

Implementation Guide

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

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Introduction

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

Each year the CDS Connect team develops CDS artifacts (i.e., CDS logic expressions), implements the CDS in a live clinical setting, and contributes the body of work to the CDS Connect Repository to: 1) demonstrate CDS Connect infrastructure, 2) ensure that the artifact performs as expected, and 3) share lessons learned for future implementers of the CDS logic. This *Implementation Guide* provides information and guidance to individuals who are considering use of this artifact. The main intent of this document is twofold: to provide insight on how the logic can be used to improve patient care and to provide information on how to integrate the CDS logic with a health information technology (IT) system. Detailed findings from the pilot implementation of this artifact are documented in the CDS Connect *Pilot Report*.

Background

To facilitate AHRQ’s vision, the CDS Connect project team created 1) the CDS Connect Repository to host and share CDS artifacts; 2) the CDS Authoring Tool, which enables CDS developers to create CDS logic using Clinical Quality Language (CQL), a Health Level 7 (HL7) standard expression language; and 3) several open-source prototype tools to facilitate creating, testing, sharing, integrating, and implementing evidence-based, interoperable CDS in health IT systems. The use of CQL in CDS Connect systems and CDS development is notable because it provides the ability to express logic that is human readable yet structured enough to process a query electronically. Furthermore, CQL is an interoperable format that eases integration with health IT systems.¹ CQL allows logic to be shared between CDS artifacts, and eventually with electronic clinical quality measures (eCQMs), in support of improving healthcare quality.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with over three dozen metadata fields to describe their work, including the artifact’s purpose, clinical uses, publisher, and sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made

while creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files and reports.

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

The CDS Connect team also developed several prototype tools, including one that facilitates CQL testing (CQL Testing Framework) and one that facilitates integration of the CQL code with a health IT system (CQL Services). The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. This framework allows CQL developers to identify bugs in the CDS logic early in the development cycle, when it is less costly to fix. In addition, these test cases enable developers to demonstrate the expected behavior of the CDS logic to bolster trust in the coded expression. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to this artifact's CQL. CQL Services is an open-source service framework for exposing CQL-based logic using the HL7 CDS Hooks application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively. See the "Integration with Health Information Technology" section of this guide for how CQL Services was used for the pilot implementation of this artifact, and the 2019 *Pilot Report* for detailed findings and lessons learned related to the use of CQL Services to pilot this artifact.

Scope, Purpose, and Audience of This Implementation Guide

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](#), referred to as the *Statin Use: Patient-Facing* artifact in this guide, along with how it can be integrated within a health IT system. This artifact shares logic with the *Statin Use: Clinician-Facing* artifact (also available on the CDS Connect Repository) but includes intervention text pertinent to patients versus clinicians.

The *Statin Use: Patient-Facing* artifact is designed to be implemented in a patient-facing IT system (e.g., a patient portal or 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 numerous sources (e.g., electronic health record [EHR], claims, pharmacy-based management systems, biometric devices, patient-reported data) to provide personalized wellness information via a mobile app.

To provide clarity, this 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, etc. 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. Targeted patients are provided with opportunities to learn more about their health status in the context of the recommendation and are encouraged to take steps toward improving their health and reducing their risk of heart disease and stroke (e.g., initiate a discussion with their primary care clinician about preventive measures including taking a statin medication).

Various audiences may find this information 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 find this document helpful 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 identifies patients 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, health app) to (1) raise awareness that they may have one or more risk factor for heart disease and stroke, (2) provide educational resources about the risks for developing CVD and the role statin therapy has in reducing lipid levels and thus reducing their CVD risk, and (3) encourage them 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 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 however, the ACC/AHA PCE calculates the 10-year risk of atherosclerotic CVD (ASCVD) events.³ CVD is the term for all types of diseases that affect the heart or blood vessels, including atherosclerotic heart disease (i.e., ASCVD or "clogged arteries").⁴

To align with USPSTF verbiage and intention, this artifact evaluates 10-year ASCVD risk scores that are already 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 health care 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 those patients at risk for developing CVD according to the logic derived from the USPSTF [*Statin Use for the Primary Prevention of Cardiovascular Disease in Adults*](#) recommendation statement. Once 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 even through secure email. The method used to notify the patient, as well as the organization-specific notification content and any additional information and/or tools provided to the patient, are not specified by the artifact but are dependent on the preferences, tools, and implementation methods used by each implementer. Sample notification text has been developed to provide some initial examples for implementers, which can be found in the *Example Intervention Content: Statin Use: Patient-Facing* document posted in the Miscellaneous Files section of the *Statin Use: Patient-Facing* artifact. In addition, examples of the notification and educational content developed by the pilot partner, b.well, are displayed in this document in the *Patient Notification and Intervention Considerations* section.

The artifact supported the following scenarios during the pilot implementation of this CDS expression. Note, each scenario is populated with a fictitious patient name and health data to provide context to the scenario.

1. Providing the patient with an alert that they may be at increased risk for heart disease and stroke

- a. Mary is 55 years old and has hypertension and diabetes, which are poorly controlled despite taking medications for both, as well as high levels of low-density lipoprotein cholesterol (LDL-C). She receives a push notification from her health app that there is some information for her to review from her healthcare team. Mary 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.
 - i. The information found in the health app provides educational topics for Mary to review regarding her risk factors and ways she could reduce her risk, including taking a statin medication to reduce her cholesterol levels, and encourages her to speak with her physician about her risk and ways to reduce it, as outlined in scenarios 2 and 3 (below). As previously noted, each implementing organization will likely develop a notification that aligns with existing organizational messages and services. This scenario provides an example of the notification that might be provided. The same is true for subsequent scenarios.
- b. John 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 is able to control with medications. 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 that there is new information to review in the patient portal from his healthcare team. 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.
 - i. The information in the patient portal also provides educational materials for John 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, and encourages him to speak with his physician about the possibility of starting a statin medication as outlined in scenarios 2 and 3 (below).

2. Providing the patient with targeted educational materials

- a. Mary 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. Mary reviews the information to learn more. The information provided also includes links to healthfinder.gov with additional resources and tools.
 - i. Healthfinder.gov is a government website that provides three kinds of publicly available consumer-facing preventive health information: (1) health and wellness topics, (2) personalized preventive services recommendations, and (3) videos about disease prevention and health promotion.⁶ The information on the healthfinder.gov website has been designed using health literacy and usability principles,⁷ and can be used by future implementers to customize the educational content for their organization.
- b. John's primary care clinician recommended several links to educational resources in the message that he sent John via the patient portal. John 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 Mary 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. John 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, John receives another email reminding him that there is still an action item outstanding 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.

Health Scenarios Supported With Customization of the Coded Expression

The coded CDS expression defines clinical concepts and criteria translated from the published USPSTF *Statin Use for the Primary Prevention of CVD in Adults: Preventive Medication* recommendation to identify patients that may benefit from statin medications to reduce the risk of developing CVD. 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 in New Jersey 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. The CDS inclusion and exclusion logic for this artifact is run on a monthly basis, and each primary care team receives a report profiling those at risk in their patient panel. The staff reaches out to the patients to suggest they schedule 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 risks and discusses options for interventions to help prevent CVD, including taking a statin medication. Data about the number of appointments scheduled as a result of the outreach as well as specific CVD outcomes are collected and analyzed on an ongoing basis to determine the impact of the interventions

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

Health First provides wellness services to its customers, which consist 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 specific risk factors for CVD, such as dyslipidemia, diabetes, hypertension, or smoking, and have a calculated 10-year risk of a cardiovascular event of 10 percent or greater. 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 technology company uses the logic in the artifact and adds additional structured representation of the comorbid conditions to develop the requested CDS. 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 such as obesity or chronic obstructive pulmonary disease, so the appropriate primary care clinicians are provided with a report generated by the CDS. The report is used to reach out to the identified patient population.

CDS Interventions and Suggested Actions

The CDS logic that generates the display of CDS interventions and suggested actions is pictured in the Artifact Semistructured Logic section of [Appendix A](#). At a very high level, the semistructured inclusion and exclusion logic looks for the following:

1. Inclusions: Individuals 40 to 75 years old with one or more risk factor for CVD (i.e., hypertension, dyslipidemia, 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); a family history of hypercholesterolemia (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); currently pregnant or breastfeeding; a diagnosis of end stage renal disease (ESRD) or receiving dialysis therapy; a diagnosis of cirrhosis; a diagnosis of rhabdomyolysis; and 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 (having high blood pressure or high cholesterol levels), 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.

Of note, the intervention and suggested actions listed above align with content that was created by the pilot partner, b.well, 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. Sample notification text has been developed to provide some initial examples for implementers, which can be found in the *Example Intervention Content: Statin Use: Patient-Facing* document posted in the Miscellaneous Files section of this artifact. Future implementers may elect to expand upon 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 no longer need to be the sole target of CDS information and alerts. Patients and their caregivers are increasingly seeking health information to help guide them in their healthcare decisions and better manage their health. As a result, development and use of patient-facing CDS should be increasingly considered. 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.⁸

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.⁹ 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.⁹ 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.

During the development of this artifact, care was taken 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, 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 patient-specific criteria, it is important to consider the interventions and workflow that should occur in

order to 1) notify the patient and 2) provide resources and/or tools to allow the patient to act upon the notification. As a component of patient-centered care, this process should account for the importance of the clinician-patient relationship, and 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.¹⁰ It allows the patient and their primary healthcare clinician to determine together the most appropriate treatment or care choice.

As noted earlier, the patient notifications included in the structured CQL expression of this artifact are fairly general, enabling implementing organizations to 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 provides additional resources in a user-friendly format and method. This user-friendly information facilitates patient action through the provision of vetted resources, and in the case of the customized piloted CDS, an opportunity to provide personalized motivational messaging and logistical support for appointments and followup.

For the initial pilot implementation, the pilot organization 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 to be motivational to the patient to encourage action. See **Figure 1** for an example.

- The notification process is tiered, based on the patient response (e.g., if the patient has not accessed the information provided, additional notification reminders are sent at specific intervals).

Figure 1. Example of Patient Notification

Initial Notification:
(push)
Take time for your health
We have a new health recommendation for you! We can walk you through what it is and why it may be right for you. Tap to learn more (and earn points while you're at it)

(email)
Have a minute for your health, {Name}?
Hi {Name},
Based on our records, we have a new health recommendation for you. We know you've got a lot going on — so let us walk you through it! We'll go over what it is and why it was selected for you, and you'll earn points when you complete the challenge. Take a look!

[Learn about my care need](#)

Warm regards,
b.well Consumer Experience Team

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Educational Resources: When the patient acts upon the notification and accesses the health app, they are able to link directly to pertinent educational resources, such as information on the importance of lowering the risk for diabetes, along with educational materials, tools, and videos to provide additional education.

- The resources found on healthfinder.gov as well as the USPSTF Consumer Fact Sheet¹¹ were used as sources for much of the content created. 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.

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Appointment Scheduling Tools and Other Resources: The 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 does not have one identified. 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!

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Facilitating patient action and ensuring that the patient perspective is considered during the CDS research, design, development, testing, implementation, and evaluation will help ensure that patient preferences as well as effective patient decision making are supported. In turn, the successful implementation of patient-facing CDS helps support quality and safety, resulting in a positive impact to 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](#). The recommendation summary states that “the USPSTF recommends initiating use of low-to-moderate-dose statins in adults aged 40 to 75 years without a history of CVD who have 1 or more CVD risk factors (dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year CVD event risk 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.

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), formed in late 2016. The Cholesterol Management WG consisted of cardiology and preventive health experts from government organizations, universities, and healthcare settings. The WG provided insight to help 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 2017 and this *Statin Use: Patient-Facing* artifact developed in 2019. The only difference between the two “Statin Use” artifacts is the text that the CDS logic produces (i.e., the *Statin Use: Clinician-Facing* artifact delivers evidence-based information to a clinician with prescribing privileges during a medical encounter and the *Statin Use: Patient-Facing* artifact delivers evidence-based information to patients outside of a medical encounter). Some of the key interpretations and decisions include:

1. **Source of artifact logic:** This artifact utilizes 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 include an additional exclusion identified by the Cholesterol Management WG (i.e., rhabdomyolysis). In addition, a new CDS intervention was designed to deliver textual information and resources that are patient-friendly and engaging (as opposed to clinician-friendly with more medical details).
2. **Defining exclusion criteria:** The USPSTF recommendation does not 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. 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 semistructured 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, “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.”¹²
- b. ***End stage renal disease (ESRD), end stage renal disease encounter, dialysis procedure, and dependence on dialysis as exclusions:*** Chronic kidney disease has been shown to be 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 comorbidities” 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. The primary focus of these software files is to allow any organization to identify patients who qualify for the recommended statin medication to reduce the risk of CVD based on patient-specific criteria such as age or CVD risk factors (dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year risk of a cardiovascular event of 10 percent or greater.

The following sections provide technical details useful for those implementing this artifact in their health IT system. First, background information on CQL is provided, since it is 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

The *Statin Use: Patient-Facing* artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7 that is currently a Standard for Trial Use (STU).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:

- [CQL Release 1 STU3](#)
- [CQL on the Electronic Clinical Quality Information \(eCQI\) Resource Center](#)
- [CQL Tools on GitHub](#)
- [CQL Execution Engine \(CoffeeScript\) on GitHub *](#)
- [CQL Evaluation Engine \(Java\) on GitHub *](#)
- [CQL Online](#)
- [CQL Runner *](#)

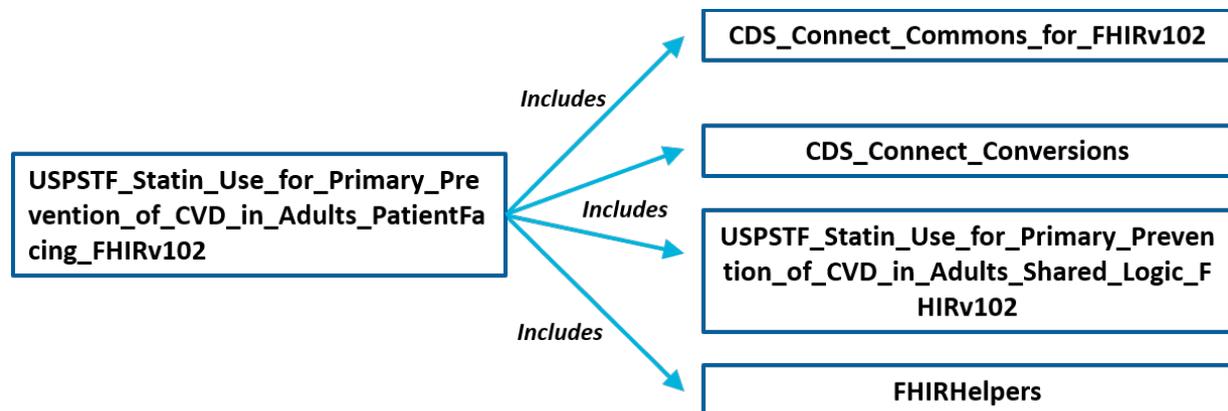
* These websites do not support the use of Internet Explorer, and recommend using Google Chrome, Microsoft Edge, or Firefox.

Library Relationship Diagram

CQL developers are encouraged to refactor commonly used functions into separate software files called libraries.¹⁵ The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. The diagram in **Figure 4** below shows the relationships between this artifact’s main library file and the four supporting libraries. As depicted in the diagram, the main CQL library references or “includes” the other four libraries.

When implementing this artifact, please ensure that all files listed in **Table 1** in the next section are present and that the filenames have not been modified. Not doing so will mean the artifact will not correctly execute since some of the artifact logic will be missing or mislabeled.

Figure 4. Artifact Relationship Diagram



Artifact Library Manifest

As mentioned in the previous section, the *Statin Use: Patient-Facing* artifact is composed of five libraries. Each library is represented in two formats: 1) CQL format and 2) JavaScript Object Notation (JSON) format. The CQL format is human readable while the JSON format is machine readable and is generated from the CQL using the CQL-to-Expression Logical Model

translator.¹⁶ Although the two formats contain the same information, they are formatted for their different purposes. The 10 software files that comprise the artifact are listed in **Table 1** below.

Table 1. Artifact Manifest

Filename	Purpose
USPSTF_Statin_Use_for_Primary_Prevention_of_CVD_in_Adults_PatientFacing_FHIRv102.cql	CQL representation of the “ <i>Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medicine</i> ” 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 human-readable than other coded formats.
USPSTF_Statin_Use_for_Primary_Prevention_of_CVD_in_Adults_PatientFacing_FHIRv102.json	JSON representation of the <i>Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medicine</i> 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, as it may be easier to parse for some IT systems.
CDS_Connect_Commons_for_FHIRv102.cql	Common CQL functions that may be called by CDS Connect artifacts.
CDS_Connect_Commons_for_FHIRv102.json	JSON representation of common CQL functions that may be called by CDS Connect artifacts.
CDS_Connect_Conversions.cql	CQL representation of a library that supports conversions from one unit to another.
CDS_Connect_Conversions.json	JSON representation of a library that supports conversions from one unit to another.
USPSTF_Statin_Use_for_Primary_Prevention_of_CVD_in_Adults_Shared_Logic_FHIRv102.cql	Support library that contains the CQL that is shared in common with the patient-facing version of the <i>Statin Use: Patient-Facing</i> artifact.
USPSTF_Statin_Use_for_Primary_Prevention_of_CVD_in_Adults_Shared_Logic_FHIRv102.json	Support library that contains the JSON that is shared in common with the patient-facing version of the <i>Statin Use: Patient-Facing</i> artifact.
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 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 three .csv files available at this

[link](#): (1) `uspstf_statin_basic_tests.csv`; (2) `uspstf_statin_exclusion_tests.csv`; and (3) `uspstf_statin_inclusion_tests.csv`

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%
- Patient excluded due to end stage renal disease
- 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

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts.¹⁷ The framework defines four “layers” of representation, as depicted in **Figure 5** and described here:

Figure 5. CDS Artifact Maturity Process



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

The CDS Connect team puts forward the information below as suggested “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 and require a separate application to convert CQL code such 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 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,¹⁸ described later in this document, 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 incorporation into a development environment, the artifact should be exhaustively tested against predefined test cases. Additionally, testing should be conducted to ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
- 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

CQL code within this artifact was developed to enact a clinical guideline, but there are portions of the CQL code that are expected to be useful for other purposes.

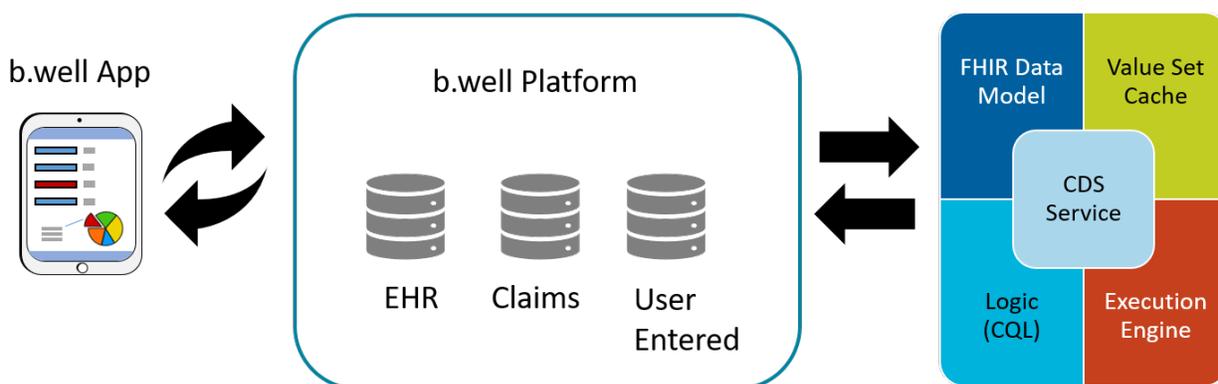
- The CDS_Connect_Commons_for_FHIRv102, FHIRHelpers and CDS_Connect_Conversions libraries included in the artifact define commonly used functions in CQL files and are not specific to the *Statin Use: Patient-Facing* artifact. They are expected to be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the *Statin Use: Patient-Facing* artifact could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to identify those female patients with an active pregnancy in other pertinent CDS.

Integration With Health Information Technology

CQL Services¹⁸ was used to facilitate integration of the *Statin Use: Patient-Facing* artifact into the b.well system. As depicted in **Figure 6** below, 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)¹⁹ 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 comes from a variety of sources, including one or more EHRs, claims, and pharmacy benefit management systems as well as user-entered information. Examples of the latter include 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

is queried and aggregated on the b.well platform, and then sent as an HyperText Transfer Protocol (HTTP) request to the CQL Service via a CDS Hooks interface.²⁰ CQL Services responds to the request by executing the requested artifact against the provided data, and then returning the result of the CQL back to the b.well platform. The response may or 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 Semistructured Logic

The first sentence of the USPSTF recommendation summary reads, “adults without a history of cardiovascular disease (CVD) (i.e. symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10 percent or greater.”²

The semistructured inclusion and exclusion logic that represents the recommendation summary (above), 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 of the terms used in the semistructured 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 narrative phrase in the USPSTF recommendation that was unclear to ensure that the evidence was translated appropriately. This log outlines how textual phrases were translated to semistructured logic and 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. For the purpose of the Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation, the USPSTF defines dyslipidemia as "an LDL-C level greater than 130mg/dL or a HDL-C level less than 40mg/dL". ² The FHIR observationStatus must be "final" or "amended" 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."

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	“MOST RECENT VALUE”	The value closest to the date of the CDS trigger; this ensures that the logic is evaluating data that is as close to the patient’s current health status as possible.
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 4- to 6-year time span. Since 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”	<p>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 Statin Use for the Primary Prevention of Cardiovascular Disease in Adults recommendation, the USPSTF defines dyslipidemia as “an LDL-C level greater than 130mg/dL or a HDL-C level less than 40mg/dL.”²</p> <p>The FHIR observationStatus must be “final” or “amended” 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.”</p>
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. ²¹ The clinicalStatus must be “active” or “relapse” 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 causes the coronary arteries to slowly become narrowed from a buildup of plaque, leading to CVD. ²² Hypertension is the strongest risk factor for developing CVD. ²³ The clinicalStatus must be “active” or “relapse” since this can be a transient diagnosis.

Location in CDS Logic	Concept	Definition and/or Rationale
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. ²⁴ The FHIR observationStatus must be “final” or “amended” to ensure the observation is complete and verified by an authorized individual.
Inclusions	“10-year CVD risk score >=10 percent	<p>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 observationStatus must be “final” or “amended” to ensure the observation is complete and verified by an authorized individual. Of note, this artifact does not calculate CVD risk. Instead, it looks 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, 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.</p> <p>Please be aware that this artifact aligns with the Grade B recommendation in the USPSTF <i>Statin Use for the Primary Prevention of Cardiovascular Disease in Adults</i> recommendation statement, which specifies a 10-year CVD risk score of greater than or equal to 10 percent. The <i>Statin Use for the Primary Prevention of Cardiovascular Disease in Adults</i> 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.</p> <p>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.²⁵ Not including the Grade C recommendation removed the chance that recommended care will not be covered by insurance.</p>

Location in CDS Logic	Concept	Definition and/or Rationale
Exclusions	CVD	CVD is defined as CAD or ischemic stroke. It is represented as a union of eight 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 <i>preventing</i> 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 persons are considered to have very high cholesterol levels and may require statin use.” 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 observationStatus must be “final” or “amended” to ensure the observation is complete and verified by an authorized individual.
Exclusions	“known familial hyper-cholesterolemia”	Diagnosis of familial hypercholesterolemia. The USPSTF states “These recommendations do not apply to adults with ...or known familial hypercholesterolemia; these persons are considered to have very high cholesterol levels and may require statin use.” 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 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 clinicalStatus of “active” must be present to ensure that the individual is currently pregnant.

Location in CDS Logic	Concept	Definition and/or Rationale
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. Of note, since 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-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Definition-of-Term-Pregnancy?IsMobileSet=false . The FHIR observationStatus must be “final” or “amended” 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 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 above in the Pregnancy Observation entry.
Exclusions	“ESRD”	A diagnosis that reflects ESRD. Impaired renal function may influence statin safety. ²⁶ For this reason, evidence of ESRD is listed as an exclusion. The clinicalStatus must be “active” to ensure there is sufficient diagnostic and/or clinical evidence to substantiate the diagnosis.
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 since the organization that piloted this logic had access to claims data (i.e., encounter claims). The encounterStatus cannot be “cancelled” to ensure that the encounter occurred.

Location in CDS Logic	Concept	Definition and/or Rationale
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. ²⁷ 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 clinicalStatus 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 clinicalStatus of “active” or “relapse” 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. ²⁶ For this reason, evidence of cirrhosis is expressed as an exclusion criterion. A clinicalStatus of “active” or “relapse” 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. ^{28 29} Evidence of rhabdomyolysis presents a safety risk related to statin therapy; therefore, it is listed as an exclusion. The clinicalStatus must be “active” or “relapse.”
Exclusions	“statin medication order, ...statement, ... dispensed... within the past 2 years”	A statin medication order (clinicalStatus “active” or “completed”), patient statement (clinicalStatus “active”), or dispensed medication (clinicalStatus “in-progress” or “completed”) within the past 2 years. 2 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

Numerous decisions were made by the CDS Development Team while 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 lists a “Decision Category,” which 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.³⁰ 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)	<p>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 subject matter experts. 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 semistructured representation of the CDS artifact.</p> <p>The <i>2018 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce ASCVD Risk in Adults</i> 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.”</p>

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	ESRD, ESRD encounter, dialysis, dependence on dialysis	<p>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.</p> <p>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.”³¹ 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</p>

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, or issued (to determine most recent) status is 'final' or 'amended' valueQuantity with '%' units
Active Cirrhosis	X	Condition	code verificationStatus is 'confirmed' status is 'active' or 'relapse' no abatement[x]attributes are present
Breastfeeding (within the last year)	X	Condition	code verificationStatus is 'confirmed' status 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, or issued (to determine most recent) status is 'final' or 'amended' 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
Percutaneous Coronary Intervention (PCI) (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed' notPerformed is absent or false

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Carotid Intervention (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed' notPerformed is absent or false
Diabetes (Type 1 or Type 2)	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html) onsetDateTime or onsetPeriod or dateRecorded
Dialysis (within the last week)	X	Procedure	code status is 'completed' notPerformed is absent or false performedDateTime or performedPeriod
Dialysis (Dependence on)	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html)
End Stage Renal Disease	X	Condition	code verificationStatus is 'confirmed' status is 'active' no abatement[x]attributes are present

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
End Stage Renal Disease Encounter	X	Encounter	status is not 'cancelled' reason (code) period
Familial Hypercholesterolemia	X	Condition	code verificationStatus is 'confirmed' status is 'active' no abatement[x]attributes are present
HDL	I	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' (see https://www.hl7.org/fhir/DSTU2/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
Hypertension	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html)

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
LDL-C Result > 130 mg/dl	I	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' (see https://www.hl7.org/fhir/DSTU2/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
LDL-C Result > 190 mg/dl	X	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' (see https://www.hl7.org/fhir/DSTU2/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
Pregnancy	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html) no abatement[x] attributes are present
Pregnancy Observation (within the last 42 weeks)	X	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' valueCodeableConcept

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Rhabdomyolysis	X	Condition	code verificationStatus is 'confirmed' status is 'active' no abatement[x]attributes are present
Smoking/Current Smoker	I	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' valueCodeableConcept
Statin Therapy (Order)	X	MedicationOrder	medicationCodeableConcept status is 'active' dateEnded is absent
Statin Therapy (Statement)	X	MedicationStatement	medicationCodeableConcept status is 'active' wasNotTaken is absent or false effectivePeriod end date is absent or in the future
Statin Therapy (Dispensed)	X	MedicationDispensed	medicationCodeableConcept status is 'in-progress' or 'complete'

Appendix C. References

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