

Implementation Guide

Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors

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

Contract No. HHS290201600001U

Prepared by:

CMS Alliance to Modernize Healthcare (The Health FFRDC)
A Federally Funded Research and Development Center

AHRQ Publication 19-0071-1-EF
September 2019

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 HHSA290201600001U from AHRQ, U.S. Department of Health and Human Services. The opinions expressed in this document are those of the authors and do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Public Domain Notice

This document is in the public domain and may be used and reprinted without permission in the United States, unless materials are clearly noted as copyrighted in the document. No one may reproduce copyrighted materials without the permission of the copyright holders. Users outside the United States must get permission from AHRQ to reprint or translate this product. Anyone wanting to reproduce this product for sale must contact AHRQ for permission. Citation of the source is appreciated.

Suggested Citation

CMS Alliance to Modernize Healthcare (The Health FFRDC). Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors. Implementation Guide. Prepared under Contract No. HHSA290201600001U. AHRQ Publication No. 19-0071-1-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2019.

Acknowledgments

Specifically, we want to thank and recognize:

- Agency for Healthcare Research and Quality (AHRQ) leadership team, including Dr. Edwin Lomotan, Steve Bernstein, Shafa Al-Showk, Roland Gamache, and Mary Nix
- Clinical Decision Support (CDS) Connect Work Group members
- b.well Pilot Project Team
- CDS Connect Subcontractor Danny Van Leeuwen
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team
- AHRQ U.S. Preventive Services Task Force Leadership Team

Contents

Introduction.....	6
Background.....	6
Scope, Purpose, and Audience of This Implementation Guide	7
Implementing and Using This Artifact	8
Artifact Description	8
Preventive Health Scenarios Supported by This Artifact	9
Health Scenarios Supported With Customization of the Coded Expression	11
CDS Interventions and Suggested Actions	12
Patient-Facing CDS Development Considerations.....	13
Development of Patient-Centered Preventive Care CDS Artifacts	13
Patient Notification and Intervention Considerations.....	13
Guideline Interpretation and Clinical Decisions.....	16
Evidence Source for Artifact Development.....	16
Guideline Translation Summary	16
Technical Details Regarding Artifact Implementation.....	18
General Information About CQL.....	18
Library Relationship Diagram	19
Artifact Library Manifest.....	19
Artifact Testing.....	20
Implementation Checklist	21
Potential Reuse Scenarios	23
Integration With Health Information Technology	23
Appendix A. Decision Log	25
Artifact Semistructured Logic.....	25
Concept Definition Decision Log.....	27
Artifact Development Decision Log.....	33
Appendix B. Data Requirements	37
Appendix C. References	42

Figures

Figure 1. Example of Patient Notification	14
Figure 2. Example of Patient Education	15
Figure 3. Example of Appointment Facilitation	15
Figure 4. Artifact Relationship Diagram	19
Figure 5. Testing Approach Diagram	21
Figure 6. CDS Artifact Maturity Process.....	22
Figure 7. Integration Approach Using CQL Services.....	24

Tables

Table 1. Artifact Manifest.....	19
Table 2. Concept Definition Decision Log.....	27
Table 3. Artifact Development Decision Log.....	33
Table 4. Data Requirements for This Artifact	37

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 artifact derived from the U.S. Preventive Services Task Force (USPSTF) full recommendation statement on [*Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease \(CVD\) Prevention in Adults With Cardiovascular Risk Factors*](#), referred to as the "Healthful Diet and Physical Activity for CVD Prevention" artifact, along with how it can be integrated within a health IT system. The CDS 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.

The CDS logic expression identifies patients who qualify for the recommended preventive care based on patient-specific criteria such as age, weight, and known CVD risk factors. Targeted patients are provided with opportunities to learn more about their health status in the context of the “Healthful Diet and Physical Activity for CVD Prevention” 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 counseling interventions to promote a healthful diet and physical activity).

Various audiences may find this information helpful, including:

1. **Clinicians and Quality Improvement 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 who are overweight or obese and have at least one other risk factor for developing CVD. It provides the opportunity to provide 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(s) for heart disease and stroke, along with how that may be impacting their health and 2) 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 healthful diet and physical activity).

Preventive Health Scenarios Supported by This Artifact

The “Healthful Diet and Physical Activity for CVD Prevention” artifact was developed, piloted, and published to identify those patients at risk for developing CVD according to the logic derived from the USPSTF statement. Once 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

- a. Susan is 47 years old, single, and overweight; has high blood pressure; and has a fairly 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. Susan 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.
 - i. The information found in the health app provides education topics for Susan 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. This scenario provides an example of the notification that might be provided. The same is true for subsequent scenarios.
- b. Jack 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 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 weight and abnormal LDL and HDL levels.

- i. The notification also provides educational materials to Jack 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

- a. Susan 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. Susan 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.² The information on the healthfinder.gov website has been designed using health literacy and usability principles,³ and can be used by future implementers to customize the education content for their organization.
- b. Jack's primary care clinician recommended several links to educational resources in the message that he sent to Jack via the patient portal. Jack reads the educational resources and watches a video on CVD risk.

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

- a. As Susan 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.
- b. Jack 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, Jack receives another email reminding him that there is still an action item outstanding on his patient portal. Jack 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 “Healthful Diet and Physical Activity for CVD Prevention” recommendation to identify patients that 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 include:

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

Johnston Primary Care (JPC) is a large 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 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 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 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:**

Procure Health provides wellness services to its customers, which consist primarily of employers and health plans. These customers contract with Procure 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. Procure Health uses the artifact logic to identify individual participants who have specific risk factors for CVD, such as hypertension, hyperlipidemia, and high glucose levels. They provide intensive wellness services to help the identified participants understand the actions and activities that may help mitigate their risk. Procure Health 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:

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 an elevated body mass index (BMI) and one or more risk factors for CVD (i.e., hypertension, dyslipidemia, impaired fasting glucose, or metabolic syndrome).
2. Exclusion: Patients who are pregnant, are already diagnosed with CVD, or are already undergoing behavioral counseling on healthful 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 pertinent to this recommendation in patient-friendly language (such as being overweight, having high blood pressure or high blood sugar), along with ways to modify those risks by eating a healthful 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.

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 is found in the *Example Intervention Content: Healthful Diet and Physical Activity for CVD Prevention* document posted in the Miscellaneous Files section of the

Healthful 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.⁴

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.⁵ 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.⁵ 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 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.⁶ 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

© 2019 b.well Connected Health, Inc.

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 cardiovascular risk and recommendations, tools, and videos to provide additional education.

- The resources found on healthfinder.gov as well as the USPSTF [patient handout](#)⁷ 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

Give Your Heart Some Love

An important conversation to have with your doctor

Did you know you may be at higher risk for heart disease? Fortunately, there's so much you can do to protect yourself. Let's walk through a key recommendation together.

We chose this challenge for you because we noticed you may have some risk factors for heart disease and stroke. Let's go over the what and why — and then talk about how you can stay healthy!

Based on our information, you may have these risk factors *(only displays end-user's risk factors)*:

The US Preventive Services Task Force recommends that you schedule time to talk with your doctor about counseling to help you eat right and stay active. Because working together, you can help turn these risk factors around.

© 2019 b.well Connected Health, Inc.

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

Take Action to Protect Your Heart

Take a moment to set up an appointment to talk about eating and physical activity with your healthcare team. We can help you with this!

Taking small steps to eat healthier and get more active is a great way to help prevent heart disease and stroke. This is why The US Preventive Services Task Force recommends that people at higher risk work with their healthcare team on these areas.

So set up an appointment today to ask your doctor for help with healthy eating and physical activity. Working together, you can lower your risk and stay healthy.

© 2019 b.well Connected Health, Inc.

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 [*Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors*](#). The 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 healthful diet and physical activity for CVD prevention.”⁸ Within the *Patient Population Under Consideration* section of the USPSTF full recommendation statement, the USPSTF goes on to define “CVD risk factors” as hypertension, dyslipidemia, impaired fasting glucose, or metabolic syndrome. The strength of the recommendation is grade “B,” indicating that the USPSTF recommends this service and there is moderate 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. 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:

1. **CVD risk factors:** The *Population* statement in the recommendation statement states that the recommendation applies to adults who have known CVD risk factors, defined as “hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome.”⁸ 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 “Healthful Diet and Physical Activity for CVD Prevention” recommendation did not meet threshold criteria to be included in the *Population* statement of the published recommendation.⁸
2. **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).⁹ It is a cluster of clinical findings made up of five characteristics: abdominal obesity, high 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).^{10 11 12}

3. ***Impaired fasting glucose and impaired glucose tolerance:*** The recommendation applies to patients who are overweight and have known CVD risk factors, including “impaired fasting glucose.” The full recommendation statement also mentions “impaired glucose tolerance” as a pertinent condition. A USPSTF SME agreed that “impaired glucose tolerance” should be included with the concept of “impaired fasting glucose,” and that both concepts should be defined as a diagnosis versus one or more abnormal lab result value(s), since abnormal lab results alone may not provide an accurate indication of a condition.
4. ***CVD as an exclusion:*** The intent of the recommendation is to identify patients who are overweight and also have one or more CVD risk factors in order to *prevent* the development of CVD. If a patient already has CVD, different types of treatment and counseling may be indicated.
5. ***Pregnancy as an exclusion:*** The BMI criteria used in the inclusion logic do not apply to pregnant women due to normal weight changes characteristic in pregnancy. In addition, other types of interventions may be needed for pregnant women. A USPSTF SME validated that excluding pregnant women was appropriate.
6. ***Suggested actions for behavioral counseling for a healthful diet and physical activity:*** The “Healthful Diet and Physical Activity for CVD Prevention” recommendation focuses on intensive behavioral counseling that encourages healthful eating and physical activity behaviors to improve cardiovascular health and prevent CVD.
 - a. The behavioral counseling value set definitions do not specifically address weight-loss programs. 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. A separate and distinct USPSTF recommendation for patients with a BMI of 30 kg/m² or greater recommends offering or referring patients to intensive, multicomponent behavioral counseling for weight loss.
 - b. Most studies reviewed by the USPSTF included interventions that combined healthful 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 five to sixteen contacts over nine to twelve months, depending on their intensity.⁸
 - c. 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 “Healthful 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 are overweight or obese, have additional CVD risk factors, and may require intensive behavioral counseling interventions to promote a healthful diet and physical activity to prevent CVD.

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 section 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 “Healthful Diet and Physical Activity for CVD Prevention” artifact is composed of several files with the primary focus of providing CQL files that any organization may use to identify individuals who are overweight or obese; have additional CVD risk factors; and may require intensive behavioral counseling interventions to promote a healthful diet and physical activity to prevent CVD.

CQL is a data standard governed by HL7 that is currently a Standard for Trial Use (STU).¹³ 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 *](#)

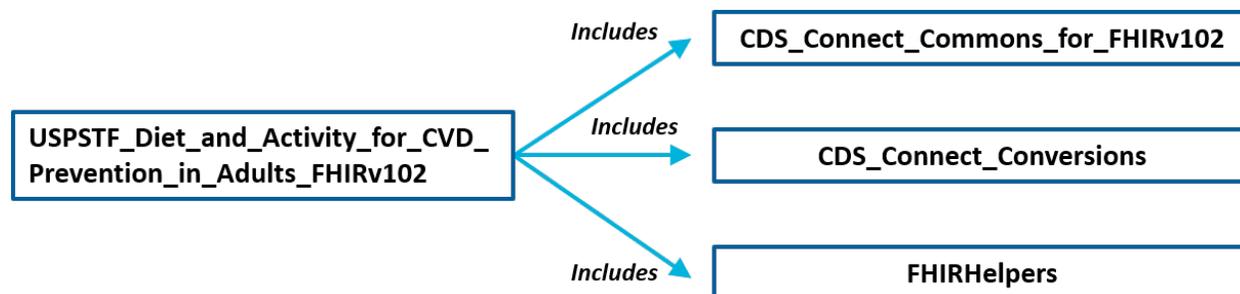
* These websites do not support the use of Internet Explorer, and recommend using either Google Chrome, Microsoft Edge, or Firefox.

Library Relationship Diagram

CQL developers are encouraged to refactor commonly used functions into separate software files called libraries.¹⁴ 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 three supporting libraries. As depicted in the diagram, the main CQL library references or “includes” the other three 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.

Figure 4. Artifact Relationship Diagram



Artifact Library Manifest

As mentioned in the previous section, the “Healthful Diet and Physical Activity for CVD Prevention” artifact is composed of four 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-ELM translator.¹⁵ Although the two formats contain the same information, they are formatted for their different purposes. The eight software files that comprise the artifact are listed in **Table 1** (below).

Table 1. Artifact Manifest

Filename	Purpose
USPSTF_Diet_and_Activity_for_CVD_Prevention_in_Adults_FHIRv102.cql	CQL representation of the “Healthful 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.

Filename	Purpose
USPSTF_Diet_and_Activity_for_CVD_Prevention_in_Adults_FHIRv102.json	JavaScript Object Notation (JSON) representation of the “Healthful 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.
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
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

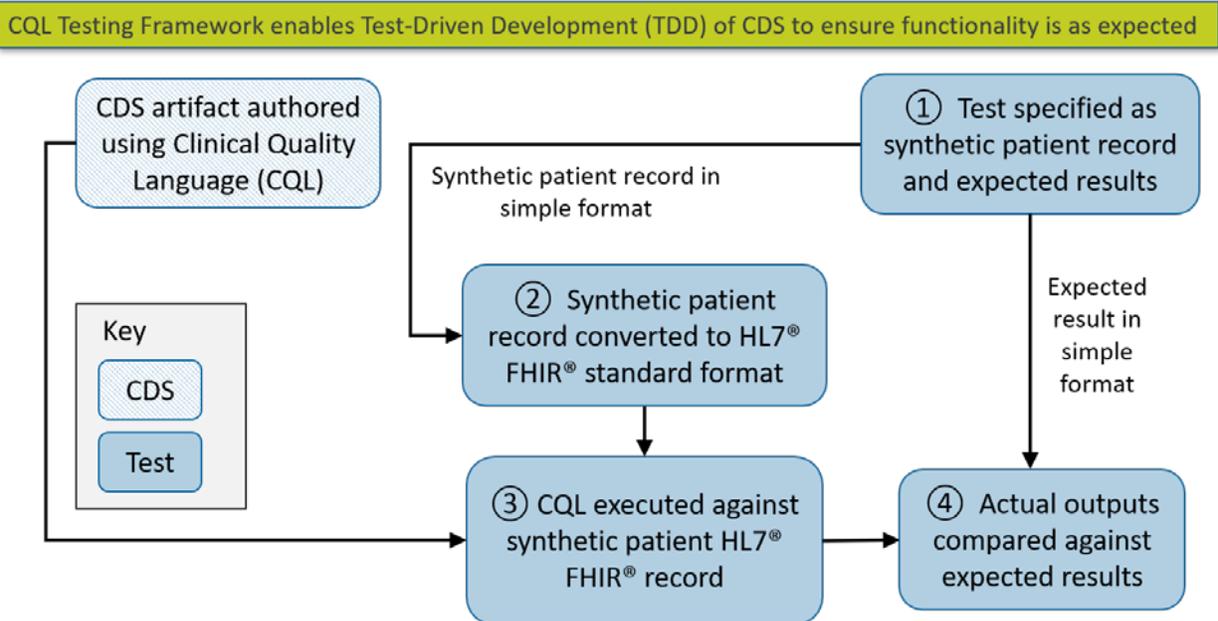
Artifact Testing

The “Healthful Diet and Physical Activity for CVD Prevention” artifact was written using a test-driven development (TDD) approach.¹⁶ TDD is important for development since it has been shown to produce software that is more robust and to contain fewer bugs.¹⁶ With TDD, a battery of test cases is created that define the expected functionality of the software, in this case the “Healthful Diet and Physical Activity for CVD Prevention” CQL. An automated CQL testing framework developed under funding by AHRQ was used 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.

The diagram in **Figure 5** depicts the TDD approach using the CQL Testing Framework. Before any CQL is written, the first step involves defining a test that specifies both the input to the CQL and the desired output. With the CQL Testing Framework, the input is specified in terms of a synthetic patient record containing the pertinent FHIR resources. For the “Healthful Diet and Physical Activity for CVD Prevention” artifact, the input may contain a waist circumference measurement of the synthetic patient, which is one of the data inputs required by the artifact (see Appendix B). Depending upon the nature of the test, the desired output may be that the CQL must return the appropriate USPSTF recommendation. Once a test has been specified in this way, the CQL of the artifact is updated until the test passes. It is in this way that the CQL is

iteratively written, 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



Test cases were developed 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 a zip file attached to the CDS artifact in the Repository. 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 (nonexhaustive) 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

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 6** and described here:

Figure 6. CDS Artifact Maturity Process



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

This “Healthful Diet and Physical Activity for CVD Prevention in Adults with CV Risk Factors” artifact The CDS Connect team puts forward the information as suggested “best practices” for including third-party CDS into an existing EHR 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,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 “Healthful Diet and Physical Activity for CVD Prevention” artifact. They are expected to be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the “Healthful 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.

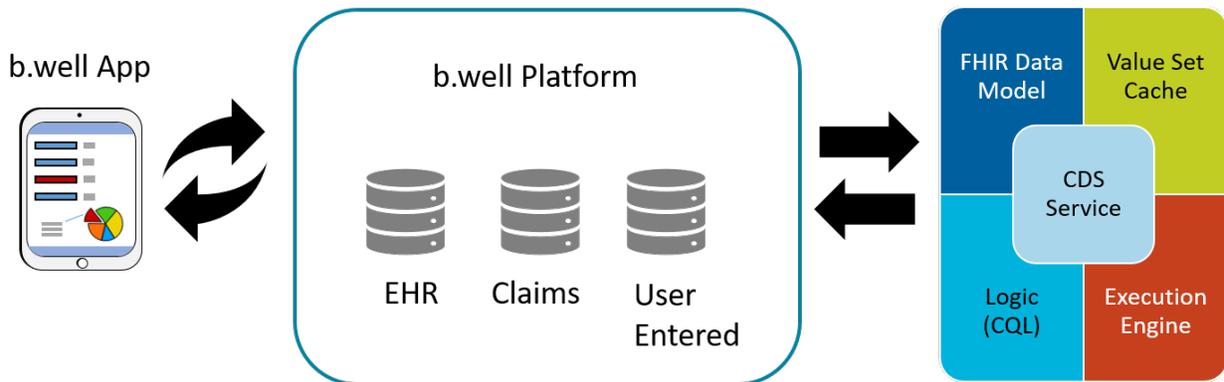
Integration With Health Information Technology

CQL Services¹⁸ was used to facilitate integration of the “Healthful Diet and Physical Activity for CVD Prevention” artifact into the b.well system. As depicted in **Figure 7** 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 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 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.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

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 “Healthful Diet and Physical Activity for CVD Prevention” artifact include:

Patient is ≥ 18 years old

AND BMI ≥ 25 kg/m², MOST RECENT VALUE

AND one or more of the following:

Hypertension (active, relapse)

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 impaired fasting glucose (IFG) within the past 12 months (active, relapse)

OR impaired glucose tolerance (IGT) within the past 12 months (active, relapse)

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 ≥ 150 mg/dL, MOST RECENT VALUE within the past 6 years
OR HDL-C < 50 mg/dL in women, MOST RECENT VALUE within the past 6 years
OR HDL-C < 40 mg/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 ≥ 100 mg/dL, MOST RECENT VALUE within the past 6 months

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 who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.**”⁸ Within the Patient Population Under Consideration section of the USPSTF recommendation statement, the USPSTF goes on to define “CVD risk factors” as hypertension, dyslipidemia, impaired fasting glucose, or metabolic syndrome.⁸

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	“overweight or obese”	The Centers for Disease Control and Prevention defines “overweight” as a BMI of 25 kg/m ² or greater and less than 30 kg/m ² , and “obese” as a BMI of 30 kg/m ² or higher (https://www.cdc.gov/obesity/adult/defining.html). A USPSTF SME confirmed that the use of these criteria was appropriate for this artifact. The “Useful Resources” section of the USPSTF recommendation states that the USPSTF does not address behavioral counseling in patients with a BMI less than 25 kg/m ² who are at increased risk of CVD. ⁸
Inclusions	“BMI”	BMI is the calculated ratio of a patient’s weight in kilograms divided by the square of height in meters (https://www.cdc.gov/obesity/adult/defining.html) defined by a single Logical Observation Identifiers Names and Codes (LOINC) code (39156-5).
Inclusions	“kg/m ² ”	Kilograms/meters ² (the unit of measure for BMI).
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.

Location in CDS Logic	Concept	Definition and/or Rationale
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” 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	“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/expansions?pr=all&rel=Latest&q=2.16.840.1.113883.3.464.1003.104.12.1012 and https://vsac.nlm.nih.gov/valueset/expansions?pr=all&rel=Latest&q=2.16.840.1.113883.3.600.873). 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/expansions?pr=all&rel=Latest&q=2.16.840.1.113883.3.600.873). 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)

Location in CDS Logic	Concept	Definition and/or Rationale
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	“impaired fasting glucose”	A recorded diagnosis of IFG (i.e., consistently elevated fasting blood sugar levels that fall short of the threshold defined for diabetes and IGT). The status must be “active” or “relapse” since this can be a transient diagnosis. Per a USPSTF SME, this concept is defined as a diagnosis versus one or more abnormal lab value(s). The rationale is that a formal diagnosis of IFG is made by a clinician after evaluating lab results in the context of the patient’s health. IFG is defined by a single International Classification of Diseases, Tenth Revision, Clinical Modification (ICD10CM) R73.01 and Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) code (390951007).
Inclusions	“within the past 12 months”	Occurring within 12 months of the CDS trigger; places restrictions on lookback periods to ensure clinical accuracy (since some diagnoses related to glucose metabolism can be very transient) and clinical relevancy (since behavioral counseling must be related to the patient’s current BMI and CVD risks and usually occurs over a time span of 9 to 12 months).
Inclusions	“impaired glucose tolerance”	A recorded diagnosis of IGT (i.e., consistently elevated fasting blood sugar levels that fall above the threshold for IFG and short of the threshold defined for diabetes). The status must be “active” or “relapse” since this can be a transient diagnosis. Per a USPSTF SME, this concept is defined as a diagnosis of IGT versus one or more abnormal lab value(s). The rationale is that a formal diagnosis of IGT is made by a clinician after evaluating lab results in the context of the patient’s health. Defined as the union of ICD10CM: R73.02 and the following value set: https://vsac.nlm.nih.gov/valueset/expansions?pr=all&rel=Latest&q=2.16.840.1.113762.1.4.1032.85 .

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. The logic phrases are listed in the inclusion logic pictured in Figure 5 in Appendix A .
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/expansions?pr=all&rel=Latest&q=2.16.840.1.113762.1.4.103.2.88 . 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/expansions?pr=all&rel=Latest&q=2.16.840.1.113883.3.600.8.81 . 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 \geq 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 \geq 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.
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.
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.

Location in CDS Logic	Concept	Definition and/or Rationale
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 define 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 healthful 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.²¹ 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	This USPSTF recommendation was published in August 2014. As of September 2019, the recommendation is under review and development by the USPSTF. The USPSTF review informs future updates to the recommendation based on new research and at times results in a new recommendation. Future implementors should monitor the USPSTF website for published updates to the recommendation, as revisions to the semi-structured and structured logic may be indicated. https://www.uspreventiveservicestaskforce.org/Page/Name/topics-in-progress
Add Specificity (Deabstract)	“overweight or obese” definition	This artifact pertains to individuals who are overweight or obese. The Centers for Disease Control and Prevention defines “overweight” as a BMI of 25 kg/m ² or greater and less than 30 kg/m ² , and “obese” as a BMI of 30 kg/m ² or higher (https://www.cdc.gov/obesity/adult/defining.html). The inclusion logic phrase “BMI >= 25 kg/m ² ” was validated by a USPSTF SME as aligning with the clinical intent of the recommendation.
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, dyslipidemia, impaired fasting glucose, or the metabolic syndrome.” These four criteria informed the development of the inclusion logic. Elsewhere in the recommendation statement, 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.

Decision Category	Concept	Rationale
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.
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/ Verify completeness	Incorporating “impaired glucose tolerance” in the logic specification	This recommendation applies to patients who are overweight and have known CVD risk factors, including “impaired fasting glucose.” The recommendation also mentioned “impaired glucose intolerance” in some areas, but not in the Population Statement. A USPSTF SME confirmed that individuals with “impaired glucose tolerance” should be considered for the CDS intervention also, as long as they do not meet exclusion criteria.

Decision Category	Concept	Rationale
Add explanation/ Add Specificity (Deabstract)/ Disambiguate	“metabolic syndrome” definition	<p>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</p> <p>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.</p>

Decision Category	Concept	Rationale
Add explanation/ Add Specificity (Deabstract)/ Disambiguate	“Behavioral counseling for a healthful diet and physical activity” definition	<p>The “Diet and Activity” recommendation focuses on behavioral counseling that encourages healthful 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 healthful 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 healthful 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 lowfat diet education) since this artifact targets individuals with CVD risks.</p> <p>For patients with a BMI of 30 kg/m² or greater, the USPSTF recommends referring them to intensive, multicomponent behavioral counseling for weight loss, as outlined in the Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions clinical guideline..</p> <p>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.</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
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
Body Mass Index (BMI)	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
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
Diastolic BP	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
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

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Hypertension	I	Condition	code verificationStatus is 'confirmed' clinicalStatus is 'active' OR 'relapse' (see https://www.hl7.org/fhir/DSTU2/valueset-condition-clinical.html)
Impaired Fasting Glucose (IFG)	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
Impaired Glucose Tolerance (IGT)	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
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

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Pregnancy Observation (within the last 42 weeks)	X	Observation	code effectiveDateTime, effectivePeriod, or issued (to determine most recent) status is 'final' or 'amended' valueCodeableConcept
Systolic BP	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
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

Appendix C. References

- 1 U.S. Department of Health and Human Services. CQL - Clinical Quality Language | eCQI Resource Center. <https://ecqi.healthit.gov/cql-clinical-quality-language>. Accessed June 16, 2019.
- 2 U.S. Department of Health and Human Services. Your Source for Reliable Health Information - healthfinder.gov. <https://healthfinder.gov/Default.aspx>. Accessed June 19, 2019.
- 3 Polinski JM, Harris LM, Shrank WH, Sussman A, Barron J. Impact of a patient engagement tool on preventive service uptake. *Healthcare*. 2018;6(3):162-167. doi:10.1016/J.HJDSI.2017.12.002
- 4 Fiks AG. Designing Computerized Decision Support That Works for Clinicians and Families. *Curr Probl Pediatr Adolesc Health Care*. 2011;41(3):60-88. doi:10.1016/j.cppeds.2010.10.006
- 5 Krist AH, Peele E, Woolf SH, et al. Designing a patient-centered personal health record to promote preventive care. *BMC Med Inform Decis Mak*. 2011;11(1). doi:10.1186/1472-6947-11-73
- 6 Barry MJ, Edgman-Levitan S. Shared Decision Making — The Pinnacle of Patient-Centered Care. *N Engl J Med*. 2012;366(9):780-781. doi:10.1056/NEJMp1109283
- 7 U.S.Preventive Services Task Force. Patient Handout: Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors | Agency for Healthcare Research & Quality. <https://www.ahrq.gov/evidencenow/heart-health/overall/uspstf-patient.html>. Published 2014. Accessed May 20, 2019.
- 8 LeFevre ML, U.S. Preventive Services Task Force. Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*. doi:10.7326/M14-1796
- 9 Samson SL, Garber AJ. Metabolic Syndrome. *Endocrinology and Metabolism Clinics of North America*. doi:10.1016/j.ecl.2013.09.009
- 10 Bittner VA. The New 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease. *Circulation*. March 2019:CIRCULATIONAHA.119.040625. doi:10.1161/CIRCULATIONAHA.119.040625

- 11 Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and Management of the Metabolic Syndrome An American Heart Association/National Heart, Lung, and Blood Institute Scientific Statement Underlying Risk Factors and Metabolic Syndrome. doi:10.1161/CIRCULATIONAHA.105.169404
- 12 National Heart Lung and Blood Institute. Metabolic Syndrome | National Heart, Lung, and Blood Institute (NHLBI). <https://www.nhlbi.nih.gov/health-topics/metabolic-syndrome>. Published 2019.
- 13 Health Level 7 (HL7). Clinical Quality Language (CQL) Release 1 STU3 (1.3). <https://cql.hl7.org/>. Accessed June 19, 2019.
- 14 Health Level 7 (HL7). Author's Guide: Using Libraries to Share Logic. <https://cql.hl7.org/02-authorsguide.html#using-libraries-to-share-logic>. Accessed June 19, 2019.
- 15 Health Level 7 (HL7). CQL-to_ELM Translator Reference Implementation. https://github.com/cqframework/clinical_quality_language/blob/master/Src/java/cql-to-elm/OVERVIEW.md. Accessed June 19, 2019.
- 16 Wikipedia. Test-driven development. https://en.wikipedia.org/wiki/Test-driven_development. Accessed June 4, 2019.
- 17 Boxwala AA, Rocha BH, Maviglia S, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc.* 2011;18 Suppl 1(Suppl 1):i132-9. doi:10.1136/amiajnl-2011-000334
- 18 Agency for Healthcare Research and Quality. CQL Services GitHub page. <https://github.com/AHRQ-CDS/AHRQ-CDS-Connect-CQL-SERVICES>. Accessed June 4, 2019.
- 19 National Library of Medicine. Value Set Authority Center. <https://vsac.nlm.nih.gov/>. Accessed June 19, 2019.
- 20 HL7 and Boston Children's Hospital. CDS Hooks. <https://cds-hooks.org/>. Accessed June 4, 2019.
- 21 Tso GJ, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. *AMIA . Annu Symp proceedings AMIA Symp.* 2016;2016:1189-1198. <http://www.ncbi.nlm.nih.gov/pubmed/28269916>. Accessed February 28, 2019.