Implementation Guide

Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention

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Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published *Implementation Guide*	Original Implementation Guide content
September 2019	Updated the *Implementation Guide* based on annual CDS artifact updates	Updated content for clarity and to enhance readability.
April 2021	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, expanded CQL library details to account for FHIR R4 update, and clarified USPSTF Grade C recommendation not included.
September 2022	Updated the *Implementation Guide* based on annual CDS artifact updates	The Background and Introduction were edited for clarity. The content was reorganized under new headings to make navigation more intuitive. Minor wording changes were made to improve clarity. Updated the CQL section to reflect new CQL library names and versions.
August 2023	Updated the *Implementation Guide* based on annual CDS artifact updates and 2022 USPSTF updated guideline	Minor wording changes and sentences or phrases were added for clarity. The difference between this guideline and the FDA guidance on statins in pregnancy was described. Updated the CQL section to reflect new CQL library versions.

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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 health 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 they are 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.

Scope and Purpose

This document provides information about the creation and uses of the CDS logic expression (referred to as an "artifact") derived from the U.S. Preventive Services Task Force (USPSTF) full recommendation statement on Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication (referred to as the Statin Use: Patient-Facing artifact in this Implementation Guide), along with how it can be integrated within a health IT system. This artifact shares logic with the Clinician Facing Statin Use artifact (also available in the CDS Connect Repository) but includes intervention text pertinent to patients instead of to clinicians.

The Statin Use: Patient-Facing artifact is designed to be implemented in a patient-facing IT system (e.g., a patient portal, a health and wellness app) to deliver preventive health recommendations outside of a traditional encounter with a clinician. Organizations that might consider implementing this logic range from a large, self-insured healthcare organization that seeks to provide health and wellness resources to their employees and patients, to a healthcare innovator that culls patient data from several sources (e.g., electronic health records [EHR], claims, pharmacy-based management systems, biometric devices, patient-reported data) to provide personalized wellness information via a mobile app.

This Implementation Guide provides information about the artifact itself (i.e., the inclusion and exclusion CDS logic that generates notification text for targeted individuals). Organizations that elect to implement this code will likely choose to expand upon the CDS intervention to align with their organization's methodology and messaging, provide the patient with the ability to schedule an appointment, and the like. The CDS logic provides the foundational structure upon which these enhanced interventions can be designed and implemented.

This Statin Use: Patient-Facing artifact is designed to identify patients who qualify for the recommended statin therapy preventive care based on patient-specific criteria such as age and known cardiovascular disease (CVD) risk factors. The Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation statement from the USPSTF also includes a Grade C recommendation that specifies a 10-year CVD risk score of 7.5 percent to 10 percent.[2] This artifact does not express the Grade C recommendation (see rationale in Table 2). Future implementers can expand the existing CDS logic if they wish to implement the Grade C recommendation. The CDS provides targeted patients opportunities to learn more about their health status in the context of the recommendation, and it encourages them to take steps toward improving their health by reducing their risk of heart disease and stroke. One such step might be to initiate a discussion with their primary care clinician about preventive measures, including taking a statin medication.

Implementing and Using This Artifact

Artifact Description

This artifact identifies adults aged 40 – 75 without a history of CVD who have at least one CVD risk factor (dyslipidemia, diabetes, hypertension, or smoking) and have a calculated 10-year risk of a cardiovascular event of 10 percent or greater. Identified patients should consider using low- to moderate-dose statins for the prevention of CVD events, such as heart attacks and strokes.[2] The Statin Use: Patient-Facing artifact provides the opportunity to present information to at-risk patients through a patient-facing health IT system (e.g., a patient portal, a health app) to:

- Raise awareness that they may have one or more risk factors for heart disease and stroke.
- Provide educational resources about the risks for developing CVD and the role that statin therapy has in reducing lipid levels (thus reducing their CVD risk).
- Encourage patients to talk to their primary care clinician about ways to reduce their risk, including starting a statin medication as a preventive measure.

A key component of this artifact is the calculation and use of an individual's 10-year risk of developing CVD. The USPSTF recommends "using the American College of Cardiology (ACC)/American Heart Association (AHA) Pooled Cohort Equations (PCE) to calculate the 10-year risk of CVD events."[2] The ACC/AHA PCE calculates the 10-year risk of an atherosclerotic CVD (ASCVD) event and does not calculate the risk of developing atherosclerosis ("clogged arteries") in the absence of an "event" such as a heart attack or stroke.[3,4]

To align with USPSTF verbiage and intention, this artifact evaluates 10-year ASCVD risk scores previously calculated using the PCE and stored within a patient record to represent a patient's "10-year risk of CVD." A structured (i.e., coded) version of the PCE entitled CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk is publicly available on the CDS Connect Repository for healthcare organizations that do not currently have the equation available in their health IT system.[5]

Preventive Health Scenarios Supported by This Artifact

The Statin Use: Patient-Facing artifact was developed, piloted, and published to identify patients who are at risk for developing CVD according to the logic derived from the USPSTF Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication recommendation statement. Once a patient who might benefit is identified, the implementer should determine the appropriate method to notify patients, as well as provide educational information and tools to help patients lower their risk. The notification may be implemented through a patient-facing portal, a health app on the patient's phone, or secure email. The artifact specifies neither the method to notify the patient nor the organization-specific notification content, nor any additional information and/or tools provided to the patient. Instead, these decisions are dependent on the preferences, tools, and methods used by each implementer. Sample notification text providing some initial examples for implementers can be found in the Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention artifact in a file named Statin Use for CVD Prevention: Patient Facing—Intervention Content posted in the Miscellaneous Files section of the artifact. In addition, this document displays examples of the notification and educational content developed by b.well, the pilot partner, in the Patient Notification and Intervention Considerations section (Figures 1, 2, and 3).

The artifact supported the following scenarios during the pilot implementation of this CDS expression. Each scenario is populated with a fictitious patient name and health data to provide context to the scenario. Each implementing organization will likely develop a notification that

aligns with existing organizational messages and services. Scenarios 1a and 1b provide examples of the range of notifications that might be provided.

1. **Providing the patient with an alert that they may be at increased risk for heart disease and stroke.**
    a. Ms. Alpha is 55 years old and has hypertension and diabetes, which are poorly controlled despite taking medications for both, in addition to high levels of low-density lipoprotein cholesterol (LDL-C). She receives a push notification from her health app that some information from her healthcare team is available for her to review. Ms. Alpha opens the notification and selects the embedded link, which opens the health app and displays information indicating that she may have an increased risk for heart disease and stroke. The information found in the health app provides educational topics for Ms. Alpha to review regarding her risk factors and ways she could reduce her risk, including taking a statin medication to reduce her cholesterol levels, as outlined in scenario 2 in this list. It also encourages her to speak with her physician about her risk and ways to reduce it, as outlined in scenario 3 in this list.
    b. Mr. Bravo is 52 years old with low high-density lipoprotein cholesterol (HDL-C) and high LDL-C levels (as evidenced by repeat cholesterol tests in the past 6 months). He has a diagnosis of hypertension, which he can control with medication. He smokes about one pack of cigarettes a day. His risk estimate for developing heart disease or stroke in the next 10 years is 15 percent. He receives an email indicating new information from his healthcare team for him to review in the patient portal. He accesses the portal and discovers a message with additional information from his primary care clinician informing him that he may have an increased risk for heart disease and stroke based on his diagnosis of hypertension, high repeat cholesterol test levels, and a 10-year risk of developing CVD of 15 percent, which is above the normal range. The information in the patient portal also provides educational materials for Mr. Bravo to review regarding his risk factors and ways he could reduce his risk through lifestyle changes, such as healthy eating to reduce his cholesterol level. It also encourages him to speak with his physician about the possibility of starting a statin medication, as outlined in scenarios 2 and 3 of this list.
2. **Providing the patient with targeted educational materials**.
    a. Ms. Alpha selects the embedded link in the information provided in her health app, which accesses personalized educational material on CVD and statin therapy to reduce CVD risk. She reviews the information to learn more. The information provided also includes links to MyHealthfinder with additional resources and tools.[6]

b. Mr. Bravo's primary care clinician recommended several links to educational resources in the message that she sent him via the patient portal. Mr. Bravo reads the educational resources and watches a video on CVD risk and statin therapy.

3. **Recommending that the patient consult with their primary care clinician.**

    a. As Ms. Alpha reviews the information on her health app, one of the suggested actions is to schedule an appointment with her primary care clinician to discuss her risk of developing CVD and the possibility of taking a statin medication to reduce her risk. She schedules an appointment through the scheduling function in the health app.

    b. Mr. Bravo decides not to act on the suggested action of making an appointment with his primary care clinician to discuss his risk factors and possible interventions. Several weeks later, he receives another email reminding him that an outstanding action item remains on his patient portal. He accesses the portal and views the notification reminder that he should consider seeing his primary care clinician. This time, he decides to schedule the suggested appointment.

Additional Health Scenarios Supported by Customization of the Coded Expression

The coded CDS expression defines clinical concepts and criteria translated from the published Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication recommendation. Portions of the coded CDS expression can be reused to support additional scenarios that drive preventive health efforts across varied organizations, workflows, end users, and health IT systems.

Additional preventive health scenarios that could be supported by enhancing portions of this CDS logic include:

1. **Enabling population management by identifying all patients requiring screening for CVD risk in a primary care setting.**

    Franklin Community Care (FCC) is a midsize practice with four primary care clinicians (two physicians, a nurse practitioner, and a physician assistant) serving about 5,000 patients. FCC has noted the prevalence of several risk factors in their patients for developing CVD—primarily hypertension, dyslipidemia, and diabetes. Therefore, they want to start a program to proactively identify those at risk of developing CVD and assist in reducing their risk. This program will also help to improve their quality metrics. After the implementing institution customizes the information to executable logic and integrates the CDS logic into their EHR, the CDS inclusion and exclusion logic for this artifact is run on a monthly basis; each primary care team receives a report profiling those at risk in their patient panel. The staff reaches out to the patients to suggest scheduling an appointment to discuss their individual risk factors and possible interventions with their

primary care clinician. During the subsequent appointment, the primary care clinician provides educational information to the patient about their personal risks and discusses options for interventions to help prevent CVD, including taking a statin medication. To determine the impact of the interventions, data about the number of appointments scheduled because of the outreach, as well as specific CVD outcomes, are collected and analyzed on an ongoing basis.

2. **Enabling wellness and preventive care for patients through identification of specific CVD risk factors.**

   Health First provides wellness services to its customers, consisting primarily of employers and health plans. These customers contract with Health First to provide a holistic package of prevention and wellness services to their employees and members. This service includes reminders when preventive health services are due, wellness education based on the individual's risk factors, and identification of resources to address those risks. Health First uses the artifact logic to identify individual participants who have one or more specific risk factors for CVD (e.g., dyslipidemia, diabetes, hypertension, or smoking), have a calculated 10-year risk of a cardiovascular event of 10 percent or greater, and do not meet any of the exclusion criteria. They provide intensive wellness services to help the identified participants understand the actions and activities that may help mitigate their risk. Health First monitors these activities and any individual progress over time. Each month, they provide statistical de-identified reports to the employers and health plans to reflect the effect of the interventions.

3. **Modifying the CDS logic to address organizational goals and strategies.**

   Optimum Health Technologies (OHT) provides CDS products to large healthcare organizations for use in their health IT. The customer, a large hospital system, has requested CDS to identify those at risk for developing CVD who also have a history of other comorbid conditions (e.g., obesity or chronic obstructive pulmonary disease) to provide the appropriate primary care clinicians with a report generated by the CDS. The technology company uses the logic in this artifact, expanding its structured representation of the comorbid conditions to develop the requested CDS. The report is used to reach out to the identified patient population.

CDS Interventions and Suggested Actions

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

1. Inclusions: Individuals 40 to 75 years old with one or more risk factors for CVD (hypertension, abnormal HDL-C or LDL-C, diabetes, smoking) and a 10-year CVD risk score of 10 percent or greater.
2. Exclusions: Patients falling outside of the age range, or with the following:

    - A history of CVD.
    - An LDL-C lab result over 190 milligrams per deciliter (mg/dL) (note: an LDL-C result of over 130 mg/dL indicates dyslipidemia, but a result of over 190 mg/dL places an individual outside the scope of the recommendation statement; therefore, is listed as an exclusion).
    - Known familial hypercholesteremia.
    - Currently pregnant or breastfeeding.
    - A diagnosis of end stage renal disease (ESRD) or receiving dialysis therapy.
    - A diagnosis of cirrhosis.
    - A diagnosis of rhabdomyolysis.
    - Those currently receiving or prescribed a statin medication.

If a patient meets the inclusion criteria and does not meet the exclusion criteria, the following interventions and suggested actions will be generated:

1. Intervention: Notify the patient that they may be at risk for CVD.
2. Suggested Action: Provide educational materials that explain CVD risks pertinent to this recommendation in patient-friendly language (e.g., framing the risk as "having high blood pressure" or "high cholesterol levels" instead of clinical descriptions), along with ways to modify those risks, such as taking a statin medication to reduce cholesterol levels.
3. Suggested Action: Suggest the patient make an appointment with their primary care clinician to discuss their CVD risk(s) and ways to mitigate the risk, such as taking a statin medication. Facilitate appointment scheduling, if possible.

These interventions and suggested actions listed align with content that was created by b.well, the pilot partner, and presented to patients via the b.well app during the pilot implementation of this artifact. However, the pilot content (e.g., graphics, educational materials, patient-friendly language) is not included in the structured representation of this artifact due to its proprietary nature. The Example Intervention Content: Statin Use: Patient-Facing document, posted in the Miscellaneous Files section of this artifact, contains sample notification text providing some initial examples for implementers. Future implementers may elect to expand upon and customize the CDS intervention portion of the logic based upon their organizational preferences, patient population, and available resources.

Patient-Facing CDS Development Considerations

Most CDS is designed to be integrated into clinical workflow, with the clinician as the primary target and user. As the use of CDS evolves, clinicians are no longer the sole target of CDS information and alerts. Patients and their caregivers also seek health information to help guide them in their decisions to better manage their health. Patient-facing, evidence-based CDS may ultimately be one of the most effective methods of improving health outcomes by providing evidence-based information directly to patients and connecting them to resources and tools.[6]

Development of Patient-Centered Preventive Care CDS Artifacts

According to Alex Krist et al. (2011), studies have shown that most Americans receive only about half of recommended preventive services.[7] Well-designed CDS would provide patients with evidence-based information on recommended preventive services based on that patient's individual health history and risk factors.[7] Consideration of the scope and complexity of patient-specific data is of utmost importance to ensure the accuracy of the CDS logic and resulting recommendation. Inaccurate results may not only decrease a patient's trust in the information presented to them but may also cause harm.

This artifact's developers took care to ensure that required data elements and their definitions were well-specified and comprehensive. For example, if a patient was already taking a statin medication, then this information was accounted for in the artifact exclusion logic to ensure that any resulting notification to the patient was as accurate as possible and personalized to that patient.

Depending on the availability and comprehensiveness of patient data sources, consideration of other methods to obtain critical patient-specific data may be necessary. For example, missing data may be supplemented by enabling data collection directly from the patient through an automated form, risk assessment, or survey. In addition, a process to allow the patient to give permission to share their data from other sources may need to be defined.

Patient Notification and Intervention Considerations

For any patient who qualifies for the recommended preventive care based on their specific criteria, it is important to consider the interventions and workflow that should occur to notify the patient, as well as to provide resources and/or tools to allow the patient to act on the notification. As a component of patient-centered care, this process should account for the importance of the clinician/patient relationship, along with the corresponding principles of trust and shared decision making (SDM). In SDM, the patient's perspective—based on their values and preferences—is critical to the decision-making process.[8] It allows the patient and their primary healthcare clinician to determine the most appropriate treatment or care choice.

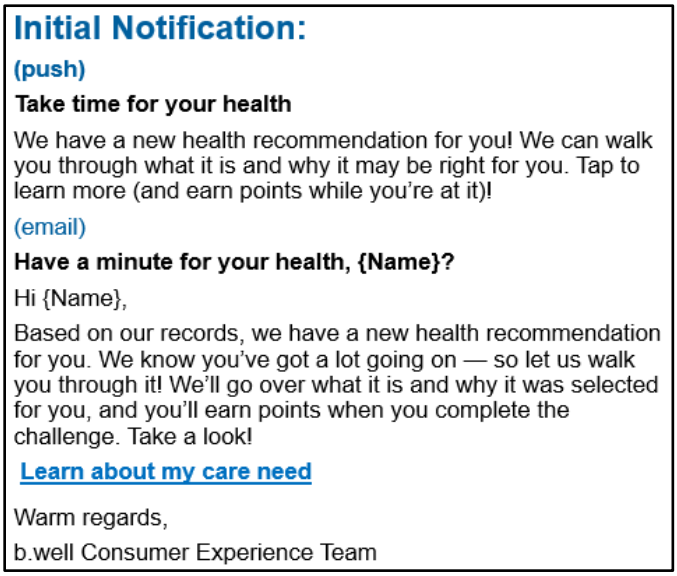
As noted earlier, the patient notifications included in the structured CQL expression of this artifact are general, meaning implementing organizations can expand upon and personalize the interventions based on their unique needs and patient population. Information provided to the patient translates the preventive care recommendation into lay language and identifies additional resources in a user-friendly format and method. This user-friendly information facilitates patient action through the provision of vetted resources; the customized piloted CDS also provides an opportunity to deliver personalized motivational messaging and logistical support for appointments and followup.

The pilot organization b.well implemented the following capabilities.

Notifications: Once the patient qualifies for the recommendation, the patient is notified through either a push notification or an email. The notifications are written in a motivational tone in order to encourage patient action. See **Figure 1** for an example.

- The notification process is tiered based on the patient response. For example, if the patient has not accessed the information provided, then additional notification reminders are sent at specific intervals.

Figure 1. Example of Patient Notification



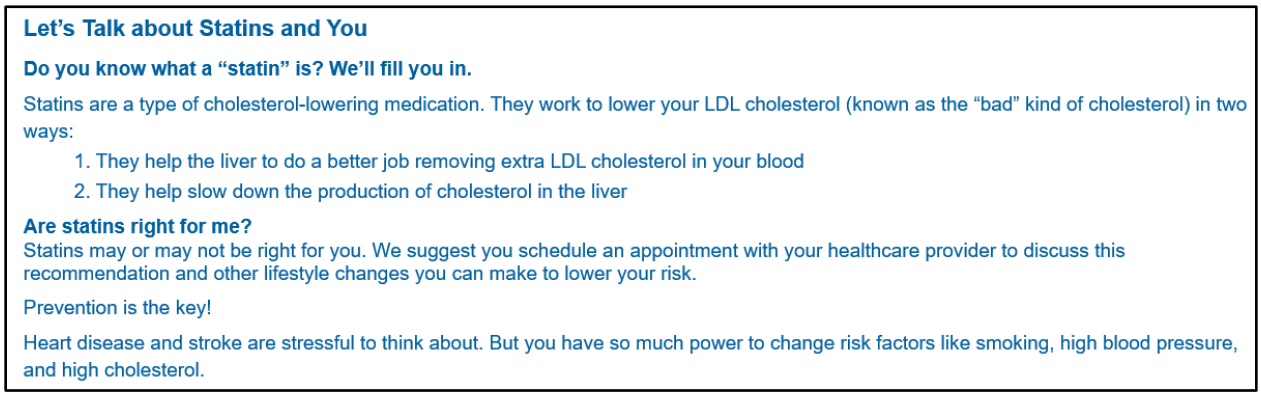
Educational Resources: Patients acting on the notification and accessing the health app can link directly to pertinent resources (e.g., information on the importance of lowering the risk for diabetes), along with educational materials, tools, and videos.

- The resources found on MyHealthfinder, as well as the USPSTF Consumer Fact Sheet,[9] were used as sources for much of the content created. Healthfinder.gov is a government website that provides three kinds of publicly available consumer-facing preventive health information:

- Health and wellness topics.
- Personalized preventive services recommendations.
- Videos about disease prevention and health promotion.[6]

- The information on healthfinder.gov employs health literacy and usability principles,[10] which can be used by future implementers to customize the educational content for their organization.
- Other sources of educational resources include cdc.gov, support organization sites, and trusted healthcare organizations. See **Figure 2** for an example of patient educational text.

Figure 2. Example of Patient Education



Let's Talk about Statins and You

Do you know what a "statin" is? We'll fill you in.

Statins are a type of cholesterol-lowering medication. They work to lower your LDL cholesterol (known as the "bad" kind of cholesterol) in two ways:

1. They help the liver to do a better job removing extra LDL cholesterol in your blood
2. They help slow down the production of cholesterol in the liver

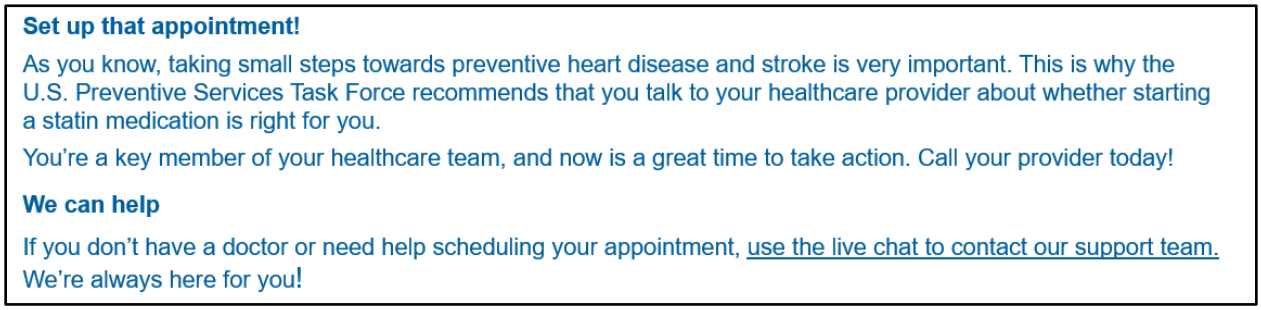
Are statins right for me?
Statins may or may not be right for you. We suggest you schedule an appointment with your healthcare provider to discuss this recommendation and other lifestyle changes you can make to lower your risk.

Prevention is the key!

Heart disease and stroke are stressful to think about. But you have so much power to change risk factors like smoking, high blood pressure, and high cholesterol.

Appointment Scheduling Tools and Other Resources: Educational resources include encouragement to discuss the recommendation with the patient's primary care clinician. The health app provides the ability to make an appointment with the patient's existing primary care clinician, or to facilitate finding a primary care clinician if the patient has not identified one. See **Figure 3** for an example.

Figure 3. Example of Appointment Facilitation



Set up that appointment!

As you know, taking small steps towards preventive heart disease and stroke is very important. This is why the U.S. Preventive Services Task Force recommends that you talk to your healthcare provider about whether starting a statin medication is right for you.

You're a key member of your healthcare team, and now is a great time to take action. Call your provider today!

We can help

If you don't have a doctor or need help scheduling your appointment, use the live chat to contact our support team. We're always here for you!

CDS research, design, development, testing, implementation, and evaluation are performed with the goal of supporting patient preferences and effective patient decision making, facilitating patient action, and ensuring consideration of the patient perspective. In turn, the successful implementation of patient-facing CDS helps support quality and safety—positively impacting patient health outcomes and satisfaction.

Guideline Interpretation and Clinical Decisions

Evidence Source for Artifact Development

This artifact is derived from the USPSTF full recommendation statement for Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. The recommendation summary states that "the USPSTF recommends that clinicians prescribe a statin for the primary prevention of CVD for adults aged 40 to 75 years who have one or more CVD risk factors (i.e. dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year risk of a cardiovascular event of 10 percent or greater."[2] The recommendation is Grade "B," indicating that the USPSTF recommends this service, and there is high certainty that the net benefit of providing this counseling to patients is moderate to substantial.[11] The recommendation summary also states:

> The USPSTF recommends that clinicians selectively offer a statin for the primary prevention of CVD for adults aged 40-75 years who have one or more of these CVD risk factors and an estimated 10-year CVD risk of 7.5% to less than 10%.[2]

This recommendation is Grade "C," indicating that the USPSTF recommends selectively offering or providing this service to individual patients, based on professional judgment and patient preferences.[11]

Guideline Translation Summary

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. To assist with development of the Statin Use: Clinician-Facing artifact, the CDS Development Team engaged with the CDS Connect Cholesterol Management Work Group (WG), which was formed in late 2016. The Cholesterol Management WG consisted of cardiology and preventive health experts from government organizations, universities, and healthcare settings. The WG helped clarify inclusions and parameters described in the recommendation statement, as well as indicated exclusions that should be added to the logic to ensure patient safety. Appendix A (the Decision Log) provides detailed information on how the USPSTF recommendation statement and the WG clarifications informed CDS development for the Statin Use: Clinician-Facing artifact developed in its original form in 2017 and the Statin Use: Patient-Facing artifact developed in its original form in 2019. There are two differences between the two "Statin Use" artifacts. First is the text that the CDS logic produces: the Clinician-Facing Statin Use artifact delivers evidence-based information to a clinician with

prescribing privileges during a medical encounter, whereas the Patient-Facing Statin Use artifact delivers evidence-based information to patients outside of a medical encounter. The second difference is the recommendation for offering a statin when the 10-year CVD risk is 7.5% to less than 10%; this recommendation appears in the clinician-facing but not the patient-facing logic.

Some of the key interpretations and decisions include the following.

1. **Source of artifact logic.** This artifact applied logic from the Statin Use for the Primary Prevention of CVD in Adults: Clinician-Facing CDS Intervention artifact as the "starting point" for development. The logic was enhanced during development of the Statin Use: Patient-Facing artifact to add the rhabdomyolysis exclusion identified by the Cholesterol Management WG. In addition, a new CDS intervention was designed to deliver patient-friendly and engaging textual information and resources (as opposed to clinician-friendly with more medical details).
2. **Defining exclusion criteria.** Because the USPSTF recommendation does not explicitly list exclusion criteria, the MITRE CDS Development Team researched statin contraindications and collaborated with the Cholesterol Management WG to build out the exclusion logic. WG members provided guidance on translation of the recommendation statement, raised considerations to ensure patient safety, aided in the design of the CDS, and validated the semi-structured representation of the CDS artifact. The Statin Use: Patient-Facing artifact leveraged this previous work.
    a. **Diagnosis of active pregnancy, pregnancy observation, breastfeeding, and breastfeeding observation as exclusions.** The 2018 AHA/ACC Guideline on the Management of Blood Cholesterol states, "[s]tatins are listed as pregnancy category X and should not be used in women of childbearing potential unless these women are using effective contraception and are not nursing."[1]In July, 2021, the FDA recommended manufacturers of statin medications remove the contraindication to their use in all pregnant patients.[12] Recent literature shows that for pregnant patients at very high risk of heart attack or stroke (including those with familial hypercholesterolemia), the benefit may outweigh the risk, and statins should not be contraindicated during pregnancy. Removing the warning will lead to shared decision making with patients and clinicians so those who need the statin will continue to receive it. This artifact follows the 2022 USPSTF guidance, which contains pregnancy as a contraindication for all CDS guidance.[2]
    b. **ESRD, ESRD encounter, dialysis procedure, and dependence on dialysis as exclusions.** Chronic kidney disease has been associated with an increased risk of CVD.[13] However, multiple studies on patients with ESRD and those on dialysis have revealed little to no benefit of statin therapy in reducing CVD risk. The ACC states, "People with chronic kidney disease are at higher risk of side effects from lipid medications due to reduced renal excretion, polypharmacy, and multiple co-

morbidities" and "there does not appear to be a benefit to treating people on chronic dialysis, likely due to excessive competing risk."[13]

Technical Details Regarding Artifact Implementation

The Statin Use: Patient-Facing artifact is composed of several software files written in CQL. Their primary focus is to allow any organization to identify patients who qualify for the recommended statin medication by providing CQL representations of the CDS logic.

The following sections provide technical details useful for those implementing this artifact in their health IT system. First, they provide background information on CQL, the programming language used to write the logic for the artifact. This information is followed by a listing, or manifest, of the main CQL files included in the artifact. The relationships between these files are described, followed by a discussion on how the artifact has been tested.

General Information About CQL

CQL is a data standard governed by HL7 that is currently a mixed Normative/Trial-Use specification.[14] 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:

- Health Level Seven (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 Use: Patient-Facing artifact provides two distinct versions of the logic files.

- **USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv102_ v2.1.0_CQL.zip**: The most recently updated FHIR DSTU2-based CQL logic files. The artifact logic has not changed after the release of version 2.0.0, but some value-set definitions have been updated. This version was not piloted in a clinical setting, but is largely based on the initial piloted version.
- **USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv401_v2.1.0_CQL.zip**: The FHIR R4-based CQL logic files. This version was not piloted. 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 changes in recent versions of this artifact can be found in the **USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacing_Change_Log.txt** file attached to this artifact in the CDS Connect Repository.

Each of these packages is comprised of five 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 the CQL format and JavaScript Object Notation (JSON) format alike. They contain the same information, but they are formatted to serve different purposes: the CQL format is human-readable; the JSON format is machine-readable and generated using the CQL-to-Expression Logical Model translator.[15]

Table 1. Artifact Manifest

Filename	Purpose
USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv102.cql (FHIR DSTU2 only) or USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv401.cql (FHIR R4 only)	CQL representation of the Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medicine recommendation. 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 readily human-readable than other coded formats.
USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv102.json (FHIR DSTU2 only) or USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsPatientFacingFHIRv401.json (FHIR R4 only)	JSON representation of the Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medicine recommendation. 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 because it may be easier to parse for some IT systems.
USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsSharedLogicFHIRv102.cql (FHIR DSTU2 only) or USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsSharedLogicFHIRv401.cql (FHIR R4 only)	Support library that contains CQL shared with the clinician-facing version of the Statin Use: Patient-Facing artifact.
USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsSharedLogicFHIRv102.json (FHIR DSTU2 only) or USPSTFStatinUseForPrimaryPreventionOfCVDInAdultsSharedLogicFHIRv401.json (FHIR R4 only)	Support library that contains JSON shared with the clinician-facing version of the Statin Use: Patient-Facing artifact.

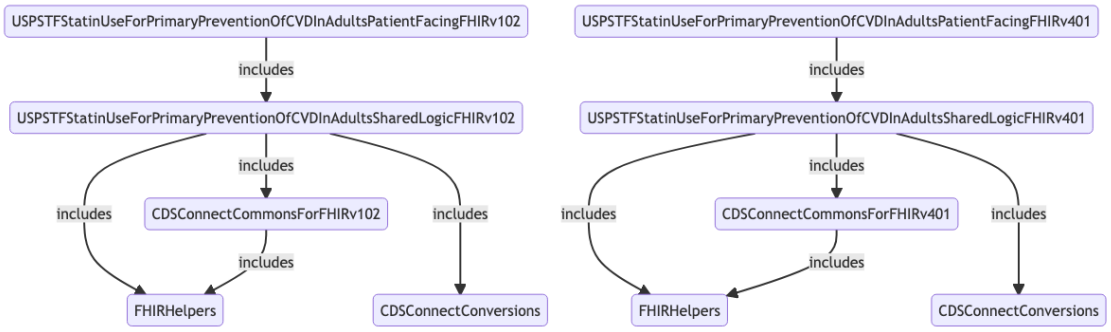
Filename	Purpose
CDSConnectCommonsForFHIRv102.cql (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.cql (FHIR R4 only)	Common CQL functions that may be called by CDS Connect artifacts.
CDSConnectCommonsForFHIRv102.json (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.json (FHIR R4 only)	JSON representation of common CQL functions that may be called by CDS Connect artifacts.
CDSConnectConversions.cql	CQL representation of a library that supports conversions from one unit to another.
CDSConnectConversions.json	JSON representation of a library that supports conversions from one unit to another.
FHIRHelpers.cql	Common CQL functions used to convert CQL data elements to FHIR and back again for FHIR DSTU2 and FHIR R4.
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again.

Artifact Library Relationship Diagram

CQL developers refactor commonly used functions into separate software files called libraries.[16] Libraries allow greater flexibility and reusability than the practice of placing all CDS logic into a single, unique file for a single artifact. **Figure 4** shows the relationships between this artifact's main library file and its four supporting libraries.

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

Figure 4. Artifact Relationship Diagram



Artifact Testing

The Statin Use: Patient-Facing artifact was tested 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 and exclusion criteria. The test cases are described in .csv files available as zipped archives attached to this artifact in the CDS Connect Repository.

Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system, which include the following (non-exhaustive) examples:

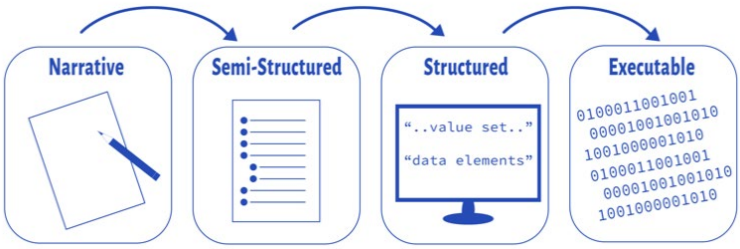
- Patient not included because their 10-year risk score is less than 10 percent.*
- Patient excluded due to ESRD.
- Patient excluded due to a recent pregnancy diagnosis.
- Patient included because of recent LDL-C lab test result greater than 130 mg/dL.
- Patient included because they have an active diagnosis of diabetes.
- Patient included because they are a smoker.

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 5** for a summary of the process).[1]

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts, as described in the introduction.[2] The framework defines four "layers" of representation, as depicted in **Figure 5** and described here:

Figure 5. CDS Artifact Maturity Process



* This is an intentional difference from the related *Statin Use for the Primary Prevention of CVD in Adults: Clinician Facing CDS Intervention* CDS artifact; the Grade C recommendation applies to a risk score of at least 7.5 percent, but the Grade B recommendation does not apply unless the risk score is at least 10 percent. For the patient-facing CDS only the Grade B recommendation (>= 10%) is reflected.

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 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 capacity to implement CQL code, along with any potential adverse impacts to existing functionality. In many pilot settings, developers have 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,[17]described later in this document, is one possible option for this component).
    - Modifications to the health IT system to:
        - 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 incorporation into a development environment, the artifact should be exhaustively tested against predefined test cases. Testing should also ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
- Depending on the end user that 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

Although the CQL code within this artifact was developed to enact a clinical guideline, portions of the CQL code will likely be useful for other purposes.

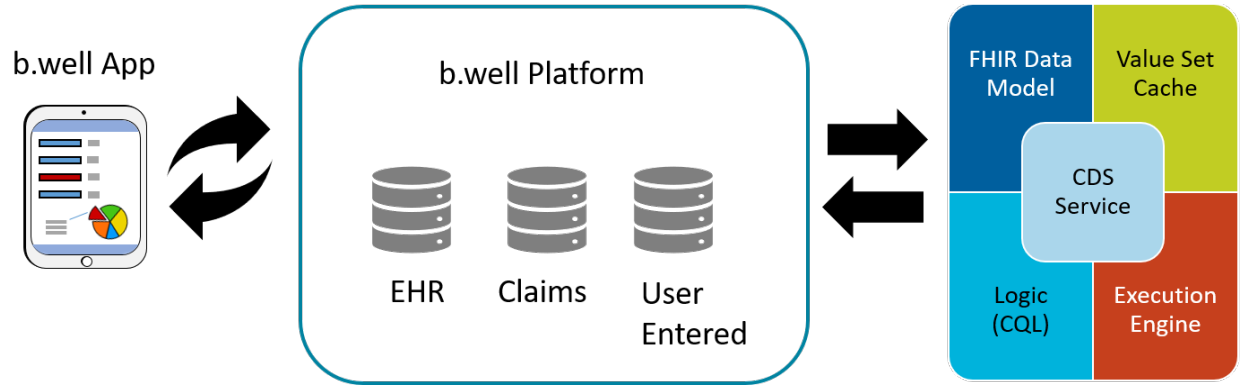
- The four libraries included the CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, FHIRHelpers, and CDSConnectConversions to define commonly used functions in CQL files; they are not specific to the Statin Use: Patient-Facing artifact. They may be used with any other CQL file that would benefit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

Integration With Health Information Technology

CQL Services[17] was used to facilitate integration of the Statin Use: Patient-Facing artifact into the b.well system during the summer 2019 pilot. As depicted in **Figure 6**, CQL Services consists of four main components:

1. A data model based on FHIR Draft Standard for Trial Use 2 (DSTU2).
2. A value set service and cache for retrieving coded clinical concepts from the National Library of Medicine (NLM) Value Set Authority Center (VSAC)[18] and local storage cache.
3. Logic represented by the CQL libraries included with this artifact.
4. An execution engine.

Figure 6. Integration Approach Using CQL Services



Data on the b.well platform come from a variety of sources, including one or more EHRs, claims, pharmacy benefit management systems, and user-entered information (e.g., self-reported family history, weight or height measurements, or inputs from a smart watch). When the artifact is triggered for a particular user, the necessary data are queried and aggregated on the b.well platform, then sent as an Hypertext Transfer Protocol (HTTP) request to the CQL Service via a CDS Hooks interface.[19] CQL Services responds to the request by executing the requested artifact against the provided data, then returning the result of the CQL back to the b.well platform. The response may not contain any recommendations for the user depending upon whether the inclusion and exclusion criteria were met. A list of the data requirements for the artifact are given in **Table 4** in Appendix B.

Appendix A. Decision Log

Artifact Semi-Structured Logic

The USPSTF recommendation summary states "[t]he USPSTF recommends that clinicians prescribe a statin for the primary prevention of CVD for adults aged 40 to 75 years who have one or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year CVD risk of 10% or greater. (B recommendation)."[2]

The semi-structured inclusion and exclusion logic that represents the recommendation summary, as well as additional criteria added for patient safety per the Cholesterol Management WG, is as follows.

Inclusion logic:

Patient is >=40 and <=75 years of age

AND one or more risk factor:

LDL-C lab result > 130 mg/dL, MOST RECENT VALUE within the past 6 years *(final, amended)*

OR HDL-C < 40 mg/dL, MOST RECENT VALUE within the past 6 years *(final, amended)*

OR diabetes (Type 1 or Type 2) *(active, relapse)*

OR hypertension *(active, relapse)*

OR smoking, MOST RECENT STATUS within the past 6 years *(final, amended)*

AND 10-year CVD risk score >=10 percent, MOST RECENT VALUE within the past 6 years *(final, amended)*

Exclusion logic:

CVD

OR LDL-C lab result >190 mg/dL, MOST RECENT VALUE within the past 6 years *(final, amended)*

OR known familial hypercholesterolemia *(active)*

OR pregnancy *(active)*

OR pregnancy observation within the past 42 weeks *(final, amended)*

OR breastfeeding *(active)*

OR breastfeeding observation, MOST RECENT within the past 1 year *(final, amended)*

OR ESRD *(active)*

OR ESRD encounter, within the past 1 month *(in progress, finished)*

OR dialysis procedure, within the past 7 days *(in progress, completed)*

OR dependence on dialysis *(active, relapse)*

OR cirrhosis *(active, relapse)*

OR rhabdomyolysis *(active, relapse)*

OR statin medication order, within the past 2 years *(active, completed)*

OR statin medication statement, within the past 2 years *(active)*

Concept Definition Decision Log

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

USPSTF final recommendations are published on the USPSTF website, along with resources outlining their extensive investigation into concepts included in the recommendation (i.e., their research review). The decisions and translations listed in this log were informed by the published full recommendation statement, research review, and supporting references. They were also informed by previous work with the CDS Connect Cholesterol Management WG (mentioned previously), which assisted with disambiguating any unclear narrative phrase in the USPSTF recommendation to ensure that the evidence was translated appropriately. This log outlines how textual phrases were translated to semi-structured logic, along with how each clinical concept and logic phrase is defined.

Table 2. Concept Definition Decision Log

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	“>=”	Greater than or equal to a given value (e.g., >=40 years old)
Inclusions	“<=”	Less than or equal to a given value (e.g., <=75 years old)
Inclusions	“AND one or more risk factor”	Defines a list of logic phrases where one or more of the phrases must be present in the patient record (i.e., evaluate as true) to meet inclusion criteria. The list of clinical risk factors is outlined in the recommendation statement (i.e., dyslipidemia, diabetes, hypertension, or smoking). Each of these clinical factors are defined in subsequent entries within this table.
Inclusions	“LDL-C lab result >130 mg/dL”	LDL-C lab result that is greater than 130 milligrams/deciliter (mg/dL). A result of >130 mg/dL is an indication of dyslipidemia, a risk factor for developing coronary artery disease (CAD) and stroke. In the 2016 Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation, the USPSTF defined dyslipidemia as “an LDL-C level greater than 130mg/dL or a HDL-C level less than 40mg/dL.” The 2022 USPSTF guideline did not define dyslipidemia, and therefore the original definition is maintained in the logic. The FHIR Observation status must be “final,” “amended,” or “corrected” to ensure the observation is complete and verified by an authorized individual. Note: the CQL code includes an equation to convert lab results measured in “moles/volume” to “mg/dL.”
Inclusions	“MOST RECENT VALUE”	The value closest to the date of the CDS trigger; this ensures that the logic is evaluating data that are as close to the patient’s current health status as possible.

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"Within the past 6 years"	The ACC/AHA recommends assessment of ASCVD risk every 4–6 years. Results older than 6 years may not reflect the patient's current condition as accurately as a result within the time span. Because lipid profile results and smoking status are inputs to ASCVD risk assessment, the CDS Connect CDS Development Team and the Cholesterol Management WG determined that a 6-year lookback supports a calculation that will most accurately reflect an individual's risk.
Inclusions	"HDL-C lab result < 40 mg/dL"	HDL-C lab result that is less than 40 mg/dL. A result of <40 mg/dL is an indication of dyslipidemia, a risk factor for developing CAD and stroke. For the purpose of the 2016 Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication recommendation, the USPSTF defined dyslipidemia as "an LDL-C level greater than 130mg/dL or a HDL-C level less than 40mg/dL." The 2022 USPSTF guideline did not define dyslipidemia, and therefore the original definition is maintained in the logic. The FHIR Observation status must be "final," "amended," or "corrected" to ensure the observation is complete and verified by an authorized individual. Note: the CQL code includes an equation to convert lab results measured in "moles/volume" to "mg/dL."
Inclusions	"Diabetes (Type 1 or Type 2)"	Diagnosis of diabetes mellitus (type 1 or type 2). High blood glucose levels for an extended time can damage blood vessels, leading to retinopathy and nephropathy, peripheral vascular disease, stroke, coronary artery disease, and systolic and diastolic heart failure.[20] The FHIR Condition clinicalStatus must be "active," "relapse," or "recurrence" to ensure that the condition is relevant to the patient's current health status.
Inclusions	"hypertension"	Defined as essential (primary) and nonessential (secondary) hypertension conditions. The excess strain and resulting damage from hypertension cause the coronary arteries to slowly become narrowed from a buildup of plaque, leading to CVD.[21] Hypertension is the strongest risk factor for developing CVD.[22] The FHIR Condition clinicalStatus must be "active," "relapse," or "recurrence" because this can be a transient diagnosis.
Inclusions	"smoking"	Defined as a cigarette or tobacco smoker. Chemicals in cigarette smoke damage the lining of the blood vessels, leading to atherosclerosis and CVD. The risk of CVD increases with the number of cigarettes smoked per day and years of smoking history.[23] The FHIR Observation status must be "final," "amended," or "corrected" to ensure the observation is complete and verified by an authorized individual.

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"10-year CVD risk score >=10 percent	A greater than or equal to 10 percent risk of an individual having a heart attack or stroke within the next 10 years. CVD risk is calculated using the ACC/AHA pooled cohort equation. The FHIR Observation status must be "final," "amended," or "corrected" to ensure the observation is complete and verified by an authorized individual. This artifact does not calculate CVD risk; it looks instead for evidence of the most recent CVD risk score that has been recorded in the past 6 years. Future implementers should determine if the ACC/AHA pooled cohort equation is implemented in their health IT system. If the equation is not embedded in their health IT system, then it is available in the CDS Connect Repository as a shared resource that is publicly available here: https://cds.ahrq.gov/cdsconnect/artifact/cmss-million-heartsr-model-longitudinal-ascvd-risk-assessment-tool-baseline-10. Please be aware that this artifact aligns with the Grade B recommendation in the USPSTF Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation statement, which specifies a 10-year CVD risk score of greater than or equal to 10 percent. The Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation statement also includes a Grade C recommendation that specifies a 10-year CVD risk score of 7.5 percent–10 percent.[2] This artifact does not express the Grade C recommendation. Future implementers can expand upon the existing CDS logic if they wish to implement the Grade C recommendation. The decision to only express the Grade B recommendation was made in partnership with the organization that piloted this CDS artifact. One factor influencing this decision is that the Affordable Care Act requires reimbursement by private insurers and government payers for care that aligns with Grade A and Grade B USPSTF recommendations only.[24] Not including the Grade C recommendation removed the chance that care recommended to a patient will not be covered by insurance.
Exclusions	CVD	CVD is defined as CAD or ischemic stroke. It is represented as multiple value sets published on the Value Set Authority Center to express CVD "conditions" (e.g., myocardial infarction, ischemic vascular disease) and procedures that imply underlying CVD (e.g., coronary artery bypass grafts, percutaneous coronary interventions, carotid interventions). CVD is expressed as an exclusion because the interventions generated by the coded logic are only relevant to *preventing* CVD. If a patient has CVD, different types of treatment and counseling may be indicated. Treatments and counseling for active CVD are outside the of scope of this artifact.
Exclusions	"LDL-C lab result >190 mg/dL"	LDL-C lab result that is greater than 190 mg/dL. The USPSTF recommendation states "These recommendations do not apply to adults with a LDL-C level greater than 190 mg/dL … these populations are at very high risk for CVD and considerations on the use of statins in these populations can be found in other organizations' guidelines."[2] This elevated risk places an individual outside the scope of the recommendation statement; therefore, LDL-C >190 mg/dL is listed as an exclusion. The FHIR Observation status must be "final," "amended," or "corrected" to ensure the observation is complete and verified by an authorized individual.

Location in CDS Logic	Concept	Definition and/or Rationale
Exclusions	"Known familial hyper-cholesterolemia"	Diagnosis of familial hypercholesterolemia. The USPSTF states that "[t]hese recommendations do not apply to adults with … or known familial hypercholesterolemia; these populations are at very high risk for CVD, and considerations on the use of statins in these populations can be found in other organizations' guidelines."[2] This elevated risk places an individual outside the scope of the recommendation statement; therefore, a diagnosis of familial hypercholesterolemia is listed as an exclusion. The FHIR Condition clinicalStatus must be "active" to ensure that the condition is relevant to the patient's current health status.
Exclusions	"pregnancy"	Diagnosis of pregnancy. Per the ACC/AHA, statins should not be used during pregnancy; therefore, pregnancy is listed as an exclusion.[12] A FHIR Condition clinicalStatus of "active" must be present to ensure that the individual is currently pregnant. Note that this artifact encodes 2022 USPSTF guidance; the FDA issued new guidance in 2021 that statin manufacturers no longer list pregnancy as an absolute contraindication to statin use.
Exclusions	"pregnancy observation within the past 42 weeks"	Pregnancy is also expressed as a FHIR Observation in the CDS logic to identify a second way that this concept can be recorded in a health IT system. "Within the past 42 weeks" is specified as a lookback timeframe so that only a current/active pregnancy is considered. The American College of Obstetricians and Gynecologists defines "early, full, and late term pregnancy" as up to 42 weeks of gestation. Because gestation date is not often specified in a health IT system, the CDS logic evaluates the date that a pregnancy observation was recorded in the system. Reference: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/11/definition-of-term-pregnancy. The FHIR Observation status must be "final," "amended," or "corrected" to ensure the observation is complete and verified by an authorized individual.
Exclusions	"breastfeeding"	Diagnosis of breastfeeding (which includes conditions associated with lactation). Per the ACC/AHA, statins should not be used by women who are breastfeeding; therefore, breastfeeding is listed as an exclusion.[12] The FHIR Condition clinicalStatus must be "active" to ensure that the patient is currently breastfeeding.
Exclusions	"breastfeeding observation within the past 42 weeks"	Breastfeeding is also expressed as a FHIR Observation in the CDS logic to identify a second way that this concept can be recorded in a health IT system. The rationale for specifying a 42-week lookback period is outlined in the Pregnancy Observation entry.
Exclusions	"ESRD"	A diagnosis that reflects ESRD. Impaired renal function may influence statin safety.[25] For this reason, evidence of ESRD is listed as an exclusion. The FHIR Condition clinicalStatus must be "active" to ensure there is sufficient diagnostic and/or clinical evidence to substantiate the diagnosis.

Location in CDS Logic	Concept	Definition and/or Rationale
Exclusions	"ESRD Encounter"	An encounter during which ESRD care was provided to an individual. This concept is included in the logic as an alternative way to identify an ESRD diagnosis because the organization that piloted this logic had access to claims data (i.e., encounter claims). The FHIR Encounter status must be "in-progress," "finished," or "completed" to ensure that the encounter occurred.
Exclusions	"dialysis procedure within the past 7 days"	Dialysis procedure performed within the past 7 days. Evidence of a dialysis procedure is included in the logic as an alternative way of identifying ESRD. The frequency of dialysis varies between patients but occurs approximately 3 times a week.[26] The CDS Connect CDS Development Team, in collaboration with the Cholesterol Management WG, determined that a lookback of 7 days would allow adequate time to determine if a patient is actively undergoing dialysis. A FHIR Procedure status of "completed" is specified to ensure that all actions involved in the procedure have taken place.
Exclusions	"dependence on dialysis"	Dependence on renal dialysis, peritoneal dialysis, or hemodialysis. Evidence of dependence on a dialysis procedure is included in the logic as an alternative way of identifying a diagnosis of ESRD. A FHIR Condition clinicalStatus of "active," "relapse," or "recurrence" is specified to ensure the condition is relevant to the patient's current health status.
Exclusions	"cirrhosis"	Diagnosis consistent with cirrhosis of the liver (regardless of morphology, histology, or etiology). Impaired hepatic function may influence statin safety.[25] For this reason, evidence of cirrhosis is expressed as an exclusion criterion. A FHIR Condition clinicalStatus of "active," "relapse," or "recurrence" must be present to ensure the condition is relevant to the patient's current health status.
Exclusions	"rhabdomyolysis"	Diagnosis of rhabdomyolysis (a syndrome characterized by muscle necrosis and the release of intracellular muscle contents into systemic circulation). Rhabdomyolysis is a well-documented side effect of statin therapy.[27,28] Evidence of rhabdomyolysis presents a safety risk related to statin therapy; therefore, it is listed as an exclusion. The FHIR Condition clinicalStatus must be "active," "relapse," or "recurrence".
Exclusions	"statin medication order, … statement, … dispensed … within the past 2 years"	A statin medication order (FHIR MedicationRequest status "active" or "completed"), patient statement (FHIR Medication Statement status "active"), or dispensed medication (FHIR MedicationDispense status "in-progress" or "completed") within the past 2 years. Two years was selected as a lookback to provide a reasonable length of time to identify evidence of therapy that is relevant to an individual's recent health status. This item is listed as an exclusion to ensure that a patient who is currently receiving statins (or has recently received statins) does not receive a notification to discuss statin therapy with their primary care team.

Artifact Development Decision Log

The CDS Development Team made many decisions when translating the USPSTF recommendation 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's "Decision Category" was 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.[29] 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
Verify completeness/ add explanation	pregnancy (and pregnancy observation), breastfeeding (and breastfeeding observation)	These concepts are listed in the exclusion logic for patient safety reasons. The USPSTF recommendation does not explicitly list exclusion criteria; therefore, the CDS Development Team researched statin contraindications and collaborated with the Cholesterol Management WG to build out the exclusion logic. The WG was comprised of primary care and cardiology SMEs. WG members provided guidance on translation of the recommendation statement, raised considerations to ensure patient safety, aided in the design of the CDS, and validated the semi-structured representation of the CDS artifact. The 2018 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce ASCVD Risk in Adults states "Statins are listed as pregnancy category X and should not be used in women of childbearing potential unless these women are using effective contraception and are not nursing."
Verify completeness/ add explanation	ESRD, ESRD encounter, dialysis, dependence on dialysis	These concepts are listed in the exclusion logic for patient safety reasons. The USPSTF recommendation does not list explicitly list exclusion criteria; therefore, the CDS Connect CDS Development Team researched statin contraindications and collaborated with the Cholesterol Management WG to build out the exclusion logic. As mentioned previously in other decision log entries, each of these concepts represent different ways to identify evidence of ESRD within an individual's health record. Kidney Disease: Improving Global Outcomes (KDIGO) organization (a group of nephrologists, lipid specialists, and epidemiologists that updated their clinical practice guidelines in 2013) states "in adults with dialysis-dependent chronic kidney disease, we suggest that statins or statin/ezetimibe combination not be initiated."[30] The ACC further states "People with chronic kidney disease are at higher risk of side effects from lipid medications due to reduced renal excretion, polypharmacy, and multiple co-morbidities. There does not appear to be a benefit to treating people on chronic dialysis, likely due to excessive competing risk."[13]

Appendix B. Data Requirements

The clinical concepts specified as data elements in the CDS logic for this artifact were documented in a Data Requirements spreadsheet, along with detailed information for each data element. **Table 4** provides some of the key information from that spreadsheet, including the complete list of all data elements used as either inclusion or exclusion criteria in the artifact. The complete spreadsheet is posted with this artifact in the Technical File section of the entry on the CDS Connect Repository.

Table 4. Data Requirements for this Artifact

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Age	I	Patient	birthDate
10-year CVD risk score	I	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is 'final,' 'amended,' or 'corrected' (R4 only) valueQuantity with '%' units
Active Cirrhosis	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active', 'relapse', or 'recurrence' (R4 only) no abatement[x] attributes are present
Breastfeeding (within the last year)	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' no abatement[x] attributes are present

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Breastfeeding Observation	X	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is 'final,' 'amended,' or 'corrected' (R4 only) valueCodeableConcept
Myocardial Infarction (MI) (Cardiovascular Disease (CVD))	X	Condition	code verificationStatus is 'confirmed'
Ischemic Vascular Disease (Cardiovascular Disease (CVD))	X	Condition	code verificationStatus is 'confirmed'
Coronary Artery Bypass Graft (CABG) (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed' notPerformed is absent or false (DSTU2 only)
Percutaneous Coronary Intervention (PCI) (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed' notPerformed is absent or false (DSTU2 only)
Carotid Intervention (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed' notPerformed is absent or false (DSTU2 only)

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Diabetes (Type 1 or Type 2)	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is ‘active’ no abatement[x] attributes are present
Dialysis (within the last week)	X	Procedure	code status is ‘completed’ notPerformed is absent or false (DSTU2 only) performedDateTime or performedPeriod
Dialysis (Dependence on)	X	Condition	code verificationStatus is ‘confirmed’ clinicalStatus is ‘active,’ ‘relapse,’ or ‘recurrence’ (R4 only)
End Stage Renal Disease	X	Condition	code verificationStatus is ‘confirmed’ clinicalStatus is ‘active’ no abatement[x] attributes are present
End Stage Renal Disease Encounter	X	Encounter	status is ‘in-progress,’ ‘finished’ (DSTU2 only), or ‘completed’ (R4 only) reason (DSTU2 only) or reasonCode (R4 only) period

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Familial Hypercholesterolemia	X	Condition	code verificationStatus is ‘confirmed’ clinicalStatus is ‘active’ no abatement[x] attributes are present
HDL	I	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is ‘final,’ ‘amended,’ or ‘corrected’ (R4 only) valueQuantity with ‘mg/dL’ or ‘mmol/L’ units
Hypertension	I	Condition	code verificationStatus is ‘confirmed’ clinicalStatus is ‘active,’ ‘relapse,’ or ‘recurrence’ (R4 only)
LDL-C Result > 130 mg/dl	I	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is ‘final,’ ‘amended,’ or ‘corrected’ (R4 only) valueQuantity with ‘mg/dL’ or ‘mmol/L’ units

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
LDL-C Result > 190 mg/dl	X	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is 'final,' 'amended,' or 'corrected' (R4 only) valueQuantity with 'mg/dL' or 'mmol/L' units
Pregnancy	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active,' 'relapse,' or 'recurrence' (R4 only) no abatement[x] attributes are present
Pregnancy Observation (within the last 42 weeks)	X	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is 'final,' 'amended,' or 'corrected' (R4 only) valueCodeableConcept
Rhabdomyolysis	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' no abatement[x] attributes are present

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Smoking/Current Smoker	I	Observation	code effectiveDateTime, effectivePeriod, effectiveInstant (R4 only), or issued (to determine most recent) status is 'final,' 'amended,' or 'corrected' (R4 only) valueCodeableConcept
Statin Therapy (Order)	X	MedicationOrder (DSTU2) MedicationRequest (R4)	medicationCodeableConcept dateWritten (DSTU2 only) or authoredOn (R4 only) (for 2-year lookback) status is 'active' or 'completed'
Statin Therapy (Statement)	X	MedicationStatement	medicationCodeableConcept effectiveDateTime or effectivePeriod (for 2-year lookback) status is 'active'
Statin Therapy (Dispensed)	X	MedicationDispensed	medicationCodeableConcept whenHandedOver or whenPrepared (for 2-year lookback) status is 'in-progress' or 'completed'

Appendix C. References

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