Implementation Guide

Statin Therapy for the Prevention and Treatment of CVD: eCQM-Derived CDS

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- Patient-Centered Clinical Decision Support Learning Network
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Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published *Implementation Guide*	
October 2019	Updated the *Implementation Guide* based on annual CDS artifact updates	Updated the *Implementation Guide's* Introduction and Background content, revised the flow of the content to enhance readability, updated the evidence source, added evidence specifications and a semi-structured representation of the artifact to Appendix A, and updated a small portion of the decision log.
April 2021	Updated the *Implementation Guide* based on annual CDS artifact updates	Clarified how this differs from the Statin CDS artifacts, revised the flow of the content to enhance readability, updated text to indicate use of version 4 of the eCQM, and expanded CQL library details to account for the CQL updates related to eCQM v4 and FHIR R4.
September 2022	Updated the *Implementation Guide* based on annual CDS artifact updates	Edited the background and introduction for clarity. Reorganized content under new topic headings to make navigation more intuitive. Updated Guideline Interpretation, Implementation, and Decision Log sections to align with v5 specification changes. Updated CQL section to reflect new CQL library names and versions.
August 2023	Updated the *Implementation Guide* based on annual CDS artifact updates	Updated Guideline Interpretation, Implementation, and Decision Log sections to align with v6 specification changes. Updated CQL section to reflect new CQL library names and versions. Incorporated new FDA guidance to include certain pregnant people in the recommendations.

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Background

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices defined by authoritative professional societies that they must incorporate into daily practice. Transforming these guidelines and best practices 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. Sharing CDS expressions enhances efficiency by removing the need for 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.

Introduction

Beginning in 2016, the MITRE CDS Connect multidisciplinary project team has facilitated AHRQ's vision to move patient-centered outcomes research (PCOR) evidence into practice by supporting implementers, clinicians, and technology vendors in developing CDS tools that are shareable, standards-based, publicly available, and person-centered. CDS Connect has created the following resources, which are described in greater detail later in this document:

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

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

CDS artifacts are classified by a "Knowledge Level"[1] that indicates the degree to which a computer can interpret the information. The four categories of Knowledge Levels are defined as:

1. Narrative – Descriptive text created by a guideline or CQM developer.
2. Semi-Structured – Human-readable text that organizes in a logical sequence the recommendations for implementation in CDS.
3. Structured – Organized or patterned code that is interpretable by a computer (includes data elements, value sets, logic).
4. Executable – Code that is interpretable by a CDS system at a local level (and will vary for each particular site).

Some artifacts developed by the MITRE project team (or other teams) 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 insights outlined in the report to inform their implementation.

CDS 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 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.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than 40 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 when creating the artifact. It also enables contributors to upload the coded logic expression and test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface to guide the creation of standards-based CDS logic using simple input 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 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 two prototype tools: one facilitates CQL testing (CQL Testing Framework); the other 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 expression. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to an 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.

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 logic expression can be used to improve patient care and 2) to provide information on how to transform the logic expression into interoperable logic code and integrate the CDS logic with a health IT system.

Various audiences may find the information in this guide helpful, including:

1. Clinicians and Quality Leaders at healthcare organizations and primary care practices who wish to implement, test, and execute CDS related to this topic in their health IT tools.
2. Healthcare Systems interested in promoting patient experience beyond traditional brick-and-mortar care to facilitate patient engagement and a patient's ability to manage their health, while enabling value-based care and quality.
3. Employers and Payers who want to manage their cost and quality through patient-facing CDS and health management tools.
4. CDS Developers and Informaticists who may use components of this CDS logic as a foundation for other preventive health CDS, or who want to use well-developed, structured logic and CQL in their own work.
5. Organizations or Individuals interested in developing their own patient-facing CDS artifacts who may employ this document as a resource for the process by which clinical guidelines are translated into mature CQL artifacts.

Implementing and Using This Artifact

Artifact Description

This artifact provides statin therapy recommendations for primary and secondary prevention of cardiovascular disease (CVD) for patients considered to be at high risk of cardiovascular events. It is a CDS logic representation of clinical guidance expressed in a CMS eCQM (i.e., CMS measure identification [ID] CMS347v6, "Statin Therapy for the Prevention and Treatment of Cardiovascular Disease").[2] This eCQM is, in part, based on the 2013 Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Disease (ASCVD) Risk in Adults from the American College of Cardiology (ACC) and the American Heart Association

(AHA),[3] as well as the 2018 update.[4] This CDS artifact addresses primary and secondary prevention alike (which aligns with and supports the eCQM measure); in comparison, the clinician- and patient-facing CDS artifacts for statin use cover only primary prevention. Further, unlike the eCQM logic itself, the logic in this artifact is not tied to a specific measurement period.

Preventive Health Scenarios Supported by This Artifact

This artifact transforms the eCQM into CDS by presenting it as a screening artifact. It checks a patient's record to see if they meet the denominator criterion for any of the three denominator-based subpopulations (see Evidence Source for Artifact Development section of this artifact). If they do, and they do not meet the contraindications, then unless they are not already on a statin, the artifact recommends that the clinician consider ordering a statin drug. The CDS diverges from the eCQM logic in one key aspect: the eCQM excludes from its measurement significant (e.g., active) cases of hepatitis A, along with mild or recently (e.g., during the measurement period) resolved cases of hepatitis A. In contrast, the CDS logic does not exclude mild or resolved cases of hepatitis A, but allows the clinician to decide whether a statin is appropriate for the individual patient's situation. Decisions made during artifact development to transform eCQM logic into CDS logic are highlighted in the Guideline Translation Summary section of this document, and detailed in Appendix A.

In the following clinical scenarios, the decision logic and recommendations are expressed as an Event-Condition-Action alert (i.e., a condition-based alert reacting to a specific event). Each scenario is populated with a fictitious patient name and health data to provide context to the scenario.

1. Any time a patient's record is opened by a clinician's direct action.
    a. 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, the CDS logic described herein executes to determine whether to recommend that Ms. Bravo begin taking statins. The relevant recommendations could appear immediately in a box on the EHR screen for the clinician's review and action or could be posted to a "to-do" list visible in the patient's record.
2. As automatic surveillance performed prior to the start of a clinician encounter (particularly in a primary care, cardiology, geriatric, or internal medicine practice).
    a. Ms. Bravo arrives for a scheduled appointment and is registered into the encounter. The registration automatically triggers the CDS logic of this artifact. The logic delivers any recommendations as a message to the clinician's inbox or a "to-do" item in the patient's record.
3. As automatic surveillance performed at a fixed time each night before the practice opens.
    a. 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 check for appropriate use of statins. When the CDS logic determines that a patient merits a statin recommendation, the logic delivers the recommendation via an inbox message to the provider or a "to-do" item on the patient's chart. The recommendation can also be printed as part of the patient's visit face-sheet.

Preventive Health Scenarios Supported With Customization of the Coded Expression

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

1. Population health: Inclusion in a requested or periodic screening scan of an entire patient panel or population.
    a. Dr. Charlie's practice is running a quarterly quality screen to find patients in need of various health maintenance and promotion services. The CDS logic is run as a report for all patients in the practice. Recommendations for appropriate patients appear on each patient's individual "to-do" list and are also compiled into an overall report that can be reviewed by staff addressing population health or care management.
2. Self-care: patients or family caregivers can use the artifact as part of self-assessment or health maintenance programs.
    a. Mr. Delta runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. Recommendations are compiled into a list and presented immediately with the assessment results or can be delivered as a secure message to the patient on a self-care website.
3. Data-driven screening: The recommendations could change when relevant data change (e.g., new results for low density lipoprotein [LDL] or high-density lipoprotein [HDL], new diagnosis of diabetes, new diagnosis of ASCVD).
    a. Ms. Epsilon, a patient, had a new cholesterol blood test panel performed as part of a recent visit; when the test is run, this CDS logic runs to see if any change in recommendations is called for. Ms. Epsilon's LDL has gone up to 195 milligrams/deciliter (mg/dL); her previous high was 155 mg/dL. The guideline recommends that she be placed on a statin if she has not already been taking one. The logic delivers recommendations as a message to the provider's general inbox and to the "to-do" section of the patient chart.

CDS Interventions and Suggested Actions

The Artifact Semi-Structured Logic section of Appendix A illustrates the CDS logic that generates the display of CDS interventions and suggested actions. At a very high level, the inclusion and exclusion logic generate the following interventions and suggested actions:

1. Recommendations for statin use in patients meeting any of the subpopulations, considering shared decision making with the patient (different messages are delivered to patients in each of the three subpopulations).
2. Notification message when insufficient data are available to process the CDS logic—in particular, if the patient has not had an LDL result in the last 3 years (to determine membership in subpopulation) or has not ever had an LDL result (to determine membership in subpopulation).
    a. The eCQM applies to all patients greater than age 21; a lipoprotein panel should be performed for all patients over that age. Many practices may not be in the habit of testing patients on the younger end of this range, which would generate many insufficient-data messages. The age range for the eCQM was carefully considered by the eCQM development group, and we have reproduced it as specified.
3. Suggested action: order a statin medication.
4. Suggested action: document any new medications being used.
5. Educational interventions: links to relevant recommendation statements, link to the USPSTF statin guideline and to the eCQM guideline, shared decision-making tools, and patient education tools.
6. Suggested action (if declined): document why the provider and patient have decided on a management strategy differing from the recommendation.
    b. Reasons for declining could include:
        i. Patient has known adverse reactions to statins.
        ii. Patient is likely to have adverse reactions to statins.
        iii. Patient understood the recommendation but elects not to take a statin.
        iv. Lab results are incorrect.
        v. Patient has an exclusion or exception that was not inferred by the CDS logic.
        vi. Patient is pregnant and meets CDS age and diabetes inclusion criteria but does not meet the FDA's suggested criteria for statin use.

Guideline Interpretation and Clinical Decisions

Evidence Source for Artifact Development

The CMS347v6 measure is a ratio of the number of patients who receive an order for statins or who are using statins (the numerator) divided by the number of patients at high risk for cardiovascular events (the denominator). The following definitions, exceptions, and exclusions are detailed in the source document.[2]

The denominator is defined in three subpopulations.

1. Individuals who have an active diagnosis of clinical ASCVD, or ever had an ASCVD procedure.
2. Individuals ≥20 years of age who have ever had a laboratory result of LDL ≥190 mg/dL, or who have a previous or active diagnosis of familial hypercholesterolemia, and who are not in the first subpopulation.
3. Individuals 40 to 75 years of age with type 1 or type 2 diabetes and who are not in the other subpopulations.

Individuals who are breastfeeding or have a diagnosis of rhabdomyolysis are *excluded*—that is, they are not counted in the denominator or numerator when determining performance on the measure.

Individuals who have an allergy to statin, are receiving palliative or hospice care, who have active liver disease or hepatic disease or insufficiency, who have statin-associated muscle symptoms, or who have end-stage renal disease (ESRD) are *excepted*—that is, they are counted in the denominator only if they are also included in the numerator (i.e., if they are on a statin).[5]

Additional reference information can be found in the Supporting Evidence: Reference section of the artifact in the CDS Connect Repository.

Guideline Translation Summary

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. Throughout the development of this artifact, the CDS Development Team engaged with eCQM subject matter experts (SME) to ensure that the evidence was translated appropriately and to clarify any narrative phrase in the measure that was unclear. Appendix A (the Decision Log) provides detailed information on how the eCQM and subsequent SME clarifications initially informed CDS development, along with later revisions in response to annual eCQM updates. Some of the key interpretations and decisions include the following:

1. Value sets (VS) were created when no existing VS in the Value Set Authority Center adequately described a concept needed by the CDS logic.
2. "Familial or pure hypercholesterolemia" was changed to use the codes only for familial hypercholesterolemia, based on the Cholesterol Management Work Group's determination that terms such as pure, primary, and polygenic hypercholesterolemia are often used incorrectly.
3. Intensity of statin therapy is not specified in the eCQM, although joint guidance from the ACC and the AHA discusses differing levels of statins that apply to certain subpopulations. The eCQM-derived CDS artifact differs from the related patient- and clinician-facing artifacts, which include specific intensity statins. The project team followed the eCQM in

simply recommending statins for appropriate patients without specifying a specific dosing level.

4. The Cholesterol Management Work Group, in interpreting "hepatic disease or failure," concluded that the best computable equivalent would be a diagnosis of cirrhosis, an active diagnosis of hepatitis A or hepatitis B, or a most recent alanine transaminase (ALT) result >150 mg/dL.
5. The ACC/AHA guideline notes that the evidence for statin use in patients over age 75 is less strong. This evidence has been turned into an additional statement on the recommendations delivered for patients in subpopulation 2.

Technical Details Regarding Artifact Implementation

This artifact is composed of several software files written in CQL. The primary focus of these software files is to allow any organization to identify patients who may benefit from statin therapy for primary or secondary prevention of CVD.

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

CQL is a data standard, governed by HL7, that is currently a Mixed Normative/Trial-Use specification.[6] 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, Evaluation Engine) on GitHub
- CQL Execution Engine (JavaScript) on GitHub

Artifact Library Manifest

The Statin Therapy eCQM artifact provides two distinct versions of the logic files:

- **StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv102_v3.0.0_CQL.zip**: The most recently updated FHIR DSTU2-based CQL logic files align with version 6 of the eCQM. Some modifications have been made to account for the differences in data models and approaches between eCQMs and CDS. This version and all previous versions have not been piloted in a clinical setting.

- **StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv401_v3.0.0_CQL.zip**: The FHIR R4-based CQL logic files align with version 6 of the eCQM. Some modifications have been made to account for the differences in data models and approaches between eCQMs and CDS. This version and all previous versions have not been piloted in a clinical setting. Although the intent of the logic remains the same as the most recently updated FHIR DSTU2-based version, changes in the FHIR specification (from DSTU2 to R4) required corresponding changes to the CQL logic.

Detailed descriptions of the most recent versions can be found in the **StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerived_Change_Log.txt** file attached to this artifact in the CDS Connect Repository.

Each of these packages is comprised of three 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.[7]

Table 1. Artifact Manifest

Filename	Purpose
StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv102.cql (FHIR DSTU2 only) or StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv401.cql (FHIR R4 only)	CQL representation of the Statin Therapy eCQM artifact. This file specifies the necessary logic to query relevant data, identify patients who meet the logic criteria, and return structured text that could be used in a patient-facing notification. This representation of the logic uses the HL7 standard for expressing CDS; it is considered more human-readable that other coded formats.
StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv102.json (FHIR DSTU2 only) or StatinTherapyForThePreventionAndTreatmentOfCVDeCQMDerivedFHIRv401.json (FHIR DSTU2 only)	JSON representation of the artifact. This file specifies the necessary logic to query relevant data, identify patients who meet the logic criteria, and return structured text that could be used in a patient-facing notification. This representation of the logic is provided as an alternative to the CQL-expressed code; some IT systems may find it easier to parse the JSON version.
CDSConnectCommonsForFHIRv102.cql (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.cql (FHIR R4 only)	Common CQL functions that may be called by CDS Connect artifacts.

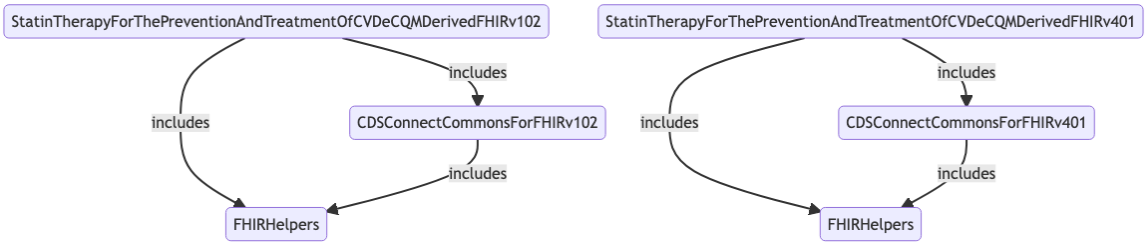
Filename	Purpose
CDSConnectCommonsForFHIRv102.json (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.json (FHIR R4 only)	JSON representation of common CQL functions that may be called by CDS Connect artifacts.
FHIRHelpers.cql	Common CQL functions used to convert CQL data elements to FHIR and back again.
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again.

Artifact Library Relationship

The project team encourages CQL developers to refactor commonly used functions into separate software files called libraries.[8] 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 1** shows the relationships between this artifact's main library file and the three 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 1. Artifact Relationship Diagram



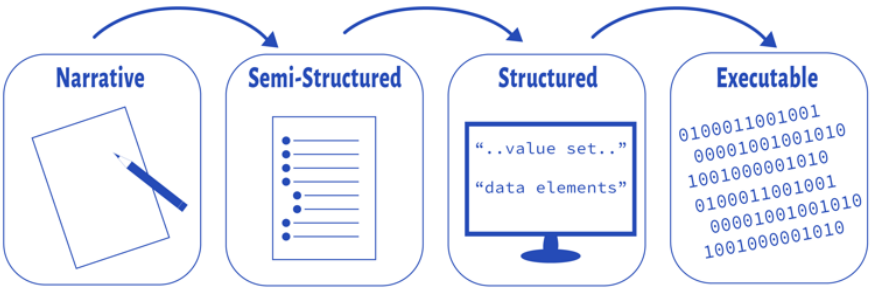
Artifact Testing

The project team tested the Statin Therapy eCQM artifact using an automated testing framework written in Node.js. This framework accepted test cases in a comma-separated value (.csv) file, executed the artifact against each test case, and reported the success or failure of each test case. These test cases verified that basic functionality, including inclusion and exclusion criteria, worked as expected. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

Implementation Checklist

As noted in the Introduction, Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts (see **Figure 2** for a summary of the process).[1]

Figure 2. CDS Artifact Maturity Process



The CDS Connect team suggests the following "best practices" for including third-party CDS into an existing health IT system.

- 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 Guideline Translation Summary section of this document and Appendix A (the 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 incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf health IT systems are unable to use CQL files natively; they require a separate application to convert CQL code so that it can be used in those health IT 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 many pilot settings, developers worked around existing health IT limitations by implementing a web service wrapper around a CQL execution engine. This is a non-trivial amount of work with two primary components.
    - A CQL execution engine with a Representational State Transfer (RESTful) Web service designed to accept requests for CQL execution and to respond with the calculated results (CQL Services[9] is one possible option for this component).
    - Modifications to the health IT system such that it will—
        - Trigger RESTful events to call the CQL execution engine.
        - Interpret the response.
        - Reflect the CQL-generated interventions and suggested actions in the health IT user interface.
- After implementers incorporate the artifact into a development environment, it 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.
- Depending on the end user who will be interacting with the CDS (as well as the intervention action that is displayed), consider whether documentation and training material may need to 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 a clinical guideline, but the project team anticipates that portions of the CQL code may be useful for other purposes.

- The three libraries included in this artifact—CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, and FHIRHelpers—define commonly used functions in CQL files and are not specific to the Statin Use eCQM artifact. They may be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the Statin Use eCQM artifact could be copied and reused in other CQL files. For example, some parties might be interested in reusing the logic in other pertinent CDS to identify patients with an active pregnancy.

Appendix A. Decision Log

Artifact Semi-Structured Logic

This artifact is derived from updated CMS measure ID CMS347v6 eCQM ("Statin Therapy for the Prevention and Treatment of Cardiovascular Disease").

The population statements, originally derived from v1 of the eCQM, are updated annually to reflect the eCQM updates.

This section presents the v6 statements of the eCQM numerator, denominator, and exclusions, followed by the CDS expressions of the same concepts. The eCQM logic is focused on a specific measurement period; the CDS logic expressed in this artifact is not time-related.

eCQM Initial Population/Denominator:

All patients who meet one or more of the following criteria (considered at "high risk" for cardiovascular events, under ACC/AHA guidelines):

- All patients with an active diagnosis of clinical ASCVD, including having ever had an ASCVD procedure
- Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory result of LDL-cholesterol (LDL-C) >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia
- Patients aged 40 to 75 years at the beginning of the measurement period with type 1 or type 2 diabetes.

eCQM Denominator Exclusions:

- Patients who are breastfeeding at any time during the measurement period
- Patients who have a diagnosis of rhabdomyolysis. at any time during the measurement period.

eCQM Denominator Exceptions:

- Patients with statin-associated muscle symptoms or an allergy to statin medication
- Patients who are receiving palliative or hospice care
- Patients with active liver disease or hepatic disease or insufficiency

- Patients with ESRD
- Patients with documentation of a medical reason for not being prescribed statin therapy.

eCQM Numerator:

- Patients who are actively using or who receive an order (prescription) for statin therapy at any point during the measurement period.

The following semi-structured inclusion and exclusion logic used in the CDS artifact were derived from the eCQM population statements. No measurement period is specified.

CDS Inclusion logic:

CDS Population 1:

Active diagnosis of ASCVD or a previous ASCVD procedure

CDS Population 2:

Age >= 20

AND LDL-C >= 190 mg/dL at any point in time

OR familial hypercholesterolemia

AND NOT active ASCVD diagnosis or previous ASCVD procedure

CDS Population 3:

Patient is >=40 and <=75 years

AND diabetes (type 1 or 2) active diagnosis

AND NOT LDL-C >= 190 mg/dL at any point in time

AND NOT active ASCVD diagnosis or previous ASCVD procedure

AND NOT familial hypercholesterolemia

CDS Exclusion logic:

Breastfeeding OR breastfeeding observation within the past year

OR rhabdomyolysis

OR hepatitis A OR hepatitis B

OR cirrhosis OR elevated ALT > 150 (> 3 times the normal limit)

OR ESRD

OR receiving palliative or hospice care

OR adverse effect, allergy, or intolerance to statin medications

OR statin-associated muscle symptoms

OR already receiving a statin medication

Concept Definition Decision Log

Table 2 defines many of the terms used in the semi-structured CDS representation to provide clarity on what each logic concept means, and why each was expressed as listed. These concepts were informed or derived from text in the recommendation statement.

The decisions and translations listed in this log were informed by the published eCQM, research review, and supporting references. The CDS Development Team engaged with eCQM and Cholesterol Management SMEs to disambiguate unclear narrative phrases to ensure that the evidence was translated appropriately. This log outlines how textual phrases were translated to semi-structured logic, as well as how SME and Cholesterol Management Work Group insight informed the CDS expression.

Table 2. Concept Definition Decision Log

Location in CDS Logic	Concept	Definition and/or Rationale
All populations	"at the beginning of the measurement period"	This is an eCQM term that does not directly apply to real-time CDS. CDS will evaluate the patient's age at the time of care. (Note: the eCQM logic looks for individuals who are 20 years of age before January of the current calendar year, which means that they will be 20–21 during the current calendar year. For subpopulation #3 in the eCQM, individuals who turned 75 years of age before January of the current calendar year would be 75–76 during the current calendar year. If they are 76 years old, then they fall outside the highest ACC/AHA recommendation). Evaluating age when care is provided enables the CDS to align more directly with the ACC/AHA recommendation.
Population 1	"clinical ASCVD"	ASCVD is defined by value sets that include diagnosis and procedure concepts that reflect signs and symptoms of the disease. It is represented using multiple value sets published on the Value Set Authority Center to express ASCVD "conditions" (e.g., myocardial infarction, ischemic vascular disease) and "procedures" that imply underlying ASCVD (e.g., coronary artery bypass grafts, percutaneous coronary interventions, carotid interventions). When a patient has ASCVD, different types of treatment and counseling may be indicated. Treatments and counseling for active ASCVD are outside the of scope of this artifact.
Population 2	"who have ever had"	At any point in time. This is to accommodate scenarios where LDL was elevated prior to therapy and is now lower.
Population 2	"previously diagnosed with or currently have an active diagnosis"	Specified in CQL code with HL7 clinicalStatus and verificationStatus attributes.
Population 2	"familial hypercholesterolemia"	Based on the Cholesterol Management Work Group's recommendations, this concept was changed to familial hypercholesterolemia only. The Cholesterol Management Work Group felt strongly that other classifications (i.e., pure, primary, polygenic) are misused in primary care due to poor definitions and understanding of the condition. The project team invites feedback on the use of this data element in practice.
Denominator exclusions	Exclusions	For CDS purposes, patients meeting the listed exclusions are not provided a statin recommendation; statins are contraindicated for individuals who are breastfeeding or have active rhabdomyolysis. As of 2023, pregnancy is no longer an exclusion because the FDA updated its guidance to no longer exclude pregnancy, and to support its use in pregnant women with ASCVD or familial hypercholesterolemia.

Location in CDS Logic	Concept	Definition and/or Rationale
Denominator exclusions	“Rhabdomyolysis” as an Exclusion	Based on the Cholesterol Management Work Group’s recommendations, only “active” cases of rhabdomyolysis and the conditions in the designated value set should be excluded. Do not exclude “resolved” cases.
Denominator exceptions	Exceptions	For CDS purposes, patients meeting these exceptions are not targets for a statin recommendation; they would not be flagged as deficient if they did not receive a statin. In most cases, the potential benefit versus harm of initiating a statin must be closely considered for patients with the listed conditions.
Denominator exception	“active liver disease or hepatic disease or insufficiency”	eCQM logic represents this phrase as three distinct data elements: liver disease, hepatitis A, and hepatitis B. Based on Cholesterol Management Work Group’s recommendations, this phrase is represented as cirrhosis, ALT > 150 (i.e., three times the upper normal limit), hepatitis A, and hepatitis B. Note: the ACC/AHA guidelines cite elevated ALT as a contraindication for statins and has been used as a proxy for severe liver disease.
Denominator exception	“hepatitis A” “hepatitis B”	The Cholesterol Management Work Group had varied opinions on whether to include active/relapsed hepatitis A and B in the exclusions or express *all* liver-related conditions in one statement (i.e., cirrhosis or ALT > 150). The current representation aligns with eCQM logic (i.e., includes hepatitis A and B). Future implementers can adjust the logic to align with what would work best in their organization.

Artifact Development Decision Log

The Artifact Development Team made many decisions when translating the eCQM and developing the structured representation of this artifact. **Table 3** provides insight on those decisions, along with where the coded representation might be expanded in the future. The table lists a "Decision Category" informed by the Tso et al. journal article, titled "Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation," that outlines a methodology for knowledge translation.[10] It also lists the high-level "Concept" related to the entry and the "Rationale" for each decision.

Table 3. Artifact Development Decision Log

Decision Category	Concept	Rationale
Select guidelines	Age >75	The ACC/AHA guideline provides no evidence on benefit of statins for patients >75yrs. Based on the Cholesterol Management Work Group's recommendations, two decisions were made. First, if age >75 and patient has ASCVD, then add a clause to the recommendation stating that benefit has not been proven. Second, if age >75 and patient evaluates as true for Population 2, then display the following notification: "Evaluate comorbidities, safety considerations, and priorities of care before considering a statin for patients over 75 years old."
Implementation guidance	Provide distinct messages for different populations	CQL coding will support the provision of distinct notification and rationale statements for each population. Currently, the recommendations align with eCQM specifications, which promote initiation of *any* intensity statin. Due to intellectual property constraints, the more-specific ACC/AHA guideline recommendations (http://circ.ahajournals.org/content/129/25_suppl_2/S1) are not implemented in this artifact; nevertheless, end users may adjust the notification text and the intensity of statin that is expressed in the notification prior to implementation of the artifact, if desired.
Deabstract	Strength of notifications	The Cholesterol Management Work Group had varied opinions on the strength of wording to use in notifications (e.g., "start," "discuss," or "consider" a statin). Members underscored the importance of the discussion between patient and provider prior to initiation of a statin. Some felt that selecting a less-directive verb (e.g., "discuss" or "consider") better represents this shared decision making.

Decision Category	Concept	Rationale
Add explanation related to logic constraints to ensure clinical relevance	CDS vs. eCQM measurement	Original “source” content of this artifact is an eCQM, which is scored annually for each patient and in aggregate. The CDS representation of the eCQM provides an intervention/recommendation/action for each patient. This affects parameters such as “measurement period,” “exclusion,” and “exception” as outlined earlier. Recommendations are synthesized to encourage all eligible patients to be scored in the numerator of the eCQM.
Add explanation related to logic constraints	Evaluation of three distinct populations	Once a patient is in the target population (any age for Population 1, age >20 for Population 2 and ages 40-75 for Population 3) and is not excluded/excepted, the three populations (i.e., ASCVD, LDL-C >190, diabetic age 40 – 75) will be tested in sequence. Current logic assesses each patient for each population as if the other tests had not been done; as a result, factors such as “no ASCVD” are included in tests for Populations 2 and 3 even though the patient would already have been included in Population 1 (and thus would have exited the artifact).
Deabstract to ensure clinical relevance	Clinical and Verification attributes	Specific FHIR clinical attributes (e.g., “resolved,” “active”) and verification attributes (e.g., “confirmed,” “refuted”) are designated in CQL code to express the accepted status for each condition.
Implementation guidance	Clarify difference between eCQM narrative and eCQM logic	The narrative description of the v6 eCQM measure states that the denominator excepts patients with statin-associated muscle symptoms or allergy. The CQL logic is unchanged from v5; it still contains adverse effects, allergies, and intolerances. A value set for muscle symptoms was added; the adverse effects, allergies, and intolerances value set remains unchanged.
Implementation guidance	Clarify difference between eCQM and CDS logic	The eCQM logic excepts “[p]atients with documentation of a medical reason for not being prescribed statin therapy.” This statement is not included in the CDS logic for multiple reasons: 1) there is not yet a clear approach to representing it in FHIR, and 2) its value in a measurement context is that the clinician is not penalized for not prescribing (in a prospective context to identify candidates for statins, it does not have that value).

Appendix B. References

1 Boxwala AA, Rocha BH, Maviglia S, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. J Am Med Inform Assoc. 2011;18 Suppl 1:i132-139.

2 Centers for Medicare and Medicaid Services Electronic Clinical Quality Measure 347 v6. https://ecqi.healthit.gov/ecqm/ec/2023/cms347v6.

3 Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63(25 Pt B):2889-2934.

4 Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;139(25):e1082-e1143.

5 Health Level 7 (HL7). CQL - Clinical Quality Language | eCQI Resource Center. https://ecqi.healthit.gov/cql-clinical-quality-language. Accessed March 25, 2022.

6 Health Level 7 (HL7). Clinical Quality Language (CQL) Release 1 STU5 (1.5). https://cql.hl7.org/. Accessed March 25, 2022.

7 Health Level 7 (HL7). CQL-to-ELM Translator Reference Implementation. https://github.com/cqframework/clinical_quality_language/blob/master/Src/java/cql-to-elm/OVERVIEW.md. Accessed March 25, 2022.

8 Health Level 7 (HL7). Author's Guide: Using Libraries to Share Logic. https://cql.hl7.org/02-authorsguide.html#using-libraries-to-share-logic. Accessed March 25, 2022.

9 Agency for Healthcare Research and Quality. CQL Services GitHub page. https://github.com/AHRQ-CDS/AHRQ-CDS-Connect-CQL-SERVICES. Accessed March 25, 2022.

10 Tso GJ, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. AMIA Annu Symp Proc. 2016; 2016:1189-1198.