Implementation Guide

Prediabetes and Type 2 Diabetes: Part One, Screening

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

Contract No. 75FCMC18D0047

Prepared by:

CMS Alliance to Modernize Healthcare (The Health FFRDC)

A Federally Funded Research and Development Center

AHRQ Publication AHRQ 24-M010-3
August 2024

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

Suggested Citation

CMS Alliance to Modernize Healthcare (The Health FFRDC). Prediabetes and Type 2 Diabetes: Part One, Screening. Implementation Guide. Prepared under Contract No. 75FCMC18D0047. AHRQ Publication No. AHRQ 24-M010-3. Rockville, MD: Agency for Healthcare Research and Quality; August 2024.

Acknowledgments

Specifically, we want to thank and recognize:

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

Record of Implementation Guide Changes

Date	Action	Notes
September 2019	Published *Implementation Guide*	
September 2020	Updated the *Implementation Guide* based on annual CDS artifact updates	Updated the *Implementation Guide's* Introduction and Background content, revised the flow of the content to enhance readability.
September 2021	Updated the *Implementation Guide* based on annual CDS artifact updates	Updated the *Implementation Guide's* Introduction and Background content, expanded CQL library details to account for the CQL updates related to FHIR R4, and added a new data requirements table in the appendix for FHIR R4.
September 2022	Updated the *Implementation Guide* based on CDS annual artifact updates	The Background and Introduction were edited for clarity. The content was reorganized under new headings to make navigation more intuitive. The artifact was revised to align with the updated USPSTF guideline published October 2021. The CQL section was updated to reflect new CQL library names and versions, as well as the newly introduced shared logic library.
September 2023	Updated the *Implementation Guide* based on CDS annual artifact updates	Minor edits were made for clarity. A Scope and Purpose section was moved to standardize format with other Implementation Guides. Updated links in data requirements table.
August 2024	Updated the *Implementation Guide* based on CDS annual artifact updates	Minor edits were made for clarity throughout. URLs in tables changed to links (or deleted, when not needed) to improve use with assistive devices. Appendix B (Data Requirements) was removed and text inserted which refers the reader to the file with the same content attached to the artifact.

Contents

Figures

Tables

Background

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices defined by authoritative professional societies that they must incorporate into daily practice. Transforming these guidelines and best practices into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own.

The Clinical Decision Support (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 CDS, enabling other organizations to leverage the publicly available expressions. Sharing CDS expressions enhances efficiency by removing the need for organizations to start CDS development from "scratch." It also contributes to a learning health community where CDS developers and implementers collaborate and enhance the shared resources.

Introduction

Beginning in 2016, the MITRE CDS Connect multidisciplinary project team has facilitated AHRQ's vision to move patient-centered outcomes research (PCOR) evidence into practice by supporting implementers, clinicians, and technology vendors in developing CDS tools that are shareable, standards-based, publicly available, and person-centered. CDS Connect has created the following resources, which are described in greater detail later in this document:

- The CDS Connect Repository to host and share CDS artifacts.
- The CDS Authoring Tool, which enables CDS authors to create CDS logic using Clinical Quality Language (CQL), a Health Level 7 (HL7) standard expression language.
- Two open-source prototype tools—the CQL Testing Framework and CQL Services—to facilitate creating, testing, sharing, integrating, and implementing evidence-based, interoperable CDS in health information technology (IT) systems.

An important feature of CDS Connect is that it supports the use of CQL, an interoperable format that eases integration with health IT systems. The use of CQL in CDS Connect development and CDS systems provides the ability to express logic that is human-readable yet structured enough to process a query electronically. CQL allows logic to be shared between CDS artifacts—and eventually with electronic clinical quality measures (eCQMs)—in support of improving healthcare quality.

CDS artifacts are classified by a "Knowledge Level"[1] that indicates the degree to which a computer can interpret the information. The four categories of Knowledge Levels are defined as:

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

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

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

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than 40 metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher, sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made when creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files, and reports.

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

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

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

This Implementation Guide provides information and guidance to individuals considering their potential use of this artifact. The main intent of this document is twofold: 1) to provide insight on how the logic expression can be used to improve patient care, and 2) to provide information on how to transform the logic expression into interoperable logic code and integrate the CDS logic with a health IT system.

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

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

Scope and Purpose

This document provides information about the creation and uses of the CDS logic expression (referred to as an "artifact") derived from the US Preventive Services Task Force (USPSTF) full recommendation statement on Prediabetes and Type 2 Diabetes: Screening (referred to as the Prediabetes and Type 2 Diabetes: Screening artifact in this guide), along with how it can be integrated within a health IT system. The Prediabetes and Type 2 Diabetes: Counseling CDS artifact addresses the second part of this USPSTF recommendation, related to offering education about the disease and preventive lifestyle interventions focusing on diet, physical activity, or both for those patients found to have an abnormal blood glucose level consistent with prediabetes.

Implementing and Using This Artifact

Artifact Description

This artifact identifies patients who are overweight or obese, as well as additional risk factors they may have for abnormal glucose metabolism. The 2021 USPSTF Recommendation Statement on Screening for Prediabetes and Type 2 Diabetes notes that abnormal glucose metabolism often precedes diabetes, and that an estimated 34.5% of all US adults (18 years or older) meet criteria for prediabetes.[2] Screening asymptomatic adults for prediabetes and type 2 diabetes may allow earlier detection, diagnosis, and treatment, with the ultimate goal of improving health outcomes. 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. Raise awareness that they may have one or more risk factor(s) for prediabetes or type 2 diabetes.
2. Provide educational materials that explain how overweight/obesity and other personal/family factors increase their risk for developing diabetes and ways to reduce the risks.
3. Encourage patients to contact their primary care clinicians about being screened for abnormal blood glucose levels.

Preventive Health Scenarios Supported by This Artifact

The Prediabetes and Type 2 Diabetes: Screening artifact was developed, piloted, and published to identify those patients at risk for abnormal glucose metabolism according to the logic derived from the USPSTF Prediabetes and Type 2 Diabetes: Screening Final Recommendation Statement. In addition to the overweight/obesity factor, the USPSTF defines risk factors for prediabetes or type 2 diabetes to include "older age, family history, a history of gestational diabetes, history of polycystic ovarian syndrome, and dietary and lifestyle factors." Additionally, the USPSTF notes differences in risk based on ancestry with "disproportionately high incidence and prevalence" among American Indian/Alaska Native, Asian American, Black, Hispanic/Latino, and Native Hawaiian/Pacific Islander persons. Further, the recommendation notes that "[a] large body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment."[2] Once the patient(s) have been identified, the implementer should determine the appropriate method of notification, 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 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; it can be found in the Prediabetes and Type 2 Diabetes, Part One, Screening – Intervention Content document posted in the Miscellaneous Files section of the Prediabetes and Type 2 Diabetes: Part One, Screening 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. Mr. Alpha is 42 years old and recently gained a lot of weight. He receives a push notification from his health app that there is some information for him to review from his healthcare team. Mr. Alpha opens the notification and selects the embedded link, which opens the health app and displays information indicating that, because of his age and weight, he may be at risk for developing high blood sugar and diabetes.

       The information found in the health app provides educational topics for him 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 being screened for abnormal blood glucose, as outlined in the following scenarios 2 and 3. As previously noted, each implementing organization will develop a notification that aligns with existing organizational messages and services. This scenario provides an example of the notification that might be provided.

    b. Ms. Bravo is a 22-year-old overweight Hispanic woman with a family history of diabetes. She recently moved to North Carolina and selected a new primary care doctor and team. She receives an email indicating that there is new information to review in her patient portal from her healthcare team. She accesses the portal and discovers a message from her primary care clinician informing her that because of her risk factors, she may be at risk for developing high blood sugar and diabetes.

       The information found in the patient portal provides educational topics for Ms. Bravo to review regarding her risk factors and ways she could reduce her risk through lifestyle changes, such as healthy eating and engaging in physical activity. The information also encourages her to speak with her physician about being screened for abnormal blood glucose, as outlined in the following scenarios 2 and 3.

2. **Providing the patient with targeted educational materials.**
    a. Mr. Alpha selects the embedded link in the information provided in his health app, which accesses personalized educational materials about prediabetes and type 2 diabetes, including methods to reduce the risk of developing them. Mr. Alpha reviews the information to learn more. The information provided includes links to the US Department of Health and Human Services' MyHealthFinder website with additional resources and tools.
    b. Ms. Bravo's primary care clinician recommended several links to educational resources in the message that he sent Ms. Bravo via the patient portal. These links address prediabetes, type 2 diabetes, and the health risk from those conditions. Ms. Bravo reads the educational resources and watches a video on diabetes.
3. **Recommending that the patient consult with their primary care clinician.**
    a. As Mr. Alpha reviews the information on his health app, one of the suggested actions is to schedule an appointment with his primary care clinician to discuss his risk of developing high blood sugar and diabetes and the possibility of having a blood glucose screening test performed. He schedules an appointment through the scheduling function in the health app.
    b. Ms. Bravo is currently too busy to make 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 that she should consider seeing her primary care clinician. This time, she decides to schedule the suggested appointment.

Other Health Scenarios Supported With Customization of the Coded Expression

The coded CDS expression defines clinical concepts and criteria translated from the first half of the published USPSTF Prediabetes and Type 2 Diabetes: Screening recommendation to identify patients that may benefit from being screened for abnormal blood glucose levels. 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.

Examples of reusing CDS logic include:

1. Enabling population management by identifying patients requiring screening for abnormal glucose metabolism risk in a primary care setting.
    a. Marriam Primary Care (MPC) is a hypothetical medium-size practice in rural West Virginia with four primary care clinicians and about 3,000 patients. Families in that

area are stable with multiple generations of family members living in the same area. The prevalence of diabetes for people living in this area is higher than the national norm, often characteristic throughout a family unit. To meet quality metrics required by its largest insurance payer, MPC decides to focus intently on identifying those patients at risk of developing diabetes, and proactively help them reduce their risk through screening for abnormal blood glucose. The CDS inclusion and exclusion logic for this artifact is run monthly, and each primary care team receives a report profiling those at risk in their patient panel. The staff reaches out to the patients to suggest they schedule an appointment to discuss their individual risk factors and possible interventions with their primary care clinician. During the subsequent appointment, the primary care clinician provides educational information to the patient about their risks of developing abnormal glucose metabolism and diabetes and discusses options for interventions to aid in the prevention. In addition, the clinician orders blood glucose testing for each patient. Data about the number of appointments scheduled because of the outreach, as well as the number of individuals who receive the blood glucose test, 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 specific risk factors for developing abnormal glucose metabolism and diabetes.

    a. 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 who have specific risk factors for developing abnormal glucose metabolism and diabetes, such as being overweight or obese, having a family history of diabetes or gestational diabetes, or being of certain race or ethnic origin. They provide intensive wellness services to help the identified participants understand the actions and activities that may help mitigate their risk. ProCare Health monitors these activities and any individual progress over time. Each month, they provide statistical deidentified reports to the employers and health plans to reflect the effect of the interventions.

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

    a. 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 comorbid conditions to develop CDS requested by one of its customers. The customer, a large hospital system, has requested CDS to identify those at risk for developing diabetes who also have a

history of other comorbid conditions, such as hypertension or hyperlipidemia, so that 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

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 35 to 70 years old with a body mass index (BMI) greater than or equal to 25 mg/kg^2 OR
    b. Individuals 18 to 34 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; a 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 personal history of gestational diabetes (regardless of their BMI)
2. Exclusion:
    a. Individuals who are pregnant OR
    b. Individuals who had a blood glucose screening test performed (hemoglobin A1C, fasting plasma glucose, glucose tolerance test) within the last 3 years OR
    c. Individuals who have a diagnosis of diabetes mellitus (type 1 or 2), prediabetes, impaired fasting glucose, or impaired glucose tolerance noted within the last 12 months.

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

1. Intervention: Notify the patient that they may be at risk for developing prediabetes or type 2 diabetes based on certain risk factors.
2. Suggested Action: Provide educational materials that explain in patient-friendly language that being overweight is a risk factors for abnormal glucose metabolism and diabetes, and that being from certain ancestry or having certain other conditions (e.g., having a family history of diabetes or a history of gestational diabetes) increases the risk.

3. Suggested Action: Suggest the patient make an appointment with their primary care clinician to discuss their risk of developing abnormal glucose metabolism and diabetes; communicate the importance of getting a blood glucose screening test. Facilitate appointment scheduling, if possible.

Of note, the intervention and suggested actions align with content that was created by the pilot partner, b.well, and presented to patients via the b.well app during the pilot implementation of this artifact. Nevertheless, the pilot content (e.g., graphics, educational materials, patient-friendly language) is not included in the structured representation of this artifact because it is proprietary. Sample notification text developed to provide some initial examples for implementers is found in the Prediabetes and Type 2 Diabetes, Part One, Screening – Intervention Content document posted in the Miscellaneous Files section of the Prediabetes and Type 2 Diabetes: Screening artifact. Future implementers may elect to expand the CDS intervention portion of the logic based on their organizational preferences, patient population, and available resources.

Patient-Facing CDS Development Considerations

Patients and their caregivers are increasingly seeking health information to help guide them in their healthcare decisions and better manage their health. Most CDS is designed to be integrated into the clinical workflow, with the clinician as the primary target and user. Yet 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.[3]

Development of Patient-Centered Preventive Care CDS Artifacts

According to Krist et al. (2011), studies have shown that most Americans receive only about half of recommended preventive services.[4] Well-designed CDS could provide patients with evidence-based information on recommended preventive services based on that patient's individual health history and risk factors.[4] 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 CDS artifact, care was taken to ensure that required data elements and their definitions were well specified and comprehensive. For example, if a patient had a recent diagnosis of diabetes or prediabetes, or if the patient was pregnant, then this information was accounted for in the CDS 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 to 1) notify the patient and 2) provide resources and/or tools to allow the patient to act on the notification. As a component of patient-centered care, this process should account for the importance of the clinician-patient relationship and the corresponding principles of trust and shared decision making (SDM). In SDM, the patient's perspective, based on their values and preferences, is critical to the decision-making process.[5] It allows the patient and their primary healthcare clinician to determine together the most appropriate treatment or care choice.

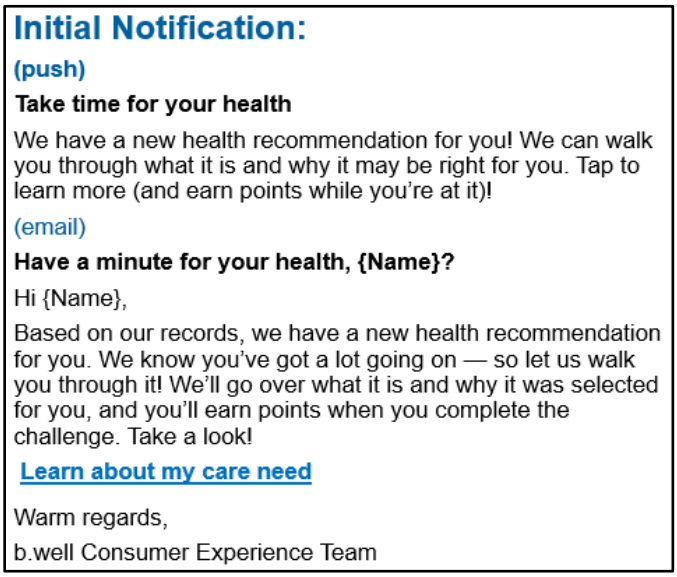
As noted earlier, the patient notifications included in the structured CQL expression of this artifact are general, enabling implementing organizations to expand upon and personalize the interventions based on their unique needs and patient population. Information provided to the patient translates the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

For the initial pilot implementation, the pilot organization implemented the following capabilities.

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

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

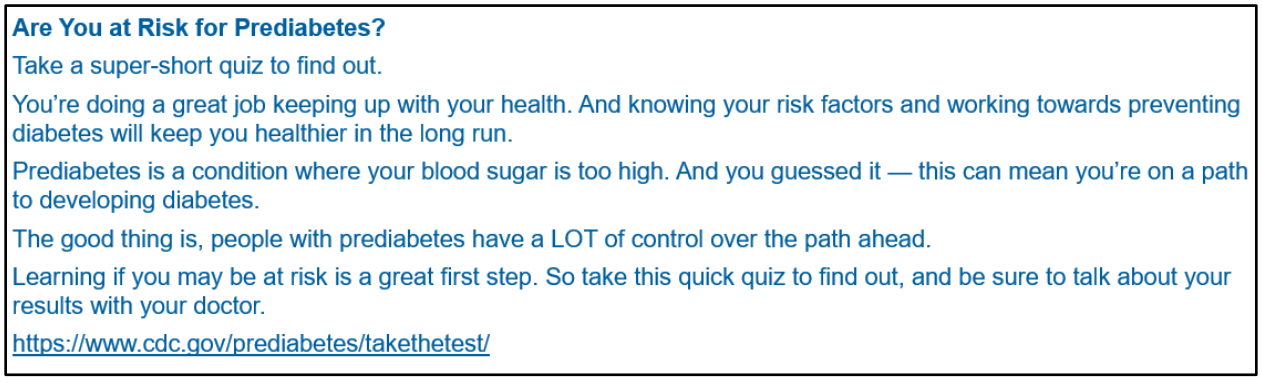
Figure 1. Example of Patient Notification



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

The resources found on MyHealthFinder as well as the USPSTF Consumer Guide[6] were used as sources for much of the content created. See **Figure 2** for an example of patient education text.

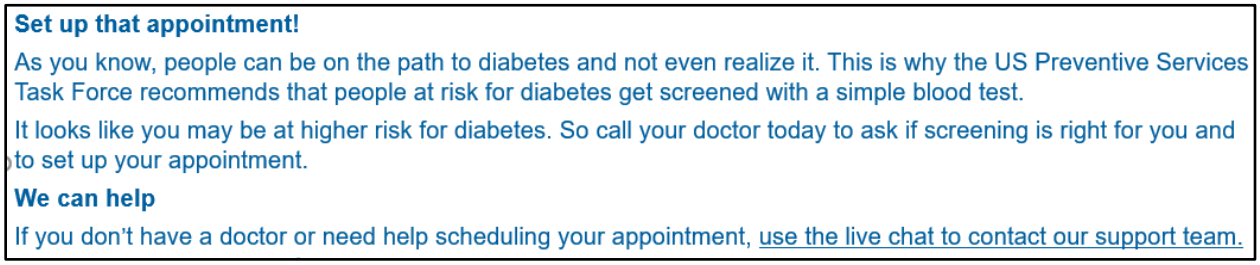
Figure 2. Example of Patient Education



Appointment Scheduling Tools and Other Resources: The educational resources include encouragement to discuss the recommendation with the patient's primary care clinician. The health app provides the ability to make an appointment with the patient's existing primary care

clinician, or to facilitate finding a primary care clinician if the patient does not have one identified. See **Figure 3** for an example.

Figure 3. Example of Appointment Facilitation



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 Prediabetes and Type 2 Diabetes: Screening. The recommendation summary states that "the USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. Clinicians should offer or refer patients with prediabetes to effective preventive interventions."[2] This artifact addresses the first part of the recommendation—screening for abnormal blood glucose in adults aged 35 to 70 years who are overweight or obese.

As part of the Patient Population Under Consideration section of the full recommendation statement, the USPSTF indicates the target population includes "nonpregnant adults aged 35 to 70 years seen in primary care settings who have overweight or obesity (defined as a BMI ≥25 [calculated as weight in kilograms divided by height in meters squared] and ≥30, respectively) and no symptoms of diabetes."[2] The USPSTF further defines risk factors for prediabetes or type 2 diabetes to include "older age, family history, history of gestational diabetes, history of polycystic ovarian syndrome, and dietary and lifestyle factors." Additionally, they note that "The prevalence of diabetes is higher among American Indian/Alaska Native (14.7%), Asian (9.2%), Hispanic/Latino (12.5%) and non-Hispanic Black (11.7%) persons than among non-Hispanic White (7.5%) persons" who may be at increased risk for diabetes at a younger age or at a lower

BMI. Further, "[a] large body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment. … Clinicians should consider screening at an earlier age in persons from groups with disproportionately high incidence and prevalence."[2] The strength of the recommendation is grade "B," indicating that the USPSTF recommends this service, due to a high certainty that the net benefit of providing this screening 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 (SME) to ensure that the evidence was translated appropriately and to clarify any narrative phrase in the USPSTF recommendation that was unclear. Appendix A (the Decision Log) provides detailed information on how the USPSTF recommendation statement and subsequent SME clarifications informed CDS development. Some of the key interpretations and decisions include the following.

- **Division of the recommendation into two parts:** The USPSTF Prediabetes and Type 2 Diabetes: Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus involves a two-step process. The first step is determining which patients require screening for abnormal blood glucose. The second step involves referring patients who have been tested and found to have abnormal blood glucose levels to effective preventive interventions. 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: CDS Connect Prediabetes and Type 2 Diabetes: Part One, Screening; and CDS Connect Prediabetes and Type 2 Diabetes: Part Two: Counseling. A USPSTF SME confirmed this approach was appropriate. This guide pertains to the Prediabetes and Type 2 Diabetes: Screening artifact.
- **Interpretation of inclusions in the recommendation statement:** The USPSTF recommends screening for abnormal blood glucose in adults aged 35 to 70 years who are overweight or obese. Within the Patient Population Under Consideration, the recommendation indicates that persons with specific conditions (e.g., a family history of diabetes, a history of gestational diabetes, or a history of polycystic ovarian syndrome) or who are members of certain racial/ethnic groups may be at increased risk for diabetes at a younger age or at a lower BMI. "Clinicians should consider screening at an earlier age in persons from groups with disproportionately high incidence and prevalence."[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. This degree of specificity allows organizations to provide notifications

customized to specific sub-populations of patients, potentially enhancing uptake of the recommendations.

- **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 because the code does not convey evidence of DM in a first-degree relative. Instead, "Family History of Diabetes" is defined as the coupling of a Familial-relationship code that represents a first-degree relative (e.g., "BRO" brother, "DAU" daughter, "FTH" father) with a DM diagnosis code associated to the first-degree relative.
- **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; and Asian American, white, 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.[7] 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.
- **Exclusion of conditions or observations representing known elevated blood glucose levels:** The intent of the recommendation is to identify patients who are overweight or obese and have additional abnormal glucose metabolism risk factors for screening for abnormal blood glucose levels. If the patient has a documented diagnosis of DM, Impaired Fasting Glucose, or Impaired Glucose Tolerance or has had one of the blood glucose lab tests performed (hemoglobin A1C, fasting plasma glucose, and 2-hour post-glucose load measurement) within a specified time period, then they should be excluded.
- **Pregnancy as an exclusion:** The BMI criteria used in the inclusion logic does not apply to pregnant patients, due to the normal weight changes characteristic in pregnancy. In addition, other types of interventions may be indicated for pregnant patients. Screening for diabetes in pregnancy is addressed in the 2021 USPSTF Recommendation Statement Gestational Diabetes: Screening. A USPSTF SME validated that excluding pregnant patients was appropriate.
- **Exclusion of logic for the descriptor "no symptoms of diabetes" under "Patient Population Under Consideration:"** This artifact is for the purpose of screening, which implies an asymptomatic individual. Individuals with symptoms would no longer meet criteria for screening. Because many symptoms of diabetes are nonspecific (e.g., hunger, tiredness), an AHRQ diabetes SME validated the appropriateness of not specifying symptoms as exclusion criteria in the logic for this artifact.

Technical Details Regarding Artifact Implementation

The Prediabetes and Type 2 Diabetes: Screening 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, 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. After providing background information on CQL (as the programming language used to write the logic for the artifact), the document presents a listing (or manifest) of the main CQL files included in the artifact, discusses the relationships among the files, and describes the testing activities.

General Information About CQL

The Prediabetes and Type 2 Diabetes: Screening artifact is composed of several files with the primary focus of providing CQL representations of the CDS logic. CQL is a data standard governed by HL7 that is currently a Mixed Normative/Trial-Use specification.[8] 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:

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

Artifact Library Manifest

The Prediabetes and Type 2 Diabetes: Screening artifact provides two distinct versions of the logic files.

- A ZIP file of FHIR DSTU2-based CQL logic files. This version differs from the originally piloted CQL due to changes in the source guidelines and implementation of emerging best practices. This version was not piloted but is largely based on the piloted version.
- A ZIP file of FHIR R4-based CQL logic files. This version was not piloted. Although the intent of the logic remains the same as the FHIR DSTU2-based version, changes in the FHIR specification (from DSTU2 to R4) required corresponding changes to the CQL logic.

Detailed descriptions of the changes in most recent versions of this artifact can be found in the change log file attached to this artifact in the CDS Connect Repository.

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

Each library is represented in two formats, each containing the same information but formatted for different purposes. The CQL format is human-readable; the JavaScript Object Notation (JSON) format is machine-readable and is generated from the CQL using the CQL-to-ELM translator.[9]

Table 1. Artifact Library Manifest

Filename	Purpose
USPSTFPrediabetesAndType2DiabetesPart1ScreeningFHIRv102.cql (FHIR DSTU2 only) or USPSTFPrediabetesAndType2DiabetesPart1ScreeningFHIRv401.cql (FHIR R4 only)	CQL representation of the Prediabetes and Type 2 Diabetes Screening 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.
USPSTFPrediabetesAndType2DiabetesPart1ScreeningFHIRv102.json (FHIR DSTU2 only) or USPSTFPrediabetesAndType2DiabetesPart1ScreeningFHIRv401.json (FHIR R4 only)	JavaScript Object Notation (JSON) representation of the Prediabetes and Type 2 Diabetes Screening 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.
USPSTFPrediabetesAndType2DiabetesSharedLogicFHIRv102.cql (FHIR DSTU2 only) or USPSTFPrediabetesAndType2DiabetesSharedLogicFHIRv401.cql (FHIR R4 only)	CQL representation of common logic used by both the screening and counseling artifacts.
USPSTFPrediabetesAndType2DiabetesSharedLogicFHIRv102.json (DSTU2 only) or USPSTFPrediabetesAndType2DiabetesSharedLogicFHIRv401.json (FHIR R4 only)	JSON representation of common logic used by both the screening and counseling artifacts.

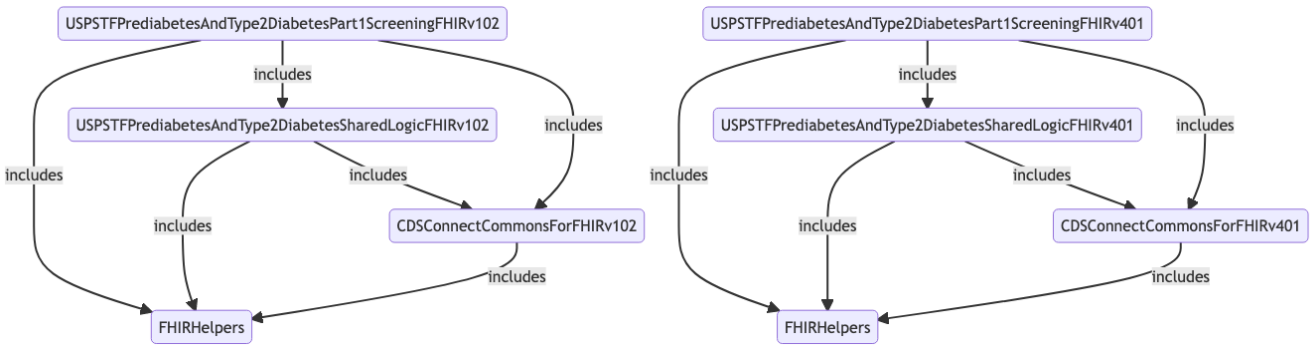
Filename	Purpose
CDSConnectCommonsForFHIRv102.cql (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.cql (FHIR R4 only)	Common CQL functions that may be called by CDS Connect artifacts.
CDSConnectCommonsForFHIRv102.json (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.json (FHIR R4 only)	JSON representation of common CQL functions that may be called by CDS Connect artifacts.
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 Library Relationship Diagram

The project team encourages CQL developers to refactor commonly used functions into separate software files called libraries.[10] The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. **Figure 4** shows the relationships between this artifact's main library file and the three supporting libraries.

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

Figure 4. Artifact Library Relationship Diagram

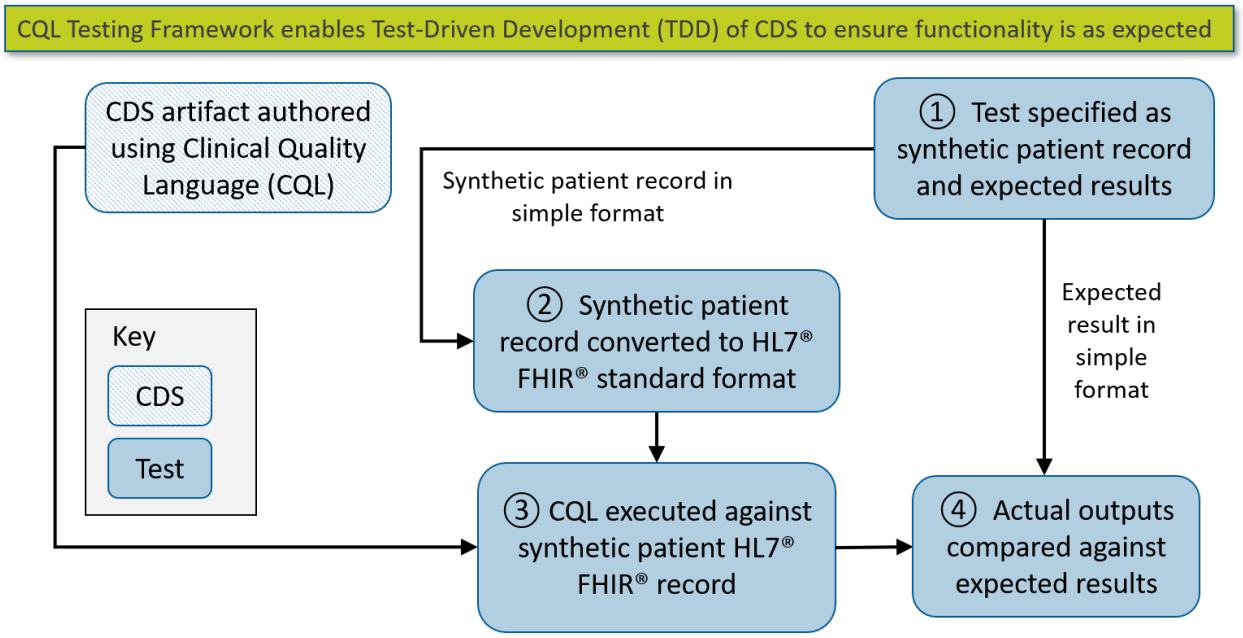


Artifact Testing

The project team developed the Prediabetes and Type 2 Diabetes: Screening artifact using a test-driven development (TDD) approach.[11] TDD is important for development; it has been shown to produce software that is more robust and to contain fewer bugs.[11] With TDD, developers create a battery of test cases that define the expected functionality of the software, in this case the Prediabetes and Type 2 Diabetes: Screening CQL. The project team leveraged an automated CQL testing framework developed under funding by AHRQ to enable the TDD approach for this artifact. Referred to as the "CQL Testing Framework," this tool accepts test cases specified in YAML Ain't Markup Language (YAML) files, executes the artifact against each test case, and reports the success or failure of each test case.[12]

The diagram in **Figure 5** depicts the TDD approach using the CQL Testing Framework. In the first step, before any CQL is written, developers define at least one test that specifies both the input to the CQL and the desired output. When using the CQL Testing Framework, developers specify the test input in terms of a synthetic patient record containing the pertinent FHIR resources. For example, test input for the Prediabetes and Type 2 Diabetes: Screening artifact might contain the BMI of the synthetic patient, which is one of the data inputs required by the artifact (see Data Requirements file attached to the artifact). An example of the desired output might be that the CQL should return the appropriate USPSTF recommendation. Once developers have specified a test in this way, they update the artifact's CQL until the test passes, demonstrating that the CQL works appropriately in that specific case. The process continues as the developer iteratively creates tests and authors logic, line by line, and clinical concept by clinical concept. The author of the CQL may not proceed to writing or updating the next portion of the code until all existing tests pass.

Figure 5. Testing Approach Diagram



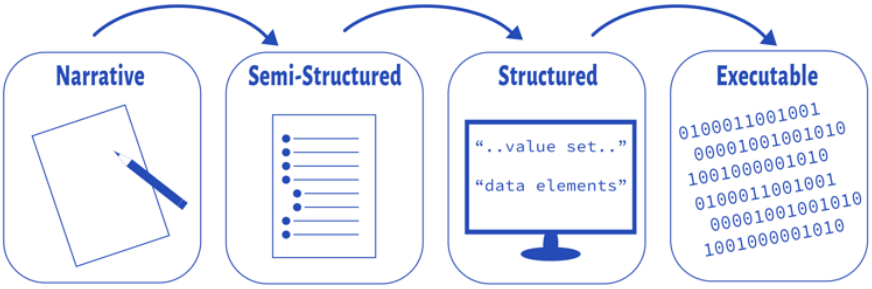
The development team created test cases to investigate efficacy for basic expected functionality and to test the expected inclusion criteria, exclusion criteria, and results (suggested interventions and actions). The entire set of test data resides in ZIP files attached to the CDS artifact in the Repository.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

- Synthetic patient excluded due to an active type 2 DM diagnosis.
- Synthetic patient excluded due to evidence that a recent blood glucose screening test was 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.
- Synthetic patient included because they are a 28-year-old Asian female with a BMI of 23 kg/m^2.

Implementation Guidance

As noted in the Introduction, Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts (see **Figure 6** for a summary of the process).[1]

Figure 6. CDS Artifact Maturity Process



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

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization understands and agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review the Guideline Translation Summary section of this document and Appendix A (the decision log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a structured, computable CDS artifact.
- Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf health IT systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those health IT systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In many pilot settings, developers have worked around existing health IT limitations by implementing a web service wrapper around a CQL execution engine. This is a 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,[13] 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.

Additional Supporting Implementation Material

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 libraries—CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, and FHIRHelpers—included in the artifact define commonly used functions in CQL files and are not specific to the Prediabetes and Type 2 Diabetes: Screening artifact. They may be used with any other CQL file that would benefit from those functions.
- Selected code blocks from the Prediabetes and Type 2 Diabetes: Screening artifact could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to identify those patients with an active pregnancy in other pertinent CDS.

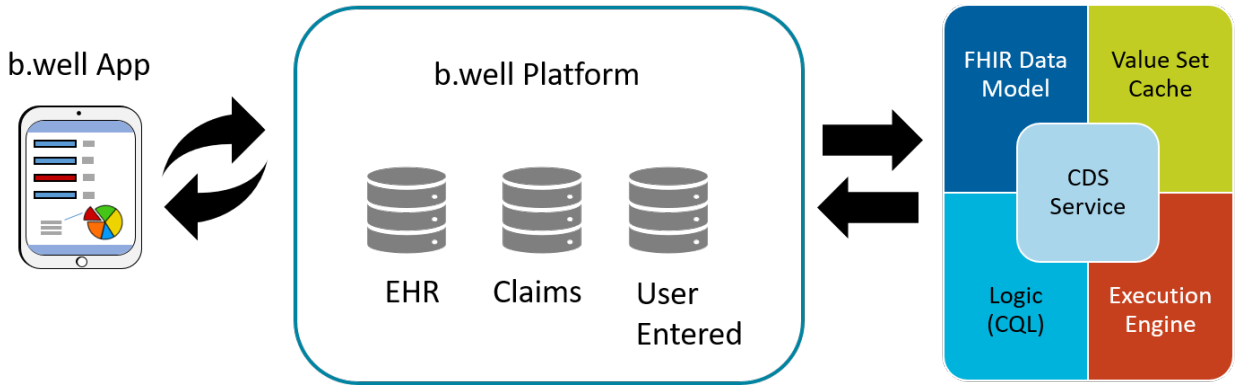
Integration With Health Information Technology

CQL Services[13] was used to facilitate integration of the Prediabetes and Type 2 Diabetes: Screening artifact into the b.well system. As depicted in **Figure 7**, CQL Services consists of four main components:

- A data model based on FHIR Draft Standard for Trial Use 2 (DSTU2).
- A value set service and cache for retrieving coded clinical concepts from the National Library of Medicine Value Set Authority Center[14] and local storage cache.
- Logic represented by the CQL libraries included with this artifact.

- 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 smartwatch. When the artifact is triggered for a particular user, the necessary data are queried and aggregated on the b.well platform, and then sent as a HyperText Transfer Protocol (HTTP) request to the CQL Service via a CDS Hooks interface.[15] 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 is found in the Data Requirements file attached to the artifact.

Appendix A. Decision Log

Artifact Semistructured Logic

This artifact is derived from the USPSTF full recommendation statement Prediabetes and Type 2 Diabetes: Screening. It addresses the first part of the recommendation summary, "The USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity."[2] Additional inclusion criteria outlined in this decision log are included in the Patient Population Under Consideration section of the full recommendation statement, and indicate that "[c]linicians should consider screening at an earlier age in persons from groups with disproportionately high incidence and prevalence (American Indian/Alaska Native, Asian American, Black, Hispanic/Latino, or Native Hawaiian/Pacific Islander persons) or in persons who have a family history of diabetes, history of gestational diabetes or polycystic ovarian syndrome, and at a lower BMI in Asian American persons."[2]

The following semistructured inclusion and exclusion logic represents the recommendation summary.

Inclusion logic:

Patient is ≥35 years old AND ≤70 years old

AND BMI ≥25kg/m^2, MOST RECENT VALUE

OR Patient is ≥18 years old and <35 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

Exclusion logic:

Pregnancy *(active)*

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

OR diabetes mellitus within the past 12 months *(active, relapse)*

OR prediabetes within the past 12 months *(active, relapse)*

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 hemoglobin A1C test result, MOST RECENT VALUE within the past 3 years *(final, amended)*

OR fasting plasma glucose test result, MOST RECENT VALUE within the past 3 years *(final, amended)*

OR glucose tolerance test result, MOST RECENT VALUE within the past 3 years *(final, amended)*

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 simultaneously on the USPSTF website and in the Journal of the American Medical Association (JAMA), 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., ≥35 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. 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 because that is the lowest threshold for "overweight or obese."
Inclusions	"BMI"	BMI is the calculated ratio of a patient's weight in kilograms divided by the square of height in meters.
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 are as close to the patient's current health status as possible.
Inclusions	"<"	Less than a given value (e.g., less than 35 years old).

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. 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 because 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) 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.[16] Because *any* evidence of PCOS in a patient's history may be relevant (e.g., "active," "resolved"), a FHIR clinicalStatus is not specified.
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.[7]
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.[17]

Location in CDS Logic	Concept	Definition and/or Rationale
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.[17]
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.[17]
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. Because *any* evidence of gestational diabetes in a patient's history may be relevant (e.g., "active," "resolved"), a FHIR clinicalStatus is not specified.
Exclusions	"Pregnancy"	Pregnancy is explicitly stated as an exclusion in the USPSTF recommendation. The clinicalStatus must be "active."

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 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 defines “early, full, and late term pregnancy” as up to 42 weeks of gestation. Because gestation date is not often specified in a health IT system, the CDS logic evaluates the date that a pregnancy observation was recorded in the system.
Exclusions	“diabetes mellitus”	Diagnosis of DM (both type 1 and type 2 because diabetic patients follow distinct protocols for glucose monitoring and preventive screening for DM is not relevant for these patients). The clinicalStatus must be “active” or “relapse” to ensure that the condition is relevant to the patient’s current health status.
Exclusions	“prediabetes”	Diagnosis of prediabetes. The purpose of the artifact is to identify patients who should be screened for prediabetes and type 2 diabetes. If the patient already has the condition, then they should not be notified that screening is appropriate. The clinicalStatus must be “active” or “relapse” to ensure that the condition is relevant to the patient’s current health status.
Exclusions	“impaired fasting glucose”	A recorded diagnosis of impaired fasting glucose (IFG) (i.e., consistently elevated fasting blood sugar levels that fall short of the threshold defined for DM and impaired glucose tolerance [IGT]). The clinicalStatus must be “active” or “relapse” because this can be a transient diagnosis. Per a USPSTF SME, this concept is appropriately defined as a diagnosis, as opposed to one or more abnormal lab value(s); a formal diagnosis of IFG should be made by a clinician after evaluating lab results in the context of the patient’s health. In other words, evidence of abnormal lab results alone, should not be construed as a diagnosis of IFG.
Exclusions	“within the past 12 months”	Occurring within 12 months of the CDS trigger. This places restrictions on a lookback period to ensure clinical accuracy (some diagnoses related to glucose metabolism can be transient).
Exclusion	“impaired glucose tolerance”	A recorded diagnosis of impaired glucose tolerance (IGT) (i.e., consistently elevated fasting blood sugar levels that fall above the threshold for IFG and short of the threshold defined for DM). The clinicalStatus must be “active” or “relapse” because this can be a transient diagnosis. Per a USPSTF SME, this concept is appropriately defined as a diagnosis of IGT, as opposed to one or more abnormal lab value(s); a formal diagnosis of IGT should be made by a clinician after evaluating lab results in the context of the patient’s health. In other words, evidence of abnormal lab results alone, should not be construed as a diagnosis of IGT.

Location in CDS Logic	Concept	Definition and/or Rationale
Exclusions	“hemoglobin A1c lab result”	Evidence of a “final” or “amended” hemoglobin A1C (HbA1c) lab result. Glucose abnormalities can be detected by measuring HbA1c, fasting plasma glucose (FPG) or with a glucose tolerance test (GTT). HbA1c tests are more convenient than FPG or oral GTT measurements because they do not require fasting.[2] HbA1c is a measure of long-term blood glucose concentration and is not affected by acute changes in glucose levels due to stress or illness. Evidence of a HbA1c result within the designated lookback period indicates that the recommended screening has been completed.
Exclusions	“within the past 3 years”	Occurring within three years of the CDS trigger. This lookback was informed by information in the recommendation statement that indicates “studies suggest that rescreening every three years may be a reasonable approach for adults with normal blood glucose levels.”[2]
Exclusions	“fasting plasma glucose test result”	Evidence of a “final” or “amended” FPG lab test result. This is one of the three recommended tests for screening blood glucose. Evidence of an FPG result within the designated lookback period indicates that the recommended screening has been completed.
Exclusions	“glucose tolerance test result”	Evidence of a “final” or “amended” GTT lab test result. This is one of the three recommended tests for screening blood glucose. Evidence of a GTT result within the designated lookback period indicates that the recommended screening has been completed.

Artifact Development Decision Log

The Artifact Development Team made several decisions when translating the USPSTF recommendation and developing the structured representation of this artifact. **Table 3** provides insight on those decisions, along with where the coded representation might be expanded in the future. The table 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.[18] 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	The 2015 USPSTF recommendation on glucose screening, "Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening," was replaced in October 2021 with a revised recommendation, "Prediabetes and Type 2 Diabetes: Screening." The new recommendation focuses on diabetes (both prediabetes and type 2 diabetes) screening alone, and no longer embeds screening as part of cardiovascular risk assessment.
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/m2 or greater and less than 30 kg/m2, and "obese" as a BMI of 30 kg/m2 or higher. 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	Incorporating "impaired glucose tolerance" in the logic specification	This recommendation applies to patients who are overweight or obese and have known risk factors, including "impaired fasting glucose" (or IFG). The recommendation also mentioned "impaired glucose tolerance (or IGT)" in some areas, but not in the Population Statement. A USPSTF SME confirmed that individuals with IGT should be considered for the CDS intervention also, as long as they do not meet exclusion criteria.

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 Prediabetes and Type 2 Diabetes: Screening "Recommendation" statement clearly describes that adults aged 35 – 70 who are overweight or obese (i.e., BMI ≥25 kg/m^2) should be considered for abnormal blood glucose screening. Potential implementers should be aware that the USPSTF goes on to describe additional populations that should be screened 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."[2] 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.
Add explanation	"No symptoms of diabetes"	The Patient Population Under Consideration section of the guideline states that the recommendation applies to adults who have "no symptoms of diabetes." Most symptoms of diabetes are nonspecific. An AHRQ SME confirmed that omitting a search for those symptoms was appropriate.
Add explanation	"A large body of evidence demonstrates strong associations between prevalence of diabetes and social factors such as socioeconomic status, food environment, and physical environment."	The Assessment of Risk section of the guideline states that social determinants are strongly associated with the prevalence of diabetes. For the logic to capture all patients who meet inclusion criteria, those attributes must be coded in the EHR. Because it is not yet common practice to reliably code Social Determinants of Health in EHRs, the decision was made not to include these attributes.

Appendix B. References

[1] 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:i132-139.

[2] US Preventive Services Task Force. Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2021;326(8):736–743. doi:10.1001/jama.2021.12531. https://jamanetwork.com/journals/jama/fullarticle/2783414. Accessed April 16, 2024.

[3] Fiks AG. Designing computerized decision support that works for clinicians and families. Curr Probl Pediatr Adolesc Health Care. 2011;41(3):60-88.

[4] 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;11:73.

[5] Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. N Engl J Med. 2012;366(9):780-781.

[6] US Preventive Services Task Force. Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Consumer Guide. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/information-for-consumers. Accessed March 13, 2023.

[7] Centers for Disease Control and Prevention. Race and Ethnicity Code Set Version 1.0. 2000; https://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf. Accessed March 30, 2022

[8] Health Level 7 (HL7). Clinical Quality Language (CQL) Release 1 STU5 (1.5). https://cql.hl7.org/. Accessed March 25, 2022.

[9] 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 March 25, 2022.

[10] 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 March 25, 2022.

[11] Wikipedia. Test-driven development. https://en.wikipedia.org/wiki/Test-driven_development. Accessed March 25, 2022.

[12] Agency for Healthcare Research and Quality. CQL Testing Framework. https://github.com/AHRQ-CDS/CQL-Testing-Framework. Accessed March 25, 2022.

[13] Agency for Healthcare Research and Quality. CQL Services GitHub page. https://github.com/AHRQ-CDS/AHRQ-CDS-Connect-CQL-SERVICES. Accessed March 25, 2022.

[14] National Library of Medicine. Value Set Authority Center. https://vsac.nlm.nih.gov/. Accessed March 25, 2022.

[15] Health Level 7 (HL7) and Boston Children's Hospital. CDS Hooks. https://cds-hooks.org/. Accessed March 25, 2022

[16] Williams T, Mortada R, Porter S. Diagnosis and Treatment of Polycystic Ovary Syndrome. Am Fam Physician. 2016;94(2):106-113.

[17] Office of Management and Budget (OMB). Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. In: Budget OoMa, ed. Vol 62(210):58782: Federal Registrar; 1997.

[18] Tso GJ, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. AMIA Annu Symp Proc. 2016;2016:1189-1198.