generally not economically feasible for proprietary software companies) allows for quick identification of bugs and other malicious software objects. A commonly used phrase to illustrate this point is "with enough eyes on the code, all bugs are shallow."

In addition to transparency, community-building, and security benefits of open-source software, the Federal Government has made a commitment to open source at least 20% of the software generated through publicly funded projects[12]. According to the US CIO's memorandum, the release of open-source software by Federal agencies encourages branches of the government to collaborate, reduces costs, streamlines development, applies uniform standards, and ensures consistency in creating and delivering information. With the selection and use of a proper open-source copyright license, AHRQ can be indemnified from liability and encourage Federal agencies, private companies, and other organizations to reuse developed software products.

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[12] https://sourcecode.cio.gov/.

CDS Authoring Tool

To encourage the maturation of CDS artifacts from semi-structured to structured, AHRQ should consider releasing the CDS authoring tool as open-source software. In doing so, AHRQ will foster the generation of a community of developers that can quickly and collaboratively improve the functionality of the tool. A strong, consistent, user-friendly tool for developing CQL is imperative to the continued success of CDS Connect, as it will allow audiences with minimal CQL coding expertise to more fully participate in artifact development.

CQL Testing Suite

As part of the artifact development work, MITRE resources developed a testing suite in Node.js to ensure that basic query logic, inclusion and exclusion logic, and edge cases were properly captured by each artifact. Currently, this code is intertwined with other artifact development items and lacks proper documentation (including sufficient code comments), but with minimal effort the CQL testing suite could be extricated and released to artifact developers. It could be released either as a module of the CDS authoring tool (to test artifacts that are output from the tool) or as a standalone software package to encourage other parties to further develop the test suite or add it to their own CDS tooling.

The 'Shim'—a RESTful Wrapper Around a CQL Execution Service

An open-source release of the Shim enables a fully transparent view of the development decisions made during the pilot project without exposing any proprietary software information about AllianceChicago or their EHR implementation. Also, other clinical organizations that wish to configure their EHR products to trigger RESTful calls for CDS can directly benefit from the release of the Shim. Organizations that wish to use different architectures for CQL execution (e.g., CDS-hooks) could still benefit from investigating the choices made throughout Shim development.

Drupal Configurations and Theme for the CDS Connect Repository

The only custom Drupal code developed for the CDS Connect Repository is the theme. The release of the Drupal configurations could show other organizations how baseline Drupal can be used effectively for a wide variety of purposes.