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Adapting Clinical Guidelines for the Digital Age: Alcohol Screening and Brief Intervention Clinical Decision Support Project Task Order No. 75D30119F05691

Alcohol Screening Using the World Health Organization (WHO) Alcohol Use Disorders Identification Test (AUDIT): Implementation Guide

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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). 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 4 or more drinks for women or 5 or more drinks for men, within about two hours) and heavy drinking (i.e., 8 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. Department of Agriculture, 2015).[1] Excessive drinking is associated with a variety of short- and long-term health risks, including motor vehicle crashes, violence, sexual risk behaviors, high blood

[1] 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.

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 women of reproductive age, who are screened for alcohol use; an increase in the number of adults screened as drinking above recommended levels who are delivered a brief intervention; and a decrease in alcohol use among women of reproductive age.
- 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:

- *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 *WHO AUDIT Alcohol Screening* artifact, which identifies adults for whom alcohol screening is indicated and delivers a series of screening questions that align with guidance published by the WHO in *AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Health Care*. The resulting WHO AUDIT-C (AUDIT-Consumption) and/or WHO AUDIT score can then guide a clinician in discussing alcohol use with the patient. Of note, mention of the AUDIT and AUDIT-C alcohol screening questionnaires developed by the WHO in 1989 are not usually prefaced with "WHO". The CDS Development Team opted to include the WHO preface to clearly distinguish the difference between this artifact and the *USAUDIT Alcohol Screening* artifact (which aligns with the AUDIT adapted for use in the U.S. i.e., *USAUDIT: A Guide for Primary Care Practitioners*). Please refer to section 2.1.1 for more information on the differences between the WHO and the US versions of the AUDIT screening questionnaires.

The logic for this CDS artifact is derived from several evidence-based guidelines. In instances where the WHO AUDIT did not provide specific guidance, the CDS Development Team used numerous additional references listed in section 4.1 and the List of References.

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). 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 interpretation and decisions, and technical implementation considerations.

Organizations that might consider implementing this CDS logic include primary healthcare practices, as well as obstetrics-gynecology clinics and other healthcare organizations interested in implementing evidence-based CDS to help deliver personalized alcohol screening to their patients.

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

- **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 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 4 or more drinks for women and 5 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 4 of 5 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 4 drinks for women or 5 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 2015 and 2017, one in nine pregnant women in the U.S. reported drinking alcohol in the past 30 days, with one-third engaging in binge drinking (Denny, Acero, Naimi, & Kim, 2019).

Although this implementation guide focuses on alcohol screening, a holistic approach to alcohol screening and brief intervention is important. This includes selecting and administering

evidence-based alcohol screening instruments to identify patients who may require brief behavioral counseling and possible referral for evaluation and treatment for alcohol use disorders, and providing information to patients 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. pointed out that when considering the implementation of alcohol screening, early evaluation and planning is necessary to determine (Centers for Disease Control and Prevention, 2014):

- Which patients will be screened and how often
- Which alcohol screening instrument will be used
- How and where the screening will take place
- How the screening results will 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-C, or Single Alcohol Screening Question [SASQ]), 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 #1 through #3 by expanding the number of responses and modifying the wording of question #3. 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, ASBI Implementation Resources, 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, and consider the need to refer the patient to evaluation and treatment if indicated by the results.

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 and capabilities 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 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 the referral for the patient to receive diagnostic evaluation and possible treatment of alcohol use disorder, if indicated.

2.3 ASBI Implementation Resources

Numerous evidence-based manuals and resources exist to guide primary care 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.

Reference	Sponsor	Additional Information
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 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.
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 *WHO AUDIT Alcohol Screening* artifact identifies adults (i.e., individuals 18 years and older) who would benefit from alcohol screening as part of their preventive health care. The artifact prompts alcohol screening on an annual basis, as recommended by the World Health Organization (WHO) (Babor et al., 2001). In addition, the artifact prompts screening during every trimester for pregnant patients to ensure clinicians have an opportunity to stress the importance of abstinence from alcohol throughout pregnancy (American College of Nurse-Midwives, 2017; Wright et al., 2016). Individuals with active alcohol use disorder (AUD) are excluded from this preventive health alcohol screening CDS because additional specialized assessment and treatment beyond a brief intervention is indicated for these patients. This decision was informed by the USPSTF *Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions* recommendation's exclusion criteria, as the systematic review population did not include persons with AUDs. ASBI has not been found to be an effective treatment for AUDs (Curry et al., 2018).

This artifact facilitates evidence-based, patient-specific alcohol screening based on the patient's sex, age, medical history, and response to individual screening questions. The artifact starts by presenting an alcohol prescreen (PS) question to patients for whom screening is indicated, as suggested by the NIAAA, to ensure patients understand that beer and wine are considered alcoholic beverages. The alcohol PS question reads, "Do you sometimes drink beer, wine, or other alcoholic beverages?" Use of the alcohol PS question also shortens the time spent on alcohol screening, as patients who respond "No", indicating that they abstain from alcohol, are not asked any further questions. If the patient responds "Yes" to the PS question, the CDS progresses to display the first three questions of the WHO AUDIT (i.e., the WHO AUDIT-C) and calculates a score if the patient responded to all three questions. Patients are presented with the remaining WHO AUDIT questions (i.e., questions #4 through #10) if their WHO AUDIT-C score is:

- Greater than or equal to "3" and they are a woman, a man over 65 years of age, or their sex at birth is recorded in the health IT system as Unknown
- Greater than or equal to "4" and they are a man, 65 years of age or younger

Finally, the CDS delivers a question to women of reproductive age (given no evidence in the patient's medical record that they are currently pregnant or have had a hysterectomy). The question is: "Are you currently pregnant or trying to become pregnant?". The patient's response to this question is used by the *Alcohol Brief Intervention and Referral* CDS artifact to ensure a pregnancy-specific intervention is presented to the clinician if indicated.

This artifact does not include care recommendations based on the patient's alcohol screening results. The CDS Development Team and the CDC sponsors of this work took a modular approach to developing 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). A modular approach allows for personalized implementation choices without the need to edit CDS code. Providing individuals engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce their alcohol use is an important component of the USPSTF recommendation (Curry et al., 2018). The *Alcohol Brief Intervention and Referral* and *Decision Aid for Your Drinking* CDS artifacts mentioned in Section 1.1 are integral "companion" CDS modules to this artifact if a healthcare organization does not have ASBI care recommendations implemented in their health IT system. Potential implementers are encouraged to remind their clinicians to consider the patient's medical condition, family history of alcohol problems and perceived honesty in responding to the AUDIT questions, prior to making care decisions related to the patient's alcohol use (Babor et al., 2001).

The *WHO AUDIT Alcohol Screening* artifact aligns with WHO AUDIT guidelines, which specify the sequencing of questions that are displayed to the patient during screening. The WHO AUDIT assumes a standard drink size of 10 grams of alcohol (Babor et al., 2001). In comparison, the USAUDIT was created to "identify individuals with risky patterns of alcohol consumption, as defined by the U.S. standard drink (14 grams) and recommended drinking limits, and those who may have an alcohol use disorder" (Babor et al., 2017). As such, responses to questions #1, #2 and #3, and the wording of question #3 varies between the U.S. and WHO version of the questionnaire, as does the scoring and a few other specifics.

Since the *WHO AUDIT Alcohol Screening* artifact was developed for use by clinicians who deliver care in the U.S., the CDS Development Team and CDC sponsors of this project elected to

heed WHO advice, which states, "In the AUDIT, Questions 2 and 3 assume that a standard drink equivalent is 10 grams of alcohol. You may need to adjust the number of drinks in the response categories for these questions in order to fit the most common drink sizes and alcohol strength in your country" (Babor et al., 2001). As a result, question #3 in this CDS representation of the WHO AUDIT is modified from the "original" question #3 (i.e., "How often do you have six or more drinks on one occasion?") which is presented to all individuals regardless of their sex or age. The modified versions of question #3 align with question #3 in the USAUDIT. They display as:

- "How often do you have five or more drinks on one occasion?" to men <= 65 years old
- "How often do you have four or more drinks on one occasion?" to men > 65 years old, women and individuals whose sex at birth is recorded as Unknown in their medical record

The CDS Development Team did not elect to adjust the number of drinks in the response categories for question #2, since the team could not identify published research that validated this modification for U.S. drink sizes. See Appendix B for a full list of WHO AUDIT screening questions, the available responses to each question, and the score associated with each response, as implemented in this artifact.

Prior to implementing this CDS, it is important to consider which version of the AUDIT is most appropriate for the country where this CDS will be utilized since the types and amounts of alcoholic drinks will vary according to culture and custom (Babor et al., 2001) and adjust the CDS code accordingly.

3.2 Health Scenarios Supported by this Artifact

The *WHO AUDIT Alcohol Screening* artifact was developed and published to: 1) help healthcare practices and clinicians identify adults who should be screened for alcohol use, and 2) deliver a series of screening questions that align with guidance published in *AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Health Care* and *USAUDIT: A Guide for Primary Care Practitioners*. The artifact supports the following scenarios when implemented in a health IT system in a healthcare setting. Note, each scenario is populated with a fictitious name and health data to provide context to the scenario.

1. **Increasing the rate of alcohol screening through automated identification of individuals who should be screened**

   Sam is 35 years old, without pre-existing conditions. He sees his primary care physician infrequently because he travels every Monday through Thursday for work and can "never find the time to take care of things in his personal life." Sam finally scheduled his annual checkup after receiving an email from his physician's office that he is overdue for his wellness exam. When the medical assistant in the physician's office opens Sam's medical record in the EHR after bringing him into the treatment room, she is presented with a notification that Sam is due for alcohol use screening, because his last screening event occurred 18 months ago. Without this notification, the medical assistant and physician may

have overlooked the gap in time between alcohol use screening events while focusing on other aspects of his checkup.

2. **Reducing clinician burden by enabling patient-facing alcohol use screening**

   Commonwealth Physicians Group (CPG) is a medium-size practice in Virginia with six primary care clinicians and approximately 10,000 patients. CPG clinicians have been struggling to remain in compliance with preventive health screening recommendations while also managing their patient population's health needs including annual wellness exams, acute illnesses, and chronic diseases. After implementing patient-facing alcohol use screening via a hand-held tablet that is integrated with the group's EHR and providing the tablet to patients during check in at the office, 1) each patient is now routinely screened at the recommended interval, 2) the screening responses and score are routinely captured, and 3) the clinician has more time to care for the patient. This includes providing a brief intervention as indicated, while meeting alcohol screening standards.

3. **Enabling office staff to consistently perform accurate, evidence-based alcohol use screening**

   Dr. Martins is the founding physician of Mobile Family Medicine, a primary care group practice located in Mobile, Alabama. He noted inconsistencies in how the medical assistants in his practice perform alcohol use screening (e.g., how they adjust the sequence of the screening questions based on the patient's medical history, how they calculate the patient's screening score). The inconsistencies forced him to double check all screening results and at times perform additional screening, which diverted him from other concerns he planned to address with the patient. He decided to have his staff members transition from manual, paper-based, AUDIT screening to an electronic version of the screening questionnaire that includes logic to ensure accurate scoring and sequencing of the questions. After transitioning to an electronic version of the WHO AUDIT, the clinic staff reported 1) having increased confidence in the screening process, and 2) the screening process requiring less time to complete, and Dr. Martins had greater trust regarding the accuracy of the screening results, freeing him to focus on other aspects of care (e.g., providing a brief intervention if needed). . Dr. Martins and his partners at Mobile Family Medicine were pleased that they could implement this evidence based, interoperable CDS within their EHR with minimal resources required from a time, money, and IT staffing effort perspective.

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 who require alcohol use screening and delivers an evidence-based sequence of questions to perform the screening. Portions of the coded CDS expression can be reused to support additional scenarios that drive preventive health efforts across varied organizations, workflows, end users, and health IT systems.

Additional preventive health scenarios that could be supported by enhancing or adjusting portions of this CDS logic include:

1. **Identifying care gaps as part of a quality improvement project to enhance population health**

   Premier Alliance is an accountable care organization 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 that evaluates the frequency that their physicians screen adults for alcohol use using a standardized tool, and provide brief counseling interventions or other follow-up care to patients who are "misusing" alcohol (e.g., have a WHO AUDIT score of greater than or equal to 8)(National Committee for Quality Assurance, n.d.). Department leaders run a report using the inclusion and exclusion logic in the first "step" of this artifact on a monthly basis, and each primary care clinician receives a report profiling those overdue for alcohol use screening in their patient panel. Staff members reach out to every patient on the list to schedule an appointment with their primary care clinician. Data regarding the number of appointments scheduled as a result of the outreach, as well as the number of individuals who received overdue screening, is collected and analyzed on an ongoing basis to determine the impact of the outreach. In parallel, the primary care clinicians were provided with brief intervention training, so they have the knowledge to deliver brief interventions, when indicated. Premier Alliance also established a recognition system to acknowledge clinicians who improved their screening rates which positively impacted the organization's HEDIS score.

2. **Identifying and mitigating patient safety issues**

   A group of CPG clinicians initiated a project to identify potential patient safety issues in patients identified as drinking *at* or *below* recommended levels. Examples included patients who were taking depression and/or anxiety medications reporting drowsiness, dizziness, and memory problems, at medical checkups. The CPG clinicians realized that for some patients, even drinking below established thresholds for excessive alcohol intake may be too much if the patient is receiving certain medications (e.g., Ativan®, Cymbalta®) or has medical conditions that may be worsened by alcohol (e.g., liver disease, pancreatitis) (Centers for Disease Control and Prevention, 2014). To reduce the cognitive burden of having to remember which medications interact with alcohol and which medical conditions may be worsened by alcohol, the clinicians engaged with the health IT team that maintains CPG's EHR to create an algorithm that notifies a clinician of a safety concern if the patient reports drinking alcohol. The clinicians and health IT team utilized clinical definitions for "pregnancy," "AUD," and "alcohol screening" expressed in this artifact's coded logic and created additional clinical definitions for concepts such as "liver disease" and "anti-depressant medications" to construct the algorithm. Now if a patient reports any level of alcohol intake during alcohol screening and the patient has evidence of specific medications

or conditions in their record (e.g., they are pregnant), the algorithm notifies the clinician of a potential safety concern. The clinician can then counsel the patient on the importance of reducing or eliminating their alcohol intake, and if the patient is unable to achieve a reduction, the clinician can adjust the patient's plan of care to mitigate the safety concern.

3. **Expanding preventive health screening to include evaluation of substances other than alcohol**

   Having experienced favorable results after implementing patient-facing alcohol screening delivered as CDS via his practice's EHR, Dr. Martins sought to integrate screening for use of other substances (such as tobacco products and illegal drugs), with the existing *WHO AUDIT Alcohol Screening* logic to provide a more comprehensive assessment of his patient's substance use. Dr. Martins selected the NIDA-Modified ASSIST screening questionnaire, which screens patients for their use of tobacco, illicit and illegal drugs, and prescription drugs used for non-medical purposes, along with alcohol. The NIDA-Modified ASSIST only includes one alcohol screening question (i.e., "In the past year, how often have you had 4 or more drinks a day [for men over 65 years and all women] or 5 or more drinks a day [for men 65 years and under]") (National Institute on Drug Abuse, 2009), which does not provide a full assessment of a patient's alcohol use. Therefore, Dr. Martins requests that his practice's IT team implement the NIDA-Modified ASSIST so that if the patient responds anything other than "Never" to the alcohol screening question in the NIDA-Modified ASSIST, the patient will then be presented with the full WHO version of the AUDIT to further evaluate their alcohol use. This decision was informed by the USPSTF *Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults* recommendation (i.e., "when patients screen positive on a brief screening instrument [e.g., SASQ or the AUDIT-C], clinicians should ensure follow-up with a more in-depth risk assessment to confirm unhealthy alcohol use and determine the next steps of care…[e.g., AUDIT]" (Curry et al., 2018). As such, his practice's IT team adjusted the code in the existing *WHO AUDIT Alcohol Screening* artifact to align with this evidence. The electronic delivery of this substance use questionnaire further improved the quality of care and reduced the burden on Dr. Martin and his staff, and he is considering expanding patient-facing preventive health screening in his EHR to include depression screening next.

3.4 CDS Interventions and Suggested Actions

The human-readable logic that enables the flow of alcohol screening questions and the scoring of patient responses is listed, in detail, in the Artifact Semistructured Logic section of Appendix A. The logic is divided into "steps" to make the objective of specific portions of logic criteria and the resultant CDS "interventions" and "suggested actions" more understandable.

At a very high level, the following information provides insight into the logic and CDS interventions and actions that this artifact supports:

Step 1: Consider if Alcohol Screening Should be Initiated (i.e. If the Alcohol PS Question Should be Displayed)

- **Logic Description:** Ensures that the patient is 18 years or older, they do not have active AUD, and there is no evidence of alcohol screening in the past 12 months if the patient is not pregnant or no evidence of alcohol screening in the past three months if the patient is pregnant. (Note: This logic is included in all subsequent logic "steps" but is not repeated in the descriptions below.)

- **CDS Actions:** Introduce the purpose of alcohol use screening, display the alcohol PS question and the standard drink size graphic, record and display the patient's response to the PS question

Step 2: Consider if WHO AUDIT-C Screening is Indicated

- **Logic Description:** Ensures that the patient responded "Yes" to the alcohol PS question

- **CDS Actions:** Display the WHO AUDIT-C screening instructions and standard drink size graphic, display question #1 of the WHO AUDIT-C, and record and display the patient's response to question #1

Step 3: Consider Administering Question #2 and Question #3 of the WHO AUDIT-C

- **Logic Description:** Ensures that the patient responded "Yes" to the alcohol PS question and they did not respond "Never" to question #1 of the WHO AUDIT-C

- **CDS Actions:** Continue to display the screening instructions and standard drink size graphic, display question #2 and question #3 with the appropriate quantity of drinks populated in question #3 based on the patient's sex and age, record and display the patient's responses, calculate the WHO AUDIT-C score, record and display the WHO AUDIT-C score

Step 4: Consider Presenting Question #9 and Question #10 if the Full WHO AUDIT is Not Indicated

(The WHO AUDIT guide provides this guidance if alcohol screening is performed via an interview or is computer-assisted, based on the patient's response to question #1 OR their responses to questions #2 and #3. This helps the clinician evaluate a potential "past problem" with alcohol, even if presenting the full WHO AUDIT is not indicated (Babor et al., 2001). Additional information on this guidance is located in Appendix A.4).

- **Logic Description:** Ensures that the 1) patient's response to WHO AUDIT-C question #1 was "Never" or 2) the patient scored a total of "0" points on questions #2 and #3 AND the patient is either a man <= 65 years old with a question #1 score < "4" OR a woman, man > 65 years old, or an individual whose sex at birth is Unknown with a question #1 score < "3"

- **CDS Actions:** Display question #9 and question #10 of the WHO AUDIT, record and display the patient's responses

Step 5: Consider if Additional Screening is Indicated

- **Logic Description:** Ensures that 1) a woman, man over 65 years old or individual whose sex at birth is recorded as Unknown in the EHR scored >= 3 on the WHO AUDIT-C, or 2) a man 65 years old or younger scored >= 4 on the WHO AUDIT-C

- **CDS Actions:** Display question #4-question #10 of the WHO AUDIT, record and display the patient's responses, calculate the WHO AUDIT score, and record and display the score

Step 6: Consider if the Patient is Pregnant or Trying to Become Pregnant

- **Logic Description:** Ensures that the woman is 18 years or older and less than 50 years old and there is no evidence of an active pregnancy or a hysterectomy in her medical record

- **CDS Actions:** Display the question "Are you currently pregnant or trying to become pregnant?", record and display the patient's response

4. Guideline Interpretation and Clinical Decisions

4.1 Evidence-based Sources for Artifact Development

This artifact is not directly derived from any one clinical guideline. It draws upon multiple evidence-based references that provide guidance to organizations and clinical professionals on how to conduct alcohol screening and provide brief interventions based on the screening result. The primary guidance comes from the following resources:

- 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/
- 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.ct.gov/dmhas/lib/dmhas/publications/USAUDIT-2017.pdf
- 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
- 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*.

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 that 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 for computation. The Decision Log (in Appendix A) provides detailed information on how the evidence-based guidelines and subsequent SME clarifications informed CDS development. Some of the key interpretations and decisions include:

1. **Screening adults only**
    - **a.** The WHO AUDIT-C/WHO AUDIT identifies (in part) individuals drinking in excess of recommended levels for healthy adults (Babor et al., 2017). Adults are individuals 18 years 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).
2. **Ensuring pregnant women receive appropriate alcohol screening**
    - **a.** Professional organizations and government entities (e.g., American College of Obstetricians and Gynecologists [ACOG], USPSTF, WHO) provide varied recommendations on how often alcohol screening should be performed during pregnancy. The CDS Development Team and CDC sponsors of this project elected to enable screening in every trimester, to ensure clinicians have an opportunity to evaluate alcohol intake and reinforce the importance of abstinence several times during pregnancy (Wright et al., 2016). Some pregnant women may believe it is safe to drink in the second or third trimester, and alcohol screening later in pregnancy provides an opportunity to educate these women and stress the importance of abstinence.
3. **Defining historical alcohol screening results that satisfy the CDS logic to determine if a patient has previously completed alcohol screening within the defined parameters.**
    - a. This artifact prompts alcohol screening of individuals 18 years and older who do not have active AUD and have not completed alcohol screening within 1) the past 12 months if they are not pregnant or 2) the past three months if they are pregnant. For the CDS logic to know what constitutes "alcohol screening," the CDS Development Team and CDC SMEs needed to define the screening instruments that would be accepted as evidence that alcohol screening had occurred in the past. "There are many screening instruments readily available, but most do not focus directly on how much patients are drinking" (Centers for Disease Control and Prevention, 2014). Furthermore, some screening instruments only evaluate binge drinking or only evaluate social problems related to alcohol use. Thus, we opted to deliver WHO AUDIT screening (which is sensitive to a broad spectrum of drinking problems, including alcohol consumption, alcohol-related harm, and dependence symptoms) to all individuals who have not recently been evaluated with an alcohol screening questionnaire that detects the full spectrum of alcohol use. As such, the CDS recognizes the following alcohol screening results as meeting the "preferred" level of

alcohol use assessment (i.e., if the patient has evidence of any of the following completed assessments within the designated timeframe, the CDS will not recommend alcohol screening for the patient):

i. A WHO AUDIT-C or WHO AUDIT score

ii. A USAUDIT-C or USAUDIT score

iii. An alcohol PS question response of "No" (where the alcohol PS question is, "Do you sometimes drink beer, wine, or other alcoholic beverages?")

1. Note: Organizations that have implemented the NIDA-Modified ASSIST in their health IT system, which contains an alcohol PS question (i.e., In your lifetime have you ever used alcoholic beverages?), can map a "No" response to the NIDA-Modified ASSIST alcohol PS question to the alcohol PS question response expressed in this artifact.

iv. An alcohol PS question response of "Yes" AND an AUDIT question #1 response of "Never" (which means that the patient had an alcoholic beverage in the past, but they have not had an alcoholic beverage in the past year)

b. Healthcare organizations that decide to implement this artifact in their health IT system can opt to edit the CQL code to include results generated from additional validated screening questionnaires (i.e., Cut down, Annoyed, Guilty, Eye-opener [CAGE]; Alcohol, Smoking and Substance Involvement Screening Test [ASSIST]; Tolerance, Worried, Eye-Opener, Amnesia, Cut-Down [TWEAK]; Tolerance, Annoyed, Cut-down, Eye-Opener [T-ACE]; Pregnancy, Past, Partner, Parents [4P's]) based on organizational policy, state reporting requirements and clinician preference. However, they are strongly encouraged to only do so for the first year after implementing this CDS, so the CDS can consider historical screening results stored in their system. The CAGE questionnaire has been shown to have low sensitivity for pregnant women (Moyer, 2013), and the CAGE, TWEAK, and T-ACE are typically used to assess alcohol dependence, as opposed to the full spectrum of alcohol use. For this reason, once this artifact has been in use for one year, screening results outside the ones listed in "3a" above should no longer be used.

c. Healthcare organizations that have implemented brief screening questionnaires (e.g., the SASQ or multi-substance screening questionnaires that do not broadly evaluate numerous aspects of a patient's alcohol use (e.g., the NIDA QS, the NIDA-Modified ASSIST) as "stand alone" alcohol screening questionnaires are encouraged to consider implementing either version of the full AUDIT in their health IT system, to further evaluate a patient's alcohol use if the patient screens positive on one of the aforementioned questionnaires. Integration of this *WHO AUDIT Alcohol Screening* artifact or the *USAUDIT Alcohol Screening* artifact with a brief alcohol screening assessment can provide additional, valuable insight into the patient's alcohol intake, which in turn can inform more appropriate patient-centered brief interventions and care.

4. **Ensuring alcohol screening questions and scoring criteria align with standard drink sizes in the U.S. and evidence-based research for the U.S. population**

    a. As mentioned in Section 2.1 of this document, this CDS presents a specific version of question #3 to each patient based on the patient's sex and age. The versions vary in the "threshold" quantity of drinks mentioned in the question (e.g., "four" or more drinks, "three" or more drinks). The drink thresholds were informed by the NIAAA definition of low-risk alcohol use cited in the USAUDIT manual (i.e., no more than 4 drinks on any single day and no more than 14 drinks per week for men 65 and younger; and no more than 3 drinks on any single day and no more than 7 drinks per week for women and men over 65 years old) (Babor et al., 2017). Thus, in this CDS artifact, the patient's sex and age determines whether "four" or "three" is populated in the base question: "How often do you have X or more drinks on one occasion?".

    b. Published evidence also informed scoring thresholds (i.e., cutoffs) specified in this CDS. The WHO AUDIT manual suggests lowering the cutoff point (i.e., the score that indicates hazardous or harmful alcohol use) for women and men over age 65: "Since the effects of alcohol vary with average body weight and differences in metabolism, establishing the cutoff point for all women and men over age 65 one point lower…will increase sensitivity for these population groups. Selection of the cutoff point should be influenced by national and cultural standards and by clinician judgement…" (Babor et al., 2001). As such, this CDS requires a WHO AUDIT-C score of greater than or equal to "3" for women, men over age 65, and individuals whose sex at birth is recorded as Unknown in a health IT system for a patient to be presented with question #4 through question #10, while retaining a cutoff score of greater than or equal to "4" for men 65 and younger.

5. **Ensuring individuals whose sex at birth is recorded as "unknown" in an EHR receive alcohol screening**

    a. 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 (The Office of the National Coordinator for Health Information Technology, n.d.). Because question #3 and the scoring criteria in this representation of the WHO AUDIT are sex-specific, the CDS Development Team and CDC SMEs strived to ensure that this CDS representation would accommodate all valid responses (i.e., Male, Female, or Unknown) to "sex assigned at birth" (Logical Observation Identifiers Names and Codes [LOINC] code "76689-9") so that all individuals would be screened for excessive alcohol consumption. To err on the side of potentially overestimating the patient's risk (as opposed to underestimating risk), the CDS presents individuals whose sex at birth is Unknown with "4 drinks a day" populated in question #3 (as opposed to "5 drinks a day," which is the higher threshold). This aligns with how the question is presented to Female patients. The CDS also defines a positive WHO AUDIT-C score as >= "3" for individuals with Unknown as their sex at birth (as opposed to >= "4," which is the higher threshold).

6. **Delivering a "pregnancy question" at the end of alcohol screening to specific women**
    a. Abstinence from alcohol is tremendously important when a woman is pregnant or trying to become pregnant (Centers for Disease Control and Prevention, 2014) (Wright et al., 2016). Although CDS specifications can evaluate data in a woman's medical record for evidence of a current pregnancy or a hysterectomy (which eliminates a woman's ability to get pregnant), this information does not represent a full picture of a woman's pregnancy status. For example:
        i. A woman may have taken a home pregnancy test that was positive, but she has not had her first prenatal visit yet, therefore a diagnosis of pregnancy is not present in her medical record.
        ii. A woman may be trying to become pregnant but if this information is present in a patient's record at all, it is usually captured as free text, therefore the CDS code cannot reason over it.

    For these reasons, the CDS Development Team and CDC SMEs elected to present adult women of reproductive age (18-49 years old) without evidence of a current pregnancy or hysterectomy in their medical record with the following question after alcohol screening has concluded: "Are you pregnant or trying to become pregnant?". The CDS records the response to this question to inform complementary CDS logic that presents ASBI care recommendations to the clinician based on the patient's age, sex, medical history, pregnancy status, screening score, and other factors can inform the interventions and suggested actions presented to the clinician (e.g., logic in the *Alcohol Brief Intervention and Referral* CDS artifact).

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.-j). 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.-o). Example resources include Condition (Health Level 7 (HL7), n.d.-e) and Observation (Health Level 7 (HL7), n.d.-i), 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 being defined.

FHIR provides a Questionnaire resource that allows interrelated questions and responses to be defined in a standard format (Health Level 7 (HL7), n.d.-m). Each Questionnaire instance is defined by a set of both required and optional data elements, which are by design general in nature, to support the capabilities most likely to be found in the majority of healthcare systems (Health Level 7 (HL7), n.d.-l). 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. As further described in Section 5.2.2, the questions and available responses of the alcohol screening instrument are represented using a FHIR Questionnaire resource.

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.-k) 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.-g), 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.-p) 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 ASBI CDS 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 three main components of the ASBI CDS can be seen in **Figure 1** and are: PlanDefinition ("the container"), Questionnaire ("the questions and available responses"), and Library ("the logic").

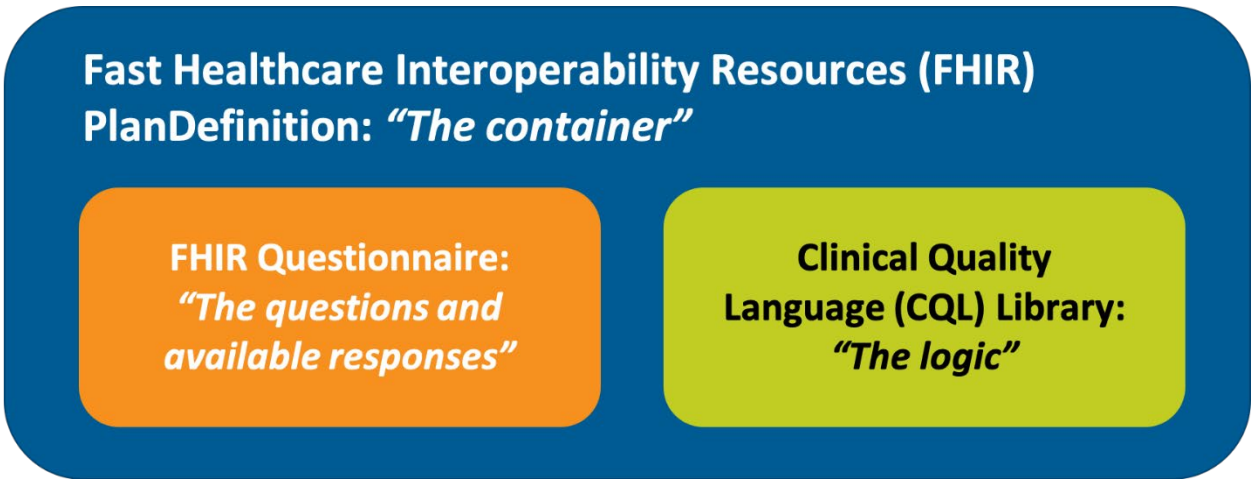

Figure 1. Depiction of the relationship between the components that define the artifact

Figure 1 shows the Questionnaire and Library components "inside" the PlanDefinition component; this depiction is meant to reflect the fact that the PlanDefinition serves as a wrapper and "contains" the other two components. 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 all three components.

5.2.1 PlanDefinition

The FHIR standard provides a PlanDefinition resource (Health Level 7 (HL7), n.d.-k) 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 two components 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.-h).

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., at the start of an encounter), under what conditions it is applicable (determined by the ApplyScreeingInstrument expression from the CQL Library), and what action should be taken (i.e., present the WHO AUDIT Questionnaire). The trigger is the name of a CDS Hook called encounter-start (Health Level 7 (HL7) & Boston Children's Hospital, n.d.); CDS Hooks is covered in Section 5.3.2 as part of the implementation discussion. The action and conditions are described in detail by the Questionnaire and Library components, respectively.

```
Instance:   AlcoholScreeningWhoAudit
InstanceOf: PlanDefinition
Title:      "AUDIT Alcohol Screening"
* url = "http://www.cdc.gov/ncbddd/fasd/audit-plandefinition"
* version = "1.0.0"
* name = "whoaudit-plandefinition"
* title = "WHO AUDIT 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 = "World Health Organization (WHO) Alcohol Use Disorders Identification Test (AUDIT)"
* date = "2020-05-04"
* library = "Library/WhoAuditLogicLibrary|1.0"
* action[0].trigger[0].type = http://hl7.org/fhir/trigger-type#named-event "Named Event"
* action[0].trigger[0].name = "encounter-start"
* 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 = "ApplyScreeningInstrument"
* action[0].condition[0].expression.reference = "Library/WhoAuditLogicLibrary|1.0"
* action[0].definitionCanonical = "Questionnaire/WHOAUDIT"
```

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

5.2.2 Questionnaire

As discussed in Section 5.1.1, the FHIR standard provides a Questionnaire resource for describing healthcare-related surveys, questionnaires, and forms. Section 5.1.3 discussed how the SDC IG provides additional guidance on how Questionnaire can be used in more complex use cases. A FHIR Questionnaire is used to specify the questions and available responses for each of the screening instruments that make up the ASBI CDS. These include the WHO AUDIT, the alcohol prescreen question, and the pregnancy question. The ASBI CDS Questionnaire defines the ordering of the questions and specifies under what conditions each question appears. An excerpt of the ASBI CDS Questionnaire is shown in **Figure 3**.

```
// ------------------------------------------------------------------------------------------
// ------------------------------------------------------------ Step 2: Consider WHOAUDIT-C Screening
// ------------------------------------------------------------------------------------------
* item[2].linkId = "audit-question-one"
* item[2].extension[0].url = "http://hl7.org/fhir/StructureDefinition/designNote"
* item[2].extension[0].valueMarkdown = "Step 2: Consider WHOAUDIT-C Screening  \\nDisplay Question #1
of the WHOAUDIT-C"
* item[2].enableWhen.question = "prescreen-question"
* item[2].enableWhen.operator = http://hl7.org/fhir/questionnaire-enable-operator|4.0.1#= "Equals"
* item[2].enableWhen.answerCoding = http://www.cdc.gov/ncbddd/fasd#APS1 "Yes"
* item[2].type = http://hl7.org/fhir/item-type|4.0.1#choice "Choice"
* item[2].text = "How often do you have a drink containing alcohol?"
* item[2].answerOption[0].valueCoding = http://www.cdc.gov/ncbddd/fasd#WHQ1A0 "Never"
* item[2].answerOption[0].extension[0].url = "http://hl7.org/fhir/StructureDefinition/ordinalValue"
* item[2].answerOption[0].extension[0].valueDecimal = 0
* item[2].answerOption[1].valueCoding = http://www.cdc.gov/ncbddd/fasd#WHQ1A1 "Monthly or less"
* item[2].answerOption[1].extension[0].url = "http://hl7.org/fhir/StructureDefinition/ordinalValue"
* item[2].answerOption[1].extension[0].valueDecimal = 1
* item[2].answerOption[2].valueCoding = http://www.cdc.gov/ncbddd/fasd#WHQ1A2 "2-4 times a month"
* item[2].answerOption[2].extension[0].url = "http://hl7.org/fhir/StructureDefinition/ordinalValue"
* item[2].answerOption[2].extension[0].valueDecimal = 2
* item[2].answerOption[3].valueCoding = http://www.cdc.gov/ncbddd/fasd#WHQ1A3 "2-3 times a week"
* item[2].answerOption[3].extension[0].url = "http://hl7.org/fhir/StructureDefinition/ordinalValue"
* item[2].answerOption[3].extension[0].valueDecimal = 3
* item[2].answerOption[4].valueCoding = http://www.cdc.gov/ncbddd/fasd#WHQ1A4 "4 or more times a
week"
* item[2].answerOption[4].extension[0].url = "http://hl7.org/fhir/StructureDefinition/ordinalValue"
* item[2].answerOption[4].extension[0].valueDecimal = 4
```

Figure 3. Portion of the WHO AUDIT Questionnaire showing Question 1 expressed in FHIR Shorthand

Figure 3 shows the portion of the Questionnaire that defines Question #1 of the WHO AUDIT. The excerpt is written compactly using FSH and demonstrates how a question in the Questionnaire can be defined by a unique identifier called a linkId, a set of conditions that specify when the question is "enabled," the actual text of the question, and a set of answerOptions that define the possible responses. From the excerpt it can be seen that the score for each response to Question #1 is encoded using the ordinalValue FHIR extension (Health Level 7 (HL7), n.d.-f).

FHIR provides a basic grammar for expressing simple conditions and constraints on each question in a Questionnaire. SDC also provides a mechanism to reference more complex logical expressions defined in an external Library. In the case of the ASBI CDS, an external CQL Library (see next section) contains the logical expressions necessary for specifying most of the complex behavior of the Questionnaire. An example of a complex logical expression is the calculation of the scores for both the WHO AUDIT-C and WHO AUDIT, which requires reading the current responses to the Questionnaire, looking up the scores for each individual response,

and then combining scores across questions. A list of the complex expressions used by the ASBI CDS Questionnaire is shown below in **Table 2**.

Table 2. List of logical expressions defined in the CQL Library and referenced in the Questionnaire

Expression Name	Expression Value	Description
DisplayScoreAuditC	Boolean (true/false)	Should the AUDIT-C score be displayed to the user?
ScoreAuditC	Numeric	AUDIT-C score (sum of Questions #1-#3)
DisplayAuditQuestions4to8	Boolean (true/false)	Should Questions #4-#8 of the AUDIT be displayed to the user?
DisplayAuditQuestions9and10	Boolean (true/false)	Should Questions #9 and #10 of the AUDIT be displayed to the user?
DisplayScoreFullAudit	Boolean (true/false)	Should the AUDIT score be displayed to the user?
ScoreFullAudit	Numeric	AUDIT score (sum of Questions #1-#10)
DisplayPregnancyQuestion	Boolean (true/false)	Should the pregnancy question be displayed to the user?

5.2.3 Library

The FHIR standard provides a Library resource (Health Level 7 (HL7), n.d.-n) 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, alongside responses the patient has made to questions from the Questionnaire described in Section 5.2.2. The CQL uses both sets of information as input data to the logical expressions, whose values are then passed back to the Questionnaire where they are used to determine the correct CDS behavior for the patient.

In addition to the expressions listed in **Table 2**, a number of intermediate expressions are evaluated within the CQL but not returned to the Questionnaire. Both sets of expressions are necessary for the CQL to provide the required functionality. An example CQL expression from the Library is shown in **Figure 4.** From the example we can see the expression DisplayPregnancyQuestion being defined using a combination of patient data (e.g., FemaleAtBirth) and information about their responses to the Questionnaire (e.g., AnsweredQuestionsOneThroughThree). DisplayPregnancyQuestion returns true if the patient's sex at birth is female, there are no indications of a current pregnancy or of a past hysterectomy, the patient age is between 18 and up to but not including 50 years, and one of the following three situations is true:

1. The patient has answered Questions #1 through #3 of the WHO AUDIT and does not qualify for Questions #4 through #10.
2. The patient has answered Questions #1 through #3, does not qualify for Questions #4 through #8, and has answered Questions #9 and #10.
3. The patient has answered all ten questions of the WHO AUDIT.

```
// Should the pregnancy question be displayed?
define DisplayPregnancyQuestion:
  FemaleAtBirth
    and not IsPregnant
    and not HasHadHysterectomy
    and AgeInYears() between 18 and 49 // 18 <= AgeInYears() < 50
    and (
      (singleton from CurrentResponse1 = 'Never' and AnsweredQuestionsNineAndTen) or // Step 6: Logic
Path #1
      (AnsweredQuestionsOneThroughThree and not DisplayAuditQuestions4to8 and not
DisplayAuditQuestions9and10) or // Step 6: Logic Path #2
      (AnsweredQuestionsOneThroughThree and not DisplayAuditQuestions4to8 and
AnsweredQuestionsNineAndTen) or // Step 6: Logic Path #2
      (AnsweredQuestionsFourThroughTen) // Step 6: Logic Path #3
    )
```

Figure 4. An excerpt from the CQL logic within the Library

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 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 encounter-start hook (Health Level 7 (HL7) & Boston Children's Hospital, n.d.) will be used as 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 5**.
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 5**, 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.

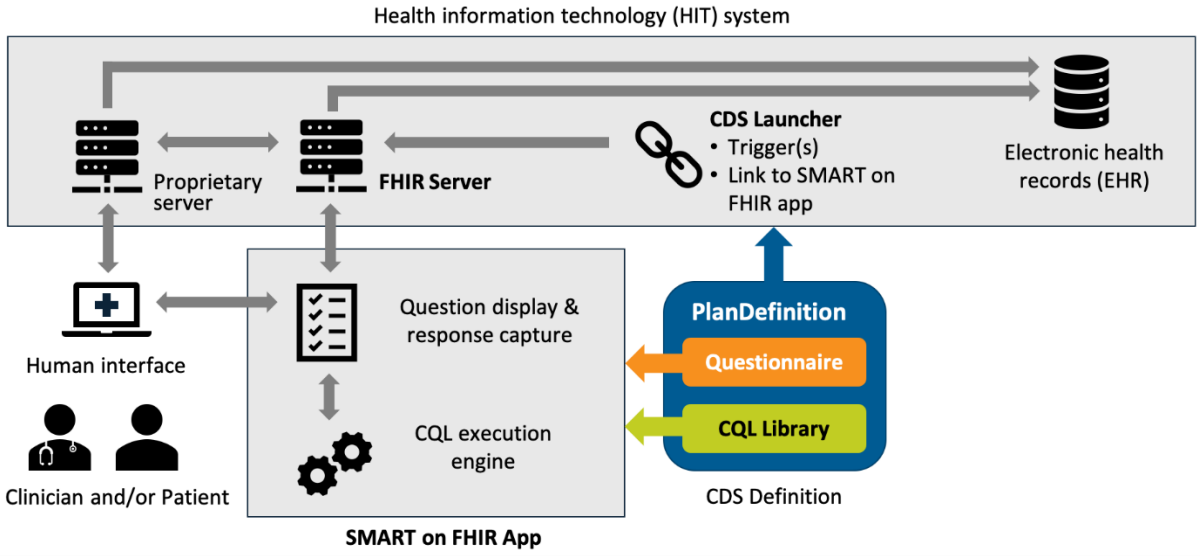

Figure 5. Notional depiction of ASBI CDS integration with a health IT system

Figure 5 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 Questionnaire and CQL Library are included in a SMART on FHIR App. The SMART on FHIR App is responsible for rendering the alcohol screening questions for display on the human interface, executing CQL logic, and capturing the patient responses for processing and storage in the EHR. 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.-d) 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 3** 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 results from the alcohol screening can be documented in the EHR.

Table 3. Required FHIR Server capabilities

FHIR Resource	**Supported Operation(s)** (Health Level 7, n.d.-d)
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 at the start of a patient encounter. 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 an alcohol screening, 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 an alcohol screening, 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 5**, 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 Questionnaire. The second main component is a software program that takes questions defined in the Questionnaire and presents them to the user via the human interface; any responses the patient and/or clinician makes are captured and sent to the CQL execution engine.

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.-e), 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 return the results of the screening 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, three different FHIR resources are necessary to define the ASBI CDS: PlanDefinition, Questionnaire, 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.-f). 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.-g).

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 5.2.3, 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 6**.

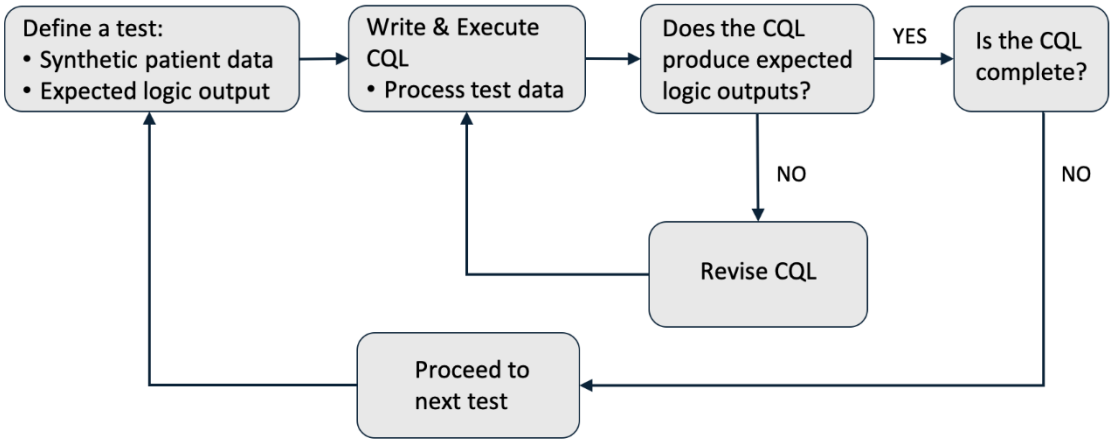

Figure 6. Diagram showing the test-driven development approach taken for authoring CQL

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 7**. 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 female patient who is under the age of 65 years, is not pregnant, and has filled out a WHO AUDIT-C instrument with a resulting score below a threshold. The responses to the WHO AUDIT-C 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 not receive the full WHO AUDIT based upon the input responses to the first three questions, but the pregnancy question should be administered.

The CQL Testing Framework works by reading the example test case file shown in **Figure 7**, 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 50 different logic tests were defined for the ASBI CDS; the list of the test case names is provided in **Table 4**. The details of each test case can be found in the separate set of testing files.

```yaml
---
name: Not Pregnant Female Under 65 Below AUDIT-C Threshold
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
-
  resourceType: QuestionnaireResponse
  questionnaire: 'http://www.cdc.gov/ncbddd/fasd/audit'
  status: 'in-progress'
  authored: 2020-03-09
  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 Monthly or less
  - linkId: 'audit-question-two'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE 1 or 2
  - linkId: 'audit-question-three'
    answer:
      valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Less than monthly
  - 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
results:
  AuditQuestion3Text: 'How often do you have 4 or more drinks on one occasion?'
  ThresholdAuditC: 3
  ScoreAuditC: 2
  DisplayAuditQuestions4to8: false
  DisplayScoreFullAudit: false
  ScoreFullAudit: 2
  DisplayPregnancyQuestion: true
```


Figure 7. Example logic test case

Table 4. List of logic tests

Number	Test Name
1	Excluded Active AUD
2	Female at Birth
3	Not Pregnant Female Under 65 Above AUDIT-C Threshold
4	Pregnant Female Under 65 Above AUDIT-C Threshold
5	Not Pregnant Female Under 65 Below AUDIT-C Threshold
6	Pregnant Female Under 65 Below AUDIT-C Threshold
7	Complete Full AUDIT
8	Complete Full AUDIT (1)
9	Continue to Full AUDIT
10	Continue to Full AUDIT (1)
11	Has had hysterectomy
12	Has Recent APS Response of No
13	Has Recent AUDIT Responses But No Scores
14	Has Recent AUDIT Score
15	Has Recent AUDIT-C Score
16	Has Two Recent AUDIT-C Scores
17	Previously answered AUDIT Question One twice before with one never
18	Previously answered AUDIT Question One twice before with two nevers

Number	Test Name
19	Is Included
20	Is Not Included
21	Male at Birth
22	Male Over 65 Above AUDIT-C Threshold
23	Male Over 65 Below AUDIT-C Threshold
24	Male Under 65 Above AUDIT-C Threshold
25	Male Under 65 Below AUDIT-C Threshold
26	Male Under 65 Below AUDIT-C Threshold with Active AUD
27	Male Under 65 Below AUDIT-C Threshold with Inactive AUD
28	Missing sex at birth extension
29	No pregnancy question (outside age range)
30	Not Included Under Age
31	Not Pregnant Alcohol Screening Lookback
32	Old Pregnant Observation
33	Pregnant Condition Active
34	Pregnant Condition Active (alternate code)
35	Pregnant Condition Old
36	Pregnant Condition Recurrence
37	Pregnant Condition Active But Not Verified

Number	Test Name
38	Pregnant Alcohol Screening Lookback (last screening after pregnancy)
39	Pregnant Alcohol Screening Lookback (last screening after pregnancy but more than 3 months ago)
40	Pregnant Alcohol Screening Lookback (last screening before pregnancy)
41	Pregnant Observation Amended
42	Pregnant Observation Corrected
43	Pregnant Observation Final
44	Previously answered "Monthly" to AUDIT Question One
45	Sex at birth unknown
46	Stop after AUDIT-C Tests
47	Stop after AUDIT-C Tests (1)
48	Stop after AUDIT-C Tests (2)
49	Stop after AUDIT-C Tests (3)
50	Stop after AUDIT-C Tests (4)

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 the other important aspects of the ASBI CDS, namely the questions and available responses defined in the Questionnaire. 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 5**.

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 [IP] constraints)
- 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 aspects:

- 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 8 depicts 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 6.2.2.2 are being released under open source licenses.

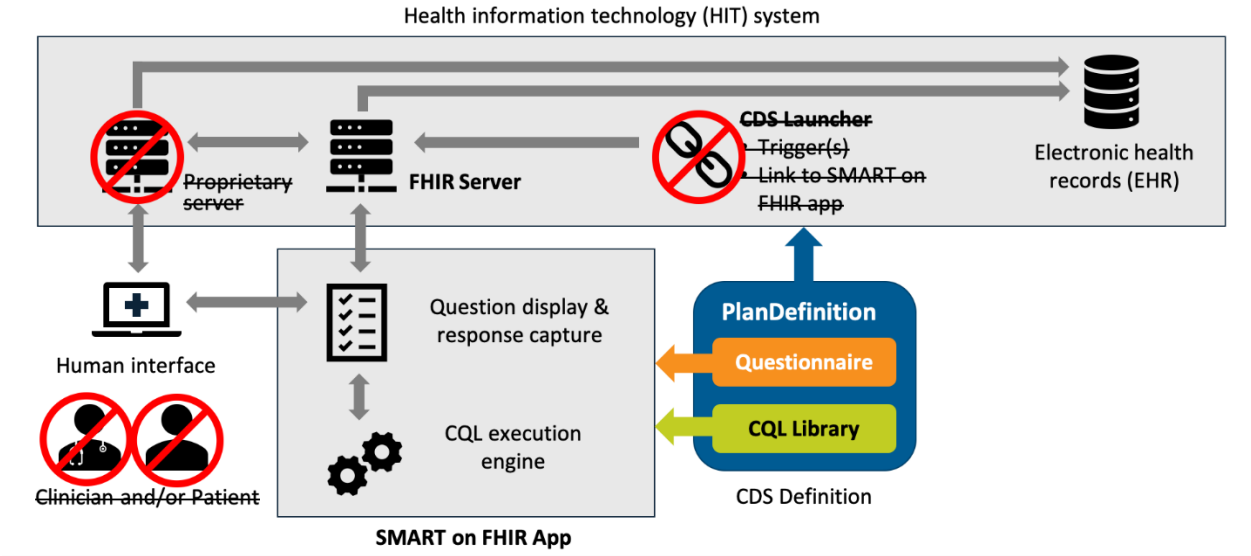

Figure 8. Notional ASBI CDS integration depicting which aspects can be emulated without a real health IT system

As seen in **Figure 8**, 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 Questionnaire on the screen and records the patient responses. The former is referred to as the "ASBI CDS FHIR Server" and the latter is called the "ASBI CDS Screening 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 Underlying Technologies

This section describes the software libraries used to build the end-to-end test harness; both existing as well as newly developed software were required to provide the necessary functionality.

6.2.2.1 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.

6.2.2.1.1 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 6.2.2.2.3 is used to provide FHIR API capabilities for the test harness.

6.2.2.1.2 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.).

6.2.2.1.3 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.).

6.2.2.1.4 SurveyJS

SurveyJS is a JavaScript library for rendering surveys and forms in a web browser and capturing user responses (SurveyJs, n.d.). The *end-to-end test harness* uses SurveyJS to mechanize the alcohol screening instrument, rendering the questions to the screen, and capturing user responses. It provides all the capabilities needed for implementing the ASBI CDS Questionnaire. Unfortunately, SurveyJS does not natively support FHIR, so a new software tool was created to translate FHIR Questionnaires to a format that SurveyJS understands (see Section 6.2.2.2.1).

6.2.2.1.5 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.

6.2.2.2 Newly Developed Software

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

6.2.2.2.1 Surveys on FHIR

Surveys on FHIR is a software library created for the ASBI CDS project so that surveys defined as FHIR Questionnaires could be used with the SurveyJS library, which does not natively support FHIR. This software library aims to broaden the ecosystem of tools for implementing FHIR Questionnaires in practice. Without Surveys on FHIR, SurveyJS could not be used to render the alcohol screening instruments, and an alternative would have to be found or developed from scratch.

6.2.2.2.2 ASBI CDS Screening App

The *ASBI CDS Screening App* is a SMART on FHIR application that presents the user with the alcohol screening instrument for assessing patient alcohol consumption behaviors. 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 FHIR Questionnaire representing the alcohol screening instrument is loaded, converted to SurveyJS format using the Surveys on FHIR library,

and then input into the SurveyJS library. SurveyJS, along with Vue, are used to render the first item of the Questionnaire to the screen.

The ASBI CDS Screening App is interactive in the sense that it reacts to user inputs, each time running the CQL logical expressions in the background using the loaded FHIR resources and the current user responses. Logic encoded in the Questionnaire and CQL Library dictate the ordering of questions and whether certain questions are presented to the user. When the alcohol screening instrument is complete, a FHIR QuestionnaireResponse resource is generated (Health Level 7, n.d.-c). If write-back capability is supported by the FHIR Server, then the patient responses to the alcohol screening are also written back to the patient record in the form of this QuestionnaireResponse.

6.2.2.2.3 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 as well as any QuestionnaireResponses sent from the ASBI CDS Screening App. The ASBI CDS FHIR Server does not implement any of the ASBI CDS logic; it is only necessary to support end-to-end testing.

Appendix A. Artifact Logic and Decision Log

A.1 Artifact CDS Logic Flow

The *WHO AUDIT Alcohol Screening* CDS artifact was informed by the AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Health Care (Babor et al., 2001). 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 CDS development progresses. The CDS logic flow diagram in **Figure 9** displays the outcome of the first "phase" of translating knowledge in the narrative World Health Organization (WHO) Alcohol Use Disorders Identification Test (AUDIT) source into a series of events and decisions that enable evidence-based alcohol screening. It displays an overview of the clinical decision support (CDS) logic and provides potential implementers with an impression of the CDS logic flow.

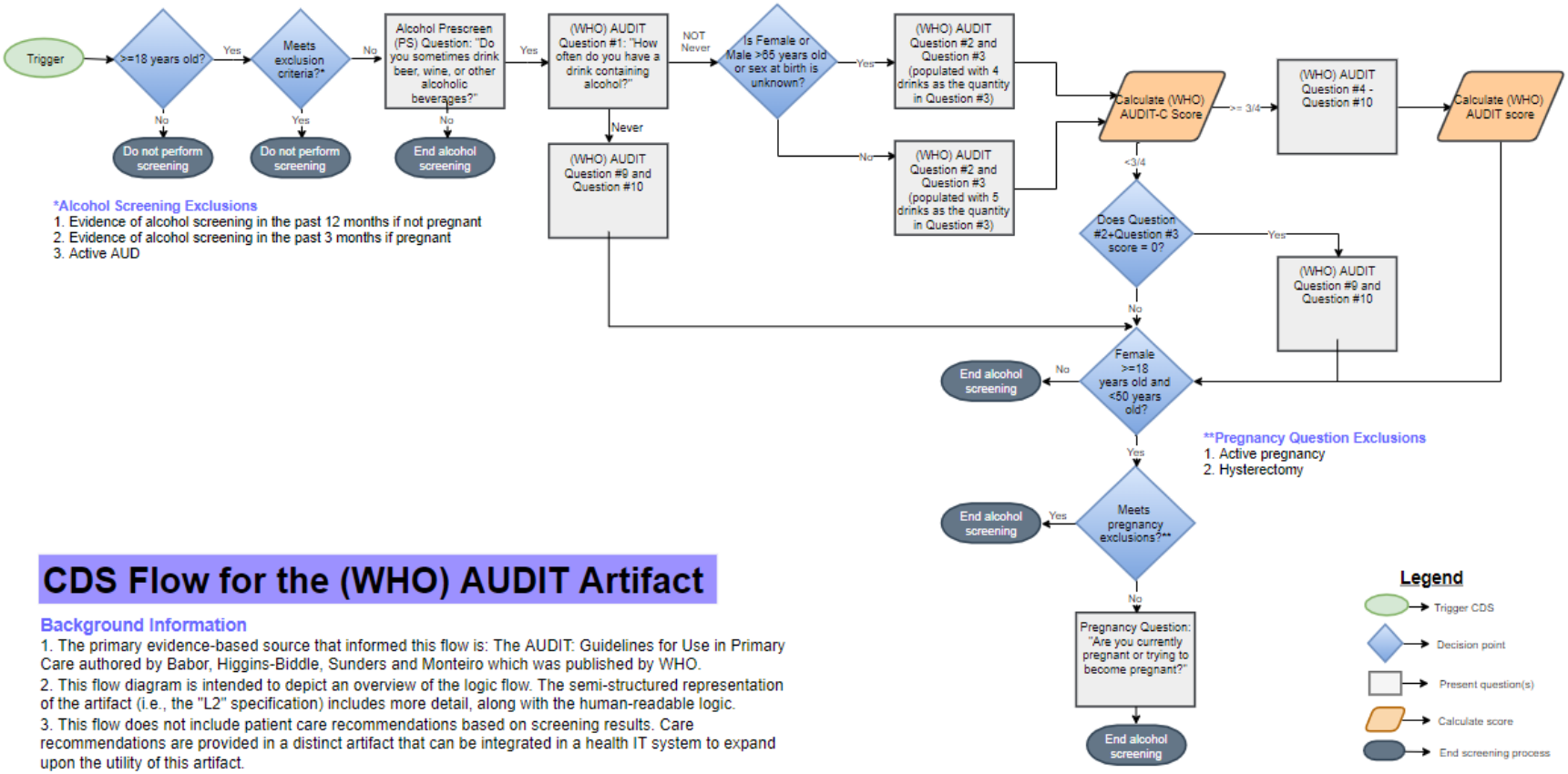

Figure 9: WHO AUDIT Alcohol Screening CDS Logic Flow

A.2 Artifact Semistructured Representation

Next, the CDS Development Team utilized the CDS flow depicted in **Figure 9** and granular details identified in the narrative WHO AUDIT guide, to inform the development of a more comprehensive semistructured (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 semistructured 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 alcohol screening 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., screening events) and diagnoses (e.g., Alcohol Use Disorder [AUD]). 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 presentation of the Alcohol Prescreen (PS) Question

Inclusion logic: Patient is >= 18 years old

Exclusion logic:

Evidence of alcohol screening in the past 12 months (final, amended, corrected)

AND NOT

Pregnant (active, recurring)

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

OR Evidence of alcohol screening in the past three months while the patient is pregnant (Note: A pregnant patient should be screened as early as possible in the first trimester and every three months while they are pregnant.)

OR AUD (active, recurrence, relapse)

CDS Actions:

Introduce the purpose of alcohol use screening

Display the alcohol PS question (i.e., "Do you sometimes drink beer, wine, or other alcoholic beverages?")

Display the standard drink size graphic

Record and display the patient's response to the alcohol PS question

Step 2: Consider WHO AUDIT-C Screening

Step 2, Logic path #1 (continue screening)

Inclusions:

Patient is >=18 years old

AND most recent alcohol PS question response is "Yes"

Exclusions: Carry over exclusions from Step 1

CDS Actions:

Display WHO AUDIT-C screening instructions

Display U.S. standard drink size graphic

Display Question #1 of the WHO AUDIT-C

Record and display the response to Question #1

Step 2, Logic path #2 (stop screening)

Inclusions:

Patient is >=18 years old

AND most recent alcohol PS question response is "No"

Exclusions: Carry over exclusions from Step 1

CDS Actions: End screening

Step 3: Consider administering Question #2 and Question #3 of the WHO AUDIT-C

Step 3, Logic path #1 (continue screening for women, men > 65 years old, and individuals whose sex at birth is unknown)

Inclusions:

Patient is >= 18 years old

AND most recent alcohol PS question response is “Yes”

AND NOT most recent WHO AUDIT-C Question #1 response is “Never”

AND

Female

OR Male > 65 years old

OR Sex at birth is Unknown

Exclusions: Carry over exclusions from Step 1

CDS Actions:

Continue to display WHO AUDIT-C screening instructions

Continue to display U.S. standard drink size graphic

Display Question #2 and Question #3 of the WHO AUDIT- C (Question #3 = “How often do you have four or more drinks on one occasion?”)

Record and display the response to Question #2 and Question #3

Calculate WHO AUDIT-C score

Record and display WHO AUDIT-C score

Step 3, Logic path #2 (continue screening for men <= 65 years old)

Inclusions:

Patient is >= 18 years old

AND most recent alcohol PS question response is “Yes”

AND NOT most recent WHO AUDIT-C Question #1 response is “Never”

AND Male <= 65 years old

Exclusions: Carry over exclusions from Step 1

CDS Actions:

Continue to display WHO AUDIT-C screening instructions

Continue to display U.S. standard drink size graphic

Display Question #2 and Question #3 of the WHO AUDIT- C (Question #3 = "How often do you have five or more drinks on one occasion?")

Record and display the response to Question #2 and Question #3

Calculate WHO AUDIT-C score

Record and display WHO AUDIT-C score

Step 4: Consider presenting Question #9 and Question #10 of the WHO AUDIT when not administering the full WHO AUDIT

Step 4, Logic path #1 (jump from Question #1 to Question #9 and #10 OR jump from the end of the WHO AUDIT-C to Question #9 and #10)

Inclusions:

Patient is >= 18 years old

AND most recent alcohol PS question response is "Yes"

AND

Most recent WHO AUDIT-C Question #1 response is "Never"

OR

Most recent WHO AUDIT-C Question #1 score < 3

AND Most recent WHO AUDIT-C Question #2 score = 0

AND Most recent WHO AUDIT-C Question #3 score = 0

AND

Female

OR Sex at birth is Unknown

OR Male > 65 years old

OR

Most recent WHO AUDIT-C Question #1 score < 4

AND Most recent WHO AUDIT-C Question #2 score = 0

AND Most recent WHO AUDIT-C Question #3 score = 0

AND Male < = 65 years old

Exclusions: Carry over exclusions from Step 1

CDS Actions:

Display Question #9 and Question #10 of the WHO AUDIT

Record and display response to Question #9 and Question #10 of the WHO AUDIT

Step 5: Consider additional screening

Step 5, Logic path #1 (provide full WHO AUDIT)

Inclusions:

Patient is >= 18 years old

AND most recent alcohol PS question response is “Yes”

AND NOT most recent WHO AUDIT-C Question #1 response is “Never”

AND

Most recent WHO AUDIT-C score >= 3

AND

Female

OR Male > 65 years old

OR Sex at birth is Unknown

OR

Most recent WHO AUDIT-C score >=4

AND Male <= 65 years old

Exclusions: Carry over exclusions from Step 1

CDS Actions:

Display Question #4 - Question #10 of the WHO AUDIT

Record and display responses to Question #4 - Question #10 of the WHO AUDIT

Calculate and record score of WHO AUDIT

Step 6: Consider pregnancy status

Step 6, Logic path #1 (post WHO AUDIT Questions #1, #9 and #10)

Inclusions:

Patient is >= 18 years old and < 50 years old

AND Female

AND most recent WHO AUDIT-C Question #1 is "Never"

AND most recent response to WHO AUDIT Question #9 and Question #10 is present

Exclusions:

Carry over exclusions for Step 1

AND

Pregnant (active, recurring)

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

OR Hysterectomy (completed)

CDS Actions:

Display "pregnancy question" (i.e., "Are you pregnant or trying to become pregnant?")

Record and display response to the pregnancy question

Step 6, Logic path #2 (post WHO AUDIT-C, with or without responses to Question #9 and Question #10)

Inclusions:

Patient is >= 18 years old and < 50 years old

AND Female

AND most recent WHO AUDIT-C score < 3

AND

Most recent WHO AUDIT-C Question #2 response ≠ to "1 or 2"

OR most recent WHO AUDIT-C Question #3 response ≠ to "Never"

OR

Most recent WHO AUDIT-C Question #2 response = "1 or 2""

AND most recent WHO AUDIT-C Question #3 response = "Never"

AND most recent response to WHO AUDIT Question #9 and Question #10

Exclusions:

Carry over exclusions for Step 1

AND

Pregnant (active, recurring)

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

OR Hysterectomy (completed)

CDS Actions:

Display "pregnancy question" (i.e., "Are you pregnant or trying to become pregnant?")

Record and display response to the pregnancy question

Step 6, Logic path #3 (post full WHO AUDIT)

Inclusions:

Patient is >= 18 years old and < 50 years old

AND Female

AND most recent WHO AUDIT-C score >=3

Exclusions:

Carry over exclusions for Step 1

AND

Pregnant (active, recurring)

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

OR Hysterectomy (completed)

CDS Actions:

Display "pregnancy question" (i.e., "Are you pregnant or trying to become pregnant?")

Record and display response to the pregnancy question

A.3 CDS Concept Definitions

Table 5 defines many of the clinical concepts and terms used in the semistructured CDS representation to provide clarity on what each logic concept means and why it was expressed as listed. These concepts were informed by or derived from text in evidence-based sources (e.g., AUDIT, research reviews).

Table 5: CDS Concept Definitions

Location in CDS Logic	Concept	Definition and/or Rationale
Every Step	“>=”	Greater than or equal to a given value (e.g., >= 18 years old)
Step 1 Exclusions	“evidence of alcohol screening”	Any “final,” “amended,” or “corrected” alcohol screening score present in the patient record. Specifically, the CDS code looks for results associated with the following screening assessments: 1) a USAUDIT-C or USAUDIT score, 2) a WHO AUDIT-C or WHO AUDIT score, 3) an alcohol PS question response of “No”, or 4) an alcohol PS question response of “Yes” AND an AUDIT Question #1 response of “Never” (which equates to a score of “0”). These screening assessments were selected because they evaluate the full spectrum of alcohol use, as opposed to evaluating binge drinking alone (e.g., the Single Alcohol Screening Question) or social problems and alcohol-related harms alone if the patient drinks alcohol. Please see additional information provided in Section 4.2, #3.
Steps 1-4 Inclusions, Exclusions	“in the past x months”	The CDS code looks for evidence of a specific event, condition, result (e.g., alcohol screening) to have occurred within a specified period of time from the current date (e.g., within the past 12 months from today).
Every Step	“AND NOT”	A CDS logic operator that ensures a specific event, condition, result, etc. is not present in the patient record
Steps 1 & 6	“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. This is included in the logic because women who are pregnant require unique care (e.g., they should be screened for alcohol use more frequently and be provided with distinct brief interventions based on whether they are drinking ANY alcohol).

Location in CDS Logic	Concept	Definition and/or Rationale
Steps 1 & 6	"pregnancy observation within the past 42 weeks"	Pregnancy is also 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.
Step 1 Exclusions	"onset date"	The date a condition (e.g., diagnosis) began
Step 1 Exclusions	"recorded date"	The date a condition (e.g., diagnosis) was recorded in the health IT system
Step 1	"AUD"	A diagnosis of Alcohol Use Disorder. In Step 1 a clinicalStatus of "active," "relapse," or "recurrence" is required to ensure the patient is currently experiencing the symptoms of the condition or there is evidence of the condition.
Step 1 CDS Actions	"introduce the purpose of alcohol use screening"	Display text that explains the rationale for conducting alcohol screening. Depending on how the CDS is implemented, this could be presented to 1) clinical staff administering the screening or 2) the patient taking the screening assessment.
Steps 1-6 CDS Actions	"display… question"	Conveys the intent to present a specific question or group of questions indicated for the patient, in support of evidence-based alcohol screening.
Steps 1-5	"alcohol prescreen (PS) question"	The alcohol PS question is, "Do you sometimes drink beer, wine, or other alcoholic beverages?". Presenting this question prior to initiating a multi-question alcohol use assessment removes the need to assess patients for risky alcohol use if they never drink alcohol.
Steps 1 & 2 CDS Actions	"display the U.S. standard drink size graphic"	Conveys the intent to present a picture of the standard drink size in the U.S. (i.e., a drink that contains 14 grams of pure alcohol) for beverages such as beer, wine, and alcoholic spirits (Centers for Disease Control and Prevention (CDC), 2018). The graphic enables a patient to provide a more accurate response about their alcohol intake by defining what is meant by a "drink."
Steps 1-4 CDS Actions	"record and display the entered response…"	Conveys the intent to capture and store any/all responses to screening questions and display them in the health IT user interface. Depending on how the CDS is implemented, the display might occur within a documentation template in the electronic health record (EHR), within an app that is integrated with the EHR, etc.

Location in CDS Logic	Concept	Definition and/or Rationale
Steps 2-4 Inclusions	"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.
Steps 2-5 Inclusions	"response is"	The CDS logic evaluates the patient's answer to specific questions to determine what interventions and actions are indicated. Response examples include "Yes," "No," "Never".
Steps 2-4 Exclusions	*"carry over exclusions from Step 1"*	This phrase conveys the need to include all exclusion specifications listed in Step 1 in the present logic path. The phrase aids in condensing the L2 expression to make the logic more readable and less repetitive.
Steps 2 & 3 CDS Actions	"screening instructions"	Directions presented to the individual administering the screening (e.g., a medical assistant) or taking the screening (e.g., the patient).
Steps 2-4 CDS Actions	"display Question #..."	To align with the WHO AUDIT guide, individual WHO AUDIT-C/ WHO AUDIT questions are presented to the patient in a designated sequence. Based on the patient's medical history, demographics and response to a given question, the logic will present a patient-specific series of screening questions that align with evidence-based guidance.
Steps 2 & 3	"WHO AUDIT-C"	The WHO Alcohol Use Disorders Identification Test-Consumption questionnaire is a short, easy-to-administer screening process using the first three questions of the WHO AUDIT. Although the AUDIT and AUDIT-C are not usually referred to as the (WHO) AUDIT and the WHO AUDIT-C, the CDS Development Team opted to preface the name of the questionnaire with the sponsoring body (i.e., WHO) to avoid confusion with the *USAUDIT Alcohol Screening* CDS artifact (a "sister" resource that is publicly available and aligns with the USAUDIT guide). In this CDS, the patient's WHO AUDIT-C score is calculated by the CDS code. If the score is >= 3 for 1) women, 2) individual's whose sex is unknown or 3) men older than 65, or if the score is >=4 for men who are <=65 years old, the remainder of the WHO AUDIT questions are administered to the patient. (Bradley et al., 2007).
Step 3 Inclusions	">"	Greater than (e.g., greater than 65 years old)
Steps 3-5	"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 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.). Because Question #3 of the WHO AUDIT as specified in this CDS is sex (and age) specific, 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.

Location in CDS Logic	Concept	Definition and/or Rationale
Step 3 CDS Actions	"How often do you have x or more drinks on one occasion?"	The quantity of drinks populated in question #3 in the WHO AUDIT-C/ WHO AUDIT as specified in this CDS can vary based on the patient's sex and age. Question #3 assesses the frequency of binge drinking behavior. The binge drinking thresholds used in this CDS were defined by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to align with U.S. standard drink sizes (Alcoholism, n.d.).
Step 3 & 4 Inclusions	"<="	Less than or equal to (e.g., less than or equal to 65 years old)
Steps 3 & 4 CDS Actions	"calculate"	The action of computing a WHO AUDIT-C or WHO AUDIT score. This computation is conducted by the CQL code in the L3 representation of the artifact, in alignment with WHO AUDIT guidance.
Steps 3 - 5	"score"	Per WHO AUDIT guidelines, the response to each question is assigned a point value (i.e., a score). The points are summed to generate a total score or screening result. The score for the WHO AUDIT-C can range from 0-12, and the score for the WHO AUDIT can range from 0-40 (Babor et al., 2001).
Step 3 & 4 Inclusions	"<"	Less than (e.g., score < 3)
Step 3 & 4 Inclusions	"="	Equal to (e.g., score = 0)
Step 5	"hysterectomy"	A surgery to remove a woman's uterus. If a woman has undergone a hysterectomy, there is no need to ask her if she is pregnant (i.e., present the pregnancy question).
Step 5	"pregnancy question"	The pregnancy question is, "Are you currently pregnant or trying to become pregnant?". This question is presented to every woman of reproductive age to capture this important information (unless they meet the exclusion criteria). The response is used by the companion *Alcohol Brief Intervention and Referral* CDS artifact to inform the care recommendations generated by the CDS.

A.4 Artifact Development Decision Log

The CDS Development Team made numerous decisions while translating the WHO AUDIT narrative text into semistructured and later, structured, CDS logic. **Table 6** provides insight on those decisions. The table lists a "Decision Category," which was informed by the 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 6: 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 orgnaizations may already use a version of the AUDIT alcohol screening questionnaire and have the ability to capture 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 already have the USAUDIT and ASBI CDS logic embedded in their system and prefer only to add WHO AUDIT screening. A modular approach allows for personalized implementation choices without the need to edit CDS code.
Add explanation	Screening adults only	The WHO AUDIT-C/ WHO 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).
Add explanation	Enabling annual screening for non-pregnant patients	The WHO recommends all patient be screened annually (Babor et al., 2001).

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	Ensuring pregnant women receive appropriate alcohol screening	The specifications outlined in the Step 1 exclusion logic facilitate alcohol screening during every trimester of a pregnancy, as recommended by Wright et al. and the American College of Nurse Midwives (Wright et al., 2016) (American College of Nurse-Midwives, 2017). Because structured data that represents a woman's current trimester (e.g., first, second, third) is not routimely available in EHR data, the logic was designed to look for evidence of alcohol screening in the past three months (the duration of a trimester). Additionally, the logic was specified to present alcohol screening to any pregnant patient who has not been screened in the past three months since becoming pregnant (i.e., the pregnancy onset date), or since the pregnancy was recorded in the EHR (i.e., the recorded date). In the absence of "onset date" or "recorded date" data, the logic will generate a screening opportunity to all pregnant women who have not been screened in the past three months of their pregnancy. Professional organizations and government entities (e.g., ACOG, USPSTF, WHO) provide varied recommendations on how often alcohol screening should be performed during pregnancy. The CDS Development Team and CDC sponsors of this project elected to enable screening every trimester to ensure clinicians have an opportunity several times during pregnancy to evaluate alcohol intake and reinforce the importance of abstinence. Some pregnant women may believe it is safe to drink in the second or third trimester, and alcohol screening provides an opportunity to educate these women and stress the importance of abstinence (Wright et al., 2016). Screening every trimester, as opposed to at every prenatal visit, also provides a balanced approach to screening so as not to increase clinician burden, cognitive demands, time, and workflow constraints. Implementing organizations are encouraged to consider their organizational policy and procedure prior to integrating this CDS. The frequency of screening pregnant woman can be increased or decreased to align with their requirements prior to integration with their health IT system.
Add explanation	Excluding individuals with active AUD from alcohol screening	Individuals with active AUD are excluded from alcohol screening per the USPSTF recommendation *Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults* (i.e., "the recommendation does not apply to persons who have a current diagnosis of or who are seeking evaluation or treatment for alcohol abuse or dependence") (Curry et al., 2018). Individuals with active AUD undergo evaluation and care specific to their condition, as opposed to what is recommended in preventive health guidelines for brief intervention.
Add explanation	Incorporating an alcohol prescreen question	The CDS Development Team and CDC sponsors of this project elected to include the alcohol prescreen question as suggested by the NIAAA, to ensure that patients understand that beer and wine are considered alcoholic beverages. Use of the prescreen question also shortens the time spent on alcohol screening for patients who abstain from alcohol.

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	Ensuring alcohol screening questions and scoring criteria align with standard drink sizes in the U.S. and evidence-based research for the U.S. population	This CDS presents a specific version of Question #3 to each patient based on the patient's sex and age. The versions vary in the "threshold" quantity of drinks mentioned in the question (e.g., "four" or more drinks", "three" or more drinks). The drink thresholds were informed by the NIAAA definition of low-risk alcohol use cited in the USAUDIT manual (i.e., no more than 4 drinks on any single day and no more than 14 drinks per week for men 65 and younger; and no more than 3 drinks on any single day and no more than 7 drinks per week for women and men over 65 years old) (Babor et al., 2017). Thus, in this CDS, the patient's sex and age determine whether "four" or "three" is populated in the base question: "How often do you have XX or more drinks on one occasion?" Published evidence also informed scoring thresholds (i.e., cutoffs) specified in this CDS. The WHO AUDIT manual suggests lowering the cutoff point (i.e., the score that indicates hazardous or harmful alcohol use) for women and men over age 65: "Since the effects of alcohol vary with average body weight and differences in metabolism, establishing the cutoff point for all women and men over age 65 one point lower…will increase sensitivity for these population groups. Selection of the cutoff point should be influenced by national and cultural standards and by clinician judgement…" (Babor et al., 2001). As such, this CDS requires a WHO AUDIT-C score of greater than or equal to "3" for women, men over age 65, and individuals whose sex at birth is recorded as Unknown in a health IT system for a patient to be presented with Question #4 through Question #10, while retaining a cutoff score of greater than or equal to "4" for men 65 and younger.
Verify completeness/ Add explanation	Presenting Question #9 and #10 based on the response to Question #1	The WHO AUDIT guide states, "If the patient answers in response to Question 1 that no drinking has occurred during the last year, the interviewer may skip to Questions 9-10, responses to which may indicate past problems with alcohol. Patients who score points on these questions may be considered at risk if they begin to drink again, and should be advised to avoid alcohol. It is recommended that this skip out instruction only be used with the interview or computer-assisted formats of the AUDIT" (Babor et al., 2001). The CDS specifications enable this sequence of questions to be displayed if the patient responds "Never" to Question #1.
Add explanation	Adjusting Question #2 responses to align with U.S. drink sizes	Question #2 reads, "How many standard drinks containing alcohol do you have on a typical day when drinking?". The WHO AUDIT manual states, "Questions 2 and 3 assume that a standard drink equivalent is 10 grams of alcohol. You may need to adjust the number of drinks in the response categories for these questions in order to fit the most common drink sizes and alcohol strength in your country" (Babor et al., 2001). Although the CDS Development Team and CDC sponsors of this project strongly considered adjusting Question #2 responses to align with U.S. standard drink sizes, the group decided against this approach since they could not identify research evidence that validated the adjustments based on U.S. standard drink sizes.

Decision Category	Concept	Rationale
Add explanation	Adjusting the quantity of drinks in Question #3	As cited above, the WHO AUDIT states, “Questions 2 and 3 assume that a standard drink equivalent is 10 grams of alcohol. You may need to adjust the number of drinks in the response categories for these questions in order to fit the most common drink sizes and alcohol strength in your country” (Babor et al., 2001). The CDS Development Team and CDC sponsors of this project opted to make these adjustments in the CDS code since the approach has been validated in research studies (Babor et al., 2017).
Verify completeness/ Add explanation	Considering how to approach screening for individuals whose sex at birth is recorded as “unknown” in their medical record	The specifications in this CDS provide different versions of Question #3 based on the patient’s sex and age (e.g.., If the patient is female, their sex is unknown, or they are male over 65 years old, the question is phrased, “How often do you have 4 or more drinks on one occasion?” (Babor et al., 2017). If the patient is a male, 65 years old or younger, the question is phrased, “How often do you have 5 or more drinks on one occasion?”). The CDS Development Team and CDC sponsors of this project opted to develop logic that reasoned over an “unknown” sex at birth response to ensure these individuals also received alcohol screening. The logic places individuals with “unknown” sex at birth in the same “drink threshold” as females and males over 65 years old, thus establishing a lower threshold for 1) the number of drinks in Question #3 and 2) scoring to determine if the full WHO AUDIT should be administered. As a result, the patient’s risk threshold may be slightly overestimated (which was preferred to potentially underestimating it). 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 male patient’s age when populating Question #3 and interpreting WHO AUDIT-C scores	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 women 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). Furthermore, as mentioned in the USAUDIT, modifying the wording of Question 3 “improves precision in measuring the frequency and quantity of drinking and enables health pactitioners to intervene according to the NIAAA low-risk drinking limits for men and women” (Babor et al., 2017). The USAUDIT contines, “NIAAA defines low-risk alcohol use for men up to age 65 as no more than 4 drinks on a single day and no more than 14 drinks per week. For women and men ages 65 and older, low-risk alcohol use is no more than 3 drinks on any single day and no more than 7 drinks per week. Research show that few people who drink within these limits have alcohol-related health conditions” (Babor et al., 2017). 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 when populating Question #3 and interpreting their WHO AUDIT-C score.

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	Presenting Questions #9 and #10 based on responses to Question #2 and Question #3	Per the WHO AUDIT, "A second opportunity to shorten AUDIT screening occurs after Question 3 has been answered. If the patient scored 0 on Questions 2 and 3, the interviewer may skip to Questions 9-10 because the patient's drinking has not exceeded the low risk drinking limits" (Babor et al., 2001). The CDS specifications in this artifact default to delivering the full WHO AUDIT when a patient tests "positive" on the WHO AUDIT-C regardless of the patient's score on Questions #2 and #3 (i.e., when a woman, individual whose sex at birth is unknown, or a man older than 65 scores >=3 OR a man 65 and younger scores >=4). The CDS Development Team made this decision to enable the most robust evidence-based screening possible. Only if the patient scores below a score of 3 or 4 AND they score 0 on Questions #2 and #3, are they presented with Questions #9 and #10.
Add explanation	Including a "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). As a result, it is imperative for the CDS logic to identify these women so an appropriate intervention can be recommended to the clinician. Because "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. A woman will not be asked this question if there is evidence of an active pregnancy in her record, if she has had a hysterectomy (making her unable to bear children), or if she is beyond reproductive age as defined in this CDS (i.e., 50 years of age or older). The rationale for defining this threshold for reproductive age is outlined in the "specifying the upper threshold for reproductive age" entry at the end of this decision log. The patient's response to this question is stored for use by the companion *Alcohol Brief Intervention and Referral* CDS artifact, to ensure that a pregnancy-specific intervention is displayed, if indicated.
Add explanation	Determining where to place the "pregnancy question" in the CDS logic flow	The CDS Development Team and the CDC sponsors of this project elected to evaluate pregnancy status after the alcohol screening questions have been answered (i.e., ask the "pregnancy question" to women of reproductive age who have not had a hysterectomy and have no evidence of an active pregnancy in their medical record). This decision was made to avoid potentially influencing alcohol screening responses. Similarly, in ACOG's Risky Alcohol Use Guide, it is only after completion of screening that a clinician considers the patient's pregnancy status, to interpret their screening score (American College of Obstetrics and Gynecologists, n.d.).

Decision Category	Concept	Rationale
Add explanation	Specifying the upper threshold for childbearing age	To be as patient-centered as possible, the CDS only displays the “pregnancy question” to women of reproductive age. Although the CDC mentions the upper threshold of reproductive age as 44 (Johnson, 2006), the CDS Development Team and CDC sponsors of this project elected to increase the upper limit to “less than 50 years old” because more women are postponing pregnancy until later in life. This age limit aligns with the upper reproductive age as defined by the National Survey of Family Growth. The benefit of delivering the question to women less than 50 years of age and identifying risky drinking far outweighes the inconvenience of delivering the question if a woman’s response was “No.”

Appendix B. AUDIT Screening Questions Implemented in this Artifact

As mentioned in section 3.1 of this document, question #3 of the WHO AUDIT was adjusted in this CDS representation of the questionnaire because the CDS was developed for use by clinicians who deliver care in the United States. This decision was informed by WHO guidance (i.e., "In the AUDIT, Questions 2 and 3 assume that a standard drink equivalent is 10 grams of alcohol. You may need to adjust the number of drinks in the response categories for these questions in order to fit the most common drink sizes and alcohol strength in your country") (Babor et al., 2001).

Table 7 lists each AUDIT question, its corresponding responses, and the score associated with each response as expressed in this CDS artifact.

Table 7: AUDIT Screening Questions Implemented in this Artifact

Question Number	Questions	Score of "0"	Score of "1"	Score of "2"	Score of "3"	Score of "4"
1	How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
2	How many standard drinks containing alcohol do you have on a typical day when drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
3	*There are two different versions of question #3:* If male < 65 years old: How often do you have five or more drinks on one occasion? If female, sex at birth is unknown, or male >= 65 years old: How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4	How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5	How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily

Question Number	Questions	Score of "0"	Score of "1"	Score of "2"	Score of "3"	Score of "4"
6	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7	How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
8	How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9	Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year
10	Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year

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., AUD, 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 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 toward the top of the CQL code 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
Age	Step 1 (Inclusions)	Patient	Patient.birthDate (see https://hl7.org/fhir/R4/patient.html)
Sex at Birth	Steps 3-5	Patient	Patient.extension ("http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex") (see https://hl7.org/fhir/R4/patient.html)
Alcohol Screening Results	Step 1 (Exclusions)	Observation* and QuestionnaireResponse**	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)

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
Pregnant	Steps 1 & 6	Condition	Condition.onset Condition.recordedDate Condition.clinicalStatus = active or recurrence Condition.verificationStatus = confirmed (see https://hl7.org/fhir/R4/condition.html)
Pregnant Observation	Steps 1 & 6	Observation	Observation.effective Observation.issued Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html)
AUD	Steps 1	Condition	Condition.clinicalStatus = inactive, remission, or resolved (in Step 4) Condition.clinicalStatus = active, recurrence, or relapse (in Step 1) (see https://hl7.org/fhir/R4/condition.html)
Alcohol PS Question Response	Steps 1-5	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)
Individual WHO AUDIT Question Responses	Steps 2-5	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)

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
WHO AUDIT-C Total Score and WHO AUDIT Total Score	Steps 1-5	Observation* and QuestionnaireResponse**	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)
Hysterectomy	Step 6	Procedure	Procedure.status = completed (see https://hl7.org/fhir/R4/procedure.html)
Pregnancy Question Response	Step 6	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)

**Expressing alcohol screening results, a WHO AUDIT-C total score, and a WHO AUDIT total score as a FHIR Observation enables the CDS to evaluate historical data stored in a health IT system (i.e., screening results and scores that were recorded and saved prior to implementation of this artifact). See section 4.2, Guideline Translation Summary, item #3, (i.e., "Defining historical screening results…") for the list of alcohol screening results considered in the CDS logic.*

***Expressing alcohol screening results, a WHO AUDIT-C total score, and a WHO AUDIT total score as a FHIR QuestionnaireResponse enables the CDS to evaluate more recently captured data in a health IT system (i.e., alcohol screening results and scores that were recorded as a result of implementing this artifact).*

Categorizing specific data elements in more than one way (e.g., as an Observation and a QuestionnaireResponse) allows for a thorough evaluation of patient data, which in turn enables the most accurate delivery of evidence based ASBI.

Acronyms

Acronym	Definition
ACOG	American College of Obstetricians and Gynecologists
API	Application Programming Interface
ASBI	Alcohol Screening and Brief Intervention
ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
AUD	Alcohol Use Disorder
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	AUDIT-Consumption
CAGE	Cut Down, Annoyed, Guilty, Eye-opener
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 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
T-ACE	Tolerance, Annoyed, Cut-down, Eye-Opener
TDD	Test Driven Development
TWEAK	Tolerance, Worried, Eye-Opener, Amnesia, Cut-Down
USAUDIT	AUDIT, adapted for use in the United States
USAUDIT-C	USAUDIT-Consumption
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

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