Implementation Guide

Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors

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Rockville, MD 20857
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Contract No. 75FCMC18D0047

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A Federally Funded Research and Development Center

AHRQ Publication 19(22)-0071-1-EF
September 2022

Disclaimer of Conflict of Interest

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

Funding Statement

This project was funded under contract/grant number 75FCMC18D0047 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services (HHS). The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or HHS.

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Suggested Citation

CMS Alliance to Modernize Healthcare (The Health FFRDC). Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors. Implementation Guide. Prepared under Contract No. H75FCMC18D0047. AHRQ Publication No. 19(22)-0071-1-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2022.

Acknowledgments

Specifically, we want to thank and recognize:

- Agency for Healthcare Research and Quality (AHRQ) leadership team, including Dr. Mario Terán, Dr. Edwin Lomotan, Steve Bernstein, Roland Gamache, James Swiger, and Mary Nix
- AHRQ U.S. Preventive Services Task Force Leadership Team
- Clinical Decision Support (CDS) Connect Work Group members
- CDS Connect Patient/Caregiver Activist, Danny Van Leeuwen
- b.well Connected Health, Inc. Pilot Project Team
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team

Record of Implementation Guide Changes

Date	Action	Notes
September 2019	Published Implementation Guide	
September 2020	Updated the Implementation Guide based on annual CDS artifact updates	Updated the Implemenation Guide content for clarity and reviewed clinical and technical content for continued use.
September 2021	Updated the Implementation Guide based on annual CDS artifact updates	Updated the Implementation Guide's Introduction and Background content, to reflect changes in the USPSTF guideline November 2020; made minor edits for clarity, expanded CQL library details to account for the CQL updates related to FHIR R4, and added a new data requirements table in the appendix for FHIR R4.
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.

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

Some artifacts developed by the MITRE project team (or other teams) go on to be piloted in a clinical setting. When this occurs, the project team includes a Pilot Report with the artifact to describe CDS integration, testing, and implementation details, along with end-user feedback. Future implementers can leverage the insights outlined in the report to inform their implementation.

CDS artifacts are not "standalone" and are not intended to be completely "plug-and-play;" healthcare systems will need to integrate each artifact with components of their health IT system for the artifact to work. Implementers should conduct extensive testing—including clinical testing in real-life workflows—of all artifacts. The project team expects that artifacts will be customized and adapted to local clinical and IT environments.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than 40 metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher, sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made 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 to guide the creation of standards-based CDS logic using simple input forms. The logic developed by the tool is expressed using HL7 Fast Healthcare Interoperability Resources® (FHIR) and CQL. It empowers organizations that have limited access to software engineers with the ability to express evidence-based guidelines as accurate, tested, and coded logic. Individuals who are interested in developing CDS logic expressions can use the tool to develop new CDS logic in the clinical domain of their choice. The interoperable format of the logic facilitates sharing and integration with a wide range of health IT systems.

The CDS Connect team also developed two prototype tools: one facilitates CQL testing (CQL Testing Framework); the other facilitates integration of the CQL code with a health IT system (CQL Services). The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. This framework allows CQL developers to identify bugs in the CDS logic early in the development cycle, when it is less costly to fix. In addition, these test

cases enable developers to demonstrate the expected behavior of the CDS logic to bolster trust in the coded expression. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to an artifact's CQL. CQL Services is an open-source service framework for exposing CQL-based logic using the HL7 CDS Hooks application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively.

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

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

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

Implementing and Using This Artifact

Artifact Description

This artifact identifies adult patients who have at least one risk factor for developing cardiovascular disease (CVD). It provides the opportunity to provide information to at-risk patients through a patient-facing health IT system (e.g., a patient portal or health app) to 1) raise awareness that they may have one or more risk factor(s) for heart disease and stroke, along with how that may be impacting their health; 2) provide educational information and tools to help patients lower their risk; and 3) encourage them to talk to their primary care clinician about steps they can take to reduce their risk (e.g., participate in behavioral counseling to promote a healthy diet and physical activity).

Preventive Health Scenarios Supported by This Artifact

The Healthy Diet and Physical Activity for CVD Prevention artifact was originally developed, piloted, and published in 2019 to identify those patients at risk for developing CVD according to the logic derived from the 2014 U.S. Preventive Services Task Force (USPSTF) statement. Once patients are identified, the implementer should determine the appropriate method to notify the 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.

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.
    - Ms. Alpha is 47 years old and overweight, has high blood pressure, and has a sedentary lifestyle. She is interested in her health and well-being but does not pursue certain activities such as eating a well-balanced diet and exercising regularly. She receives a push notification from her health app that there is some information for her to review from her healthcare team. 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 because of her weight and diagnosis of hypertension.
        - The information found in the health app provides education topics for Ms. Alpha to review regarding her risk factors and ways she could reduce her risk and encourages her to speak with her physician about receiving counseling on how to eat right and stay active, 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.
    - Mr. Bravo is 52 years old and obese and has very low high-density lipoprotein (HDL) and high low-density lipoprotein (LDL) levels. He receives an email indicating that there is new information to review in the patient portal from his primary care clinician. He accesses the portal and discovers a message from his primary care clinician informing him that he may have an increased risk for heart disease and stroke based on his weight and abnormal LDL and HDL levels.
        - The notification also provides educational materials to Mr. Bravo about his risk factors and ways he could reduce his risk through lifestyle changes such as healthy eating and engaging in physical activity. It also recommends contacting his physician to discuss whether counseling on

how to eat right and stay active is right for him, as outlined in scenarios 2 and 3 (below).

2. Providing the patient with targeted educational materials.
    - Ms. Alpha selects the embedded link in the information provided in her health app, which accesses personalized educational material on healthy eating and increased physical activity to reduce CVD risk. Ms. Alpha reviews the information to learn more. The information provided also includes links to healthfinder.gov with additional resources and tools.
    - Mr. Bravo's primary care clinician recommended several links to educational resources in the message that he sent to Mr. Bravo via the patient portal. Mr. Bravo reads the educational resources and watches a video on CVD risk.
3. Recommending that the patient consult with their primary care clinician.
    - 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 concerns and possible interventions (e.g., counseling for a healthy diet and physical activity regimen). She immediately schedules an appointment through the scheduling function in the health app.
    - 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, Mr. Bravo receives another email reminding him that there is still an action item outstanding on his patient portal. Mr. Bravo 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 2020 USPSTF full recommendation statement Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling Interventions to identify patients who may benefit from behavioral counseling related to diet and activity. 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 are described in the following hypothetical cases.

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

    - Johnston Primary Care (JPC) is a large (hypothetical) practice located in the rural South with six primary care clinicians and about 5,000 patients. The prevalence of CVD for people living in this area is higher than the national norm. To meet quality metrics required by their largest insurance payer, JPC decides to focus intently on identifying those at risk of developing CVD and proactively assist in reducing their risk. The CDS inclusion and exclusion logic for this artifact is run monthly, and each primary care team receives a report profiling those at risk in their patient panel. The staff reaches out to the patients suggesting 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 aid in prevention of CVD. 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 to determine the impact of the interventions.

- Enabling wellness and preventive care for patients through identification of specific CVD risk factors.
    - Procare Health provides wellness services to its customers, which consist primarily of employers and health plans. These customers contract with Procare Health 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. Procare Health uses the artifact logic to identify individual participants who have specific risk factors for CVD, such as hypertension, hyperlipidemia, and an ASCVD 10-year risk score >= 7.5%. They provide intensive wellness services to help the identified participants understand the actions and activities that may help mitigate their risk. Procare Health monitors these activities and any individual progress over time. Each month, they provide statistical deidentified reports to the employers and health plans to reflect the effect of the interventions.
- Modifying the CDS logic to address organizational goals and strategies.
    - Swift Health Technologies provides CDS products to large healthcare organizations for use in their health IT. The technology company uses the logic in this artifact and adds additional structured representation of comorbid conditions to develop CDS requested by one of their customers. 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 diabetes or chronic obstructive pulmonary disease so the appropriate primary care clinicians can be provided with a report generated by the CDS. This report can be used to reach out to the identified patient population.

CDS Interventions and Suggested Actions

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. Inclusion: Adults who have one or more risk factors for CVD (i.e., hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors such as metabolic syndrome or an estimated 10-year CVD risk of >= 7.5%).

2. Exclusion: Patients who are pregnant, are already diagnosed with CVD, or are already undergoing behavioral counseling on healthy diet and physical activity.

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 in patient-friendly language (such as having elevated or high blood pressure, non-normal cholesterol levels, or an increased risk for stroke or heart attack), along with ways to modify those risks by eating a healthy diet and increasing physical activity.

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. Facilitate appointment scheduling, if possible.

These suggested actions 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 it is found in the Example Intervention Content: Healthy Diet and Physical Activity for CVD Prevention document posted in the Miscellaneous Files section of the Healthy Diet and Physical Activity for CVD Prevention 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.[2]

Development of Patient-Centered Preventive Care CDS Artifacts

According to Krist et al. (2011), studies have shown that most Americans receive only about half of recommended preventive services.[3] 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.[3] 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 undergoing behavioral counseling for either diet or physical activity, 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 needed 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, the implementer will need to consider the interventions and workflow that should occur to 1) notify the patient and 2) 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 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.[4] It allows the patient and their primary healthcare clinician to determine together the most appropriate treatment or care choice.

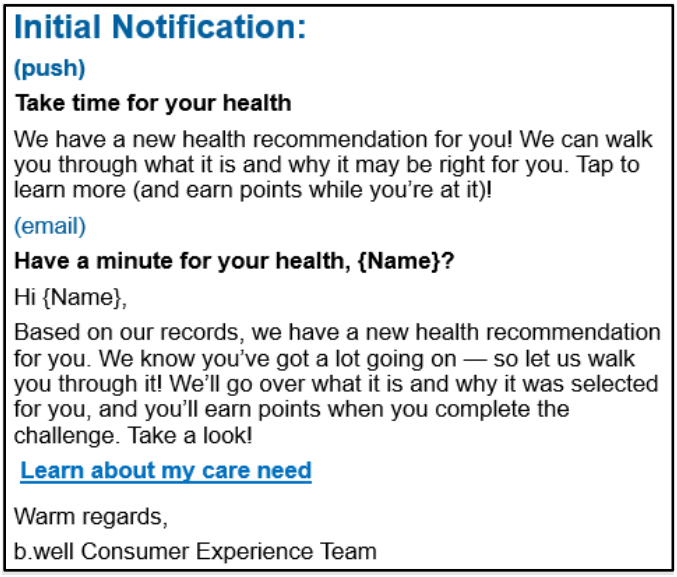
As noted earlier, the patient notifications included in the structured CQL expression of this artifact are general, enabling implementing organizations to expand upon and personalize the interventions based on their unique needs and patient population. The preventive care recommendations provided to the patient have been expressed in lay language and provide additional resources in a user-friendly format and method. This user-friendly information facilitates patient action by providing 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).

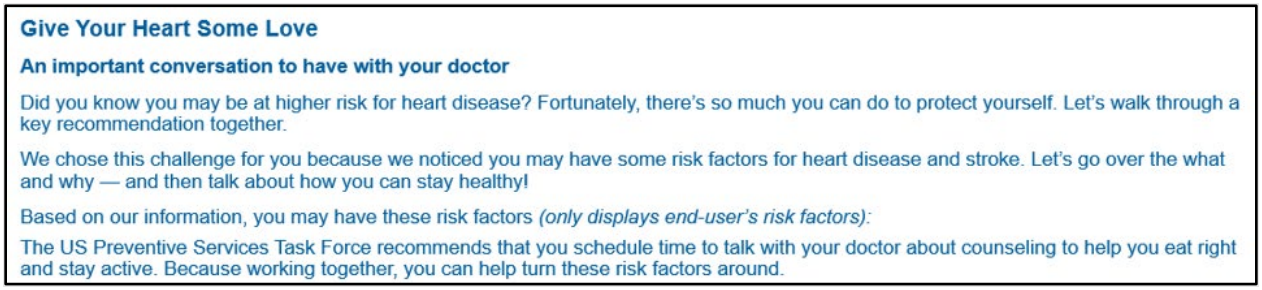
Figure 1. Example of Patient Notification



Educational Resources: When the patient acts on the notification and accesses the health app, they can link directly to pertinent educational resources, such as information on cardiovascular risk and recommendations, tools, and videos to provide additional education.

- The resources found on healthfinder.gov as well as the USPSTF patient handout[5] were used as sources for much of the content created. See **Figure 2** for an example of patient education text.

Figure 2. Example of Patient Education



Appointment Scheduling Tools and Other Resources: The education 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

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 care, resulting in a positive impact to patient health outcomes and satisfaction.

Guideline Interpretation and Clinical Decisions

Evidence Source for Artifact Development

This artifact was originally derived from the 2014 USPSTF full recommendation statement Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling. This recommendation summary states that "the USPSTF recommends offering or referring adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthy diet and physical activity for CVD prevention."[6] In 2020, the USPSTF published updated guidance as Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling Interventions. The Patient Population Under Consideration section defines "CVD risk factors" as known hypertension or elevated blood pressure, elevated lipid levels or dyslipidemia, and mixed or multiple risk factors such as metabolic syndrome or an estimated 10-year CVD risk of >= 7.5%. The strength of 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.[5]

Guideline Translation Summary

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

- **CVD risk factors:** The Patient Population section in the recommendation statement states that the recommendation applies to adults who have known CVD risk factors, defined as "hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors such as metabolic syndrome or an estimated 10-year CVD risk of >= 7.5%."[6] These four criteria informed the development of the inclusion logic. Elsewhere in the recommendation, smoking and diabetes are mentioned as potential risk factors. A USPSTF SME confirmed that smoking and diabetes should not be included in the CDS logic as CVD risk factors, as the scientific evidence reviewed to generate the Healthy Diet and Physical Activity for CVD Prevention recommendation did not meet threshold criteria to be included in the Patient Population section of the published recommendation.[6]

- **Metabolic syndrome:** Metabolic syndrome is not a disease but rather a term that highlights traits that may lead to an increased risk of disease (approximately twofold for CVD and fivefold or more for Type 2 Diabetes Mellitus).[7] It is a cluster of clinical findings made up of five characteristics: abdominal obesity, high fasting glucose, high triglycerides, low HDL, and hypertension. Thresholds for the five characteristics vary slightly when listed by different professional organizations and government agencies. The threshold values specified in this artifact are from the National Heart, Lung, and Blood Institute and the American Heart Association. Future implementers may choose to utilize other definitions (e.g., some definitions list different waist circumference values based on race and ethnicity).[8-10]
- **Impaired fasting glucose and impaired glucose tolerance:** The USPSTF elected to remove these conditions, as well as overweight/obesity, from this recommendation as screening and counseling for those conditions are covered in other recommendations. Elevated fasting glucose remains in the logic as part of the logic for diagnosing metabolic syndrome.
- **CVD as an exclusion:** The intent of the recommendation is to identify patients who have one or more CVD risk factors to prevent the development of CVD. If a patient already has CVD, different types of treatment and counseling may be indicated.
- **Pregnancy as an exclusion:** Other types of interventions may be needed for pregnant patients. A USPSTF SME validated that excluding pregnant patients was appropriate.
- **Suggested actions for behavioral counseling for a healthy diet and physical activity:** The Healthy Diet and Physical Activity for CVD Prevention recommendation focuses on intensive behavioral counseling that encourages healthy eating and physical activity to improve cardiovascular health and prevent CVD.
    - The specified value sets that define behavioral counseling include codes representing counseling activities related to CVD risk reduction (such as low-salt and low-fat diet education), as this artifact targets individuals with CVD risks. Note that for the patients who are overweight, a separate and distinct USPSTF recommendation and CDS artifact for patients with a BMI of 25 kg/m^2 or greater recommends offering or referring patients to intensive, multicomponent behavioral counseling for weight loss.
    - Most studies reviewed by the USPSTF included interventions that combined healthy diet and physical activity counseling that is considered "intensive" (e.g., with multiple contacts that may include individual or group counseling sessions over extended periods). Interventions span an average of 5 to 16 contacts over 9 to 12 months, depending on their intensity.[6]
    - The CDS logic looks for any evidence of behavioral counseling in available patient data in the form of a referral for counseling, an order for counseling, the counseling event/procedure itself, or the counseling encounter. Organizations may need to adjust the logic to search for additional ways the data may be stored in their system (such as claims data). Alternatively, they may choose to map qualifying data in their system to the CQL code and value sets as currently represented.

Technical Details Regarding Artifact Implementation

The Healthy Diet and Physical Activity for CVD Prevention artifact is composed of several software files written in CQL. The primary focus of these software files is to allow any organization to identify individuals who have CVD risk factors and may require intensive behavioral counseling interventions to promote a healthy diet and physical activity to prevent CVD.

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

General Information About CQL

The Healthy Diet and Physical Activity for CVD Prevention artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7 that is currently a Mixed Normative/Standard for Trial Use (STU) specification.[11] 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:

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

Artifact Library Manifest

The Healthy Diet and Physical Activity for CVD Prevention artifact provides two distinct versions of the logic files—

1. **USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv102_v2.0.0_CQL.zip**: The version 2.0.0 update includes changes to better align with best practices specified in the FHIR Clinical Guidelines implementation guide. Its logic files were compiled using the CQL 1.5.x translator. This version was not piloted but is largely based on the piloted version.
2. **USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv401_v2.0.0_CQL.zip**: The version 2.0.0 update of the FHIR R4-based CQL logic files includes changes to better align with best practices specified in the FHIR Clinical Guidelines implementation guide. Its logic files were compiled using the CQL 1.5.x translator. This version was not piloted but is largely based on the piloted version.

Detailed descriptions of the changes in these logic files can be found in the **USPSTFDietAndActivityForCVDPreventionInAdults_Change_Log.txt** file attached to this artifact in the CDS Connect Repository.

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

Each library is represented in two formats containing the same information but formatted for different purposes. The CQL format is human readable; the JavaScript Object Notation (JSON) format is machine readable and is generated from the CQL using the CQL-to-ELM translator.[12] The eight software files that comprise the artifact are listed in **Table 1**.

Table 1. Artifact Manifest

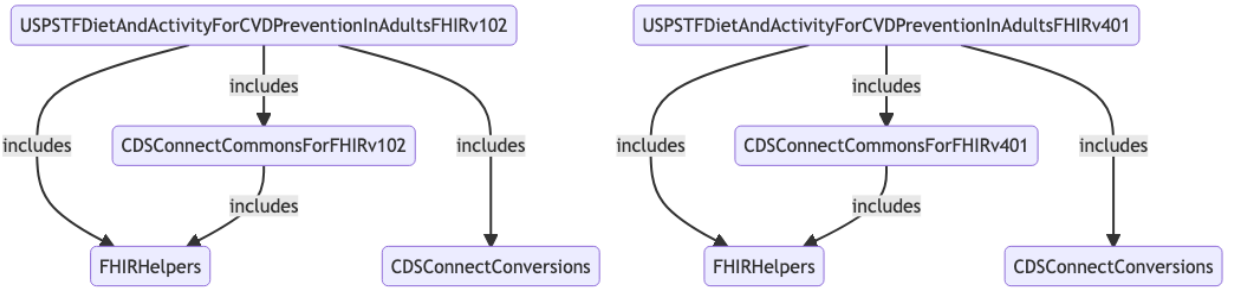
Filename	Purpose
USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv102.cql (FHIR DSTU2 only) or USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv401.cql (FHIR R4 only)	CQL representation of the Healthy Diet and Physical Activity for CVD Prevention recommendation. This file specifies the necessary logic 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.
USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv102.json (FHIR DSTU2 only) or USPSTFDietAndActivityForCVDPreventionInAdultsFHIRv401.json (FHIR R4 only)	JavaScript Object Notation (JSON) representation of the Healthy Diet and Physical Activity for CVD Prevention 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.
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.
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again.

Library Relationship Diagram

The project team encourages CQL developers to refactor commonly used functions into separate software files called libraries.[13] The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. **Figure 4** shows the relationships between this artifact's main library file and the three supporting libraries.

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

Figure 4. Artifact Relationship Diagram



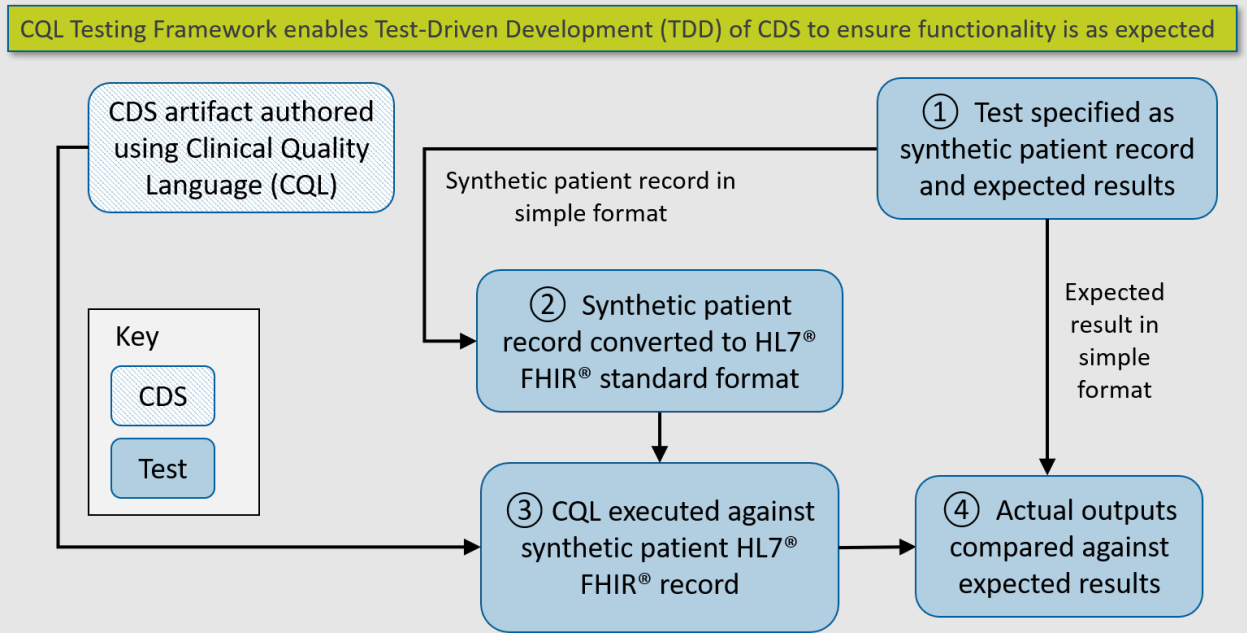
Artifact Testing

The project team developed the Healthy Diet and Physical Activity for CVD Prevention artifact using a test-driven development (TDD) approach.[14] TDD is valuable for development since it has been shown to produce software that is more robust and to contain fewer bugs because it requires consideration of edge cases.[14] With TDD, developers create a battery of test cases that define the expected functionality of the software, in this case the Healthy Diet and Physical Activity for CVD Prevention CQL. The project team leveraged an automated CQL testing framework developed under funding by AHRQ to enable the TDD approach for this artifact. Referred to as the "CQL Testing Framework," this tool accepts test cases specified in YAML Ain't Markup Language (YAML) files, executes the artifact against each test case, and reports the success or failure of each test case.[15]

The diagram in **Figure 5** depicts the TDD approach using the CQL Testing Framework. In the first step, before any CQL is written, developers define at least one test that specifies both the input to the CQL and the desired output. When using the CQL Testing Framework, developers specify the test input in terms of a synthetic patient record containing the pertinent FHIR resources. For example, test input for the Healthy Diet and Physical Activity for CVD Prevention artifact might contain a waist circumference measurement of the synthetic patient, which is one of the data inputs required by the artifact (see Appendix B). An example of the desired output might be that the CQL should return the appropriate USPSTF recommendation. Once developers have specified a test in this way, they update the artifact's CQL until the test passes, demonstrating that the CQL works appropriately in that specific case. The process continues as the developer iteratively creates tests and authors logic, line by line, and clinical concept by

clinical concept. The author of the CQL may not proceed to writing or updating the next portion of the code until all existing tests pass.

Figure 5. Testing Approach Diagram



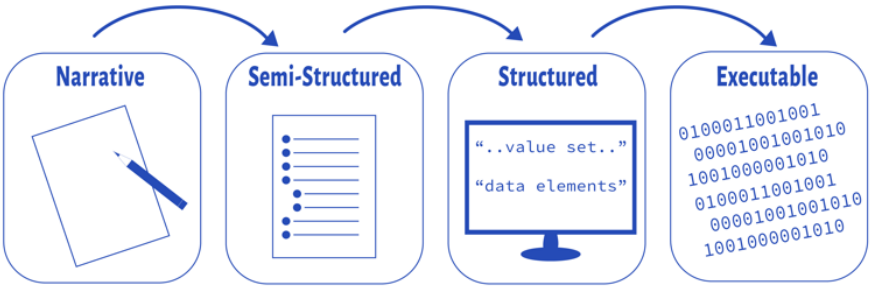
The development team created test cases to investigate efficacy for basic expected functionality and to test the expected inclusion criteria, exclusion criteria, and results (suggested interventions and actions). The entire set of test data resides in zip files attached to the CDS artifact in the Repository. One zip file provides test cases in the FHIR DSTU2 format while the other provides test cases in the FHIR R4 format. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system. Implementers are encouraged to use the test cases included with this artifact as a guide, which include the following (non-exhaustive) examples:

- Synthetic patient excluded due to previous CVD diagnosis.
- Synthetic patient excluded due to a recent behavioral counseling referral.
- Synthetic patient excluded due to a recent pregnancy diagnosis.
- Synthetic patient included because of recent low HDL-C lab test.
- Synthetic patient not included because they have fewer than three metabolic syndrome risk factors.

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

Figure 6. CDS Artifact Maturity Process



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

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization understands and agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review the Guideline Interpretation and Clinical Decisions 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 nontrivial 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,[16] 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.

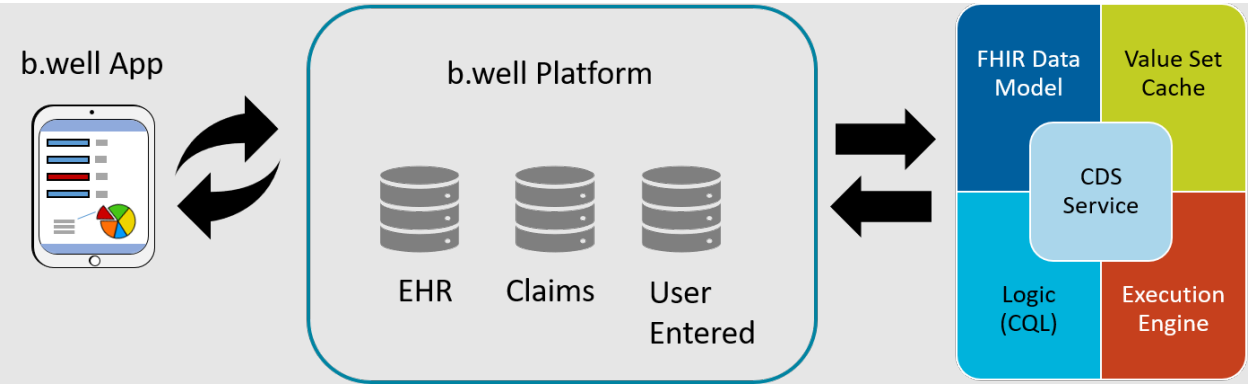
- The four libraries—CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, FHIRHelpers, and CDSConnectConversions—included in the artifact define commonly used functions in CQL files and are not specific to the Healthy Diet and Physical Activity for CVD Prevention artifact. They may be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the Healthy Diet and Physical Activity for CVD Prevention artifact could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to identify those patients at risk for metabolic syndrome in other pertinent CDS.

Integration With Health Information Technology

CQL Services[16] was used to facilitate integration of the Healthy Diet and Physical Activity for CVD Prevention artifact into the b.well system. As depicted in **Figure 7**, 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 Value Set Authority Center (VSAC)[17] and local storage cache.
3. Logic represented by the CQL libraries included with this artifact.
4. An execution engine.

Figure 7. 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 HTTP request to the CQL Service via a CDS Hooks interface.[18] 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

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 recommendation statement, research review, and supporting references. The CDS Development Team engaged with USPSTF SMEs to disambiguate 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, as well as the outcome of discussions with USPSTF SMEs that informed how to translate ambiguous text.

The semistructured logic statements for the **inclusion criteria** of the Healthy Diet and Physical Activity for CVD Prevention artifact include:

Patient is >=18 years old

AND one or more of the following:

- Hypertension (active, recurrence, relapse)
- OR elevated blood pressure, specified as:
  - Elevated blood pressure condition (active, recurrence, relapse)
  - OR blood pressure panels with coded interpretation indicating elevated blood pressure, TWO MOST RECENT within the past 6 years
- OR low-density lipoprotein-cholesterol (LDL-C) lab result >130 milligrams/deciliter (mg/dL), MOST RECENT VALUE within the past 6 years
- OR high-density lipoprotein-cholesterol (HDL-C) lab result <40 mg/dL, MOST RECENT VALUE within the past 6 years
- OR presence of three or more of the following measurements (as a representation of metabolic syndrome):
  - Waist circumference in men >=40 inches, MOST RECENT VALUE within the past 6 years
  - OR waist circumference in women >=35 inches, MOST RECENT VALUE within the past 6 years
  - OR triglyceride lab result >=150mg/dL, MOST RECENT VALUE within the past 6 years
  - OR HDL-C <50mg/dL in women, MOST RECENT VALUE within the past 6 years
  - OR HDL-C <40mg/dL in men, MOST RECENT VALUE within the past 6 years
  - OR systolic blood pressure (SBP) >=130 mm Hg, MOST RECENT VALUE within the past 6 years

OR diastolic blood pressure (DBP) >=85 mm Hg, MOST RECENT VALUE within the past 6 years

OR fasting glucose lab result >=100mg/dL, MOST RECENT VALUE within the past 6 years

OR estimated 10-year CVD risk score >= 7.5 %, MOST RECENT VALUE within the past 6 years

The semistructured logic statements for the **exclusion criteria** of this artifact include:

CVD

OR pregnancy (active)

OR pregnancy observation within the past 42 weeks

OR one or more of the following:

Behavioral counseling for nutrition and activity **referral** within the past 12 months (requested, active, accepted, completed)

OR Behavioral counseling for nutrition and activity **order** within the past 12 months (requested, received, accepted, in-progress, completed)

OR Behavioral counseling for nutrition and activity **procedure** within the past 12 months (in-progress, completed)

OR Behavioral counseling for nutrition and activity **encounter** within the past 12 months (in-progress, finished)

Concept Definition Decision Log

Table 2 defines many of the terms used in the semistructured CDS representation to provide clarity on what each logic component means and why it was expressed as listed. To provide reference, the USPSTF recommends "offering or referring adults with CVD risk factors behavioral counseling interventions to promote a healthy diet and physical activity."[9] Within the Patient Population Under Consideration section of the USPSTF recommendation statement, the USPSTF goes on to define "CVD risk factors" as "one or more of hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors such as metabolic syndrome or an estimated 10 yr CVD risk of≥ 7.5%."[9]

Table 2. Concept Definition Decision Log

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	">="	Greater than or equal to (e.g., >= 18 years old).
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	"AND one or more of the following"	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.
Inclusions	"Hypertension"	Defined as essential and nonessential hypertension conditions. The status must be "active," "recurrence," or "relapse" since this can be a transient diagnosis. This concept is defined by the following value set: (https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.9/expansion).
Inclusions	"Elevated blood pressure"	Defined as a condition with status "active," "recurrence," or "relapse" since this can be a transient diagnosis; or as a blood pressure panel with a coded interpretation indicating elevated blood pressure. In the latter case, the two most recent blood pressure panels must indicate elevated blood pressure in order to ensure currency and consistency. Elevated blood pressure is defined as the union of two value sets: (https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1047.513/expansion and https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1047.512/expansion).

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"LDL-C lab result >130 mg/dL"	LDL-C lab result that is greater than 130 mg/dL. A result of > 130 mg/dL is an indication of dyslipidemia. LDL-C is defined as the union of two value sets: (https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.464.1003.198.11.1029/expansion and https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.117.1.7.1.215/expansion). Note: the CQL code includes an equation to convert lab results measured in "moles/volume" to "mg/dL."
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. HDL-C is defined as the union of two value sets: (https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.464.1003.104.12.1012/expansion and https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.600.873/expansion). Note: the CQL code includes an equation to convert lab results measured in "moles/volume" to "mg/dL."
Inclusions	">"	Greater than a given value (e.g., > 130 mg/dL).
Inclusions	"<"	Less than a given value (e.g., < 40 mg/dL).
Inclusions	"Within the past 6 years"	Occurring within 6 years of the CDS trigger. Six years represents the longest value of this time range. This lookback was informed by the CDS Connect Cholesterol Work Group in 2017 when developing CVD prevention CDS. The American College of Cardiology/American Heart Association recommends screening for CVD risk every 6 years between the ages of 40 and 79. Beyond 6 years, lab results and health observations should be reassessed prior to calculating risk. Reference: https://www.acc.org/latest-in-cardiology/articles/2019/04/29/07/42/key-points-from-the-2019-acc-aha-guidelines-on-the-primary-prevention-of-cvd.
Inclusions	"Within the past 12 months"	Occurring within 12 months of the CDS trigger; places restrictions on lookback periods to ensure clinical accuracy and clinical relevancy (since behavioral counseling must be related to the patient's current CVD risks and usually occurs over a time span of 9 to 12 months).

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"Presence of three or more of the following measurements (as a representation of metabolic syndrome)"	Defines a list of logic phrases where three or more of the phrases must be present in the patient record (i.e., evaluate as true) to meet inclusion criteria for metabolic syndrome, which is considered a CVD risk factor.
Inclusions (metabolic syndrome criteria)	"Waist circumference"	The measurement around an individual's waist as defined by the following value set: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.88/expansion. When evaluating for metabolic syndrome, men and women are evaluated against different thresholds (i.e., for men: >= 40 inches, for women: >=35 inches). Note: the CQL code includes an equation to convert centimeters to inches when circumference is measured in centimeters.
Inclusions (metabolic syndrome criteria)	"Triglyceride lab result >=150 mg/dL"	Triglyceride laboratory result greater than or equal to 150 mg/dL. When evaluating for metabolic syndrome, this is one of several criteria that is considered. Defined by the following value set: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.600.881/expansion. Note: the CQL code includes an equation to convert lab results measured in "moles/volume" to mg/dL.
Inclusions (metabolic syndrome criteria)	"HDL-C < 50 mg/dL in women"… "HDL-C < 40 mg/dL in men"	HDL-C lab result less than 50 mg/dL in women or 40 mg/dL in men. When evaluating for metabolic syndrome, a patient's HDL-C level is one of several criteria that is considered. Defined as outlined earlier.
Inclusions (metabolic syndrome criteria)	"systolic blood pressure >= 130 mm Hg"	SBP greater than or equal to 130 millimeters of mercury (mm Hg). When evaluating for metabolic syndrome, a patient's SBP is one of several criteria that is considered. Defined by a single LOINC code (8480-6).

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions (metabolic syndrome criteria)	“diastolic blood pressure >= 85 mm Hg”	DBP greater than or equal to 85 mm Hg. When evaluating for metabolic syndrome, a patient’s DBP is one of several criteria that is considered. Defined by a single LOINC code (8462-4).
Inclusions (metabolic syndrome criteria)	“fasting glucose lab result >= 100 mg/dL”	Fasting glucose test lab result that is greater than or equal to 100 mg/dL. When evaluating for metabolic syndrome, a patient’s fasting glucose level is one of several criteria that is considered. Defined by the following value set: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.87/expansion. Note: the CQL code includes an equation to convert lab results measured in “moles/volume” to mg/dL.
Inclusions	“estimated 10-year CVD risk of 7.5% or greater”	The estimated 10-year CVD risk score represents the result from the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) pooled cohort equation (PCE) to calculate the risk for developing a first-time “hard” ASCVD event, defined as nonfatal myocardial infarction (MI), coronary heart disease (CHD) death, nonfatal stroke, or fatal stroke. The result may be calculated using the CMS’s Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk CQL library or other available implementations of the ACC/AMA calculation. The CQL in this artifact expects the result to be provided as a FHIR Observation with the appropriate LOINC code (79423-0). A score of 7.5% or higher satisfies the inclusion criteria for this artifact.
Exclusions	“CVD”	CVD is defined as coronary artery disease or ischemic stroke via the union of eight value sets available on the Value Set Authority Center that express myocardial infarction, ischemic vascular disease, coronary artery bypass grafts, percutaneous coronary interventions, and carotid interventions. The value sets are listed in the CQL code. CVD is expressed as an exclusion because the CDS interventions generated by this CDS are only relevant to preventing CVD. If a patient has CVD, different types of treatment and counseling may be indicated. This approach and rationale were validated as accurate by a USPSTF SME.

Location in CDS Logic	Concept	Definition and/or Rationale
Exclusions	"pregnancy"	Pregnancy is defined by the union of the following two value sets: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.526.3.378/expansion and https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.80/expansion, with a clinical status of "active." It is part of the exclusions because weight gain is a normal part of pregnancy and different types of counseling are indicated for pregnant individuals. Pregnancy is stated as an exclusion in the USPSTF recommendation.
Exclusions	"pregnancy observation within the past 42 weeks"	Pregnancy is also expressed as an observation in the CDS logic to identify a second way that this concept can be recorded in health IT. It is defined by LOINC code: 82810-3 (pregnancy status) and SNOMED-CT code: 77386006 (finding), based on the Interoperability Standards Advisory guidance for "Representing Patient Pregnancy Status" (https://www.healthit.gov/isa/representing-patient-pregnancy-status). "Within the past 42 weeks" is specified as a lookback to consider only a current/active pregnancy. The American College of Obstetricians and Gynecologists defines early, full, and late term up to 42 weeks of gestation. Since gestation date is not often specified in health IT, the CDS logic evaluates the date that a pregnancy observation is recorded in the health IT. Reference: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Definition-of-Term-Pregnancy?IsMobileSet=false
Exclusions	"one or more of the following"	One or more of four behavioral counseling "events" related to nutrition and activity (i.e., a referral for counseling, an order for counseling, a counseling procedure, or a counseling encounter). Evidence of any one of these events in the designated time period would exclude the patient from receiving a notification to seek behavioral counseling.
Exclusions	"Behavioral counseling for nutrition and activity **referral**"	A referral generated by a clinician for a patient to receive behavioral counseling for a healthy diet and physical activity as defined by the following referral value set: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.79/expansion
Exclusions	"Behavioral counseling for nutrition and activity **order**, …**procedure** …or **encounter**"	Behavior counseling for nutrition and activity orders, procedures, and encounters are defined by the union of three values, accessed here: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1195.112/expansion, https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.464.1003.195.11.1004/expansion, and https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.464.1003.118.11.1042/expansion.

Artifact Development Decision Log

The Artifact Development Team made numerous decisions 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.[19] 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
Add explanation	Revisions to the recommendation	On November 24, 2020, the USPSTF published an updated recommendation for counseling on healthy diet and physical activity replacing the 2014 recommendation. This new recommendation targets adults with known hypertension or elevated blood pressure, elevated lipid levels or dyslipidemia, and mixed or multiple risk factors (e.g., metabolic syndrome or estimated 10-year CVD risk of ≥7.5%). The CDS artifact has been updated to add elevated blood pressure to inclusions and to remove BMI, impaired fasting glucose and impaired glucose tolerance from the inclusions.
Add explanation/ Verify completeness	CVD risk factor definition	The Population Statement states that this recommendation applies to adults who have known CVD risk factors, defined as "hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors such as metabolic syndrome or an estimated 10-year CVD risk of >=7.5%." These five criteria informed the development of the inclusion logic. A USPSTF SME confirmed that smoking and diabetes should not be included in the CDS logic as CVD risk factors.
Add explanation/ Verify completeness	dyslipidemia definition	This recommendation applies to adults who have known CVD risk factors, including dyslipidemia. The USPSTF Statin Use for the Primary Prevention of CVD in Adults recommendation defines dyslipidemia as "LDL-C > 130 mg/dL or HDL-C < 40 mg/dL." A USPSTF SME confirmed that these lab values appropriately define dyslipidemia for this artifact.

Decision Category	Concept	Rationale
Add explanation	HDL cholesterol logic phrases	HDL cholesterol is expressed in three logic phrases: 1) as part of the CVD “dyslipidemia” risk factor (i.e., < 40 mg/dL), 2) as part of the “metabolic syndrome” criteria for men (i.e., < 40 mg/dL), and 3) as part of the “metabolic syndrome” criteria for women (i.e., < 50 mg/dL). The artifact development team decided to include “HDL-C level of < 40 mg/dL in men” within the metabolic syndrome logic statement, despite redundancy of the logic, to minimize confusion if viewers reviewed the evidence-based resources used to define “metabolic syndrome” and found the criterion missing. In reality, if a man had an HDL-C of < 40 mg/dL, he would automatically evaluate “true” for the inclusion logic that defines dyslipidemia.
Add explanation/ Add Specificity (Deabstract)/ Disambiguate	“Metabolic syndrome” definition	Samson and Garber state in their “Metabolic Syndrome” abstract that metabolic syndrome is not a disease, but a term that highlights traits that may lead to an increased risk of disease (approximately twofold for CVD and fivefold or more for Type 2 Diabetes Mellitus). It is a clustering of clinical findings made up of five characteristics: abdominal obesity, high glucose, high triglyceride, low high-density lipoprotein, and hypertension. Reference: https://www.ncbi.nlm.nih.gov/pubmed/24582089 Thresholds for the five characteristics vary slightly when listed by different professional organizations and government agencies. The threshold values specified in this artifact are from the National Health Lung and Blood Institute and the American Heart Association. Future implementers may choose to implement other definitions (e.g., some definitions list different waist circumference values based on ethnicity). See information available at https://www.nhlbi.nih.gov/health-topics/metabolic-syndrome and https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.105.169404.

Decision Category	Concept	Rationale
Add explanation/ Add Specificity (Deabstract)/ Disambiguate	"Behavioral counseling for a healthy diet and physical activity" definition	The "Diet and Activity" recommendation focuses on behavioral counseling that encourages healthy eating and physical activity behaviors to improve cardiovascular health. It does not address weight-loss programs. The USPSTF recommends that clinicians selectively initiate behavioral counseling to promote a healthy diet and physical activity in patients who are not obese and not at increased cardiovascular risk. Most studies reviewed by the USPSTF included interventions that combined healthy diet and physical activity counseling that is intensive, with multiple contacts (which may have included individual or group counseling sessions) over extended periods. Interventions involved an average of 5 to 16 contacts over 9 to 12 months, depending on their intensity. Reference: https://www.ncbi.nlm.nih.gov/pubmed/25155419. Value sets that define behavioral counseling include codes representing counseling activities related to CVD risk reduction (such as low-salt and low-fat diet education) since this artifact targets individuals with CVD risks. Finally, the CDS logic looks for any evidence of behavioral counseling in the available data (i.e., as a referral for counseling, an order for counseling, the counseling event/procedure itself, or the counseling encounter). Organizations may need to adjust the logic to search for additional ways that the data may be stored in their system (e.g., as claims data). Alternatively, they may choose to map qualifying data in their system to the CQL code as is.

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** and **Table 5** 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. FHIR DSTU2 Data Requirements for This Artifact

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Age	I	Patient	birthDate
Behavioral Counseling for Nutrition and Activity Referral	X	ReferralRequest	serviceRequested status is 'requested,' 'accepted,' 'active,' or 'completed' (see https://www.hl7.org/fhir/DSTU2/valueset-referralstatus.html) dateSent
Behavioral Counseling for Nutrition and Activity Order	X	ProcedureRequest	code status is 'request,' 'received,' 'accepted,' 'in-progress,' or 'completed' (see https://www.hl7.org/fhir/DSTU2/valueset-procedure-request-status.html) orderedOn
Behavioral Counseling for Nutrition and Activity Procedure	X	Procedure	code status is not 'entered-in-error' notPerformed is not true performedDateTime or performedPeriod

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Behavioral Counseling for Nutrition and Activity Encounter	X	Encounter	status is not 'cancelled' reason (code) period
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
Carotid Intervention (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
Diastolic BP (preferred representation)	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) component.code component.valueQuantity
Diastolic BP (alternate representation)	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
Elevated blood pressure	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html)
Elevated blood pressure Observation interpretation	I	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine two most recent) status is 'final' or 'amended' (see https://www.hl7.org/fhir/DSTU2/valueset-observation-status.html) interpretation

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Estimated 10-year CVD risk	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 '%' units
Fasting plasma glucose test	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
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	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
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
Systolic BP (preferred representation)	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) component.code component.valueQuantity
Systolic BP (alternate representation)	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
Triglyceride	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

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Waist circumference	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

Table 5. FHIR R4 Data Requirements for This Artifact

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Age	I	Patient	birthDate
Behavioral Counseling for Nutrition and Activity Referral	X	ServiceRequest	code status is 'active' or 'completed' (see http://hl7.org/fhir/R4/valueset-request-status.html) authoredOn
Behavioral Counseling for Nutrition and Activity Order	X	ServiceRequest	code status is 'active' or 'completed' (see http://hl7.org/fhir/R4/valueset-request-status.html) authoredOn
Behavioral Counseling for Nutrition and Activity Procedure	X	Procedure	code status is not 'preparation,' 'not-done,' 'entered-in-error,' or 'unkown' performedDateTime or performedPeriod
Behavioral Counseling for Nutrition and Activity Encounter	X	Encounter	status is not 'cancelled,' 'entered-in-error,' or 'unknown' reasonCode period
Myocardial Infarction (MI) (Cardiovascular Disease (CVD))	X	Condition	code verificationStatus is 'confirmed'

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
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'
Percutaneous Coronary Intervention (PCI) (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed'
Carotid Intervention (Cardiovascular Disease (CVD))	X	Procedure	code status is 'completed'
Diastolic BP (preferred representation)	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is ‘final,’ ‘corrected,’ or ‘amended’ (see http://hl7.org/fhir/R4/valueset-observation-status.html) component.code component.valueQuantity

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Diastolic BP (alternate representation)	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity
Elevated blood pressure	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active,' 'recurrence,' OR 'relapse' (see http://hl7.org/fhir/R4/valueset-condition-clinical.html)
Elevated blood pressure Observation interpretation	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine two most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) interpretation
Estimated 10-year CVD risk	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity with '%' units

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Fasting plasma glucose test	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is ‘final,’ ‘corrected,’ or ‘amended’ (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
HDL	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is ‘final,’ ‘corrected,’ or ‘amended’ (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
Hypertension	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active,' 'recurrence,' OR 'relapse' (see http://hl7.org/fhir/R4/valueset-condition-clinical.html)
LDL-C	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is ‘final,’ ‘corrected,’ or ‘amended’ (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Pregnancy	X	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active,' 'recurrence,' OR 'relapse' (see http://hl7.org/fhir/R4/valueset-condition-clinical.html) no abatement[x] attributes are present
Pregnancy Observation (within the last 42 weeks)	X	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueCodeableConcept
Systolic BP (preferred representation)	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) component.code component.valueQuantity

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Systolic BP (alternate representation)	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity
Triglyceride	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity with 'mg/dL' or 'mmol/L' units
Waist circumference	I	Observation	code effectiveDateTime, effectiveInstant, effectivePeriod, or issued (to determine most recent) status is 'final,' 'corrected,' or 'amended' (see http://hl7.org/fhir/R4/valueset-observation-status.html) valueQuantity

Appendix C. References

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