Implementation Guide

CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

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Prepared by:

CMS Alliance to Modernize Healthcare (The Health FFRDC)
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Disclaimer of Conflict of Interest

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

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- Clinical Decision Support (CDS) Connect Work Group members
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team
- Million Hearts® Model Leadership Team

Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published *Implementation Guide*	
January 2020	Updated the *Implementation Guide* based on annual artifact updates	Updated the *Implementation Guide*'s Introduction and Background content, revised the flow of the content to enhance readability, added evidence specifications and a semistructured representation of the artifact to Appendix A, and updated a small portion of the decision log.
September 2021	Updated the *Implementation Guide* based on annual artifact updates	Applied minor edits to improve clarity and expanded CQL library details to account for FHIR R4 update.

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Introduction

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices identified by peers that they must incorporate into daily practice. Transforming these large volumes of research into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own. The CDS Connect project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), provides an opportunity for healthcare organizations to share evidence-based knowledge expressed as clinical decision support (CDS), enabling other organizations to leverage the publicly available expressions. The ability to share CDS expressions enhances efficiency by removing the need for subsequent organizations to start CDS development from "scratch." It also contributes to a learning health community where CDS developers and implementers collaborate and enhance the shared resources.

Each year, the CDS Connect team develops CDS artifacts (i.e., CDS logic expressions) and contributes the body of work to the CDS Connect Repository to demonstrate CDS Connect infrastructure and publicly share the CDS. Some of the artifacts developed by the project team go on to be piloted in a clinical setting. When this occurs, the project team includes a Pilot Report with the artifact to describe CDS integration, testing, and implementation details, along with end-user feedback. Future implementers can leverage the insight outlined in the report to inform their implementation.

Other artifacts, like this one, are published one step earlier in the CDS development process (i.e., they are published as a human-readable logic statement that aligns with an evidence-based source, as opposed to a computer-coded version of the evidence). Because this artifact has not been fully coded, it has not been field-tested in electronic health record (EHR) systems or other technologies currently in use. However, the human-readable artifacts provide a valuable starting point for healthcare organizations that seek to develop CDS due to the sizable amount of research and analysis required to translate narrative clinical practice guidelines into human-readable logic. CDS Connect artifacts are not "standalone" and are not intended to be completely plug-and-play; healthcare systems will need to integrate each artifact with components of their health information technology (IT) system for the artifact to work. Implementers should conduct extensive testing—including clinical testing in real-life workflows—of all artifacts. The project team expects that artifacts will be customized and adapted to local clinical and IT environments.

This Implementation Guide provides information and guidance to individuals considering their potential use of this artifact. The main intent of this document is twofold: 1) to provide insight on how the human-readable logic expression can be used to improve patient care, and 2) to provide information on how to transform the human-readable logic expression into interoperable logic code and integrate the CDS logic with a health IT system.

Background

To facilitate AHRQ's vision, the CDS Connect project team created—

- The CDS Connect Repository to host and share CDS artifacts
- The CDS Authoring Tool, which enables CDS developers to create CDS logic using Clinical Quality Language (CQL), a Health Level 7 (HL7) standard expression language
- Several open-source prototype tools to facilitate creating, testing, sharing, integrating, and implementing evidence-based, interoperable CDS in health IT systems

The use of CQL in CDS Connect systems and CDS development provides the ability to express logic that is human-readable yet structured enough to process a query electronically. Furthermore, CQL is an interoperable format that eases integration with health IT systems.[1] CQL allows logic to be shared between CDS artifacts, and eventually with electronic clinical quality measures (eCQMs), in support of improving healthcare quality.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than three dozen metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher, sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made while creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface for creating standards-based CDS logic using simple forms. The logic developed by the tool is expressed using HL7 Fast Healthcare Interoperability Resources® (FHIR) and CQL. It empowers organizations that have limited access to software engineers with the ability to express evidence-based guidelines as accurate, tested, and coded logic. Individuals who are interested in developing CDS logic expressions like this artifact can use the tool to develop new CDS logic in the clinical domain of their choice. The interoperable format of the logic facilitates sharing and integration with a wide range of health IT systems.

The CDS Connect team also developed several prototype tools, including one that facilitates CQL testing (CQL Testing Framework) and one that facilitates integration of the CQL code with a health IT system (CQL Services). The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. This framework allows CQL developers to identify bugs in the CDS logic early in the development cycle, when it is less costly to fix. In addition, these test cases enable developers to demonstrate the expected behavior of the CDS logic to bolster trust in the coded expressions. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to this artifact's CQL. CQL Services is an open-source service framework for exposing CQL-based logic using the HL7 CDS Hooks application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively.

Scope, Purpose, and Audience of This Implementation Guide

This document is intended to provide information about the generation, implementation, and routine operation of the Longitudinal atherosclerotic cardiovascular disease (ASCVD) Risk Assessment Tool for Baseline 10-Year ASCVD Risk artifact. Various audiences may find this information helpful, including:

1. **Clinicians and Quality Leaders** at healthcare organizations and practices who wish to implement, test, and execute CDS related to this topic in their EHR and other health IT tools.
2. **Patients and Family Caregivers** who wish to have active CDS to help them direct self-care activities or who are interested in the process of CDS development and implementation for shared decision-making more generally.
3. **Healthcare Systems** interested in promoting patient experience to facilitate patient engagement and a patient's ability to manage their health, while enabling value-based care and quality.
4. **CDS Developers and Informaticists** who may have suggestions or additions, or seek to add CDS artifacts on similar topics, or want to make use of well-developed semistructured logic in their own work.
5. **Organizations or Individuals** interested in developing their own CDS artifacts, who may find this document helpful as a guideline for the process by which clinical guidelines are translated into semistructured artifacts.

Implementing and Using This Artifact

Artifact Description

This CDS artifact provides the ability to calculate and display the baseline 10-Year ASCVD risk score for an individual to help in considering initiation or optimization of therapy for primary prevention of ASCVD. It utilizes the 2013 ACC/AHA pooled cohort equation to calculate the risk for developing a first-time "hard" ASCVD event, defined as: nonfatal myocardial infarction (MI), coronary heart disease (CHD) death, nonfatal stroke, or fatal stroke.

This artifact addresses the first of three clinical scenarios where CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool might be used—

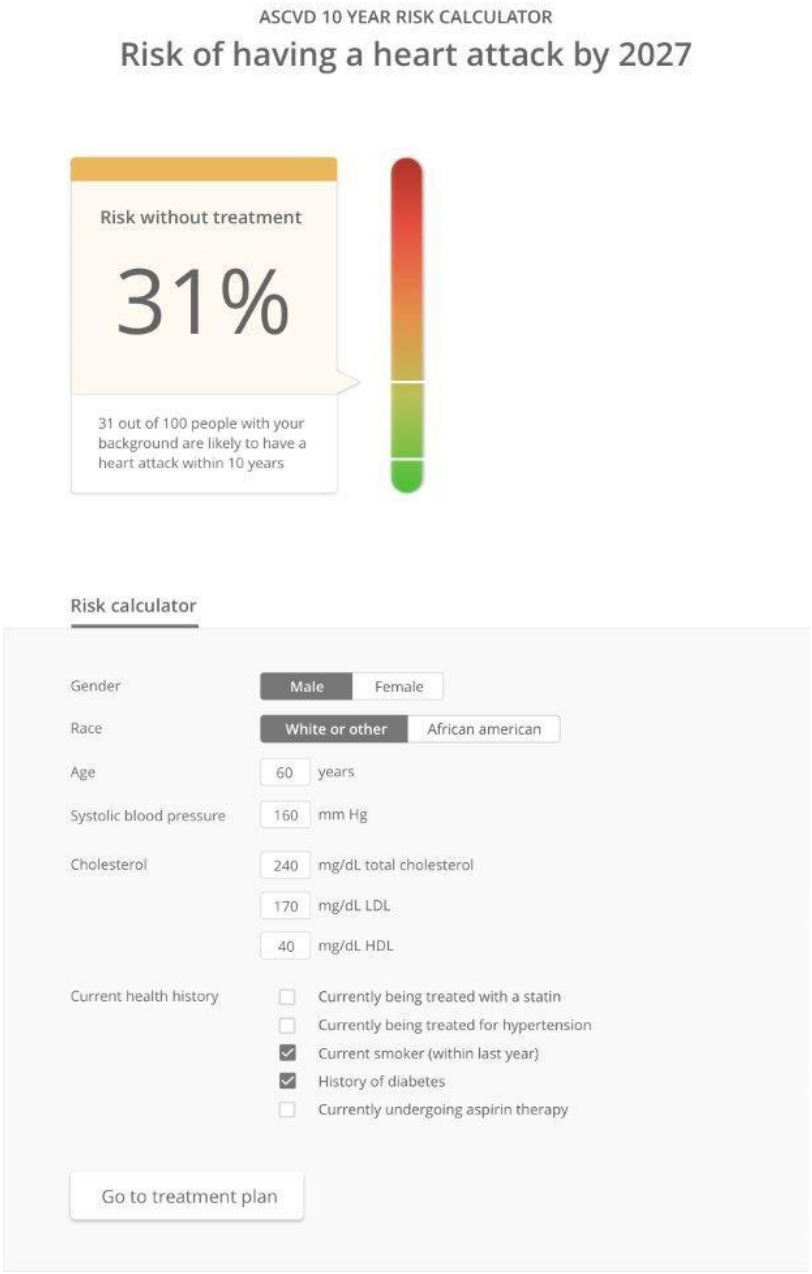
1. Calculation of a baseline 10-Year ASCVD risk assessment score, prior to initiation of any new therapies to address this risk.
2. Prospective estimations of ASCVD risk in support of shared decision making while considering the benefits of therapies, alone or in combination.
3. Calculation of updated risk after preventive therapies have been initiated.

Preventive Health Scenarios Supported by This Artifact

The three ASCVD risk calculations in this Million Hearts® Model family of artifacts are primarily for use by clinicians and patients performing assessment and treatment planning in a primary care or cardiology practice setting. The artifacts are suitable for producing an intelligent data display. An implementation of the Baseline ASCVD Risk artifact can produce: 1) a "calculator" view of the parameters used in the calculation, with opportunity for the user to correct or adjust any values; and 2) a calculated risk score displayed on the screen and potentially available for other CDS artifacts (e.g., cholesterol-lowering CDS algorithms) that make use of the risk score as part of their calculation.

A typical calculator view might look like **Figure 1**, where the score is prominently displayed while the supporting parameters, whether filled in automatically from EHR data or adjusted manually, appear below.

Figure 1: ASCVD Risk Calculator Example



The baseline risk is calculated for patients between the ages of 40 and 79 without ASCVD.

This artifact can be used to support various preventive health scenarios, including those listed below. Note, each scenario is populated with a fictitious patient name and health data to provide context to the scenario.

- Upon request, typically as part of a patient encounter:
    - Ms. Bravo, a 55-year-old African-American nondiabetic patient with hypertension, comes in for a regular annual checkup. She has not had an ASCVD risk calculation done previously. Her clinical practitioner requests the risk calculator to execute. Using data from Ms. Bravo's EHR, the algorithm executes and a data view or calculator view is displayed on screen, showing all the relevant parameters and her calculated risk score of 10.9%. In some implementations, this view also allows manual adjustment of parameters that might not have been fully or correctly captured, such as smoking status.
- Any time that the patient's record is opened by a clinician's direct action:
    - Dr. Alpha is going through the records of his patients to be seen this afternoon, and is currently reviewing the record of Ms. Bravo, a scheduled patient. When the record is opened in the EHR, CDS logic could trigger if the patient is of the appropriate age and has not had a prior ASCVD risk calculation. The risk score is displayed on the patient's chart, and the calculator can be brought up with a manual request.
- As part of another CDS artifact:
    - A CDS artifact is being run on Mr. Delta to consider whether to recommend a statin. This artifact requires the risk score to be known as part of its logic. In some systems, that artifact can invoke this one as a subtask. Dr. Charlie is notified that the statin artifact requires this logic in support and can approve its execution and work through its user interface. It is also possible for this artifact to run unattended, but there are more caveats about missing data (refer to "Additional Use Cases").

Additional Use Cases

Additional use cases make use of the decision logic and recommendations, but may require adjustments for a different workflow, type of user, or mode of operation. Additional use cases for this artifact could include:

- As automatic surveillance run at a fixed time the night before the practice opens each day:
    - Dr. Charlie's practice automatically runs a review each evening on all patients to be seen the following day. This review sets up face-sheets and requests charts for the intake personnel to use the next day. As part of this review, the computer scans each patient for several health maintenance gaps, including using this CDS artifact to identify patients with elevated risk scores. Since this runs in bulk, it is not usually possible to have a direct user interface to modify individual patient parameters. Thus, the artifact could record an exception if the necessary parameters do not exist, or it could assume worst case of parameters that are not already captured in the EHR or other health IT tool. In this use case, the artifact posts a message in the inbox of the provider or quality manager, or a To-do item on the chart for each patient whose risk score is above a certain threshold. The recommendation can also be printed as part of the patient's visit face-sheet. The logic to determine which parameters are required and what minimum risk score should be called out for this automated operation is beyond the scope of this implementation guide.

- Population health—Inclusion in a requested or periodic screening scan of an entire patient panel or population:
    - Dr. Delta's practice is running a quarterly quality screen to find patients in need of various health maintenance and promotion services. The ASCVD risk artifact is run as a report for all patients in the practice. Recommendations and suggested actions (RSAs) for appropriate patients appear on each patient's individual to-do list and are also compiled into an overall report that can be addressed by population health or case management staff. The additional considerations for unattended bulk operation noted above also apply to this use case.
- Patient self-care/family caregivers as part of self-assessment or health maintenance:
    - Mr. Echo runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. The risk score display is presented immediately with the assessment results, or can be delivered as a secure message to the patient on a self-care website. The former is preferred because it allows adjustment of parameters and allows the self-assessment tool to chain to other CDS based on the risk score.

Recommendations and Suggested Actions

The recommendations, warnings, and interventions provided by this CDS artifact can be found in detail under "Potential Intervention(s) and Action(s)" in the Semi-Structured Representation section of the artifact. In summary, they include:

1. Notify the user if the patient is excluded because of age less than 40 or greater than 79.
2. Notify the user that, although the algorithm is executing, it may not be fully valid or may need to be adjusted for patients with familial hypercholesterolemia, or patients who are not White or African-American.
3. Display the ASCVD risk calculation as a calculator view or data view.
4. Fill in known parameters to this calculation from EHR data, while indicating which parameters could not be obtained, if any.
5. Notify the user that certain parameters (including total cholesterol, HDL cholesterol, and systolic blood pressure) were out of the validated range and have been adjusted to the nearest in-range value.
6. Display the ASCVD risk score as derived from the collected and entered parameters.
7. Document the ASCVD risk score in the patient's record. This is not a standard EHR data element, and currently each implementation needs to identify where this is stored in the record for applications that make use of the score and for documenting that a score was performed.

Guideline Interpretation and Clinical Decisions

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. In addition, the CDS Connect Cholesterol Management Work Group provided insight to clarify exclusions, inclusions, and parameters that were specified in the guideline statement, outlined in the original reference describing the guideline, or deemed to be otherwise important to the proper application of the guideline as CDS. Decisions outlined in Appendix A explain, in detail, how source content text was interpreted and representations were defined during artifact creation.

Some of the more meaningful interpretations and decisions found in Appendix A include:

1. Maintain a modular approach to CDS creation by separating the calculation of ASCVD risk (in this artifact) from statin therapy recommendations presented in other artifacts. These artifacts will be tagged as being related to each other but allow the user options in what is implemented.
2. Indicate that non-White, non-African-American patients may need score adjustment, but still provide the risk calculation as specified.
3. Replace values for systolic hypertension, HDL cholesterol, and total cholesterol that are outside the validated ranges for this algorithm with the nearest in-range value and proceed with the calculation but notify the user that this adjustment was made.
4. At present, the CQL code does not evaluate for evidence of ASCVD in the patient record since this artifact is a representation of the risk assessment equation alone, as opposed to a more comprehensive CDS expression. Future implementers may choose to represent ASCVD as an exclusion based on their needs.
5. Define "treatment for hypertension" as the existence of an active antihypertensive medication in the patient's file and a diagnosis of hypertension since several antihypertensive medications are used for other indications.
6. Limit data evaluation to concepts required to calculate a baseline 10-year ASCVD risk score. Future implementers may choose to evaluate and track a "baseline" low-density lipoprotein (LDL) value, or treatment with statin therapy or aspirin therapy prior to changing or initiating therapy. At present, these concepts are not expressed in the CQL code.
7. Align CQL code with the precision implemented in the Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool and online calculators, as opposed to the 2013 Report on the Assessment of Cardiovascular Risk: Full Work Group Report Supplement (which calculates risk scores that may be off by as much as 0.1%).
8. CQL code does not evaluate ethnicity or a history of familial hypercholesterolemia. End users should be aware that these factors can impact the accuracy of the calculated score. This information is listed in the "Caution" Repository metadata.

Technical Details Regarding Artifact Implementation

This CDS artifact is composed of several software files written in CQL. The primary focus of these software files is to allow any organization to calculate a baseline ASCVD risk score using patient data in the FHIR format.

The following sections provide technical details useful for those implementing this artifact in their health IT system. After providing background information on CQL (as the programming language used to write the logic for the artifact), the document presents a listing (or manifest) of the main CQL files included in the artifact, discusses the relationships among the files, and describes the testing activities.

General Information About CQL

This artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7 that is currently a Mixed Normative / Standard for Trial Use (STU) specification.[2] CQL expresses logic in a human-readable format that is also structured enough for electronic processing of a query. It can be used within both the CDS and eCQM domains.

The following hyperlinks provide additional information on CQL:

- HL7 CQL Specification
- CQL on the Electronic Clinical Quality Information (eCQI) Resource Center
- CQL Tools (e.g., CQL-to-ELM Translator) on GitHub
- CQL Execution Engine (JavaScript) on GitHub
- CQL Evaluation Engine (Java) on GitHub

Artifact Library Manifest

CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk artifact provides two distinct versions of the logic files—

- **Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv102_v1.0.2_CQL.zip**: The FHIR DSTU2-based CQL logic files were last updated in December 2018 to reflect changes in CQL 1.2 errata and CQL 1.3.
- **Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv400_v1.0.0_CQL.zip**: The FHIR R4-based CQL logic files were compiled using the CQL 1.5.x translator. Although the intent of the logic remains the same as the FHIR DSTU2-based version (listed above), changes in the FHIR specification (from DSTU2 to R4) required corresponding changes to the CQL logic.

Detailed descriptions of the changes in the FHIR R4 version of this artifact can be found in the **Million_Hearts_Baseline_10_Year_ASCVD_Risk_Change_Log.txt** file attached to this artifact in the CDS Connect Repository.

Each of these packages is comprised of four distinct libraries listed in Table 1 according to their file names. Although the file names and purposes may be the same across multiple versions (e.g., FHIRHelpers), the technical content of the files varies from version to version.

Each library is represented in two formats containing the same information but formatted for different purposes. The CQL format is human readable; the JavaScript Object Notation (JSON) format is machine readable and is generated from the CQL using the CQL-to-ELM translator.[3]

Table 1: Artifact Manifest

Filename	Purpose	Author(s)
Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv102.cql (FHIR DSTU2 only) or Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv401.cql (FHIR R4 only)	CQL representation of CMS's Million Hearts Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-year ASCVD Risk. The CQL provides the ability to calculate the base 10-year ASCVD risk score for an individual that is not receiving therapy for primary prevention of ASCVD. It utilizes the 2013 ACC/AHA pooled cohort equation to calculate the risk of developing a first time "hard" ASCVD event, defined as: nonfatal myocardial infarction (MI), coronary heart disease (CHD) death, nonfatal stroke, or fatal stroke.	Rute Martins, Chris Moesel, Sharon Sebastian
Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv102.json (FHIR DSTU2 only) or Million_Hearts_Baseline_10_Year_ASCVD_Risk_FHIRv401.json (FHIR R4 only)	JSON representation of CMS's Million Hearts Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-year ASCVD Risk. The CQL provides the ability to calculate the base 10-year ASCVD risk score for an individual that is not receiving therapy for primary prevention of ASCVD. It utilizes the 2013 ACC/AHA pooled cohort equation to calculate the risk of developing a first time "hard" ASCVD event, defined as: nonfatal myocardial infarction (MI), coronary heart disease (CHD) death, nonfatal stroke, or fatal stroke.	Rute Martins, Chris Moesel, Sharon Sebastian
CDS_Connect_Commons_for_FHIRv102.cql (FHIR DSTU2 only) or CDS_Connect_Commons_for_FHIRv401.cql (FHIR R4 only)	Common CQL functions that may be called by CDS Connect artifacts.	Rute Martins, Chris Moesel, Sharon Sebastian
CDS_Connect_Commons_for_FHIRv102.json (FHIR DSTU2 only) or CDS_Connect_Commons_for_FHIRv401.json (FHIR R4 only)	JSON representation of common CQL functions that may be called by CDS Connect artifacts.	Rute Martins, Chris Moesel, Sharon Sebastian

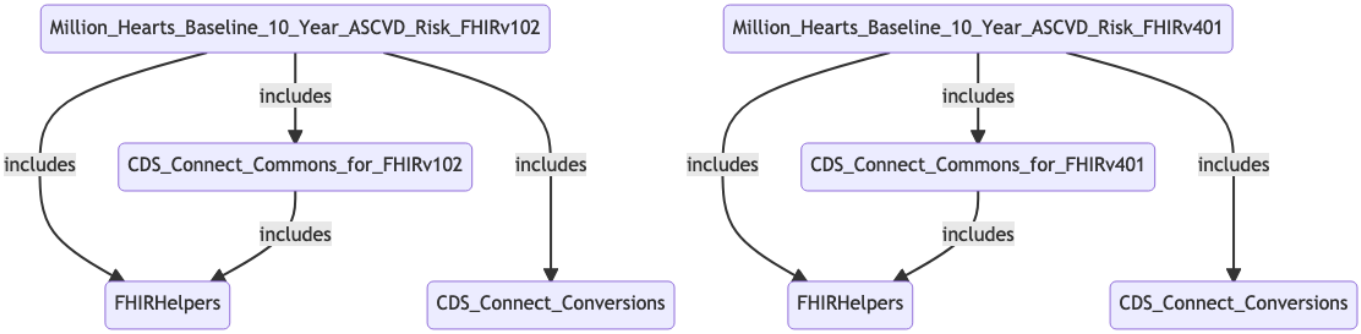
Filename	Purpose	Author(s)
CDS_Connect_Conversions.cql	A library that supports conversions from one unit to another.	Rute Martins, Chris Moesel, Sharon Sebastian
CDS_Connect_Conversions.json	JSON representation of a library that supports conversions from one unit to another.	Rute Martins, Chris Moesel, Sharon Sebastian
FHIRHelpers.cql	Common CQL functions used to convert CQL data elements to FHIR and back again.	Rute Martins, Chris Moesel, Sharon Sebastian
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again.	Rute Martins, Chris Moesel, Sharon Sebastian

Artifact Library Relationship Diagram

The project team encourages CQL developers to refactor commonly used functions into separate software files called libraries. The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. Figure 2 below shows the relationships between this artifact's main library file and the two supporting libraries.

When implementing this artifact, ensure that all files listed in Table 1 in the previous section are present and that the filenames have not been modified.

Figure 2: Artifact Relationship Diagram



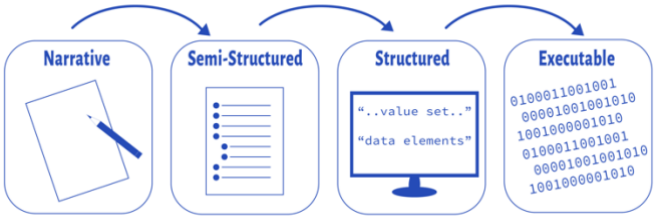
Artifact Testing

The project team tested CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk artifact using an automated testing framework written in Node.js. This framework accepted test cases in a .csv (comma-separated value) file, executed the artifact against each test case, and reported the success or failure of each test case. Test cases were developed to investigate efficacy for basic expected functionality and to test the expected inclusion criteria. A selection of the test data used for this artifact is included in Appendix B. In addition, test data provided by the ACC/AHA were used to further test the expressed equation. The ACC/AHA test data are available at: Final Technical Report: Estimating Benefits in Risk Reduction from Cardiovascular Preventive Therapies in Medicare Patients: Development of the Longitudinal ASCVD Risk Estimator. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

Implementation Checklist

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts.[4] The framework defines four "layers" of representation, as depicted in Figure 3.

Figure 3: CDS Artifact Maturity Process



1. **Narrative** text created by a guideline or clinical quality measure (CQM) developer (e.g., the recommendation statement described as a sentence).
2. **Semistructured text** that describes the recommendation logic 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 into 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.

Prior to incorporating this artifact in a production setting, implementers should consider the following items:

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization understands and agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review the "clinical considerations" section of this document (including the cited decision log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a structured, computable CDS artifact.
- Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be successfully incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf EHR systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those EHR systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In a pilot setting, developers have worked around existing EHR limitations by implementing a web service wrapper around a CQL execution engine, such as CDS Connect's CQL Services prototype tool. This is a non-trivial amount of work with two primary components:
    1. A CQL execution engine with a RESTful web service designed to accept requests for CQL execution and to respond with the calculated results.
    2. Modifications to the EHR system such that it will
        - Trigger RESTful events to call the CQL execution engine
        - Interpret the response
        - Reflect the CQL-generated recommendations and suggested actions in the EHR user interface.
- After incorporation into a development environment, the artifact should be exhaustively tested against predefined test cases. Additionally, testing should be conducted to ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
- Documentation and training materials for clinical staff should be drafted and distributed. These training materials should include descriptions of modified functionality, directions for interacting with CDS rules (if different than in the current system), and contact information for assistance if functionality does not meet expectations.

Potential Reuse Scenarios

CQL code within this artifact was developed to enact an ASCVD risk calculation, but there are portions of the CQL code that are expected to be useful for other purposes.

- The four libraries: CDS_Connect_Commons_for_FHIRv102, CDS_Connect_Commons_for_FHIRv401, FHIRHelpers, and CDS_Connect_Conversions included in the artifact define commonly used functions in CQL files and are not specific to this artifact. They may be used with any other CQL file that could benefit from those functions.
- Selected code blocks from CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk artifact's CQL could be copied and reused in other CQL files. For example, developers might reuse this code to develop portions of the expanded CMS's Million Hearts® Model Longitudinal ASCVD Risk Tool, which facilitates calculation of an updated ASCVD risk score after treatment has been initiated.

Appendix A. Decision Log

The decision log was generated per procedures published by Tso et al.,[5] which incorporates and extends steps that Shiffman et al.[6] outlined for translating clinical practice guidelines to CDS. Brief descriptions of the steps in this process are included in the following table.

Table 2: Definitions of Shiffman's Steps

Decision Category	Definition
Select Guidelines	Choosing specific guidelines and specific recommendations within the selected guidelines to be implemented
Markup	Identifying and tagging guideline knowledge components relevant to operationalization
Atomize	The process of extracting and refining single concepts from the narrative text recommendations
Deabstract	The process of adjusting the level of generality at which a decision variable or action is described to permit operationalization
Disambiguate	The process of establishing a single semantic interpretation for a recommendation statement
Build Executable Statements	Arranging the atomized, de-abstracted, and disambiguated decision variables and actions into logical statements that can be translated readily into computable statements
Verify Completeness	The process of making sure that each recommendation provides guidance in all situations that a clinician is likely to face
Add Explanation	A facility to describe the reasoning behind recommendations
Identify Origin	Identifying a source or origin in the clinical environment for each decision variable
Insert Recommendations	Identifying an insertion point in the care process for each recommended action
Define Action Type	Categorizing guideline-recommended activities per predefined action types
Define Associated Beneficial Services	Linking action types to associated beneficial services that offer design patterns for facilitating clinical care
Design User Interface	Selecting and grouping user interface elements to best deliver CDS output

Artifact Recommendation Statements

ACC/AHA Recommendation Statement

The race- and sex-specific PCE to predict 10-year risk of a first hard ASCVD event should be used in non-Hispanic African Americans and non-Hispanic whites, 40 – 79 years of age.

Decision Logs

Table 3: Decisions Based on "Atomized" Components of the Recommendation Statement

Recommendation Statement	"Atomized" Word or Phrase	Interpretation
ACC/AHA	"race"	Per ACC/AHA guidelines: African American or White
ACC/AHA	"sex"	Per ACC/AHA guidelines: Male or Female
ACC/AHA	"pooled cohort equations"	Provides race- and sex-specific 10-year ASCVD risk calculations for African American and White men and women between 40-79 years of age
ACC/AHA	"predict"	Determine the likelihood of occurring
ACC/AHA	"10-year risk"	Risk of showing evidence of ASCVD within the next 10 years
ACC/AHA	"hard"	Nonfatal MI, CHD death, nonfatal stroke, or fatal stroke
ACC/AHA	"ASCVD"	Arteriosclerotic cardiovascular disease. For the purposes of this artifact, ASCVD is represented by a grouped value set that represents an array of conditions and procedures that would only occur if a patient has CVD. High level concepts include: "Diagnosis: "Ischemic Vascular Disease" "Diagnosis: Myocardial Infarction" "Procedure, Performed: CABG Surgeries" "Procedure, Performed: PCI" "Procedure, Performed: Carotid Intervention"
ACC/AHA	"non-Hispanic"	Individual does not report as being of Hispanic ethnicity
ACC/AHA	"40-79 years"	>=40 years of age and <=79 years of age

Several decisions were made outside the scope of the atomized words and phrases in the recommendation statements. These additional decisions were made based on the best available clinical knowledge and were encountered at various stages in the artifact development process.

Table 4: Additional Decisions

Decision Category	Concept	Rationale
Reconcile multiple guidelines	Presence of CVD risk factors as a requirement to calculate 10-year risk	The U.S. Preventive Services Task Force (USPSTF) guidelines recommend the calculation of 10-year risk only in the presence of 1 or more risk factors (e.g., smoking, hypertension), whereas the ACC/AHA guidelines do not require the presence of a risk factor. Based on Cholesterol Management Work Group feedback and to more closely align with the ACC/AHA Special Report, risk factors were not added to inclusion logic. Local implementers can add these specifications if desired, based on their organization's policy and practice.
Implementation guidance	Use of the Longitudinal ASCVD Tool (i.e., PCE) on Hispanic individuals	The Cholesterol Management Work Group felt the benefit of calculating ASCVD risk for Hispanic individuals using the PCE outweighs the chance that it may slightly over- or underestimate ASCVD risk, and providers can and should use their judgment on how the risk score might be adjusted for each unique individual. Consider adding a notification that caveats the risk score if the patient is Hispanic during structured specification of this artifact.
Implementation guidance	Age specification in the Inclusion logic	The ACC/AHA recommends 10-year ASCVD risk assessment for eligible 40-79-year-old individuals every 4-6 years, which is specified in the CDS logic. Upper and lower age parameters can be changed during implementation if a risk score is needed for an individual outside this age range. Refer to the ACC/AHA Special Report and ACC/AHA Guideline on the Assessment of Risk for additional information.
Implementation guidance	History of ASCVD	The PCE calculates the risk of developing ASCVD within the coming 10 years. If an individual already has ASCVD, use of the calculator is not indicated. At present, the CQL code does not evaluate for evidence of ASCVD in the patient record since this artifact is a representation of the risk assessment equation alone, as opposed to a more comprehensive CDS expression. Future implementers may choose to represent ASCVD as an exclusion based on their needs.

Decision Category	Concept	Rationale
Implementation guidance	History of Familial Hypercholesterolemia (FH)	Based on Cholesterol Management Work Group feedback, individuals with a history of FH should not be excluded from a risk score calculation (because the PCE underestimates risk in these individuals). The score is valuable information that can guide care. At present, the CQL code does not caveat the calculated score if a patient has a history of FH. Implementers may choose to add this capability in the future.
Verify completeness of logic and add explanation	Facilitate calculation of ASCVD risk, when possible	The Longitudinal Tool includes parameters for several values (e.g., minimum and maximum systolic blood pressure [SBP] and lab values). If patient data is outside the defined range, a score will not calculate. In this scenario: • CDS logic will replace the value with the nearest "allowable" value so the ASCVD score can be calculated. • The score is caveated. • The provider is notified of the replacement (e.g., true SBP value = 212, SBP value used for calculation = 200). Per the Cholesterol Management Work Group, it is far more important to know the approximated risk score than to have no score on which to base decisions.
Deabstract	Logic definition of "Diabetes" for data input to risk equation	Diabetes is defined as Type 1 and Type 2 based on text in the ACC/AHA guidelines. The presence of a Type 1 or Type 2 Diabetes SNOMED-CT or ICD code will translate as "Y" for the calculation.
Disambiguate	Logic definition of "Treated for Hypertension" for data input to risk equation	Per the Cholesterol Management Work Group, the presence of an anti-hypertensive medication in the patient record is not sufficient evidence that the patient is being treated for hypertension, since some anti-hypertensive medications can be prescribed for other medical conditions. To evaluate positively as being treated for hypertension, the patient must have a diagnosis of hypertension *and* evidence that they are being treated for hypertension (e.g., an appropriate medication order).
Verify completeness of logic	MOST RECENT for lab and SBP values and smoking status to ensure clinical relevance	The most recent values are most reflective of the patient's current condition. Use of the MOST RECENT values assumes that they were recorded using best practices (i.e., if highly abnormal or unreasonable the results would be completed; therefore, the MOST RECENT result indicates a valid result).

Decision Category	Concept	Rationale
Verify completeness of logic	Lookback of 6 years for lab values and SBP value and a lookback of 1 year for smoking status to ensure clinical relevance	The ACC/AHA recommends assessment of ASCVD risk every 4 – 6 years. Results older than 6 years may not accurately reflect the individual's current condition. Since lipid profile results, SBP, are inputs to ASCVD risk assessment, a 6-year lookback supports a calculation that will most accurately reflect risk. In addition, the ACC/AHA specifies "current smoker" (i.e., within the past year), since the impact that smoking has on the body and ASCVD risk changes after that period. If the most recent result of any of these items is greater than the designated lookback period, a notification warning or error will be presented to the provider to provide awareness and prompt updates.
Implementation guidance	Precision of risk score calculation	The CQL code in this artifact aligns with the more precise calculations implemented in the Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool and online calculators, as opposed to the 2013 Report on the Assessment of Cardiovascular Risk: Full Work Group Report Supplement. In addition, discrepancies were noted in the test data included in the 2013 Report (i.e., copy/paste errors and incorrect rounding, which can lead to results that are off by as much as 0.001).
Implementation guidance	"LDL," "Statin Therapy," and "Aspirin Therapy"	The concepts of LDL, statin therapy, and aspirin therapy are not required or evaluated against to determine baseline ASCVD risk; therefore, they are not expressed in the CQL code. Future implementers may choose to evaluate and track a "baseline" low-density lipoprotein (LDL) value, or treatment with statin therapy or aspirin therapy prior to changing or initiating therapy by adding to the CQL specifications.

Appendix B. Test Data

In conjunction with a custom Node.js testing framework, the following data tables were used to test CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk artifact:

Table 5: Basic Tests

TestCase	Patient	age	race	Total Cholesterol	Value Quantity Code	HDL	Value Quantity Code	Systolic BP	Smoking Status	Diabetes	Hypertension	Anti Hypertensive Order	RESULT: In Demographic	RESULT: ErrorsAndWarnings	RESULT: Patient Baseline Risk
Table A White Women	female	55	white	213	-	50	-	120	never	-	-	-	TRUE	<empty>	0.02050996
Table A African American Women	female	55	black	213	-	50	-	120	never	-	-	-	TRUE	<empty>	0.0299259 1
Table A White Men	male	55	white	213	-	50	-	120	never	-	-	-	TRUE	<empty>	0.0538698 2
Table A African American Men	male	55	black	213	-	50	-	120	never	-	-	-	TRUE	<empty>	0.0607581 7
Healthy Patient	male	47	white	187	-	58	-	107	never	-	-	-	TRUE	<empty>	0.0139984 1
At Risk Patient	female	42	black	215	-	37	-	143	current	+	+	+	TRUE	<empty>	0.3224190 2

TestCase	Patient	age	race	Total Cholesterol	Value Quantity Code	HDL	Value Quantity Code	Systolic BP	Smoking Status	Diabetes	Hypertension	Anti Hypertensive Order	RESULT: In Demographic	RESULT: ErrorsAndWarnings	RESULT: Patient Baseline Risk
Cholesterol in mmol/L	male	47	white	4.835820031	Mmol/L	1.4998 8001	mmol/L	107	never				TRUE	<empty>	0.0139984 1
Off-label Med	male	47	white	187	-	58	-	107	never	-	-	+	TRUE	<empty>	0.0139984 1
Above Total Cholesterol Range	male	47	white	350	-	58	-	107	never	-	-	-	TRUE	~WARNING: Total cholesterol 350 mg/dL	0.032685
Below Total Cholesterol Range	male	47	white	120	-	58	-	107	never	-	-	-	TRUE	~WARNING: Total cholesterol 120 mg/dL	0.0078593 3
Above HDL Range	male	47	white	250	-	120	-	107	never	-	-	-	TRUE	~WARNING: HDL 120 mg/dL	0.0117197 5
Below HDL Range	male	47	white	150	-	15	-	107	never	-	-	-	TRUE	~WARNING: HDL 15 mg/dL	0.0341958 7
Above Systolic BP Range	male	47	white	187	-	58	-	220	never	-	-	-	TRUE	~WARNING: Systolic blood pressure 220 mmHg	0.0416030 8

TestCase	Patient	age	race	Total Cholesterol	Value Quantity Code	HDL	Value Quantity Code	Systolic BP	Smoking Status	Diabetes	Hypertension	Anti Hypertensive Order	RESULT: In Demographic	RESULT: ErrorsAndWarnings	RESULT: Patient Baseline Risk
Below Systolic BP Range	male	47	white	187	-	58	-	70	never	-	-	-	TRUE	~WARNING: Systolic blood pressure 70 mmHg	0.01033553
Other Race	male	47	asian	187	-	58	-	107	never	-	-	-	TRUE	~For non-White and non-African American ethnic groups	0.01399841
Other Gender	other	47	white	187	-	58	-	107	never	-	-	-	TRUE	~ERROR: Inadequate data to process CDS: gender	<null>
Too Old	male	80	white	187	-	58	-	107	never	-	-	-	FALSE	~ERROR: This CDS is not applicable	<null>
Too Young	male	39	white	187	-	58	-	107	never	-	-	-	FALSE	~ERROR: This CDS is not applicable	<null>

Table 6: Missing or Old Data Tests

TestCase	Patient	age	race	Total Cholesterol	issued	HDL	issued	Systolic BP	issued	Smoking Status	issued	RESULT: In Demographic	RESULT: ErrorsAnd Warnings	RESULT: Patient Baseline Risk
Missing gender	+	47	white	187	-	58	-	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: gender	<null>
Missing birthdate	male		white	187	-	58	-	107	-	never	-	<null>	~ERROR: Inadequate data to process CDS: birthdate	<null>
Missing race	male	47		187	-	58	-	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: race	<null>
Missing Total Cholesterol	male	47	white		-	58	-	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: total cholesterol	<null>
Old Total Cholesterol	male	47	white	187	1/1/12	58	-	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: total cholesterol	<null>
Missing HDL	male	47	white	187	-		-	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: HDL	<null>

TestCase	Patient	age	race	Total Cholesterol	issued	HDL	issued	Systolic BP	issued	Smoking Status	issued	RESULT: In Demographic	RESULT: ErrorsAnd Warnings	RESULT: Patient Baseline Risk
Old HDL	male	47	white	187	-	58	1/1/12	107	-	never	-	TRUE	~ERROR: Inadequate data to process CDS: HDL	<null>
Missing Systolic BP	male	47	white	187	-	58	-		-	never	-	TRUE	~ERROR: Inadequate data to process CDS: systolic blood pressure	<null>
Old Systolic BP	male	47	white	187	-	58	-	107	1/1/12	never	-	TRUE	~ERROR: Inadequate data to process CDS: systolic blood pressure	<null>
Missing Smoking Status	male	47	white	187	-	58	-	107	-		-	TRUE	~ERROR: Inadequate data to process CDS: smoking status	<null>
Old Smoking Status	male	47	white	187	-	58	-	107	-	never	1/1/12	TRUE	~ERROR: Inadequate data to process CDS: smoking status	<null>

Appendix C. Reference List

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