Implementation Guide

Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part Two, Counseling

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Introduction

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

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

Background

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

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

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

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

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

Scope, Purpose, and Audience of This Implementation Guide

This document provides information about the creation and uses of the CDS logic expression (referred to as an "artifact") derived from the U.S. Preventive Services Task Force (USPSTF) full recommendation statement on *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus*, referred to as the *Abnormal Glucose: Counseling* artifact in this guide, along with how it can be integrated within a health IT system. The *Abnormal Glucose: Counseling* CDS artifact addresses the second part of this USPSTF recommendation, related to offering intensive behavioral counseling to promote a healthful diet and physical activity for those patients found to have an abnormal blood glucose level. Behavioral counseling is encouraged to inform lifestyle changes that can reduce an individual's risk of developing diabetes or heart disease. The first part of this USPSTF recommendation, related to screening patients for abnormal blood glucose as part of cardiovascular (CVD) risk assessment, is represented in a distinct CDS artifact and implementation guide (i.e., Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part One, Screening).

The *Abnormal Glucose: Counseling* artifact is designed to identify patients who have known abnormal glucose screening levels along with additional patient-specific criteria such as age, body mass index (BMI), and known diabetes risk factors. Targeted patients are provided with opportunities to learn more about their health status in the context of the recommendation and are encouraged to take steps toward improving their health and reducing their risk of heart disease and diabetes (e.g., initiate a discussion with their primary care clinician about receiving behavioral counseling to promote a healthful diet and physical activity).

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 *Abnormal Glucose: Counseling* 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.

Various audiences may find this information helpful, including:

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

Implementing and Using This Artifact

Artifact Description

This artifact identifies patients who have abnormal glucose levels as well as other risk factors such as age, an elevated body mass index (BMI), or other specific characteristics that may lead to diabetes as well as heart disease. Abnormal glucose metabolism is frequently associated with additional CVD risk factors (such as hypertension, hyperlipidemia or dyslipidemia, smoking, physical inactivity, and an unhealthy diet).[2] The artifact provides the opportunity to present information to at-risk patients through a patient-facing health IT system (e.g., a patient portal, health app) to (1) provide educational resources for learning about the risks for developing diabetes, (2) provide resources on how reduce those risks, (3) provide information on the role diabetes plays in CVD, and (4) encourage them to talk to their primary care physician about additional interventions such as counseling to promote a healthy diet and physical activity.

Preventive Health Scenarios Supported by This Artifact

The *Abnormal Glucose: Counseling* artifact was developed, piloted and published to identify those patients who have abnormal blood glucose levels and are overweight or obese, or have additional risk factors for developing diabetes, according to the logic derived from the USPSTF *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* 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. Sample notification text has been developed to provide some initial examples for implementers, which can be found in the *Example Intervention Content: Abnormal Blood Glucose, Part Two, Counseling* document posted in the Miscellaneous Files section of the *Abnormal Glucose: Counseling* artifact. In addition, examples of the notification and educational content developed by the pilot partner, b.well, are displayed in this document in the *Patient Notification and Intervention Considerations* section.

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

1. **Providing the patient with an alert that they may be at risk for high blood sugar and diabetes**
    a. Frank is 42 years old, overweight, and smokes. He does not like to cook, so he eats out a lot. He recently visited his primary care physician, who ordered a blood glucose test. Frank receives a push notification from his health app that

there is some information for him to review from his healthcare team. Frank opens the notification and selects the embedded link, which opens the health app and displays information indicating that because of his weight and sugar levels in his blood, he may be at risk for developing diabetes.

i. The information found in the health app provides education topics for Frank to review regarding his risk factors and ways he could reduce his risk through lifestyle changes such as healthy eating, and encourages him to speak with his physician about receiving counseling on how to eat healthy 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. Mary is a 28-year-old mother of two children. She developed gestational diabetes during her last pregnancy. She and her family recently enrolled with a new primary care provider. During the initial visit, she received several baseline blood tests, including one for blood glucose. She receives an email indicating that there is new information to review in her patient portal from her primary care clinician. She accesses the portal and discovers a message indicating that because the results of her recent blood test showed high blood sugar levels, as well as her history of diabetes during pregnancy, she may be at risk for developing diabetes.

i. The information found in the health app provides educational topics for Mary to review about her risk factors and ways she could reduce her risk through lifestyle changes such as healthy eating and engaging in physical activity. It also recommends contacting her physician to discuss whether counseling on how to eat healthy and stay active is right for her, as outlined in scenarios 2 and 3 (below).

2. Providing the patient with targeted educational materials

a. Frank selects the embedded link in the information provided in his health app, which accesses personalized educational material about prediabetes and diabetes. He learns that having a high sugar level in his blood is a risk factor for developing diabetes. Additional information available for John includes educational material on healthy eating and increased physical activity to reduce his diabetes risk. 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.[3] The information on the healthfinder.gov website has been designed using health literacy and usability principles,[4] and can be used by future implementers to customize the education content for their organization.

b. Mary's primary care clinician recommended several links to educational resources in the message that he sent Mary via the patient portal. These address prediabetes, diabetes, the risk factors for developing CVD, and the importance of healthy eating and increased physical activity to reduce CVD risks. Mary reads the educational resources and watches a video on diabetes**.**

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

    a. As Frank reviews the information on his health app, one of the suggested actions is to schedule an appointment with his primary care clinician to discuss any concerns he may have and possible interventions for reducing his risk of developing diabetes, including counseling for a healthy diet and physical activity regimen. He schedules an appointment through the scheduling function in the health app.

    b. Mary decides not to act on the suggested action of making an appointment with her primary care clinician to discuss her risk factors and possible interventions. Several weeks later, she receives another email reminding her that there is still an action item outstanding on her patient portal. She accesses the portal and views the notification reminder on the importance of seeing her primary care clinician. This time, she 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 second part of the published USPSTF *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* recommendation, to identify patients with abnormal blood glucose levels as well as other risk factors. 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 patients who have elevated blood glucose levels in a primary care setting:**

   Marriam Primary Care (MPC) is a medium-size practice in Florida with four primary care practitioners and about 4,000 patients. It is a multicultural clinic with a large number of Asian and Hispanic enrollees as well as a high incidence of diabetes mellitus (DM). To address one of the potential health needs of its population, MPC decides to focus intently on ensuring that those patients at risk of developing DM are receiving the appropriate follow-up care, including behavioral counseling. 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 any patient who has not yet scheduled a followup appointment with their primary care clinician, to encourage them to schedule an appointment to discuss their individual risk factors and possible interventions with their primary care clinician. Data regarding the number of appointments scheduled as a result of the outreach as well as the number of individuals who are referred to behavioral counseling are collected and analyzed on an ongoing basis to determine the impact of the outreach.

2. **Enabling wellness and preventive care for patients through identification of individuals with elevated blood glucose levels and other 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 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 with elevated blood glucose levels and other risk factors for developing diabetes, such as being overweight or obese, having a family history of diabetes or history of gestational diabetes, or being of certain race or ethnic origins. They encourage the identified participants to make an appointment with their primary care clinician and facilitate appointment scheduling. They also provide educational resources to help the 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 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:**

   Smart 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 the comorbid conditions to develop CDS requested by one of their customers. The customer, a large healthcare system, has requested CDS to identify those patients with elevated blood glucose levels and other characteristics which

are risk factors for developing prediabetes or diabetes, and have a history of CVD comorbid conditions(e.g., hypertension), so that the appropriate primary care clinicians can be alerted through a report generated by the CDS. This report can be used to reach out to the identified patient population.

CDS Interventions and Suggested Actions

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

1. Inclusion:
    a. Individuals 40 to 70 years old with a BMI greater than or equal to 25 mg/kg^2 OR
    b. Individuals 18 to 39 years old with a BMI greater than or equal to 25 mg/kg^2, and who have one or more of the following: a family history of diabetes; history of polycystic ovary syndrome; are a member of the African American, American Indian or Alaskan Native, or Native Hawaiian or Pacific Islander race; or the ethnicity of Hispanic or Latino OR
    c. Individuals 18 to 70 years old with a BMI of greater than or equal to 23 kg/m^2 and a member of the Asian race OR
    d. Individuals 18 to 70 years old with a history of gestational diabetes (regardless of their BMI)
2. AND:
    a. Hemoglobin A1c greater than or equal to 5.7% OR
    b. Fasting plasma glucose level (FPG) greater than or equal to 100 mg/dl OR
    c. Oral glucose tolerance test result (OGTT) greater than or equal to 140 mg/dl
3. Exclusion: Patients who are pregnant, or who previously had behavioral counseling for nutrition and 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 developing diabetes based on having elevated blood glucose levels and other pertinent risk factors.
2. Suggested Action: Provide educational materials that explain diabetes risk factors pertinent to this recommendation in patient-friendly language (such as being overweight, being of certain race and ethnic origins, having a family history of diabetes, or a history of gestational diabetes).
3. Suggested Action: Suggest the patient make an appointment with their primary care clinician to discuss their blood glucose levels, risk of developing diabetes, and ways to mitigate the risk including healthy diet and physical activity counseling. 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: Abnormal Blood Glucose, Part Two, Counseling* document posted in the Miscellaneous Files section of the *Abnormal Glucose: Counseling* 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.[5]

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.[6] 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.[6] 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.[7] It allows the patient and their primary healthcare clinician to determine together the most appropriate treatment or care choice.

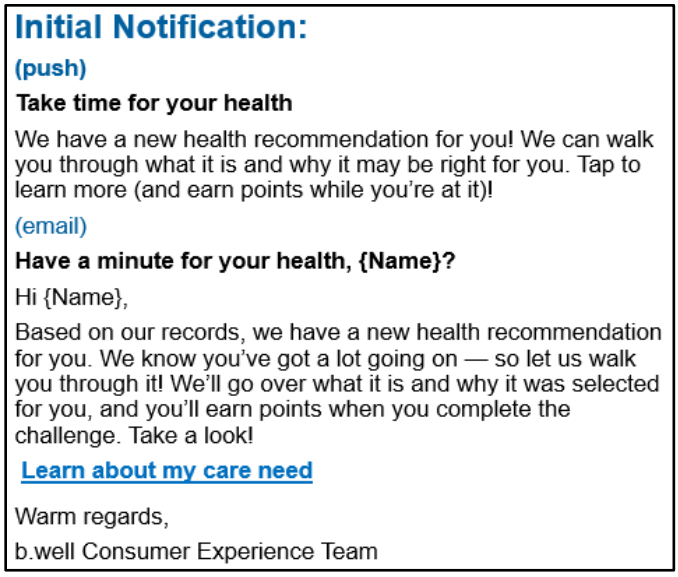
As noted earlier, the patient notifications included in the structured CQL expression of this artifact are fairly general, enabling implementing organizations to expand upon and personalize the interventions based on their unique needs and patient population. Information provided to the patient translates 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).

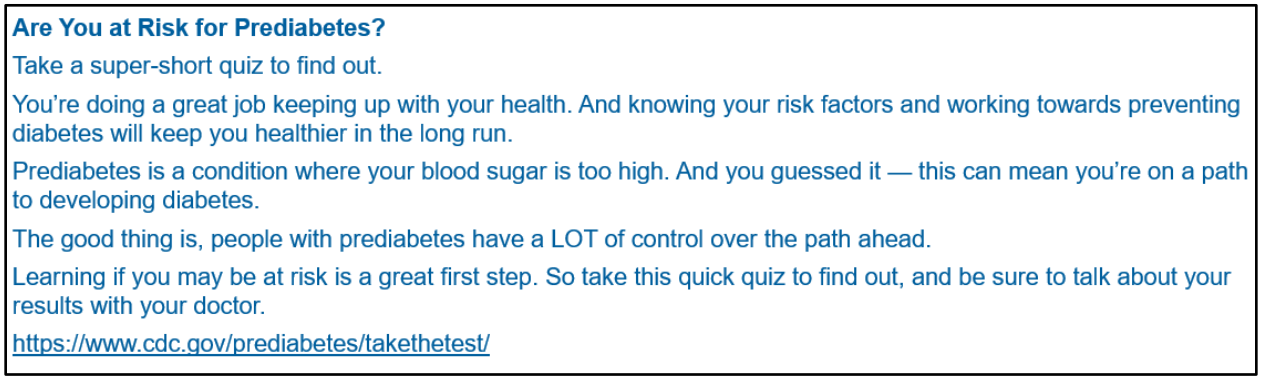
Figure 1. Example of Patient Notification



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

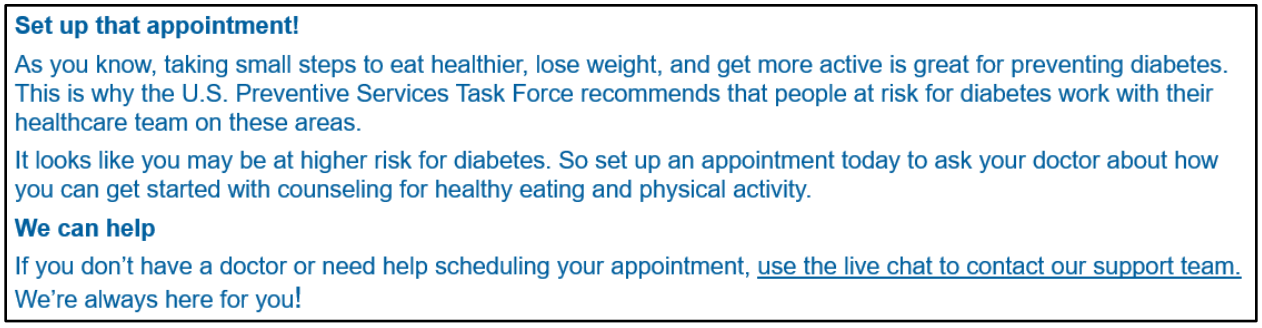
- The resources found on healthfinder.gov as well as the USPSTF Consumer Fact Sheet[8] were used as sources for much of the content created. See **Figure 2** for an example of patient education text.

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 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 *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus*. The recommendation summary states that "the USPSTF recommends screening for abnormal blood glucose as part of CVD risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling to promote a healthful diet and physical activity."[2] This artifact addresses the second part of the recommendation, offering intensive behavioral counseling to promote a healthful diet and physical activity for those patients found to have an abnormal blood glucose level.

Within the *Patient Population Under Consideration* section of the USPSTF full recommendation statement, the USPSTF indicates the target population includes persons who may be at increased risk for diabetes at a younger age or at a lower body mass index, which would include "persons who have a family history of diabetes, a history of gestational diabetes or polycystic ovarian syndrome, or are members of certain racial/ethnic groups (that is, African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders)."[2] 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. ***Division of the recommendation into two parts:*** The USPSTF *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* recommendation involves a two-step process. The first step is determining which patients require screening for abnormal blood glucose. The second step involves referring patients with abnormal blood glucose levels to intensive counseling to promote a healthy diet and physical activity. The inclusion and exclusion criteria are different for each of these. Therefore, the recommendation is divided into two separate artifacts for ease of use and implementation: *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part One, Screening (i.e., Abnormal Glucose: Screening*) and *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part Two, Counseling (i.e., Abnormal Glucose: Counseling*). A USPSTF SME confirmed this approach was appropriate. This guide pertains to the *Abnormal Glucose: Counseling* artifact.
2. ***Interpretation of inclusions in the recommendation statement:*** The USPSTF recommends screening for abnormal blood glucose as part of CVD risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling to promote a healthful diet and physical activity. Within the *Patient Population Under Consideration*, the recommendation indicates that persons with specific conditions such as a "…family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome, or are members of certain racial/ethnic groups… may be at increased risk for diabetes at a younger age or at a lower body mass index."[2] A USPSTF SME helped to inform the clinical interpretation and specified four distinct inclusion groups as outlined in the CDS Interventions and Suggested Actions section of this document, which is more than what a casual reader of the two sentence recommendation statement might expect.
3. ***Family history of diabetes:*** A family history of diabetes mellitus (DM), Type 1 or Type 2, must occur in *a first degree relative* (i.e., parent, sibling, or child). Due to this specificity, the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code that represents "Family history of diabetes mellitus" (i.e., Z83.3) was not used in this concept definition since the code does not convey evidence of DM in a first degree relative. Instead, "Family History of Diabetes" is defined as the union of a Familial-relationship code that represents a first degree relative

(e.g. ‘BRO’ brother; ‘DAU’ daughter; ‘FTH’ father, etc.) with a DM diagnosis code associated to the first degree relative.

4. ***Race and ethnicity:*** The USPSTF recommendation specifies several race and ethnicity groups to include African American; American Indian or Alaskan Native, Native Hawaiian or Pacific Islander; Asian American and Hispanic or Latino. All race and ethnicity groups in this artifact are defined by *OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997* using the code set based on these standards defined in the *CDC Race and Ethnicity Code Set Version 1.0.*[9] Because the concept of “Asian American” is not included in either the OMB standards or the CDC Code Set, the code for “Asian” was used to represent “Asian American.” A USPSTF SME confirmed this approach was appropriate.
5. ***Exclusion of behavioral counseling referral, order, procedure, or encounter:*** The intent of the recommendation is to identify patients who should be screened for abnormal blood glucose levels, and if they are identified as having abnormal blood glucose levels, refer them to intensive behavioral counseling to promote a healthful diet and physical activity. If the patient has a documented history of behavioral counseling within a specified time period, they should be excluded since they show evidence of receiving the indicated care.
6. ***Pregnancy as an exclusion:*** The BMI criteria used in the inclusion logic does not apply to pregnant women due to normal weight changes characteristic in pregnancy. In addition, other types of interventions may be indicated for pregnant women. A USPSTF SME validated that excluding pregnant women was appropriate.

Technical Details Regarding Artifact Implementation

The *Abnormal Glucose: Counseling* artifact is composed of several software files written in CQL. The primary focus of these software files is to allow any organization to identify patients who qualify for the recommended glucose screening preventive care based on patient-specific criteria such as age, body mass index (BMI), and known abnormal glucose metabolism risk factors.

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 *Abnormal Glucose: Counseling* artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7

that is currently a Standard for Trial Use (STU).[10] CQL expresses logic in a human-readable format that is also structured enough for electronic processing of a query. It can be used within both the CDS and eCQM domains.

The following hyperlinks provide additional information on CQL:

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

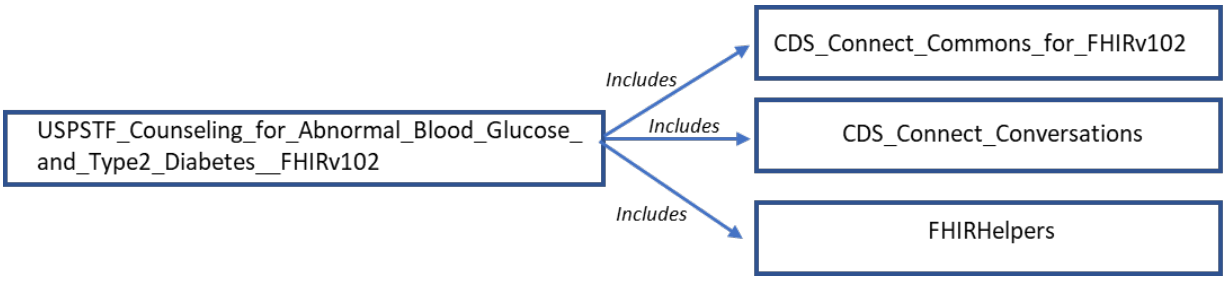
* These websites do not support the use of Internet Explorer, and recommend using Google Chrome, Microsoft Edge, or Firefox.

Library Relationship Diagram

CQL developers are encouraged to refactor commonly used functions into separate software files called libraries.[11] 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 *Abnormal Glucose: Counseling* 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.[12] 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_Counseling_for_Abnormal_Blood_Glucose_and_Type2_Diabetes__FHIRv102.cql	CQL representation of the *Counseling for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* 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 that other coded formats.
USPSTF_Counseling_for_Abnormal_Blood_Glucose_and_Type2_Diabetes__FHIRv102.json	JavaScript Object Notation (JSON) representation of the *Counseling for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* 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

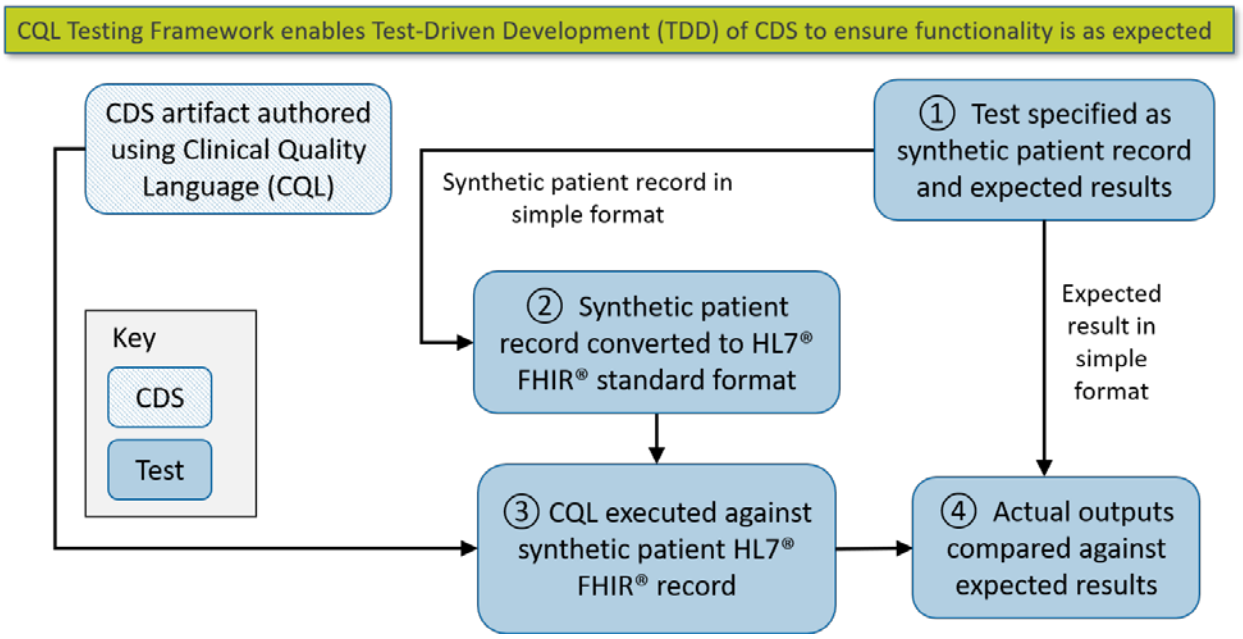
Artifact Testing

The *Abnormal Glucose: Counseling* artifact was written using a test-driven development (TDD) approach.[13] TDD is important for development since it has been shown to produce software that is more robust and to contain fewer bugs.[13] With TDD, a battery of test cases is created that define the expected functionality of the software, in this case the *Abnormal Glucose: Counseling*

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 *Abnormal Glucose: Counseling* artifact, the input may contain the body mass index (BMI) 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 evidence that behavioral counseling was either ordered or performed
- Synthetic patient excluded due to a recent pregnancy diagnosis
- Synthetic patient included because they are 30 years old with a history of gestational diabetes, and their most recent fasting plasma glucose level is 120 mg/dl
- Synthetic patient included because they are a 24-year-old Asian female with a BMI of 23 kg/m^2 and their most recent oral glucose tolerance test result is 160mg/dl

Implementation Checklist

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts.[14] 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.

The CDS Connect team puts forward the information below 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 Translation Summary section of this document and Appendix A (the decision log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a structured, computable CDS artifact.

- Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf health IT systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those health IT systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In many pilot settings, developers have worked around existing health IT limitations by implementing a web service wrapper around a CQL execution engine. This is a non-trivial amount of work with two primary components:
    - A CQL execution engine with a Representational State Transfer (RESTful) Web service designed to accept requests for CQL execution and to respond with the calculated results
        - CQL Services,[15] 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 *Abnormal Glucose: Counseling* artifact. They are expected to be used with any other CQL file that would benefit from those functions.

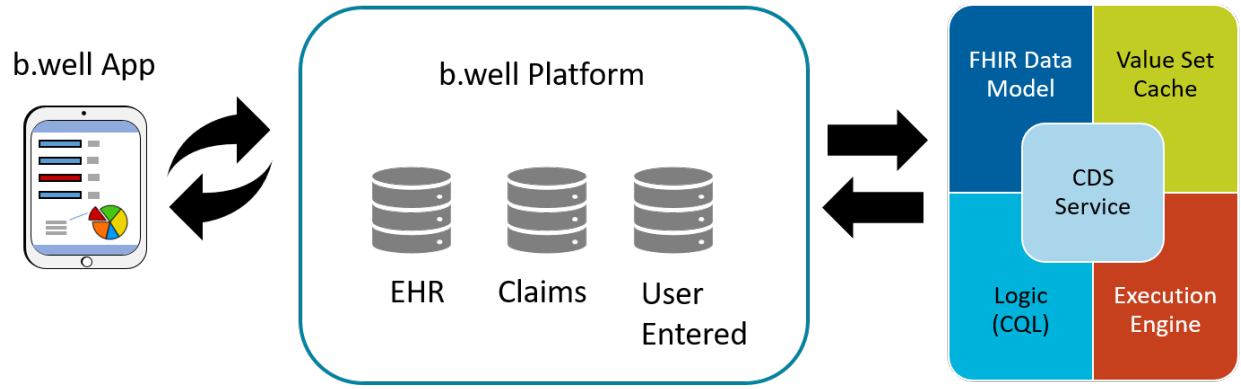
- Selected code blocks from the *Abnormal Glucose: Counseling* artifact could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to identify those female patients with an active pregnancy in other pertinent CDS.

Integration With Health Information Technology

CQL Services[15] was used to facilitate integration of the *Abnormal Glucose: Counseling* 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)[16] 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 HyperText Transfer Protocol (HTTP) request to the CQL Service via a CDS Hooks interface.[17] 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

This artifact is derived from the USPSTF full recommendation statement for *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus*, and addresses the second part of the recommendation summary, "The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. **Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity."**[2] Additional inclusion criteria outlined in this decision log are included in the Patient Population Under Consideration section of the full recommendation statement, and indicates that individuals with specific conditions such as a "…family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome, or are members of certain racial/ethnic groups… may be at increased risk for diabetes at a younger age or at a lower body mass index. Clinicians should consider screening earlier in persons with one or more of these."[2] A USPSTF SME provided guidance on the clinical interpretation of the additional inclusion criteria.

The semistructured inclusion and exclusion logic that represents the second part of the recommendation summary (above) is as follows:

Inclusion logic:

Patient is >=40 years old AND <=70 years old

AND BMI >=25kg/m^2, MOST RECENT VALUE

OR Patient is >=18 years old and <40 years old

AND BMI >=25kg/m^2, MOST RECENT VALUE

AND one of more of the following:

Family history of diabetes

OR polycystic ovary syndrome

OR race = African American; American Indian or Alaskan Native; or Native Hawaiian or Pacific Islander

OR ethnicity = Hispanic or Latino

OR Patient is >=18 years old and <=70 years old

AND BMI >=23kg/m^2, MOST RECENT VALUE

AND race = Asian American

OR Patient is >=18 years old and <=70 years old

AND gestational diabetes

AND

Hemoglobin A1c level >=5.7%, MOST RECENT VALUE within the past 3 years *(final, amended)*

OR fasting plasma glucose test result >=100 mg/dl, MOST RECENT VALUE within the past 3 years *(final, amended)*

OR oral glucose tolerance test result >=140 mg/dl, MOST RECENT VALUE within the past 3 years *(final, amended)*

Exclusion logic:

Pregnancy *(active)*

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

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 concept means and why it was expressed as listed. These concepts were informed or derived from text in the recommendation statement.

USPSTF final recommendations are published on the USPSTF website, along with resources outlining their extensive investigation into concepts included in the recommendation (i.e., their research review). The decisions and translations listed in this log were informed by the published full recommendation statement, research review and supporting references. 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.

Table 2. Concept Definition Decision Log

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	">="	Greater than or equal to a given value (e.g., >=40 years old)
Inclusions	"<="	Less than or equal to a given value (e.g., <=70 years old)
Inclusions	"overweight or obese"	The Centers for Disease Control and Prevention (CDC) define "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 the CDC thresholds is appropriate for this artifact. A BMI of >=25 kg/m^2 is specified in this artifact since that is the lowest threshold for "overweight or obese."
Inclusions	"Body Mass Index"	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).
Inclusions	"kg/m^2"	Kilograms/$meters^2$ (the unit of measure for BMI)

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"MOST RECENT VALUE"	The value closest to the date of the CDS trigger; this ensures that the logic is evaluating data that is as close to the patient's current health status as possible.
Inclusions	"<"	Less than a given value (e.g., less than 40 years old)
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. The list of criteria is outlined in the *Patient Population Under Consideration* section of the recommendation statement (e.g., family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome member of certain racial/ethnic groups).
Inclusions (from the Patient Population Under Consideration section)	"Family history of diabetes"	Family history of DM, where DM is defined as Type 1 or Type 2 to be as inclusive as possible to identify patients at potential risk. As noted in the recommendation statement, the DM must occur in *a first-degree relative* (i.e., parent, sibling, or child). Due to this specificity, the ICD-10-CM diagnosis code that represents "family history of diabetes mellitus" (i.e., Z83.3) was not used in this concept definition since the code does not convey evidence of DM in a first degree relative. As a result, "Family history of diabetes" is defined as a union of a familial-relationship code that represents a first degree relative (e.g. 'BRO' brother; 'DAU' daughter; FTH father, etc.) combined with a DM diagnosis code associated with the first degree relative.
Inclusions (from the Patient Population Under Consideration section)	"Polycystic ovary syndrome"	History of polycystic ovary syndrome (PCOS). This syndrome is an endocrinopathy in females hypothesized to be associated with insulin resistance resulting in a four-fold increase in the incidence of developing DM Type 2.[18] Since *any* evidence of PCOS in a patient's history may be relevant (e.g., "active," "resolved"), a FHIR clinicalStatus is not specified.

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions (from the Patient Population Under Consideration section)	"Race = African American"	Patients with a recorded race of "African American." All race and ethnicity groups in this artifact are defined by *OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997*, using the code set based on these federal standards defined in the CDC Race and Ethnicity Code Set Version 1.0 standards.[9]
Inclusions (from the Patient Population Under Consideration section)	"Race = American Indian or Alaskan Native"	Patients with a recorded race of "American Indian or Alaskan Native." This includes individuals who have origins in any of the original peoples of North and South America (including Central America) and maintain cultural identification through tribal affiliation or community attachment.[19]
Inclusions (from the Patient Population Under Consideration section)	"Race = Native Hawaiian or Pacific Islander"	Patients with a recorded race of "Native Hawaiian or Pacific Islander." This includes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
Inclusions (from the Patient Population Under Consideration section)	"Ethnicity = Hispanic or Latino"	Patients with a recorded ethnicity of "Hispanic or Latino." The *OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997* revised this category from "Hispanic" to the current classification of "Hispanic or Latino." Hispanic is commonly used in the eastern portion of the United States, whereas Latino is commonly used in the western portion and defines a person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.[19]

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions (from the Patient Population Under Consideration section)	"Race = Asian American"	Patients with a recorded race of "Asian American." Although the racial/ethnic groups identified in the Patient Population Under Consideration section of the USPSTF recommendation statement include "Asian American," neither the OMB nor CDC standards include a specific race or code representing "Asian Americans." Thus, as mentioned previously, the code for "Asian" was used to represent "Asian American." A USPSTF SME confirmed this approach was appropriate. This racial group is defined as people having origins in the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.[19]
Inclusions (from the Patient Population Under Consideration section)	"Gestational diabetes"	History of a diagnosis of gestational diabetes. This includes diabetes during pregnancy, childbirth and the puerperium, regardless of how the condition is controlled. It excludes Type 1 and Type 2 DM, steroid-induced DM, and codes representing conditions occurring in infants born to a mother with gestational diabetes. Since *any* evidence of gestational diabetes in a patient's history may be relevant (e.g., "active," "resolved"), a FHIR clinicalStatus is not specified.
Inclusions	"Hemoglobin A1c level >= 5.7%"	Hemoglobin A1c (HbA1c) lab result greater than or equal to 5.7 percent. The recommendation indicates a normal HgA1c value is < 5.7%. A HbA1c value of 5.7-6.9% may indicate impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), and a HbA1c of >=6.5 may indicate Type 2 DM.[2]
Inclusions	"Fasting plasma glucose level >=100 mg/dl"	Fasting plasma glucose (FPG) lab result greater than or equal to 100 milligrams per deciliter (mg/dl). The recommendation lists a normal FPG value as < 100 mg/dL; a level of 100-125 mg/dl may indicate IFG or IGT; and a level of >=126 mg/dl may indicate Type 2 DM.[2] Note: the CQL code converts all lab results returned in millimoles/liter (mmol/L) to mg/dl to ensure evaluation of relevant data.

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusions	"Oral glucose tolerance test result >= 140 mg/dl"	Oral glucose tolerance test (OGTT) result of greater than or equal to 140 mg/dl. The recommendation lists a normal OGTT level as < 140 mg/dL; a level of 140-199 mg/dl may indicate IFG or IGT; and a level of >=200 mg/dl may indicate Type 2 DM.[2] Note: the CQL code converts all lab results returned in mmol/L to mg/dl to ensure evaluation of relevant data.
Exclusions	"Pregnancy"	Pregnancy is explicitly stated as an exclusion in the USPSTF recommendation. The clinicalStatus must be "active."
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 a health IT system. "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 pregnancy" as up to 42 weeks of gestation. Since gestation date is not often specified in a health IT system, the CDS logic evaluates the date that a pregnancy observation was recorded in the system. Reference: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Definition-of-Term-Pregnancy?IsMobileSet=false
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.

Location in CDS Logic	Concept	Definition and/or Rationale
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.
Exclusions	"Behavioral counseling for nutrition and activity **order**, …**procedure** …or **encounter**"	Behavior counseling for nutrition and activity orders, procedures and encounters.

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.[20] 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 October 2015. 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 semistructured and structured logic may be indicated. https://www.uspreventiveservicestaskforce.org/Page/Name/topics-in-progress
Add explanation	Repetition of inclusion and exclusion criteria	This artifact can be used as a stand-alone artifact or in conjunction with a second artifact (i.e., *Abnormal Blood Glucose: Screening*) that expresses the first half of the USPSTF *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* recommendation. Please note that there is considerable redundancy in the logic associated with each artifact. If both artifacts are implemented, implementors can remove the redundant logic for expediency.
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/m2" was validated by a USPSTF SME as aligning with the clinical intent of the recommendation.

Decision Category	Concept	Rationale
Add explanation/ verify completeness	Second, third and fourth inclusion logic phrases beginning with "OR" that outline distinct criteria for persons with "specific conditions" (e.g., family history of DM, history of gestational diabetes or PCOS, member of certain racial/ethnic groups)	The USPSTF *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* "Recommendation" statement clearly describes that adults aged 40 to 70 who are overweight or obese (i.e., BMI >= 25 kg/m^2) should be considered for abnormal blood glucose screening, and offered or referred to behavioral counseling if they have abnormal blood glucose levels. Potential implementers should be aware that the USPSTF goes on to describe an additional population in the Patient *Population Under Consideration* section of the recommendation, where they indicate that persons with "specific conditions" such as a "…family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome, or are members of certain racial/ethnic groups… may be at increased risk for diabetes *at a younger age or at a lower body mass index.* Clinicians should consider screening earlier in persons with one or more of these." This guidance was less specific, therefore challenging to translate into a coded expression and required consultation with a USPSTF SME. The SME clarified that based on USPSTF review of research literature the correct way to express the additional logic phrases is as listed in the three "OR" logic phrases pictured in **Figure 8.**

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
Family History of Diabetes	I	FamilyMemberHistory	condition relationship
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
Gestational Diabetes	I	Condition	code verificationStatus is 'confirmed'

Data Element	Inclusion (I) vs Exclusion (X)	FHIR Resource	Required Elements
Glucose Tolerance Test (#1)	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
Hemoglobin A1c Test (HbA1c)	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
Polycystic ovarian syndrome	I	Condition	code verificationStatus is 'confirmed'
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
Race = American Indian or Alaskan Native	I	Patient Extension	url: http://hl7.org/fhir/StructureDefinition/us-core-race valueCodeableConcept
Ethnicity = Hispanics or Latino	I	Patient Extension	url: http://hl7.org/fhir/StructureDefinition/us-core-ethnicity valueCodeableConcept
Race = Native Hawaiian or Pacific Islander	I	Patient Extension	url: http://hl7.org/fhir/StructureDefinition/us-core-race valueCodeableConcept
Race = African American	I	Patient Extension	url: http://hl7.org/fhir/StructureDefinition/us-core-race valueCodeableConcept
Race = Asian	I	Patient Extension	url: http://hl7.org/fhir/StructureDefinition/us-core-race valueCodeableConcept

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