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Brief Behavioral Counseling Interventions for Excessive Alcohol Consumption with Optional Referral to Treatment: Implementation Guide

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Table of Contents

1. Introduction 5

1.1 Background 5
1.2 Scope, Purpose, and Audience of this Implementation Guide 7

2. Alcohol Screening and Brief Intervention: Clinical Implementation Considerations 8

2.1 Alcohol Screening Implementation Considerations 9
2.2 Brief Behavioral Counseling Intervention Implementation Considerations 11
2.3 ASBI Implementation Resources 12

3. Artifact Description and Use 14

3.1 Artifact Description 14
3.2 Health Scenarios Supported by this Artifact 15
3.3 Health Scenarios Supported with Customization of the Coded Expression 17
3.4 CDS Logic Descriptions and Recommended Actions 18

4. Guideline Interpretation and Clinical Decisions 20

4.1 Evidence-based Sources for Artifact Development 20
4.2 Guideline Translation Summary 21

5. Technical Details 22

5.1 Artifact Definition Standards 22
5.2 Artifact Definition Structure 24
5.3 Artifact Implementation Standards 27
5.4 Artifact Implementation Structure 28

6. Artifact Testing 31

6.1 Levels of Testing 31
6.2 End-to-End Test Harness 36

List of References 39

Acronyms 45

Appendix A. Artifact Logic and Decision Log 47

A.1 Artifact CDS Logic Flow 47
A.2 Artifact Semi-structured Representation 50
A.3 CDS Concept Definitions 68
A.4 Artifact Development Decision Log 72

Appendix B. CDS Actions and Brief Intervention Content 75

B.1 Brief Interventions Related to Alcohol Use 75
B.2 Brief Interventions related to Non-Alcohol Substance Use 88

Appendix C. Data Requirements 93

Notice 96

List of Figures

Figure 1. Depiction of the relationship between the components that define the artifact 24
Figure 2. PlanDefinition component expressed in FHIR Shorthand (FSH) 25
Figure 3. An excerpt from the CQL logic within the Library..... 26
Figure 4. Notional depiction of ASBI CDS integration with a health IT system. 29
Figure 5. Diagram showing the test-driven development approach taken for authoring CQL..... 32
Figure 6. Example logic test case 34
Figure 7. Notional ASBI CDS integration depicting which aspects can be emulated without a real health IT system..... 37
Figure 8: Alcohol Brief Intervention and Referral CDS Logic Flow for Pregnant Patients..... 48
Figure 9: Alcohol Brief Intervention and Referral CDS Logic Flow for All Males and Female Patients That Are Not Pregnant 49

List of Tables

Table 1. ASBI Implementation Resources..... 13
Table 2: Zone Levels and Descriptions 15
Table 3. List of key logical expressions defined in the CQL Library..... 27
Table 4. Required FHIR Server capabilities 30
Table 5. List of logic tests..... 35
Table 6: CDS Concept Definitions 68
Table 7: Artifact Development Decision Log..... 72
Table 8: FHIR Data Requirements for this Artifact..... 93

1. Introduction

The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is the primary federal agency responsible for safeguarding the nation's public health through the control and prevention of disease, injury, and disability. Within CDC, the National Center on Birth Defects and Developmental Disabilities' (NCBDDD) mission is to advance the health and well-being of babies, children, and people with disabilities. NCBDDD aims to save babies through surveillance, research, and prevention of birth defects and infant disorders. As part of these efforts, the NCBDDD engaged the CMS Alliance to Modernize Healthcare federally funded research and development center (Health FFRDC) to collaborate on a project that seeks to help prevent prenatal alcohol use. Alcohol use during pregnancy can cause birth defects and developmental disabilities, collectively known as fetal alcohol spectrum disorders (FASDs)[1]. Alcohol use during pregnancy is also linked to other negative outcomes, such as miscarriage, stillbirth, preterm (early) birth, and sudden infant death syndrome (SIDS). This project seeks to develop standards-based, interoperable alcohol screening and brief intervention (ASBI) clinical decision support (CDS) artifacts (i.e., actionable medical knowledge such as clinical practice guidelines, peer-reviewed articles, or local best practices, translated into computable and interoperable CDS logic expressions) that can help decrease alcohol use during pregnancy and reduce the risk of FASDs and other negative pregnancy and birth outcomes.

The U.S. Preventive Services Task Force (USPSTF) and other organizations have provided evidence-based recommendations for the implementation of ASBI in primary care settings for adults age 18 years or older, including pregnant women, to reduce unhealthy alcohol use (Curry et al., 2018). To encourage the adoption of ASBI, CDC engaged with the Health FFRDC to support transformation of the recommendation guidance and other evidence-based resources into shareable and standards-based CDS that can be integrated into electronic health record (EHR) systems and other health information technology (IT).

1.1 Background

Unhealthy alcohol use encompasses a spectrum of behaviors, from risky drinking (drinking more than the recommended daily, weekly, or per-occasion amounts) to alcohol use disorder (harmful alcohol use, abuse, or dependence). Any alcohol use is considered unhealthy in pregnant women (Curry et al., 2018). Excessive alcohol consumption (i.e., excessive drinking) includes binge drinking (i.e., drinking four or more drinks for women or five or more drinks for men, within about two hours) and heavy drinking (i.e., eight or more drinks a week for women and 15 or more drinks a week for men). Excessive alcohol use also includes any drinking by pregnant women or those under 21 years of age (U.S. Department of Health and Human Services and U.S.

[1] The following document mentions pregnancy-related or associated events. It makes use of concepts or descriptions that align with the traditional gender definitions by using concepts like "pregnant women" or "women." However, the concepts described are translatable to all persons that experience pregnancy, regardless of their gender identity. Wherever possible, we have used the term "people who are pregnant" in this document to describe individuals that experience pregnancy, unless citing research studies or other scientific resources that used the term "pregnant women," or "women."

Department of Agriculture, 2015).[2] Excessive drinking is associated with a variety of short- and long-term health risks, including motor vehicle crashes, violence, sexual risk behaviors, high blood pressure, and various cancers. The risk of harms increases with the amount of alcohol consumed. For some conditions, like some cancers, the risk increases even at very low levels of alcohol consumption (i.e., less than one drink) (Centers for Disease Control and Prevention, 2018). Excessive drinking was responsible for nearly 10 percent of deaths in the United States from 2006 to 2010 (O'Connor et al., 2018) (Mokdad, Marks, Stroup, & Gerberding, 2004), and is the third leading cause of preventable deaths in the U.S. (National Institute on Alcohol Abuse and Alcoholism, n.d.) (Stahre, Roeber, Kanny, Brewer, & Zhang, 2014). In addition, prenatal alcohol exposure is a leading preventable cause of birth defects and developmental disabilities (Ismail, Buckley, Budacki, Jabbar, & Gallicano, 2010).

There are a number of screening instruments with documented evidence of having acceptable sensitivity and specificity for detecting unhealthy alcohol use (Curry et al., 2018). Screening, followed by a brief intervention when indicated, has been shown to reduce episodes of binge drinking and the amount of alcohol consumed weekly and to increase compliance with recommended drinking limits (O'Connor et al., 2018). In a 2018 recommendation statement, the USPSTF recommended that ASBI be implemented for all adults 18 years and older, including pregnant individuals, in primary healthcare settings (Curry et al., 2018). However, multiple reports indicate that ASBI is not occurring routinely or consistently (McKnight-Eily et al., 2014, 2020).

As part of this project, the Health FFRDC worked with NCBDDD to develop ASBI CDS artifacts, with the aim to accomplish the following outcomes:

- Drive improved public health outcomes by enabling consistent interpretation and implementation of evidence-based guidelines for ASBI. Improved public health outcomes include an increase in the number of adults, including persons of reproductive age, who are screened for alcohol use; an increase in the number of adults who are delivered a brief intervention after screening indicates they drink above recommended levels; a decrease in excessive alcohol use among persons of reproductive age; and a decrease in any alcohol use among persons who may be pregnant or are trying to become pregnant.
- Exercise a reproducible process for translating clinical practice guidelines into standards-based, interoperable formats for integration into local health IT systems.
- Contribute to efforts to improve speed, efficiency, accuracy, consistency, and effectiveness of dissemination and implementation of clinical practice guidelines.

To facilitate NCBDDD's mission and progress toward these outcomes, the Health FFRDC Development Team created three alcohol screening CDS artifacts and two alcohol brief intervention CDS artifacts:

[2] When referring to drinking alcohol above recommended guidelines, the terms "excessive alcohol consumption", "excessive alcohol use" or "excessive drinking" are used in this guide to align with the U.S. Department of Health and Human Services and the U.S. Department of Agriculture's 2015-2020 Dietary Guidelines for Americans. If an alternate term is used within a cited reference (e.g., "unhealthy alcohol use"), the alternate term has been retained.

- *Alcohol Screening Using the USAUDIT (Alcohol Use Disorders Identification Test, Adapted for Use in the United States)*, referred to as the *"USAUDIT Alcohol Screening"* artifact
- *Alcohol Screening Using the World Health Organization (WHO) Alcohol Use Disorders Identification Test (AUDIT)*, referred to as the *"WHO AUDIT Alcohol Screening"* artifact
- *Alcohol and Other Substance Use Screening Using the National Institute on Drug Abuse Quick Screen (NIDA QS) and USAUDIT (Alcohol Use Disorders Identification Test, Adapted for Use in the United States)*, referred to as the *"NIDA QS to USAUDIT Alcohol Screening"* artifact
- *Brief Behavioral Counseling Interventions for Excessive Alcohol Consumption with Optional Referral to Treatment*, referred to as the "*Alcohol Brief Intervention and Referral*" artifact
- *Facilitating Shared Decision Making For People Who Drink Alcohol: A Patient Decision Aid*, referred to as the *"Decision Aid for Your Drinking"* artifact

These CDS artifacts are available to the public and are posted on CDS Connect, a web-based platform for authoring and sharing CDS artifacts. The information posted includes tools and resources (i.e., implementation guides, synthetic testing data, links to any CDS software and other accompanying material) that serve as building blocks when evidence-based practice recommendations are translated into interoperable CDS.

1.2 Scope, Purpose, and Audience of this Implementation Guide

This implementation guide provides information about the development and potential uses of the *Alcohol Brief Intervention and Referral* CDS artifact.

This artifact identifies patients screened for alcohol use and provides brief intervention care (e.g., brief interventions recommendations) to consider based on the patient's alcohol screening results and reported level of drinking, including suggestions for brief interventions and links to targeted patient education materials and tools. The artifact also suggests and facilitates a referral for the patient to receive diagnostic evaluation and possible treatment of alcohol use disorder, if indicated. The logic for the CDS artifact is derived from several evidence-based guidelines that are described in Section 4.1. When additional guidance was needed, the CDS Development Team used the numerous additional references listed in the References section of this document.

Section 2 of this implementation guide provides high-level information and additional references for healthcare organizations considering implementing this CDS artifact (and any of the associated ASBI CDS artifacts) to support alcohol screening and brief intervention. The information focuses on the adoption of ASBI by clinical staff, and the references listed in Table 1 contain much more detailed guidance on the clinical aspects of ASBI implementation. The remaining sections of this implementation guide contain details about the CDS artifact, logic expressions, guideline interpretations and decisions, and technical implementation considerations.

Organizations who might consider implementing this CDS logic include primary care practices, as well as perinatal care clinics and other healthcare organizations interested in implementing evidence-based CDS to help deliver personalized alcohol use brief interventions to their patients.

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

- **Clinicians, Quality Improvement Leaders, and Health Administrators** at healthcare organizations and primary care practices who wish to implement, test, and execute CDS related to alcohol screening and brief intervention in their EHRs or other health IT systems
- **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 Clinical Quality Language (CQL) in their own work
- **Organizations or Individuals** interested in developing their own CDS artifacts, who may find this document helpful as a resource for the process of translating clinical guidelines into mature Clinical Quality Language (CQL) artifacts.

2. Alcohol Screening and Brief Intervention: Clinical Implementation Considerations

As mentioned previously, the USPSTF recommends alcohol screening in primary care settings for adults 18 years or older, including pregnant women, and providing brief behavioral counseling interventions to those individuals engaged in unhealthy alcohol consumption. Alcohol screening and brief behavioral counseling interventions have been shown to be effective in reducing unhealthy alcohol use (Curry et al., 2018). Although 81 percent of U.S. adults in 13 states and the District of Columbia reported being asked by their healthcare provider about alcohol use, only about 38 percent reported being asked about binge drinking (i.e., drinking four or more drinks for women and five or more drinks for men on one occasion) during a routine checkup in the last two years (McKnight-Eily et al., 2020). Among adults who reported binge-level consumption, 80 percent (or four of five persons) were not counseled to reduce their drinking at that checkup (McKnight-Eily et al., 2020).

Increasing the rate of alcohol screening and brief behavioral counseling for excessive alcohol consumption is an important priority for preventive care. According to CDC, alcohol is the third leading cause of preventable death in the United States (Mokdad et al., 2004), with more than 88,000 people dying from alcohol-related causes annually (Stahre et al., 2014). The rate of alcohol-related deaths more than doubled from 1999 to 2017, along with an increase in alcohol consumption (White, Castle, Hingson, & Powell, 2020). In addition, 55.3 percent of people 18 years or older reported that they drank alcohol within the past month, with more than 25 percent engaging in binge drinking, defined as having more than four drinks for women or five drinks for men in about two hours (National Institute on Alcohol Abuse and Alcoholism, n.d.) (Substance Abuse and Mental Health Services Administration, 2018).

Prenatal exposure to alcohol can lead to several adverse events and increases the risk of birth defects and developmental disabilities such as FASDs. Despite this fact, between 2018 and 2020, nearly 1 in 7 pregnant people in the U.S. reported drinking alcohol in the past 30 days and about 1 in 20 reported binge drinking (Gosdin, Deputy, Kim, Dang, & Denny, 2022).

Although this implementation guide focuses on brief behavioral counseling interventions, a holistic approach to alcohol screening and brief intervention is important. This includes selecting and administering evidence-based alcohol screening instruments to identify people who may require brief behavioral counseling and possible referral for evaluation and treatment for alcohol use disorders. A holistic approach also includes providing information to people to help them understand their drinking and consider the need to reduce consumption or quit.

The following sections provide high-level information for potential implementers to consider before integrating alcohol screening and brief intervention into their clinical practice. The information focuses on the adoption of ASBI by clinical staff. Resources that provide more detailed guidance on planning, implementing, and ongoing process improvement for ASBI implementation are provided in Section 2.3.

2.1 Alcohol Screening Implementation Considerations

Higgins-Biddle et al. (Centers for Disease Control and Prevention, 2014) pointed out that when considering the implementation of alcohol screening, early evaluation and planning is necessary to determine:

- Which patients will be screened and how often?
- Which alcohol screening instrument will be used?
- How and where will the screening take place?
- How will screening results be stored and shared with other staff, as well as recorded in the patient's record?

2.1.1 Alcohol Screening Instrument Selection

Selecting an alcohol screening instrument is an important decision. Numerous alcohol screening instruments are available, but only a few have been fully tested for sensitivity and specificity. The full, 10-question AUDIT is considered the "gold standard" of alcohol screening instruments, with the first three questions measuring alcohol consumption, and the next seven questions measuring alcohol-related harm and symptoms of dependence (Centers for Disease Control and Prevention, 2014).

The developers of the WHO version of the AUDIT assumed a standard drink size of 10 grams; averaging drink sizes across the countries studied as the typical serving size of drinks and recommendations on what constitutes "drinking too much" varies from country to country (Higgins-Biddle & Babor, 2018). Consequently, the WHO AUDIT manual recommends adapting AUDIT questions #2 and #3 based on the standard drink size and recommended alcohol consumption levels in the country where it will be used (Babor & Higgins-Biddle, 2001).

When researching the evidence on the sensitivity and specificity of various screening instruments, the USPSTF identified the original WHO version of the AUDIT-C (i.e., AUDIT-Consumption), followed by the more detailed questions of the full WHO AUDIT, as providing both high sensitivity and specificity (O'Connor et al., 2018). The USPSTF further recommended that if patients screen positive on a brief screening instrument (e.g., the AUDIT-C, USAUDIT-Consumption [USAUDIT-C], or Single Alcohol Screening Question), clinicians should follow up with a more in-depth assessment with greater specificity (e.g., the AUDIT) (Curry et al., 2018). In their recommendation statement for screening and behavioral counseling to reduce unhealthy alcohol use, the USPSTF found that the WHO version of the AUDIT-C and AUDIT "appeared to be the best overall instruments for screening adults for the full spectrum of unhealthy alcohol use" (Curry et al., 2018). The Task Force also noted that although no studies on the USAUDIT or USAUDIT-C were published during their evidence search window, the use of the U.S. versions of the AUDIT-C and AUDIT, designed to use U.S. standard drink sizes and align with National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommendations, were likely to improve on the performance of the WHO versions of the AUDIT and AUDIT-C (O'Connor et al., 2018).

The USAUDIT is based on the same 10 questions developed by WHO, adjusted for the standard U.S. drink size of 14 grams and U.S. low-risk drinking guidelines recommended by the United States Dietary Guidelines and the NIAAA (Higgins-Biddle & Babor, 2018). The USAUDIT further adjusts questions one through three by expanding the number of responses and modifying the wording of question three. Questions #4 through #10 are identical to the WHO AUDIT. When comparing the WHO AUDIT and USAUDIT screening results, the authors concluded that when used in the U.S., the USAUDIT provides greater accuracy than the WHO AUDIT, identifying reported drinking above recommended levels with no false positives and only a few false negatives (Higgins-Biddle & Babor, 2018).

Either the U.S. or WHO versions of the AUDIT alcohol screening questionnaires are expressed in each of the following CDS artifacts:

- *USAUDIT Alcohol Screening*
- *WHO AUDIT Alcohol Screening*
- NIDA QS to USAUDIT Alcohol Screening

In addition to the USAUDIT, the NIDA QS is also expressed in the third artifact, *NIDA QS to USAUDIT Alcohol Screening*. The NIDA QS is a validated, brief 4-question screening tool for multiple substances (i.e., alcohol, tobacco, nonmedical use of prescription drugs, and illicit drugs) appropriate for patients age 18 or older (National Institute on Drug Abuse, 2009). It enables clinicians to evaluate the frequency with which patients have used these substances in the past year so further screening can be performed, if indicated. The *NIDA QS to USAUDIT Alcohol Screening* CDS artifact flows from presenting the patient with the four NIDA QS questions (one of which evaluates the frequency of "heavy drinking" days in the past year) to the full USAUDIT if the patient screens positive for heavy drinking. NIDA defines heavy drinking

as having one or more days in the past year when a man had five or more drinks or a woman had four or more drinks (National Institute on Drug Abuse, 2009).

Implementers are encouraged to carefully evaluate the differences in each screening questionnaire, considering which one aligns best with their organizational needs and clinician preference. Section 2.3 includes resources that contain additional information and guidance on implementing the USAUDIT and the WHO AUDIT.

2.1.2 Alcohol Screening Implementation

When implementing alcohol screening as CDS embedded in an EHR or health IT system, it is necessary to determine current health IT capabilities and limitations, and workflow modifications that might be required. The screening CDS can be integrated into clinical workflow in several different ways. Examples include:

- As an electronic questionnaire administered to the patient by clinic staff, such as a medical assistant or nursing professional, with the patient responses entered into the health IT system
- As a patient-facing questionnaire completed electronically by the patient, through either a patient portal, on a tablet or similar device, or even a mobile app

Delivering the screening questionnaire in an electronic format directly to patients can help lower the burden on clinical staff, although these capabilities may not yet be available in most health IT systems. As the use of health IT and CDS evolves, clinicians no longer need to be the sole target of CDS information and alerts. Engaged patients and their caregivers are increasingly seeking health information to help guide them in their healthcare decisions and better manage their health. 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 (Fiks, 2011).

Regardless of how the screening questionnaire is displayed and the responses are captured, the resulting score should be reviewed by a clinician who can offer brief behavioral counseling to the patient based on the screening results. The clinician should also consider the need to refer the patient to evaluation and treatment if indicated by the screening responses.

2.2 Brief Behavioral Counseling Intervention Implementation Considerations

The USPSTF identified evidence that providing brief behavioral counseling to adults ≥ 18 years of age with positive alcohol screening results reduced excessive drinking. Evidence showed "reductions in alcohol use (by a mean of 1.6 drinks per week) and in the odds of exceeding recommended drinking limits (by 40%) and heavy use episodes (by 33%) at 6 to 12 months of follow-up" (O'Connor et al., 2018). For pregnant women, the use of brief counseling increased the likelihood of maintaining abstinence during their pregnancy (Curry et al., 2018).

Consequently, when alcohol screening indicates a patient is drinking above recommended levels, providing a brief intervention is a critical step in lowering their risk.

Tailoring the provision of brief intervention to the organization's needs, capabilities, and resources is critical to the success of ASBI implementation in a healthcare setting. In the step-by-step guide written by Higgins-Biddle et al. (Centers for Disease Control and Prevention, 2014), these considerations include determining the following:

- Who will deliver the intervention, based on time availability, knowledge and experience, and interpersonal skills?
- When will the interventions be delivered (i.e., during the same visit as the screening, or at a follow-up visit)?
- How will clinicians be trained on providing brief interventions?
- How will follow-up occur with patients who receive an intervention?
- How will the intervention be documented?
- If a referral for further evaluation and possible treatment is needed, what is the process today for these referrals? For example, how will the patient be guided to accept additional help, to whom should the referral be directed, and how is follow-up with the referring provider handled?

The resources listed in Section 2.3 include detailed guidance to assist your practice in addressing the above implementation questions and other considerations in providing brief interventions. In addition, the *Alcohol Brief Intervention and Referral* CDS artifact described in this implementation guide identifies patients screened for alcohol use and provides care recommendations to consider based on the patient's reported level of drinking, including suggestions for brief counseling interventions and links to targeted patient education materials and tools. The artifact also suggests and facilitates a referral for the patient to receive diagnostic evaluation and possible treatment of alcohol use disorder, if indicated. Prior to implementing this CDS artifact, organizations are encouraged to evaluate clinician expertise related to providing brief interventions to patients with excessive alcohol consumption and provide additional training as indicated.

2.3 ASBI Implementation Resources

Numerous evidence-based manuals and resources exist to guide practices in the implementation of alcohol screening and brief intervention for those patients who demonstrate excessive drinking based on their screening. Some of these include the following resources:

Table 1. ASBI Implementation Resources

Reference	Sponsor	Additional Information
Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices (Centers for Disease Control and Prevention, 2014)	CDC NCBDDD	This guide is written to help practices plan and adapt ASBI to their unique operations, providing the steps to plan, implement, and continually improve this preventive care service. Additional information on implementing the USAUDIT is also included.
The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001)	WHO	This manual describes how to use the WHO version of the AUDIT screening tool. It is designed to be used with the WHO manual "Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care" to provide a comprehensive approach to ASBI.
The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners (Babor, Higgins-Biddle, & Robaina, 2017)	Substance Abuse and Mental Health Services Administration	Based on the U.S. adaption of the Alcohol Use Disorders Identification Test (USAUDIT), this guide provides instruction for the clinical application of the USAUDIT for primary care practices.
A review of the Alcohol Use Disorders Identification Test (AUDIT), AUDIT-C, and USAUDIT for screening in the United States: Past issues and future directions (Higgins-Biddle & Babor, 2018)	N/A	This paper describes the WHO version of the AUDIT-C and AUDIT, and provides the rationale for development of the USAUDIT, adapted to U.S. standard drink sizes. It provides details on the differences between the WHO and U.S. versions.
2015-2020 Dietary Guidelines for Americans (U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015)	HHS and U.S. Department of Agriculture	These dietary guidelines provide guidance for choosing a healthy diet and preventing diet-related chronic diseases. Appendix 9 provides specific guidance on alcohol use.
Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement (Curry et al., 2018)	USPSTF	These guidelines provide an update on the original USPSTF 2013 recommendation on screening for unhealthy alcohol use in primary care settings.
Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care (Babor & Higgins-Biddle, 2001)	WHO	This manual focuses on conducting brief interventions for patients with alcohol use disorders, or who may be at risk of developing them, and is designed to be used with the WHO manual "The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care."
Fetal Alcohol Spectrum Disorders (FASD) Training and Resources (Centers for Disease Control and Prevention, n.d.)	CDC NCBDDD	Free, online training available for healthcare providers who care for women at risk for an alcohol-exposed pregnancy, and for those who work with individuals living with fetal alcohol spectrum disorders (FASDs).
Guidelines for the identification and management of substance use and substance use disorders in pregnancy (World Health Organization, 2014)	WHO	Guidelines for professionals to assist women who are pregnant and use alcohol or drugs or have a substance use disorder, to achieve healthy outcomes for themselves and their fetus.

Reference	Sponsor	Additional Information
Alcohol Screening and Brief Intervention: A Guide for Public Health Practitioners (American Public Health Association and Education Development Center, 2008)	American Public Health Association	This manual provides background information and steps for conducting ASBI in a variety of public health settings, with guidance on conducting screening and brief intervention.

3. Artifact Description and Use

3.1 Artifact Description

The *Alcohol Brief Intervention and Referral* artifact identifies patients who were screened for alcohol use using either the U.S. or the WHO version of the AUDIT questionnaire within the past 12 months but have no evidence of receiving a brief intervention. For each patient identified as needing a brief intervention, the CDS artifact logic considers the appropriate inclusion and exclusion logic, and provides patient-specific alcohol screening results information, brief behavioral counseling intervention care (from here on referred to as "brief interventions") recommendations, and targeted patient education resources to the clinician. The brief interventions are formulated based on the patient's overall AUDIT score, reported level of drinking, AUDIT Zone (see Table 2), and other patient attributes (e.g., being pregnant or trying to become pregnant, or having a history of alcohol use disorder). The CDS artifact also suggests and facilitates a referral for the patient to receive diagnostic evaluation and possible treatment for alcohol use disorder, based on the patient's AUDIT score, screening responses, and relevant patient-specific information (see Appendix B for more information on the brief intervention content). Potential implementers are encouraged to remind their clinicians to consider the patient's pregnancy status, medical conditions, medications, social history, and any family history of alcohol problems in responding to the AUDIT questions prior to making care decisions related to the patient's alcohol use (Babor et al. 2001).

The CDS logic is dependent on the ability to ascertain a patient's AUDIT alcohol screening score to determine the appropriate Zone designated for each patient (see Table 2) (Babor et al., 2017; Babor & Higgins-Biddle, 2001). Thus, the capability to record and store alcohol screening results within an EHR or health IT system using either the U.S. or WHO version of the AUDIT questionnaire must be in place prior to implementing this CDS artifact. Although this artifact does not include the logic for alcohol screening using a version of the AUDIT questionnaire, the CDS Development Team created three alcohol screening CDS artifacts as part of this project, available on CDS Connect for implementation (see Section 1.1 for the names and links to these artifacts). The CDS Development Team and the CDC sponsors of this work took a modular approach to developing ASBI CDS artifacts to lessen the complexity of each artifact and enable organizations to only integrate portions of logic that they really need (e.g., are not already present in their health IT system). A modular approach allows for personalized implementation choices without the need to edit CDS code.

If the *NIDA QS to USAUDIT Alcohol Screening* CDS screening artifact has been implemented, or a compatible version of NIDA QS to AUDIT screening is being used, this artifact provides brief interventions and associated patient education resources relevant to both the patient's AUDIT alcohol screening and NIDA QS substance use responses (i.e., tobacco, nonmedical use of prescription drugs, illicit drugs).

Table 2: Zone Levels and Descriptions [3]

Zone Levels	USAUDIT Score: Female or Male age greater than 65	USAUDIT Score: Male age less than or equal to 65	WHO AUDIT Score: Female or Male age greater than 65	WHO AUDIT Score: Male age less than or equal to 65	Description
1	0 to 6	0 to 7	0 to 6	0 to 7	Low-risk drinking
2	7 to 15	8 to 15	7 to 15	8 to 15	Drinking in excess of guidelines
3	16 to 24	16 to 24	16 to 19	16 to 19	Harmful or hazardous drinking
4	25 or more	25 or more	20 or more	20 or more	High-risk drinking

3.2 Health Scenarios Supported by this Artifact

The *Alcohol Brief Intervention and Referral* artifact was developed and published based on the patient's alcohol screening results to: 1) help healthcare practices and clinicians identify adults screened for alcohol use but not yet provided a brief intervention; 2) provide suggested content for brief interventions and links to targeted patient education materials and tools; and 3) suggest and facilitate a patient referral for diagnostic evaluation and possible treatment of alcohol use disorder, if needed. The guidance is derived from several evidence-based references described in Section 4.1. This artifact supports the following scenarios when implemented in a health IT system in a healthcare setting. Note that each scenario is populated with a fictitious name and health data to provide context to the scenario.

Scenario 1: Increasing the rate of brief intervention through automated identification of individuals screened for alcohol use with no evidence of receiving a brief intervention.

> Commonwealth Physicians Group (CPG) is a medium-size practice in Virginia with six primary care clinicians and approximately 10,000 patients. CPG recently implemented patient-facing alcohol use screening using the *USAUDIT Alcohol Screening* CDS artifact via a hand-held tablet provided to patients during check-in at the office. The screening results are integrated with the group's electronic health

[3] *Adapted from "The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners" by Babor, et al., 2017, p. 12, and "Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care" by Babor & Higgins-Biddle, 2001, p.12.*

record (EHR). As a result, CPG has seen a large increase in the percentage of patients being screened for alcohol use, but their clinicians have been struggling to ensure each patient is also offered the appropriate brief intervention. It requires additional time to review the patient's screening results to determine which brief interventions are appropriate, especially while managing all of their patient population's health needs including annual wellness exams, acute illnesses, and chronic diseases, The brief interventions they are providing are not consistent with recommendations or patient-specific. After implementing the *Alcohol Brief Intervention and Referral* artifact, CPG's rates for providing brief interventions improved and their clinicians reported improved satisfaction and greater confidence in their ability to provide an appropriate brief intervention to their patients. Patient satisfaction scores also increased after implementation of the CDS artifact.

Scenario 2: Ensuring all people who are pregnant or trying to become pregnant receive brief intervention on the importance of abstinence from alcohol and any substance use during pregnancy.

Summer Women's Health (SWH) is an obstetrics and gynecology (OB-GYN) practice in Tennessee. The SWH clinicians are concerned that their pregnant patients (and those who are trying to become pregnant) may not understand the risks of drinking alcohol or using other substances at any time during their pregnancy (World Health Organization, 2014)(Centers for Disease Control and Prevention, 2014). They have determined that implementing an electronic method of screening all of their patients for substance use is an important first step to address this issue but want to ensure that their patients are also receiving the appropriate brief intervention(s) and relevant patient education on the risks of alcohol and other substance use during pregnancy. After implementing substance use screening using the *NIDA QS to USAUDIT Alcohol Screening* CDS artifact, along with this *Alcohol Brief Intervention and Referral* artifact, the SWH clinicians now feel confident that not only is each patient routinely screened for substance use, and provided information reinforcing the importance of not using alcohol and other substances (i.e., tobacco, nonmedical use of prescription drugs, and illicit drugs) throughout their pregnancy, additional screening and brief intervention on alcohol use can be provided. SWH clinicians experience a reduction in cognitive burden as a result of incorporating this CDS into their workflow and feel more confidence in the quality of care being provided to their patients. SWH's practice-wide metrics for substance use screening in pregnancy improve for all providers.

Scenario 3: Reducing clinician burden by streamlining the referral process for evaluation and treatment of possible alcohol use disorder.

Sam is 35 years old, travels every week for business, and relaxes on the weekends with his friends at a local bar that offers his favorite craft beer and artisan tequila. During his recent annual wellness exam visit to his primary care physician, Dr. Booker, Sam completed alcohol use screening using a hand-held tablet containing the USAUDIT screening questionnaire, and the results were integrated in the physician's EHR. During Dr. Booker's initial preparation to examine Sam, he first opened Sam's medical record to review his history and any new problems Sam reported. He

received a notification that Sam had new alcohol screening results available for his review. While reviewing the results, Dr. Booker noted that Sam's alcohol screening results indicated excessive alcohol consumption and some symptoms of dependence, with the score falling within Zone 3 (indicating harmful or hazardous drinking). Dr. Booker reviewed the screening results with Sam, providing additional brief intervention counseling guided by the patient-specific suggested text offered by the *Alcohol Brief Intervention and Referral* CDS. Sam admitted he was having trouble controlling his drinking and agreed that it might be good for him to see a specialized provider for additional evaluation and possible treatment for his alcohol use. Using the link provided by the CDS app, Dr. Booker initiated the referral order.

3.3 Health Scenarios Supported with Customization of the Coded Expression

This coded CDS expression defines clinical concepts and criteria informed by references listed in Section 4.1. The artifact identifies patients recently screened for alcohol use who have not had a brief intervention and delivers evidence-based suggestions for brief counseling interventions and links to targeted patient education materials and tools based on the patient's screening results. Portions of the coded CDS expression can be reused to support additional scenarios that help improve efficiencies and drive preventive health efforts across varied organizations, workflows, end users, and health IT systems.

Additional preventive health scenarios that could be supported by enhancing or adjusting portions of this CDS logic by the implementing organization include the following.

Scenario 1: Improving care gaps as part of a quality improvement project to enhance population health.

Premier Alliance is an accountable care organization (ACO) comprised of 250 primary care clinicians that care for 15,000 Medicare beneficiaries. The Quality Improvement department at Premier discovered their organization had very low scores on a Healthcare Effectiveness Data and Information Set (HEDIS) quality measure which evaluates the frequency that their physicians screen adults for unhealthy alcohol use and follow-up care with patients who are drinking above recommended levels (National Committee for Quality Assurance, n.d.). Premier implemented an alcohol screening CDS artifact (*USAUDIT Alcohol Screening*) almost a year ago. As a result, their metrics for alcohol screening increased exponentially, however their metrics for providing a brief intervention remained flat. Premier decided to implement the *Alcohol Brief Intervention and Referral* CDS artifact. In addition, they added a feature that enabled their clinicians to document that a brief intervention was delivered in a structured format within their EHR. The structured data was then available to use for reporting purposes, to indicate the true rate of brief interventions being performed. In parallel, the primary care clinicians were also provided with brief intervention training, so they had the knowledge to deliver brief interventions more confidently and consistently.

Scenario 2: Expanding the provision of brief interventions to include documentation within the EHR that facilitates patient billing.

When implementing the capabilities mentioned in Scenario 1, Premier also decide to add new logic to the CDS artifact to ensure that the information captured within their EHR for alcohol screening and brief intervention included the appropriate local billing codes required for payment. This new logic accounted for variability in payment rules and billing codes based on the patient's insurance provider, and any other documentation requirements to enhance their reimbursement for ASBI services. This local enhancement reduced the clinician's documentation time and improved reimbursement rates for the care being provided in their clinics.

Scenario 3: Integrating the ability to assess the patient for alcohol use disorder using the DSM-5 alcohol symptom checklist.

After successfully implementing ASBI-related patient care, CPG wanted to improve their clinician's ability to evaluate those patients who might need a referral for evaluation and possible treatment for AUD, by integrating the assessment of Diagnostic and Statistical Manual of Mental Disorders-fifth edition (DSM-5) AUD criteria into the brief intervention CDS logic. The new logic considers those patients whose alcohol screening scores indicate possible alcohol dependence as a result of their 1) alcohol screening scores, 2) corresponding Zone (or risk level), and 3) responses to the USAUDIT questions. The list of criteria is presented to the clinician at the same time as the brief intervention suggestions, so the clinician can review them with the patient. The resulting score helps confirm the diagnosis of AUD and assists the clinician in evaluating the severity of the patient's AUD (mild, moderate, or severe), based on the number of criteria met. This facilitates the utilization of the proper diagnosis codes for documentation, billing, and referrals.

3.4 CDS Logic Descriptions and Recommended Actions

The human-readable CDS logic that generates the display of patient-specific brief interventions along with patient education resources to the clinician is listed in detail in Appendix A. The brief intervention content is provided in detail in Appendix B..

The logic is divided into "steps" to make the objective of specific portions of logic criteria and the resulting CDS actions more understandable. At a very high level, the following information provides insight into the CDS logic and actions that this artifact supports.

Step 1: Consider availability of AUDIT screening results or alcohol prescreen (PS) question responses with no brief intervention recorded

- **Logic Description:** Ensures that the patient is 18 years or older and has evidence of either AUDIT screening results or an alcohol PS question response within the past 12 months, with no evidence of an associated brief intervention. Note: This logic is included in all subsequent logic "steps" but is not repeated in the descriptions.
- **CDS Actions:** Continue to Step 2

Step 2: Consider patients that are pregnant or trying to become pregnant and have screening results with no brief intervention recorded

- **Logic Description:** Ensures that patients who are pregnant or trying to become pregnant are provided a brief intervention, even if the results of their alcohol screening indicate they are not drinking. Determines the appropriate intervention and related resources based on whether they are drinking any amount of alcohol, and for any "positive" response to the NIDA QS questions on use of tobacco and drugs (e.g., any response other than "Never").
- **CDS Actions**: Provide a notification to the clinician that new alcohol screening information is available for this patient. Display the patient's screening results, brief intervention content for pregnant patients based on whether they are drinking any amount of alcohol (e.g., if they are not drinking, reinforce the importance of abstinence during pregnancy), targeted patient education resources, and NIDA QS-related resources.

Step 3: Consider all male patients and female patients that are not pregnant, have alcohol screening results with no brief intervention recorded, and did not respond to a NIDA QS questionnaire

- **Logic Description:** Ensures that all males and female patients who are not pregnant are provided appropriate interventions based on their AUDIT screening score and associated Zone (see Table 2).
- **CDS Action:** Provide a notification to the clinician that new alcohol screening information is available for this patient. Display the patient's screening results, brief counseling care recommendations, and patient education resources targeted for that patient's Zone. If the patient's screening score falls within Zone 3 or Zone 4, display recommendation to consider the need for further diagnostic evaluation and possible treatment of alcohol use disorder, and present clinician with the option to generate a referral order.

Step 4: Consider all male patients and female patients that are not pregnant, have alcohol screening results with no brief intervention, and have positive responses to a NIDA QS questionnaire

- **Logic Description:** Ensures that all males and female patients who are not pregnant are provided appropriate interventions based on their AUDIT screening score and associated Zone (see Table 2), and for any "positive" response to the NIDA QS questions on use of tobacco and drugs (e.g., any response other than "Never").
- **CDS Action:** Provide a notification to the clinician that new alcohol screening information is available for this patient. Display the patient's screening results, brief counseling care recommendations, and patient education resources targeted for that patient's Zone. Display references for clinicians and patient education resources for any positive responses to NIDA QS questions on use of tobacco and drugs. If the patient's alcohol screening score falls within Zone 3 or Zone 4, display recommendation to consider the need for further diagnostic evaluation and possible treatment of alcohol use disorder, and present clinician with the option to generate a referral order.

4. Guideline Interpretation and Clinical Decisions

4.1 Evidence-based Sources for Artifact Development

This artifact is not derived from a single clinical guideline. It draws upon multiple evidence-based references that provide guidance to clinicians on conducting brief behavioral counseling interventions for patients, based on their alcohol screening results and other factors (e.g., if the patient is pregnant or has a history of alcohol use disorder). The primary guidance comes from the following resources:

- The American College of Obstetricians and Gynecologists. (2011). At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications - ACOG. Retrieved from https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2011/08/at-risk-drinking-and-alcohol-dependence-obstetric-and-gynecologic-implications
- Babor, T. F., & Higgins-Biddle, J. C. (2001). Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care. Retrieved from https://apps.who.int/iris/handle/10665/67210
- Babor, T. F., Higgins-Biddle, J. C., & Robaina, K. (2017). The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners. Retrieved from https://sbirt.webs.com/USAUDIT-Guide_2016_final-1.pdf
- Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., & Monteiro, M. G. (2001). The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care. Retrieved from https://www.who.int/publications/i/item/audit-the-alcohol-use-disorders-identification-test-guidelines-for-use-in-primary-health-care
- Centers for Disease Control and Prevention. (2014). Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices. *Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities*. Retrieved from https://www.cdc.gov/ncbddd/fasd/documents/AlcoholSBIImplementationGuide-P.pdf
- Curry, S. J., Krist, A. H., Owens, et al. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. JAMA - Journal of the American Medical Association, 320(18), 1899–1909. Retrieved from https://doi.org/10.1001/jama.2018.16789
- National Institute on Alcohol Abuse and Alcoholism. (2019). Helping Patients Who Drink Too Much: A Clinician's Guide. Retrieved from https://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf
- World Health Organization. (2014). Guidelines for the identification and management of substance use and substance use disorders in pregnancy. WHO (Vol. 34). Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24783312

4.2 Guideline Translation Summary

Throughout the development of this artifact, the CDS Development Team collaborated with CDC subject matter experts (SMEs) to interpret and clarify recommendations within each clinical guideline to: 1) ensure the evidence was translated appropriately, 2) clarify any guidance found in the evidence-based resources that was unclear, and 3) arrive at a representation of the guideline that is specific enough to be suitable for computation. The Decision Log (see Appendix A-4) provides detailed information on how the evidence-based guidelines and subsequent SME clarifications informed CDS development. Some of the key interpretations and decisions include the following.

Key Decision 1: Ensuring people who are pregnant receive appropriate brief intervention care recommendations, even if they are not drinking.

> Professional organizations and government entities (e.g., American College of Obstetricians and Gynecologists [ACOG], USPSTF, WHO) provide varied recommendations on providing brief interventions to people who are pregnant, even if they are not drinking. The CDS Development Team and CDC sponsors of this project elected to enable the provision of a brief intervention to people who are pregnant whose screening results indicate they are abstinent from alcohol use, as well as those who are currently drinking. Some people who are pregnant may believe it is safe to drink in the second or third trimester, and providing an intervention to pregnant patients who are currently abstinent provides an opportunity to continue to educate these individuals on the importance of abstinence throughout their pregnancy (Wright et al., 2016) (Curry et al., 2018) (Centers for Disease Control and Prevention, 2014).

Key Decision 2: Ensuring individuals whose sex at birth is recorded as "unknown" in an EHR receive the appropriate brief intervention care recommendations.

> Unknown is a valid response for an individual's "sex assigned at birth" by Health Level 7® (HL7®) standards outlined in the Interoperability Standards Advisory published by the Office of the National Coordinator for Health Information Technology (ONC) (The Office of the National Coordinator for Health Information Technology, n.d.). During the development of the alcohol screening artifacts, the CDS Development Team and CDC sponsors of this project opted to develop logic that reasoned over Unknown as a sex at birth response to ensure these individuals also received alcohol screening. The logic places individuals with Unknown recorded as their sex at birth in the same threshold category as all females or males over 65 years old. For this CDS artifact, patients whose sex at birth is recorded as Unknown are included in the logic for female patients when considering whether a patient is pregnant. In addition, they are included in the same AUDIT scoring criteria and associated Zone as all females or males over 65 years old. As a result, the patient's risk threshold and resulting care recommendations for brief intervention may be slightly overestimated (which was preferred to potentially underestimating risk).

Key Decision 3: Establishing the appropriate cut off point for all females and males over age 65 when determining the patient's Zone based on their AUDIT screening score.

In the section of the WHO AUDIT manual that defines the range of WHO AUDIT scores for each Zone, or risk level, the guidance suggests lowering the cut off point for women and men over age 65: "Since the effects of alcohol vary with average body weight and differences in metabolism, establishing the cut off point for all women or men over age 65 one point lower…will increase sensitivity for these population groups. Selection of the cut-off point should be influenced by national and cultural standards and by clinician judgement…" (Babor et al., 2001). For these reasons, the CDS Development Team and CDC sponsors of this project elected to consider the sex of the patient and a male patient's age to determine the patient's Zone assignment, based on their WHO AUDIT score. This also aligns with the guidance in the USAUDIT manual.

5. Technical Details

This section provides the technical details regarding the definition and implementation of the ASBI CDS artifact. The underlying standards used to define the artifact are first listed and discussed. Then, the structure of the artifact definition is described. Finally, implementation considerations are provided as a prelude to the testing discussion in the next section.

5.1 Artifact Definition Standards

A number of health IT standards are used to define the ASBI CDS artifact. These standards are introduced in the following sections, alongside rationale for why they have been selected for use as the technical foundation of the ASBI CDS definition.

5.1.1 Fast Healthcare Interoperability Resources®

Fast Healthcare Interoperability Resources (FHIR®) is an international IT standard for exchanging healthcare information electronically (Health Level 7 (HL7), n.d.-i). FHIR provides a number of general data structures or "resources" for representing a variety of clinical and healthcare-related data (Health Level 7 (HL7), n.d.-n). Example resources include Condition (Health Level 7 (HL7), n.d.-e) and Observation (Health Level 7 (HL7), n.d.-h), which can respectively be used to represent clinical diagnoses and laboratory test results (among other things). The ASBI CDS uses FHIR Release 4 to not just model information about the patient to whom the CDS is being applied but also to describe the questions, responses, and logic that constitute the alcohol screening instrument which drives the brief intervention approach used by this CDS.

FHIR provides a Questionnaire resource that allows interrelated questions and responses to be defined in a standard format (Health Level 7 (HL7), n.d.-l). Each Questionnaire instance is defined by a set of both required and optional data elements, which are by design general in nature, in order to support the capabilities most likely to be found in the majority of healthcare systems (Health Level 7 (HL7), n.d.-k). This flexibility is one of the reasons why FHIR has been growing in popularity; the use of FHIR is expected to continue to grow due to it being the basis

for the application programming interface (API) required by the 21st Century Cures Act Interoperability Final Rule (Office of the National Coordinator (ONC), 2020). For these reasons, FHIR has been selected for use in the ASBI CDS definition. The questions and available responses of the alcohol screening instrument are represented using a FHIR Questionnaire resource. The responses a patient makes are recorded using a FHIR Questionnaire Response resource; it is this Questionnaire Response resource which serves as the main input to this CDS.

5.1.2 Clinical Reasoning Module

The Clinical Reasoning Module (CRM) is a subset of the FHIR standard; it provides resources and operations for representing and distributing clinical knowledge artifacts such as CDS (Health Level 7 (HL7), n.d.-d). The structure of the ASBI CDS artifact described in this document is based upon the guidance provided by CRM for designing and building CDS. PlanDefinition (Health Level 7 (HL7), n.d.-j) is a key resource from CRM and, as described in Section 5.2.1, is used as one of the three main components of the ASBI CDS artifact definition. Guidance from the FHIR Clinical Guidelines implementation guide (IG) (Health Level 7 (HL7), n.d.-f), also known as "Clinical Practice Guidelines (CPG) on FHIR," has been incorporated into the ASBI CDS PlanDefinition resource.

5.1.3 Structured Data Capture

Structured Data Capture (SDC) (Health Level 7 (HL7), n.d.-o) is another FHIR IG that has been leveraged to help define the ASBI CDS. SDC provides guidance on how questionnaires, surveys, and forms should be represented in an open and interoperable way. Specifically, it builds upon the base FHIR Questionnaire resource so that more complex use cases can be supported. Features described in SDC and used in the alcohol screening Questionnaire include advanced form rendering (Health Level 7 (HL7), n.d.-b) and advanced form behavior logic (Health Level 7 (HL7), n.d.-a). While a simplified version of the alcohol screening instrument could be described using only a base FHIR Questionnaire resource, SDC is required for expressing the complete instrument.

5.1.4 Clinical Quality Language

CQL is a domain-specific computer programming language focused on the expression of clinical quality concepts (Health Level 7 (HL7), n.d.-c). It can be used to author CDS logic and is designed to easily integrate with the other standards described in this section. That latter fact constitutes one of CQL's advantages over other more general-purpose programming languages when it comes to authoring CDS logic. An additional advantage is that CDS logical expressions written in CQL tend to read more like natural language than as a computer program, making them more accessible to audiences outside the realm of software engineering.

The ASBI CDS requires logic that can be expressed naturally and efficiently using CQL. Computer code written in CQL is human readable but can be translated or "compiled" into a more structured format that is interpretable by computers. This computer-friendly format is called the Expression Logical Model (ELM) and it is this format of the logic that is interpreted

when the CDS logic is executed against patient data. Both formats have been produced as part of the ASBI CDS development.

5.2 Artifact Definition Structure

This section describes the main components of the ASBI CDS, how they are based on the standards described in the previous section, and how together they compose the complete artifact definition. The two main components of the ASBI CDS can be seen in Figure 1 and are PlanDefinition ("the container") and Library ("the logic").

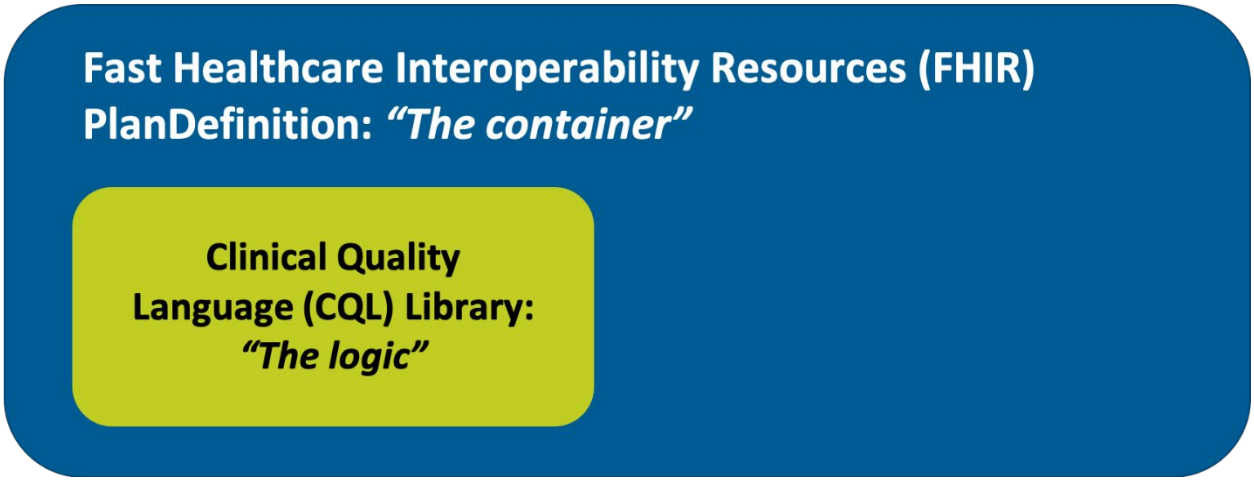

Figure 1. Depiction of the relationship between the components that define the artifact

Figure 1 shows the Library component "inside" the PlanDefinition component; this depiction is meant to reflect the fact that the PlanDefinition serves as a wrapper and "contains" the other component. As discussed in the following sections, each component serves a specific purpose and is equally important; the ASBI CDS could not be fully expressed without both components.

5.2.1 PlanDefinition

The FHIR standard provides a PlanDefinition resource (Health Level 7 (HL7), n.d.-j) for describing pre-defined groups of actions that should occur under certain circumstances. The PlanDefinition resource provides the key data elements needed to describe the overall CDS behavior in a structured and standard way. The details of the CDS are not listed directly in the PlanDefinition; it simply references the other component where those details can be found. The PlanDefinition for the ASBI CDS is shown below in Figure 2, where it has been expressed in compact notation using the draft FHIR Shorthand (FSH) standard (Health Level 7 (HL7), n.d.-g).

The PlanDefinition shown in Figure 2 contains metadata regarding the ASBI CDS. Of most interest are the lines starting with * `library` and * `action`. The former is simply a reference to the CQL Library component. The latter is a more complicated structure that describes how the CDS should be triggered (i.e., when a new QuestionnaireResponse has been recorded), under what conditions it is applicable (determined by the `DisplayNotification` expression from

the CQL Library), and what action should be taken (i.e., evaluate two expressions from the CQL library). The trigger type comes from the set of values allowed by the FHIR specification. The action and conditions are described in detail by the Library component.

```
Instance:   AlcoholBriefIntervention
InstanceOf: PlanDefinition
Title:      "Brief Intervention"
* url = "http://www.cdc.gov/ncbddd/fasd/briefintervention-plandefinition"
* version = "1.0.0"
* name = "briefintervention-plandefinition"
* title = "Brief Intervention PlanDefinition"
* type = http://terminology.hl7.org/CodeSystem/plan-definition-type#eca-rule "ECA Rule"
* status = http://hl7.org/fhir/publication-status#draft "Draft"
* experimental = true
* publisher = "The Health FFRDC, operated by The MITRE Corporation, in support of the National Center
on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention."
* description = "Brief intervention counseling suggestions."
* date = "2020-05-04"
* library = "Library/BriefInterventionLogicLibrary|1.0"
* action[0].trigger[0].type = http://hl7.org/fhir/trigger-type#data-added "Data Added"
* action[0].trigger[0].data[0].type = http://hl7.org/fhir/resource-types#QuestionnaireResponse
"QuestionnaireResponse"
* action[0].trigger[0].data[0].codeFilter[0].path = "QuestionnaireResponse.questionnaire"
* action[0].condition[0].kind = http://hl7.org/fhir/action-condition-kind#applicability
"Applicability"
* action[0].condition[0].expression.language = http://hl7.org/fhir/expression-language|4.0.1#text/cql
"CQL"
* action[0].condition[0].expression.expression = "DisplayNotification"
* action[0].condition[0].expression.reference = "Library/BriefInterventionLogicLibrary|1.0"
* action[0].dynamicValue[0].expression.language = http://hl7.org/fhir/expression-
language|4.0.1#text/cql "CQL"
* action[0].dynamicValue[0].expression.expression = "NotificationText"
* action[0].dynamicValue[0].expression.reference = "Library/BriefInterventionLogicLibrary|1.0"
* action[0].dynamicValue[1].expression.language = http://hl7.org/fhir/expression-
language|4.0.1#text/cql "CQL"
* action[0].dynamicValue[1].expression.expression = "BriefInterventions"
* action[0].dynamicValue[1].expression.reference = "Library/BriefInterventionLogicLibrary|1.0"
```

Figure 2. PlanDefinition component expressed in FHIR Shorthand (FSH)

5.2.2 Library

The FHIR standard provides a Library resource (Health Level 7 (HL7), n.d.-m) that acts as a descriptive wrapper around a logic library. In the case of the CDS described in this document, a Library resource is used to wrap logic written in CQL. As described in Section 5.1.4, CQL logical expressions can be interpreted in the context of a single patient EHR formatted in FHIR. The concept of operations for the ASBI CDS is that FHIR resources pulled from the patient record are provided to the executing CQL. The CQL uses the information from the patient record as input data to the logical expressions, whose values are then used to determine the correct CDS behavior for the patient.

An example CQL expression from the Library is shown in Figure 3. From the example we can see the expression `PregnantAndDrinking` being defined using a combination of patient data (e.g., `DoesMeetPregnancyInclusionCriteria`) and information about their responses to the alcohol screening Questionnaire (e.g., `HasRecentNeverResponseUsAuditQuestionOne`). `PregnantAndDrinking` returns true if the patient meets the inclusion criteria for being considered pregnant and if none of the following are true:

1. The patient has recently responded "No" to the alcohol prescreen question
2. The patient has recently responded "Yes" to the alcohol prescreen question but subsequently answered "Never" to Question #1 of either the WHO AUDIT or USAUDIT
3. The patient has a recent WHO AUDIT or USAUDIT screening score of zero and no responses to the non-alcohol-related questions from the NIDA Quick Screen

```
define PregnantAndDrinking:
  DoesMeetPregnancyInclusionCriteria
  and not (
    HasRecentNoApsResponse
    or (HasRecentYesApsResponse
      and (HasRecentNeverResponseUsauditQuestionOne
        or HasRecentNeverResponseAuditQuestionOne))
    or (MostRecentScreeningScore = 0
      and not Exists(NonAlcoholQuestionResponsePairs))
  )
```

Figure 3. An excerpt from the CQL logic within the Library

The excerpt shown in Figure 3 is an example of an intermediate CQL expression, one that is necessary for the CQL to function as intended but does itself comprise the set of key expressions which are meant to serve as the main outputs. The set of six main output CQL expressions are listed in Table 3; these six expressions are enclosed within a single expression called BriefInterventions, which was referenced in the PlanDefinition shown in Figure 2.

Table 3. List of key logical expressions defined in the CQL Library

Expression Name	Expression Value	Description
AlcoholScreeningResultsSummary	Tuple (structured)	A summary of the patient's most recent alcohol screening results, including their score, zone number, and list of responses.
AlcoholCounselingSuggestions	Tuple (structured)	A set of patient-specific counseling suggestions, including references to evidence sources and an indication to whether the patient should be given a referral for alcohol treatment.
AlcoholPatientEducationResources	String (text)	A bulleted list of patient-specific education resources.
NonAlcoholScreeningResultsSummary	Tuple (structured)	A summary of the patient's most recent responses to the NIDA Quick Screen questions not related to alcohol.
NonAlcoholRelatedCounselingSuggestions	Tuple (structured)	A set of patient-specific counseling suggestions for non-alcohol-related substance use.
NonAlcoholRelatedPatientEducationResources	String (text)	A bulleted list of patient-specific education resources.
BriefInterventions	Tuple (structured)	Contains all of the above expressions in a single structure.

5.3 Artifact Implementation Standards

The CDS artifact definition described above details what, according to the underlying evidence, should be done under certain circumstances. The artifact definition does not necessarily describe how those actions should be implemented in an actual health IT system. This section describes the interoperable health IT standards used to provide guidance for how the ASBI CDS can be implemented and integrated.

5.3.1 Sustainable Medical Applications, Reusable Technologies

The Sustainable Medical Applications, Reusable Technologies (SMART®) standard facilitates the integration of software applications, or "apps," with health IT systems (Boston Children's Hospital, n.d.). "SMART on FHIR apps," or sometimes simply "SMART apps," are software applications that securely interact with patient EHRs and other healthcare-related data via a

FHIR API. SMART apps are interoperable in the sense that they can interface with any health IT system that supports the SMART standard and the data requirements of the app. Instead of writing a different software application to provide the same capability for each different health IT system, a single application can be written that works with many different health IT systems. The ASBI CDS concept of operation requires secure access to an EHR, to provide the capabilities described in the previous section; the SMART standard fulfills that need.

A key component of SMART has been documented in the SMART App Launch IG (Health Level 7 & Boston Children's Hospital, n.d.-c). It is the sequence of steps taken so that an app can be authenticated and authorized by a health IT system before any FHIR resources are accessed. This SMART App Launch Framework helps to ensure that a particular SMART app is only granted access to the EHR data that it needs and that its user is authorized to access. The ASBI CDS design presupposes that SMART will be available in the system to which it is to be integrated. Without SMART, a custom interface would have to be designed for each health IT system, which defeats the intent and benefit of interoperable CDS.

5.3.2 CDS Hooks

The CDS Hooks standard describes how CDS services, which are simply software that provide CDS, can be integrated with health IT systems (Health Level 7 & Boston Children's Hospital, n.d.-b). While SMART is more general in nature, CDS Hooks focuses on integrating CDS into the clinician workflow. This is accomplished through the use of a number of so-called "hooks," which is a software term for a technique for altering the behavior of a software program (Wikipedia, n.d.-a). Essentially, CDS Hooks provides a standardized way of specifying where in the clinician workflow a CDS service should be used, as well as how results from the service should be formatted for communication back to the health IT system.

The ASBI CDS design assumes that the CDS Hooks will be used to facilitate the initial trigger for the CDS; recall the discussion on triggering in Section 5.2.1. How the triggering of the CDS actually occurs is an implementation detail that will be specific to the type of health IT system to which the ASBI CDS is being integrated. CDS Hooks only provides the standard that describes when the CDS should be triggered and what information is passed back and forth between the health IT system and the CDS service. Without CDS Hooks, there could be a different interface between a CDS service and each health IT system, which defeats the intent and benefit of interoperable CDS.

5.4 Artifact Implementation Structure

This section describes how the standards from Section 5.3 can be used to integrate the ASBI CDS into a health IT system. A notional depiction of this is shown in Figure 4.
The figure shows a patient and/or clinician interacting with a hypothetical health IT system via a human interface (a computing device of some sort). The human interface provides access to the EHR through a proprietary computer called a server, which in this case is proprietary because it is not using open standards for communication of patient health information. In the notional scenario depicted in Figure 4, interoperability has been added to the health IT system through

the inclusion of a FHIR Server, which allows patient health information in the EHR to be accessed as FHIR resources. Additionally, SMART and CDS Hooks interfaces are available so that SMART apps and CDS services can be integrated with less effort.

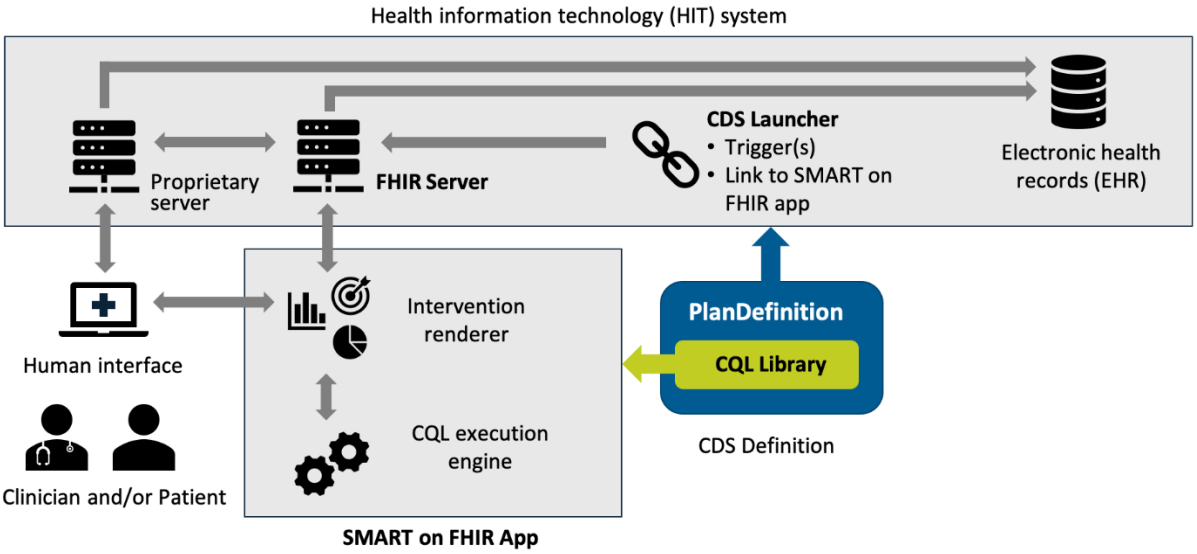

Figure 4. Notional depiction of ASBI CDS integration with a health IT system.

Figure 4 also shows the ASBI CDS definition being integrated into the health IT system via two mechanisms. First, the PlanDefinition is included in a CDS Hooks service called the CDS Launcher, which is responsible for triggering the ASBI CDS. Second, the CQL Library is included in a SMART on FHIR App. The SMART on FHIR App is responsible for rendering the brief intervention for display on the human interface and executing CQL logic. These three main integration components - the FHIR Server, the CDS Launcher, and the SMART on FHIR App - are described in more detail in the following sections.

5.4.1 FHIR Server

The FHIR Server interfaces with the health IT system and provides access to a patient's health information in the EHR. This is accomplished through the use of an API that follows the Representational State Transfer (REST) software architectural pattern, which is frequently referred to as a "RESTful" API (Wikipedia, n.d.-c). The FHIR standard defines the general guidelines and options for this RESTful API (Health Level 7, n.d.-c) and the recent final rule from HHS on interoperability and information blocking provides more specific requirements for certified health IT systems (Office of the National Coordinator (ONC), 2020). The ASBI CDS design assumes that any health IT system into which it will be integrated has a FHIR Server accessible through a RESTful API. Table 4 lists the basic requirements for the FHIR Server and its RESTful API capabilities. It should be noted that certified health IT systems are only required to support read and search operations (Office of the National Coordinator (ONC), 2020); the ASBI CDS additionally requires create operation support so that the brief intervention can be documented in the EHR.

Table 4. Required FHIR Server capabilities

FHIR Resource	**Supported Operation(s)** (Health Level 7, n.d.-c)
Condition	Read, search
Observation	Read, search, create
Procedure	Read, search, create
Questionnaire	Read, search
QuestionnaireResponse	Read, search, create

5.4.2 CDS Launcher

The CDS Launcher is a CDS Hooks service that specifies the trigger necessary for launching the CDS. As described in Section 5.3.2, the ASBI CDS should be triggered when a new QuestionnaireResponse resource is created in the system. When this occurs, the CDS Launcher is consulted to determine whether the patient meets the inclusion and does not meet the exclusion criteria of the ASBI CDS. Determination of ASBI CDS applicability is made by executing CQL logical expressions against the patient record. If the results of the CQL expressions indicate the patient should receive a brief intervention, then a CDS Hooks "card" (Health Level 7 & Boston Children's Hospital, n.d.-a) is returned to the health IT system with a link to the SMART on FHIR App. If the results of the CQL expressions indicate the patient should not receive a brief intervention, no further actions are taken.

5.4.3 SMART on FHIR App

The SMART on FHIR App is used to implement most of the ASBI CDS definition. As seen in Figure 4, there are two main components to the SMART on FHIR App. The first is a software program called an "engine," whose role it is to execute the CQL expressions defined in the Library. This is done in the context of both patient data accessed via SMART and the FHIR API, as well as with the patient responses to the alcohol screening Questionnaire. The second main component is a software program that takes the outputs from the CQL expressions and presents them to the user via the human interface.

The SMART on FHIR App is launched after the CDS Launcher has determined the patient should receive an alcohol screening and has returned a link to the App. There are a number of different contexts (e.g., a specific patient or encounter) in which a SMART on FHIR App can be launched (Health Level 7, n.d.-d), and it is up to the implementor to decide which one is best supported by their health IT system. Once screening is completed, the SMART on FHIR App must document the brief intervention by sending a FHIR Procedure resource to the FHIR Server for storage in the EHR.

6. Artifact Testing

It is not sufficient to simply define and implement a CDS artifact. The definition and implementation must also be thoroughly tested to ensure the CDS behaves as the underlying evidence intends. Because of the complexity of the ASBI CDS a significant amount of testing software has been developed and this section discusses the testing that has been applied to the ASBI CDS artifact.

This section first presents the different levels of testing that have been applied during the validation of the ASBI CDS. The most rigorous level of testing involves exercising all aspects of the ASBI CDS in an integrated and end-to-end fashion. This has required development of special testing software, called a test harness, which is described in Section 6.2. As the test harness is described, comparisons are drawn between it and the implementation structure from Section 5.4. These similarities are not by chance, because the test harness is meant to mimic, or "mock," the key aspects of a real CDS integration. This section concludes with an enumeration of the technology components of the testing harness.

6.1 Levels of Testing

A number of different types, or "levels," of testing have been applied to the ASBI CDS. Each level of testing focuses on a different aspect of the ASBI CDS as well as on a different granularity or scale of functionality. This section provides a description of each level of testing as well as some sample testing results. Complete testing results can be found in a set of separate test files included with the artifact definitions on CDS Connect.

6.1.1 Format Validation

The simplest level of testing, called Format Validation, focuses on ensuring the ASBI CDS definitions correctly adhere to the underlying health IT standards. Because two main standards are used to define the ASBI CDS, two types of Format Validation must occur; these are next described in turn.

6.1.1.1 FHIR

As described in Section 5.2, two different FHIR resources are necessary to define the ASBI CDS: PlanDefinition and Library. These resources are written using FSH and then converted to full FHIR resources using the SUSHI tool (SUSHI is a recursive acronym that stands for "SUSHI Unshortens ShortHand Inputs") (Health Level 7, n.d.-e). SUSHI does provide some validation during the conversion process, which is followed by passing each generated resource through the official FHIR Validator tool (Health Level 7, n.d.-f).

The FHIR Validator is a software program written in the Java programming language. It is capable of checking FHIR resource instances to ensure they adhere to the FHIR specification. The FHIR Validator can identify errors such as misspelled element names, missing elements, or value formatting issues. Because FHIR is such a complex and extensible specification, validation of the ASBI CDS definitional resources is a key first step for testing. A set of test files are

packaged with the CDS definition files published with this document on CDS Connect. These test files include FHIR Validator outputs for all resources used in the CDS definitions.

6.1.1.2 CQL

As described in Section 5.2.2, most of the complex behavior of the ASBI CDS is defined by logical expressions written in CQL. Also recall from Section 5.1.4 that the human readable version of CQL must be converted or translated to the machine friendly format (i.e., ELM) before it can be used in an executable CDS. The CQL-to-ELM Translator Reference Implementation is an open source software package written in the Java programming language (Health Level 7, n.d.-a). It has been used to translate the ASBI CDS CQL, which as a by-product checks the CQL for conformance to the CQL specification. As with FHIR Format Validation, this process checks to make sure what has been written is, from a software standpoint, "grammatically correct." It does not provide any insight into whether the CQL as written correctly implements the intended CDS logic. This is accomplished by the level of testing described in the next section.

6.1.2 Logic Testing

While Format Validation is a good first step when it comes to testing, it does not indicate whether the ASBI CDS is functioning as intended. Because CQL logical expressions dictate so much of the behavior of the CDS, the next level of testing consists of testing the validity of the CQL itself. All CQL written for the ASBI CDS has been done using a test-driven development (TDD) approach (Wikipedia, n.d.-d). TDD involves iteratively developing software by first writing a test consisting of input data and a set of expected results and then writing just enough software to ensure the test passes. Each test should focus on a different aspect of the desired behavior of the software. The TDD process is depicted graphically in Figure 5.

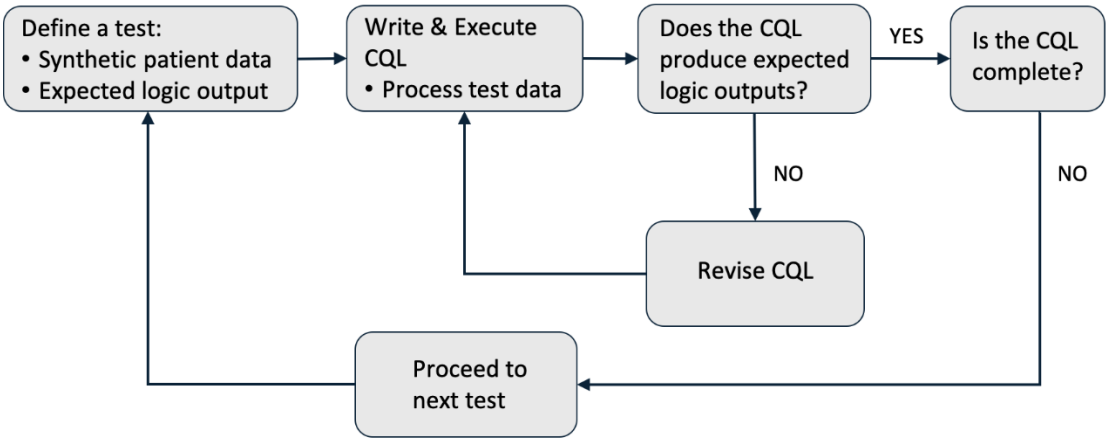

Figure 5. Diagram showing the test-driven development approach taken for authoring CQL

To support TDD development of CQL, the CQL Testing Framework open source tool has been leveraged (Agency for Healthcare Research and Quality, n.d.). The CQL Testing Framework allows test cases to be defined in specially formatted files; each test file consists of the following components:

- Human readable test name
- Set of synthetic FHIR data (inputs to the CQL)
- Set of expected results (outputs from the CQL)

An example logic test case can be seen in Figure 6. The name of the test provides a general indication about the nature of what is being tested; in this case it indicates the input FHIR data is meant to represent a patient who meets the criteria of a Zone 2 drinker. The responses to the WHO AUDIT can be seen within the `QuestionnaireResponse` resource under the `data` section. The `results` section lists the names of the CQL expressions being tested; next to each expression name is the value that the test asserts is the correct result. According to the test, the synthetic patient should be correctly classified by the CDS as a Zone 2 drinker.

The CQL Testing Framework works by reading the example test case file shown in Figure 6, using the items listed in the `data` section to generate FHIR resources, which are then used as input data as the CQL is executed using the CQL Execution Framework Reference Implementation (The MITRE Corporation, n.d.), and then finally the outputs from the executed CQL are compared to those listed under the `results` section of the test case file. Any incorrect results are reported back via the CQL Testing Framework, which are then used to refine the CQL until the test passes. A total of 17 different logic tests were defined for the ASBI CDS; the list of the test case names is provided in Table 5. The details of each test case can be found in the set of testing files that accompany the CDS definition files.

```yaml
name: Zone 2 AUDIT
externalData:
- resources
data:
-
  resourceType: Patient
  name: Jane Smith
  gender: female
  extension:
  - url: http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex
    valueCode: 'F'
  birthDate: 1978-07-16
-
  $import: *AuditQuestionnaire
-
  resourceType: QuestionnaireResponse
  questionnaire: 'http://www.cdc.gov/ncbddd/fasd/audit'
  status: 'completed'
  authored: 2020-01-20
  item:
  - linkId: 'prescreen-question'
    answer:
    - valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Yes
  - linkId: 'audit-question-one'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE 2-4 times a month
  - linkId: 'audit-question-two'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE 3 drinks
  - linkId: 'audit-question-three'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Monthly
  - linkId: 'auditc-score'
    answer:
      valueDecimal: 7
  - linkId: 'audit-question-four'
    answer:
    - valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-five'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-six'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-seven'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-eight'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-nine'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE No
  - linkId: 'audit-question-ten'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE No
  - linkId: 'audit-score'
    answer:
      valueDecimal: 7
results:
  IsIncluded: true
  HasRecentScoreUsAuditC: false
  HasRecentScoreFullUsAudit: false
  HasRecentScoreAuditC: true
  HasRecentScoreFullAudit: true
  HasRecentYesApsResponse: true
  RecentScoreAuditC: 7
  RecentScoreFullAudit: 7
  IsZoneTwoDrinker: true
  IsZoneThreeDrinker: false
  ZoneNumber: 2
  ZoneRomanNumeral: 'II'
  PregnantAndDrinking: false
  NidaQsWasPerformed: false
  NonAlcoholRelatedCounselingSuggestionText: ''
  NonAlcoholRelatedPatientEducationResources: ''
```

Figure 6. Example logic test case

Table 5. List of logic tests

Number	Test Name
1	Zone 2 AUDIT
2	Zone 3 AUDIT
3	Zone 4 AUDIT
4	Excluded
5	Has Recent AUDIT Score
6	Has Recent USAUDIT Score
7	Included Recent No APS Response
8	Complete NIDA QS and USAUDIT
9	Complete NIDA QS and USAUDIT (1)
10	Not Included No Recent Screening
11	Not Included Old No APS Response
12	Not Included Under Age
13	Pregnant and drinking (Zone 2, USAUDIT)
14	Pregnant and not drinking
15	Zone 2 USAUDIT
16	Zone 3 USAUDIT
17	Zone 4 USAUDIT

6.1.3 End-to-End Testing

Logic testing is useful because it helps ensure that the CDS logic, defined by CQL expressions, returns the correct results when provided the appropriate data. Logic testing does not, however, evaluate all aspects of the ASBI CDS. End-to-end testing provides an evaluation of the CDS where all components are executing together as intended in the design. Ideally this would be accomplished by integrating the ASBI CDS into a real health IT system, as depicted in Figure 4.

Lacking a real health IT system for this purpose, a stand-in must be replicated that will mimic, or "mock," the key aspects required by the ASBI CDS. This is accomplished by creating a software program, called a test harness, described in the next section. End-to-end testing is accomplished by running the test harness with the ASBI CDS definitions and the appropriate FHIR resources as input data; a subset of the test cases defined in Section 6.1.2 were considered. Having the test harness also allows ad-hoc "kick the tires" sorts of tests to be easily and quickly conducted. This can be useful for uncovering errors in the CDS that were not anticipated during the design or logic testing phases.

6.2 End-to-End Test Harness

The end-to-end test harness is a software program capable of executing the ASBI CDS in a simulated context. The end-to-end test harness not only facilitates end-to-end testing of the ASBI CDS, but it can also serve as a starting point for an integration with a real health IT system. This section describes the end-to-end test harness, starting with a high-level overview of its structure. Next, the individual software components in the test harness are listed and described.

6.2.1 Test Harness Structure

This section describes the overall structure of the test harness used for end-to-end testing. There are certain aspects of a real health IT integration which can be mimicked or mocked, and others which cannot be. Specifically, the following aspects cannot be easily mimicked or mocked:

- Real patients and real clinicians (would pose concerns with personally identifiable information)
- Proprietary servers and software (details regarding these are either not known or not usable given intellectual property)
- Triggers (are very specific to the type of system being integrated with and do not generalize well)

However, appropriate stand-ins can be provided for the following:

- FHIR Server (based on open standards and software)
- EHRs (can be simulated using synthetic data formatted using open standards)
- SMART on FHIR App (based on open standards and software)

Figure 7depicts this using the notional ASBI CDS integration shown previously; any component that cannot be easily emulated has been crossed off. What remains constitutes aspects which are simulated using the end-to-end test harness. It should be emphasized that the end-to-end test harness is operational software that can serve as a starting point for an integration of the ASBI CDS with a real health IT system. This is why the software components discussed in Section 6.2.3 are being released under open source licenses.

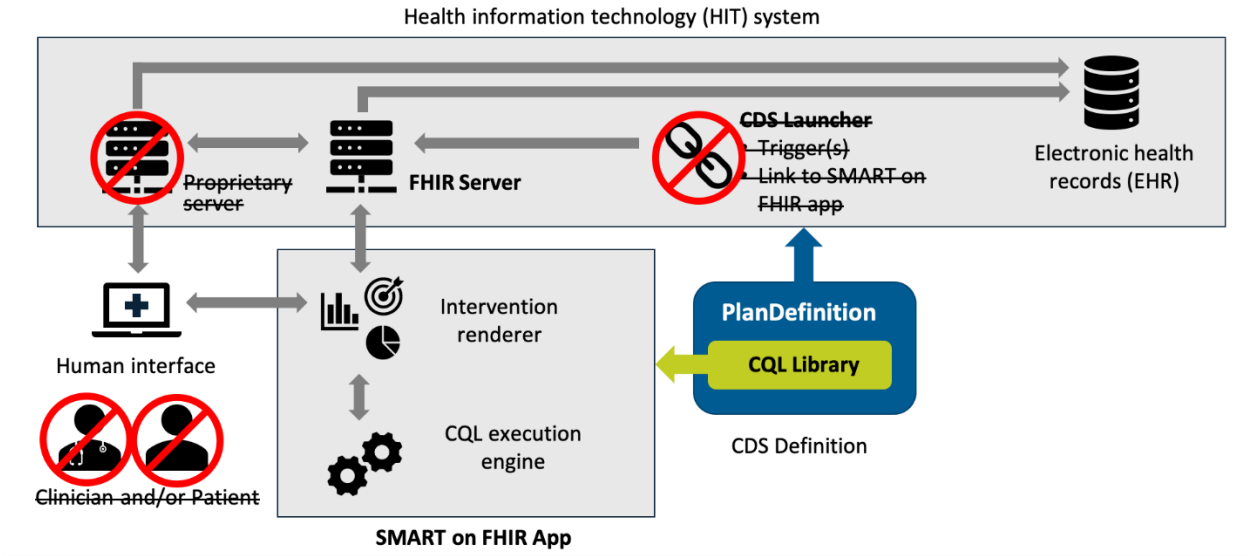

Figure 7. Notional ASBI CDS integration depicting which aspects can be emulated without a real health IT system

As seen in Figure 7, there are two main software components in the test harness: 1) a FHIR Server (with an accompanying "EHR" containing synthetic test data) and 2) a SMART on FHIR App that renders the brief intervention on the screen after executing the CQL. The former is referred to as the "ASBI CDS FHIR Server" and the latter is called the "ASBI CDS Intervention App." These two software components must communicate with each other via a SMART on FHIR interface and must realistically emulate the CDS experience for users during end-to-end testing; they are both discussed in more detail below.

6.2.2 Existing Open Source Software

This section describes the existing open source software libraries that have been leveraged in the construction of the end-to-end test harness.

6.2.2.1 Asymmetrik Node Server

Asymmetrik has produced a FHIR server implementation (Asymmetrik, n.d.) based upon the Node.js JavaScript runtime engine (OpenJS Foundation, n.d.). A version of Asymmetrik's implementation was the Stage 1 winner of the Secure API Server Showdown Challenge sponsored by ONC. The Asymmetrik implementation is available under an open source license and as described in Section 6.2.3.2 is used to provide FHIR API capabilities for the test harness.

6.2.2.2 Oauth Express Server

SMART on FHIR requires a server (Health Level 7, n.d.-b) that provides an authorization protocol that adheres to the OAuth standard (Wikipedia, n.d.-b). In order to fully test the SMART on FHIR launch sequence during end-to-end testing, the test harness must have some sort of OAuth implementation available. The Express OAuth Server, an open source OAuth

implementation based upon Node.js, is used to provide this capability in the test harness (Oauthjs, n.d.).

6.2.2.3 CQL Execution Engine

All CQL calculations in the test harness are executed using the same CQL execution engine used for the logic testing (The MITRE Corporation, n.d.).

6.2.2.4 Vue.js

Vue is a JavaScript front-end framework for building user interfaces (Vue.js, n.d.). Vue allows the user-facing aspects of the end-to-end test harness to be rapidly assembled and debugged.

6.2.3 De Novo Software

This section describes the custom software developed for this project that has been released as open source software to facilitate future integrations of the ASBI CDS with real health IT systems.

6.2.3.1 ASBI CDS Intervention App

The ASBI CDS Intervention App is a SMART on FHIR application that presents the user with the patient-specific brief intervention. After the app is authorized and launched, the required patient data is requested from the FHIR server. In the case of the end-to-end test harness, this is the ASBI CDS FHIR Server described in the next section. Once the FHIR resources are loaded, the CQL logical expressions are executed and Vue is used to render the brief intervention text to the screen. After the brief intervention has been conducted, a FHIR Procedure resource should be generated to document its occurrence in the EHR.

6.2.3.2 ASBI CDS FHIR Server

The ASBI CDS FHIR Server combines the Asymmetrik FHIR Server and the OAuth Express Server projects to supply a SMART on FHIR compliant endpoint to support end-to-end testing. A file-based database representing the simulated EHR is used to store test FHIR resources which simulated the EHR. The ASBI CDS FHIR Server does not implement any of the ASBI CDS logic; it is only necessary to support end-to-end testing.

List of References

Accreta, P. (2002). Definition of Term Pregnancy by American College of Obstetricians and Gynecologists Committee. *Obstetrics & Gynecology*, *99*(1), 169–170. Retrieved from https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co579.pdf?dmc=1&ts=20200220T1514182134

Agency for Healthcare Research and Quality. (n.d.). CQL Testing Framework. Retrieved August 23, 2019, from https://github.com/AHRQ-CDS/CQL-Testing-Framework

American Public Health Association and Education Development Center. (2008). *Alcohol Screening and Brief Intervention: A Guide for Public Health Practitioners*. Washington DC. Retrieved from https://www.integration.samhsa.gov/clinical-practice/alcohol_screening_and_brief_interventions_a_guide_for_public_health_practitioners.pdf

Asymmetrik. (n.d.). FHIR API Server. Retrieved May 12, 2020, from https://github.com/Asymmetrik/node-fhir-server-core

Babor, T. F., & Higgins-Biddle, J. C. (2001). *Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care*. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/67210/WHO_MSD_MSB_01.6b.pdf?sequence=1

Babor, T. F., Higgins-Biddle, J. C., & Robaina, K. (2017). The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners, 24. Retrieved from https://www.dshs.wa.gov/sites/default/files/BHSIA/dbh/wasbirt/USAUDIT-Guide_2016.pdf

Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., & Monteiro, M. G. (2001). *The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care*. Retrieved from https://www.who.int/substance_abuse/publications/audit/en/

Boston Children's Hospital. (n.d.). Sustainable Medical Applications, Reusable Technologies (SMART) . Retrieved May 12, 2020, from https://smarthealthit.org/

Centers for Disease Control and Prevention. (n.d.). Fetal Alcohol Spectrum Disorders (FASD) Training and Resources. Retrieved April 27, 2020, from https://nccd.cdc.gov/FASD/

Centers for Disease Control and Prevention. (2014). Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices. *Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities*. Retrieved from https://www.cdc.gov/ncbddd/fasd/documents/AlcoholSBIImplementationGuide-P.pdf

Centers for Disease Control and Prevention. (2018). Alcohol and Public Health: Frequently Asked Questions. Retrieved February 7, 2020, from https://www.cdc.gov/alcohol/faqs.htm

Curry, S. J., Krist, A. H., Owens, D. K., Barry, M. J., Caughey, A. B., Davidson, K. W., … Wong, J. B. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. *JAMA - Journal of the American Medical Association*, *320*(18), 1899–1909. https://doi.org/10.1001/jama.2018.16789

Gosdin LK, Deputy NP, Kim SY, Dang EP, Denny CH. Alcohol Consumption and Binge Drinking During Pregnancy Among Adults Aged 18–49 Years — United States, 2018–2020. MMWR Morb Mortal Wkly Rep 2022;71:10–13. DOI: http://dx.doi.org/10.15585/mmwr.mm7101a2Fiks, A. G. (2011). Designing Computerized Decision Support That Works for Clinicians and Families. *Current Problems in Pediatric and Adolescent Health Care*, *41*(3), 60–88. https://doi.org/10.1016/j.cppeds.2010.10.006.

Health Level 7. (n.d.-a). CQL-to-ELM Translator Reference Implementation. Retrieved June 19, 2019, from https://github.com/cqframework/clinical_quality_language/blob/master/Src/java/cql-to-elm/OVERVIEW.md

Health Level 7. (n.d.-b). Profile audience and scope. Retrieved May 12, 2020, from http://hl7.org/fhir/smart-app-launch/index.html#profile-audience-and-scope

Health Level 7. (n.d.-c). RESTful API. Retrieved May 12, 2020, from https://www.hl7.org/fhir/http.html

Health Level 7. (n.d.-d). SMART App Launch: Scopes and Launch Context. Retrieved May 12, 2020, from http://hl7.org/fhir/smart-app-launch/scopes-and-launch-context/index.html

Health Level 7. (n.d.-e). SUSHI. Retrieved May 12, 2020, from https://github.com/FHIR/sushi

Health Level 7. (n.d.-f). Using the FHIR Validator. Retrieved May 12, 2020, from https://wiki.hl7.org/Using_the_FHIR_Validator

Health Level 7 (HL7). (n.d.-a). Advanced form behavior and calculation - FHIR v4.0.0. Retrieved May 12, 2020, from http://hl7.org/fhir/uv/sdc/2019May/behavior.html

Health Level 7 (HL7). (n.d.-b). Advanced form rendering - FHIR v4.0.0. Retrieved May 12, 2020, from http://hl7.org/fhir/uv/sdc/2019May/rendering.html

Health Level 7 (HL7). (n.d.-c). Clinical Quality Language (CQL) Release 1 STU4 (1.4). Retrieved May 12, 2020, from https://cql.hl7.org/

Health Level 7 (HL7). (n.d.-d). Clinicalreasoning-module - FHIR v4.0.1. Retrieved May 12, 2020, from http://www.hl7.org/fhir/clinicalreasoning-module.html

Health Level 7 (HL7). (n.d.-e). Condition Event Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/condition.html

Health Level 7 (HL7). (n.d.-f). FHIR Clinical Guidelines. Retrieved May 12, 2020, from http://hl7.org/fhir/uv/cpg/2019Sep/

Health Level 7 (HL7). (n.d.-g). FHIR Shorthand. Retrieved May 12, 2020, from https://build.fhir.org/ig/HL7/fhir-shorthand/

Health Level 7 (HL7). (n.d.-h). Observation Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/observation.html

Health Level 7 (HL7). (n.d.-i). Overview - FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/overview.html

Health Level 7 (HL7). (n.d.-j). PlanDefinition Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from http://www.hl7.org/fhir/plandefinition.html

Health Level 7 (HL7). (n.d.-k). Questionnaire Resource- Content: Structured Data Capture, FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/questionnaire.html#sdc

Health Level 7 (HL7). (n.d.-l). Questionnaire Resources - Content, FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/questionnaire.html

Health Level 7 (HL7). (n.d.-m). Resource Library - Content, FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/library.html

Health Level 7 (HL7). (n.d.-n). Resourcelist - FHIR v4.0.1. Retrieved May 12, 2020, from https://www.hl7.org/fhir/resourcelist.html

Health Level 7 (HL7). (n.d.-o). SDC Home Page - FHIR v4.0.0. Retrieved May 12, 2020, from http://hl7.org/fhir/uv/sdc/2019May/

Health Level 7, & Boston Children's Hospital. (n.d.-a). CDS Cards. Retrieved August 22, 2019, from https://cds-hooks.org/#cds-cards

Health Level 7, & Boston Children's Hospital. (n.d.-b). CDS Hooks. Retrieved June 4, 2019, from https://cds-hooks.org/

Health Level 7, & Boston Children's Hospital. (n.d.-c). SMART App Launch Framework. Retrieved May 12, 2020, from http://hl7.org/fhir/smart-app-launch/index.html

Higgins-Biddle, J. C., & Babor, T. F. (2018). A review of the Alcohol Use Disorders Identification Test (AUDIT), AUDIT-C, and USAUDIT for screening in the United States: Past issues and future directions. *American Journal of Drug and Alcohol Abuse*, *44*(6), 578–586. https://doi.org/10.1080/00952990.2018.1456545

Ismail, S., Buckley, S., Budacki, R., Jabbar, A., & Gallicano, G. I. (2010). Screening, diagnosing and prevention of fetal alcohol syndrome: Is this syndrome treatable? *Developmental Neuroscience*. https://doi.org/10.1159/000313339

McKnight-Eily, L. R., Liu, Y., Brewer, R. D., Kanny, D., Lu, H., Denny, C. H., … Collins, J. (2014). Vital signs: Communication between health professionals and their patients about alcohol use - 44 states and the district of Columbia, 2011. *Morbidity and Mortality Weekly Report*, *63*(1), 16–22.

McKnight-Eily, L. R., Okoro, C. A., Mejia, R., Denny, C. H., Higgins-Biddle, J., Hungerford, D., … Sniezek, J. E. (2020). Screening for excessive alcohol use and brief counseling of adults — 17 states and the District of Columbia, 2017. *Morbidity and Mortality Weekly Report*, *60*(10), 265–270. https://doi.org/10.15585/mmwr.mm6612a1

Mokdad, A. H., Marks, J. S., Stroup, D. F., & Gerberding, J. L. (2004). Actual Causes of Death in the United States, 2000. *Journal of the American Medical Association*, *291*(10), 1238–1245. https://doi.org/10.1001/jama.291.10.1238

National Committee for Quality Assurance. (n.d.). HEDIS Measure: Unhealthy Alcohol Use Screening and Follow-Up (ASF). Retrieved May 22, 2020, from https://www.ncqa.org/hedis/reports-and-research/hedis-measure-unhealthy-alcohol-use-screening-and-follow-up/

National Institute on Alcohol Abuse and Alcoholism. (n.d.). Alcohol Facts and Statistics | National Institute on Alcohol Abuse and Alcoholism (NIAAA). Retrieved February 18, 2020, from https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/alcohol-facts-and-statistics

National Institute on Drug Abuse. (n.d.). The NIDA Quick Screen | National Institute on Drug Abuse (NIDA). Retrieved December 4, 2019, from https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/nida-quick-screen

National Institute on Drug Abuse. (2009). Screening for Drug Use in General Medical Settings: A Resource Guide for Providers. Retrieved from https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/introduction

O'Connor, E. A., Perdue, L. A., Senger, C. A., Rushkin, M., Patnode, C. D., Bean, S. I., & Jonas, D. E. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA - Journal of the American Medical Association*, *320*(18), 1910–1928. https://doi.org/10.1001/jama.2018.12086

Oauthjs. (n.d.). Express OAuth Server. Retrieved May 12, 2020, from https://github.com/oauthjs/express-oauth-server

Office of the National Coordinator (ONC). (2020). ONC's Cures Act Final Rule. Retrieved May 12, 2020, from https://www.healthit.gov/curesrule/

OpenJS Foundation. (n.d.). Node.js. Retrieved May 12, 2020, from https://nodejs.org/en/

Stahre, M., Roeber, J., Kanny, D., Brewer, R. D., & Zhang, X. (2014). Contribution of Excessive Alcohol Consumption to Deaths and Years of Potential Life Lost in the United States. *Preventing Chronic Disease*, *11*, 130293. https://doi.org/10.5888/pcd11.130293

Substance Abuse and Mental Health Services Administration. (2018). *Table 2.1B—Tobacco Product and Alcohol Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older, by Age Group: Percentages, 2017 and 2018. 2018 National Survey of Drug Use adn Health (NSDUH)*. Retrieved from https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2018R2/NSDUHDetTabsSect2pe2018.htm#tab2-1b

The American College of Obstetricians and Gynecologists. (2011). At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications - ACOG. Retrieved January 21, 2020, from https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/At-Risk-Drinking-and-Alcohol-Dependence-Obstetric-and-Gynecologic-Implications

The MITRE Corporation. (n.d.). CQL Execution Framework Reference Implementation. Retrieved May 12, 2020, from https://github.com/cqframework/cql-execution/blob/master/OVERVIEW.md

The Office of the National Coordinator for Health Information Technology. (n.d.). Interoperability Standards Advisory: Representing Patient Sex (At Birth).

Tso, G. J., Tu, S. W., Oshiro, C., Martins, S., Ashcraft, M., Yuen, K. W., … Goldstein, M. K. (2016). Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. *AMIA ... Annual Symposium Proceedings. AMIA Symposium*, *2016*, 1189–1198.

U.S. Department of Health and Human Services and U.S. Department of Agriculture. (2015). *2015-2020 Dietary Guidelines for Americans*. Retrieved from https://health.gov/our-work/food-nutrition/2015-2020-dietary-guidelines/guidelines/

Vue.js. (n.d.). The Progressive JavaScript Framework. Retrieved May 12, 2020, from https://vuejs.org/

White, A. M., Castle, I. J. P., Hingson, R. W., & Powell, P. A. (2020). Using Death Certificates to Explore Changes in Alcohol-Related Mortality in the United States, 1999 to 2017. *Alcoholism: Clinical and Experimental Research*, *44*(1), 178–187. https://doi.org/10.1111/acer.14239

Wikipedia. (n.d.-a). Hooking. Retrieved May 12, 2020, from https://en.wikipedia.org/wiki/Hooking

Wikipedia. (n.d.-b). OAuth. Retrieved May 12, 2020, from https://en.wikipedia.org/wiki/OAuth

Wikipedia. (n.d.-c). Representational state transfer. Retrieved May 12, 2020, from https://en.wikipedia.org/wiki/Representational_state_transfer

Wikipedia. (n.d.-d). Test-driven development. Retrieved June 4, 2019, from https://en.wikipedia.org/wiki/Test-driven_development

World Health Organization. (2014). *Guidelines for the identification and management of substance use and substance use disorders in pregnancy. WHO* (Vol. 34). Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24783312

Wright, T. E., Terplan, M., Ondersma, S. J., Boyce, C., Yonkers, K., Chang, G., & Creanga, A. A. (2016). The role of screening, brief intervention, and referral to treatment in the perinatal period. *American Journal of Obstetrics and Gynecology*, *215*(5), 539–547. https://doi.org/10.1016/j.ajog.2016.06.038

Acronyms

Acronym	Definition
ACOG	American College of Obstetricians and Gynecologists
API	Application Programming Interface
ASBI	Alcohol Screening and Brief Intervention
AUD	Alcohol Use Disorder
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	AUDIT-Consumption
BI	Brief Intervention
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CMS	Centers for Medicare & Medicaid Services
CQL	Clinical Quality Language
CRM	Clinical Reasoning Module
EHR	Electronic Health Record
ELM	Expression Logical Model
FASD	Fetal Alcohol Spectrum Disorders
FHIR	Fast Healthcare Interoperability Resources
FFRDC	Federally Funded Research and Development Center
FSH	FHIR Shorthand
HHS	Department of Health and Human Services
HL7	Health Level 7
IG	Implementation Guide
IT	Information Technology
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIDA	National Institute on Drug Abuse
NIDA QS	National Institute on Drug Abuse Quick Screen
ONC	U.S. Office of the National Coordinator for Health Information Technology
PS	Prescreen
SASQ	Single Alcohol Screening Question

Acronym	Definition
SDC	Structured Data Capture
SMART	Sustainable Medical Applications, Reusable Technologies
SME	Subject Matter Expert
SUSHI	SUSHI Unshortens ShortHand Inputs
TDD	Test Driven Development
USAUDIT	AUDIT, adapted for use in the United States
USAUDIT-C	USAUDIT-Consumption
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

Appendix A. Artifact Logic and Decision Log

A.1 Artifact CDS Logic Flow

The *Alcohol Brief Intervention and Referral* CDS artifact was informed by multiple evidence-based references that provide guidance to clinicians on conducting brief behavioral counseling interventions for patients based on their alcohol screening results and other factors (e.g., if the patient is pregnant, or has a history of alcohol use disorder). See Section 4.1 for additional information.

Translating knowledge in narrative evidence-based sources requires a considerable level of effort and interpretation. When translating complex guidelines, it is often helpful to develop a high-level depiction of the evidence that can serve as the foundation for more detailed representations of the knowledge as clinical decision support (CDS) development progresses. Because the logic in this CDS artifact is quite complex, two separate CDS logic flow diagrams were developed to display the outcome of the first "phase" of translating knowledge from published guidance into a series of events and decisions that enable evidence-based brief interventions for alcohol use. The two diagrams provide potential implementers with an impression of the CDS logic flow.

The CDS logic flow diagram in Figure 8 displays an overview of the CDS logic that applies to patients that are either currently pregnant (based on information found in their patient record in the EHR or health IT system) or responded "Yes" to the pregnancy question (i.e., "Are you currently pregnant or trying to become pregnant?") in the associated screening CDS artifacts mentioned at the beginning of this implementation guide. The CDS logic flow diagram in Figure 9 displays an overview of the CDS logic that applies to all other patients (i.e., all males and female patients that are not currently pregnant or did not respond "Yes" to the pregnancy question).

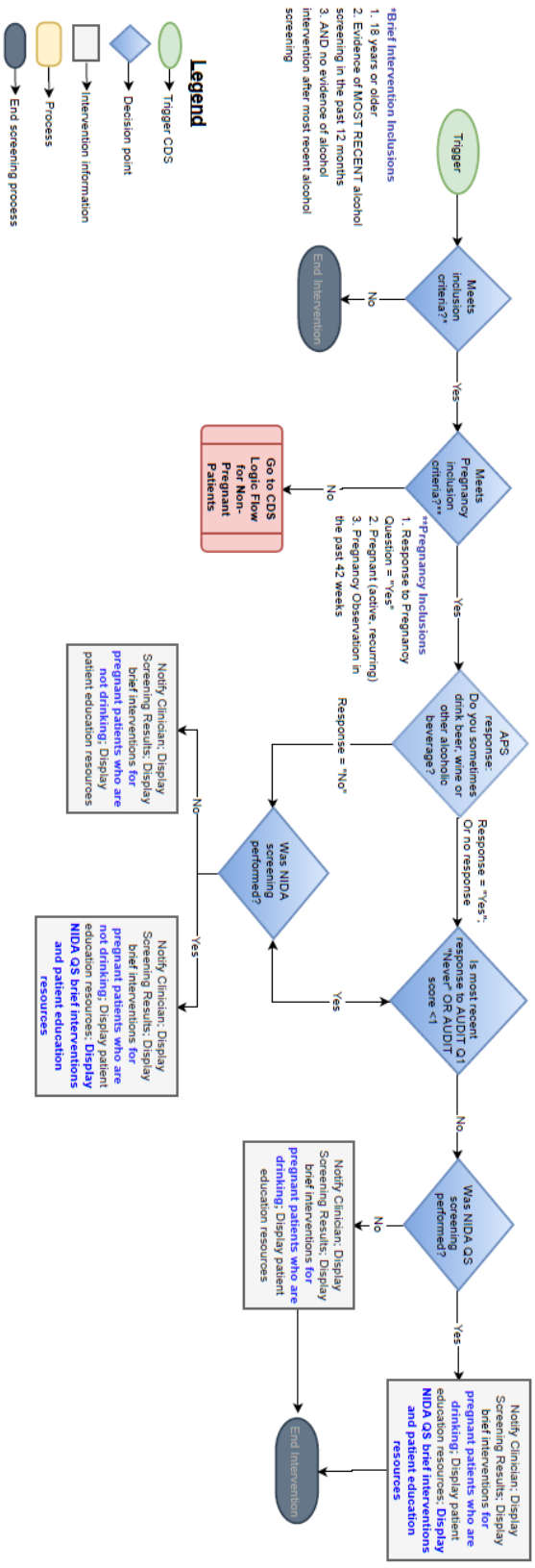

Figure 8: Alcohol Brief Intervention and Referral CDS Logic Flow for Pregnant Patients

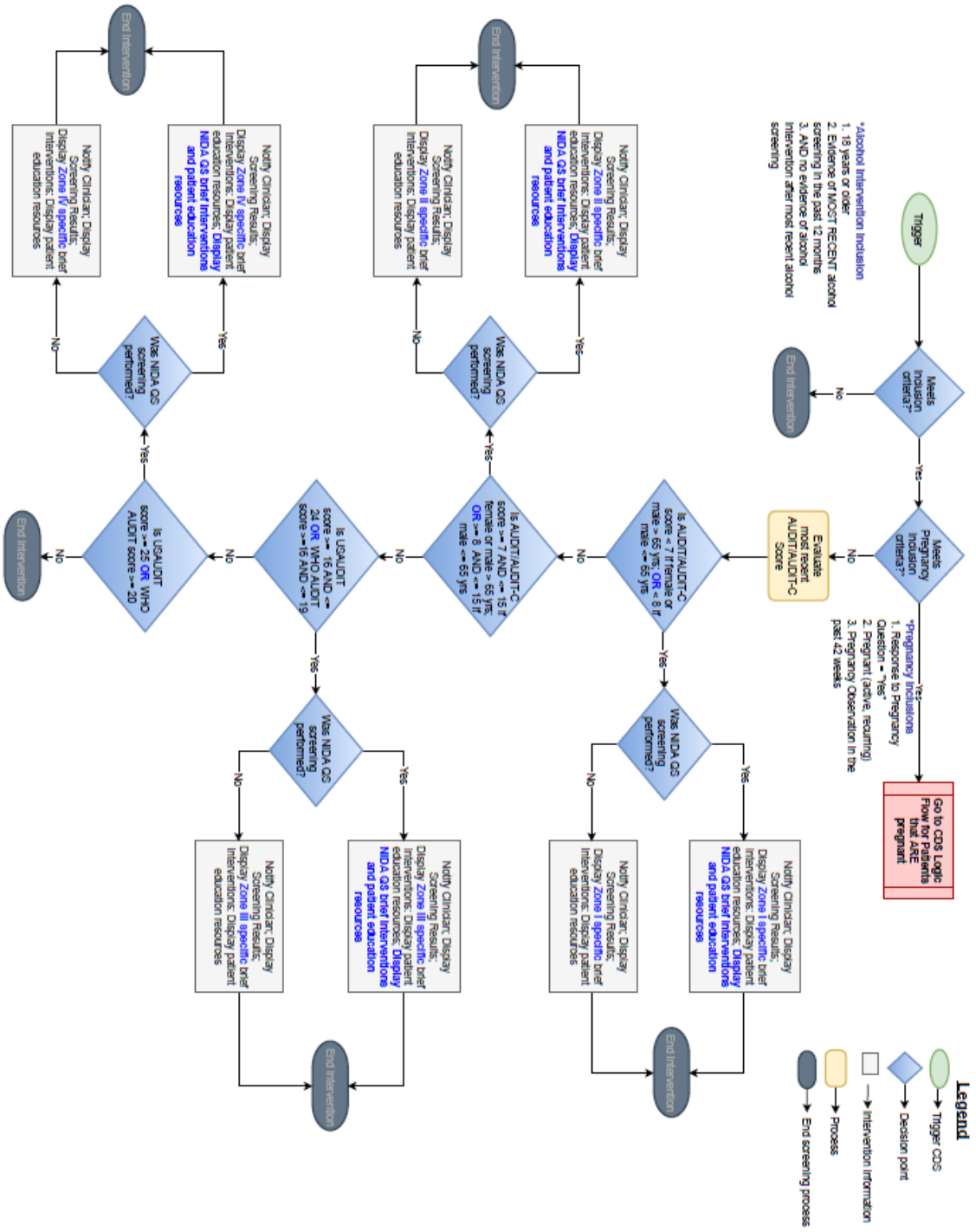

Figure 9: Alcohol Brief Intervention and Referral CDS Logic Flow for All Males and Female Patients That Are Not Pregnant

A.2 Artifact Semi-structured Representation

Next, the CDS Development Team utilized the CDS flow depicted in Figure 8 and Figure 9, along with granular details identified in the narrative references to inform the development of a more comprehensive semi-structured (i.e., Level 2, L2, human readable) representation of the knowledge. During this phase of development, the Development Team clarified guidance that was imprecise to provide the specificity required by software engineers to develop the structured (i.e., coded, Level 3, L3) representation. Decisions made while interpreting and clarifying the guidelines are outlined in Appendix A.4 to provide transparency on the artifact development process and enhance trust in the artifact.

The semi-structured logic listed in this section of the appendix is divided into several "steps" to make the sequencing of the logic more understandable. Each step roughly aligns with a decision point during the intervention process. Implementing organizations can decide what triggering event best complements the workflow in their organization to initiate Step 1 (e.g., the start of a patient encounter). Words listed in parenthesis within the logic are Fast Healthcare Interoperability Resources (FHIR) attributes that specify the "status" of clinical concepts such as observations (e.g., Pregnancy) and diagnoses (e.g., Pregnant). The status of a clinical concept can be an important component of logic specifications in some instances. For example, the CDS is specified to only evaluate screening results with a status of "final," "amended" and "corrected" as TRUE (i.e., valid for the purpose of this CDS). Therefore, screening results with a status of "preliminary," "cancelled," and "entered in error" will be evaluated as FALSE (i.e., invalid for the purpose of this CDS).

Step 1: Consider availability of AUDIT screening results or an alcohol PS question response with no brief intervention recorded

Inclusion logic:

Patient is >= 18 years old

AND

Evidence of USAUDIT score recorded in the past 12 months (final, amended, corrected)

OR evidence of USAUDIT-C score recorded in the past 12 months (completed, amended) WHERE no USAUDIT score recorded

OR evidence of WHO AUDIT score recorded in the past 12 months (completed, amended)

OR evidence of WHO AUDIT-Consumption (AUDIT-C) score recorded in the past 12 months (completed, amended) WHERE no WHO AUDIT score recorded

OR evidence of alcohol PS question response recorded in the past 12 months (completed, amended) WHERE alcohol PS question response is "No"

OR evidence of alcohol PS question response recorded in the most recent past 12 months (completed, amended) WHERE alcohol PS question response is “Yes"

AND evidence of most recent WHO AUDIT question #1 response is "Never"

Exclusion logic:

BI intervention (completed) AFTER most recent AUDIT screening results recorded

OR BI intervention (completed) AFTER most recent alcohol PS question response recorded

CDS Actions: Continue to Step 2

Step 2: Consider female patients that are pregnant or trying to become pregnant

Step 2, Logic Path #1 (Patient is pregnant or may be trying to become pregnant, did not respond to the NIDA QS as part of their screening, and is not drinking)

Inclusions:

Patient is >= 18 years old

AND

Female

OR Sex at birth Unknown

AND

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent alcohol PS question response is "No" (completed, amended)

OR most recent alcohol PS question response is "Yes" (completed, amended)

AND most recent response to WHO AUDIT Question #1 = “Never” (completed, amended)

OR most recent alcohol PS question response is "Yes" (completed, amended)

AND most recent response to USAUDIT Question #1 = “Never” (completed, amended)

OR most recent WHO AUDIT score = 0

OR most recent WHO AUDIT-C score = 0 WHERE no WHO AUDIT score recorded

OR most recent USAUDIT score = 0

OR most recent USAUDIT -C score = 0 WHERE no USAUDIT score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is "No"

OR evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is “Yes”
AND most recent response to USAUDIT question #1 = “Never” (completed, amended)
OR evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is “Yes”
AND most recent response to WHO AUDIT question #1 = “Never” (completed, amended)
OR evidence of NIDA QS results <= 1 day BEFORE the most recent AUDIT score = 0

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for pregnant patients that do not drink alcohol

Display patient education resources for pregnant patients that do not drink alcohol

Step 2, Logic Path #2 (Patient is pregnant or may be trying to become pregnant, responded to the NIDA QS as part of their screening, and is not drinking)

Inclusions:

Patient is >= 18 years old

AND

Female

OR Sex at birth Unknown

AND

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent alcohol PS question response is "No" (completed, amended)

OR most recent alcohol PS question response is "Yes" (completed, amended)
AND most response to WHO AUDIT question #1 = “Never” (completed, amended)

OR most recent alcohol PS question response is "Yes" (completed, amended)
AND most response to USAUDIT question #1 = “Never” (completed, amended)

OR most recent WHO AUDIT score = 0

OR most recent WHO AUDIT-C score = 0 WHERE no WHO AUDIT score recorded

OR most recent USAUDIT score = 0

OR most recent USAUDIT -C score = 0 WHERE no USAUDIT score recorded

AND

Evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is "No"

OR evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is “Yes”
AND most response to USAUDIT question #1 = “Never” (completed, amended)
OR evidence of NIDA QS results <= 1 day before the most recent alcohol PS question response is “Yes”
AND most response to WHO AUDIT question #1 = “Never” (completed, amended)
OR evidence of NIDA QS results <= 1 day BEFORE the most recent AUDIT score = 0

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display NIDA QS screening responses

Display counseling suggestions for pregnant patients that do not drink alcohol

Display patient education resources for pregnant patients that do not drink alcohol

Display NIDA QS-specific counseling suggestions for pregnant patients (based on positive NIDA QS responses to questions #2, #3 and #4) (see Appendix B for details)

Display NIDA QS-specific education resources for pregnant patients (based on positive NIDA QS responses to questions #2, #3 and #4) (see Appendix B for details)

Step 2, Logic Path #3 (Patient is pregnant or may be trying to become pregnant, responded to the NIDA QS as part of their screening, and indicates they are drinking)

Inclusions:

Patient is >= 18 years old

AND

Female

OR Sex at birth Unknown

AND

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score >= 1

OR most recent USAUDIT-C score >= 1 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 1

OR most recent WHO AUDIT-C score >= 1 WHERE no WHO AUDIT score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS screening results <= 1 day prior to the most recent USAUDIT score recorded

WHERE the USAUDIT score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent USAUDIT-C score recorded

WHERE the USAUDIT-C score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent WHO AUDIT score recorded

WHERE the WHO AUDIT score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent WHO AUDIT-C score recorded

WHERE the WHO AUDIT-C score >= 1 (completed, amended)

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for pregnant patients that drink alcohol

Display verbiage to clinician to consider referring patient for evaluation and treatment

Present clinician with option to generate referral for evaluation and treatment

Display patient education resources for pregnant patients that drink alcohol

Step 2, Logic Path #4 (Patient is pregnant or may be trying to become pregnant, responded to the NIDA QS as part of their screening, and indicates they are drinking)

Inclusions:

Patient is >= 18 years old

AND

Female

OR Sex at birth Unknown

AND

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score >= 1

OR most recent USAUDIT-C score >= 1 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 1

OR most recent WHO AUDIT-C score >= 1 WHERE no WHO AUDIT score recorded

AND

Evidence of NIDA QS screening results <= 1 day prior to the most recent USAUDIT score recorded

WHERE the USAUDIT score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent USAUDIT-C score recorded

WHERE the USAUDIT-C score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent WHO AUDIT score recorded

WHERE the WHO AUDIT score >= 1 (completed, amended)

OR evidence of NIDA QS screening results <= 1 day prior to the most recent WHO AUDIT-C score recorded

WHERE the WHO AUDIT-C score >= 1 (completed, amended)

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening responses

Display NIDA QS responses

Display counseling suggestions for pregnant patients that drink alcohol

Display verbiage to clinician to consider referring patient for evaluation and treatment if warranted

Present clinician with option to generate referral for evaluation and treatment

Display NIDA QS-specific counseling suggestions (based on positive NIDA QS responses to questions #2, #3, and #4)

Display patient education resources for pregnant patients that drink alcohol

Display NIDA QS-specific education resources for pregnant patients (based on positive NIDA QS responses to questions #2, #3, and #4)

Step 3: Consider all male patients and female patients that are not pregnant; and did not respond to the NIDA QS as part of their screening

Step 3, Logic Path #1 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 1 [low-risk drinking levels], and did not respond to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND Male > 65 years old

OR

Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score < 7 (completed, amended)

OR most recent USAUDIT-C score < 7 (completed, amended) WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score < 7 (completed, amended)

OR most recent WHO AUDIT-C score < 7 (completed, amended) WHERE no WHO AUDIT score recorded

OR Male <= 65 years old

AND

Most recent USAUDIT score < 8 (completed, amended)

OR most recent USAUDIT-C score < 8 (completed, amended) WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score < 8 (completed, amended)

OR most recent WHO AUDIT-C score < 8 (completed, amended) WHERE no WHO AUDIT score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for patients in Zone 1 (low-risk drinking levels)

Display patient education resources for patients in Zone 1 (low-risk drinking levels)

Step 3, Logic Path #2 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 2 [drinking in excess of guidelines], and did not respond to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND Male > 65 years old

OR

Female OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score >= 7 AND <= 15

OR most recent USAUDIT-C score >= 7 AND <= 15 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 7 AND <= 15

OR most recent WHO AUDIT-C score >= 7 AND <= 15 WHERE no WHO AUDIT score recorded

OR Male <= 65 years old

AND

Most recent USAUDIT score >= 8 AND <= 15

OR most recent USAUDIT-C score >= 8 AND <= 15 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 8 AND <= 15

OR most recent WHO AUDIT-C score >= 8 AND <= 15 WHERE no WHO AUDIT score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for patients in Zone 2 (drinking in excess of guidelines)

Display patient education resources for patients in Zone 2 (drinking in excess of guidelines)

Step 3, Logic Path #3 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 3 [harmful or hazardous drinking], and did not respond to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND

Most recent USAUDIT score >= 16 AND <= 24

OR most recent USAUDIT-C score >= 16 AND <= 24 WHERE no USAUDIT score recorded

OR most recent (WHO) AUDIT score >= 16 AND <= 19

OR most recent WHO AUDIT-C score >= 16 AND <= 19 WHERE no WHO AUDIT score recorded

AND Male

OR

Female

OR Sex at birth Unknown

AND NOT

response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for patients in Zone 3 (harmful or hazardous drinking)

Display verbiage to clinician to consider referring patient for evaluation and treatment if warranted

Present clinician with option to generate referral for evaluation and treatment

Display patient education resources for patients in Zone 3 (harmful or hazardous drinking)

Step 3, Logic Path #4 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 4 [high-risk drinking], and did not respond to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND

Most recent USAUDIT score >= 25

OR most recent USAUDIT-C score >= 25 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 20

OR most recent WHO AUDIT-C score >= 20 WHERE no WHO AUDIT score recorded

AND Male

OR
Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display counseling suggestions for patients in Zone 4 (high-risk drinking)

Display verbiage to clinician to consider referring patient for evaluation and treatment if warranted

Present clinician with option to generate referral for evaluation and treatment

Display patient education resources for patients in Zone 4 (high-risk drinking)

Step 4: Consider all male patients and female patients that are not pregnant; and responded to the NIDA QS as part of their screening

Step 4, Logic Path #1 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 1 [low-risk drinking levels], and responded to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND Male > 65 years old

OR

Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score < 7 (completed, amended)

OR most recent USAUDIT-C score < 7 (completed, amended) WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score < 7 (completed, amended)

OR most recent WHO AUDIT-C score < 7 (completed, amended) WHERE no WHO AUDIT score recorded

OR Male <= 65 years old

AND

Most recent USAUDIT score < 8 (completed, amended)

OR most recent USAUDIT-C score < 8 (completed, amended) WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score < 8 (completed, amended)

OR most recent WHO AUDIT-C score < 8 (completed, amended) WHERE no WHO AUDIT score recorded

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display NIDA QS screening responses

Display counseling suggestions for patients in Zone 1 (low-risk drinking levels)

Display NIDA QS counseling suggestions (based on positive NIDA QS responses to questions #2, #3, and #4)

Display patient education resources for patients in Zone 1 (low-risk drinking levels)

Display NIDA QS patient education resources (based on positive NIDA QS responses to questions #2, #3, and #4)

Step 4, Logic Path #2 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 2 [drinking in excess of guidelines], and responded to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND Male > 65 years old

OR Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Most recent USAUDIT score >= 7 AND <= 15

OR most recent USAUDIT-C score >= 7 AND <= 15 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 7 AND <= 15

OR most recent WHO AUDIT-C score >= 7 AND <= 15 WHERE no WHO AUDIT score recorded

OR Male <= 65 years old

AND

Most recent USAUDIT score >= 8 AND <= 15

OR most recent USAUDIT-C score >= 8 AND <= 15 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 8 AND <= 15

OR most recent WHO AUDIT-C score >= 8 AND <= 15 WHERE no WHO AUDIT score recorded

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display NIDA QS screening responses

Display counseling suggestions for patients in Zone 2 (drinking in excess of guidelines)

Display NIDA QS counseling suggestions (based on positive NIDA QS responses to questions #2, #3, and #4)

Display patient education resources for patients in Zone 2 (drinking in excess of guidelines)

Display NIDA QS patient education resources (based on positive NIDA QS responses to questions #2, #3, and #4)

Step 4, Logic Path #3 (Patient is male or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 3 [harmful or hazardous drinking], and responded to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND

Most recent USAUDIT score >= 16 AND <= 24

OR most recent USAUDIT-C score >= 16 AND <= 24 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 16 AND <= 19

OR most recent WHO AUDIT-C score >= 16 AND <= 19 WHERE no WHO AUDIT score recorded

AND Male

OR

Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display NIDA QS screening responses

Display counseling suggestions for patients in Zone 3 (harmful or hazardous drinking)

Display verbiage to clinician to consider referring patient for evaluation and treatment if warranted

Present clinician with option to generate referral for evaluation and treatment

Display NIDA QS counseling suggestions (based on positive NIDA QS responses to questions #2, #3, and #4)

Display patient education resources for patients in Zone 3 (harmful or hazardous drinking)

Display NIDA QS patient education resources (based on positive NIDA QS responses to questions #2, #3, and #4)

Step 4, Logic Path #4 (Patient is male, or female and not pregnant or trying to become pregnant, has an AUDIT score within Zone 4 [high-risk drinking], and responded to the NIDA QS)

Inclusions:

Patient is >= 18 years old

AND

most recent USAUDIT score >= 25

OR most recent USAUDIT-C score >= 25 WHERE no USAUDIT score recorded

OR most recent WHO AUDIT score >= 20

OR most recent WHO AUDIT-C score >= 20 WHERE no WHO AUDIT score recorded

AND Male

OR Female

OR Sex at birth Unknown

AND NOT

Response to pregnancy question is "Yes"

OR Pregnant (active, recurring)

OR Pregnancy observation in the past 42 weeks (final, amended, corrected)

AND

Evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent USAUDIT-C score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT score recorded

OR evidence of NIDA QS responses recorded <= 1 day prior to most recent WHO AUDIT-C score recorded

Exclusions:

BI intervention (completed) AFTER most recent alcohol screening results

CDS Actions: (see Appendix B for details of specific text and information to insert for each action)

Display notification to clinician

Display alcohol screening results

Display NIDA QS screening responses

Display counseling suggestions for patients in Zone 4 (high-risk drinking)

Display verbiage to clinician to consider referring patient for evaluation and treatment if warranted

Present clinician with option to generate referral for evaluation and treatment

Display NIDA QS counseling suggestions (based on positive NIDA QS responses to questions #2, #3, and #4)

Display patient education resources for patients in Zone 4 (high-risk drinking)

Display NIDA QS patient education resources (based on positive NIDA QS responses to questions #2, #3, and #4)

A.3 CDS Concept Definitions

Table 6 defines many of the clinical concepts and terms used in the semi-structured CDS representation to provide clarity on what each logic concept means and why it was expressed as listed. These concepts were informed by or derived from text in evidence-based sources (e.g., AUDIT, research reviews).

Table 6: CDS Concept Definitions

Location in CDS Logic	Concept	Definition and/or Rationale
Trigger	"alcohol screening results"	To trigger the CDS, the logic looks for evidence of alcohol screening results present in the patient record. Depending on the local implementation of alcohol screening in the EHR, this could include scores from several different screening instruments, which are defined in Step 1.
Step 1	"evidence of …"	Any "final", "amended", or "corrected" alcohol screening results that are present in the patient record. Specifically, the CDS code looks for results associated with the following screening tools: 1) USAUDIT; 2) USAUDIT-C if no USAUDIT score; 3) WHO AUDIT; 4) WHO AUDIT-C if no WHO AUDIT score; 5) evidence of a response of "No" to an alcohol prescreen (PS) question ("Do you drink beer, wine or other alcoholic beverages"); and 6) evidence of a response of "Yes" to an alcohol PS question AND evidence of a response to either the USAUDIT or the WHO AUDIT question #1 of "Never". The USAUDIT, USAUDIT-C, WHO AUDIT, and WHO AUDIT-C screening results were selected because the scores generated by each of them align with the evidence used to determine the appropriate intervention.
Step 1	"in the past x months"	The CDS code looks for evidence of a specific event, condition, result (e.g., alcohol screening results) to have occurred within a specified period of time from the current date (e.g., within the past 12 months from today).
Step 3-4	"BUT NOT" or "AND NOT"	CDS logic operators that ensure a specific event, condition, result, etc. is not present in the patient record

Location in CDS Logic	Concept	Definition and/or Rationale
Step 1 – 4 Inclusion and Exclusion	"most recent"	Enables the CDS code to evaluate data that was recorded as near to the screening event as possible. Data that is "most recent" is most likely to reflect the patient's current status.
Every Step	">="	Greater than or equal to a given value (e.g., >= 18 years old)
Step 1-4 Exclusions	"BI intervention"	Any "final", "amended", or "corrected" brief intervention that is present in the patient record.
CDS Actions Step 1	Continue to Step 2	The logic in Step 1 of this artifact determines if the patient meets the inclusion and exclusion criteria of having alcohol screening results that have not been acted upon. If so, the CDS logic will continue to determine the appropriate intervention for the patient based on the remaining logic.
Step 2 Inclusions	"="	Equal to (e.g., score = 0)
Steps 2-4	"sex at birth is Unknown"	The patient's sex at birth is recorded in the health IT system as "Unknown". Unknown is a valid response for an individual's sex at birth by HL7 standards outlined in the Interoperability Standards Advisory published by the Office of the National Coordinator for Health Information Technology (ONC) (The Office of the National Coordinator for Health Information Technology, n.d.). There are two specific areas in the CDS that are sex-specific. The first is when considering whether a patient is pregnant, and the second is when considering the alcohol screening score and appropriate intervention. Thus, it is important to consider all valid responses for "sex at birth" otherwise an individual whose sex at birth is recorded as Unknown would not be presented with question #3.
Step 2-4	"pregnancy question"	The pregnancy question is, "Are you currently pregnant or trying to become pregnant?". If one of the alcohol screening CDS artifacts mentioned in Section 1.1 is implemented, this question is presented to every woman of reproductive age unless they meet the exclusion criteria defined in that CDS artifact. If the pregnancy question is not implemented, thus no response is available, the CDS looks for one of the next two concepts to determine if the patient is pregnant. This is included in the logic because people who are pregnant require unique care (e.g., they should be screened for alcohol use more frequently than people who are non-pregnant and be provided with distinct brief interventions based on whether they are abstinent or drinking ANY amount of alcohol).
Steps 2-4	"pregnant"	A diagnosis of pregnancy. An "active" or "recurring" FHIR resource clinicalStatus must be associated with the pregnancy to ensure the individual is currently pregnant.

Location in CDS Logic	Concept	Definition and/or Rationale
Steps 2-4	"pregnancy observation within the past 42 weeks"	Pregnancy can also be expressed as a FHIR "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 timeframe so that only a current/active pregnancy is considered. The American College of Obstetricians and Gynecologists (ACOG) defines "early, full, and late term pregnancy" as up to 42 weeks of gestation (Accreta, 2002). Of note, since gestation date is not often specified in a health IT system, the CDS logic evaluates the date a pregnancy observation was recorded in the system. The FHIR ObservationStatus must be "final" or "amended" to ensure the observation is complete and verified by an authorized individual.
Steps 2-3	"alcohol prescreen (PS) question"	The alcohol PS question "Do you sometimes drink beer, wine, or other alcoholic beverages?" may be presented during alcohol screening prior to initiating an alcohol questionnaire such as the AUDIT. If one of the alcohol screening CDS artifacts mentioned in Section 1.1 is implemented, this question is presented to all patients when beginning alcohol screening. A response of "No" removes the need for further assessment of risky alcohol use. Because it is important to reinforce abstinence in all people who are pregnant, an intervention reinforcing the importance of not drinking will be recommended for pregnant patients who indicate they are not drinking (Curry et al., 2018) (Centers for Disease Control and Prevention, 2014).
Steps 2-4	"AUDIT score", "USAUDIT score", "USAUDIT-C score", "WHO" AUDIT score", "WHO AUDIT-C score"	"AUDIT" refers to the Alcohol Use Disorders Identification Test alcohol screening questionnaire, and "score" is the calculation of the point value generated when responding to the AUDIT screening questions. There are two versions of the AUDIT, the USAUDIT and the WHO AUDIT. In addition, both the US and WHO AUDIT provide a shorter version containing only the first 3 questions, referred to as the USAUDIT-C or WHO AUDIT-C. In the CDS logic, if it does not matter which version of the AUDIT is associated with the screening score, the general term "AUDIT score" is used. Sometimes, because the calculation of the scores differ between the US and WHO AUDIT versions, the CDS specifies which version of the AUDIT is associated with a specific score in order to calculate the appropriate intervention.
Step 2-4 Exclusions OR Inclusions	"NIDA Quick Screen (QS)"	The NIDA QS is a brief, four question assessment that evaluates how often an individual has used the following substances in the past year: illicit drugs, prescription drugs for non-medical reasons, tobacco and alcohol (i.e., had 5 or more drinks a day if a man or had 4 or more drinks if a woman). If a patient has responses to the NIDA QS, the specific responses will be included in the screening responses presented to the clinician by the CDS intervention and action.

Location in CDS Logic	Concept	Definition and/or Rationale
CDS Actions Steps 2 - 4	"Display notification to clinician"	If the patient meets the inclusion criteria and not the exclusion criteria, the CDS actions are generated. This first intervention provides a notification that new screening information is available. The specific method of delivery and content for this notification will be an implementation decision, to allow each implementor to determine a best method that fits with the current EHR or health IT capabilities.
CDS Actions Steps 2 - 4	"screening results"	Specific information about the patient's alcohol screening results is provided, based on the inclusion and exclusion criteria of the CDS logic. See Appendix B, CDS Actions and Brief Intervention Content, for additional information.
CDS Actions Steps 2 - 4	"Zone"	Administering an AUDIT questionnaire results in a numeric score, which is used to place the patient into one of four "Zones", based on the level of risk identified. Each Zone calls for a different level of intervention. See Appendix B, CDS Actions and Brief Intervention Content, for additional information, and **Table 2** for a description of each Zone threshold and definition.
CDS Actions Steps 2 - 4	"brief intervention suggestions"	Brief behavioral counseling intervention considerations are formulated based on the patient's overall AUDIT score, reported level of drinking, and other patient attributes (e.g., being pregnant or trying to become pregnant, or having a history of alcohol use disorder). See Appendix B, CDS Actions and Brief Intervention Content, for additional information.
CDS Actions Steps 2 - 4	"referral for evaluation and treatment"	For patients whose AUDIT score falls within Zone 3 and their past history indicates possible alcohol use disorder, as well as patients with scores within Zone 4, referral to a specialist for diagnostic evaluation and possible treatment for alcohol use dependence should be considered (Babor et al., 2017) (Centers for Disease Control and Prevention, 2014) (Babor et al., 2001). In addition, pregnant patients who are drinking and are unable to reduce or eliminate their drinking may also need to be referred (World Health Organization, 2014) (The American College of Obstetricians and Gynecologists, 2011).
CDS Actions Steps 2 - 4	"Patient Education Resources"	Patient education materials based on the patient's overall AUDIT score, reported level of drinking, and other patient attributes (e.g., being pregnant or trying to become pregnant) are provided and can be shared with the patient. See Appendix B, CDS Action and Brief Intervention Content, for additional information.
Step 2 – 4 Inclusions and Exclusions	"<="	Less than or equal to (e.g., less than or equal to 1 day)
Step 3 & 4 Inclusions	">"	Greater than (e.g., greater than 65 years old)
Step 3 & 4 Inclusions	"<"	Less than (e.g., score < 3)

A.4 Artifact Development Decision Log

The CDS Development Team made numerous decisions while translating the narrative text found in the references into semi-structured and later, structured, CDS logic. Table 7 provides insight on those decisions. 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 (Tso et al., 2016). It also lists the high-level "Concept" related to the entry and the "Rationale" for each decision.

Table 7: Artifact Development Decision Log

Decision Category	Concept	Rationale
Add explanation	Separating CDS logic that delivers brief intervention from CDS logic that delivers alcohol screening	The CDS Development Team took a modular approach to developing alcohol screening and brief intervention (ASBI) CDS artifacts to 1) lessen the complexity of each artifact and 2) enable organizations to only integrate portions of logic that they really need (e.g., are not already present in their health IT system). Some organizations may already use a version of the AUDIT alcohol screening questionnaire and have the ability to capture either the individual patient responses and/or the AUDIT score in their health IT system, but not have CDS to deliver evidence-based care recommendations. As a result, they may prefer to implement the *Alcohol Brief Intervention and Referral* CDS artifact only. Others may not have implemented the ability to capture the results of alcohol screening in their system and may need to implement one of the CDS artifacts for AUDIT screening. A modular approach allows for personalized implementation choices without the need to edit CDS code.
Add explanation	Screening and intervention for adults only	The AUDIT-C/AUDIT identifies (in part) individuals who are drinking in excess of recommended levels for healthy adults (Babor et al., 2001). Adults are individuals 18 years old and older. Other screening tools, such as CRAFFT (i.e., Car, Relax, Alone, Forget, Friends, Trouble), are validated screening instruments for adolescents (i.e., individuals under 18 years of age (Centers for Disease Control and Prevention, 2014).
Verify completeness/ Add explanation	Considering annual screening results for all patients	The WHO recommends that all patient be screened annually (Babor et al., 2001). Thus, this artifact identifies new alcohol screening results recorded in the past 12 months when determining if an intervention is needed and looks for the most recent evidence to accommodate more frequent screening, which may occur for people who are pregnant.

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	Ensuring that people who are pregnant receive appropriate alcohol brief interventions	The specifications outlined in the Step 2 inclusion logic facilitate brief interventions for women that are pregnant, including those who indicate abstinence. The interventions are formulated based on whether the screening results indicate that the patient is abstinent or is currently drinking. Professional organizations and government entities (e.g., ACOG, USPSTF, WHO) provide varied recommendations on providing brief interventions to people who are pregnant, even if they are not drinking. The CDS Development Team and CDC sponsors of this project elected to enable the provision of a brief intervention to people who are pregnant whose screening results indicate that they are abstinent, as well as those who are currently drinking. Some people who are pregnant may believe that it is safe to drink in the second or third trimester, and providing an intervention to pregnant patients who are currently abstinent provides an opportunity to continue to educate these patients on the importance of abstinence throughout their pregnancy (Wright et al., 2016) (Curry et al., 2018) (Centers for Disease Control and Prevention, 2014).
Verify completeness/ Add explanation	Considering how to approach providing an intervention to those individuals whose “sex assigned at birth” is recorded as Unknown in their medical record	During the development of the CDS artifacts for alcohol screening, the CDS Development Team and CDC sponsors of this project opted to develop logic that reasoned over a “sex assigned at birth” response that is recorded as Unknown to ensure these individuals also received alcohol screening. The logic places individuals with “unknown” sex at birth in the same “drink threshold” as all females (age 18 and older) and men over 65 years old. For this CDS artifact, *Alcohol Brief Intervention and Referral*, these patients are included in the logic for female patients, to determine if a patient is pregnant. In addition, they are included in the same AUDIT scoring criteria and associated Zone as females and males over 65 years old. As a result, the patient’s risk threshold may be slightly overestimated (which was preferred to potentially underestimating risk). Future implementers are encouraged to evaluate the accuracy and reliability of the “sex at birth” data in their system and consider if adjustments to the coded expression (i.e., L3) are indicated before implementing this artifact in their system.
Add explanation	Considering a patient’s Zone to identify the appropriate intervention	Administering an AUDIT questionnaire results in a numeric score, which is used by this logic to place the patient into one of four “Zones”, based on the level of risk identified. Each Zone calls for a different level of intervention. Zone 1 indicates low-risk drinking; Zone 2 indicates drinking in excess of guidelines; Zone 3 indicates harmful or hazardous drinking; and Zone 4 indicates high-risk drinking and probable alcohol use disorder. See Appendix B, CDS Actions and Brief Intervention Content, for additional information, and Table 2 for the description and score thresholds of each Zone

Decision Category	Concept	Rationale
Add explanation	Establishing the appropriate cut off point for women, individuals with Unknown recorded as "sex assigned at birth", and men over age 65 when determining the patient's Zone based on their AUDIT screening score	Per the WHO AUDIT, "Since the effects of alcohol vary with average body weight and differences in metabolism, establishing the cut off point for all females (age 18 and older) and men over age 65 one point lower…will increase sensitivity for these population groups. Selection of the cut-off point should be influenced by national and cultural standards and by clinician judgement…" (Babor et al., 2001). For these reasons, the CDS Development Team and CDC sponsors of this project elected to consider the sex of the patient and a male patient's age in the logic to determine the patient's "Zone", based on their AUDIT score. Each Zone calls for a different level of intervention. See Appendix B, CDS Actions and Brief Intervention Content, for additional information, and Table 2 for the description and score thresholds of each Zone
Verify completeness/ Add explanation	Considering the response to the "pregnancy question" in this CDS	Per CDC and ACOG guidance, women who are pregnant or *trying to become pregnant* should abstain from alcohol (Centers for Disease Control and Prevention, 2014) (The American College of Obstetricians and Gynecologists, 2011). Since "trying to become pregnant" is not routinely entered in a patient's record, there is no way to identify evidence of this without asking a woman and capturing their response. The three CDS artifacts for AUDIT screening referred to previously include asking this question within the screening logic flow, and the patient's response is used by this CDS artifact to ensure that a pregnancy-specific intervention is displayed, if indicated.

Appendix B. CDS Actions and Brief Intervention Content

The *Alcohol Brief Intervention and Referral* CDS artifact identifies patients screened for alcohol use and provides brief intervention care recommendations to consider, based on the patient's alcohol screening results and reported level of drinking. The brief intervention content includes the patient's screening results, suggestions for brief interventions, and links to targeted patient education materials and tools. The brief interventions are formulated based on the patient's overall AUDIT score, reported level of drinking, Zone (i.e., risk level) and other patient attributes (e.g., being pregnant or trying to become pregnant, or having a history of alcohol use disorder). The artifact also suggests and facilitates a referral for the patient to receive diagnostic evaluation and possible treatment of alcohol use disorder, if indicated by the results of the alcohol screening. Refer to Section 3.1 for a more detailed description of the artifact, including the dependencies regarding capture of alcohol and other substance use screening information (i.e., NIDA QS).

The content described in this appendix is incorporated into the CDS semi-structured logic detailed in Appendix A.2, and when integrated into a health IT system, displays to the clinician. Future implementers may elect to expand upon or modify this content based on their organizational preferences, policies, and other factors.

Note: Information on the importance of providing training and other assistance to clinicians on how to conduct a brief intervention is mentioned in Section 2.2, with additional resources listed in Section 2.3. Prior to implementing this CDS, organizations are encouraged to evaluate clinician expertise related to providing brief interventions to patients with excessive alcohol consumption and provide additional training as indicated.

B.1 Brief Interventions Related to Alcohol Use

This section describes the brief intervention content based on a patient's alcohol use screening results that are presented to the clinician when indicated by the semi-structured logic described in Appendix A.2. The logic in the CDS looks for new alcohol screening results that have not been acted upon (i.e., patient has not received a brief intervention). Also, local implementation of the CDS may display some kind of notification to the clinician that a brief intervention is due.

B.1.1 Female Patients that are Pregnant or Trying to Become Pregnant and Not Drinking Alcohol

The content in this section is meant to help guide a brief intervention with patients that are pregnant or trying to become pregnant and not drinking alcohol. The content is based upon evidence that brief counseling interventions increase the likelihood that patients will remain

abstinent during pregnancy[4] and it incorporates guidance from ACOG and several other organizations.[5,6,7]

B.1.1.1 General guidance

Display general guidance to the clinician delivering the brief intervention that is specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

Guidance for Pregnant Patients Not Drinking Alcohol

For patients who are pregnant or trying to become pregnant whose screening response indicates they are not currently drinking alcohol, brief counseling interventions increase the likelihood that they will remain abstinent during pregnancy. ACOG and several other organizations suggest the following talking points.

Additional Guidance on Brief Intervention Elements

- Raise the subject
- Provide feedback about screening results
- Ask patients what they like and what they don't like about their drinking (in that order)
- Ask if they would like your medical advice
- Listen for "change talk" to assess how ready the patient is to modify his or her behavior
- Provide options the patient can choose from to develop a plan
- Seek agreement for a follow-up visit
- Thank patient

Reference:

Centers for Disease Control and Prevention. (2014). Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices. Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities. Retrieved from https://www.cdc.gov/ncbddd/fasd/documents/AlcoholSBIImplementationGuide-P.pdf

B.1.1.2 Provide feedback on screening results

[4] Curry SJ, Krist AH, Owens DK, et al. Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. JAMA - J Am Med Assoc. 2018;320(18):1899-1909. doi:10.1001/jama.2018.16789

[5] The American College of Obstetricians and Gynecologists. At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications - ACOG. Committee on Health Care for Underserved Women. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/At-Risk-Drinking-and-Alcohol-Dependence-Obstetric-and-Gynecologic-Implications. Published 2011. Accessed January 21, 2020.

[6] World Health Organization. Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy. Vol 34.; 2014. http://www.ncbi.nlm.nih.gov/pubmed/24783312. Accessed October 2, 2019.

[7] Centers for Disease Control and Prevention (CDC). CDC's Alcohol Screening and Brief Intervention Efforts. https://www.cdc.gov/ncbddd/fasd/alcohol-screening.html. Accessed February 18, 2020.

Instructions to Clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your alcohol screening results indicate that [you are not drinking alcohol. That's a great decision].

Not drinking is important for your health and the health of your baby.

B.1.1.3 Reinforce the following information with the patient

Instructions to Clinician

Reinforce the impact of alcohol use on fetal development and outcomes.

Patient-Specific Text

There is no known safe amount, no safe time, and no safe type of alcohol use during pregnancy.

Alcohol use during pregnancy can cause birth defects and developmental disabilities, collectively known as fetal alcohol spectrum disorders (FASDs).

FASDs are preventable if a developing baby is not exposed to alcohol before birth.

Alcohol use during pregnancy is also linked to other outcomes, such as miscarriage, stillbirth, preterm (early) birth, and sudden infant death syndrome (SIDS).

B.1.1.4 Offer an appropriate follow-up visit with the patient

Instructions to Clinician

None.

Patient-Specific Text

No follow-up indicated, based on your screening results.

B.1.1.5 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

If you'd like to learn more about the impact of drinking during pregnancy, this information can help:

- Find out more about “Alcohol Use in Pregnancy”: https://www.cdc.gov/ncbddd/fasd/alcohol-use.html

- Fact Sheet on Fetal Alcohol Spectrum Disorders (FASDS): https://www.cdc.gov/ncbddd/fasd/documents/fasd_english-508.pdf
- An Alcohol-Free Pregnancy is the Best Choice for Your Baby (brochure): https://www.cdc.gov/ncbddd/fasd/documents/FASDBrochure_final-508.pdf

B.1.2 Female Patients that are Pregnant or Trying to Become Pregnant and Drinking Alcohol (Any Amount)

The content in this section is meant to help guide a brief intervention with patients that are pregnant or trying to become pregnant and are drinking alcohol. The content is based upon guidance from ACOG and several other organizations.[4,5,7]

B.1.2.1 General guidance

Display general guidance to the clinician delivering the brief intervention, specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

Guidance for Pregnant Patients Drinking Alcohol

For patients that are pregnant or trying to become pregnant whose screening responses indicate they are currently drinking alcohol, ANY alcohol use is considered excessive. ACOG and several other organizations suggest the following talking points.

Additional Guidance on Brief Intervention Elements

See Section B.1.1.1.

B.1.2.2 Provide feedback on screening results

Instructions to Clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your screening responses indicate that [you are drinking alcohol]. Any alcohol use is considered excessive if you are pregnant or trying to become pregnant.

Your screening score is [SCORE] (out of 40), and falls within [ZONE], which for people that aren't pregnant indicates harmful or hazardous drinking.

[Display ZONE graphic with an arrow pointing to where this patient falls]

Your responses to questions 1 to 3:

1. You have a drink containing alcohol [RESPONSE 1]
2. On a typical day, you have [RESPONSE 2] drinks
3. [RESPONSE 3], you have [4] or more drinks on one occasion

B.1.2.3 Reinforce the following information with the patient

Instructions to Clinician

Reinforce the impact of alcohol use on fetal development and outcomes.

Patient-Specific Text

There is no known safe amount of alcohol use in pregnancy or while trying to become pregnant.

Alcohol use during pregnancy can cause birth defects and developmental disabilities, collectively known as fetal alcohol spectrum disorders (FASDs).

These are preventable if a developing baby is not exposed to alcohol before birth.

Alcohol use during pregnancy is also linked to other outcomes, such as miscarriage, stillbirth, preterm (early) birth, and sudden infant death syndrome (SIDS).

B.1.2.4 Offer an appropriate follow-up visit with the patient

Instructions to Clinician

If you think the patient may be unable to reduce or eliminate their alcohol use, or may be dependent on alcohol, consider referring the patient for diagnostic evaluation and possible treatment of alcohol use disorder.

Patient-Specific Text

I'd like to follow-up with you [AT NEXT VISIT; IN 3 MONTHS; OTHER TIMELINE].

[OR]

I'd like you to consider seeing a specialist that can help you with your drinking.

B.1.2.5 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

If you'd like to learn more about the impact of drinking during pregnancy, this information can help:

- 5 Things You Should Know About Drinking Alcohol During Pregnancy: https://www.cdc.gov/ncbddd/fasd/women.html
- Alcohol Use in Pregnancy: https://www.cdc.gov/ncbddd/fasd/alcohol-use.html
- Fact Sheet on Fetal Alcohol Spectrum Disorders (FASDS): https://www.cdc.gov/ncbddd/fasd/documents/fasd_english-508.pdf
- An Alcohol-Free Pregnancy is the Best Choice for Your Baby (brochure): https://www.cdc.gov/ncbddd/fasd/documents/FASDBrochure_final-508.pdf

B.1.3 Male Patients and Female Patients who are Not Pregnant or Not Trying to Become Pregnant: Zone 1

The content in this section is meant to help guide a brief intervention with patients who are not pregnant or not trying to become pregnant and are in Zone 1. The content is based upon evidence that brief counseling interventions can serve to reinforce low-risk drinking and could be effective if the patient underreported their drinking when responding to the screening questions or might have had past problems with risky drinking.[8,9,10]

B.1.3.1 General guidance

Display general guidance to the clinician delivering the brief intervention, specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

Guidance for Low-risk Drinking (Zone 1)

For patients in Zone 1, brief counseling can serve to reinforce low risk drinking, and could be effective if the patient underreported their drinking when responding to the screening questions or might have had past problems with risky drinking.

Additional Guidance on Brief Intervention Elements

See Section B.1.1.1.

B.1.3.2 Provide feedback on screening results

Instructions to clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your screening responses and total score indicate [you do not drink alcohol, or drink in moderation].

Your screening score is [SCORE] (out of 40), and falls within [Zone 1], which indicates [low-risk drinking].

[DISPLAY ZONE GRAPHIC WITH ARROW POINTING TO PATIENT'S ZONE]

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[8] Babor TF, Higgins-Biddle JC. *Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care*.; 2001. https://apps.who.int/iris/bitstream/handle/10665/67210/WHO_MSD_MSB_01.6b.pdf?sequence=1

[9] Babor TF, Higgins-Biddle JC, Robaina K. *The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners*.; 2017. https://www.dshs.wa.gov/sites/default/files/BHSIA/dbh/wasbirt/USAUDIT-Guide_2016.pdf.

[10] Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. *The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care*.; 2001. https://www.who.int/substance_abuse/publications/audit/en/. Accessed October 10, 2019.

Your responses to questions 1 to 3:

1. You have a drink containing alcohol [RESPONSE 1]
2. On a typical day, you have [RESPONSE 2] drinks
3. [RESPONSE 3] have [4 OR 5] or more drinks on one occasion

B.1.3.3 Reinforce the following information with the patient

Instructions to Clinician

Reinforce standard drink size and recommended frequency and quantity of alcohol intake to stay within low-risk guidelines.

Patient-Specific Text

Let's discuss a standard drink size.

[DISPLAY DRINK SIZE GRAPHIC]

Here's how your drinking compares to recommended limits for low-risk drinking levels for [MEN 65 OR YOUNGER] [WOMEN] [MEN OVER 65].

[DISPLAY TABLE COMPARING PATIENT VS. LOW-RISK DRINKING LEVELS]

B.1.3.4 Discuss the patient's responses to questions 4 to 10

Instructions to Clinician

Discuss the patient's response to any screening question that may indicate particular concern about alcohol dependence symptoms or past problems with alcohol. Ask the patient how they feel about their responses.

Patient-Specific Text

Let's discuss your responses to these screening questions.

[SHOW RESPONSES TO QUESTIONS 4, 5, AND 6]

The responses to these three questions could indicate serious issues with alcohol.

[SHOW RESPONSES TO QUESTIONS 7 AND 8]

[SHOW RESPONSES TO QUESTIONS 9 AND 10]

The responses to these two questions could indicate past problems with alcohol.

B.1.3.5 Provide education on when to avoid alcohol

Instructions to Clinician

Provide education regarding when the patient should avoid drinking alcohol, based on relevant patient factors.

Patient-Specific Text

You should avoid drinking alcohol if you are:

- Taking medications that interact with alcohol
- Planning to drive or operate machinery
- Managing a medical condition that may be made worse by drinking
- Pregnant or trying to become pregnant

B.1.3.6 Offer an appropriate follow-up visit with the patient

Instructions to Clinician

None.

Patient-Specific Text

No follow-up indicated, based on your screening results.

B.1.3.7 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

You may want to explore these tools and information about drinking alcohol:

- What Is A Standard Drink?: https://www.niaaa.nih.gov/what-standard-drink
- Alcohol Use And Your Health: https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm

B.1.4 Male Patients and Female Patients that are Not Pregnant or Not Trying to Become Pregnant: Zone 2

The content in this section is meant to help guide a brief intervention with patients who are not pregnant or not trying to become pregnant and are in Zone 2. The content is based upon evidence that brief counseling interventions that use simple advice on the reduction of drinking, engage the patient in reflective motivational conversations, and provide patient education materials may be the most appropriate course of action.[8,9,11]

B.1.4.1 General guidance

Display general guidance to the clinician delivering the brief intervention, specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

[11] Babor TF, Higgins-Biddle JC. *Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care*.; 2001. https://apps.who.int/iris/bitstream/handle/10665/67210/WHO_MSD_MSB_01.6b.pdf?sequence=1

Guidance for Risky Drinking (Zone 2)

For patients in Zone 2, a brief intervention using simple advice on the reduction of drinking, engaging the patient in reflective motivational conversations, and providing patient education materials may be the most appropriate course of action.

Additional Guidance on Intervention Elements

See Section B.1.1.1.

B.1.4.2 Provide feedback on screening results

Instructions to Clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your screening responses and total score indicate that [you are drinking above low-risk guidelines].

Your screening score is [SCORE] (out of 40), and falls within [Zone 2], which indicates [that you are drinking in excess of the guidelines].

[DISPLAY ZONE GRAPHIC WITH ARROW POINTING TO PATIENT'S ZONE]

Your responses to questions 1 to 3:

1. You have a drink containing alcohol [RESPONSE 1]
2. On a typical day, you have [RESPONSE 2] drinks
3. [RESPONSE 3], you have [4 OR 5] or more drinks on one occasion

B.1.4.3 Reinforce the following information with the patient

See Section B.1.3.3.

B.1.4.4 Discuss the patient's responses to questions 4 to 10

See Section B.1.3.4.

B.1.4.5 Provide education on when to avoid alcohol

See Section B.1.3.5.

B.1.4.6 Offer an appropriate follow-up visit with the patient

Instructions to Clinician

None.

Patient-Specific Text

No follow-up indicated, based on your screening results.

B.1.4.7 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

You may want to explore these tools and information about drinking alcohol:

- Rethinking Drinking: Alcohol & Your Health: https://www.rethinkingdrinking.niaaa.nih.gov/
- Alcohol Use And Your Health: https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm

B.1.5 Male Patients and Female Patients that are Not Pregnant or Not Trying to Become Pregnant: Zone 3

The content in this section is meant to help guide a brief intervention with patients who are not pregnant or not trying to become pregnant and are in Zone 3. The content is based upon evidence that interventions using a combination of feedback, brief counseling, and continued monitoring may be effective, with further diagnostic evaluation indicated if the patient fails to respond or is suspected of alcohol dependence.[8,9,11]

B.1.5.1 General guidance

Display general guidance to the clinician delivering the brief intervention, specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

Guidance for Harmful or Hazardous Drinking (Zone 3)

For patients in Zone 3, a combination of feedback, brief counseling, and continued monitoring may be effective, with further diagnostic evaluation indicated if the patient fails to respond or is suspected of alcohol dependence.

Additional Guidance on Brief Intervention Elements

See Section B.1.1.1.

B.1.5.2 Provide feedback on screening results

Instructions to Clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your screening responses and total score indicate that [you are drinking at harmful levels].

Your screening score is [SCORE] (out of 40), and falls within [Zone 3], which indicates [harmful or hazardous drinking].

[DISPLAY ZONE GRAPHIC WITH ARROW POINTING TO PATIENT'S ZONE]

Your responses to questions 1 to 3:

1. You have a drink containing alcohol [RESPONSE 1]
2. On a typical day, you have [RESPONSE 2] drinks
3. [RESPONSE 3], you have [4 OR 5] or more drinks on one occasion

B.1.5.3 Reinforce the following information with the patient

See Section B.1.3.3.

B.1.5.4 Discuss the patient's responses to questions 4 to 10

See Section B.1.3.4.

B.1.5.5 Provide education on when to avoid alcohol

See Section B.1.3.5.

B.1.5.6 Offer an appropriate follow-up visit with the patient

Instructions to clinician

If you think the patient may be dependent on alcohol, consider referring the patient for diagnostic evaluation and possible treatment of alcohol use disorder.

Patient-Specific Text

I'd like to follow-up with you [at your next visit; in 3 months; other preferred timeline].

OR

I'd like you to consider seeing a specialist that can help you with your drinking.

B.1.5.7 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

You may want to explore these tools and information that could help you cut down on your drinking:

- Rethinking Drinking: Alcohol & Your Health: https://www.rethinkingdrinking.niaaa.nih.gov/
- Alcohol Use And Your Health: https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm
- Find Your Way to Alcohol Treatment (NIAAA Alcohol Treatment Navigator): https://alcoholtreatment.niaaa.nih.gov/

- Find Treatment for Substance Use Disorder: https://findtreatment.gov/

B.1.6 Male Patients and Female Patients that are Not Pregnant or Not Trying to Become Pregnant: Zone 4

The content in this section is meant to help guide a brief intervention with patients who are not pregnant or not trying to become pregnant and are in Zone 4. The content is based upon evidence that brief counseling interventions should include a referral to a specialist for diagnostic evaluation and possible treatment for alcohol dependence.[8,9,11]

- Provide feedback to the patient on their screening results, including the following:
  - The patient's level of drinking far exceeds safe guidelines, and specific problems related to drinking are already present.
  - The patient has signs of alcohol dependence.
- Discuss the need for referral to a specialist for diagnostic evaluation and possible treatment of alcohol use disorder with the patient, and encourage the patient to see the specialist.
  - To initiate a referral order, please click here.
- Offer an appropriate follow-up visit with the patient.
- Provide the patient with the patient education resources.
- If you think the patient may be dependent on alcohol, consider referring the patient for diagnostic evaluation and possible treatment of alcohol use disorder.

B.1.6.1 General guidance

Display general guidance to the clinician delivering the brief intervention, specific to the patient's screening results. Provide access to additional guidance for delivering a brief intervention, through a hyperlink or some other method.

Guidance for Severe Drinking Levels (Zone 4)

Patients in Zone IV, which suggests alcohol dependence, should be referred to a specialist for diagnostic evaluation and possible treatment.

Additional Guidance on Brief Intervention Elements

See Section B.1.1.1.

B.1.6.2 Provide feedback on screening results

Instructions to Clinician

Provide feedback to the patient on their screening results.

Patient-Specific Text

Your screening responses and total score indicate that [your drinking is at high-risk drinking levels].

Your screening score is [SCORE] (out of 40), and falls within [Zone 4], which indicates [high-risk drinking and probable alcohol dependence].

[DISPLAY ZONE GRAPHIC WITH ARROW POINTING TO PATIENT'S ZONE]

Your responses to questions 1 to 3:

1. You have a drink containing alcohol [RESPONSE 1]
2. On a typical day, you have [RESPONSE 2] drinks
3. [RESPONSE 3], you have [4 OR 5] or more drinks on one occasion

B.1.6.3 Reinforce the following information with the patient

Instructions to Clinician

Reinforce standard drink size and recommended frequency and quantity of alcohol intake to stay within low-risk guidelines.

Patient-Specific Text

Your level of drinking far exceeds safe guidelines, and specific problems related to drinking are already present.

You may have signs of alcohol dependence.

Here's how your drinking compares to recommended limits for low-risk drinking levels for [MEN 65 OR YOUNGER] [WOMEN] [MEN OVER 65].

[DISPLAY TABLE COMPARING PATIENT VS. LOW-RISK DRINKING LEVELS]

B.1.6.4 Discuss the patient's responses to questions 4 to 10

See Section B.1.3.4.

B.1.6.5 Provide education on when to avoid alcohol

See Section B.1.3.5.

B.1.6.6 Discuss referral to a specialist with the patient

Instructions to Clinician

Discuss the need for referral to a specialist with the patient, and encourage the patient to see a specialist. Consider offering a follow-up visit to the patient.

Patient-Specific Text

I'd like you to consider seeing a specialist that can help you with your drinking.

[OR]

I'd like to follow-up with you [AT NEXT VISIT; IN 3 MONTHS; OTHER TIMELINE].

B.1.6.7 Share patient education resources

Instructions to Clinician

Instructions found here would depend on the local CDS implementation. An implementor may integrate the patient educational materials into their specific policies and procedures.

Patient-Specific Text

You may want to explore these tools and information that could help you cut down on your drinking:

- Treatment for Alcohol Problems: Finding and Getting Help: https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/treatment-alcohol-problems-finding-and-getting-help
- Find Your Way to Alcohol Treatment (NIAAA Alcohol Treatment Navigator): https://alcoholtreatment.niaaa.nih.gov/
- Find Treatment for Substance Use Disorder: https://findtreatment.gov/

B.2 Brief Interventions related to Non-Alcohol Substance Use

This section describes the non-alcohol substance use brief intervention content related to use of non-alcohol substances that should be presented to the clinician when indicated by the semi-structured logic described in Appendix A.2.

This verbiage only displays if the patient responded to the NIDA QS. The wording [i.e., used/did not use] is specific to the patient's responses to the substance use questions #2 through question #4. The CDS provides access to the NIDA QS questions and patient responses when selected.

Each section of this section represents one or more of the "steps" defined in Appendix A.2 . The information contained within each section is presented using the following standards:

- The numbered captions in bold represent the "CDS Actions" section of the semi-structured logic for each CDS logic path.
- Any text in *italics* and parenthesis or brackets represents explanatory information for the implementer.
- The remaining text represents the information that is intended to display to the clinician.
- References used throughout the text are noted in footnotes, to allow the implementer to easily identify and display the references to the clinician through their desired implementation method (e.g., a hyperlink or infobutton)

B.2.1 Female Patients that are Pregnant or Trying to Become Pregnant

The CDS Actions shown below are invoked based on meeting the inclusion and exclusion criteria listed in the semi-structured logic for Step 2, "Consider female patients that are pregnant or trying to become pregnant."

1. **Display NIDA QS Results for Question #2, #3, And #4 (Which Assess Tobacco, Non-Medical Prescription Drug, And Illegal Drug Use). Provide Access to The NIDA QS Questions And Patient Responses:**

   ***(Note:** This verbiage only displays if the patient responded to the NIDA QS. The wording [i.e., used/did not use] is specific to the patient's responses to the substance use questions #2 through question #4. The CDS provides access to the NIDA QS questions and patient responses when selected.)*

   The patient indicates that in the past year, they *[used/did not use]* tobacco products*;* they *[used/did not use]* prescription drugs for nonmedical reasons; and that they [*used/did not use]* illegal drugs.

   To review the patient's NIDA Quick Screen responses, click here. *(If selected, display the NIDA QS questions and patient responses.)*

2. **Display Counseling Suggestions Applicable to Pregnant Patients With Non-Alcohol-Related NIDA QS Positive Responses:**

   The National Institute on Drug Abuse (NIDA)[12] suggests the following when reviewing the results of the NIDA QS with patients:

   - Review the results of the NIDA QS screening with the patient.
   - Avoid any tone that could be considered judgmental or confrontational.
   - Offer additional counseling on the impact of the patient's specific substance use (especially while pregnant) and assess their readiness to quit.
   - If the patient seems responsive, offer assistance in their efforts to reduce or eliminate their use of the substance.

   (If positive response to question #2 [related to the use of tobacco products]):

   - If the patient is using tobacco products, consider providing them with the following information:[13,14]
     - Smoking during pregnancy increases the risk of health problems for developing babies, including preterm birth, low birth weight and birth defects of the mouth and lips. Smoking during pregnancy can also increase the risk of sudden infant death syndrome.
     - Quitting smoking is an important way to protect both your own health and the health of your baby.
   - Consider providing the patient with the patient education resources listed below

[12] National Institute on Drug Abuse. The NIDA Quick Screen | National Institute on Drug Abuse (NIDA). https://www.drugabuse.gov/publications/resource-guide-screening-drug-use-in-general-medical-settings/nida-quick-screen. Accessed December 4, 2019.

[13] Centers for Disease Control and Prevention (CDC). Substance Use During Pregnancy | CDC. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/substance-abuse/substance-abuse-during-pregnancy.htm. Published 2019. Accessed March 11, 2020.

[14] The American College of Obstetricians and Gynecologists. Smoking Cessation During Pregnancy - ACOG. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Smoking-Cessation-During-Pregnancy?IsMobileSet=false. Published 2017. Accessed March 11, 2020.

(If positive response to question #3 [related to prescription drug use for nonmedical reasons], and/or question #4 [related to illegal drug use]):

- If the patient is using illegal drugs or prescription drugs for nonmedical reasons, and agrees to discuss the screening results, consider providing the patient with the following information:[13, 15]
  - Substance use, and in particular, non-medical use of opioid pain medications during pregnancy, is linked to several serious health impacts for you and your baby (e.g., preterm birth, stillbirth, maternal mortality).
  - Marijuana use is also linked to health concerns, and should be discouraged during pregnancy.
- Consider referring the patient for further evaluation and treatment of their substance use.
- Consider providing the patient with the patient education resources listed below

3. Display Patient Education Resources for Pregnant Patients With Non-Alcohol Related NIDA QS Positive Responses:

(If positive response to use of tobacco products [NIDA QS question #2]):

- MotherToBaby Fact Sheet about exposure to cigarette smoke in pregnancy and while breastfeeding: https://mothertobaby.org/fact-sheets/cigarette-smoking-pregnancy/pdf/
- March of Dimes: Smoking During Pregnancy: https://www.marchofdimes.org/pregnancy/smoking-during-pregnancy.aspx#
- Smoking, Pregnancy, and Babies: https://www.cdc.gov/tobacco/campaign/tips/diseases/pregnancy.html

(If positive response to use of prescription drugs for nonmedical reasons [NIDA QS question #3] and/or illegal drugs [NIDA QS question #4]):

- CDC: Opioid Use During Pregnancy: https://www.cdc.gov/pregnancy/opioids/index.html
- CDC: What You Need to Know About Marijuana Use and Pregnancy: https://www.cdc.gov/marijuana/factsheets/pregnancy.htm
- Step by Step Guide to Finding Treatment for Drug Use Disorders: https://www.drugabuse.gov/publications/step-by-step-guides-to-finding-treatment-drug-use-disorders/if-you-have-problem-drugs-adults

B.2.2 All Male Patients and Female Patients that are Not Pregnant or Not Trying to Become Pregnant

The CDS Actions shown below are invoked based on meeting the inclusion and exclusion criteria listed in the semi-structured logic for Step 4, "Consider all male patients, and female

[15] The American College of Obstetricians and Gynecologists. Marijuana Use During Pregnancy and Lactation - ACOG. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation. Published 2019. Accessed March 12, 2020.

patients that are not pregnant or trying to become pregnant; and responded to the NIDA QS as part of their screening."

1. **Display NIDA QS Results For Question #2, #3, and #4 (Which Assess Tobacco, Non-Medical Prescription Drug, and Illegal Drug Use). Provide Access to the NIDA QS Questions and Patient Responses:**

   (This verbiage only displays if the patient responded to the NIDA QS. The wording [used/did not use] is specific to the patient's responses to the substance use questions #2- #4. The CDS provides access to the NIDA QS questions and patient responses when selected.)

   The patient indicates that in the past year, they *[used/did not use]* tobacco products*;* they *[used/did not use]* prescription drugs for nonmedical reasons; and that they [*used/did not use]* illegal drugs

   To review the patient's NIDA Quick Screen responses, click here. *(If selected, display the NIDA QS questions and patient responses)*

2. **Display Counseling Suggestions for Patients with Non-Alcohol Related NIDA QS Positive Responses:**

   The National Institute on Drug Abuse (NIDA)[12] suggests the following when reviewing the results of the NIDA QS with patients:

   - Review the results of the NIDA QS with the patient.
   - Avoid any tone that could be considered judgmental or confrontational.
   - Offer additional counseling on the impact of the patient's specific substance use and assess their readiness to quit.
   - If the patient seems responsive, offer assistance with their effort to reduce or eliminate their use of the substance(s).

   (If positive response to question #2 [related to the use of tobacco products]):

   - If the patient is using tobacco products, advise them to quit:[16]
     - If the patient seems willing to quit, provide appropriate interventions to assist them.
   - Consider providing the patient with the patient education resources listed below.

   (If positive response to question #3 [related to the use of prescription drugs for nonmedical reasons], and/ or question #4 [related to the use of illegal drugs]):

   - If the patient is using illegal drugs or prescription drugs for nonmedical reasons and agrees to discuss the screening results, consider doing additional screening or information gathering to determine the extent of the patient's drug use.
   - Provide medical advice specific to the patient's drug use.

[16] Agency for Healthcare Research and Quality. Treating Tobacco Use and Dependence. https://www.ahrq.gov/prevention/guidelines/tobacco/clinicians/references/quickref/index.html. Published 2009. Accessed March 14, 2020.

- Consider referring the patient for further evaluation and treatment of their substance use.
- Consider providing the patient with the patient education resources listed below.

3. Display Patient Education Resources for Patients with Non-Alcohol Related NIDA QS Positive Responses:

(If positive response to use of tobacco products [question #2]):

- Planning and support to help quit smoking: https://smokefree.gov/quit-smoking
- Information and tools to "Quit Smoking": https://www.cdc.gov/tobacco/quit_smoking/index.htm

(If positive response to use of prescription drugs for nonmedical reasons [question #3], and/or illegal drugs [question #4]):

- Step by Step Guide to Finding Treatment for Drug Use Disorders: https://www.drugabuse.gov/publications/step-by-step-guides-to-finding-treatment-drug-use-disorders/if-you-have-problem-drugs-adults
- Helpful Materials for Patients Living With Chronic Pain: https://www.cdc.gov/drugoverdose/patients/materials.html
- Find Treatment for Substance Use Disorder: https://findtreatment.gov/

Appendix C. Data Requirements

The CDS logic for this artifact is comprised of data elements that represent each of the clinical concepts in the CDS (e.g., Pregnancy, alcohol screening results). Table 8 lists each data element expressed in this artifact, along with the location(s) of the data element in CDS logic, the FHIR R4 resource that is used to express the data element, and the required FHIR R4 attributes and elements. The list provides a glimpse into the data required by this CDS to execute so implementers can gain a sense of how feasible it may be to utilize this CDS expression (based on availability of the required data in their health IT system). The standardized codes and value sets used to define each of the data elements can be found towards the top of the CQL code that is included in the zip file attached to this artifact in the CDS Connect repository.

Table 8: FHIR Data Requirements for this Artifact

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
Alcohol Screening Results	Step 1 (Inclusions)	Observation[17] and QuestionnaireResponse[18]	Observation Resource Observation.effective Observation.issued Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html) QuestionnaireResponse Resource QuestionnaireResponse.questionnaire = "alcohol PS question response; USAUDIT, USAUDIT-C, WHO AUDIT or WHO AUDIT-C scores; WHO AUDIT or USAUDIT question #1 response" (see https://hl7.org/fhir/R4/questionnaireresponse.html)
BI Intervention	Steps 1 – 4 (Exclusions)	Procedure	Procedure Procedure.performed Procedure.status = completed (See https://www.hl7.org/fhir/procedure.html)

[17] *Expressing alcohol screening results, a USAUDIT-C total score, a USAUDIT total score, a WHO AUDIT-C total score, or a WHO AUDIT total score as a FHIR Observation enables the CDS to evaluate alcohol screening responses stored in a health IT system but not using the same method (i.e., as a FHIR QuestionnaireResponse) as the three alcohol screening CDS artifacts developed by the Health FFRDC working with NCBDDD, listed in Section 1.1.*

[18] *Expressing alcohol screening results, a USAUDIT-C total score, a USAUDIT total score, a WHO AUDIT-C total score, or a WHO AUDIT total score as a FHIR QuestionnaireResponse enables the CDS to evaluate alcohol screening responses stored in a health IT system using the same method as the three alcohol screening CDS artifacts developed by the Health FFRDC working with NCBDDD, listed in Section 1.1.*

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
Age	Step 1 (Inclusions)	Patient	Patient.birthDate (see https://hl7.org/fhir/R4/patient.html)
Sex at Birth	Steps 2 - 4	Patient	Patient.extension ("http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex") (see https://hl7.org/fhir/R4/patient.html)
Pregnancy Question Response	Steps 2 - 4	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "alcohol PS question, WHO AUDIT questions #1-#10, WHO AUDIT -C and WHO AUDIT scores, and pregnancy question" (see https://hl7.org/fhir/R4/questionnaireresponse.html)
Pregnant	Steps 2 - 4	Condition	Condition.onset Condition.recordedDate Condition.clinicalStatus = active or recurrence Condition.verificationStatus = confirmed (see https://hl7.org/fhir/R4/condition.html)
Pregnant Observation	Steps 2 - 4	Observation	Observation.effective Observation.issued Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html)
Alcohol PS Question Response	Steps 1 - 4	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "alcohol PS question, WHO AUDIT questions #1-#10, WHO AUDIT -C and WHO AUDIT scores, and pregnancy question" (see https://hl7.org/fhir/R4/questionnaireresponse.html)
NIDA QS Responses	Steps 2 - 4	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "NIDA QS questions #1-#4" (see https://hl7.org/fhir/R4/questionnaireresponse.html
Individual USAUDIT or WHO AUDIT Question Responses	Steps 2-5	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "US AUDIT or WHO AUDIT questions #1-#3" (see https://hl7.org/fhir/R4/questionnaireresponse.html)

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
USAUDIT Total Score, USAUDIT-C Total Score, WHO AUDIT-C Total Score and WHO AUDIT Total Score	Steps 1 - 4	Observation[17] and QuestionnaireResponse[18]	Observation Resource Observation.effective Observation.issued Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html) QuestionnaireResponse Resource QuestionnaireResponse.questionnaire = "alcohol PS question, WHO AUDIT questions #1-#10, WHO AUDIT -C and WHO AUDIT scores, and pregnancy question" (see https://hl7.org/fhir/R4/questionnaireresponse.html)

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