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Brief Intervention Clinical Decision Support Project Task Order No.
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Facilitating Shared Decision Making For People Who Drink Alcohol: A Patient Decision Aid: 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 *Decision Aid for Your Drinking* CDS artifact.

This artifact identifies those patients who 1) have been screened for alcohol use using either the U.S. or WHO version of the AUDIT screening questionnaire; 2) are not pregnant; and 3) based on their reported level of drinking and alcohol screening score, are determined to be drinking in excess of recommended guidelines. The resulting CDS actions provide patient-specific information to the patient and their healthcare provider to help them understand the patient’s level of drinking compared to alcohol consumption above recommended guidelines (i.e., for men 65 years and younger, 5 or more drinks per day or 15 or more drinks per week; for women and men over 65 years, 4 or more drinks per day or 8 or more drinks per week) (U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015). The CDS also offers information to support the patient’s consideration of reducing their alcohol consumption. The information provided includes targeted messaging and resources about the patient’s reported alcohol consumption based on the patient’s AUDIT screening results, and links to other educational references that include tools to help the patient manage their drinking. The CDS logic was informed by several evidence-based guidelines that are described in [Section 4.1](#). When further guidance was needed, the CDS Development Team used the additional references listed in the [Reference section](#) of this document.

The *Decision Aid for Your Drinking* artifact excludes women that are pregnant or trying to become pregnant, as no amount of drinking is safe for pregnant women (Centers for Disease Control and Prevention, 2014) (The American College of Obstetricians and Gynecologists, 2011). The importance of not drinking and the risks of drinking during pregnancy or when trying to become pregnant are stressed in the companion CDS artifact, *Alcohol Brief Intervention and Referral*, as part of the brief intervention care recommendations. Organizations that wish to ensure the appropriate brief interventions are provided to pregnant women should consider implementing that CDS artifact. More information can be found in the *Alcohol Brief Intervention and Referral* implementation guide.

The *Decision Aid for Your Drinking* CDS artifact is used as a tool to provide information and options for reducing alcohol consumption that patients can consider and discuss with their healthcare provider. The information that the CDS provides helps to increase a patient’s knowledge about their level of drinking and risk level. The artifact could be used as a patient-

facing tool, provided directly to the patient through health IT capabilities such as a patient portal or mobile app; or used by a clinician to share with the patient during brief intervention and counseling, to help promote a dialog between the patient and clinician on their current alcohol use and provide resources to help them consider quitting or cutting back.

[Section 2](#) of this implementation guide provides high-level information and additional references for healthcare organizations considering implementing this CDS artifact (and any of the associated ASBI CDS artifacts) to support alcohol screening and brief intervention. The information focuses on the adoption of ASBI by clinical staff, and the references listed in **Table 1** contain much more detailed guidance on the clinical aspects of ASBI implementation.

The remaining sections of this implementation guide contain details about this CDS artifact, including the logic expressions, guideline interpretation and decisions made, and technical implementation considerations.

Organizations that might consider implementing this CDS logic include primary healthcare practices, as well as other healthcare organizations interested in delivering personalized interventions based on a patient's alcohol use, either directly to the patient, or by a clinician when providing a brief intervention to the patient. The artifact may also be of interest to a healthcare innovator that seeks to provide personalized health and wellness information on alcohol consumption directly to individuals via a mobile app.

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

- **Clinicians, Quality Improvement Leaders and Health Administrators** at healthcare organizations and primary care practices who wish to implement, test, and execute CDS related to alcohol screening and brief intervention in their EHRs or other health IT systems
- **Healthcare-focused Organizations** interested in promoting patient-centered care through a decision aid to facilitate an individual's ability to understand their alcohol risk and make treatment decisions
- **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 four or more drinks for women and five or more drinks for men on one occasion) during a routine checkup in the last two years (McKnight-Eily et al., 2020). Among adults who reported binge-level consumption, 80 percent (or four of five persons) were not counseled to reduce their drinking at that checkup (McKnight-Eily et al., 2020).

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

Prenatal exposure to alcohol can lead to several adverse events and increases the risk of birth defects and developmental disabilities such as FASDs. Despite this fact, between 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 providing patient-specific information to a patient and their healthcare provider about the patient's alcohol consumption, based on previously reported results of 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. (2014) pointed out that when considering the implementation of alcohol screening, early evaluation and planning is necessary to determine:

- Which patients will be screened and how often
- Which alcohol screening instrument will be used
- How and where 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-Consumption [USAUDIT-C], or Single Alcohol Screening Question), clinicians should follow up with a more in-depth assessment with greater specificity (e.g., the AUDIT) (Curry et al., 2018). In their recommendation statement for screening and behavioral counseling to reduce unhealthy alcohol use, the USPSTF found that the WHO version of the AUDIT-C and AUDIT “appeared to be the best overall instruments for screening adults for the full spectrum of unhealthy alcohol use” (Curry et al., 2018). The Task Force also noted that although no studies on the USAUDIT or USAUDIT-C were published during their evidence search window, the use of the U.S. versions of the AUDIT-C and AUDIT, designed to use U.S. standard drink sizes and align with National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommendations, were likely to improve on the performance of the WHO versions of the AUDIT and AUDIT-C (O’Connor et al., 2018).

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

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

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

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

Implementers are encouraged to carefully evaluate the differences in each screening questionnaire, considering which one aligns best with their organizational needs and clinician preference. [Section 2.3](#), 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. (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.
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)	World Health Organization	This manual focuses on conducting brief interventions for patients with alcohol use disorders, or who may be at risk of developing them, and is designed to be used with the WHO manual “The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care.”
Fetal Alcohol Spectrum Disorders (FASD) Training and Resources (Centers for Disease Control and Prevention, n.d.)	CDC NCBDDD	Free, online training available for healthcare providers who care for women at risk for an alcohol-exposed pregnancy, and for those who work with individuals living with fetal alcohol spectrum disorders (FASDs).
Guidelines for the identification and management of substance use and substance use disorders in pregnancy (World Health Organization, 2014)	WHO	Guidelines for professionals to assist women who are pregnant and use alcohol or drugs or have a substance use disorder, to achieve healthy outcomes for themselves and their fetus.

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

3. Artifact Description and Use

3.1 Artifact Description

The *Decision Aid for Your Drinking* artifact identifies adults (i.e., individuals 18 years or older) who were screened for alcohol use using either the U.S. or WHO version of the AUDIT questionnaire within the past 12 months, and the results of the screening indicate that they are drinking above recommended drinking limits. It excludes those patients that are identified as being pregnant or trying to become pregnant, as any level of drinking is risky for these individuals (Centers for Disease Control and Prevention, 2014) (The American College of Obstetricians and Gynecologists, 2011). The importance of not drinking and the risks of drinking during pregnancy or when trying to become pregnant are stressed in the companion CDS artifact, *Alcohol Brief Intervention and Referral*, as part of the brief intervention care recommendations. Organizations that wish to ensure the appropriate brief interventions are provided to pregnant women should consider implementing that CDS artifact. More information can be found in the *Alcohol Brief Intervention and Referral* implementation guide.

For each patient identified as needing an intervention, the CDS logic considers the patient's alcohol screening results available in the health IT system or EHR. The CDS actions provide information based on the patient-specific alcohol consumption information, to display as a decision aid. The information displayed is formulated based on the patient's overall AUDIT alcohol screening score and the availability of individual recorded responses to the first three AUDIT screening questions, which measure alcohol consumption.

The CDS logic is dependent on the ability to reason over a patient's AUDIT score to determine the appropriate Zone, or risk level (see **Table 2**) (Babor et al., 2017; Babor & Higgins-Biddle, 2001). The inclusion criteria verify that the patient's calculated Zone (based on their AUDIT score) falls within Zone II, Zone III, or Zone IV, indicating that the patient is drinking more than recommended guidelines. Thus, the capability to record and store the results of an alcohol screening within the EHR or health IT system using either the U.S. or WHO version of the AUDIT questionnaire must be implemented prior to implementing this CDS artifact. Although the *Decision Aid for Your Drinking* artifact was designed to accommodate a variety of implementations of an AUDIT screening questionnaire (as long as a final AUDIT screening score is captured and recorded), the CDS Development Team also created two alcohol screening CDS artifacts and one substance use screening CDS artifact using either the U.S. or WHO version of the AUDIT as part of this project, available on the [CDS Connect repository](#) for implementation. (See [Section 1.1](#) for the names and links to the implementation guides for these artifacts.)

Table 2: Zone Levels and Descriptions

Zone Levels	USAUDIT Score: Female Or Male > 65	USAUDIT Score: Male <= 65	WHO AUDIT Score: Female Or Male > 65	WHO AUDIT Score: Male <= 65	Description
I	0 – 6	0 – 7	0 – 6	0 – 7	Low-risk drinking
II	7 – 15	8 – 15	7 – 15	8 – 15	Drinking in excess of guidelines
III	16 – 24	16 – 24	16 – 19	16 – 19	Harmful or hazardous drinking
IV	25+	25+	20+	20+	High-risk drinking

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

3.1.1 Use of a Patient Decision Aid to Support Shared Decision Making for Excessive Drinking

As stated previously, this CDS artifact is designed to be used as a patient decision aid to provide guidance to patients to help them: 1) understand their level of drinking compared to alcohol consumption above recommended guidelines based on their individual alcohol screening results; 2) consider reducing their alcohol consumption; and 3) provide access to information and tools if they are ready to make a change. The Cochrane Collaboration defines a decision aid as an evidence-based tool designed to help patients participate in making specific, deliberate choices among healthcare options. Patient decision aids supplement clinician’s counseling about their patient’s health condition and the options for treatment (National Quality Forum, 2016).

This CDS artifact is designed to be implemented as either a patient-facing tool, provided directly to the patient, or a clinician-facing tool that can be shared with the patient during brief intervention and counseling. Most CDS is designed to be integrated into clinical workflow, with the clinician as the primary target and user. As the use of CDS evolves, clinicians no longer need to be the sole target of CDS information and alerts. Patients and their caregivers are increasingly seeking health information to help guide them in their healthcare decisions and better manage their health. Patient-centered, evidence-based CDS that is patient-facing 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).

Patient decision aids that provide up-to-date information on treatment options and facilitate patient-clinician communication help support shared decision making, increase patient-centered care, and can improve patient outcomes (National Quality Forum, 2016). Patient-centered CDS informs and facilitates patient-centered care for *specific* patients and their caregivers/care teams. As a component of patient-centered care, shared decision making allows an individual and their healthcare provider together to determine the most appropriate treatment or care choices (SAMHSA-HRSA Center for Integrated Health Solutions, n.d.). Patient-centered care and shared decision making are two essential components for providing high quality substance use disorder treatment and promoting a dialog between patients and clinicians. (Bradley & Kivlahan, 2014).

Decision aids that include CDS logic based on patient-specific health information help support evidence-based care decisions, and can be used before, during, or after a clinical encounter to enable patients to become active, informed care participants (Stacey et al., 2017).

3.1.2 Implementation Considerations

Prior to implementing this artifact, it is important to consider any modifications desired to the information displayed within the decision aid, and how to best integrate this decision aid into existing clinical workflow and the implementer's health IT system. For example, the notification included in this artifact could be delivered directly to the patient, allowing the patient to view the decision aid information independently. Or, the implementer may choose to have the notification delivered to the clinician, with the intention that the clinician might share the decision aid information with the patient during a brief intervention about the patient's drinking.

There is also a distinction between the information and text that the CQL logic generates as a CDS action, and how the content will be implemented and displayed within the health IT system, which may require additional user interface design and technical effort. Implementing organizations may also wish to expand upon and personalize the information provided by the decision aid, based on their unique needs and patient population. Individual implementers should consider these potential modifications and any additional efforts needed to integrate and display the decision aid according to their unique situation and requirements.

3.2 Health Scenarios Supported by this Artifact

The *Decision Aid for Your Drinking* artifact was developed and published to identify patients who have been screened for alcohol use using either the U.S. or WHO version of the AUDIT screening questionnaire, and are determined to be drinking in excess of recommended guidelines. The resulting CDS actions provide patient-specific information to the patient and their healthcare provider to help them understand the patient's level of drinking compared to alcohol consumption above recommended guidelines, and offer information to support the patient's consideration of reducing their alcohol consumption. This CDS artifact excludes women who are pregnant or trying to become pregnant, as no amount of drinking is safe for pregnant women (Centers for Disease Control and Prevention, 2014) (The American College of Obstetricians and Gynecologists, 2011). Organizations that wish to ensure appropriate brief interventions are provided to pregnant women should consider implementing the *Alcohol Brief Intervention and Referral* CDS artifact, which stresses the risks of drinking during pregnancy or when trying to become pregnant and the importance of abstinence from alcohol at any time during pregnancy.

The guidance for the development of this CDS artifact is derived from several evidence-based references described in [Section 4.1](#). This artifact supports the following scenarios when implemented in a health IT system in a healthcare setting. Note, each scenario is populated with a fictitious name and health data to provide context to the scenario.

1. Providing patient-specific evidence-based information directly to patients identified as drinking in excess of recommended guidelines

Sam is 35 years old, travels every week for business, and relaxes on the weekends with his friends at a local bar that offers his favorite craft beer and artisan tequila. In preparation for his annual wellness exam visit to his primary care physician, Sam was sent an email from his physician asking him to complete a few pre-visit assessments provided through the practice's patient portal, including the USAUDIT screening questionnaire. After completing the USAUDIT, Sam received a notification through the patient portal asking him if he would like to review the results of his alcohol screening, and providing him with a link to do so. Sam was curious, so he clicked on the link. He was surprised to see that his alcohol screening results indicated excessive alcohol consumption, with the score falling within Zone II (indicating that he was drinking in excess of guidelines). He reviewed the information on how many drinks he was consuming every week and realized he might need to cut back on his drinking. The information included a link to a website called [Rethinking DrinkingSM](#). Sam reviewed the information on the website and realized that his social drinking was becoming a problem, and that he needed to make a change. He committed to using some of the tools provided to help him cut back. Sam was glad he had this information before his physician visit, as he felt more prepared to discuss his alcohol use and his plans to cut back with his physician.

2. Enhancing shared decision-making between the clinician and his/her patients during alcohol brief intervention and counseling

Commonwealth Physicians Group (CPG) is a medium-size practice in Virginia with six primary care clinicians and approximately 10,000 patients. CPG recently implemented patient-facing alcohol use screening using the *USAUDIT Alcohol Screening* CDS artifact via a hand-held tablet provided to patients during check in at the office. The screening results are integrated with the group's electronic health record (EHR). CPG also implemented the *Alcohol Brief Intervention and Referral* and *Decision Aid for Your Drinking* CDS artifacts to assist their clinicians in providing evidence-based brief counseling interventions to their patients based on each patient's screening responses. After using the CDS for a few weeks, the CPG clinicians reported high satisfaction. They liked the fact that they can share the patient-specific screening information provided by the *Decision Aid for Your Drinking* artifact with the patient during the brief intervention. The information provided by this CDS artifact helped to support shared decision-making between the clinician and the patient, allowing them to collaborate together on the patient's next steps. The clinicians can also forward any relevant patient education links provided by the artifact directly to the patient through the patient portal, allowing the patient to review the education materials in more detail. The information provided by the *Decision Aid for Your Drinking* artifact supports and reinforces the brief intervention provided by the clinician during the office visit.

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 provides patient-specific information to the patient and/or their healthcare provider based on the patient's alcohol screening results. This helps the patient understand their level of drinking compared to alcohol consumption above recommended guidelines and provides information to support the patient's consideration of reducing their alcohol consumption, such as targeted patient education materials and tools based on the patient's screening results. Portions of the coded CDS expression can be reused to support additional scenarios that help improve efficiencies and 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. **Enabling wellness and preventive care through identification of excessive alcohol consumption and provision of self-management tools and resources**

Procure Health provides wellness services to its customers, who consist primarily of employers and health plans. The customers contract with Procure Health to provide a holistic package of wellness and preventive care services to each customer's employees or members. The services are provided in a health app that includes individual-specific reminders of preventive health services due, tools for different types of health screening relevant to the preventive health measures, and patient education resources based on the individual's risk factors. Recently, several of Procure Health's customers raised concern over the impact of excessive alcohol consumption on the health of individuals under their care, and asked Procure Health if they could implement something in the health app to address this concern. Procure Health implemented the *USAUDIT Alcohol Screening* CDS artifact as a patient-facing alcohol screening questionnaire, and the *Decision Aid for Your Drinking* CDS artifact to provide patient-specific information to individuals whose alcohol screening results indicate they are drinking in excess of recommended guidelines. Procure Health modified the logic in the CDS artifact by adding the ability for the patient to communicate their alcohol screening results directly to their primary care clinician, and to schedule an appointment with their clinician to discuss the results. As a result of implementing this CDS, Procure Health provides statistical de-identified reports to their customers to reflect the effect of the CDS on preventive health actions taken by each customer's members/employees (e.g., number of individuals screened; number of appointment requests sent; alcohol screening score trends over time). Procure Health has received positive feedback from their customers about the artifacts as well as the reports.

2. Modifying the CDS logic to include targeted information for pregnant women

Summer Women’s Health (SWH) is an obstetrics and gynecology (OB-GYN) practice in Tennessee. The SWH clinicians are concerned that their patient population may be at risk for alcohol-related harms, and are particularly worried that their pregnant patients (and those who are trying to become pregnant) may not understand the risks of drinking alcohol at any time during pregnancy (World Health Organization, 2014) (Centers for Disease Control and Prevention, 2014). They determined that implementing an electronic method of screening all of their patients for alcohol use and providing the appropriate brief interventions and patient education is critical for *all* patients, but want to ensure that patients who are pregnant or trying to become pregnant are receiving additional reinforcement on the dangers of drinking alcohol during pregnancy. SWH implemented ASBI using the *USAUDIT Alcohol Screening, Alcohol Brief Intervention and Referral*, and *Decision Aid for Your Drinking* CDS artifacts. They decided to present the information provided by the *Decision Aid for Your Drinking* CDS artifact directly to patients through their patient portal. To ensure that pregnant patients or those trying to become pregnant were presented an appropriate decision aid, the SWH clinicians asked their IT department and clinical informaticists to work with them to modify the CDS logic in the *Decision Aid for Your Drinking* artifact to include targeted information for pregnant patients. Once the modified CDS was in place, the SWH clinicians felt confident that not only are each of their patients routinely screened for alcohol use and provided a brief intervention, additional reinforcement is also provided directly to all patients through the decision aid, including targeted information presented to pregnant women on the importance of abstinence from alcohol throughout their pregnancy.

3.4 CDS Logic Descriptions and Recommended Actions

The human-readable CDS logic that generates the patient-specific alcohol screening information to populate the patient decision aid is listed in detail in the [Artifact Semistructured Representation](#) section of Appendix A. The logic is divided into “steps” to make the objective of specific portions of logic criteria and the resulting CDS actions more understandable.

At a very high level, the following information provides insight into the CDS logic and actions supported by this artifact.

Step 1: Consider availability of AUDIT screening results

This step determines which patients have screening results that meet the inclusion criteria. It excludes female patients that are pregnant, along with all other patients whose screening score falls within Zone 1, low-risk drinking.

- **Logic Description:** Ensures that the patient is 18 years or older, has evidence of an AUDIT screening score recorded within the past 12 months, is NOT pregnant, and their AUDIT score is 1) greater than “7” if the patient is a woman, a man over 65 years of age or their sex at birth is recorded as Unknown in the health IT system, or 2) greater than “8” if the patient is a man 65 years or younger (i.e., the screening score indicates Zone II, III or IV). (Note: this logic is included in all subsequent logic “steps” but is not repeated in the descriptions below.)
- **CDS Actions:** Continue to Step 2

Step 2: Consider whether to display Decision Aid version “A”

There are two different versions of the Decision Aid. Version “A” is dependent on the presence of recorded patient responses to AUDIT questions #1 through #3.

- **Logic Description:** Ensures that there is evidence of patient responses to AUDIT questions #1 through #3 and adjusts the information displayed in the decision aid accordingly.
- **CDS Actions:**
 - Notify clinician and/or patient that new decision aid information is available
 - Display and populate Decision Aid “A” (see [Appendix A2, Artifact Semistructured Representation](#), for a list of information that is displayed in this version of the decision aid).

Step 3: Consider whether to display Decision Aid version “B”

As mentioned previously, there are two different versions of the Decision Aid. Version “B” is dependent on the presence of a total AUDIT score and the absence of recorded patient responses to AUDIT questions #1 through #3.

- **Logic Description:** Ensures that a total AUDIT score is available and responses to AUDIT questions #1 through #3 are not recorded. The CDS adjusts the information displayed on the decision aid accordingly.
- **CDS Actions:**
 - Notify clinician and/or patient that new decision aid information is available
 - Display and populate Decision Aid “B” (see [Appendix A2, Artifact Semistructured Representation](#), for a list of information that is displayed in this version of the decision aid)

4. Guideline Interpretation and Clinical Decisions

4.1 Evidence-based Sources for Artifact Development

This artifact is not derived from a single clinical guideline. It draws upon multiple evidence-based references that provide guidance on developing patient decision aids to 1) provide information to patients to help them understand their level of drinking compared to recommended guidelines, and 2) aid the patient in considering a reduction of their alcohol consumption. The primary guidance comes from the following resources:

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

- Babor, T. F., Higgins-Biddle, J. C., & Robaina, K. (2017). The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners. Retrieved from https://www.dshs.wa.gov/sites/default/files/BHSIA/dbh/wasbirt/USAUDIT-Guide_2016.pdf
- Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., & Monteiro, M. G. (2001). The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care. Retrieved from https://www.who.int/substance_abuse/publications/audit/en/
- Bradley, K. A., & Kivlahan, D. R. (2014). Bringing patient-centered care to patients with alcohol use disorders. *JAMA - Journal of the American Medical Association*, 311(18), 1861–1862. <https://doi.org/10.1001/jama.2014.3629>
- 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*.
- National Institute on Alcohol Abuse and Alcoholism. (n.d.). Rethinking Drinking Homepage - NIAAA. Retrieved March 3, 2020, from <https://www.rethinkingdrinking.niaaa.nih.gov/>

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 to be suitable 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. Ensuring that patients are presented with an intervention if they are drinking in excess of low-risk guidelines

- a. Administering an AUDIT questionnaire results in a numeric score, which is used by this artifact logic to place the patient into one of four “Zones”, or risk levels, based on the level of risk identified. Each Zone calls for a different level of intervention. Zone I indicates low-risk drinking, and Zone I patients are excluded from receiving an intervention (i.e., a decision aid) because their level of drinking is within recommended guidelines. Patients receiving an intervention (i.e., a decision aid) have AUDIT scores that place them in either Zone II, indicating drinking in excess of guidelines; Zone III, indicating harmful or hazardous drinking; or Zone IV, indicating high-risk drinking and probable alcohol use disorder. See [Section 3.4](#), CDS Logic Descriptions and Recommended Actions, for additional information, and **Table 2** for the description and score thresholds of each Zone.

2. **Ensuring that pregnant women receive the appropriate brief intervention to reinforce the importance of abstinence from alcohol during pregnancy.**
 - a. The CDS logic outlined in Step 1 excludes women that are pregnant or trying to become pregnant. Per CDC and American College of Obstetricians and Gynecologists (ACOG) guidance, women who are pregnant should abstain from drinking any alcohol (Centers for Disease Control and Prevention, 2014) (The American College of Obstetricians and Gynecologists, 2011). The CDS Development Team and CDC sponsors of this project elected to exclude pregnant women from receiving this intervention, as pregnant women who are drinking any amount of alcohol should receive a brief behavioral counseling intervention from their primary care provider, and if they are not drinking, receive a brief intervention reinforcing the importance of abstinence.
 - b. As mentioned previously, the importance of not drinking and the risks of drinking during pregnancy or when trying to become pregnant are stressed in the companion CDS artifact, *Alcohol Brief Intervention and Referral* CDS, as part of the brief intervention care recommendations. Organizations that wish to ensure the appropriate brief interventions are provided to pregnant women should consider implementing that CDS artifact. More information can be found in the *Alcohol Brief Intervention and Referral* implementation guide.
3. **Ensuring that individuals whose sex at birth is recorded as “unknown” in an EHR receive the appropriate brief intervention recommendations**
 - 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 (ONC) (The Office of the National Coordinator for Health Information Technology, n.d.). During the development of the alcohol screening artifacts, the CDS Development Team and CDC sponsors of this project opted to develop logic that reasoned over Unknown as a “sex assigned at birth” response to ensure that these individuals also received alcohol screening. The logic places individuals with Unknown recorded as their sex at birth in the same threshold category as females and males over 65 years old. For this CDS artifact, patients whose sex at birth is recorded as Unknown are included in the logic for female patients when considering whether a patient is pregnant. In addition, they are included in the same AUDIT scoring criteria and associated Zone as females and males over 65 years old. As a result, the patient’s risk threshold and resulting recommendations for brief intervention may be slightly overestimated (which was preferred to potentially underestimating risk).

5. Technical Details

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

5.1 Artifact Definition Standards

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

5.1.1 Fast Healthcare Interoperability Resources®

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

FHIR provides a [Questionnaire resource](#) that allows interrelated questions and responses to be defined in a standard format (Health Level 7 (HL7), n.d.-l). Each Questionnaire instance is defined by a set of both [required and optional data elements](#), which are by design general in nature, in order to support the capabilities most likely to be found in the majority of healthcare systems (Health Level 7 (HL7), n.d.-k). This flexibility is one of the reasons why FHIR has been growing in popularity; the use of FHIR is expected to continue to grow due to it being the basis for the application programming interface (API) required by the 21st Century Cures Act Interoperability Final Rule (Office of the National Coordinator (ONC), 2020). For these reasons, FHIR has been selected for use in the ASBI CDS definition. The questions and available responses of the alcohol screening instrument are represented using a FHIR Questionnaire resource. The responses a patient makes are recorded using a FHIR [QuestionnaireResponse](#) resource; it is this QuestionnaireResponse resource which serves as the main input to this CDS.

5.1.2 Clinical Reasoning Module

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

5.1.3 Structured Data Capture

[Structured Data Capture](#) (SDC) (Health Level 7 (HL7), n.d.-o) is another FHIR IG that has been leveraged to help define the ASBI CDS. SDC provides guidance on how questionnaires, surveys, and forms should be represented in an open and interoperable way. Specifically, it builds upon

the base FHIR Questionnaire resource so that more complex use cases can be supported. Features described in SDC and used in the alcohol screening Questionnaire include [advanced form rendering](#) (Health Level 7 (HL7), n.d.-b) and [advanced form behavior logic](#) (Health Level 7 (HL7), n.d.-a). While a simplified version of the alcohol screening instrument could be described using only a base FHIR Questionnaire resource, SDC is required for expressing the complete instrument.

5.1.4 Clinical Quality Language

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

The ASBI CDS requires logic that can be expressed naturally and efficiently using CQL. Computer code written in CQL is human readable but can be translated or “compiled” into a more structured format that is interpretable by computers. This computer-friendly format is called the Expression Logical Model (ELM) and it is this format of the logic that is interpreted when the CDS logic is executed against patient data. Both formats have been produced as part of the ASBI CDS development.

5.2 Artifact Definition Structure

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



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

Figure 1 shows the Library component “inside” the PlanDefinition component; this depiction is meant to reflect the fact that the PlanDefinition serves as a wrapper and “contains” the other

component. As discussed in the following sections, each component serves a specific purpose and is equally important; the ASBI CDS could not be fully expressed without both components.

5.2.1 PlanDefinition

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

The PlanDefinition shown in **Figure 2** contains metadata regarding the ASBI CDS. Of most interest are the lines starting with * library and * action. The former is simply a reference to the CQL Library component. The latter is a more complicated structure that describes how the CDS should be triggered (i.e., when a new QuestionnaireResponse has been recorded), under what conditions it is applicable (determined by the DisplayNotification expression from the CQL Library), and what action should be taken (i.e., evaluate two expressions from the CQL library). The trigger type comes from the [set of values allowed](#) by the FHIR specification. The action and conditions are described in detail by the Library component.

```

Instance:   AlcoholDecisionAid
InstanceOf: PlanDefinition
Title:      "Alcohol Decision Aid"
* url = "http://www.cdc.gov/ncbddd/fasd/decisionaid-plandefinition"
* version = "1.0.0"
* name = "decisionaid-plandefinition"
* title = "Decision Aid 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 = "Decision aids based on alcohol screening responses."
* date = "2020-05-04"
* library = "Library/DecisionAidLogicLibrary|1.0"
* action[0].trigger[0].type = http://hl7.org/fhir/trigger-type#data-added "Data Added"
* action[0].trigger[0].data[0].type = http://hl7.org/fhir/resource-types#QuestionnaireResponse "QuestionnaireResponse"
* action[0].trigger[0].data[0].codeFilter[0].path = "QuestionnaireResponse.questionnaire"
* action[0].condition[0].kind = http://hl7.org/fhir/action-condition-kind#applicability "Applicability"
* action[0].condition[0].expression.language = http://hl7.org/fhir/expression-language|4.0.1#text/cql "CQL"
* action[0].condition[0].expression.expression = "DisplayNotification"
* action[0].condition[0].expression.reference = "Library/DecisionAidLogicLibrary|1.0"
* action[0].dynamicValue[0].expression.language = http://hl7.org/fhir/expression-language|4.0.1#text/cql "CQL"
* action[0].dynamicValue[0].expression.expression = "NotificationText"
* action[0].dynamicValue[0].expression.reference = "Library/DecisionAidLogicLibrary|1.0"
* action[0].dynamicValue[1].expression.language = http://hl7.org/fhir/expression-language|4.0.1#text/cql "CQL"
* action[0].dynamicValue[1].expression.expression = "DecisionAids"
* action[0].dynamicValue[1].expression.reference = "Library/DecisionAidLogicLibrary|1.0"

```

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

5.2.2 Library

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

An example CQL expression from the Library is shown in **Figure 3**. From the example we can see the expression Excluded being defined using a combination of patient data (e.g., FemaleAtBirth) and information from their responses to the alcohol screening Questionnaire (e.g., RecentScoreFullUsAudit). Excluded returns true if the patient meets the criteria for exclusion for being considered for a decision aid if any of the following are true:

1. The patient's sex at birth is either female or unknown and the patient does meet the CDS criteria for being considered pregnant
2. The patient has a recent alcohol screening score that is below the threshold for consideration of a decision aid
3. The patient does not have a recent alcohol screening score

```
define Excluded:
  if HasRecentScoreFullUsAudit then
    ((FemaleAtBirth or SexAtBirthUnknown) and DoesMeetPregnancyExclusionCriteria)
    or (convert RecentScoreFullUsAudit as String to Integer) < ExclusionThreshold
  else if HasRecentScoreAuditC then
    ((FemaleAtBirth or SexAtBirthUnknown) and DoesMeetPregnancyExclusionCriteria)
    or (convert RecentScoreAuditC as String to Integer) < ExclusionThreshold
  else if HasRecentScoreFullAudit then
    ((FemaleAtBirth or SexAtBirthUnknown) and DoesMeetPregnancyExclusionCriteria)
    or (convert RecentScoreFullAudit as String to Integer) < ExclusionThreshold
  else if HasRecentScoreAuditC then
    ((FemaleAtBirth or SexAtBirthUnknown) and DoesMeetPregnancyExclusionCriteria)
    or (convert RecentScoreAuditC as String to Integer) < ExclusionThreshold
  else true
```

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

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

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

Expression Name	Expression Value	Description
YourResponses	String (text)	Patient-specific text that describes the patient's most recent alcohol screening results.
YourDrinking	Tuple (structured)	Describes the patient's drinking behavior and compares them with low-risk peers.
YourZone	Tuple (structured)	Lists the patient's drinking zone.
LowRiskDrinkingLevels	String (text)	Lists the limits for being considered a low-risk drinker.
ForAdditionalInfo	String (text)	A link to NIAAA Rethinking Drinking website.
WhatCountsAsADrink	String (text)	HTML with embedded drink size graphic.
ZoneTable	Tuple (structured)	Defines the four zones of drinking to provide context for the patient.
DecisionAids	Tuple (structured)	Includes all of the above expressions in a single structure.

5.3 Artifact Implementation Standards

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

5.3.1 Sustainable Medical Applications, Reusable Technologies

The [Sustainable Medical Applications, Reusable Technologies](#) (SMART®) standard facilitates the integration of software applications, or “apps,” with health IT systems (Boston Children’s Hospital, n.d.). “SMART on FHIR apps,” or sometimes simply “SMART apps,” are software applications that securely interact with patient EHRs and other healthcare-related data via a FHIR API. SMART apps are interoperable in the sense that they can interface with any health IT system that supports the SMART standard and the data requirements of the app. Instead of writing a different software application to provide the same capability for each different health IT system, a single application can be written that works with many different health IT systems. The ASBI CDS concept of operation requires secure access to an EHR, to provide the capabilities described in the previous section; the SMART standard fulfills that need.

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

5.3.2 CDS Hooks

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

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

5.4 Artifact Implementation Structure

This section describes how the standards from Section 5.3 can be used to integrate the ASBI CDS into a health IT system. A notional depiction of this is shown in **Figure 4**.

The figure shows a patient and/or clinician interacting with a hypothetical health IT system via a human interface (a computing device of some sort). The human interface provides access to the EHR through a proprietary computer called a server, which in this case is proprietary because it is not using open standards for communication of patient health information. In the notional scenario depicted in **Figure 4**, interoperability has been added to the health IT system through the inclusion of a FHIR Server, which allows patient health information in the EHR to be accessed as FHIR resources. Additionally, SMART and CDS Hooks interfaces are available so that SMART apps and CDS services can be integrated with less effort.

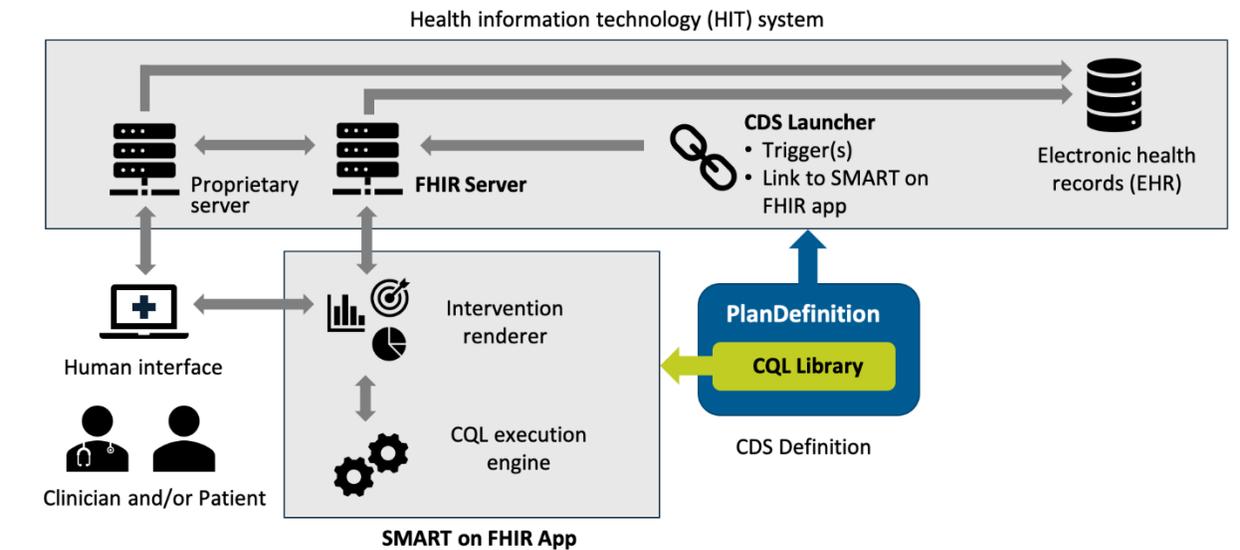


Figure 4. Notional depiction of ASBI CDS integration with a health IT system.

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

5.4.1 FHIR Server

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

Table 4. Required FHIR Server capabilities

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

5.4.2 CDS Launcher

The CDS Launcher is a CDS Hooks service that specifies the trigger necessary for launching the CDS. As described in Section 5.3.2, the ASBI CDS should be triggered when a new QuestionnaireResponse resource is created in the system. When this occurs, the CDS Launcher is consulted to determine whether the patient meets the inclusion and does not meet the exclusion criteria of the ASBI CDS. Determination of ASBI CDS applicability is made by executing CQL logical expressions against the patient record. If the results of the CQL expressions indicate the patient should receive an alcohol decision aid, 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 decision aid, no further actions are taken.

5.4.3 SMART on FHIR App

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

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

6. Artifact Testing

It is not sufficient to simply define and implement a CDS artifact. The definition and implementation must also be thoroughly tested to ensure the CDS behaves as the underlying evidence intends. Because of the complexity of the ASBI CDS a significant amount of testing

software has been developed and this section discusses the testing that has been applied to the ASBI CDS artifact.

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

6.1 Levels of Testing

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

6.1.1 Format Validation

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

6.1.1.1 FHIR

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

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

6.1.1.2 CQL

As described in Section 5.2.2, most of the complex behavior of the ASBI CDS is defined by logical expressions written in CQL. Also recall from Section 5.1.4 that the human readable version of CQL must be converted or translated to the machine friendly format (i.e., ELM)

before it can be used in an executable CDS. The [CQL-to-ELM Translator Reference Implementation](#) is an open source software package written in the Java programming language (Health Level 7, n.d.-a). It has been used to translate the ASBI CDS CQL, which as a by-product checks the CQL for conformance to the CQL specification. As with FHIR Format Validation, this process checks to make sure what has been written is, from a software standpoint, “grammatically correct.” It does not provide any insight into whether the CQL as written correctly implements the intended CDS logic. This is accomplished by the level of testing described in the next section.

6.1.2 Logic Testing

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

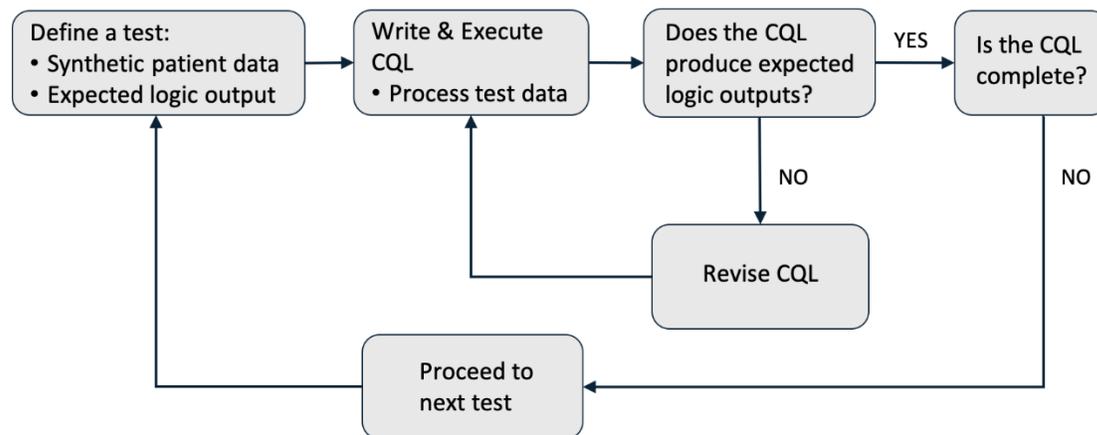


Figure 5. Diagram showing the test-driven development approach taken for authoring CQL

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

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

An example logic test case can be seen in **Figure 6**. The name of the test provides a general indication about the nature of what is being tested; in this case it indicates the input FHIR data is

meant to represent a patient who meets the criteria of a Zone II drinker. The responses to the WHO AUDIT can be seen within the QuestionnaireResponse resource under the data section. The results section lists the names of the CQL expressions being tested; next to each expression name is the value that the test asserts is the correct result. According to the test, the synthetic patient should be correctly classified by the CDS as a Zone II drinker.

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

```

name: Zone 2 AUDIT
externalData:
- resources
data:
-
  resourceType: Patient
  name: Jane Smith
  gender: female
  extension:
  - url: http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex
    valueCode: 'F'
  birthDate: 1978-07-16
-
  $import: *AuditQuestionnaire
-
  resourceType: QuestionnaireResponse
  questionnaire: 'http://www.cdc.gov/ncbddd/fasd/audit'
  status: 'completed'
  authored: 2020-01-20
  item:
  - linkId: 'prescreen-question'
    answer:
    - valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Yes
  - linkId: 'audit-question-one'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE 2-4 times a month
  - linkId: 'audit-question-two'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE 3 drinks
  - linkId: 'audit-question-three'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Monthly
  - linkId: 'auditc-score'
    answer:
    valueDecimal: 7
  - linkId: 'audit-question-four'
    answer:
    - valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-five'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-six'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-seven'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-eight'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-nine'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE Never
  - linkId: 'audit-question-ten'
    answer:
    valueCoding: http://www.cdc.gov/ncbddd/fasd#CODE No
  - linkId: 'audit-score'
    answer:
    valueDecimal: 7
results:
  IsIncluded: true
  HasRecentScoreUsAuditC: false
  HasRecentScoreFullUsAudit: false
  HasRecentScoreAuditC: true
  HasRecentScoreFullAudit: true
  HasRecentYesApsResponse: true
  RecentScoreAuditC: 7
  RecentScoreFullAudit: 7
  IsZoneTwoDrinker: true
  IsZoneThreeDrinker: false
  ZoneNumber: 2
  ZoneRomanNumeral: 'II'
  AuditVariant: 'AUDIT'
  DecisionAidType: 'A'
  DrinkThreshold: '4'
  QuestionOneResponse: '2-3 times a week'
  QuestionTwoResponse: '5 or 6'
  QuestionThreeResponse: 'Monthly'

```

Figure 6. Example logic test case

Table 5. List of logic tests

Number	Test Name
1	Zone 2 AUDIT (51ms)
2	Zone 3 AUDIT
3	Zone 4 AUDIT
4	Excluded
5	Has Recent Audit Score
6	Has Recent USAUDIT Score
7	Included Recent No APS Response
8	Complete NIDA QS and USAUDIT
9	Complete NIDA QS and USAUDIT (1)
10	Not Included No Recent Screening
11	Not Included Old No APS Response
12	Not Included Under Age
13	Pregnant and drinking (Zone 2, USAUDIT)
14	Pregnant and not drinking
15	Zone 2 USAUDIT
16	Zone 3 USAUDIT
17	Zone 4 USAUDIT

6.1.3 End-to-End Testing

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

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

6.2 End-to-End Test Harness

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

6.2.1 Test Harness Structure

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

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

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

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

Figure 7 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.

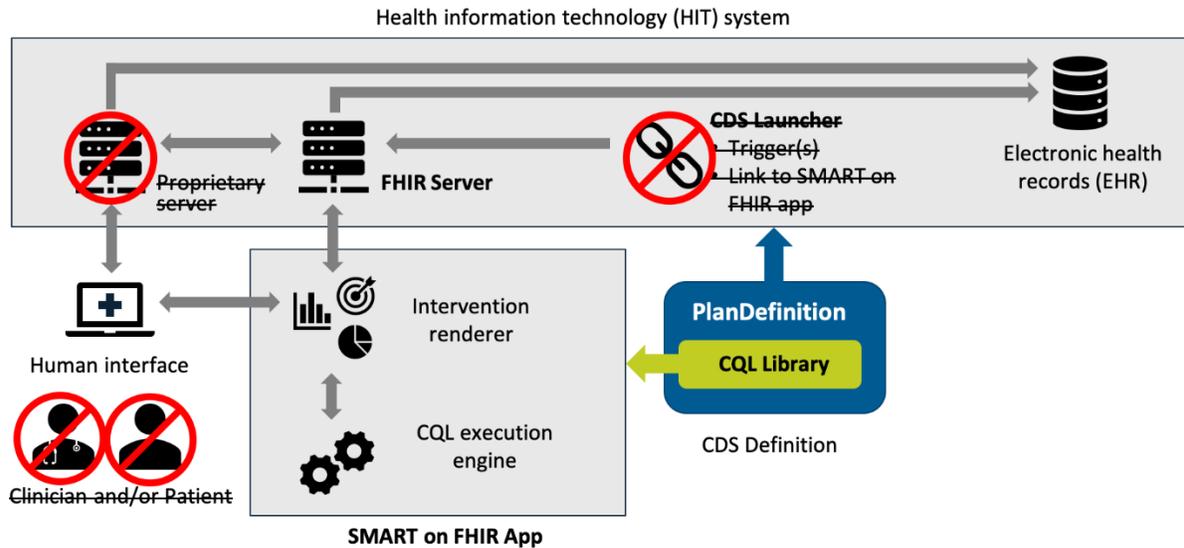


Figure 7. Notional ASBI CDS integration depicting which aspects can be emulated without a real health IT system

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

6.2.2 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 6.2.2.2.2 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 *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 *ASBI CDS Intervention App*

The *ASBI CDS Intervention App* is a SMART on FHIR application that presents the user with the patient-specific alcohol decision aid. After the app is authorized and launched, the required patient data is requested from the FHIR server. In the case of the end-to-end test harness, this is the ASBI CDS FHIR Server described in the next section. Once the FHIR resources are loaded, the CQL logical expressions are executed and Vue is used to render the decision aid content to the screen.

6.2.2.2.2 *ASBI CDS FHIR Server*

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

Appendix A. Artifact Logic and Decision Log

A.1 Artifact CDS Logic Flow

The *Decision Aid for Your Drinking* CDS artifact was informed by multiple evidence-based references that provide guidance on developing patient decision aids to help patients 1) understand their level of drinking compared to recommended guidelines, based on their individual alcohol screening results; 2) consider reducing their alcohol consumption; and 3) provide access to information and tools if they are ready to make a change. See [Section 4.1, Evidence-based Sources for Artifact Development](#), for additional information.

Translating knowledge in narrative evidence-based sources requires a considerable level of effort and interpretation. When translating complex guidelines, it is often helpful to develop a high-level depiction of the evidence that can serve as the foundation for more detailed representations of the knowledge as CDS development progresses. The CDS logic flow diagram in **Figure 8** displays the outcome of the first “phase” of translating knowledge from published guidance into a series of events and decisions that enable evidence-based brief interventions for alcohol use. It displays an overview of the CDS logic and provides potential implementers with an impression of the CDS logic flow.

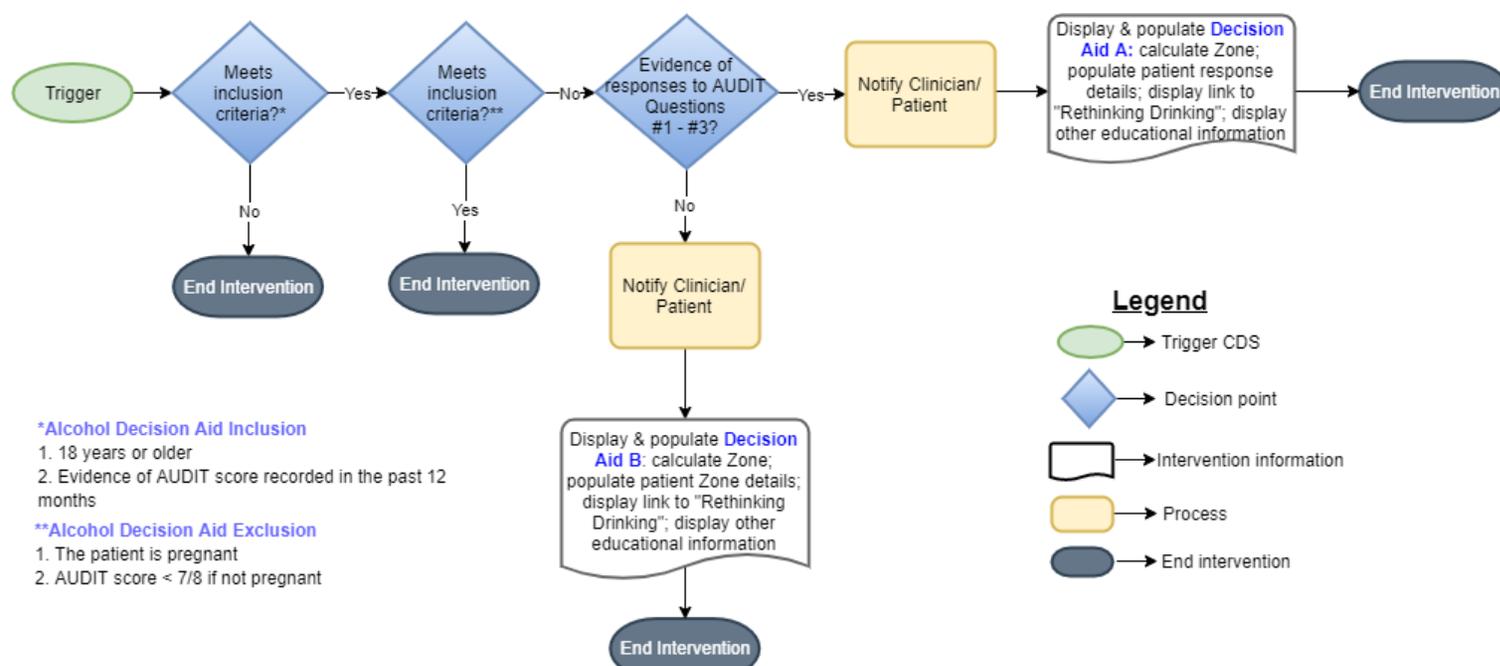


Figure 8: Decision Aid for Your Drinking CDS Logic Flow

A.2 Artifact Semistructured Representation

Next, the CDS Development Team utilized the CDS flow depicted in **Figure 8** along with granular details identified in the narrative references 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 intervention process. Implementing organizations can decide what triggering event best complements the workflow in their organization to initiate Step 1 (e.g., a new AUDIT screening score is recorded). Words listed in parenthesis within the logic are FHIR attributes that specify the “status” of clinical concepts such as

observations (e.g., Pregnancy) and diagnoses (e.g., Pregnant). The status of a clinical concept can be an important component of logic specifications in some instances. For example, the CDS is specified to only evaluate screening results with a status of “final,” “amended” and “corrected” as TRUE (i.e., valid for the purpose of this CDS). Therefore, screening results with a status of “preliminary,” “cancelled,” and “entered in error” will be evaluated as FALSE (i.e., invalid for the purpose of this CDS).

Step 1: Consider availability of AUDIT screening results, excluding those female patients that are pregnant, AND all other patients whose screening score falls within Zone 1 (AUDIT Score of <7/8)

Inclusion logic:

Patient is \geq 18 years old

AND

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

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

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

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

Exclusion logic:

Female OR Sex at birth Unknown

AND

Response to Pregnancy Question is “Yes”

OR Pregnant (active, recurring)

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

OR

Male $>$ 65 years old

OR Sex at birth Unknown

OR Female

AND most recent AUDIT score < 7

OR

Male <= 65 years old

AND most recent AUDIT score < 8

CDS Actions: Continue to Step 2

Step 2: Consider whether to display Decision Aid Version “A” (Version “A” is dependent on the presence of recorded patient responses to AUDIT questions #1 through #3)

Inclusions: As listed in Step 1 inclusion logic

AND evidence of responses to USAUDIT question #1 through question #3 in most recent USAUDIT Screening

OR

Evidence of responses to USAUDIT-C question #1 through question #3 in most recent USAUDIT-C Screening

OR evidence of responses to WHO AUDIT question #1 through question #3 in most recent WHO AUDIT Screening

OR evidence of responses to WHO AUDIT-C question #1 through question #3 in most recent WHO AUDIT-C Screening

Exclusions: As listed in Step 1 exclusion logic

CDS Actions:

Notify patient/clinician that new alcohol screening information is available

Display and Populate the Decision Aid “A” (*which may include the following*)

Calculate the patient’s Zone based on their AUDIT score

Display targeted patient messaging on their drinking level based on the Zone

Populate the patient's AUDIT score, Zone, Zone description AND individual responses to AUDIT question #1 through question #3

Display a graphic that illustrates the patient's drinking level versus low-risk drinking levels

Calculate the number of drinks per week or per month the patient consumes, based on AUDIT question #2 response multiplied by AUDIT question #1 response

Populate the patient's "drinks per week" with the result

Populate the patient's "drinks per day" with the response to AUDIT question #2

Display Zone levels graphic

Indicate patient's Zone within the Zone levels graphic

Display text “For additional information and tools to help cut down and quit, visit:” and display link <https://www.rethinkingdrinking.niaaa.nih.gov/>

Display additional educational information:

Information on when any drinking is excessive

Graphic illustrating drink sizes

Table showing each Zone, AUDIT score for that Zone, and Zone description

Step 3: Consider whether to display Decision Aid version “B” (Version B displays if no individual responses to AUDIT questions #1 through question #3 are recorded, only a total AUDIT score)

Inclusions: As listed in Step 1 inclusion logic

AND NOT

Evidence of responses to USAUDIT-C question #1 through question #3 in most recent USAUDIT-C Screening

OR evidence of responses to WHO AUDIT question #1 through question #3 in most recent WHO AUDIT Screening

OR evidence of responses to WHO AUDIT-C question #1 through question #3 in most recent WHO AUDIT-C Screening

evidence of responses to AUDIT question #1 through question #3 in most recent AUDIT Screening

Exclusions: As listed in Step 1 exclusion logic

CDS Actions:

Notify patient/clinician that new alcohol screening information is available

Display and populate the Decision Aid “B” (*which may include the following*)

Calculate the patient’s Zone based on their AUDIT score

Display targeted patient messaging on their drinking level based on the Zone

Display Zone levels graphic

Indicate the patient's Zone within the Zone levels graphic

Display a graphic showing each Zone (I - IV), the AUDIT score range for each Zone (based on USAUDIT or WHO AUDIT), and description of each Zone

Indicate patient's Zone on that graphic picture

Display text “For additional information and tools to help cut down and quit, visit:” and display link <https://www.rethinkingdrinking.niaaa.nih.gov/>

Display additional educational information:

Information on when any drinking is excessive

Graphic illustrating drink sizes

Table showing each Zone, AUDIT score for that Zone, and Zone description

A.3 CDS Concept Definitions

Table 6 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 6: CDS Concept Definitions

Location in CDS Logic	Concept	Definition and/or Rationale
Step 1, Step 2, Step 3	<p>“USAUDIT score”</p> <p>“USAUDIT-C score”</p> <p>“WHO AUDIT score”</p> <p>“WHO AUDIT-C score”</p>	<p>“AUDIT” refers to the Alcohol Use Disorders Identification Test alcohol screening questionnaire, and “score” is the calculation of the point value generated when responding to the AUDIT screening questions. There are two versions of the AUDIT, the USAUDIT and the WHO AUDIT. In the CDS logic, if it does not matter which version of the AUDIT is associated with the screening score, the general term “AUDIT score” is used. Sometimes, because the calculation of the scores differ between the U.S. and WHO AUDIT versions, the CDS specifies which version of the AUDIT is associated with a specific score in order to calculate the appropriate intervention.</p>
Step 1 Inclusions	“>=”	Greater than or equal to a given value (e.g., >= 18 years old)
Step 1 Inclusions	“evidence of ...”	<p>Any “final”, “amended”, or “corrected” alcohol screening results that are present in the patient record. Specifically, the CDS code looks for results associated with the following screening tools: 1) USAUDIT; 2) USAUDIT-C if no USAUDIT score; 3) WHO AUDIT; 4) WHO AUDIT-C if no WHO AUDIT score; 5) evidence of a response of “No” to an alcohol prescreen question (“Do you drink beer, wine or other alcoholic beverages”); or 6) evidence of responses to WHO AUDIT question #9 and #10 where the response to WHO AUDIT question #1 is “Never” and there is no evidence of responses to WHO AUDIT questions #2 through #8.</p> <p>The USAUDIT, USAUDIT-C, WHO AUDIT, and WHO AUDIT-C screening results were selected because the scores generated by each of them align with the evidence used to determine the appropriate intervention.</p>
Step 1 Inclusions	“in the past x months”	The CDS code looks for evidence of a specific event, condition, result (e.g., alcohol screening results) to have occurred within a specified period of time from the current date (e.g., within the past 12 months from today).

Location in CDS Logic	Concept	Definition and/or Rationale
Step 1 Exclusions	“sex at birth is Unknown”	The patient’s sex at birth is recorded in the health IT system as “Unknown”. Unknown is a valid response for an individual’s sex at birth by HL7 standards outlined in the Interoperability Standards Advisory published by the Office of the National Coordinator for Health Information Technology (ONC) (The Office of the National Coordinator for Health Information Technology, n.d.). There are two specific areas in the CDS that are sex-specific. The first is when considering whether a patient is pregnant, and the second is when considering the alcohol screening score and appropriate intervention. Thus, it is important to consider all valid responses for “sex at birth” otherwise an individual whose sex at birth is recorded as Unknown would not be presented with question #3.
Step 1 Exclusions	“pregnancy question”	The pregnancy question is, “Are you currently pregnant or trying to become pregnant?”. If one of the alcohol screening CDS artifacts mentioned in section 1.1 is implemented, this question is presented to every woman of reproductive age unless they meet the exclusion criteria defined in that CDS artifact. If the pregnancy question is not implemented, thus no response is available, the CDS looks for one of the next two concepts to determine if the patient is pregnant. This is included in the logic because 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 abstinent or drinking ANY amount of alcohol).
Step 1 Exclusions	“pregnant”	A diagnosis of pregnancy. An “active” or “recurring” FHIR resource clinicalStatus must be associated with the pregnancy to ensure that the individual is currently pregnant.
Step 1 Exclusions	“pregnancy observation within the past 42 weeks”	Pregnancy can also be expressed as a FHIR “Observation” in the CDS logic to identify a second way that this concept can be recorded in a health IT system. “Within the past 42 weeks” is specified as a lookback timeframe so that only a current/active pregnancy is considered. The American College of Obstetricians and Gynecologists (ACOG) defines “early, full, and late term pregnancy” as up to 42 weeks of gestation (Accreta, 2002). Of note, because gestation date is not often specified in a health IT system, the CDS logic evaluates the date that a pregnancy observation was recorded in the system. The FHIR ObservationStatus must be “final” or “amended” to ensure the observation is complete and verified by an authorized individual.
Step 1 Exclusions	“>”	Greater than (e.g., greater than 65 years old)
Step 1 Exclusions	“<”	Less than (e.g., score < 3)
Step 1 Exclusions	“<=”	Less than or equal to (e.g., less than or equal to 1 day)

Location in CDS Logic	Concept	Definition and/or Rationale
Step 1 Exclusions	“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.
Intervention and Actions Step 1	Continue to Step 2	The logic in Step 1 of this artifact determines if the patient meets the inclusion and exclusion criteria of having alcohol screening results that have not been acted upon. If so, the CDS logic will continue to determine the appropriate intervention for the patient based on the remaining logic.
Step 3 Inclusions	“AND NOT”	CDS logic operators that ensure a specific event, condition, result, etc. is not present in the patient record
Step 2 Inclusions	“=”	Equal to (e.g., score = 0)
Intervention and Actions Steps 2 - 3	“Notify patient/clinician that new alcohol screening information is available”	If the patient meets the inclusion criteria and not the exclusion criteria, the interventions and actions are generated. This first intervention provides a notification that new screening information is available. The specific method of delivery and content for this notification will be an implementation decision, to allow each implementor to determine a best method that fits with the current EHR or health IT capabilities.
Intervention and Actions Steps 2 - 3	“decision aid”	The Cochrane Collaboration defines a decision aid as an evidence-based tool designed to help patients to participate in making specific, deliberate choices among healthcare options (National Quality Forum, 2016).
Intervention and Actions Steps 2 - 3	“AUDIT Score”	Specific information about the patient’s alcohol screening results is provided, based on the inclusion and exclusion criteria of the CDS logic. See Section 3.4 , CDS Logic Descriptions and Recommended Actions, for additional information.
Intervention and Actions Steps 2 - 3	“Zone”	Administering an AUDIT questionnaire results in a numeric score, which is used to place the patient into one of four “Zones”, based on the level of risk identified. Each Zone calls for a different level of intervention. See Section 3.4 , CDS Logic Descriptions and Recommended Actions, for additional information, and Table 2 for a description of each Zone threshold and definition.
Intervention and Actions Steps 2 - 3	“educational information”	Patient education materials that help inform the patient on additional aspects of excessive drinking.

A.4 Artifact Development Decision Log

The CDS Development Team made numerous decisions while translating the narrative text found in the references into semistructured and later, structured, CDS logic. **Table 7** provides insight on those decisions. The table lists a “Decision Category,” which was informed by the Tso et al. journal article titled, “Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation” that outlines a methodology for knowledge translation (Tso et al., 2016). It also lists the high-level “Concept” related to the entry and the “Rationale” for each decision.

Table 7: Artifact Development Decision Log

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

Decision Category	Concept	Rationale
Verify completeness/ Add explanation	Excluding pregnant women from receiving this intervention	The specifications outlined in the Step 1 exclusion logic exclude women that are pregnant. Per CDC and ACOG guidance, women who are pregnant should abstain from any alcohol (Centers for Disease Control and Prevention, 2014)(The American College of Obstetricians and Gynecologists, 2011). The CDS Development Team and CDC sponsors of this project elected to exclude pregnant women from receiving this intervention, as pregnant women who are drinking any amount of alcohol should receive a brief behavioral counseling intervention from their primary care provider. As mentioned previously, the importance of not drinking and the risks of drinking during pregnancy or when trying to become pregnant are stressed in the Alcohol Brief Intervention and Referral CDS artifact as part of the brief intervention care recommendations. Those organizations that wish to ensure the appropriate brief interventions are provided to pregnant women should consider implementing this companion CDS artifact. More information on this artifact can be found in the Alcohol Brief Intervention and Referral implementation guide.
Verify completeness/ Add explanation	Considering how to approach providing an intervention to those individuals whose “sex assigned at birth” is recorded as Unknown in their medical record	During the development of the CDS artifacts for alcohol screening, the CDS Development Team and CDC sponsors of this project opted to develop logic that reasoned over a “sex assigned at birth” response that is recorded as Unknown to ensure that 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. For this CDS artifact, <i>Decision Aid for Your Drinking</i> , these patients are included in the logic for female patients, to determine if a patient is pregnant. In addition, they are included in the same AUDIT scoring criteria and associated Zone as females and males over 65 years old. As a result, the patient’s risk threshold may be slightly overestimated (which was preferred to potentially underestimating risk). Future implementers are encouraged to evaluate the accuracy and reliability of the “sex at birth” data in their system and consider if adjustments to the coded expression (i.e., L3) are indicated before implementing this artifact in their system.
Add explanation	Considering a patient’s Zone to identify the appropriate intervention	Administering an AUDIT questionnaire results in a numeric score, which is used by this logic to place the patient into one of four “Zones”, based on the level of risk identified. Each Zone calls for a different level of intervention, and only patients in Zone II through IV are included. Zone I indicates low-risk drinking, and Zone I patients are excluded for this artifact, <i>Decision Aid for Your Drinking</i> , because their level of drinking is within recommended guidelines. Zone II indicates drinking in excess of guidelines; Zone III indicates harmful or hazardous drinking; and Zone IV indicates high-risk drinking and probable alcohol use disorder. See Section 3.4 , CDS Logic Descriptions and Recommended Actions, for additional information, and Table 2 for the description and score thresholds of each Zone.

Appendix B. Data Requirements

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

Table 8: FHIR Data Requirements for this Artifact

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
Age	Step 1 (Inclusions)	Patient	Patient.birthDate (see https://hl7.org/fhir/R4/patient.html)
USAUDIT Score, USAUDIT-C Score, WHO AUDIT-C Score and WHO AUDIT Score	Steps 1 - 3	Observation* and QuestionnaireResponse**	<p><u>Observation Resource</u></p> <p>Observation.effective</p> <p>Observation.issued</p> <p>Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html)</p> <p><u>QuestionnaireResponse Resource</u></p> <p>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)</p>
Sex at Birth	Step 1	Patient	Patient.extension (“ http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex ”) (see https://hl7.org/fhir/R4/patient.html)

Data Element	Location in CDS Logic	FHIR R4 Resource	Required FHIR R4 Elements
Pregnancy Question Response	Steps 1 - 3	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "alcohol PS question, WHO AUDIT questions #1-#10, WHO AUDIT -C and WHO AUDIT scores, and pregnancy question" (see https://hl7.org/fhir/R4/questionnaireresponse.html)
Pregnant	Steps 1- 3	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 – 3	Observation	Observation.effective Observation.issued Observation.status = final, corrected, or amended (see https://hl7.org/fhir/R4/observation.html)
Individual USAUDIT or WHO AUDIT Question Responses (Question #1 - #3)	Steps 2, 3	QuestionnaireResponse	QuestionnaireResponse.questionnaire = "US AUDIT or WHO AUDIT questions #1-#3" (see https://hl7.org/fhir/R4/questionnaireresponse.html)

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

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

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
AUD	Alcohol Use Disorder
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	AUDIT-Consumption
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
NIDA	National Institute on Drug Abuse
NIAAA	National Institute on Alcohol Abuse and Alcoholism
ONC	U.S. Office of the National Coordinator for Health Information Technology
PS	Prescreen
SDC	Structured Data Capture
SMART	Sustainable Medical Applications, Reusable Technologies
SME	Subject Matter Expert

Acronym	Definition
SUSHI	SUSHI Unshortens ShortHand Inputs
TDD	Test Driven Development
USAUDIT	AUDIT, adapted for use in the U.S.
USAUDIT-C	USAUDIT-Consumption
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

List of References

- Accreta, P. (2002). Definition of Term Pregnancy by American College of Obstetricians and Gynecologists Committee. *Obstetrics & Gynecology*, 99(1), 169–170. Retrieved from <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co579.pdf?dmc=1&ts=20200220T1514182134>
- Agency for Healthcare Research and Quality. (n.d.). CQL Testing Framework. Retrieved August 23, 2019, from <https://github.com/AHRQ-CDS/CQL-Testing-Framework>
- American Public Health Association and Education Development Center. (2008). *Alcohol Screening and Brief Intervention: A Guide for Public Health Practitioners*. Washington DC. Retrieved from https://www.integration.samhsa.gov/clinical-practice/alcohol_screening_and_brief_interventions_a_guide_for_public_health_practitioners.pdf
- Asymmetrik. (n.d.). FHIR API Server. Retrieved May 12, 2020, from <https://github.com/Asymmetrik/node-fhir-server-core>
- Babor, T. F., & Higgins-Biddle, J. C. (2001). *Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care*. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/67210/WHO_MSD_MSB_01.6b.pdf?sequence=1
- Babor, T. F., Higgins-Biddle, J. C., & Robaina, K. (2017). The Alcohol Use Disorders Identification Test, Adapted for Use in the United States: A Guide for Primary Care Practitioners, 24. Retrieved from https://www.dshs.wa.gov/sites/default/files/BHSIA/dbh/wasbirt/USAUDIT-Guide_2016.pdf
- Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., & Monteiro, M. G. (2001). *The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care*. Retrieved from https://www.who.int/substance_abuse/publications/audit/en/
- Boston Children’s Hospital. (n.d.). Sustainable Medical Applications, Reusable Technologies (SMART) . Retrieved May 12, 2020, from <https://smarthealthit.org/>
- Bradley, K. A., & Kivlahan, D. R. (2014). Bringing patient-centered care to patients with alcohol use disorders. *JAMA - Journal of the American Medical Association*, 311(18), 1861–1862. <https://doi.org/10.1001/jama.2014.3629>
- Centers for Disease Control and Prevention. (n.d.). Fetal Alcohol Spectrum Disorders (FASD) Training and Resources. Retrieved April 27, 2020, from <https://nccd.cdc.gov/FASD/>
- Centers for Disease Control and Prevention. (2014). Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices. *Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities*. Retrieved from <https://www.cdc.gov/ncbddd/fasd/documents/AlcoholSBIImplementationGuide-P.pdf>

- Centers for Disease Control and Prevention. (2018). Alcohol and Public Health: Frequently Asked Questions. Retrieved February 7, 2020, from <https://www.cdc.gov/alcohol/faqs.htm>
- Curry, S. J., Krist, A. H., Owens, D. K., Barry, M. J., Caughey, A. B., Davidson, K. W., ... Wong, J. B. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. *JAMA - Journal of the American Medical Association*, 320(18), 1899–1909. <https://doi.org/10.1001/jama.2018.16789>
- Denny, C. H., Acero, C. S., Naimi, T. S., & Kim, S. Y. (2019). Consumption of Alcohol Beverages and Binge Drinking Among Pregnant Women Aged 18-44 Years - United States, 2015-2017. *MMWR. Morbidity and Mortality Weekly Report*, 68(16), 365–368. <https://doi.org/10.15585/mmwr.mm6816a1>
- Fiks, A. G. (2011). Designing Computerized Decision Support That Works for Clinicians and Families. *Current Problems in Pediatric and Adolescent Health Care*, 41(3), 60–88. <https://doi.org/10.1016/j.cppeds.2010.10.006>.
- Health Level 7. (n.d.-a). CQL-to-ELM Translator Reference Implementation. Retrieved June 19, 2019, from https://github.com/cqframework/clinical_quality_language/blob/master/Src/java/cql-to-elm/OVERVIEW.md
- Health Level 7. (n.d.-b). Profile audience and scope. Retrieved May 12, 2020, from <http://hl7.org/fhir/smart-app-launch/index.html#profile-audience-and-scope>
- Health Level 7. (n.d.-c). RESTful API. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/http.html>
- Health Level 7. (n.d.-d). SMART App Launch: Scopes and Launch Context. Retrieved May 12, 2020, from <http://hl7.org/fhir/smart-app-launch/scopes-and-launch-context/index.html>
- Health Level 7. (n.d.-e). SUSHI. Retrieved May 12, 2020, from <https://github.com/FHIR/sushi>
- Health Level 7. (n.d.-f). Using the FHIR Validator. Retrieved May 12, 2020, from https://wiki.hl7.org/Using_the_FHIR_Validator
- Health Level 7 (HL7). (n.d.-a). Advanced form behavior and calculation - FHIR v4.0.0. Retrieved May 12, 2020, from <http://hl7.org/fhir/uv/sdc/2019May/behavior.html>
- Health Level 7 (HL7). (n.d.-b). Advanced form rendering - FHIR v4.0.0. Retrieved May 12, 2020, from <http://hl7.org/fhir/uv/sdc/2019May/rendering.html>
- Health Level 7 (HL7). (n.d.-c). Clinical Quality Language (CQL) Release 1 STU4 (1.4). Retrieved May 12, 2020, from <https://cql.hl7.org/>
- Health Level 7 (HL7). (n.d.-d). Clinicalreasoning-module - FHIR v4.0.1. Retrieved May 12, 2020, from <http://www.hl7.org/fhir/clinicalreasoning-module.html>
- Health Level 7 (HL7). (n.d.-e). Condition Event Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/condition.html>
- Health Level 7 (HL7). (n.d.-f). FHIR Clinical Guidelines. Retrieved May 12, 2020, from <http://hl7.org/fhir/uv/cpg/2019Sep/>

- Health Level 7 (HL7). (n.d.-g). FHIR Shorthand. Retrieved May 12, 2020, from <https://build.fhir.org/ig/HL7/fhir-shorthand/>
- Health Level 7 (HL7). (n.d.-h). Observation Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/observation.html>
- Health Level 7 (HL7). (n.d.-i). Overview - FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/overview.html>
- Health Level 7 (HL7). (n.d.-j). PlanDefinition Resource - Content, FHIR v4.0.1. Retrieved May 12, 2020, from <http://www.hl7.org/fhir/plandefinition.html>
- Health Level 7 (HL7). (n.d.-k). Questionnaire Resource- Content: Structured Data Capture, FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/questionnaire.html#sdc>
- Health Level 7 (HL7). (n.d.-l). Questionnaire Resources - Content, FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/questionnaire.html>
- Health Level 7 (HL7). (n.d.-m). Resource Library - Content, FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/library.html>
- Health Level 7 (HL7). (n.d.-n). Resourcelist - FHIR v4.0.1. Retrieved May 12, 2020, from <https://www.hl7.org/fhir/resourcelist.html>
- Health Level 7 (HL7). (n.d.-o). SDC Home Page - FHIR v4.0.0. Retrieved May 12, 2020, from <http://hl7.org/fhir/uv/sdc/2019May/>
- Health Level 7, & Boston Children’s Hospital. (n.d.-a). CDS Cards. Retrieved August 22, 2019, from <https://cds-hooks.org/#cds-cards>
- Health Level 7, & Boston Children’s Hospital. (n.d.-b). CDS Hooks. Retrieved June 4, 2019, from <https://cds-hooks.org/>
- Health Level 7, & Boston Children’s Hospital. (n.d.-c). SMART App Launch Framework. Retrieved May 12, 2020, from <http://hl7.org/fhir/smart-app-launch/index.html>
- Higgins-Biddle, J. C., & Babor, T. F. (2018). A review of the Alcohol Use Disorders Identification Test (AUDIT), AUDIT-C, and USAUDIT for screening in the United States: Past issues and future directions. *American Journal of Drug and Alcohol Abuse, 44*(6), 578–586. <https://doi.org/10.1080/00952990.2018.1456545>
- Ismail, S., Buckley, S., Budacki, R., Jabbar, A., & Gallicano, G. I. (2010). Screening, diagnosing and prevention of fetal alcohol syndrome: Is this syndrome treatable? *Developmental Neuroscience. https://doi.org/10.1159/000313339*
- McKnight-Eily, L. R., Liu, Y., Brewer, R. D., Kanny, D., Lu, H., Denny, C. H., ... Collins, J. (2014). Vital signs: Communication between health professionals and their patients about alcohol use - 44 states and the district of Columbia, 2011. *Morbidity and Mortality Weekly Report, 63*(1), 16–22.
- McKnight-Eily, L. R., Okoro, C. A., Mejia, R., Denny, C. H., Higgins-Biddle, J., Hungerford, D., ... Sniezek, J. E. (2020). Screening for excessive alcohol use and brief counseling of adults — 17 states and the District of Columbia, 2017. *Morbidity and Mortality Weekly Report, 60*(10), 265–270. <https://doi.org/10.15585/mmwr.mm6612a1>

- Mokdad, A. H., Marks, J. S., Stroup, D. F., & Gerberding, J. L. (2004). Actual Causes of Death in the United States, 2000. *Journal of the American Medical Association*, 291(10), 1238–1245. <https://doi.org/10.1001/jama.291.10.1238>
- National Institute on Alcohol Abuse and Alcoholism. (n.d.). Alcohol Facts and Statistics | National Institute on Alcohol Abuse and Alcoholism (NIAAA). Retrieved February 18, 2020, from <https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/alcohol-facts-and-statistics>
- National Quality Forum. (2016). *National Standards for the Certification of Patient Decision Aids*.
- O'Connor, E. A., Perdue, L. A., Senger, C. A., Rushkin, M., Patnode, C. D., Bean, S. I., & Jonas, D. E. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA - Journal of the American Medical Association*, 320(18), 1910–1928. <https://doi.org/10.1001/jama.2018.12086>
- Oauthjs. (n.d.). Express OAuth Server. Retrieved May 12, 2020, from <https://github.com/oauthjs/express-oauth-server>
- Office of the National Coordinator (ONC). (2020). ONC's Cures Act Final Rule. Retrieved May 12, 2020, from <https://www.healthit.gov/curesrule/>
- OpenJS Foundation. (n.d.). Node.js. Retrieved May 12, 2020, from <https://nodejs.org/en/>
- SAMHSA-HRSA Center for Integrated Health Solutions. (n.d.). Shared Decision Making / SAMHSA-HRSA. Retrieved February 11, 2020, from <https://www.integration.samhsa.gov/clinical-practice/shared-decision-making>
- Stacey, D., Légaré, F., Lewis, K., Mj, B., Cl, B., Kb, E., ... Trevena, L. (2017). Decision aids for people facing health treatment or screening decisions (Review) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON. *Cochrane Database of Systematic Reviews*, (4), 1–242. <https://doi.org/10.1002/14651858.CD001431.pub5>. www.cochranelibrary.com
- Stahre, M., Roeber, J., Kanny, D., Brewer, R. D., & Zhang, X. (2014). Contribution of Excessive Alcohol Consumption to Deaths and Years of Potential Life Lost in the United States. *Preventing Chronic Disease*, 11, 130293. <https://doi.org/10.5888/pcd11.130293>
- Substance Abuse and Mental Health Services Administration. (2018). *Table 2.1B—Tobacco Product and Alcohol Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older, by Age Group: Percentages, 2017 and 2018. 2018 National Survey of Drug Use and Health (NSDUH)*. Retrieved from <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2018R2/NSDUHDetTabsSect2pe2018.htm#tab2-1b>
- The American College of Obstetricians and Gynecologists. (2011). At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications - ACOG. Retrieved January 21, 2020, from <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/At-Risk-Drinking-and-Alcohol-Dependence-Obstetric-and-Gynecologic-Implications>

- The MITRE Corporation. (n.d.). CQL Execution Framework Reference Implementation. Retrieved May 12, 2020, from <https://github.com/cqframework/cql-execution/blob/master/OVERVIEW.md>
- The Office of the National Coordinator for Health Information Technology. (n.d.). Interoperability Standards Advisory: Representing Patient Sex (At Birth).
- Tso, G. J., Tu, S. W., Oshiro, C., Martins, S., Ashcraft, M., Yuen, K. W., ... Goldstein, M. K. (2016). Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. *AMIA ... Annual Symposium Proceedings. AMIA Symposium, 2016*, 1189–1198.
- U.S. Department of Health and Human Services and U.S. Department of Agriculture. (2015). *2015-2020 Dietary Guidelines for Americans*. Retrieved from <https://health.gov/our-work/food-nutrition/2015-2020-dietary-guidelines/guidelines/>
- Vue.js. (n.d.). The Progressive JavaScript Framework. Retrieved May 12, 2020, from <https://vuejs.org/>
- White, A. M., Castle, I. J. P., Hingson, R. W., & Powell, P. A. (2020). Using Death Certificates to Explore Changes in Alcohol-Related Mortality in the United States, 1999 to 2017. *Alcoholism: Clinical and Experimental Research*, *44*(1), 178–187. <https://doi.org/10.1111/acer.14239>
- Wikipedia. (n.d.-a). Hooking. Retrieved May 12, 2020, from <https://en.wikipedia.org/wiki/Hooking>
- Wikipedia. (n.d.-b). OAuth. Retrieved May 12, 2020, from <https://en.wikipedia.org/wiki/OAuth>
- Wikipedia. (n.d.-c). Representational state transfer. Retrieved May 12, 2020, from https://en.wikipedia.org/wiki/Representational_state_transfer
- Wikipedia. (n.d.-d). Test-driven development. Retrieved June 4, 2019, from https://en.wikipedia.org/wiki/Test-driven_development
- World Health Organization. (2014). *Guidelines for the identification and management of substance use and substance use disorders in pregnancy*. *WHO* (Vol. 34). Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/24783312>

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