

CDS Connect Pilot Report

Preventive Health CDS Interventions

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Introduction

The CDS Connect project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), provides the infrastructure for healthcare organizations to share evidence-based knowledge expressed as clinical decision support (CDS) logic (or “CDS artifacts”) via the CDS Connect Repository, 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 can collaborate and enhance the shared resources.

Each year, the CDS Connect team develops one or more CDS artifacts; implements the CDS in a healthcare setting, including integration into health information technology (IT); and contributes the body of work to the CDS Connect Repository. This serves to: (1) demonstrate CDS Connect infrastructure, (2) ensure that the artifact(s) perform as expected, and (3) share lessons learned for future implementers of the CDS logic. This document focuses on the key task of piloting CDS artifacts in a healthcare setting.

Background

The primary objectives of the CDS Connect pilot were to demonstrate the feasibility of implementing evidence-based CDS artifacts hosted on the CDS Connect Repository, and to share lessons learned to inform future implementers. To achieve this, the CDS Connect project team enabled:

1. Development of a systematic and replicable process for translating evidence-based practice into executable CDS, validated through a pilot study in a healthcare environment, that can be undertaken by other CDS developers
2. Successful hosting and sharing of CDS artifacts on production-level infrastructure (i.e., the AHRQ CDS Connect Repository)
3. Technical integration of one or more CDS Connect-developed, standards-based interoperable artifacts into a health IT system and implementation of the CDS into the workflow of a healthcare setting
4. Sharing of insights from the overall project—and specifically the pilot organization and the CDS Connect project team—to support others in adopting, sharing, and implementing CDS

CDS artifact development during the 2018 – 2019 timeframe centered on the domain of preventive health, informed by the [U.S. Preventive Services Task Force](#) (USPSTF) evidence-based recommendations for clinical preventive services and health promotion. The USPSTF recommendations provide valuable evidence-based guidance on those clinical preventive services that help primary care clinicians and patients make informed healthcare decisions. The

CDS Connect team collaborated with the USPSTF and the pilot partner to determine the recommendations that were of most benefit to the targeted population, while considering any potential challenges in creation, integration, or pilot use of each recommendation. The selected USPSTF recommendations were then transformed into four patient-facing CDS artifacts. The recommendations, and the artifacts that they inspired, include:

1. [*Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease \(CVD\) Prevention in Adults With Cardiovascular Risk Factors*](#): The artifact developed from this recommendation statement is referred to as the *Healthful Diet and Physical Activity for CVD Prevention* artifact in this report.
2. [*Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus*](#): This recommendation statement was divided into two distinct artifacts to enable implementers to select the “screening” component of the recommendation (referred to as the *Glucose Part 1, Screening* artifact in this report) or the “counseling” component of the recommendation (referred to as the *Glucose Part 2, Counseling* artifact in this report). The pilot organization opted to implement both components of the recommendation (i.e., both artifacts).
3. [*Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention*](#): The artifact developed from this recommendation statement is referred to as the *Statin Use for the Primary Prevention of CVD* artifact in this report

Of note, the *Statin Use for the Primary Prevention of CVD* artifact logic requires a calculated 10-year risk score for atherosclerotic cardiovascular disease (ASCVD), and the b.well platform did not have the capability to calculate this required score. As a result, b.well also implemented a fifth CDS artifact developed by the CDS Connect project team in 2018 (i.e., [*CMS’s Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk*](#), referred to as the *ASCVD Risk Calculator* in this report).

The piloted CDS artifacts are designed to be implemented in a patient-facing health IT system (e.g., a patient portal or health and wellness app) to deliver preventive health recommendations directly to patients/consumers outside of a traditional encounter with a clinician.

Pilot Goals and Scope

The primary goals of the pilot were to: (1) translate evidence-based clinical guidelines into interoperable CDS artifacts; (2) inform and enhance the specification of the artifact(s) based on pilot integration, testing, and implementation findings; (3) gain an understanding of pilot stakeholder views as they experience pilot activities; and (4) contribute evidence-based CDS

artifacts for inclusion in the CDS Connect Repository. These goals were accomplished by the following activities:

1. **Design:** Develop the CDS artifacts using a process or “case study” that aligns with the [Analytic Framework for Action](#) and the [CDS 5 Rights](#) Frameworks.
2. **Implement:** Implement the CDS with a pilot organization.
3. **Measure:** Conduct qualitative and quantitative measurement on resource needs for pilot integration efforts, availability of required data to meet inclusion and exclusion criteria, and perceptions of the target end users on the usefulness of the CDS.
4. **Iterate:** Support and document a responsive process for evaluating the pilot CDS performance and updating the pilot CDS (i.e., tracking and documenting issues) based on stakeholder feedback.
5. **Document:** Document all pilot activities, and disseminate lessons learned and work products on the CDS Connect Repository.

The scope of the pilot included engaging with a designated pilot organization to implement the selected preventive health CDS artifacts across all or part of the appropriate patient population for a multi-week intervention period.

Pilot Partnership

Pilot Partner Requirements

For the pilot, the project team sought a collaborator with both technical readiness and a suitable healthcare environment to pilot the CDS. Several key factors influenced the selection of the pilot organization. Identifying a pilot organization that was invested in supporting either the clinician and/or patient/consumer decision-making process via CDS was critical. In addition, the clinical domain (i.e., evidence-based preventive health recommendations formulated from one or more of the USPSTF recommendations) needed to resonate with the organization. Ideally, preventive health was already identified as a high-value quality improvement (QI) imperative, and the idea of gaining well-specified CDS via a pilot partnership was viewed as an optimal opportunity to gain a “leg up” on executing a QI initiative in this domain. In addition, working with a pilot organization that provided patient/consumer-facing capabilities was deemed highly desirable.

The project team considered several different organizational types during the initial pilot site identification:

- Traditional primary care ambulatory physician practice or Federally Qualified Health Center (FQHC) with the capacity to deliver patient-facing CDS
- Innovative primary care solution (e.g., enabling virtual patient visits or other alternative model of care) with the ability to deliver patient-facing interventions via their technology

- Patient/employee-facing site with focus on wellness and preventive care, such as an employee health/occupational health setting

Additional preferred characteristics of a pilot organization were also identified as important for consideration when evaluating potential pilot organizations:

1. Focused on adult primary care, if an ambulatory physician practice (e.g., internal medicine, family medicine).
2. Possessed the required ability and experience to implement the integration to address patient-facing CDS intended to be integrated with a patient portal or personal health record.
3. Demonstrated the need for the pilot CDS (i.e., CDS that facilitates preventive health).
4. Provided the required structured data in the site's health IT system.
5. Confirmed the availability and support of clinical, operational, and technical staff.
6. Possessed the technical capability to implement the pilot CDS.
7. Confirmed that the pilot CDS can be used operationally, based on the organization's clinical operations.
8. Communicated the organizational commitment and operational resources to meet pilot needs before, during, and after implementation, including:
 - a. Provision of end-user workflow materials and/or guidance on current process.
 - b. Consultation on the pilot CDS and its placement into the end-user workflow.
 - c. Ability to perform site-based training and scheduling if needed.
 - d. Coordination and support of Institutional Review Board (IRB) requirements
 - e. Commitment of designated point(s) of contact for technical, clinical, and operational domains.

To enhance the value proposition of the pilot partnership, AHRQ and the project team offered potential pilot partners the opportunity to provide input on what CDS artifact(s) they would pilot (from a previously vetted list of options). This approach was a strategic decision to garner optimal commitment to the partnership and a “win-win” opportunity for both organizations.

Pilot Partner Selection

The project team collected background information on potential pilot organizations through discussions and email conversations with more than 20 different organizations, and general impressions were captured in a working document. In addition, the project team held two separate decision-briefing meetings with AHRQ in January 2019 to provide information on each potential pilot organization and to discuss how each organization met the desired pilot characteristics and criteria.

After evaluating all potential pilot partners, [b.well® Connected Health](#) (b.well) was selected in collaboration with and approval of AHRQ. b.well offers a platform with personalized health-management resources targeted to consumers to help self-manage the entire healthcare process. Their mission is “to reduce the prevalence of chronic disease and make healthcare simple,

personal, and affordable.”¹ Their targeted customers are employers and health plans interested in improving the health of their employees/members. These customers sponsor the use of the b.well app for the people in their organization, who are the actual end users of the b.well app. These consumer end users are incentivized to use the app through personalized educational information and “challenges.” (Note that throughout this document, reference to the b.well end users specifically refers to these “consumer end users,” while more general references may use the term “patient” as is commonly used in literature when discussing CDS or decision making targeted to individuals, and not clinicians [e.g., patient-centered, patient-facing CDS]).

With their expertise in understanding patient/consumer needs, b.well provided the opportunity to create patient-facing CDS, which was of high interest to AHRQ. In addition, b.well met all the defined pilot-partner criteria, and was already focused on providing preventive health CDS and information to their consumer end users. b.well was awarded a subcontract through the MITRE Corporation for the performance period of March 13 through August 31.

Initial Pilot Outcome Definition

Prior to beginning the pilot, the CDS Connect project team identified several high-level outcomes for evaluating the preventive health CDS pilot implementation that were important to pilot success:

1. The pilot organization can incorporate the pilot CDS into their health IT system.
2. The pilot CDS launches when appropriate and evaluates information as designed.
3. The end users use the pilot CDS when appropriate and believe it adds value.
4. The project team gains information from the pilot site to document and evaluate the pilot CDS development, implementation, and dissemination process, along with integration requirements, testing results, any required enhancements to the specifications, and outcomes from the pilot experience.

In addition to the high-level pilot outcomes, the project team created research questions that could be investigated during the pilot across the three domains of people, process, and technology. The research questions shown in **Table 1** were used to structure the measurement techniques, evaluation methods, and final survey content for the pilot.

Table 1: Reference Questions by Domain

Domain	Potential Research Questions
People	Do patients gain greater insight into their own health or risks when using the pilot CDS, and does this influence their actions?
People	Are patients receptive to and ready to use the pilot CDS?

Domain	Potential Research Questions
People	Is the pilot CDS user-friendly? Do patients value the pilot CDS?
Process	Do patients require training or any additional support in order to use the pilot CDS? If yes, how much and what kind, and what is the cost to the organization?
Process	Did the CDS notification result in additional patient action (e.g., the patient reviews the educational material, or schedules an appointment with their primary care doctor)?
Technology	Are the resource requirements needed to implement CDS feasible (e.g., expertise, skill mix, hours of labor, new equipment, training)?
Technology	Can a site integrate CDS Connect artifacts with their health IT system? Could the CDS implementation process be replicated in the future?
Technology	Does the pilot CDS identify a component of patient care that could have been missed or a subset of a previously undetected population in need?

The CDS Connect project approach is grounded in agile development; for the purposes of outcome measurement, this approach translates into an ongoing, iterative, as-needed model for discussing findings and ways to enhance the work to ensure outcomes (to the extent possible) are met.² This approach also supports the collection of both formal and informal information and data that can be both qualitative and quantitative, and incorporates the knowledge and lessons learned into a feedback loop that improves the CDS artifact and benefits the broader community of users.

During the partnership period, the CDS Connect project team and b.well engaged in collaborative communication, discussions, and activities that provided both qualitative and quantitative data to inform ongoing evaluation and outcome assessment. This included weekly technical and management conference calls, weekly generation of analytical reports, and the distribution of an end-user survey at the end of the pilot period. These activities are described in this report.

Institutional Review Board Approval

Given the research and evaluation nature of the work and the project’s goal to provide both specific and generalizable knowledge to a broad community of stakeholders, the CDS Connect

project team engaged in the IRB process to ensure compliance with applicable human-subject protection policies.

On February 28, 2019, the CDS Connect team initiated contact with a MITRE IRB representative and began completing the required application forms and supplementary materials. The application included a description of the research effort, the proposed implementation and evaluation process, an assessment of risk, and a clear statement that outlined how the consumer end users might be engaged in the research. The project team submitted the completed application along with a research consent form, a list of study staff, and a draft of the end-user survey discussion topics. On May 8, the MITRE IRB provided an official response, granting the project exempt status (i.e., the research does not exceed a minimal risk to human subjects and falls into an exempt category)³ and providing their approval.

Pilot Implementation Planning

Pilot Work Plan and Kickoff Meeting

After initiating the pilot subcontracting process and executing a mutual nondisclosure agreement, b.well and the CDS Connect project team met several times in advance of the executed contract to begin discussion of the preventive health CDS and the CDS integration approach, and to learn more about the b.well platform and app. The project team confirmed the data sources available to b.well, including claims, EHR, pharmacy benefits management (PBM), reference laboratories, and patient-generated health data (PGHD) (e.g., data from wearable devices, surveys and questionnaires, and mobile applications).

The project team also provided a list of potential USPSTF recommendations for b.well to consider implementing as CDS. b.well prioritized the recommendations by considering: (1) which recommendations they had not yet introduced in their platform but were of high interest, (2) the overall consumer end-user population and data availability for each recommendation, and (3) any concerns related to potentially sensitive topics (e.g., mental health or sexually transmitted diseases).

b.well also gave a demonstration of their app to provide additional information and context to AHRQ and the project team, and provided login information for the teams to access the demo app and associated test data for further exploration.

Once the pilot subcontract was executed, the b.well and CDS Connect project teams began planning for the pilot kickoff meeting. b.well identified key personnel that would be engaged in the pilot to help ensure a successful implementation, including the project lead/manager, the clinical lead, and the technical lead.

The 2-day kickoff meeting was conducted in mid-April 2019, with key CDS Connect and b.well team members who addressed the following agenda topics:

1. Review the pilot scope and work plan (to establish the proposed pilot timeline and implementation details, as well as the critical path activities and risks).
2. Review the high-level CDS expressions and data requirements for each USPSTF recommendation selected by b.well.
3. Determine the most optimal method for integrating the CDS artifacts.
4. Develop the process to evaluate data availability and the need for mapping.
5. Develop the initial pilot analytic plan.
6. Discuss the pilot consumer end-user selection and engagement needs.

Communication and Collaboration

To maintain ongoing situational awareness and communication, CDS Connect project leadership held a weekly management call with the b.well project leadership from mid-April through August. Additionally, a weekly technical call provided an opportunity for the organizations' operational, clinical, and technical leadership to discuss the integration and implementation of the CDS artifacts, along with any implications on clinical execution and, ultimately, pilot outcomes and goals. Throughout the pilot period of performance, b.well and CDS Connect leadership were readily available to address questions or issues as needed.

Pilot Analytic Plan

The CDS Connect project team and b.well collaboratively developed an analytic plan to provide quantitative data to evaluate the potential population size available for each CDS artifact, as well as data availability for meeting inclusion and exclusion criteria. The reporting was performed at predetermined intervals (e.g., pre-pilot site implementation, during the pilot, and after the pilot conclusion).

The results of the analysis are detailed further in the Pilot Findings and Lessons Learned section of this report.

b.well Pilot Participants

To identify the consumer end-user population that would pilot the preventive health CDS, b.well initiated discussions with their customers interested in the preventive health domain. To support the b.well recruitment efforts, the CDS Connect project team developed a one-page CDS Connect Pilot Partnership document that described the project, as well as a second document outlining the known evidence-based outcomes and benefits for each of the selected USPSTF recommendations. b.well decided to include all of their employer customers and associated consumer end-user population, consisting of more than 3,000 end users.

Because the preventive health CDS was integrated with the existing b.well app and "Care Needs" functionality, no other onboarding or training was needed for the consumer end users.

Preventive Health CDS Technical Integration

Integrating specific CDS capabilities or artifacts into an existing system requires a significant amount of planning, and often requires custom development and configuration. The current landscape of health IT is such that sufficient CDS standards exist, and many health IT vendors plan to support them, but most have not yet implemented full support. The CDS Connect project team developed CDS logic for all five artifacts to collect and organize relevant data to inform the end user's decision-making process on recommended preventive care. This section describes the integration of the CDS logic into b.well's IT platform, as well as associated technology implemented.

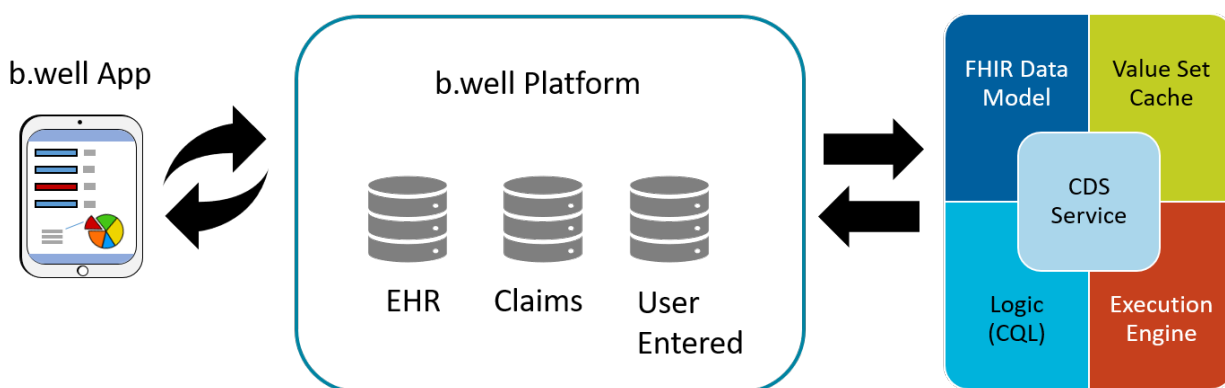
The CDS Connect project team worked with b.well to elicit their input regarding the best approach to the technical integration of the preventive health CDS. During the pilot kickoff technical discussion, the project team described the typical approach to integrating similar CDS and explained that the CDS logic would be expressed using the Health Level 7 (HL7) Clinical Quality Language (CQL). CQL is a data standard that is currently a Standard for Trial Use (STU).⁴ CQL expresses logic in a human-readable format that is also structured enough for electronic processing of a query, and it is open source. It can be used within both the CDS and electronic clinical quality measure domains.

The CDS Connect project team also described several options for integrating the CDS within the current b.well environment, including: (1) [CDS Hooks](#); (2) as a Substitutable Medical Applications, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resources (FHIR) application ([SMART on FHIR](#) app); or (3) a more custom, nonstandard approach. The SMART on FHIR app was not considered a feasible option, primarily because b.well desired to control the user interface design and development for any information presented to their end users in order to provide a consistent user experience. CDS Hooks provided a plugin framework for custom CDS and seemed like the best approach, and the CDS Connect project team had already developed a CDS service framework that conformed to the CDS Hooks specification. Although b.well had never integrated CDS Hooks, they felt it was feasible for the pilot CDS integration, and it was agreed that this option would be the method used.

CQL Services,⁵ the CDS service framework developed by the project team, was used to facilitate integration of the preventive health artifacts into the b.well system. As depicted on the right-hand side of **Figure 1**, the CDS Service framework consists of four main components:

1. FHIR Data Model: Based on FHIR Draft Standard for Trial Use 2 ([DSTU2](#))
2. Value Set Cache: A service for retrieving coded clinical concepts from the National Library of Medicine Value Set Authority Center (VSAC)⁶ with a local storage cache
3. Execution Engine: Evaluates the CQL logic against the data inputs
4. Logic (CQL): The CQL libraries included with the artifact(s)

Figure 1. Integration Approach Using CQL Services



Integration of the Preventive Health Artifacts Within b.well’s Platform

Data on the b.well platform comes from a variety of sources, including one or more EHRs, claims, reference laboratories, and PBM systems as well as PGHD. Examples of PGHD include self-reported family history, weight or height measurements, or inputs from a smart watch. When an artifact is triggered for a particular user, the necessary data are queried and aggregated on the b.well platform. These data are then sent as a hypertext transfer protocol (HTTP) request to CQL Services via a CDS Hooks interface; since the request remains within b.well’s platform, secure HTTP (HTTPS) is not necessary. CQL Services responds to the request by executing the requested artifact logic 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 criteria were met.

b.well elected to run the CDS as a batch process during the night, aligning with the current method they use for other “Care Needs” developed within their application. End users who qualify for the recommended preventive care based on their specific criteria (i.e., meets the inclusion criteria but not the exclusion criteria) are notified through either a push notification or an email. The notifications developed by b.well are not personalized due to privacy constraints, but are written to be motivational to the end user to encourage action (e.g., “access the app to find out more”). See **Figure 2** for an example of a notification.

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

Figure 2. Example of Patient Notification

Initial Notification:
(push)
Take time for your health
We have a new health recommendation for you! We can walk you through what it is and why it may be right for you. Tap to learn more (and earn points while you're at it!)
(email)
Have a minute for your health, {Name}?
Hi {Name},
Based on our records, we have a new health recommendation for you. We know you've got a lot going on — so let us walk you through it! We'll go over what it is and why it was selected for you, and you'll earn points when you complete the challenge. Take a look!
[Learn about my care need](#)
Warm regards,
b.well Consumer Experience Team

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Educational Resources: When the end user acts upon the notification and accesses the health app, they are able to link directly to pertinent educational resources based on their individual health history and identified risk factors (e.g., information on cardiovascular risk and recommendations, tools, and videos to provide additional education that is tailored to the end user and specific USPSTF recommendation).

- The resources found on healthfinder.gov and the USPSTF consumer guides were used as sources for much of the educational content created by b.well. See **Figure 3** for an example of consumer education text.

Figure 3. Example of Patient Education

Give Your Heart Some Love
An important conversation to have with your doctor
Did you know you may be at higher risk for heart disease? Fortunately, there's so much you can do to protect yourself. Let's walk through a key recommendation together.
We chose this challenge for you because we noticed you may have some risk factors for heart disease and stroke. Let's go over the what and why — and then talk about how you can stay healthy!
Based on our information, you may have these risk factors (*only displays end-user's risk factors*):
The US Preventive Services Task Force recommends that you schedule time to talk with your doctor about counseling to help you eat right and stay active. Because working together, you can help turn these risk factors around.

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Appointment Scheduling Tools and Other Resources: Educational resources include encouragement to discuss the recommendation with the end user's primary care clinician. The b.well health app provides the ability to make an appointment with the end user's existing primary care clinician, or to facilitate finding a primary care clinician if the end user does not have one identified. See **Figure 4** for an example.

Figure 4. Example of Appointment Facilitation

Take Action to Protect Your Heart

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

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

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

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Facilitating end user action and ensuring that the patient perspective was considered during the CDS research, design, development, testing, implementation, and evaluation helped to ensure that patient preferences and effective patient decision making, were supported. In turn, the successful implementation of patient-facing CDS helped support quality and safety, and in the long term may result in a positive impact to patient health outcomes and satisfaction.

Preventive Health CDS Enhancements

Throughout the pilot integration and testing period, enhancement opportunities were identified for the pilot CDS logic or required data concepts. This information helped to improve the reliability, validity, and usefulness of the CDS. The CDS Connect team worked with b.well to determine which updates were needed during the pilot integration timeframe to support the pilot efforts. Additional enhancements that future implementers may want to consider prior to integrating the CDS into their system are also discussed in this section.

Enhancements Made to the CQL or CQL Services During Pilot Integration

During the integration and testing phase of the pilot, several refinements were made to provide additional information requested by the b.well technical team, or to address errors identified. These enhancements were made to either the CQL (the executable logic expression) or CQL Services (a CDS service framework used to facilitate integration of the logic into the b.well platform) during the pilot partnership, and included:

- Adding the ability to support CDS Hooks extensions⁷ in CQL Services, so that specific information could be sent to b.well regarding missing data needed by the inclusion or exclusion criteria for each artifact. This facilitated additional manual investigation by b.well to help determine potential resolution (e.g., mapping of data; discussion with the data source organization). This change involved:
 - Adding a software feature to support CDS Hooks extensions in CQL Services.
 - Updating each artifact's "CQL Hooks" configuration files, to define the specific extensions to be returned.

- Modifying the CQL for each artifact to provide a new output that lists all data elements that have missing data (e.g., no smoking status observation).
- Addressing error messages that originated from CQL Services caused by duplicate CQL libraries with different versions. This issue was due to combining the artifacts together in the same execution environment. To address this issue, updated CQL libraries were provided to b.well.
- Modifying the error returned by CQL Services when invalid units of measurement appear in laboratory observations. Initially, CQL Services returned an HTTP 500 (server error) response; this error message was replaced with a more appropriate HTTP 422 (unprocessable entity) response.
- Increasing the default size of the data that could be sent in a single request to CQL Services. The original default value was not large enough in cases where users had large numbers of records. The maximum data input size was made a configurable parameter that b.well was able to adjust.

Enhancements Needed to Clinical Concept Definitions

During the integration and subsequent pilot use of the CDS, the CDS Connect and b.well teams identified several issues concerning four clinical concepts definitions that required analysis and determination of how to proceed. The clinical concepts impacted, along with the associated artifacts, background information, and resolution, are discussed here.

1. “Hemoglobin A1c” (HbA1c)

- **Artifacts:** *Abnormal Glucose: Screening; Abnormal Glucose: Counseling.*
- **Background:** HbA1c is one of the lab tests used to identify abnormal blood glucose levels.
- **Identified concern:** The structured logic contains one Logical Observation Identifiers Names and Codes (LOINC) code to define HbA1c (i.e., 4548-4), and the pilot site identified two additional HbA1c LOINC codes in their system (i.e., 17856-6 and 17855-8).
- **Implementation decision:** Have the pilot organization map the two additional codes to the specified code. Per LOINC mapping guidance, “all HbA1c measurements reported in the U.S. and many other countries are standardized to the National Glycohemoglobin Standardization Program (NGSP) protocol, which states that LOINC: 4548-4 should be used for reporting HbA1c in the U.S.”⁸
- **Suggestions for future implementers:** Monitor this issue and changes to the NGSP protocol. In the interim, organizations can map relevant HbA1c LOINC codes to the current definition (4548-4) in the CDS logic. If NGSP guidance expands the number

of codes that properly define HbA1c, then future implementers may elect to create a value set comprised of those codes.

2. “Diabetes”

- **Artifacts:** *Abnormal Glucose: Screening; Statin Use; Patient-Facing 10-Year ASCVD Risk Tool.*
- **Background:** Because diabetes is a risk factor for CVD, it is represented in several of the piloted CDS artifacts.
- **Identified concern:** The pilot site identified a valid diabetes Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) code that is not present in the diabetes value set used in artifact logic (i.e., SNOMED-CT code “368051000119109” is not included in the [National Committee for Quality Assurance \(NCQA\) diabetes value set](#) published on the [VSAC](#)).
- **Implementation decision:** Have the pilot organization map the identified code to a similar code in the specified value set so the data could be properly evaluated by the CDS logic.
- **Suggestions for Future Implementers:** The CDS Connect team notified NCQA (the value set steward) of the missing code so they could update their value set. Future implementers may want to evaluate the NCQA value set prior to using it in order to determine whether the identified code has been added to the value set.

3. “Gestational diabetes”

- **Artifacts:** *Abnormal Glucose: Screening; Abnormal Glucose: Counseling.*
- **Background:** Gestational diabetes is a condition that can impact an individual’s risk for developing abnormal glucose or diabetes later in life. It is part of inclusion logic for both artifacts.
- **Identified concern:** Gestational diabetes was originally defined by a value set that included International Classification of Diseases (ICD), Tenth Revision, Clinical Modification (CM) and SNOMED-CT codes. The b.well pilot team identified valid ICD-9-CM codes that also represent gestational diabetes.
- **Implementation decision:** Since this concern was identified late in the pilot, b.well mapped the relevant ICD-9-CM codes to an ICD-10-CM code present in the gestational diabetes value set specified in the CQL logic expression (e.g., O24.4).
- **Formal resolution:** The CDS Connect project team authored a new ICD-9-CM value set that represents gestational diabetes (i.e., <https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.99/definition>). Code selection for the value set was informed by a CodeWrite newsletter (i.e.,

https://newsletters.ahima.org/newsletters/Code_Write/2011/October/diabetes.html).

The new ICD-9-CM value set was added to the grouped value set (which includes ICD-10-CM and SNOMED-CT codes) already represented in the CQL logic (i.e., <https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.90/definition>). As a result, the published coded expression now includes all relevant standard terminology codes that are appropriate for representing a diagnosis of gestational diabetes.

4. “Polycystic ovary syndrome”

- **Artifacts:** *Abnormal Glucose: Screening; Abnormal Glucose: Counseling.*
- **Background:** Polycystic ovary syndrome can impact an individual’s risk for developing abnormal glucose or diabetes. It is part of inclusion logic for both artifacts.
- **Identified concern:** Polycystic ovary syndrome was originally defined by one ICD-10-CM code (i.e., E28.2) and one SNOMED-CT code (i.e., 69878008). The b.well pilot team identified a valid ICD-9-CM code that represents polycystic ovary syndrome also (i.e., 256.4).
- **Implementation decision:** Because this concern was identified late in the pilot, b.well mapped the relevant ICD-9-CM code to the ICD-10-CM code present in the specified CQL logic expression. Since there is only one ICD-9-CM code that identifies polycystic ovaries, this resolved the issue for b.well.
- **Formal resolution:** The CDS Connect project team updated the CQL expression of both Abnormal Glucose artifacts to include the ICD-9-CM code. As a result, the published coded expression now includes all relevant standard terminology codes that are appropriate for representing a diagnosis of polycystic ovary syndrome.

Enhancements to CDS Intervention Text

Initially, the CDS Connect team inserted “placeholder” CDS intervention text in the structured representation of the four patient-facing artifacts. As mentioned previously, patient-friendly, customized intervention content was developed in partnership with the pilot organization in order to provide personalized motivational notification messaging, as well as educational information and logistical support for appointments and followup to the pilot end users.

In collaboration with the project’s patient advocate, the CDS Connect team created enhanced notification and educational content, which can be found in the *Example Intervention Content* document posted in the Miscellaneous Files section of each patient-facing artifact. The notifications are fairly general, enabling implementing organizations to expand upon and personalize the interventions based on their unique needs and patient population. Prior to publishing each artifact on the CDS Connect Repository, the notification and educational content was inserted into the CQL logic for each artifact.

Examples of the notification and educational content developed by b.well are displayed in this document in the section on *Integration of the Preventive Health Artifacts Within b.well's Platform*. The *Patient Notification and Intervention Considerations* section of the implementation guide that accompanies each artifact in the repository contains additional examples.

Pilot Implementation and Testing

The integration and implementation of these preventive health artifacts required significant effort from both the CDS Connect project team and b.well. The project team was responsible for developing the CQL logic for artifacts as well as any modifications to CQL Services, and b.well was responsible for integrating the artifacts within the b.well environment. This required a significant level of data analysis and data mapping from b.well.

The b.well technical team did not have prior experience using CQL and CDS Hooks and had limited experience with the FHIR data model. This was not unexpected, considering the newness and evolving nature of these standards. The project team provided detailed documentation to assist with the integration efforts, and monitored a communication software tool called “[Slack](#)” for real-time collaboration and discussion with b.well’s technical team. As mentioned previously, the project team and b.well also held collaborative weekly meetings for approximately 8 weeks prior to the pilot launch date, and these meetings continued during the pilot live period.

Data Analysis and Mapping Requirements

To ensure accurate and reliable CDS interventions, the data used in the logic for each CDS artifact must be available and as complete and specific as possible (e.g., represented using the appropriate FHIR data model resource and attributes, and represented by a standard terminology code). b.well receives data from multiple sources, which served to complicate the format and specificity of each data element.

The CDS Connect project team created a *Data Requirements* spreadsheet to assist b.well in evaluating their data. The spreadsheet listed every data element, along with associated information used for each artifact. The data requirements worksheet for each individual artifact is included in each *Implementation Guide* as an appendix and contains the following information:

- A listing of each data element name
- Information on whether each data element is an inclusion or exclusion criterion for the artifact
- The FHIR resource defined for each data element (e.g., “observation,” “condition,” “MedicationOrder,” “ReferralRequest”)

- The FHIR attributes required for each data element (e.g., “status,” “verificationStatus,” “onsetDateTime,” “valueQuantity”), along with the required concepts for each attribute (e.g., for the attribute “status”: “active,” “final,” “complete”)
- The value set(s) or specific terminology code(s) used to represent each data element

During pilot integration and testing of the CDS artifacts, the CDS Connect and b.well teams identified multiple gaps in the completeness and specificity of the required data available on the b.well platform. Extensive data mapping by b.well was required to address many of these gaps.

- **Laboratory test results:** More than 85 percent of lab results did not contain [LOINC](#) codes, the freely available standard terminology used for identifying health measurements such as laboratory results, observations, and other documents. Because most of b.well’s lab result data originated directly from reference laboratories, it was surprising that LOINC codes were not included.
- **Procedures:** More than 95 percent of procedures were represented using a Current Procedural Terminology ([CPT](#)[®]) code. Because CPT[®] is a proprietary coding system used for billing that requires a licensing agreement to use, the CDS Connect team represented procedures as either a [SNOMED-CT](#) or an ICD Version 10, Procedure Coding System (PCS) code. Most of the b.well procedure data originated from claims data, thus was coded using CPT.[®] The CDS Connect project team provide detailed information to help b.well map each procedure to the most appropriate SNOMED-CT or ICD-10-PCS code.
- **Medications:** More than 95 percent of the medications in the b.well database were represented using a National Drug Code (NDC), which are primarily used in medication manufacturing, packaging, or distribution. [RxNorm](#), the standard terminology used for clinical drugs, is commonly used in EHRs, pharmacy information management systems, and drug interaction software. Most of the b.well medication data originated from PBM systems (a third-party administrator of prescription drug programs for commercial and other health plans). b.well used an existing reference for cross-mapping NDC to RxNorm codes to resolve this issue.
- **Missing Data for ASCVD Calculation:** In a large population of end users, both a defined race code and smoking status were missing or did not align with the standardized terminology codes used to represent these concepts. Because both of these data elements are required in order to return an ASCVD risk score from the *ASCVD Risk Calculator* artifact (and the risk score is required as an inclusion criterion for the *Statin Use for the Primary Prevention of CVD* artifact), the CDS Connect team and b.well decided to map the missing codes for both race and smoking to the value that would return the lowest risk score to prevent over-estimation of CVD risk. This allowed the risk score to be calculated, but likely underestimated the score for an unknown percentage of end users.

b.well has already implemented several processes to address the missing data, including collecting the information directly from the end users via a health questionnaire.

- **FHIR “Status” attribute:** Many of the FHIR resources (e.g., “condition,” “observation,” “procedure”) required a status to be present in order to accurately include or exclude the specified data element (e.g., a status of “active” in order for a condition such as hypertension to be included). Most of the data received by b.well from other sources did not include status indicators. The CDS Connect team worked with b.well to determine how to handle each data element that required a status indicator. For condition data elements where status was not a critical element, mapping instructions were provided for each concept. For those conditions and the medications that required a more accurate status indication, additional recommendations were provided to further evaluate the data available:
 - For specific conditions such as diabetes and hypertension, a status of “active” is required, since both diabetes and hypertension are diseases that have the potential to be resolved. The project team recommended that b.well perform additional analysis and/or reporting to determine if any additional information was available to indicate an active status, such as a recent claim or diagnosis assignment.
 - For antihypertensive and statin medications, it was important to discern an active status (i.e., the individual is currently taking the medication) versus a historical medication (i.e., the patient took the medication at some point in the past, but is no longer taking it). The project team recommended that b.well perform additional analysis and/or reporting to determine if additional information was available to indicate an active status, such as the date that the medication was dispensed by a pharmacist.
- **Active Pregnancy or Breastfeeding:** b.well found it challenging to discern an active pregnancy or if an end user was currently breastfeeding, due to the nature and specificity of the data required to satisfy both observations. This information is used as exclusion criteria for several of the artifacts but was not available for the logic to use due to this absence of accurate data. b.well recognized that because of the latency of most claims data and their limited access to EHR data, data to identify this information would not be available for the pilot CDS. In the future, they intend to acquire more EHR data as well as information directly from the end user to help close this gap.

To assist b.well with these mapping activities, the CDS Connect team provided extensive instructions for each of the required mappings and assisted b.well throughout the process.

Preventive Health Artifacts Validation and Testing

Robust testing is integral to release accurate, reliable, and valid CDS. The preventive health artifacts were written using a test-driven development (TDD) approach.⁹ TDD is reputed to

produce software that is more robust and to contain fewer bugs than other approaches.⁹ With TDD, a battery of test cases is first created that defines the expected functionality of the software; the software is not considered complete until all defined test cases are successfully passed. For more information on the artifact testing, please refer to the *Implementation Guide* for each artifact located on the CDS Connect Repository.

The project team tested the preventive health artifacts throughout the development cycle using a comprehensive set of test cases and synthetic patient data. This testing provided assurance that the CQL logic was sound before beginning the pilot implementation and testing. More information on development testing is found in each artifact *Implementation Guide*.

Following the integration of the artifacts in the b.well environment, b.well began formal testing. The project team provided synthetic data to support testing each artifact. The b.well quality assurance analyst created end-user profiles to meet the inclusion and exclusion criteria for each artifact, and performed end-to-end testing for each recommendation. As part of their testing strategy, b.well coded each of the CDS artifacts independently using their existing methodology and the documentation provided by the CDS Connect project team, and compared the results from their coded expression to the results of the CDS logic implemented in their system. The results showed very close alignment, with differences primarily due to the code set definition for certain conditions (i.e., diagnoses). b.well uses a process to infer whether individuals are “at risk” for specific diagnoses without a verified diagnosis, thus capturing a larger population than the more specific definition defined by the USPSTF.

Pilot Findings and Lessons Learned

Pilot Objectives

The objectives established during the initial pilot planning for the CDS Connect project were met by the pilot activities. Through their collaborative efforts, b.well and the CDS Connect team incorporated the pilot CDS artifacts into the b.well platform, achieving a successful technical integration. Through artifact development, validation, technical integration, and testing activities, the project team confirmed that the preventive health CDS logic was triggered when appropriate, and that it captured and shared information as designed by the artifact logic and CQL integration engine.

Through the end-user survey, b.well and the CDS Connect team learned that end users generally found the educational information and challenges to be useful and that they planned to take action on the preventive health recommendation.

Through the pilot work, the CDS Connect team gained valuable information from b.well to support the CDS Connect Concept of Operations, and the information will enhance and validate the pilot CDS moving forward. The feedback and experiences of the b.well pilot team provided

important input to the CDS Connect project from CDS consumer and contributor perspectives alike. Detailed information on the findings are provided in the following sections.

Patient/End User Survey Findings

The team created a brief user survey for distribution to a limited number of nine b.well end users who completed challenges related to the USPSTF CDS. (The restriction to nine end users is based on limitations required by the Paperwork Reduction Act [PRA]). The questions and responses to the survey are shown in **Figure 5**.

Survey feedback provided valuable information to help understand the end user's perceptions and reactions to the preventive health CDS recommendations, although the limited number of respondents did not allow any statistically significant data analysis. b.well also felt it might have been more effective to survey end users directly following an event (e.g., completion of an educational challenge); the short pilot timeframe did not allow such implementation.

Figure 5. End User Survey Questions and Responses

Questions	Responses	% of Total
☐ Think about the health recommendation you received. Did you feel the information was relevant to you and your current health?	9	99.99%
I don't remember receiving this	2	22.22%
Strongly agree	1	11.11%
Somewhat agree	3	33.33%
Neither disagree or agree	1	11.11%
Somewhat disagree	1	11.11%
Strongly disagree	1	11.11%
☐ Please explain why you feel that way. Please select all that apply.	7	100.00%
This is an area I already know I need to work on	4	57.14%
I appreciated learning I need to work on this	0	0.00%
I do not agree this is something I need to do	0	0.00%
The information did not give me tips I can use	0	0.00%
I have not heard this information from my healthcare team	0	0.00%
The information gave me tips I can use	3	42.86%
This is something I'd like to talk about with my healthcare team	0	0.00%
Other	0	0.00%
The health information was based on the preventive care recommendations developed by the United States Preventive Services Task Force to help people stay healthy. Was the health information new to you, or had you heard this before?	7	100.00%
New	1	14.29%
Heard it before	6	85.71%
☐ Where did you hear about this health information previously? Please select all that apply.	5	100.01%
My healthcare team	2	50.00%
My insurance plan	1	16.67%
Another website	1	16.67%
A magazine	0	0.00%
b.well	1	16.67%
Other	0	0.00%
☐ The educational information was easy to understand.	7	100.01%
Strongly agree	2	28.57%
Somewhat agree	3	42.86%
Neither disagree or agree	1	14.29%
Somewhat disagree	0	0.00%
Strongly disagree	1	14.29%
☐ The information will help me improve my health.	7	100.00%
Strongly agree	2	28.57%
Somewhat agree	2	28.57%
Neither disagree or agree	2	28.57%
Somewhat disagree	0	0.00%
Strongly disagree	1	14.29%
☐ I plan to take action based on the recommendation(s) I received.	7	100.01%
Strongly agree	3	42.86%
Somewhat agree	2	28.57%
Neither disagree or agree	1	14.29%
Somewhat disagree	0	0.00%
Strongly disagree	1	14.29%

Overall, the respondents seemed to think the preventive health information was relevant to them, with more than 65 percent of respondents either agreeing or feeling neutral. Although a high percentage (86 percent) of respondents reported that the information was not new to them, more than 70 percent reported that they planned to take action on the recommendations received, and only one respondent reported that they did not plan to take action. In addition, more than 70 percent of respondents found the information easy to understand, and more than 55 percent thought the information would help improve their health, with 29 percent neutral.

In conclusion, the respondents were generally positive regarding the preventive health recommendations, although a greater number of surveyed respondents as well as a more refined survey process may have yielded additional useful data.

Quantitative Data Analysis

As mentioned previously in the [Pilot Implementation Planning](#) section of this document, the project team developed an analytic plan to provide quantitative data to help evaluate the effectiveness, accuracy, usefulness, and impact of the four patient-facing preventive health artifacts. The plan included pulling specified data into formatted reports at predetermined intervals (i.e., pre-pilot site implementation, during the pilot, and after the pilot conclusion) during the pilot process.

Pre-Pilot Site Implementation

The initial objective of the pre-pilot data analytics was to confirm that the pilot site had a sufficient number of end users who met the inclusion criteria for the five artifacts; further, for those end users, gain an understanding of the availability of data required for both the inclusion and exclusion logic for each artifact.

During the Pilot

During the pilot, data were collected to ensure the CDS artifacts were functioning as expected. The data included the number of end users with sufficient data available to determine inclusion, the number of end users that meet the inclusion criteria, the number of included end users with sufficient data to determine exclusions, and the total number of end users qualifying for each recommendation.

Pilot Conclusion

At the conclusion of the pilot, b.well provided data on the previously described metrics, on notifications rates for each CDS recommendation, and on completion rates for related educational challenges. The final analysis of the reports revealed the following high-level findings:

- During the 8-week clinical pilot, the total population of end users was 3,114, consisting of 54 percent male and 46 percent female, with the majority of end users between the ages of 21 to 60, inclusively.
- The number of unique users identified by each preventive health recommendation as meeting the inclusion criteria and not meeting the exclusion criteria is shown in **Figure 6**. Note that an end user may be counted as a “unique user” for each of the four recommendations.

Figure 6. Unique Users by Recommendation

Unique Users by Recommendation	
RECOMMENDATION	USERS
Glucose Part 1, Screening	591
Glucose Part 2, Counseling	104
Healthful Diet and Physical Activity for CVD Prevention	456
Statin Use for the Primary Prevention CVD	7

Figure 7 displays the completion rates of the related educational and action challenges on the b.well platform. In this chart, “Total Users” refers to the total number of end users targeted to receive the challenge. (This number is slightly less than the number of unique users by recommendation shown in Figure 6, as b.well applies their own methodology to the notification process, to avoid over-notification or the presentation of duplicate challenges to an end user.)

Figure 7. Challenges Completed by CDS Artifact and Challenge Content

Recommendation	Challenge	Total Users	Total User Completed	% Completed
Glucose Part 1, Screening	Get Screened for Diabetes	461	88	19%
Glucose Part 1, Screening	Schedule that Screening!	461	69	15%
Glucose Part 2, Counseling	Take Steps to Prevent Diabetes!	101	23	23%
Glucose Part 2, Counseling	You Can Lower Your Risk for Diabetes!	102	28	27%
Glucose Part 2, Counseling	Schedule that Appointment Today!	101	16	16%
Healthful Diet and Physical Activity for CVD Prevention	Give Your Heart Some Love	377	94	25%
Healthful Diet and Physical Activity for CVD Prevention	A Heart-Healthy Plate	377	91	24%
Healthful Diet and Physical Activity for CVD Prevention	Strong Body, Strong Heart	376	92	24%
Healthful Diet and Physical Activity for CVD Prevention	Take Action to Protect Your Heart	376	75	20%
Statin Use for the Primary Prevention CVD	Let's Talk about Statins and You	11	0	0%
Statin Use for the Primary Prevention CVD	Schedule That Appointment To Talk About Statins And You!	11	0	0%

Given the relatively short pilot duration of 8 weeks, the team was not able to draw any conclusive findings on the impact to patient care or outcomes.

Post-Pilot Plans for the CDS

b.well expressed positive feedback on their participation in the preventive health CDS pilot and felt that providing the CDS along with the educational challenges is extremely beneficial to their end users. They would strongly consider continued use of the CDS and identified enhancement opportunities that would benefit integration, data availability, educational content, and notifications that were not possible during the pilot, due to the short integration and implementation timeframe.

Key Lessons Learned and Future Recommendations

Throughout the pilot process, several valuable lessons surfaced that impacted the pilot activities as well as provided critical information to use when planning any additional CDS work. Some of these are incorporated into other areas of the pilot report, but key lessons learned and recommendations include:

1. **Aggregating data from multiple sources presents great opportunities while introducing challenges:** b.well receives end-user data from multiple sources, including claims, EHRs, PBM systems, reference laboratories, and PGHD (e.g., data from wearable devices, surveys and questionnaires, and mobile applications). While these rich sources of data provided additional opportunities for ensuring greater coverage of required data elements, challenges were also identified related to data specificity. As described in the section on *Data Analysis and Mapping Requirements*, multiple gaps were identified in the completeness and specificity of the required data available on the b.well platform, and extensive data mapping by b.well resources was required. Implementers should recognize that multiple sources of data may compound the data analysis and mapping efforts. Potential gaps in data availability, definition, and specificity should also be considered.
2. **Data mapping is a resource intensive process and can impact the implementation timeline:** b.well estimated that data mapping consumed nearly 25 percent of their engineering resource hours, equaling about 80 hours, with another 20 hours required for clinical and data analytics resources. Future implementation efforts should consider this mapping effort when developing an integration and implementation timeline, and should ensure access to clinical informaticists to assist in these efforts. In addition, the health IT industry would benefit from broader adoption of standardized terminologies and the FHIR data model in the future, supporting increased interoperability and aggregation of data.
3. **Integration and pilot FHIR support:** The b.well technical team had no experience with CQL or CDS Hooks, and only limited experience with FHIR. This lack of experience was not surprising given the relative newness of these standards. This made the aggressive integration timeframe even more challenging. Although the CDS Connect team provided documentation, tools, and technical support to assist b.well in these efforts, the original target date to implement the CDS in the b.well platform and turn on the notification process was moved forward by 1 week to accommodate the efforts. In future pilot efforts, the experience of the pilot technical team with FHIR and other standards should be considered during the technical evaluation and planning stages.
4. **Engaging patients as CDS end users:** 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.¹⁰ The CDS pilot benefitted from the experience and expertise of b.well in providing patient-facing health management resources and tools. However, due to the tight implementation timeline, there were limited opportunities to engage the b.well end users to provide feedback on educational materials and other pilot aspects. b.well also desired to personalize the recommendations provided to each end user to include individual risk factors identified by the CDS but were unable to accomplish this within the integration timeframe. Future patient-facing CDS pilots should consider a pilot

partner with consumer/patient-facing experience and expertise, and should ensure a pilot timeframe that allows personalization and engagement opportunities to be realized.

Conclusion

The pilot implementation achieved the goal of developing, refining, and verifying that the preventive health CDS performed as expected when integrated into a consumer-facing health IT platform. The objectives established during the initial pilot planning for the CDS Connect project were met by the pilot activities, including: (1) successful integration with the b.well platform; (2) validation of the five preventive health CDS artifacts and associated logic; and (3) experience by the pilot site that the information provided was valuable and contributed to their overall mission to reduce the prevalence of avoidable chronic disease, while putting consumers at the center of their healthcare.¹

In this pilot collaboration, CDS Connect benefitted from b.well's technical, clinical, and operational expertise. The CDS Connect team gained valuable information to support the CDS Connect Concept of Operations, and to enhance and validate the piloted CDS moving forward. The feedback and experiences of the b.well pilot team provided valuable input to the ongoing CDS Connect project from the perspective of a developer and implementer of shared CDS. In addition, although the use of standards such as FHIR and HL7 CQL has gained additional traction since the inception of the CDS Connect project in 2016, there remains a significant opportunity for broader adoption of these standards to further enhance the ease of implementing CDS and advance the interoperability of data across multiple health IT platforms.

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