MITRE

Alcohol Screening and Brief Intervention (ASBI) Clinical Decision Support (CDS)

Pilot Final Report

Sponsor: CDC CSELS DLS
Contract No.: 75FCMC18D0047
Project No.: 37218213

Author(s):
Sally E. Turbyville
Sean P. Mikles
Ginny Meadows
David W. Winters
Michelle Lenox

May 31, 2022

Acknowledgments

Specifically, we want to thank and recognize:

- Centers for Disease Control and Prevention (CDC) Project team, including Shin Kim, Amy Board, Elizabeth Dang, Kathryn Miele, Tineka Yowe Conley and Mary Kate Weber
- The AllianceChicago Pilot Project Team, including Jeff Panzer, Jodi Simon, Shannon Pohl, Jeremy Carr, Liz Adetoro, Abbey Ekong, Ta-Yun Yang, Chris Cole, Rhein Punzalan, Nicole Padula, Tina Aggarwal, Azin Tanni, and Carlos Salgado
- The Heartland Health Centers clinical site leadership, medical assistants, and clinician end users
- The Health FFRDC Pilot Project Team, including Nalini Ambrose, Hanzhe Zhang, Ginny Meadows, David Winters, Michelle Lenox, Sean Mikles, and Sally Turbyville
- The Health FFRDC CDS Connect Project Team
- MITRE Program Management Chain

The CDC sponsored federally funded research and development center for health and human services (Health FFRDC) accelerates innovation by connecting people and data to reinvent health systems, enhance the care experience, and protect and promote health and well-being. Created by the Centers for Medicare & Medicaid Services (CMS), available to all of the Department of Health and Human Services (HHS) and operated by MITRE, the Health FFRDC serves as an objective adviser to all HHS organizations and other federal agencies with health and human services missions.

Executive Summary

Excessive alcohol use is responsible for substantial mortality in the adult U.S. population. Alcohol use during pregnancy can also cause negative outcomes such as miscarriage, birth defects, and developmental disabilities. To encourage the adoption of alcohol screening and brief intervention (ASBI), the Centers for Disease Control and Prevention (CDC) engaged its federally funded research and development center for health and human services (Health FFRDC) operated by MITRE to support transformation of ASBI guidelines into shareable clinical decision support (CDS) artifacts that can be integrated into electronic health record (EHR) and other health information technology (health IT) systems.

This report describes a pilot of two ASBI CDS tools: Alcohol Screening Using the World Health Organization (WHO) Alcohol Use Disorders Identification Test (AUDIT) and Brief Behavioral Counseling Interventions for Excessive Alcohol Consumption with Optional Referral to Treatment. The goals of the pilot included:

- Demonstrate CDS artifact integration with health IT and performance as expected.
- Understand the impact of the ASBI CDS in a primary care setting by analyzing a limited set of pre- and post-implementation alcohol screening and brief intervention quantitative and qualitative clinical data.
- Evaluate the performance of the ASBI CDS in a clinical setting.

Both qualitative and quantitative analysis were used to assess the pilot against these goals.

In addition to the assessment of the pilot goals, other key pilot activities are described in this report, including: pilot implementation planning, clinical site selection and training, ASBI tool selection and design, CDS technical integration, and CDS testing and validation.

Key Lessons Learned and Recommendations

The key lessons learned and recommendations presented in this report aim to inform implementors of CDS tools, researchers, health leaders, and clinicians that are looking for opportunities to improve the quality of care and patient outcomes, especially in the area of alcohol screening and brief intervention.

CDS tools can be succesfully integrated with health IT.

- Implementing innovative CDS tools is feasible.
- Integration and maintenance of CDS can require substantial resources.
- A successful team is engaged and multi-disciplinary with executive and clinical leadership.

The impact of the ASBI CDS in a primary care setting is mixed.

- CDS improved documented alcohol screenings but the impact on brief intervention remains uncertain.
- Questions arose about the ability of validated screening questionnaires to accurately screen in some populations.

- There is “off-label” use of CDS apps.

The ASBI CDS use by clinicians had variable success.

- Even when CDS content are highly regarded by clinicians using the CDS, cost and workflow disruptions in time-constrained primary care settings are a barrier for sustaining CDS tools.
- Addressing clinical workflow disruption is critical for CDS uptake.
- Introduction of CDS requires comprehensive planning, training, and ongoing support.
- Using data with the objective to take action during CDS implementation is critical.

Select Recommendations

- Future projects should make extensive use of CDS implementation guides and associated technologies to create innovative and cutting-edge tools.
- Conduct assessments of technical readiness, need for third-party tools, staff expertise, ongoing or upcoming Health IT priorities, and project management/coordination readiness to inform resource and timeline planning for CDS implementations.
- Engage influential executive and clinical leadership to secure adequate resources and motivate CDS app uptake.
- Anticipate and track off-label uses of the CDS content for the purposes of measuring impact.
- Engage the clinical staff and clinician end users early and often; be responsive to their input and do not underestimate their perceived disruption in workflow.
- Ensure training provides important background that is meaningful to the end users, for example why alcohol screening is so important, what we know about drinking behaviors and patient population, and evidence on the effectiveness of the intervention.
- Solicit both formal and informal qualitative feedback and extract EHR data early and regularly to monitor for unexpected usage patterns and system errors.

Conclusion

Importantly, this pilot demonstrated the feasibility of integrating innovative CDS tools that interact (bi-directional) with the EHR system and can customize real-time content during the patient’s clinical visit. This paves the way for person-centered, real-time customized clinical support decision for CDS tools.

The implementation guides for all five ASBI CDS tools, including the two used in this implementation, are freely available on CDS Connect (https://cds.ahrq.gov), and software for the tools used in this implementation are on GitHub (https://github.com/asbi-cds-tools).

Table of Contents

List of Figures

List of Tables

1 Introduction

The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services, is the primary federal agency responsible for safeguarding the nation's public health through the control and prevention of disease, injury, and disability. Nationally, excessive alcohol use is responsible for over 140,000 deaths in the U.S. each year.[1] Yet, alcohol screening and brief intervention remains critically underutilized in primary care. For example, a recent CDC report from 13 states and Washington, D.C. found that, among those asked about alcohol use and who reported current binge drinking, 80% received no advice to reduce their drinking.[2] 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. Alcohol use during pregnancy can cause birth defects and developmental disabilities, collectively known as fetal alcohol spectrum disorders (FASDs) and is also linked to other negative outcomes, such as miscarriage, stillbirth, preterm birth, and sudden infant death syndrome.

The U.S. Preventive Services Task Force and other organizations have provided evidence-based recommendations for the implementation of alcohol screening "in primary care settings in adults age 18 years or older, including pregnant women[3], and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use".[4] To encourage the adoption of alcohol screening and brief intervention (ASBI), CDC engaged the Health FFRDC (the federally funded research and development center for health and human services operated by MITRE) to support transformation of the recommendation guidance and other evidence-based resources into shareable clinical decision support (CDS) artifacts that can be integrated into electronic health record (EHR) systems and other health information technology (health IT). CDS "artifacts" are actionable medical knowledge such as clinical practice guidelines, peer-reviewed articles, or local best practices, that can be translated into interoperable CDS software that implement clinical logic. The initial phase of this project involved developing the standards-based, interoperable ASBI CDS tools that can help decrease alcohol use during pregnancy and reduce the risk of FASDs and other negative pregnancy and birth outcomes.

To evaluate the performance of the ASBI CDS tools, CDC asked the Health FFRDC to conduct a clinical pilot of one of the alcohol screening tools and one of the brief intervention tools. The Health FFRDC team for this project utilized MITRE experts in clinical decision support

[1] Centers for Disease Control and Prevention, "Deaths from Axcessive Alcohol Use in the United States." [Online]. Available: https://www.cdc.gov/alcohol/features/excessive-alcohol-deaths.html. [Accessed: 26-May-2022]

[2] L. R. McKnight-Eily et al., "Screening for excessive alcohol use and brief counseling of adults — 17 states and the District of Columbia, 2017," Morb. Mortal. Wkly. Rep., vol. 60, no. 10, pp. 265–270, 2020.

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

[4] S. J. Curry *et al.*, "Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement," *JAMA - J. Am. Med. Assoc.*, vol. 320, no. 18, pp. 1899–1909, 2018.

development and validation, clinical quality standards and informatics, cognitive engineering, health technology, program implementation and evaluation, and project management.

This document focuses on the clinical pilot implementation of the CDS tools in a healthcare setting.

1.1 Background

During the initial phase of the project, the Health FFRDC worked with its sponsor, CDC, to develop the ASBI CDS tools, 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 people who can become pregnant, 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 people who can become pregnant.
- Exercise a reproducible process for translating clinical practice guidelines into standards-based, interoperable formats for integration into local health IT systems (including EHR systems).
- Contribute to efforts to improve speed, efficiency, accuracy, consistency, and effectiveness of dissemination and implementation of clinical practice guidelines.
- To facilitate CDC's mission and progress toward these outcomes, CDC's Health FFRDC Development Team created three alcohol screening and two alcohol brief intervention CDS tools:
- Alcohol Screening Using the USAUDIT (Alcohol Use Disorders Identification Test, Adapted for Use in the U.S.), 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 U.S.) 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 in the CDS Connect Repository, 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 CDS software,

and other accompanying material) that can serve as building blocks when evidence-based practice recommendations are translated into interoperable CDS.

1.2 Pilot Goals and Scope

The purpose of the initial phase of the CDC project was to create ASBI CDS tools that enabled consistent interpretation and implementation of evidence-based guidelines to improve relevant public health outcomes.

While CDC sought to understand the impact of the ASBI CDS on people who are pregnant, it was determined early in the project that the selected primary care pilot site's patient population included relatively few pregnant patients; thus, limiting the ability to assess the CDS impact on pregnant patients.

This phase of the ASBI CDS project focused on conducting a clinical pilot of the ASBI CDS tools created during the initial phase, with the following goals:

- Demonstrate CDS artifact integration with health IT and performance as expected.
- Understand the impact of the ASBI CDS in a primary care setting by analyzing a limited set of pre- and post-implementation alcohol screening and brief intervention quantitative and qualitative clinical data.
- Evaluate the performance of the ASBI CDS in a clinical setting.

The scope of the clinical pilot included selecting and engaging with a pilot organization willing and able to implement one of the alcohol screening CDS tools and one of the brief intervention CDS tools over a multi-week intervention period.

2 Pilot Partnership

The Health FFRDC team established a systematic approach and methodology for conducting the ASBI CDS pilot. Figure 1 depicts the high-level steps for selecting the appropriate pilot site, developing the pilot design, conducting the evaluation, and disseminating the pilot findings.

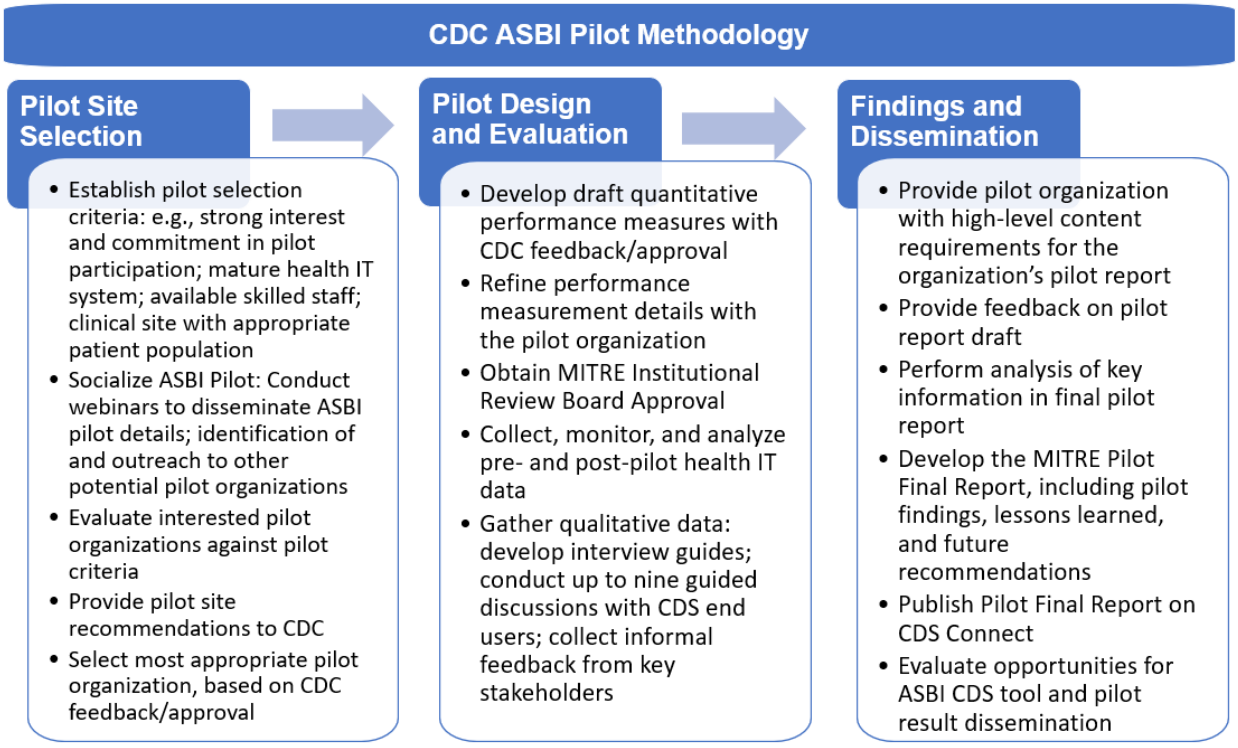


Figure 1. CDC ASBI Pilot Methodology

2.1 Pilot Partner Requirements

The Health FFRDC team worked closely with CDC to develop specific criteria and characteristics to select the ideal pilot organization and associated clinical sites. This work provided a set of criteria to evaluate the appropriateness of each potential pilot organization and inform decision making. A pilot organization typically represents a healthcare system, and the clinical sites are settings or practices within the larger organization. For the pilot, the team sought a collaborator with both technical readiness and a suitable healthcare environment to pilot the CDS. The team considered these high-level factors during the initial pilot site identification:

- Demonstration by the potential pilot organization's leadership team of (1) a strong commitment to participate in the pilot, (2) an ability to execute a pilot contract in a timely manner, and (3) a commitment to securing any required Institutional Review Board (IRB) approvals.
- Strong interest by the pilot organization and clinical sites in the implementation of CDS to screen adults 18 years and older for alcohol use, and in the provision of a brief intervention when indicated.

- An organization with a mature health IT system and available skilled staff at the pilot organization to work with the Health FFRDC's informaticists and engineers to facilitate CDS integration, testing and troubleshooting, evaluation, training, and implementation.
- Selection of clinical sites focused on ambulatory care in an appropriate medical specialty (e.g., internal medicine, family medicine, obstetrics-gynecology) with a patient population that includes, at a minimum, people who can become pregnant as well as people who are currently pregnant.

The detailed criteria included desired characteristics of an ideal pilot organization and clinical site (e.g., commitment of executive leadership and operational resources), technical requirements, and health IT staffing availability and capabilities (see Pilot Organization Ideal Characteristics).

2.2 Pilot Partner Selection

The Health FFRDC team socialized the pilot broadly. For example, the team conducted a webinar for CDC-invited grantees, attended by more than 50 individuals from various healthcare organizations. The team delivered a second webinar to over 40 members of the Agency for Healthcare Research and Quality (AHRQ) CDS Connect Work Group. In addition, the team collected background information on potential pilot organizations through discussions and email conversations with more than 20 different organizations. This approach helped the team compile a wide variety of potential collaborators.

After the Health FFRDC team conducted follow-up discussions with the various organizations, several expressed strong interest in participating in the pilot. As part of the review and evaluation process, the team determined the extent to which each potential pilot organization met the ideal pilot characteristics and criteria. The team prepared an analysis of the potential pilot organizations, along with the team's recommendations, and presented the final results to CDC for review and input. After evaluation of all potential pilot partners, the Health FFRDC and CDC selected AllianceChicago as the ASBI pilot partner. AllianceChicago is a large Health Center Controlled Network (HCCN) that supports more than 50 community health centers and other safety net providers in three core areas:

- Engaging and supporting their partners to optimize quality, efficiency, experience, and outcomes.
- Empowering partners to deliver high-quality care using an extensive data infrastructure and "leading-edge" health IT.
- Leveraging the technology infrastructure and collaborations to engage partners in research and education, with the goal of promoting health equity.

AllianceChicago provides support for health IT that enables practice improvement and advanced data analytics, and curates a comprehensive health database comprising over 3.5 million highly diverse patients. The communities represented include urban and rural populations, low-income and uninsured individuals, racial and ethnic minorities, the LGBTQ community, and refugee and homeless populations. AllianceChicago also serves as an incubator for innovative healthcare solutions. They have significant staff expertise (e.g., Chief Research Officer, Chief Medical

Information Officer, Physician Innovator, project managers, informaticists, data analysts, and software engineers) and resources to meet pilot requirements.

2.3 Institutional Review Board Approval

Given the measurement and evaluation nature of the work, the Health FFRDC team engaged with the MITRE IRB to ensure compliance with applicable human-subject protection policies.

The Health FFRDC team initiated contact with the MITRE IRB and began completing the required application forms and supplementary materials. The application included a description of the project, the proposed implementation and evaluation process, an assessment of risk, and a clear statement that outlined how the end users might be engaged in the evaluation process. The team submitted the completed application along with an informed consent form, a list of project staff, and a draft of the end-user interview discussion topics. In August 2021, the MITRE IRB provided an official response, granting the project exempt status (i.e., the evaluation does not exceed a minimal risk to human subjects and falls into an exempt category).[5] AllianceChicago ceded IRB review and oversight to the MITRE IRB. Human subject review was not required at CDC since this project was deemed a non-research activity.

3 Pilot Implementation Planning

After initiating the pilot subcontracting process, the Health FFRDC team met with AllianceChicago several times in advance of the executed contract and official project kickoff. Meeting topics included selection of the ASBI CDS tools to be implemented, the technical integration of the CDS tools within the AllianceChicago EHR system, and the development and review of an evaluation and measurement plan (i.e., the "Analytic and Evaluation" plan) to help measure the impact of the CDS tools. The Health FFRDC team and AllianceChicago also discussed the need to select a specific AllianceChicago clinical site (or sites) that would implement and use the new CDS tools. In addition, AllianceChicago provided a demonstration of the current alcohol screening tools that are already in use in its EHR, athenahealth, and a tool, Care Gap Manager, that facilitates the display of specific clinical screenings and actions that are currently due for a patient. Care Gap Manager is a third-party application designed to support primary preventative care visits.

A clinical champion is a clinical staff member and leader, who promotes and facilitates process or quality improvement efforts within a healthcare organization. A critical role for success, a clinical champion is influential and often involved throughout the project's lifecycle, including funding, planning, implementation, assessment, and sustainability. [6]

[5] U.S. Department of Heath and Human Services, "Protection of Human Research Subjects: Exempt Status." [Online]. Available: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html. [Accessed: 09-Mar-2022].

[6] Wood K, Giannopoulos V, Louie E, et al. The role of clinical champions in facilitating the use of evidence-based practice in drug and alcohol and mental health settings: A systematic review. *Implementation Research and Practice*. January 2020. doi:10.1177/2633489520959072

Once the pilot subcontract was finalized, the AllianceChicago and Health FFRDC teams began planning additional implementation details. AllianceChicago identified key personnel that would be engaged in the pilot and help ensure a successful implementation. This core team included the project lead/manager, the clinical champion, and the Health IT technical lead and staff. Ideally, the team leaders have adequate influence to engage and garner support and needed resources from the organization's executive and senior leadership, as well as the participation of medical staff and clinicians (the end users).

Along with CDC input, its Health FFRDC team developed a timeline of important milestones, which was revisited and modified throughout the project. Figure 2 illustrates the final timeline of the ASBI CDS pilot.

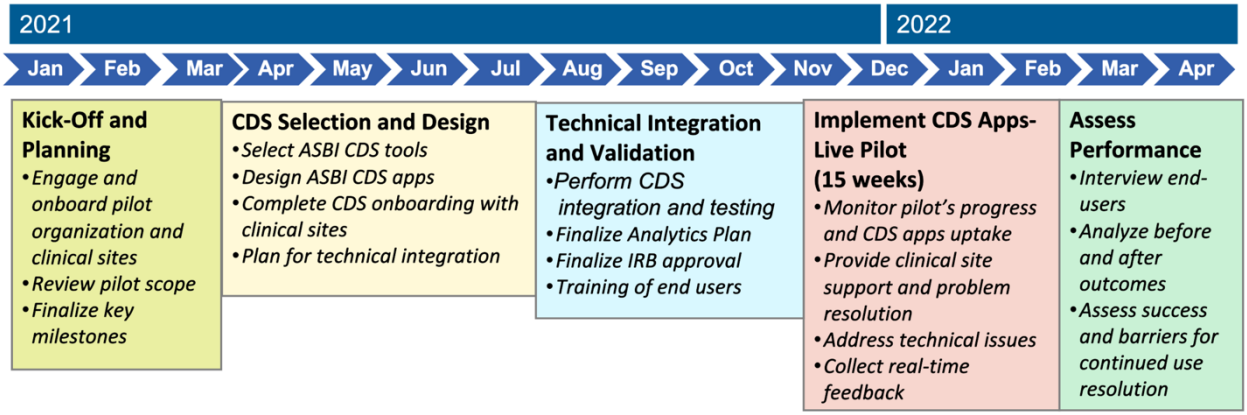


Figure 2. Final Pilot Project Timeline

3.1 Pilot Work Plan and Kickoff Meeting

The Health FFRDC began drafting the initial work plan early in the pilot planning process to clearly define the sequential work efforts required by both the Health FFRDC and AllianceChicago teams. The initial work plan established the proposed timeline and implementation details, as well as critical path activities and risks.

The Health FFRDC team conducted a formal kickoff with the AllianceChicago leadership and technical teams to provide an overview of the project, review pilot tasks, and initiate the software integration and testing processes. This two-day virtual kick-off meeting occurred in early April 2021 with key AllianceChicago and Health FFRDC team members and included the following discussion topics:

1. Overview of the initial project background and objectives and the ASBI CDS tools.
2. Development of the process to evaluate data availability and the need for mapping.
3. Discussion of the human-centered design approach to refine the CDS tools.
4. Review of the pilot scope, work plan, timeline, and deliverables.
5. Discussion of the pilot analytic plan.
6. Overview of the technical tasks and dependencies.

3.2 Communication and Collaboration

To maintain ongoing situational awareness and communication, Health FFRDC team leadership held a weekly project management call with AllianceChicago project leadership throughout the duration of the pilot. Additionally, a weekly technical call provided an opportunity for the organizations' operational, clinical, and technical leadership to discuss the integration and implementation of the CDS artifacts and how the CDS tools impact clinical execution and pilot outcomes. Throughout the pilot period of performance, AllianceChicago and Health FFRDC leadership were readily available to address questions or issues as needed.

The Health FFRDC team set up an external collaboration SharePoint site for sharing documents and other artifacts with AllianceChicago and extended invitations to each of the AllianceChicago team members to set up secure accounts to access the site. The SharePoint site facilitated the review and sharing of key documents throughout the pilot project.

3.3 Pilot Analytic and Evaluation Plan

One of the objectives of the CDS pilot was to evaluate the effectiveness, usefulness, and impact of the ASBI CDS tools by collecting and analyzing a limited set of quantitative and qualitative data before and after implementation. In addition, data were collected to monitor fidelity to the pilot implementation plan and inform uptake of the CDS applications (apps) at the clinic sites.

The measures (i.e., data) focused on capturing information of interest to AllianceChicago and CDC (and mutually agreed upon with the Health FFRDC team) and relevant to the introduction of ASBI CDS (e.g., number of patients screened for alcohol use). We list these measures in Appendix B.

The results of the pilot also provided an initial set of data to evaluate the performance of the CDS logic. Qualitative information based on user experience was used to correct any critical errors or malfunctions that arose during the live pilot and provide future implementers with lessons learned and recommendations to improve the functionality of the CDS. The detailed results of the analysis can be found in Section 8, Pilot Findings and Lessons Learned.

3.4 Clinical Pilot Site Selection

The Health FFRDC team worked with AllianceChicago and CDC to identify one or more suitable clinical sites to pilot the ASBI CDS tools. To support AllianceChicago's clinical site recruitment, the Health FFRDC team collaborated with AllianceChicago to develop a brief informational document describing the project.

AllianceChicago identified several potential clinical sites that might be suitable for the pilot. The team determined clinical site suitability based on the site's patient population, desired characteristics, and commitment to using the CDS during patient encounters for the length of the live pilot period. Desired characteristics include a focus on ambulatory care in an appropriate medical specialty (e.g., internal medicine, family medicine, obstetrics-gynecology) and an appropriate population of both people who can become pregnant and people who are currently pregnant.

The ongoing COVID-19 pandemic impacted clinical site recruitment efforts, which caused changes in clinical workflows and placed demands on community health centers to focus efforts

on vaccinating their qualified patient population. Many AllianceChicago patient visits utilized telehealth remote tools, which did not provide the technical capabilities needed to integrate the ASBI CDS tools.

AllianceChicago persisted in their recruitment efforts and successfully engaged Heartland Health Centers (HHC), a clinical organization comprised of seven clinical sites within the Chicago area, to participate in the pilot project. The physician serving as the Director of Innovation for AllianceChicago and the Vice President of Care Transformation at HHC filled the important role of the clinical champion at the pilot sites.

3.4.1 Clinical Pilot Site Onboarding and Training

An introductory meeting was held with the clinical champion to provide an overview of the ASBI CDS tools, the pilot goals and objectives, timeline, and high-level tasks, and discuss the design approach the Health FFRDC team planned to use to develop the ASBI user interface. Due to the aforementioned impact of COVID-19, most of the ongoing activities were conducted with AllianceChicago and the pilot clinical champion (the ideal approach would have also included end users at the pilot clinic sites). These activities included discussions on the proposed clinical workflow to perform alcohol screening and brief intervention tools. Additional details on efforts to incorporate the current clinical workflow with the ASBI design efforts are discussed in Section 4.2, ASBI CDS App Design Process.

The Health FFRDC team worked in partnership with AllianceChicago and HHC's training specialist to develop and provide training on the CDS tools to clinicians, other end users of the ASBI tools, and a trainer responsible for training the clinic site end users. The training included a description of how the CDS works, how to use the CDS tools, and how to provide feedback and report problems related to the CDS tools. The training plan consisted of providing live virtual training sessions, which were recorded for future distribution, and a one-page quick-start guide to be distributed across pilot sites. In preparation for development of materials for the live training sessions, the AllianceChicago team collected and mapped the existing alcohol screening and brief intervention workflow at HHC sites and validated the workflow with the clinical champion and EHR managers at each site. The live training sessions walked attendees through the workflow using the CDS tools within Care Gap Manager. The clinical champion also presented an overview of the CDS tools at all clinician and clinical leadership meetings.

AllianceChicago and the HHC training specialist were provided access to additional online training materials developed by CDCs' FASD grantees on alcohol screening and brief intervention to share with the clinicians. These training resources can be accessed through CDC's *FASD Training and Resources* website.

4 ASBI CDS Selection and Design

For this pilot project, we sought to implement one alcohol screening CDS and one brief intervention CDS. The pilot partner, AllianceChicago, selected the CDS with input from the Health FFRDC and CDC based on their clinic site needs, organizational priorities, and the pilot's compressed timeline.

4.1 ASBI CDS Selection

Providing several CDS options for both screening and brief intervention allows implementers to select the tools that best align with their needs, organizational policies, technical capabilities, and clinician preferences. As mentioned in Section 1.1, during the initial project phase, the Health FFRDC completed the development of five ASBI CDS. Each of the three alcohol screening tools represents a validated alcohol and/or substance use screening questionnaire. The two brief intervention tools include one that is clinician-facing and one that is patient-facing. (For more detailed information on each of the alcohol screening and brief intervention CDS, please refer to the Implementation Guide posted on CDS Connect for each CDS.)

Based on discussions with the Health FFRDC and input from CDC, AllianceChicago selected the *WHO AUDIT Alcohol Screening* CDS and the clinician-facing *Alcohol Brief Intervention and Referral* CDS. The selection of the *WHO AUDIT Alcohol Screening* CDS was primarily driven by the clinical sites' (medical assistants (MAs) and clinicians) familiarity with a version of the WHO AUDIT alcohol questionnaire, which was already integrated into their EHR. The selection of the *Alcohol Brief Intervention and Referral* CDS was driven by AllianceChicago's enthusiasm for the brief intervention's content that is individualized based on the patient's alcohol screening results using evidence-based guidance. AllianceChicago determined that this ASBI CDS would support the clinicians in conversations with their patients to consider reducing their alcohol use. In addition, AllianceChicago did not have the health IT capability or capacity to accommodate the implementation of the direct-to-patient display in a patient-facing CDS app.

4.2 ASBI CDS App Design Process

The Health FFRDC chose a human-centered design approach using the Cognitive Engineering Lifecycle process (Figure 3)[7] to develop the graphic user interface (GUI) prototypes for the alcohol screening and the brief intervention CDS apps.

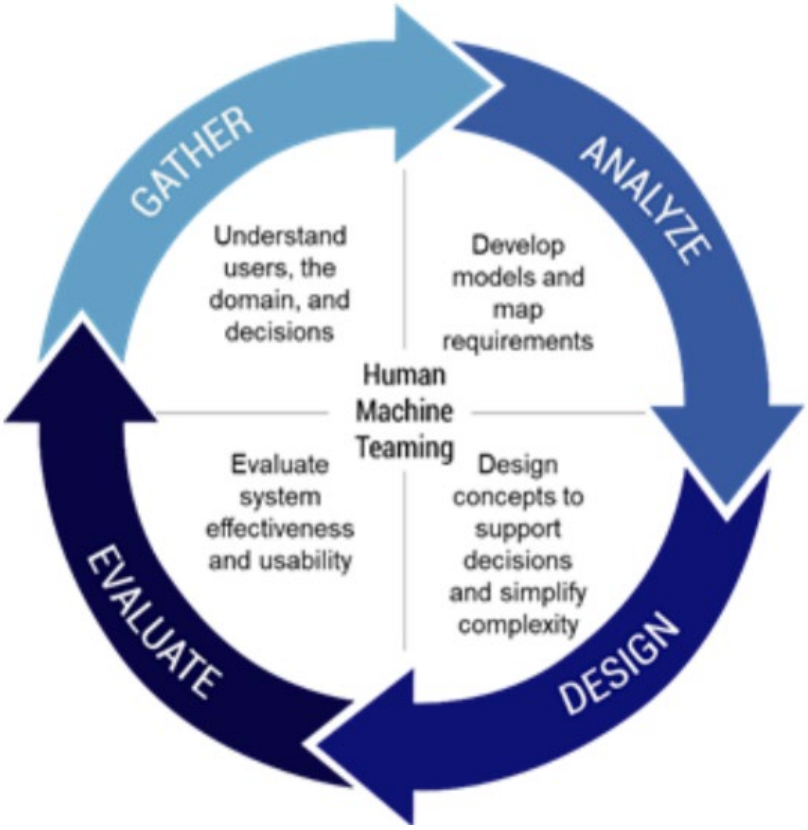


Figure 3. Cognitive Engineering Lifecycle - MITRE (2020) Cognitive Engineering Toolkit

For each CDS app design concept iteration, we used the following techniques:

1. **Gather** – Capture information about the users and their work
   - Conduct walkthroughs of EHR and interviews with site staff
2. **Analyze** – Develop models of work and define requirements
   - Validate workflows
   - Identify design constraints and opportunities
3. **Design** – Develop design concepts. i.e., the operational interactions and interfaces of end users
   - Generate low- to mid-fidelity prototypes

[7] E. D. C.O. Dominguez, C.A. Bonaceto, C. Johnson, M. Bryant, M. Rohman, "Cognitive Engineering Toolkit." [Online]. Available: https://www.mitre.org/publications/technical-papers/cognitive-engineering-toolkit.

- Apply human factors, usability, and visual design principles

4. **Evaluate and Iterate** – Test design concepts and inform future design iterations or finalize
   - Conduct design reviews with stakeholders
   - Demonstrate designs to stakeholders
   - Perform cognitive walkthroughs/user testing with site staff
   - Perform heuristic evaluations on designs
   - Iterate on designs

4.2.1 CDS App Design Approach

Human-centered design approaches work closely with the end users throughout the development and design phases. However, due to the added pressures on clinicians and clinical staff brought on by the COVID-19 pandemic, it was not feasible to gather clinical workflows and design feedback from end users (i.e., the medical assistants, physicians, other clinicians that would use the apps) across all seven pilot clinic sites. Instead, the team did work closely with the director of informatics and the clinical champion. Both are clinicians and one is a practicing clinician at one of the clinic sites. The Health FFRDC team met with these two end user representatives remotely, conducting three recorded walkthroughs of the EHR systems and clinical workflows. The team supplemented these sessions with feedback from members of the CDC and Health FFRDC teams who had relevant healthcare experience.

A variety of tools were used for analysis and design activities, including:

- *MURAL* a collaborative web-based platform for workflow exploration, design ideas, and design reviews
- Microsoft *PowerPoint* and *Balsamiq* for generating low-fidelity mockups and exploring alerting options
- *Sketch* for generating higher fidelity wireframes and interactions
- *Adobe XD* for selected graphics

The Health FFRDC team analyzed demonstration videos of primary care visit use patterns within the EHR and Care Gap Manager interface to understand the current information layout and to confirm overall clinical workflow (e.g., tasking and interactions of medical assistants, patients, and clinicians). The team annotated screenshots of the videos to map the typical paths used through the EHR and Care Gap Manager interfaces during a patient visit. Once the Health FFRDC team confirmed the clinical workflow steps with the AllianceChicago team, the team used the screenshots to build strawman designs in *Balsamiq* and *Microsoft PowerPoint* to explore implementation options and design constraints:

- What options are available (i.e., technically feasible) for alerting clinician users about the need for screening/intervention?
- What workflow options are possible (i.e., clinically feasible) for the new CDS apps?
- What amount of screen real estate or Care Gap Manager interface are available to design within?

These strawman designs illustrated different alerting methods and locations, potential display and location of a screening app pop-up window, and various display and interactions of the screening questions. The team then used the strawman designs to support the development and integration of each of the CDS apps.

4.2.2 Integration of the CDS Apps Within the EHR

There were two options for developing and integrating the CDS apps within the EHR: (1) a singular approach, with one application that operationalized both the alcohol screening CDS and brief intervention CDS or (2) a dual approach, with two applications that separately implement the alcohol screening CDS and the brief intervention CDS. It was ultimately decided that integrating two CDS applications was the better choice since it more closely aligned with the current clinical workflow involving separate persons delivering the screening and intervention.

Based on the clinical champion's recommendation and strong agreement from the entire AllianceChicago team, the team decided that an alcohol screening and brief intervention workflow consisting of two healthcare professionals interacting during the visit was ideal. Specifically, a workflow where the medical assistant is responsible for taking the patient to an assigned exam room, collecting vitals (e.g., blood pressure and weight), and performing select screenings (e.g., smoking status, depression screening, COVID screening, alcohol use). The clinician would follow, building patient care goals with information gleaned from verbal exchange with the medical assistant, the screening results, along with other critical information found in the EHR, including Care Gap Manager forms, EHR text, and notes fields. Maintaining two separate CDS apps allows each healthcare worker to independently complete their tasks and record results specific to their role with the CDS implementation.

For medical assistants and clinicians, Care Gap Manager was readily accessible through a region of the EHR called the Forms panel. The Forms panel, on the left side of the EHR screen, is the region of the EHR medical assistants and clinicians use to access the set of site-specific and visit-specific customized forms that drive intake and encounters. While the functionality for orders, medications list, problems list, and text notes are accessible from other points within the EHR, a form collected functionality around specific tasks or visit types. The Care Gap Manager form has a specialized feature that utilizes color coding and button text to indicate status of recommended care. The effect is to create a scannable, "at-a-glance" dashboard of needed patient assessments, labs, and tests, along with results, to help guide clinicians.

Balsamiq wireframes were generated to demonstrate potential alerting scenarios; the design was limited by what was technically feasible within the pilot period. Alerting needed to be salient but non-intrusive—allowing the EHR user to observe the alert but not require further interaction. This approach aligned with AllianceChicago's design philosophy of not forcing interactions or constraining the workflow within the EHR. The team used the alerting scenarios to identify implementation options for alerting the medical assistants or the clinicians to use the CDS apps to perform the alcohol screening or provide a brief intervention. These alerting scenarios within the EHR interface are further described in Appendix C.1.

Integration design options included a pop-up window that would overlap regions of the browser-based EHR, or directly integrating into the form windows as it displayed in the interface. However, integrating the apps directly into a forms window, in either the singular or dual form,

was not technically workable during the pilot. As the site selection was being finalized, the option to re-use the alert pattern in the Care Gap Manager form became available, which also aligned with the pilot sites workflows.

4.2.3 Care Gap Manager Integration

The teams decided that Care Gap Manager was the optimal integration location for the screening and brief intervention apps since it was being used for intake screening at the pilot clinic sites. In addition, Care Gap Manager was already in use at the pilot clinic sites, the clinical champion recommended its use as the integration location for both apps, and using Care Gap Manager would be technically feasible within the pilot's technical integration timeline. Strawman designs of alerting options (e.g., labels for buttons; location of buttons in form; visibility of button; color of buttons in response to score; display of screening score on button) were developed and shared with the AllianceChicago team to assess its technical feasibility and clinical impact.

Within the Assessment region of the Care Gap Manager form, the CDS apps were integrated within the existing alcohol screening workflow. The alcohol row consisted of three components —an "Alcohol" button, a text region that would display screen results, and an action/trigger button, that indicated, by label and color, if an AUDIT or a brief intervention was recommended for the patient.

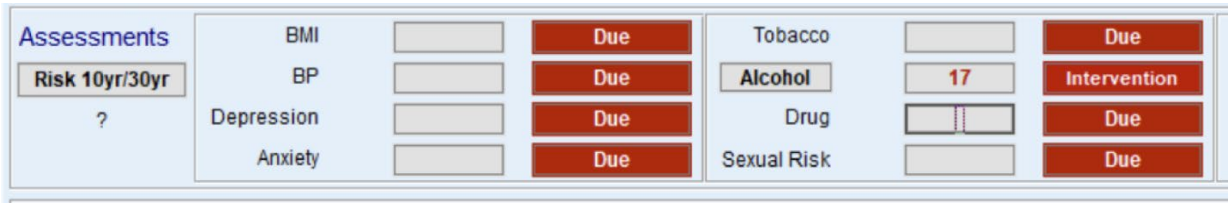


Figure 4. Assessment Row of Care Gap Manager Showing the Results of Screening and the Alert for a Brief Intervention

The "Alcohol" button, when activated, triggers a text pop-up that displays all previous screening responses in the patient's EHR record. The middle text region displays the score of the screen, allowing a clinician to view the screening results without taking further action. The action trigger button displays either "AUDIT" or "Intervention," depending on which next step was being recommended by the CDS. Responsive color coding, based on risk level calculated, was proposed for the middle text region and intervention button but this change was only able to be implemented toward the end of pilot period. On activation of the "AUDIT" button or the "Intervention" button, a separate browser window opens, displaying either the screening app or the brief intervention app to the end user to further interact with its content.

4.2.4 Alcohol Screening App Design

The *WHO AUDIT Alcohol Screening* CDS is designed to identify adults (i.e., individuals 18 years and older) who would benefit from alcohol screening as part of their preventive healthcare and to trigger the appropriate alcohol screening questions as indicated by the CDS logic. The alcohol screening app helps guide a clinician or other healthcare professional in gathering the patient's responses to the tool's screening questions. After the patient response to the initial

alcohol pre-screen question (i.e., "Do you sometimes drink beer, wine, or other alcoholic beverages?") is recorded, the CDS logic controls the next actions. If the patient responds "No," this ends the screening process. If the patient responds "Yes," the alcohol screening app displays the first question of the WHO AUDIT screening questionnaire. Based on the patient response to of the AUDIT screening questions, the CDS logic appropriately skips or prompts subsequent questions, up to the full 10 WHO AUDIT question list. In addition, the CDS will prompt a pregnancy question dependent on the patient's age and sex at birth. For each question displayed, the healthcare professional selects the response option that best matches the patient's answer to the screening questions.

Starting from an existing alcohol screening prototype developed during an earlier ASBI CDS project (and posted on software development hosting platform *GitHub*), the design activities aimed to confirm any modifications needed for implementation. For example, the existing prototype design displayed screening questions one at a time and only advanced to the next question once a response had been submitted. The team decided that this approach was burdensome and contrary to the medical assistants' current workflow within the EHR. The medical assistant's current workflow placed no limit on the navigation of the overall content of the screener and displayed all AUDIT questions at once, allowing prior items to be updated when needed. Design changes to the prototype to address these issues included:

- A progressive reveal of screening questions within a single screen
- Persistent display of prior questions and selected responses
- Shading of completed questions and selected responses to visualize progress
- Making the submit button more prominent

Additionally, the team integrated a more extensive drink size graphic illustrating seven drinks that appeared at the start of the AUDIT, after the pre-screen question was submitted by the clinician. This image remained displayed throughout the screening process and was intended to help clarify with the patient what constituted a single "alcoholic drink." This graphic and the final design of the screener are in Appendix C.2.

4.2.5 Brief Intervention App Design

The *Alcohol Brief Intervention and Referral* CDS identifies patients who were screened for alcohol use within the past 12 months whose alcohol screening score indicates the need for a brief intervention. It also provides patient-specific alcohol screening results information, brief behavioral counseling intervention care recommendations, and targeted patient education resources. The brief intervention app displays the relevant information to a clinician to assist them in conducting a brief intervention with the patient. It is not meant to be a substitution for training to clinicians on how to successfully conduct a brief intervention, but rather serves as a support tool, with prompts, high-level guidance on motivational interviewing, customized content based on patient screening responses, and information helpful in educating patients, such as graphics and external informational resources.

To explore content layout, the team generated low-fidelity wireframes based on the brief intervention content developed during the previous ASBI project phase. For these designs, the intervention app window would be split into two components, a left panel outlining the steps of a brief intervention and right panel whose content would change based on selections of hyperlinks in the left panel. This interactive format minimized scrolling and allowed clinicians to scan for and activate the information they personally found useful for their brief intervention conversation.

After the design review of these wireframes with the clinical champion, the clinical champion suggested including information that could be directly shared with the patient, such as what was found in the patient-facing *Decision Aid for Your Drinking* CDS. They also suggested that initial brief intervention content be made conversational and patient friendly. Based on this feedback, the team adjusted the language and added graphics of the standard drink size, the low-risk drinking table, and the risk zone triangle to the design. Wireframes were then generated with this additional content, in both a one panel, scrollable layout, and an alternative navigation format. The team used these wireframes to gather additional feedback from the clinical champion and the CDC team on new content and interactions, along with exploring implementation options with the internal team. The clinical champion preferred having access to the full brief intervention content with fewer click interactions. When combined with feasibility of implementing/testing an alternative navigation format within the pilot timeline, the single panel design became the focus of higher fidelity wireframes and iterations. See Appendix C.3 for the wireframes illustrating this design progression.

Once graphics, content, and general layout were established, the team developed high-fidelity wireframes of the different brief intervention screens. Design use cases, which fully described the customized content expected with each different intervention, were created in Excel. These design cases helped demonstrate not only customized content based on patient age, sex, screening responses, and drinking zone calculation, but also placeholders for functionality, such as automatically generating a referral and sharing/printing educational materials for patients. The final designs, resulting from reviews with technical teams, clinical champion, and CDC stakeholders, resulted in the wireframes seen in the Appendix C.4. The elements of the design and usability are discussed in the next section.

4.2.5.1 Layout of the Brief Intervention Content

The brief intervention design used three informational regions within a single panel to support delivery of customized brief intervention content (Figure 5). The upper, page-wide region presents high-level guidance on conducting a brief intervention at the patient's calculated risk level, as well as access to further brief interventions education. The left side of the design presents an outline for conducting a brief intervention at the patient's calculated risk level along with a short explanation of the goal of each step. Across from each step, and forming the right side of the design, are conversational prompts and patient customized information to support the discussion around each step. Once familiar with the design and content, during an intervention, a clinician would focus on scanning and reading the content down the right side of the panel, while consulting the other regions, as needed, to refresh their understanding about brief interventions delivery.

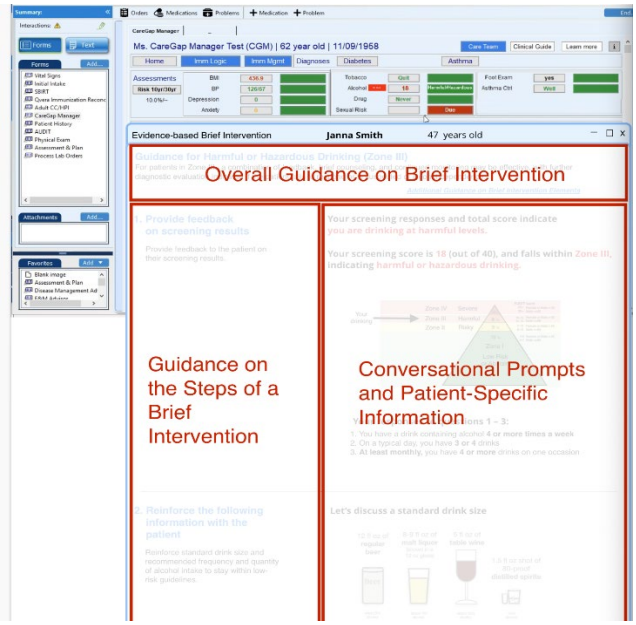


Figure 5. Three Informational Regions of the Brief Intervention Design

4.2.5.2 Graphics

The team developed three graphics for inclusion in the brief intervention app. This included a standard drink size illustration (Figure 6), a table comparing patient drinking levels with low-risk levels, and a risk zone triangle graphic on which to contextualize the patient's screening results. These resulting graphics owe their inspiration to other U.S.-based alcohol screening and brief intervention programs and resources.

Figure 6. Standard Drink Size Graphic for Brief Intervention

The brief intervention app also displays the risk zone triangle and the low-risk levels table, which varied based on patient responses (Figure 7). The risk zone triange included a "Your drinking" level arrow pointing to the patient's scored Zone and corresponding drinking level. For additional context, it also included the percentage populations with similar Zone results and AUDIT score ranges. The Low-Risk Drinking Limits Comparison table displayed the patient self-reported drinking levels ("Your Drinking") with Low-Risk Drinking Limits for similar sex and aged respondents. "Your Drinking" values displayed in red when high, to increase the saliency of the values and draw attention to the specific levels.

4.2.5.3 Display of Customized Intervention Content

While the overall steps of the brief intervention were consistent (e.g., *1. Provide feedback on screening results*), the conversational brief intervention content displayed was specific to the patient's alcohol screening responses and screening scores (Figure 8). Within the conversational prompts section on the right side of the design, information such as patient drinking level, screening score, Zone score, score relation to guidance, and patient responses to questions 4-10 of the AUDIT, were made salient to draw the clinician's eye to the patient-centered information within the text. The customized content, along with select conversational prompts, were bolded, colored red, or displayed in larger fonts to achieve this effect.

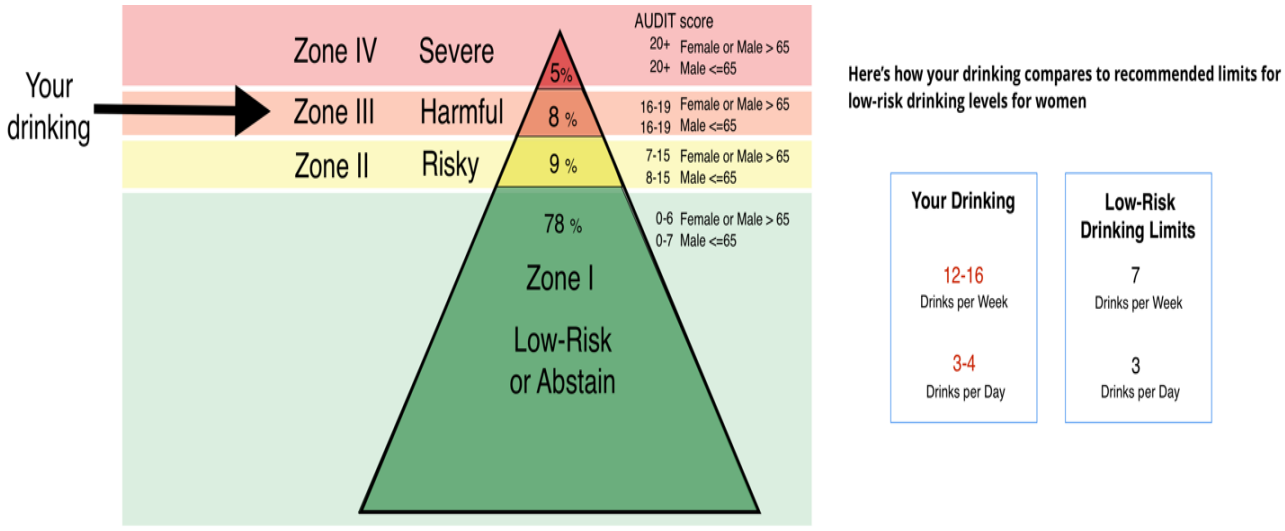


Figure 7. Risk Zone Triangle (Left) and Low-Risk Drinking Limits Comparison (Right)

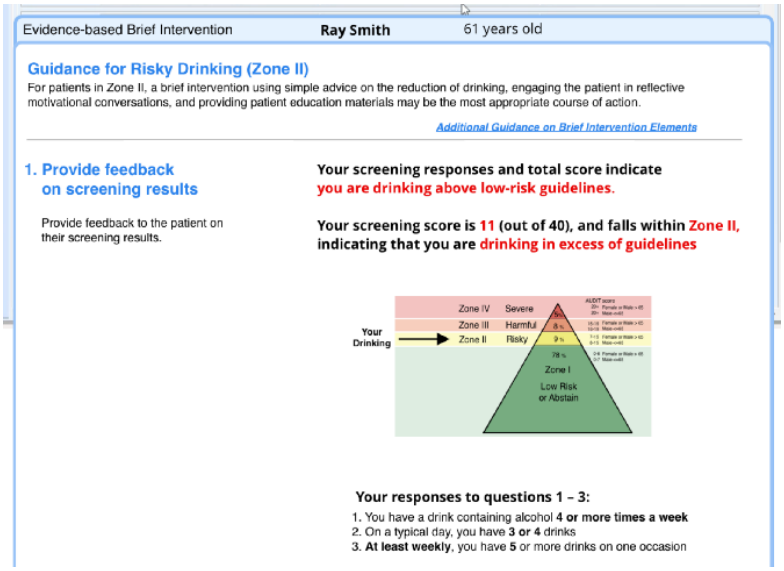


Figure 8. Customized Brief Intervention Content Showing Increased Saliency Within Design

4.2.5.4 Education Resources

The intervention step, "*Share patient education resources,*" was designed to be adapted based on site practice, preferences, and referral sites. The hyperlinks to tools and information could be modified to point to any website or source. This section might also be customizable to include prompts to remind the clinician to share or print their site's own paper materials. More advanced functionality, such as adding education resources to the visit summary, were also under consideration in the first designs. Heartland Health Centers chose to conduct the pilot with the default URL resources provided by CDC and its Health FFRDC and did not customize it to include local materials to print (Figure 9).

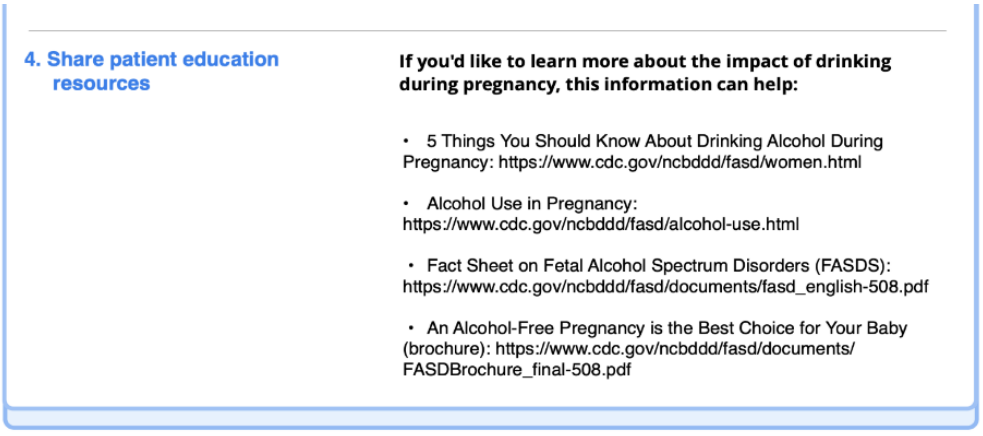


Figure 9. Education Resource on the Brief Intervention for a Pregnant Patient Who Drinks

5 ASBI CDS Technical Integration

This section describes the process of integrating the ASBI CDS tools into the AllianceChicago instance of the athenahealth EHR. The Health FFRDC team took a standards-based approach when designing the ASBI CDS in preparation for the pilot. This involved leveraging open health IT standards to facilitate integration with a wide variety of EHRs. However, some pilot-specific customizations were needed for the ASBI CDS to integrate with athenahealth. Because these customizations were not generally applicable to other types of EHRs, the team did not incorporate them into the baseline ASBI CDS published on CDS Connect and GitHub. This contrasts with the enhancements described in Section 7, which included changes made for or during the pilot when they changes were deemed to be of enough value to include in the baseline ABSI CDS.

5.1 Technical Integration Approach

The ASBI CDS tools are software apps that run inside of a web browser. These "apps" are launched to a web browser from the pilot health IT system when the end user (e.g., medical assistant or clinician) clicks specific buttons within the EHR user interface. The launched app is provided specific information (i.e., "context") so that it can authenticate to the EHR and request the information necessary to execute the ASBI CDS logic. This context includes the identification of the current end user, patient, and encounter. The end user then interacts with the ASBI CDS and any data entered into the app is written back to the patient record in the EHR. When the end user is done using the app, they close the web browser window and return to the EHR user interface.

The Substitutable Medical Applications, Reusable Technology (SMART) standard defines how third-party web apps, such as the ASBI CDS tools, can securely connect to an EHR and retrieve electronic medical record data associated with an authenticated context (end user, patient, encounter).[8] SMART ensures secure transfer of information between the EHR and web application by leveraging the Secure Hypertext Transfer Protocol (HTTPS)[9] and the OAuth 2.0 authorization protocol,[10] both mature and widely-used internet technologies. The Fast Healthcare Interoperable Resources (FHIR®) standard defines how different healthcare data can be electronically represented, formatted, and transported. FHIR was designed so that different EHRs and other health IT systems could exchange data using a standard interoperable interface.[11] Both SMART and FHIR have been called out specifically in the ONC 21st Century Cures Act Final Rule on Interoperability and Information Blocking as well as the ONC Health IT Certification Program as required standards for any certified EHR.[12] The ASBI CDS tools have been designed to leverage both SMART and FHIR to facilitate pilot integration. Interested readers can consult the ASBI CDS implementation guides for additional details.

[8] https://smarthealthit.org/

[9] https://datatracker.ietf.org/doc/html/rfc2818

[10] https://datatracker.ietf.org/doc/html/rfc6749

[11] https://www.hl7.org/fhir/summary.html

[12] https://www.healthit.gov/curesrule/

5.2 Pilot-Specific Technical Integration Customizations

While together SMART and FHIR can be used to facilitate CDS integration, each EHR is going to have its own idiosyncrasies that will require custom integration efforts. This section describes the customizations put in place to support integration of the ASBI CDS tools with the AllianceChicago instance of the athenahealth EHR. These customizations likely will not generalize to integration with other EHRs.

5.2.1 App Launch

The first type of customization needed to support the pilot involved how the ASBI CDS tools were launched and how they were provided context about the end user, patient, and encounter for which they were launched. The SMART standard defines a launch sequence whereby the button in the EHR opens a web browser to the app.[13] The app then redirects the browser to the authorization server, which approves or rejects any access requests for the patient's electronic medical record data. If access is granted, the authorization server redirects the browser back to the app, which can then query the EHR for the necessary patient data. The integration of the ASBI CDS tools was complicated due to the athenahealth authentication process not completely aligning with the SMART standard.

Athenahealth provides developer documentation and an online testing environment that is also known as a "sandbox."[14,15] The sandbox allows developers to test their apps with the athenahealth authentication process and provides access to a limited set of synthetic patient records. During early integration testing of the ASBI CDS tools, the team discovered that athenahealth authentication deviates from the SMART specification by default. A non-standard parameter must be set during application launch to ensure a SMART authentication process is followed.[16] If this parameter is not set, app authentication will not follow the process specified in the SMART standard. This means the ASBI CDS tools could not function "out of the box" with athenahealth, since they were designed around the SMART standard.

A third-party software library was used to provide SMART capabilities within the ASBI CDS tools.[17] As described in Section 7, this software library was modified to allow support of non-SMART authentication processes. During early testing, the ASBI CDS tools could successfully authenticate to the athenahealth sandbox once this third-party library was updated.[18] However, another restriction with the athenahealth authentication process was discovered, which forced the end users to enter their login credentials every time the ASBI CDS tools were launched.[19] An alternative approach was possible by setting up a surrogate account for the purpose of providing specific services within the system. This account was associated with the ASBI CDS tools so that the authentication process could be streamlined. When the end user pressed the specific button within the EHR user interface, the app would launch and authenticate using the service account

[13] http://hl7.org/fhir/smart-app-launch/index.html

[14] https://mydata.athenahealth.com/access-the-apis

[15] https://github.com/athenahealth/apiserver-athenaFlex

[16] https://github.com/athenahealth/apiserver-athenaFlex/issues/172

[17] https://github.com/smart-on-fhir/client-js

[18] https://github.com/smart-on-fhir/client-js/pull/122

[19] https://github.com/athenahealth/apiserver-athenaFlex/issues/207

credentials. Context (patient, end user, encounter) would be directly provided by the EHR at launch time, which the app would then use to request the appropriate data. While this authentication approach worked, it does not generalize to non-athenahealth EHRs. When the athenahealth EHR software is upgraded to fully support the SMART standard, this custom workaround will be unnecessary.

5.2.2 FHIR API

The second type of customization needed to support the pilot involved the athenahealth FHIR application programming interface (API). The ASBI CDS tools were designed around FHIR Revision 4 (R4), the version of FHIR called out by the previously mentioned ONC Rule. However, the athenahealth FHIR API currently only supports the older FHIR Draft Standard for Trial Use 2 (DSTU2). Because of differences between FHIR DSTU2 and FHIR R4, adjustments had to be made with how the ASBI CDS tools requested data from the athenahealth FHIR API. These adjustments mostly involved nuanced differences with how the patient data was structured. Since the ONC Rule requires FHIR R4, it is unlikely that the changes made to the ASBI CDS Tools to support FHIR DSTU2 will be reusable for integration with other EHRs.

The athenahealth FHIR API also required adjusting how data was "written" back from the ASBI CDS tools to the EHR database. In the case of the alcohol screening app, results must be written back to the EHR so that the brief intervention app can subsequently read them and construct customized brief intervention content. The athenahealth FHIR API allowed writeback to occur but required the end user to take multiple steps to "finalize" the data before it could be available for use. Again, due to concerns about impacts to efficiency, acceptance, and usage of the app, an alternative approach using a service called Qvera was adopted.[20] Instead of writing the alcohol screening results back to the FHIR API, the screening app instead sent them to a Qvera service, which then directly injected them into the EHR. One limitation of this approach was that Qvera could not be configured to support writeback of alcohol screening results that did not contain AUDIT scores. (This occurred if a patient responded "no" to the alcohol prescreen question.) The workaround proposed by AllianceChicago involved the screening app sending a value of zero for the alcohol screening scores if none existed based upon the patient responses. The consequence of this workaround was that the response of the alcohol prescreen question would have to be consulted to determine if the AUDIT was actually filled out or not.

5.2.3 Determination of Patient Pregnancy Status

The third and final type of customization needed to support the pilot involved how pregnancy status was determined for each patient. The original CDS logic examined the patient electronic medical record for FHIR Condition and Observation resources using the standard defined terminology codes. However, at AllianceChicago the typical approach for documenting pregnancy status used a non-standard code to represent a patient's estimated delivery date (EDD). Pregnancy status is then determined by looking to see if an EDD is present and occurs within the next 10 months. The CDS logic had to be modified for the pilot to also check for an EDD when determining patient pregnancy status. Since this approach is non-standard, it was not incorporated into the baseline CDS.

[20] https://www.qvera.com/

6 Pilot Implementation and Testing

This section describes the implementation, integration, testing, and validation of the screening and the brief intervention CDS apps into AllianceChicago's EHR system, athenahealth. Successful integration and deployment of the apps required data mapping and analysis, alignment with security and connectivity protocols between athenahealth and the CDS apps, and validating that once fully implemented, the CDS apps functioned as expected. The Health FFRDC and AllianceChicago teams collaborated through email, a shared issues tracking spreadsheet, and regular weekly meetings to solve issues related to software deployment and end user experience throughout the pilot period.

6.1 EHR Integration of the CDS Tools

The integration of the ASBI CDS apps into AllianceChicago's EHR required substantial efforts from the AllianceChicago team, including expanding the team's CQL and FHIR standards knowledgebase, planning, and technical preparations to install the CDS apps on their server, integrating the CDS tools into athenahealth, and drafting test scenario scripts.

In collaboration with the CDC and AllianceChicago, we adjusted the initial implementation timeline several times to accommodate emerging business and clinical priorities. The integration of the third-party tool Care Gap Manager, which was intended to serve as the launch point for the ASBI CDS apps within the EHR, required more resources than originally anticipated due to its acquisition by a new company. In addition, site and clinical activities to address the COVID-19 pandemic by the HHC pilot locations, such as planning for testing and vaccination activities, often took precedence over the ASBI CDS pilot activities.

After the pilot kick-off and app design activities, the Health FFRDC team assisted the AllianceChicago team in integrating the CDS apps into their EHR environment. Integration activities included the installation of the CDS tools on AllianceChicago's servers, testing the launching of the CDS tools from Care Gap Manager, applying use cases to test the CDS logic (discussed in Section 6.3) and mimicking typical HHS clinical workflows, and baseline data extracts to monitor the pilot's implementation fidelity and project outcomes (discussed in Section 8.3).

After installation, technical discussions focused on establishing secure connections between the EHR and CDS tools and establishing services to launch both the screening and intervention apps. The initial personal information exchange (PFX) format used for the HTTPS security certificate only allowed one app to be launched at a time, so the certificates were altered to use CRT/KEY formats which allowed the apps to be run simultaneously. The services that launch the CDS apps were also merged into one service to allow both screening and intervention apps to be launched from athenahealth.

6.2 EHR Data Capture Analysis and Mapping Requirements

To ensure accurate and reliable CDS interventions, the data used by the logic for each CDS tool must be available within the EHR and in a format as complete and specific as possible (e.g., represented using the appropriate FHIR data model resource and attributes, using standard terminology code). Each data element represents a clinical concept, such as "alcohol use disorder," "pregnancy," or "alcohol screening results." The Health FFRDC team worked with

AllianceChicago on the analysis of the specific data elements available in their EHR to identify any gaps in data completeness and specificity.

To aid in this process, the Health FFRDC team created a *Data Requirements* spreadsheet to assist AllianceChicago in evaluating their data for completeness and specificity. The spreadsheet listed each data element used for both the alcohol screening and the brief intervention CDS tools, and for each data element included:

- The clinical concept (i.e., data element) name and description.
- Whether the clinical concept is used in the *WHO AUDIT Alcohol Screening* and/or the *Alcohol Brief Intervention and Referral* CDS tool, or both.
- How the CDS logic uses the data element (e.g., to determine whether the pregnancy question should be asked).
- The FHIR "resource" defined for each data element. A resource is a discrete unit representing information of interest to healthcare, such as clinical and administrative concepts. (Examples of administrative concepts include, "observation," "condition," "questionnaireResponse," "procedure.")
- The FHIR "attributes" required for each data element (e.g., "observation.status," "condition.onset," "procedure.performed,") along with any additional FHIR concepts for each attribute (e.g., for the attribute "status:" "final," "complete").
- The value set(s) or specific terminology code(s) used to represent each data element. Each value set (i.e., set of codes) includes an object identifier (OID). The value set can be looked up using the OID on the National Library of Medicine Value Set Authority Center.

The analysis of the existing EHR data revealed the need to update one data element's value set and map locally-defined codes to standard terminology codes. The primary data elements that required updates or mapping to ensure capture of the appropriate data included:

- **Hysterectomy Definition:** Initially, Health FFRDC did not include ICD-10-CM (diagnosis codes) in the original value set for "Hysterectomy" [only ICD-10-PCS (procedure codes) and SNOMED-CT codes were used]. However, analysis determined that AllianceChicago used two ICD-10-CM codes to document history of a hysterectomy. Health FFRDC added these two ICD-10-CM codes to the hysterectomy value set.
- **Pregnancy Observation Definition:** Mapped local code to standard code. Health FFRDC defined this concept using the standard definition representing "estimated date of delivery" used in the ONC Interoperability Standards Advisory (ISA). However, the analysis determined AllianceChicago was not using this standard code. AllianceChicago mapped their local code to the ISA standard code.
- **Alcohol Screening Intervention Definition:** Mapped local codes to standard codes. Health FFRDC defined this as a procedure using standard codes, but AllianceChicago used local codes that required mapping.
- **Sex at Birth:** EHR data capture alignment with the CDS definition. "Sex at Birth" refers to the sex assigned at birth to an individual. This concept was rarely completed in the AllianceChicago EHR database. A data record called "administrative gender,"

called such because it is commonly used for *administrative* purposes such as insurance billing, was determined to be more frequently completed, and thus was mapped to identify the individual's birth sex.

To assist AllianceChicago with the mapping activities, the Health FFRDC team met with the AllianceChicago informatics team regularly throughout the process, responded to questions, and reviewed logic throughout these activities.

6.3 ASBI CDS Testing and Validation

A critical component of this pilot project was the testing and validation of the CDS tools and the integration of the CDS apps into the AllianceChicago's EHR system. In section 6.3, we summarize the testing and validation key findings and subsequent decisions.

6.3.1 CDS Artifacts and CDS Tool Development Testing

During the development of the five ASBI CDS screening and brief intervention artifacts and tools, and prior to their posting on the AHRQ CDS Connect portal, the Health FFRDC team tested the logic for the tools using a comprehensive set of test cases and synthetic patient data. Using the test cases and procedures outlined in the implementation guides, various tools were used to validate the formatting of the FHIR resources and CQL logical expressions, test the accuracy of the CQL logic, and perform end-to-end testing of an internal software program that executes the ASBI CDS tools in a simulated environment. These test cases covered all paths elaborated in the associated CQL logic and expected outcomes and provided assurance that the logic worked as intended before beginning the pilot integration phase. See details in the implementation guides for a full account of the testing tools used, enumerated test cases, and open-source software that can be used to create a test system for the ASBI CDS tools.

6.3.2 Pilot Site Testing

The Health FFRDC team developed and shared scenarios with the AllianceChicago team to test the integration and implementation of the CDS apps. They based the test scenarios on test cases defined in the implementation guides and were represented as FHIR bundles of synthetic patient data and a narrative description (see the implementation guides for details on the test cases). The AllianceChicago team used these scenarios to develop test scripts and team members applied them. Prior to the live pilot launch, the AllianceChicago team applied all the test scenarios and resolved key issues. During the live pilot phase, we continued to capture and prioritize issues for resolution. Descriptions of the pilot site testing and pilot phase issue tracking and resolution process are below.

6.3.3 Approach

Following the integration of the CDS apps into the AllianceChicago EHR environment, AllianceChicago began formal in situ testing. Initial testing by AllianceChicago focused on a "closed loop" workflow that tested communication between the CDS apps and the EHR. The closed loop workflow included:

1. Consistent and appropriate launch of the CDS screening app from Care Gap Manager.
2. Screening app's communication of the screening results back to the EHR.

3. Communication of the screening results from the EHR to the CDS brief intervention app when launched from Care Gap Manager.
4. Appropriate launch of the brief intervention CDS app based on the patient's characteristics (e.g., pregnancy) and screening responses.

Both teams monitored the results of this testing and worked together to resolve discrepancies in data mapping between AllianceChicago EHR and CDS apps. After, the closed loop workflows were validated and the CDS app software was updated, the AllianceChicago team installed the app updates and updated the FHIR API calls accordingly.

After the initial closed loop workflow testing, the team applied the scripted test scenarios. The test scenarios defined test patients with specific demographic and clinical attributes (e.g., age, sex, pregnancy status, alcohol use disorder diagnosis). The scripted scenarios sought to test key components of the alcohol screening and intervention CDS apps:

- Patient inclusion criteria (e.g., 18 years of age or older, evidence of pregnancy)
- Patient exclusion criteria (e.g., under 18 years of age, evidence of active alcohol use disorder diagnosis)
- Branching logic (e.g., screened out based on pre-screen response, triggered skip logic, brief intervention alert appropriately triggered)
- Accuracy of the brief intervention's content for each scenario (i.e., whether the content changed appropriately based on the patient's screening AUDIT score)

During the testing process and throughout the pilot, AllianceChicago documented and shared user-reported suggestions. On an ongoing basis, the Health FFRDC team collaborated with AllianceChicago to prioritize issues, and develop resolution plans. After the CDS apps went live in HHC's clinics, each clinic's EHR managers reported CDS-related feedback from clinicians to the internal issue tracking system. The AllianceChicago team monitored the tracking system for reports of the CDS tools deviating from expected functionality, or feedback requesting new functionality to improve the user experience. The Health FFRDC and AllianceChicago teams worked with the pilot's clinical champion to prioritize issues based on expected clinical impact and anticipated resources needed for resolution (e.g., design, programming, and testing). When a decision was made to address a reported issue, the AllianceChicago technical team would develop the scope of work and development timelines, and code would be installed and tested in alignment with AllianceChicago's standard monthly EHR update process.

6.3.4 CDS Testing and Integration Findings

The team addressed all issues necessary for the successful implementation and integration of the CDS apps. During the scenario testing, several issues around the user interface arose. Specifically, issues related to the organization and formatting of buttons used to launch the CDS apps from the Care Gap Manager, mappings for AUDIT response data, and utilization of appropriate EHR data related to sex and pregnancy status. We addressed these issues with design (Section 4.2) and data mapping updates (Section 6.2).

Testers also reported inconsistencies in the display functionality between the ASBI app and similar screenings in Care Gap Manager. Because the team assessed this issue as lower priority

given that it did not prevent CDS app implementation and it required resources beyond the pilot scope, the team decided to monitor the impact on end users during the live pilot phase. Based on the success of the CDS apps' implementation (integration, testing, and validation), the Health FFRDC, AllianceChicago, and CDC teams confirmed the feasibility of the pilot's "go live" start date of November 15, 2021.

After the start of the pilot, end users reported twelve issues of which seven were resolved during the pilot phase. See Table 1 for details on the issues identified and their resolution. After discussion among the Health FFRDC, AllianceChicago, and CDC teams, they decided that changes requiring additional design work or clinical validation could not be accomplished during the pilot and should be explored in future CDS implementations.

Table 1. Issues Identified During the Pilot and Their Resolution

Issue Description	Location	Priority	Resolution
For one test patient, the brief intervention app was blank when launched due to the app not accepting blank responses to AUDIT questions.	CDS Intervention app	High	Fix developed and installed.
The number of drinks per week in the brief intervention app can appear in a confusing format (i.e., showing '0.999999996' instead of '1').	CDS Intervention app	High	Fix developed and installed.
After the CDS tools were installed, unrelated cancer and eye screening documentation no longer would appear in a text-translated version of the clinical notes.	EHR	High	Fix developed and installed.
For pregnant women, the pop-up displaying historic AUDIT scores shows an AUDIT due date in one year instead of three months.	Care Gap Manager	High	Fix developed and installed.
AUDIT scores do not appear in a text-translated version of the clinical note.	EHR	High	Fix developed and installed.
The brief intervention launch button originally disappeared after being clicked once. Users requested that it stay available so that it can be accessed multiple times.	Care Gap Manager	Medium	Fix developed and installed.
Users reported inconsistencies between the presentation of the ASBI CDS functionality and other elements within Care Gap Manager. These inconsistencies include the placement of the launch buttons and the display of screening result information.	Care Gap Manager	Medium	Fix developed and installed.

Issue Description	Location	Priority	Resolution
For pregnant patients, there was a suggestion to change text formatting and update the risk zone triangle to emphasize that alcohol use is considered excessive for patients who are pregnant or trying to become pregnant.	CDS Intervention app	Medium	Enhancement should be considered for future implementations.
The brief intervention launch button color was not red for pregnant patients who do not drink or who were in Zone 1. There was a suggestion that it should be red for all pregnant patients to indicate the priority of addressing this population.	Care Gap Manager	Medium	Enhancement should be considered for future implementations.
Users requested the ability to print content from the brief intervention app to give to the patient.	CDS Intervention app	Low	Enhancement should be considered for future implementations.
Some users were confused by the description and formatting of the low-risk drinking limits comparison table. In certain cases, the calculated 'drinks per day' value would be larger than the 'drinks per week' value due to patient AUDIT responses. This seemed illogical to some users, who suggested rewording the table descriptions.	CDS Intervention app	Low	Enhancement should be considered for future implementations.
The button that launched the brief intervention only stays green for the encounter where it was launched. A user suggested that the button remain green until the next AUDIT screening was due.	Care Gap Manager	Low	Enhancement should be considered for future implementations.

6.4 Pilot Staffing Resources

The Health FFRDC and AllianceChicago teams provided a multi-disciplinary team to support this pilot. The teams spanned executive leadership, clinical leadership, project management, program evaluation, health informatics and IT, software design, and training. The clinical leadership and project management team coordinated efforts across multiple departments and supported all aspects of the project. This team also led the workflow mapping, system testing, and the recruitment and scheduling of end users. The program evaluation team led the design and execution of quantitative and qualitative evaluation activities. The design and technical integration team provided expertise with CDS app design, EHR integration, and the secure integration of health IT tools at the clinic sites. The training team focused on health IT training and developed materials for distribution across clinic sites.

Many of these activities were led or driven by the AllianceChicago team, with the Health FFRDC team providing varying degrees of leadership or support. In general, the Health FFRDC team's role was two-fold. First, to provide unique expertise and experience with the ASBI CDS tools and relevant health IT data standards, health data interoperability, and user-centered design. And second, to supplement the AllianceChicago's team with additional resources for project management, program evaluation and analytics, and technical integration. The Health FFRDC team served as a resource to the AllianceChicago team on the use of the implementation guides, data mapping, system networking, the design of user interfaces, and the design and execution of both quantitative and qualitative evaluation activities. Table 2 provides an overview of the resources engaged in this pilot project, expertise and activities, and estimated effort throughout the pilot period. While a majority of the technical design and integration efforts were needed before the CDS tools were implemented at the pilot clinics, substantial effort is still needed after implementation to design and install software enhancements based on end user feedback and extract evaluation data to monitor performance of the CDS.

Table 2. AllianceChicago and Health FFRDC Team Staffing and Effort for the ASBI CDS Pilot Over a 13-Month Period From January 2021 Through February 2022

Teams	Expertise and Activities	# Staff	Estimated FTE*
Pilot Executive Leadership	• Clinical subject matter expertise • Project strategy	2	Minimal
Clinical Champion, Project Management, and Evaluation	• Overall project leadership • Project management • Health center recruitment • Health center leadership and clinician engagement • Clinical workflow mapping • System testing • Recruitment and scheduling for training sessions and evaluation interviews • EHR data extraction • Data aggregation and validation • Administrative support	10	0.41
Design and Technical Integration	• Integration and informatics project leadership • Solution architecture design • Algorithm translation • Clinical and informatics subject matter expertise • Data and interoperability standard subject matter expertise • Integration connectivity and development • Integration and informatics support • Data integrity • Workflow expertise	12	0.70

Teams	Expertise and Activities	# Staff	Estimated FTE*
Training for ASBI CDS Apps (pilot organization and clinic site end users)	• Development and creation of training materials • Administering health center trainings • Technical assistance	3	0.29

*** FTE is based on an estimated 2080 hours for a 13-month period**

7 Technical Enhancements

In this section, we describe the technical enhancements made to the ASBI CDS tools based upon the pilot and integration activities. These enhancements are changes that were deemed to benefit other potential implementors of the CDS. Section 5 described changes made to the ASBI CDS tools needed to support the pilot with AllianceChicago but which were not general enough to include in the official ASBI CDS tools published online at GitHub[21] and CDS Connect.[22] Enhancements suggested by end users can be found in Sections 6.3.4 and 8.1.3.

7.1 Enhancements Made to the CDS Software

The athenahealth EHR required a custom parameter to be set before the ASBI CDS Tools could be launched according to the SMART standard (as described in Section 5). A third-party open-source library is leveraged to provide the ASBI CDS Tools with SMART capabilities.[15] This library required changes so that the non-SMART athenahealth authorization process could be supported. The Health FFRDC team made the required changes and submitted them back to the third-party open-source library since the changes were deemed to be useful to other projects developing SMART web apps.[16] The changes to the third-party open-source library involved adding an option to intercept the first redirect in the SMART launch sequence; this functionality allows developers to make any necessary changes to the SMART request that might be required by the EHR they are integrating with. This was how the ASBI CDS tools were connecting with the non-SMART athenahealth EHR prior to the adoption of the service account approach described in Section 5.

FHIR provides a number of data structures called "resources" which can represent different kinds of clinical information.[23] The ASBI CDS tools were originally published in 2020 and represented alcohol screening results using "QuestionnaireResponse".[24] However, "QuestionnaireResponse" was not supported by the athenahealth FHIR API. We determined that there are likely other EHR FHIR APIs that also do not support it. Therefore, the option was added to the ASBI CDS tools to allow alcohol screening results to be written back instead as a FHIR Observation resource,[25] which was supported by the athenahealth FHIR API. This issue is

[21] https://github.com/asbi-cds-tools

[22] https://cds.ahrq.gov/

[23] https://www.hl7.org/fhir/resourcelist.html

[24] https://www.hl7.org/fhir/questionnaireresponse.html

[25] https://www.hl7.org/fhir/observation.html

different from the one described in Section 5, where the Qvera service was used to allow a more streamlined writeback of alcohol screening results to the EHR. The customization described here involves a more general writeback change involving the type of FHIR resource that was used to represent the alcohol screening results. Other implementors will now be able to select which resource to use when integrating the ASBI CDS tools into their systems.

Additional changes to the ASBI CDS tools focused on their visual appearance and functionality when presented to the user. The screening app previously presented a single alcohol screening question at a time; when a user responded to the presented question, it would disappear, and the next question would appear. Feedback from prospective end users leading up to the pilot indicated that it would be more useful to keep previous questions and responses on the same screen while the AUDIT was being filled out. This change required updates to the interoperable representation of the AUDIT that uses a FHIR Questionnaire resource.[26] It also required changes to an open-source software library that had been developed to support the ASBI CDS tools and the pilot.[27]

Another visual change to the screening app involved replacing the radio buttons used for the response selection with more traditional looking buttons. This was done based upon feedback from prospective users and to align with the updated design described in Section 4. Care was taken to ensure that the screening app remained accessible to end users using a keyboard to navigate the AUDIT questions. Previously, when a user completed the alcohol screening questionnaire, a very basic message would display; in preparation for the pilot the team enhanced this message to inform the end user they could close the window.

The intervention app received extensive updates based upon clinical feedback received during the integration phase of the pilot. These revisions are described in Section 4 and include having both clinician-facing instructions as well as information that can be reviewed with the patient. The team also added informative graphics and tables, which previously had not been included in the brief intervention content. The final updated CDS brief intervention text is available in the *Alcohol Brief Intervention and Referral* implementation guide.

7.2 Enhancements to Clinical Concept Definitions

The clinical concepts used by the CDS tools were specified using standard definitions (e.g., FHIR resources and attributes, value set(s), and terminology codes) to enable interoperability of the CDS. As described in Section 6.1, during the pilot implementation and testing, Health FFRDC and AllianceChicago identified several issues in the clinical concept definitions that required the following adjustments:

1. **“Sex at Birth”, i.e., birth sex**

   - This clinical concept enhancement involves how the CDS determines the sex of the patient based upon data recorded in their electronic medical record. Previously, the CDS logic examined the FHIR Patient resource,[28] checking first for the U.S. Core Birth Sex

[26] https://www.hl7.org/fhir/questionnaire.html

[27] https://github.com/asbi-cds-tools/questionnaire-to-survey

[28] https://www.hl7.org/fhir/patient.html

extension[29] and then for the Patient gender element.[30] However, it was determined that at AllianceChicago this information is most typically contained in a FHIR Observation with the appropriate code. The CDS logic was updated to also look for these Observations when trying to determine the sex at birth of the patient.

2. Hysterectomy Value Set Definition

- Health FFRDC did not include ICD-10-CM (diagnosis codes) in the original value set representing "Hysterectomy," only ICD-10-PCS (procedure codes) and SNOMED-CT codes. However, AllianceChicago's process of documenting the history of a hysterectomy involved using 2 ICD-10-CM codes, so these two codes were added to the existing Value Set.

8 Pilot Findings and Lessons Learned

This section discusses the results of both the quantitative and qualitative data analyses related to the use of the CDS tools during the pilot. Integrating the findings from both analyses allowed the teams to gather new insights that supported assessment activities, informed data interpretation, and helped characterize user experience and usage of the CDS apps.

8.1 Qualitative Data Analysis

Qualitative data were gathered to understand the end user's experience with the CDS and add context for the quantitative data analysis. The qualitative data collected was both informal feedback from end users during the active pilot period and formal feedback at the end of the pilot. The Health FFRDC team collected formal feedback through guided discussions around usability and user acceptance with nine end users. The specific goals of these interviews were to better understand the usability and perceived effectiveness of the implemented CDS and identify end user recommendations for enhancements.

8.1.1 Process

During the pilot, the project's clinical champion shared informal feedback, both written and verbal, with the Health FFRDC team. The feedback shared included not only the champion's personal impressions but also those offered by medical assistants and clinicians across practice locations.

The Health FFRDC team worked with AllianceChicago and CDC to identify discussion topics of interest to the project, and from there, interview questions to probe these topics. The teams developed questions to explore use of the tool in terms of design and content, end user and patient acceptance, and comfort with the screening during the pilot. They created separate interview scripts for both the screener and brief intervention app. Scripts were piloted with both Health FFRDC team members and CDC clinical subject matter experts to refine their length and language. See Appendix D for the interview scripts.

[29] http://hl7.org/fhir/us/core/StructureDefinition-us-core-birthsex.html

[30] https://www.hl7.org/fhir/patient-definitions.html#Patient.gender

AllianceChicago provided the Health FFRDC team with a pool of 46 target users who had either attended training, demonstrated usage of the tools during the pilot period, or had relevant experience with screeners. Sampling criteria considered for interviewees included role, training status, practice site(s), site type (i.e., if integrated care setting) tool usage, and medical assistant-clinician pairs (i.e., a medical assistant and the clinician they regularly support) if available. Health FFRDC applied their sampling criteria across the pool to identify a targeted recruitment list for three screener interviews and six brief intervention interviews. The number of total interviews was limited to nine to comply with The Paperwork Reduction Act of 1995. AllianceChicago sent email requests for participation and the Health FFRDC team scheduled interviews with those who expressed interest.

8.1.1.1 Selected Interviewees and Analysis Approach

The final interviewees consisted of three medical assistants and six clinicians, three of whom were family nurse practitioners, and three who were physicians. This sample contained two medical assistant-clinician dyads who work together in clinic. Interviewees represented five out of the seven targeted sites that took part in the pilot. Of the nine interviewees, seven used the CDS tools at clinics providing primary care, while two used the tools in an integrated care setting and/or a setting with a substance use disorder treatment program. Four of the interviewees regularly provided care for patient populations with alcohol use disorder or substance use disorders.

At the end of the pilot, 30-minute interviews were conducted via Microsoft Teams video conferencing by a Health FFRDC team consisting of two interviewers and a primary notetaker. The team obtained participant consent prior to the interview session and confirmed it again at the start of the discussion. The interview team debriefed at the conclusion of each interview to identify and document emerging themes, findings, or any areas for further exploration. AllianceChicago provided a gift card to each participant as compensation for their time.

Reported use of the CDS content (e.g., information displayed in pop-up windows once CDS tool was triggered) among all interviewees during the pilot period was mixed. Of the three screening interviews, all interviewees screened patients with the screening app regularly during the period. Of the brief intervention interviews, three shared they did not use the brief intervention app content during the pilot period. Yet these three interviewees, on their review either prior to interview session or within the session itself, commented on its value and their desire to integrate this content more frequently into their work. Feedback from all interviewees is integrated in the finding below.

Along with the debrief sessions, analysis consisted of basic qualitative coding of the compiled interview notes by one team member along the sampling criteria, interview topics, and emergent themes. A second team member reviewed these results. Given the intent and timeline of the project, and the short duration of interviews, formal content analysis was not conducted by the team. Team members reviewed compiled notes for discussion, agreement, and identification of additional categories and findings. Categorizations and coded excerpts formed the basis of results. User stories (see Section 8.2.3 for description) were generated to describe results and further communicate findings and recommendations, as appropriate.

8.1.2 Qualitative Interview Findings

8.1.2.1 Use of Applications During Pilot Period

As designed, the screening app was expected to be used by medical assistants while rooming patients, with clinicians regularly using the brief intervention app when indicated by screening results. Medical assistants interviewed reported regular use of the screener on all eligible patients when the 'AUDIT' button was present, one reporting use as recently as the day of the interview. Another characterized the screener as something they used on all long-term established and preventive care visits. The integration of the screener within the Care Gap Manager dashboard aligned with the medical assistant workflow while rooming a patient. As each screener was completed, its trigger button would change from red to green and creating a quick way to scan for remaining work. As one medical assistant described their work, they were motivated to "turn the Care Gap Manager (the dashboard) green" for each rooming.

> *"I love that it's in Care Gap Manager, it's a one stop shop. We go right through it. I love where it is because it's right near the smoking and drugs questions. Works well because I'm just going through the flow of asking questions." – Medical Assistant*

Medical assistants interviewed did not feel using the screening app took any more time than the previous way of screening conducted with the EHR. Early career medical assistants found the CDS screening app helpful, easy to administer, and liked how it guided them through the process of screening for alcohol use.

Clinician-reported brief intervention use was mixed, with two clinicians reporting no regular use during the pilot period, two using the screening app instead, and two using both the screening and brief intervention app together. Clinicians with no to low use cited reasons as only low screening scores displaying (i.e., no red "Interventions" alerts), other visit priorities, and a potential mismatch with their current notes-based intervention workflow. Some clinicians reported that they did not open Care Gap Manager while documenting their notes, and that accessing the ASBI apps would therefore be a disruption to their normal workflow. Two clinicians reported no regular use of the brief intervention content, one citing the reluctance of their medical assistant to address the screening topic, and another choosing to do their own screening but then changing to their preferred notes-based brief intervention workflow to document the discussion.

> *"We tend to be creatures of habit with the EHR. They have been pushing Care Gap Manager, but it's just one more thing to click when you're seeing so many patients, so I don't always look at it." – Clinician*

Two clinicians who regularly saw a population with alcohol or substance use disorders reported they used both the screening app and brief intervention app during the pilot. These clinicians both found the screening and brief intervention app helpful and did not note any workflow or time issues with their use.

The impact of current care team practices was suggested as having an impact on if and how screenings or brief interventions were done. These differing care team practices prioritized anxiety and depression screenings due to the pandemic, leaving less time for additional screenings.

8.1.2.2 Feedback on the Screening Application

Interviews revealed two use cases for the screening app during the pilot. The first use case, as designed, was for medical assistants, when indicated by the 'AUDIT" button, to use during intake, with the results informing a primary care clinician if a brief intervention was recommended. A variation of this occurred when clinicians used the screening app themselves, in cases where time constraints, visit priorities, or comfort level with screening content had prevented a medical assistant from completing the tool. The second use case that emerged was the screening app being intentionally invoked by a clinician, knowing that it would begin a conversation around drinking with their patients. Time constraints, visit priority, and comfort level with screening content were different in this second use case, and feedback here was very positive, with the standard drink size graphic and objectivity of the tool being of value for the clinician. In this second use case, the screening may even be functioning as the first half of an intervention. Given this difference, the following sections focus on feedback given on the first use case.

Medical assistants interviewed did not find it uncomfortable asking the screening questions, though for patients with a low-risk score who had to fill out the full AUDIT, having to answer all the questions was perceived as confusing or annoying. A suggestion was made to allow the clinician to skip questions, with the ability to indicate reason (e.g., low-risk drinking, past AUD). Similarly, one interviewee asked if there was a way to submit a partial AUDIT when time, workflow, or patient reaction did not allow for a full AUDIT. Yet overall, medical assistants interviewed liked having the prompts and structure for when a patient did drink.

Interviewees liked the standard drink size graphic and considered it a good visual feature of the screener. It was helpful in educating both app users and patients around what constitutes an alcoholic drink and standard drink sizes.

> *"I was impressed, (the standard drink graphic) taught me something. That opened my eyes to how to measure patient's drinking. It helped to categorize the drinking, it was another way to look at things, other than just saying 'It's alcohol.'" – Medical Assistant*

Even when a patient might not be able to read, the graphics helped in communicating drink types. More than one user commented on experiencing patient pushback on being asked about beer and wine drinking, since some patients only considered drinking problems to be associated with drinking hard liquor. And for those patients who did drink liquor or mixed drinks, it was equally useful in discussing numbers of drinks.

> *"I did like the visuals of drink sizes because many people don't know what drinks are - if they fill the cup full of whiskey, it's not just one drink." – Clinician*

There was feedback on translating patient responses to screener questions into the available responses in the screening app. When a patient responded with "sometimes" or "only at a party" there was difficulty in translating that to the response options for some users. An interviewee gave example of a patient response of "I drink a lot on beer on the weekend" being followed up with a conversation that "felt like pulling teeth" to get more specific information to map to input. The lived experience of the patients, as discussed with the medical assistant, were sometimes hard to accurately translate to the needed input. Though a known issue with measuring alcohol use, and one that might be addressed with trainings around specific screeners, it might also be an opportunity to explore with future screening app development.

One clinician remarked on having the screening app available on a portable device or paper for the patient to self-administer. They noted self-administration does offer privacy that some patients might need to answer most truthfully, but it also creates an opportunity for the patient to make their own realizations about their drinking behavior as they come to understand what a standard drink size is. This self-realization could help in behavior change. Another clinician remarked that patient self-administration could help alleviate the time pressure they felt in using the screener during a limited visit window, since current design did not offer flexibility to exit from the screener once it was activated.

8.1.2.3 Objectivity Provided by the Applications

Clinicians reported that the objectivity provided by the brief intervention app was helpful for what even experienced interventionists considered an uncomfortable and challenging conversation with patients.

> *"Mostly the brief interventions are people in the yellow zone [on triangle], and those are the folks where it's difficult to talk to them. They're like 'I only drink on the weekend' and I'm like that's a binge and that's the problem. The tool would give me things to back me up when I'm talking to these patients." – Clinician*

One clinician noted how the tool helped them overcome any uncertainty around the need to have a discussion around alcohol use.

> *"Alcohol use is more socially acceptable, it's recreational, it's legal, and less shame around. It's a harder conversation; opioids are an easier conversation. (With alcohol) I'll sometimes wonder if they actually have a problem. I can convince myself that there isn't a problem here, based on their responses. But seeing it objectively on the screen, made me more comfortable to say that there is indeed a problem, and talk about it." – Clinician*

The value of objectivity was reported by another clinician. They noted that the patient perceived objectivity of the screening app could be useful in working through potentially difficult interactions around the topic.

> *"Speaking for my MA, I think it makes it easy for a non-clinician to just step through them. From my perspective as a patient, seeing that they are asking a script of questions with a natural progression seems less awkward than just pulling random questions off the top of your head. I like the AUDIT questions from that standpoint." – Clinician*

This sentiment was supported by medical assistants who shared that "sometimes tough questions need to be asked" to provide care and the screening app helps structure and facilitate that until a relationship with patients can be established.

8.1.2.4 Customization of the Brief Intervention: Visualizations and Patient Responses

Clinicians universally praised having the standard drink size graphics and the customized risk triangle available within the brief intervention app. As one interviewee spontaneously and enthusiastically exclaimed on the topic of the brief intervention app, "The graphics were clutch!" meaning they considered the graphics vital and effective. Most clinicians commented on how

useful the customized risk triangle was, or would be, during a brief intervention or in communicating screening results in a way that was easy to understand. One clinician described how they might use it to structure a conversation around how changing drinking behaviors moves a patient "Your Drinking" arrow up or down the risk levels.

The low-risk drinking levels graphic was found confusing to end users. Initially the comparison between a patient's calculated drinking levels and low-risk drinking levels were displayed as a table. Mid-pilot, the format was updated to present the same comparison as two cards with updated labeling. Some clinicians reported having trouble quickly understanding how to talk through the table and the cards. It was also confusing for patients who may have stopped drinking, but whose responses to questions about their past made them high-risk scorers.

When used, the text capturing the patient's responses to the screening questions was helpful for guiding conversation, but if used by the same clinician who also did the screening, was reported to have felt cumbersome to repeat this content again.

One clinician suggested that future iterations of the brief intervention remove even more textual content from the layout, and only display a minimal amount of response information along with the graphics. They would like the content that they can scan quickly and decide whether to discuss further with the patient.

8.1.2.5 Prompts and Guidance in Conducting a Brief Intervention

There was little to no mention of the language around guidance, steps in the intervention, or the conversational prompts that surrounded the customized information or graphics. This may be due to the lack of regular use of the brief intervention as well as the experience of the clinicians interviewed in conducting a brief intervention. One clinician suggested information about motivational interviewing be included.

8.1.2.6 Sharing Patient Education Resources and Printing

Most clinicians reported not using or even reviewing the educational links provided under this section. The clinician who did use them liked them because it meant they did not have to go to another window to find that information.

Multiple clinicians requested the ability to print the brief intervention information customized for the patient. Whereas early static designs included a generic printing feature, that functionality was not able to be customized prior to go-live dates and was removed. Mid-pilot feedback as well as post-pilot feedback suggests that a single page, printed handout, consisting of the patient responses, customized graphics, standard drink sizes and education links, would be very helpful to use during the discussion or give to a patient to reference later. Being able to provide the patient with a printout of information that they can review later would be especially helpful when clinicians must prioritize competing health concerns during a visit.

> *"If it [drinking] is not something they came in for, then there are other things I need to cover in the visit. Talking about it would take too much time during the visit. Printing it [the brief intervention] would give information to hand to them." – Clinician*

This clinician who did not use the brief intervention app regularly during the pilot agreed that providing printed patient resources might overcome their reluctance to change their workflow

and interact with Care Gap Manager, but it would not overcome the challenge of having limited time within a visit.

8.1.2.7 Use of Applications During Telehealth Visits

Though not designed specifically for the online experience, given the rise of telehealth visits during the pandemic, there was interest in knowing if the CDS apps were used during a telehealth visit. The screen app was reported having been used by medical assistants and a clinician who were doing telehealth visits. Beyond a single visit, the brief intervention was not reported to have been used regularly during telehealth visits.

8.1.2.8 Screensharing of the Applications

Two interviewees reported showing patients their computer screen to share the graphics contained in the two apps. One medical assistant reported using the risk zone triangle to communicate screening results, and one clinician reported using the standard drink sizes, risk zone triangle, and patient responses during their alcohol discussion with patients.

8.1.2.9 Interest in Using Applications After the Pilot Period

Seven interviewees were directly asked whether they would continue to use the tools if they were available after the pilot period, and all seven said they would. Six interviewees indicated a desire to continue using the screening app for either themselves or their medical assistants. Four clinicians said they would like to use the brief intervention app, but one with the caveat they would like additional? training and to learn how other clinicians are using it within their own workflows. One clinician would like their medical assistant to start using the screening app but said that they would not likely change their workflow to access Care Gap Manager to use the brief intervention app.

8.1.3 End User Recommendations

Besides feedback for enhanced usability (e.g., embedding tools directly within the main EHR window to avoid pop-up window), end users shared additional enhancements and suggestions for improvement of the implemented CDS apps. These recommendations address concerns with the use of the apps in addition to envisioning new features for future iterations. User stories have been written to capture this feedback.

User stories[31] are a method of establishing system requirements by creating an high-level description of a software feature written from an end-user perspective that captures its function and value. Taking the form, *"As a* ***<end user/persona>****, I want* ***<intent/some goal>,*** *so that* ***< reason>"*** they help to focus development discussions on the end user and their needs. It is not meant to be the complete description of the feature, but a starting point for planning discussions. They can communicate the results of interviews, focus groups, and user testing sessions in a way that can be easily interpreted by software development teams while also being accessible to product managers, stakeholders, or those unfamiliar with the technology.

[31] https://www.atlassian.com/agile/project-management/user-stories

Auto population of the screening results into other areas of the EHR

- *As a clinician, I want a quick way to associate a high screening result with the patient's problem list. I think this type of integration might lead to more clinician follow-up since a diagnosis/problem could spur other clinicians to address drinking behavior in their visit.*
- *As a clinician, I want my high-risk screening results to automatically add a referral to behavioral health services. This could help lead to increased follow-up by patients.*
- *As a clinician who has a notes-based workflow within EHR and is very comfortable with conducting brief interventions, I want my notes to be automatically updated with the screening app AUDIT score so that I can keep my visit within my documentation workflow.*

Information from patient record customizing the brief intervention app

- *As a clinician conducting a brief intervention, it would be helpful if patient's co-morbidities were included as part of the customization around "Providing education on when to avoid drinking alcohol." Identifying how uncontrolled hypertension or diabetes are affected by alcohol use could help lead to a more impactful conversation around changing behavior.*

Additional content for the brief intervention app

- *As a clinician conducting brief interventions, I would like impacts of risky drinking on liver and brain functions included so that the conversation around behavior change guides me from sounding judgmental. It can be fine line between providing best information for your health and sounding judgmental.*
- *As a clinician conducting brief interventions, I would like a more comprehensive list of the impacts of excessive alcohol use, like potential effects on finances or emotional health, so that I can counter pushback I get from patients who don't think they have a drinking problem just because they aren't showing overt health implications, like liver problems or cirrhosis.*
- *As a clinician who talks with patients in Zone II and Zone III regularly, I would like information on motivational interviewing included near the customized Risk Triangle so that it is readily accessible.*

Ways to share results with patients

- *As a clinician, I would like to be able to print a patient-facing version of the customized brief intervention so patients can use as a resource. This handout would also be useful when I do not have the time to complete a brief intervention or if the patient does not seem ready to discuss the topic.*

Adding support for the screening process

- *As a bilingual medical assistant, I would like to be able to access the Spanish language version of the screening questions so that the screener is as easy to administer as the English version.*
- *As a medical assistant using the screening app, I would like the option to click on a drink type on the standard drink size graphic then see questions and responses based on that selection. Digging in by drink type the patient mentions could help me get to a more accurate number and frequency.*

- *As someone using the screening app with an established patient, I would like the flexibility to skip screening questions by clicking on "one drink a year" or a "one drink a month" or "stopped drinking." It better reflects what I'm hearing and avoids the later screening questions that do not make sense with a patient who I know will screen low or has past use issues.*
- *As someone using the screening app, I would like a patient handout with the standard drink size graphic and the questions made available for me to share with the patient. This could make it easier to work through the screening questions with the patient.*

8.2 Quantitative Data Analysis

Throughout the pilot period, the Health FFRDC team and AllianceChicago collaborated to define EHR data that represented the CDS logic and could be used to measure clinician engagement with the CDS tools and impact on relevant patient outcomes. The primary questions to be explored included:

1. What is the size of the screening-eligible and pregnant patient populations, and how many are excluded based on the criteria for the CDS?
2. For eligible patients, what is the availability and completeness of the data used by the CDS logic?
3. What was the fidelity or uptake of the CDS usage?
4. How many eligible patients were screened for alcohol use before the CDS implementation and during the pilot period?
5. Of those patients who screened positive for excessive alcohol use, how many received a brief intervention before the CDS implementation and during the pilot period?

Data related to patient outcomes were extracted before the start of the pilot period and after its conclusion to conduct a pre-post pilot analysis of process-based outcomes related to the provision of alcohol screening and brief interventions. Patient outcomes data were collected at a clinic level, and counts less than 10 were suppressed to protect patient privacy. Calculations including suppressed data provide a range of potential values (i.e. assuming a value of 1 or 9). Data related to CDS uptake was collected throughout the pilot to understand the trajectory of CDS tool usage. Additional objectives included finalizing data mapping needs, potential problem areas, and adjustments needed prior to final integration of the CDS logic, and using data related to CDS tool usage to identify target users to engage with post-pilot qualitative evaluation interviews.

8.2.1 Pre-Pilot Site Implementation

One objective of the pre-pilot data analysis was to confirm that the clinical sites being considered had a sufficient number of patients that were eligible for alcohol screening based on the ASBI CDS criteria. A second objective was to understand the availability of EHR data elements that the CDS logic uses. To assess both these objectives, the Health FFRDC team developed a data requirements worksheet mapping the CDS logic to select data elements in an EHR. This worksheet included information on clinical concepts in the logic such as age, pregnancy status, alcohol screening responses, how these data are represented in the FHIR API, and relevant code sets used to represent these concepts. These concepts included terms from the Systemized Nomenclature of Medicine (SNOMED), Logical Observation Identifiers Names and Codes

(LOINC), or the International Classification of Diseases, 10th Revision (ICD-10). AllianceChicago used this worksheet to identify data elements in their EHR that could be used to implement the ASBI logic and verify whether the EHR data were adequately populated for patients seen at the pilot sites.

The initial data extract validated the existence of patient data used by the CDS logic, such as age and diagnoses for alcohol use disorder, and prompted discussions about the accurate measurement of data related to a patient's sex and pregnancy status, and documentation around the delivery of brief interventions for alcohol use. See Table 3 for data used to validate the CDS logic.

Table 3. Baseline Extract of Data to Validate Existence of Data Used by CDS Logic and Patient Volumes, November 15, 2020, Through November 14, 2021

Measure Description	Total Count	Percent of Total
Total # of patients seen in the year period	20,984	N/A
Total # of patients 18 years old or over	15,611	74.4%
Total # of patients >= 18 years old eligible for alcohol screening	15,178	72.3%
Total # of male patients between the ages of 18 – 65	5,596	26.7%
Total # of female patients between the ages of 18 – 65	8,716	41.5%
Total # of female patients currently pregnant within the last year	614	2.9%
Total # of patients with a history of alcohol use disorder	18	<1%
Total # of patients with a history of hysterectomy	135	<1%
Total # of patients screened for alcohol use	313	1.5%
Total # of patients who received a brief intervention for alcohol use	24	<1%

The teams also constructed and revised an Analytic and Evaluation Plan using these data elements to create metrics related to screening and intervention rates at the pilot sites. The full analysis consisted of a baseline extract of data gathered during the year prior to the pilot implementation (November 15, 2020 through November 14, 2021) and a pilot extract of data gathered throughout the pilot period (November 15, 2021 through February 25, 2022). Both extracts included data for all patients seen at the seven selected pilot sites. Due to the introduction of the CDS tools, metric definitions differed between the baseline and pilot extracts. Specifically, CDS tools use alcohol screening eligibility questions not in use prior to the pilot, including one related to pregnancy. These additional CDS questions changed the eligibility criteria, capturing a slightly different population of patients deemed eligible for alcohol screening or brief intervention.

8.2.2 During the Pilot

Starting in January 2022, weekly reports of EHR data were extracted to measure the uptake of the CDS apps and the trajectory of their use during the course of the pilot. To allow for the timely extraction of data and to avoid the suppression of small counts of patient-related data to

protect patient privacy, AllianceChicago created EHR-based reports extracting the number of times that buttons related to the usage of the CDS tools were clicked by MAs and/or clinicians at the pilot sites. This included the number of times that the AUDIT screening button, the brief intervention button, and the historical AUDIT score button were clicked. While these data do not measure whether an alcohol screening or brief intervention was completed using the CDS apps during a patient visit, they did provide a proxy for the MA and clinical engagement with the CDS apps.

The pilot data extracts demonstrated a consistent increase in the number of CDS app engagements (the number of clicks) over time (see Figure 10), with engagement more than doubling during the pilot period.

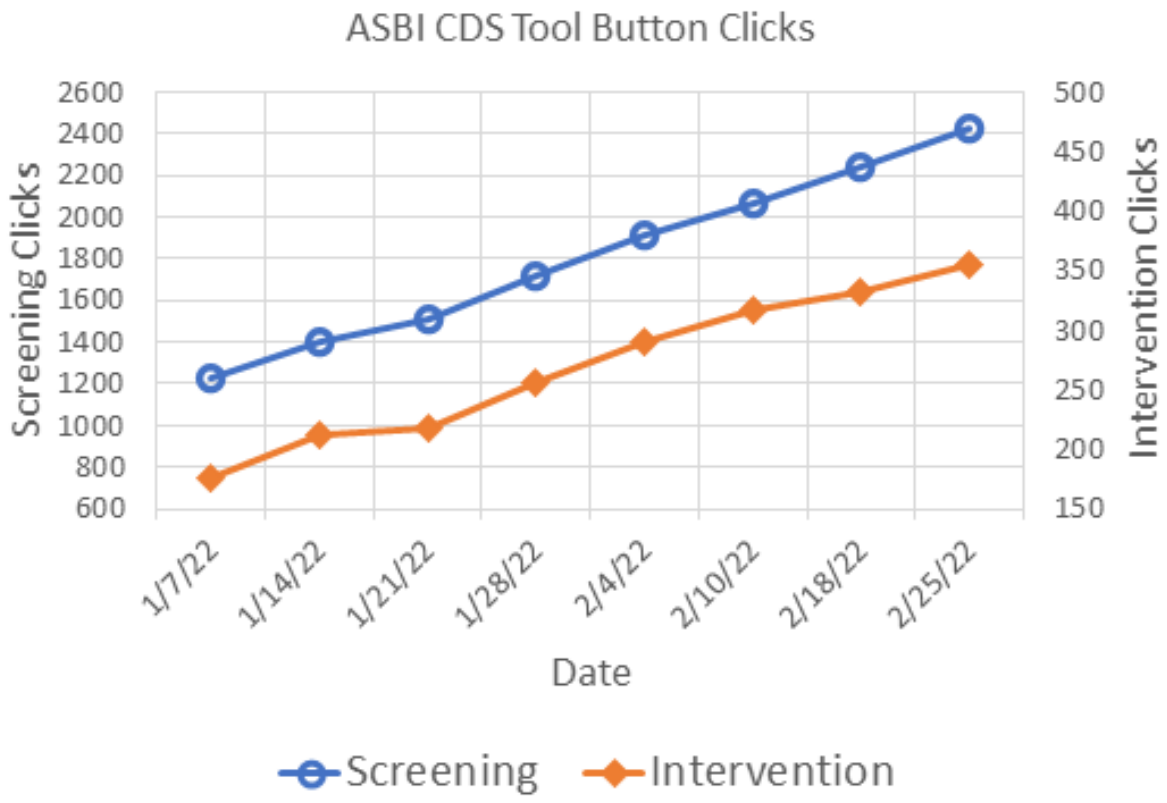


Figure 10. Cumulative ASBI CDS App Clicks Over the Pilot Period

To further inform our analysis and support the selection of MAs and clinicians for the qualitative assessment, the pilot organization extracted an expanded report of the volume of CDS app clicks toward the end of the pilot. This expanded report summarized MA- and clinician-level CDS app engagement (see Section 8.2.1 for details on interview recruitment).

8.2.3 Baseline and Pilot Data Extract Results

Compared with the documented 2.1% screening rate prior to the pilot period, 33% of patients during the pilot period completed the prescreen or full screen (i.e., had documented answers to

the alcohol prescreening question or full screening questions); this difference was statistically significant ($p<0.00001$). This increase suggests a meaningful impact of the CDS on eligible patients receiving and/or having a documented alcohol screening in the EHR. While these data suggest an increased rate of screening for alcohol use, it is possible that the increase is in part due to an increase in documentation of screenings which the CDS app reports into the EHR at the time of its completion. The CDS' impact on eligible patients receiving a brief intervention is less clear. Of the patients who were screened, there was a slight increase in the percent receiving a brief intervention during the CDS pilot period. Further, because the pre-pilot data extracts only identified patients who completed the full screen, it was important to also compare the percent of brief interventions for patients who completed a full screen (i.e., exclude patients who prescreened out). As Table 4 shows, the percent of fully screened patients receiving a brief intervention was much higher during the pilot period (from 28.5% to 29.5%) than the pre-pilot period (7.7%). Results of the baseline and pilot data extracts are in Table 4.

Table 4. Comparison of Quantitative Baseline and Pilot Data Related to Alcohol Screening and Brief Intervention

Measure Description	Baseline Count (11/15/20 – 11/14/21)	Percent	Pilot Count (11/15/21 – 02/25/22)	Percent
Measures for All Eligible Patients:				
Total patients eligible for screening (N)	15,178[a]	N/A	8,048	N/A
Eligible patients who were screened	313	2.1%	2,652	33.0%
Prescreened out (reported no alcohol usage)	N/A	--	1,855	69.9%
Completed Screen (Fully Screened)	313	2.1%	797	30.1%[b]
Screened patients (n_b=313; n_p=2,652) in Zones:				
1 and 2 (low risk)	292	93.2%	797	30.1%
3 and 4 (high risk)	21	6.7%	0	0%
Screened patients who received a brief intervention	24	7.7%	227 to 235[c]	8.6% to 8.9%[c,d]
Fully screened patients (n_b=313; n_p=797) who received a brief intervention	24	7.7%	227 to 235[c]	28.5 to 29.5%[c,d]
Measures for Pregnant Eligible Patients:				
Pregnant or plan to become pregnant	614	4.0%	320 to 328[c]	4.0% to 4.1%[c]

Measure Description	Baseline Count (11/15/20 – 11/14/21)	Percent	Pilot Count (11/15/21 – 02/25/22)	Percent
Pregnant patients who completed screening	0	0%	77	23.5% to 24.1%[c]
Screened pregnant patients (n_b=0; n_p=77) who received brief intervention	0	0%	1 to 9[c,e]	1.3% to 11.7%[c]

[a] A greater number of eligible patients were identified during the baseline period in large part because it counted the number of eligible patients across a 12-month period compared to a 4-month period during the pilot period, as well as the differing eligibility criteria.
[b] Difference is statistically significant at a level of P<0.00001
[c] At least one of the seven clinic sites had less than 10 patients. For those clinics with less than 10 patients, HHC reported a value of "<10" to preserve patient privacy. The count range reported here was calculated by replacing "<10" with "1" to estimate the lowest possible value and "9" to estimate the highest possible value.
[d] "Screened" patients were engaged in the screening process (313 at baseline, 2,652 during the pilot). "Fully screened" patients were engaged in the screening process and not prescreened out of the full AUDIT (313 at baseline since there was no prescreening question, 797 during the pilot).
[e] None of the seven clinic sites had at least 10 patients.

During the pilot period, the majority of eligible patients, 69.9%, reported that they did not drink, and all remaining eligible patients, 30.1%, scored in the low-risk Zones 1 and 2 (using the alcohol screening CDS app). Similar reported alcohol use patterns were reported during the baseline period, where almost all patients, 93.2%, completing the full screen had scores in the low-risk Zones 1 and 2. (When comparing the baseline and pilot periods eligible patients who reported they did not drink are excluded because this prescreen question was only used in the alcohol screening CDS app.) These data indicate substantially lower levels of drinking and excessive drinking behaviors among the clinic sites' patient population than the general population. According to 2020 figures from the National Survey of Drug Use and Health (NSDUH), 50% of respondents reported drinking alcohol in the past month, 22% reported binge drinking, and 6% reported heavy alcohol use.[32]

There are several potential explanations for this discrepancy between reported drinking levels of the clinic sites' eligible population and the general population. As noted in the qualitative interview data (see Section 8.2 for details), some MAs reported different levels of comfort with discussing alcohol use with patients, and respondents noted that some patients may prefer

[32] Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health*, vol. 170. 2020, pp. 51–58. Available: https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf.

answering sensitive screening questions on paper to preserve privacy. In addition, during the qualitative interviews some clinicians reported varied patient-interpretation of alcoholic beverages. Specifically, that among their patient population, some patients do not interpret these types of questions to include wine or beer consumption. Upon further investigation by the Health FFRDC team, the AllianceChicago team shared that they have found similar results with other validated screening questionnaires (e.g., depression screenings)—that is, positive screening rates for their patient population are substantially lower than expected when compared to the general population. The root causes of these meaningful differences in screening rates are being explored by AllianceChicago in a study funded by the American Medical Association (AMA).

The data related to provision of a brief intervention indicates that 7.7% of screened patients received an intervention at baseline, and that during the pilot, the intervention app was launched for an estimated 8.6% to 8.9% of patients who answered either the prescreening question or a full screen, and 28.5% to 29.5% of fully screened patients. The pilot period data, however, should be interpreted with caution since the number of intervention app button clicks is an imperfect measure of the provision of a brief intervention. Importantly, during the post-pilot evaluation interviews (see Section 8.2), the Health FFRDC team discovered that MAs had launched the intervention app during patient visits not to provide a brief intervention, but to show patients their AUDIT scores in relation to the risk zone triangle graphic. In addition, some clinicians reported using the CDS brief intervention app not based on the patient's screening results, but to facilitate a discussion about alcohol usage even for patients who were excluded from the CDS logic (e.g., an active AUD diagnosis).

The data do suggest that the CDS apps increased screening and intervention percentages (or their documentation) for patients who were pregnant or who planned to become pregnant. The baseline data indicate that no pregnant patients had a documented screen or intervention, whereas the pilot data indicated that an estimated 23.5 to 24.1% of patients who were pregnant or planning to become pregnant completed a screen, and that the intervention app was launched for 1.3 % to 11.7% of those patients. These data must be interpreted with caution, however, due to the small proportion of pregnant patients who had clinical encounters at pilot sites during the pilot period.

9 Post-Pilot Plans for the CDS at Clinic Sites

During the pilot, the Health FFRDC and AllianceChicago teams worked with HHC leadership to determine whether to continue usage of the tools after the pilot period. Ultimately, HHC leadership decided to discontinue use of the CDS tools several months after the conclusion of the pilot period. This decision was based on several considerations, including the cost of maintaining the CDS apps and the challenges posed by the unresolved disruption in workflow and usability considerations reported by end users. In addition, consideration was given to the unrealized value of the tools given the low brief intervention uptake, and potential plans for future changes to HHC's health IT infrastructure.

While the CDS implementation guides for the WHO AUDIT screening and brief intervention tools are available for free on the CDS Connect website and require no licensing to use, and the code for the apps is available on GitHub, substantial resources are needed. This includes resources to maintain the code within the EHR environment and support its operation over time.

The major factors that drove HHC leadership decision to discontinue use of the CDS apps were:

1. Feedback from end users that the integration with Care Gap Manager was not seamless.
2. Lack of utilization of the brief intervention app, despite a reported high regard for the content.
3. The costs associated with maintaining an interface engine license to facilitate communication between the CDS apps and the EHR.
4. Lack of resources to perform ongoing maintenance activities.
5. Timing considerations related to future plans to implement new health IT technologies.

10 Key Lessons Learned and Future Recommendations

Throughout the planning and execution of the pilot important data and feedback were gathered that can inform future implementors of the ASBI CDS tools. The CDC, Health FFRDC, and AllianceChicago teams collaborated to distill this information into key lessons learned and recommendations. The lessons learned and recommendations seek to guide future CDS implementation, provide suggestions for enhancements to the ASBI CDS tools, and inform related research. Grouped by the pilot objectives (see Section 1.2), this section describes these key lessons learned and recommendations.

10.1 Demonstrate Success of CDS Integration with Health IT

10.1.1 Implementing Innovative CDS Tools Is Feasible

This pilot project demonstrated the feasibility of integrating standards-based, interoperable ASBI CDS tools into an EHR. It is notable that the integration and implementation of the CDS tools occurred during a public health emergency and within a short pilot period.
Recommendation: Future projects should aim to use health IT to support clinical ASBI workflows and make extensive use of the implementation guides and associated technologies to create innovative and cutting-edge tools.

10.1.2 Integration and Maintenance of CDS Can Require Substantial Resources

Although the CDS tools are based on current standards to facilitate interoperability with disparate health IT systems, they are not "plug-and-play" apps. Implementation may require substantial effort to harmonize standardized data elements between systems and support communication with local EHRs, including commercial EHR systems. Resources and costs associated with the CDS integration and its sustainability may include:

- Capabilities and staffing resources, including understanding of FHIR standards, standard clinical terminologies, local coding practices, competing health IT priorities, and management and coordination of integration activities.
- EHR systems and third-party proprietary tools or solutions, including:
  - FHIR standard version embedded in tool.
  - Options to resolve potential misalignments with planned CDS integration.
  - Costs associated with updates or proprietary solutions, including licensing fees.
- Existing EHR data extraction and report writing infrastructure that can be leveraged to extract patient and clinician data to evaluate CDS usage over time.

Recommendation: Conduct careful assessments of technical readiness, need for third-party tools, staff expertise, ongoing or upcoming health IT priorities, and project

management/coordination readiness to inform resource and timeline planning for the CDS implementation.

10.1.3 A Successful, Multi-Disciplinary Team Is Engaged With Executive and Clinical Leadership

A multi-disciplinary team dedicated to the success of the CDS implementation is critical. A successful team requires executive-level ownership, clinical leadership, relevant clinical practice experience, health IT technical expertise, software design expertise, and project monitoring, evaluation, and management expertise. Strong leadership is necessary to implement and sustain an effort that not only impacts an organization's IT and EHR systems, but the clinical workflow as well. Domain-specific clinical expertise and clinical staff end user engagement may bolster motivation and the understanding of the value-add for end-users.

Recommendation: Engage influential executive and clinical leadership (clinical champion and clinical domain expertise) throughout CDS implementation to secure adequate resources and motivate CDS app uptake.
Recommendation: Include technical staff who know domain-specific interoperability and health data standards, or if needed, plan adequate time to train existing staff in these areas during implementation.

10.2 Use of ASBI CDS Improved Alcohol Screening in the Primary Care Setting

10.2.1 CDS Improved Documented Screenings Among Eligible Patients but Brief Intervention Use Remains Uncertain

From pre- to post-pilot, there was statistically significant increase in the percent of eligible patients who received an alcohol screening using the CDS app. The data also suggested an increase in the precent of pregnant patients who were screened for alcohol use using the CDS, though the small number of pregnant patients did not allow for the detection of statistical significance. Findings for the brief intervention were mixed, mainly due to unresolved workflow disruption which minimized uptake.

Recommendation: Continue to assess and validate the use of the alcohol screening CDS among primary care patients, including those who are pregnant.

Recommendation: Resolve workflow and other barriers associated with the brief intervention CDS and assess the use of the brief intervention CDS.

10.2.2 There Is "Off-Label" Use of CDS Apps

Off-label uses (i.e., uses not part of the underlying clinical logic) of the CDS app were reported by clinical staff and clinician end users. This included using the customized graphics to share screening results with the patient without conducting the brief intervention, and using the brief intervention content to bolster alcohol use discussions with patients excluded by the CDS tool

(e.g., those who have an active AUD diagnosis). The relevance or value-add of these off-label uses were not assessed during the CDS app design, or as part of the pilot assessment.

Recommendation: Anticipate and track off-label uses of the CDS content for the purposes of measuring impact, which can be valuable to decisions to sustain the CDS, future CDS efforts, and to clinical staff and clinicians.

10.3 Facilitating a Successful CDS Implementation

10.3.1 Understanding Clinical Workflow Is Critical for CDS Uptake

The disruption in workflow created barriers, with varying degrees, for both the screening and brief intervention CDS apps. For the screening app, the lack of skip, save, or print options for the screening questionnaire led to lower uptake or completion. For the brief intervention CDS app, the location of the app in the EHR did not meet the clinician's needs. These barriers were exasperated by the amount of time allotted for a patient visit and competing clinical and patient priorities.

Recommendation: Engage the clinical staff and clinician end users early and often; be responsive to their input and do not underestimate their perceived disruption in workflow. During the CDS app design phase, capture existing workflow issues, and test various app design features with the end users, including features that minimize the time it takes to use, or allow for varied workflows.

Recommendation: During the CDS app implementation, consider rapid-cycle implementation (or similar) strategies to assess the implementation of CDS apps and make adjustments to the CDS apps or workflow accordingly. Rapid-cycle implementation is a quality improvement approach that allows for the identification and implementation of solutions to barriers for a process or a system. Solutions are tested and measured with the goal of improvement.

Recommendation: Develop and validate alternative CDS design features or workflows, including patient-administered screenings within and outside of the clinical setting, or patient-facing brief interventions content that can be administered before, after, or as a supplement to the patient's time with the clinician. These alternatives should be designed to meet the specific needs of the patient population being served.

10.3.2 A Comprehensive Training Approach Is Necessary for Success

Training focused solely on the CDS functions and EHR workflows is necessary but not adequate. It is equally critical to motivate clinical staff and illustrate the value-add of the CDS apps for them and their patients.

Recommendation: Use the CDC *Planning and Implementing Screening and Brief Intervention for Risky Alcohol Use: A Step-by-Step Guide for Primary Care Practices* or other available tools as a resource. For example, include an orientation during training that discusses the full spectrum

of alcohol use behaviors, train MAs about how to approach alcohol use issues with patients, and use demonstrations to illustrate how to conduct a brief intervention.[4]

Recommendation: Ensure training provides important background that is meaningful to the end users. For example, why alcohol screening is so important, what we know about drinking behaviors in the general or patient population, and evidence on the effectiveness of the brief intervention.

Recommendation: Provide booster trainings, reminders, motivators, and feedback to end users to encourage increased engagement with the CDS tools.

10.3.3 Use Data to Track and Monitor CDS Implementation

It is important to track the uptake and fidelity of the CDS app implementation. Both qualitative and quantitative inputs help inform whether the CDS app uptake is as expected and whether the CDS app is being used appropriately. Quantitative and qualitative monitoring should uncover specific problem spots with technical integration or clinical workflow and inform improvements or enhancements.

Recommendation: Solicit both formal and informal feedback on the CDS during implementation to provide valuable information on the user experience with the objective to take action.

Recommendation: Extract EHR data early and on a regular basis to track CDS app utilization at the individual end user level, monitor for unexpected usage patterns and system errors with the objective to take action.

11 Conclusion

The pilot implementation achieved its goal of designing, refining, and verifying the successful integration of the two ASBI CDS tools into the pilot sites' health IT. The ASBI CDS tools available on CDS Connect provide several alcohol screening instruments and brief intervention decision aids based upon evidence-based guidance and implemented using the health IT interoperability standards required by the 21st Century Cures Act Final Rule. Further, while most interoperable CDS provide "read only" access to the EHR, the ASBI CDS requires bidirectional data access with the EHR so that the alcohol screening responses are captured by the tool and used to inform a patient-specific customized brief intervention discussion with the patient.

While it was decided not to sustain the ASBI CDS apps, this decision was primarily driven by resource capabilities for ongoing IT support and to address the disruption on the existing clinical workflow. While these challenges could not be adequately resolved in the pilot, it is important to note that the CDS content and content-display were regarded highly by the medical assistants and clinicians, which led to some off-label uses. End user clinicians shared that the lack in the brief intervention CDS uptake was primarily due to unaddressed workflow disruption, including the limited amount of time they have with a patient to address an increasing number of patient priorities during their primary care visit.

Importantly, this pilot demonstrated that the integration of the ASBI CDS tools into a commercial EHR is feasible, paving the way for person-centered, real-time customized clinical support decision for CDS tools. The fact that the ASBI CDS tools have now been pilot tested means other organizations can integrate and use them with greater confidence in the robust capabilities they provide.

Appendix A

A.1 Pilot Organization Ideal Characteristics

The **pilot organization** has the organizational commitment and operational resources to meet pilot needs before, during, and after implementation, including:

1. Availability and ongoing support of executive leadership, clinical, operational, and technical staff
    a. Commitment of designated point(s) of contact for technical, clinical, and operational domains
2. Identification of a clinical champion to engage with the pilot team and support clinicians in their use of the CDS
3. Ability of pilot organization staff to provide consultation on the pilot CDS and its placement into the user workflow
    a. This includes the provision of clinical/user workflow materials and/or guidance on the integration of the pilot CDS into the clinical site workflow
4. Ability to perform site-based training on use of the CDS and support scheduling of training sessions, as needed
5. Ability to provide coordination and secure final approval with their IRB
6. Commitment to provide ongoing support of the clinical site throughout the pilot timeframe (e.g., troubleshooting nontechnical issues and concerns, providing additional training if needed)

A.2 Clinical Site Ideal Characteristics

1. Ambulatory practice in an appropriate medical specialty (e.g., Internal Medicine, Family Medicine, Obstetrics-Gynecology)
2. Patient population that includes, at a minimum, people who can become pregnant as well as people who are currently pregnant
3. Demonstrated need and desire for the pilot CDS (i.e., CDS that facilitates the ability to screen adults 18 years and older for excessive alcohol consumption, and provides a brief intervention when indicated)
4. Additional criteria developed by the Health FFRDC team with CDC's input and approval, to aid in the evaluation of potential clinical sites:
    a. Percentage of patient population by age group
    b. Percentage of patient population that is female
    c. Percentage of patient population that is pregnant
    d. History of implementing behavioral screenings and interventions (e.g., depression screening)

A.3 Technical Requirements and Capabilities

5. The EHR or health IT product to be integrated with is preferably one of the more common systems (e.g., Cerner, Epic, Nextgen) so that integration efforts and lessons learned can benefit a greater number of organizations
6. The EHR/health IT product supports the following technical standards and capabilities:
    a. HL7 FHIR API for accessing patient data
    b. FHIR release #4 (ideally)
    c. SMART on FHIR standard for authorizing and launching third-party apps and allowing write-back of data to the EHR/health IT system
    d. CDS Hooks standard for triggering and receiving CDS suggestions
    e. HL7 Clinical Quality Language for the purposes of executing CDS logic
7. The required structured data are captured in the EHR/health IT system:
    a. Clinical concepts are represented using standard terminologies, and the pilot organization has a well-understood process for mapping concepts when necessary and has experience with the Value Set Authority Center
8. Technical staff are capable of performing custom integrations, APIs, and/or data mapping
9. Testing resources are capable of writing and executing a test plan
10. Analysts are proficient in business intelligence, reporting, and analytics

Appendix B Analytic Data Measures

Data Extracted Before "Live" Pilot Use

- Percentage and number of patient population by age group as compared with total patient population:
  1. Total patients <18 years
  2. Total patients ≥18 years
  3. Number of Male patients 18–65 years, and percent as compared to #2
  4. Number of Male patients >65 years, and percent as compared to #2
  5. Number of Female patients 18 years and older, and percent as compared to #2
  6. Number of Female patients >65, and percent as compared to #2
- Percentage and number of patients that are female and within reproductive age (18 – 49) as compared with total patient population 18 years and older
- Percentage and number of patients that are currently pregnant, as compared with total patient population 18 years and older
- Percent of patients that meet the inclusion and not the exclusion criteria for the alcohol screening CDS compared with total patient population 18 years and older
- Queries to evaluate data element coverage (e.g., number of patients with documented history of: alcohol use disorder; hysterectomy; current [active] pregnancy)

Data Extracted During the "Live" Pilot to Answer the Following Questions

1. Are the CDS tools being triggered as expected?
2. Is the alcohol screening AUDIT questionnaire being completed?
3. Are clinicians receiving brief intervention recommendations from the CDS?
4. Are these brief interventions being documented in the EHR?
5. Are patients being referred to evaluation and treatment as a result of the CDS recommendation?
6. What is the comparison between the opportunity for an alcohol screening versus the actual rate of alcohol screening?

Data Extracted Before and After the "Live" Pilot Period

1. Prior to CDS Implementation (measure period – last 12 months)
   - Number and percent of patients screened for alcohol use
     - Denominator - the number of patients 18 years and older that are eligible for alcohol screening, based on an appropriate encounter type
   - Number and percent of patients whose alcohol screening score are in each "Zone"
     - Denominator - the number of patients 18 years and older that were screened for alcohol use

  - Number and percent of patients receiving a brief intervention
    - Denominator - the number of patients 18 years and older that were screened for alcohol use and determined to need a brief intervention
  - Number and percent of patients referred to behavioral health for evaluation and treatment for alcohol use disorder, both:
    - As a result of a referral from the CDS (post CDS implementation)
    - Overall rates of referral

- After CDS Implementation (During and After Live Pilot Use)
  - Number and percent of patients screened for alcohol use using the CDS
    - Denominator - the number of patients 18 years and older that were eligible for alcohol screening using the CDS tool
  - Number and percent of patients whose alcohol screening score are in each "Zone"
    - Denominator - the number of patients screened for alcohol use using the CDS
  - Number and percent of patients who were recommended for a brief intervention by the CDS
    - Denominator - the number of patients screened for alcohol use using the CDS tool and triggered the brief intervention CDS
  - Number and percent of patients who received a brief intervention for alcohol use
    - Denominator - the number of patients screened for alcohol use using the CDS and triggered the brief intervention CDS.
  - Number and percent of patients triggering a referral for evaluation and treatment.
    - Numerator - the number of patients for whom a referral for evaluation and treatment was recommended
    - Denominator - the number of patients 18 years and older that were screened for alcohol use
  - Number and percent of patients referred for evaluation and treatment.
    - Numerator - the number and percent of patients who were actually referred
    - Denominator - the number of patients 18 years and older that were screened for alcohol use for whom a referral for evaluation and treatment was recommended by the CDS

Appendix C

C.1 Alerting Scenarios

Table 5. Alerting Scenarios

Alerting Scenario	Design Description
Interaction Alert	Add a yellow triangular alert similar to current "Interaction" warning in upper left of panel of EHR.
Forms Alert	Change the font or appearance (e.g., append an asterisk) of a new ASBI "Audit" form in the Forms panel.
Automatic Alert	Automatically display the screener to the medical assistant on activation of the selected form.
Task Bar Alert	Add alerts to the lower task bar window of the browser-based EHR, with varying degrees of saliency (i.e., color changes) and results of the screening (e.g., High Risk). See Figure 9.
Navigation Alert	Add an "AUDIT" button to the persistent tab navigation at the top of the EHR. See Figure 10.
Social Personal History Alert	Change in appearance of the social personal history tab See Figure 11.

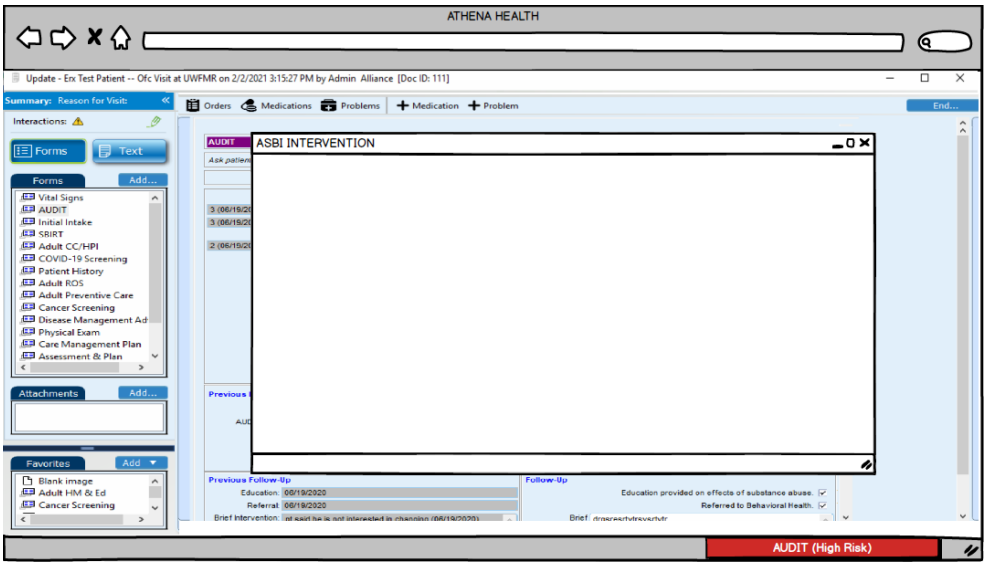


Figure 11. Brief Intervention Alerting Option: Task Bar Location With High Saliency Alert Displaying Screening Results and a Pop-Up Window Intervention

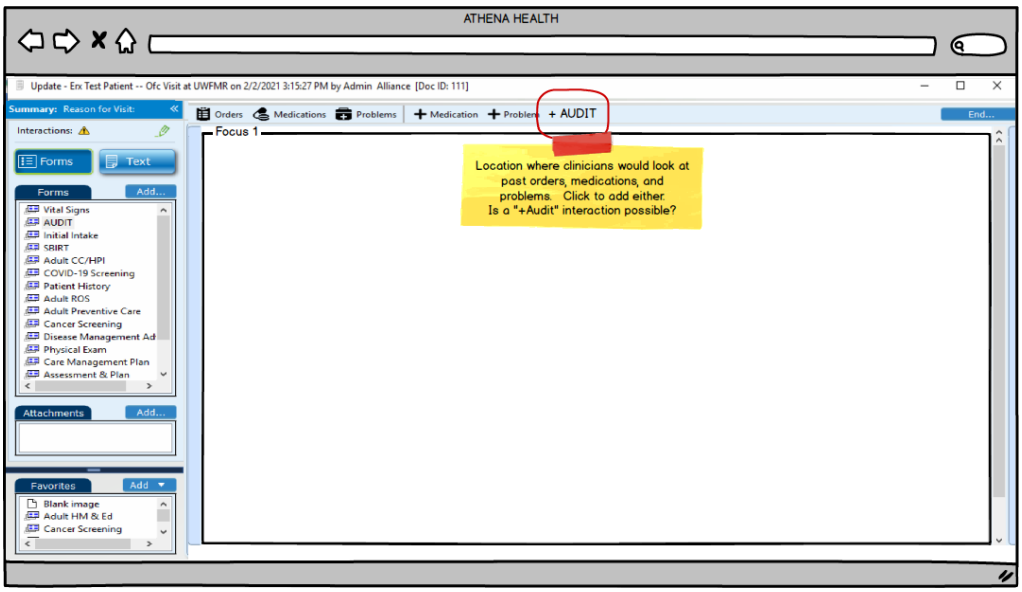


Figure 12. Navigation Alert Option: CDS App Accessible as Both a Form Listed on Side Bar and as a Persistent Tab Integrated Into EHR

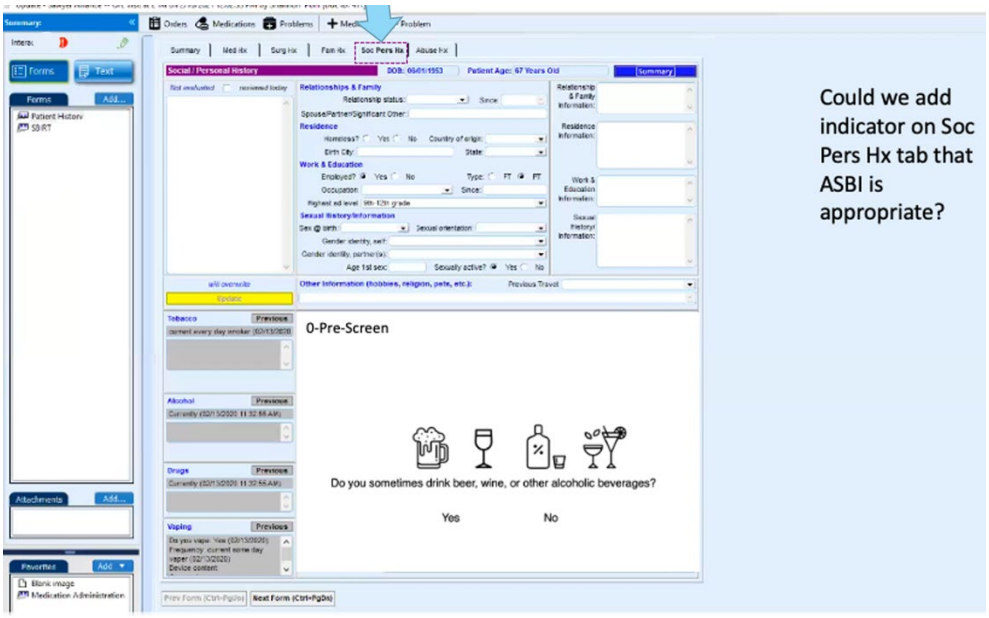


Figure 13. Social Personal History Alert: Alerting on the Social Personal History Tab With a Forms Embedded Screener

C.2 Screening App Final Designs for Implementation

Final design of the screening application, showing the progression of questions and responses for a pregnant patient.

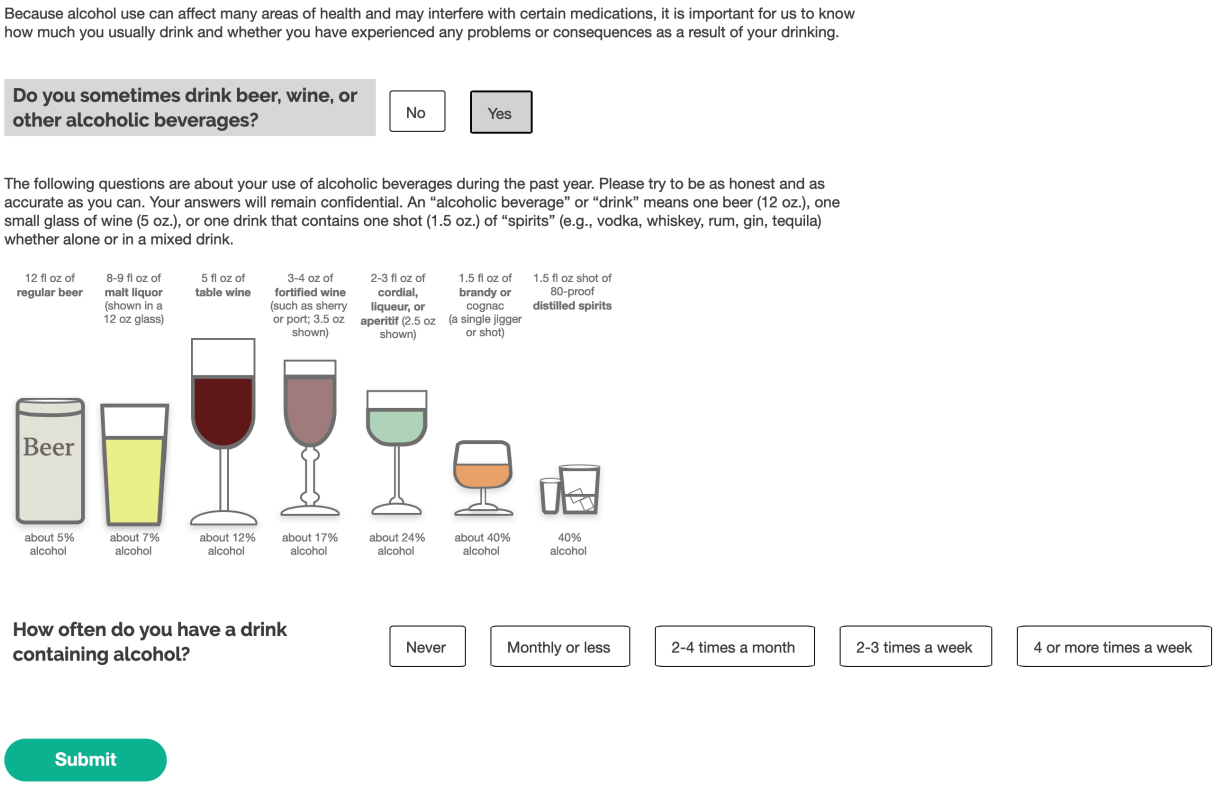


Figure 14. ASBI Screening App Showing Pre-Screen Question and Drink Size Graphic

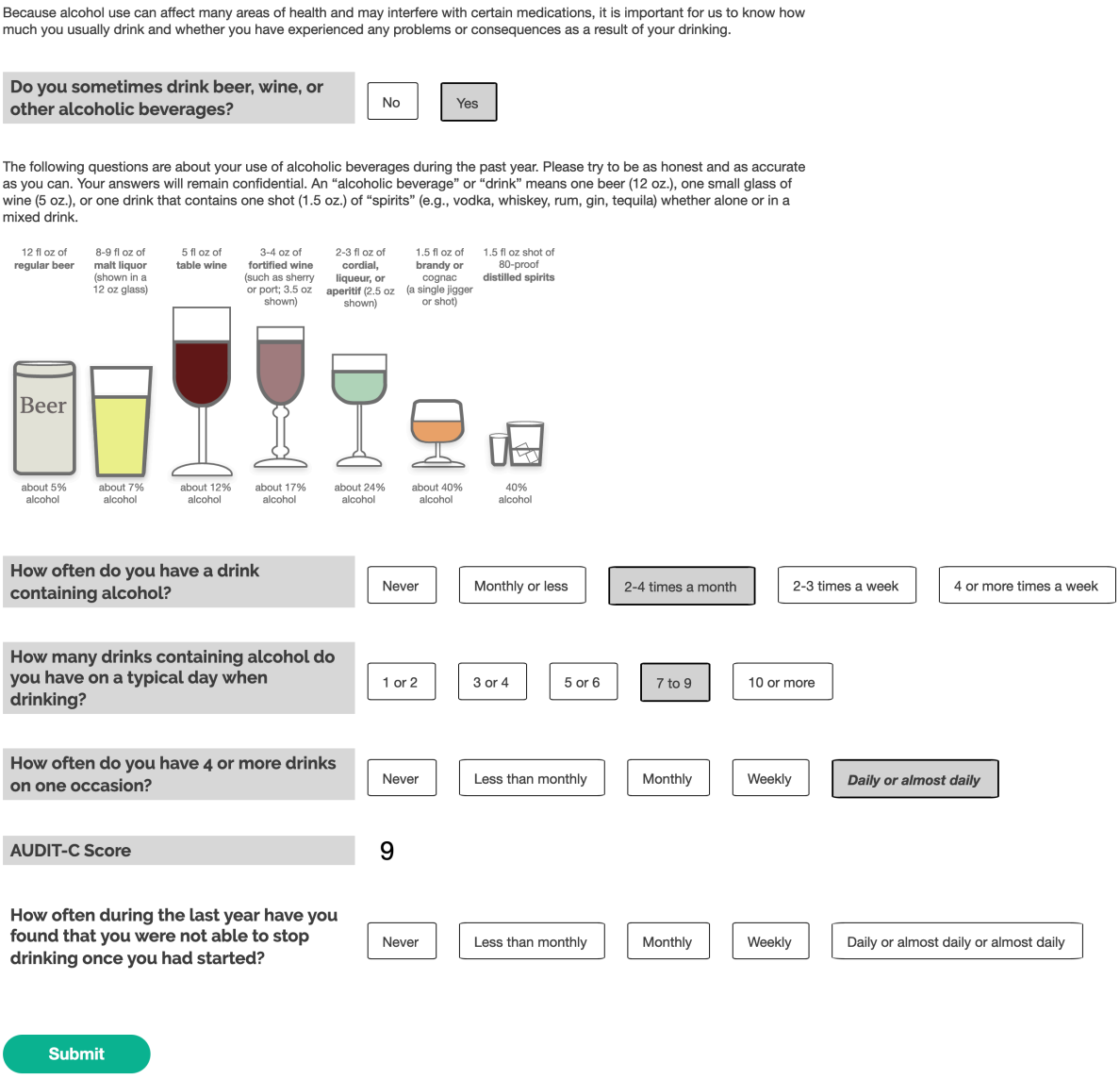
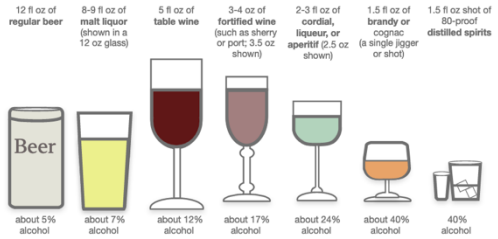


Figure 15. ASBI Screening App Showing Progression From Pre-Screen Question to an AUDIT-C Score

Because alcohol use can affect many areas of health and may interfere with certain medications, it is important for us to know how much you usually drink and whether you have experienced any problems or consequences as a result of your drinking.

Do you sometimes drink beer, wine, or other alcoholic beverages?	No / **Yes**

The following questions are about your use of alcoholic beverages during the past year. Please try to be as honest and as accurate as you can. Your answers will remain confidential. An "alcoholic beverage" or "drink" means one beer (12 oz.), one small glass of wine (5 oz.), or one drink that contains one shot (1.5 oz.) of "spirits" (e.g., vodka, whiskey, rum, gin, tequila) whether alone or in a mixed drink.



How often do you have a drink containing alcohol?	Never / Monthly or less / **2-4 times a month** / 2-3 times a week / 4 or more times a week
How many drinks containing alcohol do you have on a typical day when drinking?	1 or 2 / 3 or 4 / 5 or 6 / **7 to 9** / 10 or more
How often do you have 4 or more drinks on one occasion?	Never / Less than monthly / Monthly / Weekly / **Daily or almost daily**
AUDIT-C Score	9
How often during the last year have you found that you were not able to stop drinking once you had started?	Never / Less than monthly / Monthly / **Weekly** / Daily or almost daily or almost daily
How often during the last year have you failed to do what was normally expected of you because of drinking?	Never / **Less than monthly** / Monthly / Weekly / Daily or almost daily or almost daily
How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never / Less than monthly / **Monthly** / Weekly / Daily or almost daily or almost daily
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never / Less than monthly / Monthly / **Weekly** / Daily or almost daily or almost daily
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never / Less than monthly / **Monthly** / Weekly / Daily or almost daily or almost daily
Have you or someone else been injured as a result of your drinking?	No / **Yes, but not in the last year** / Yes, during the last year
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?	No / Yes, but not in the last year / **Yes, during the last year**
AUDIT Score	26
Are you pregnant or trying to be become pregnant?	No / Yes

Submit

Figure 16. ASBI Screening App Showing Progression From Pre-Screen Question to an AUDIT-C Score

C.3 Brief Intervention App Design Progression

In Figure 17, are low-fidelity wireframes demonstrating, on the left, the general split panel layout and on the right, how content would change when the “See List and Links” hyperlink beside “Step 5: Offer educational resources” was activated.

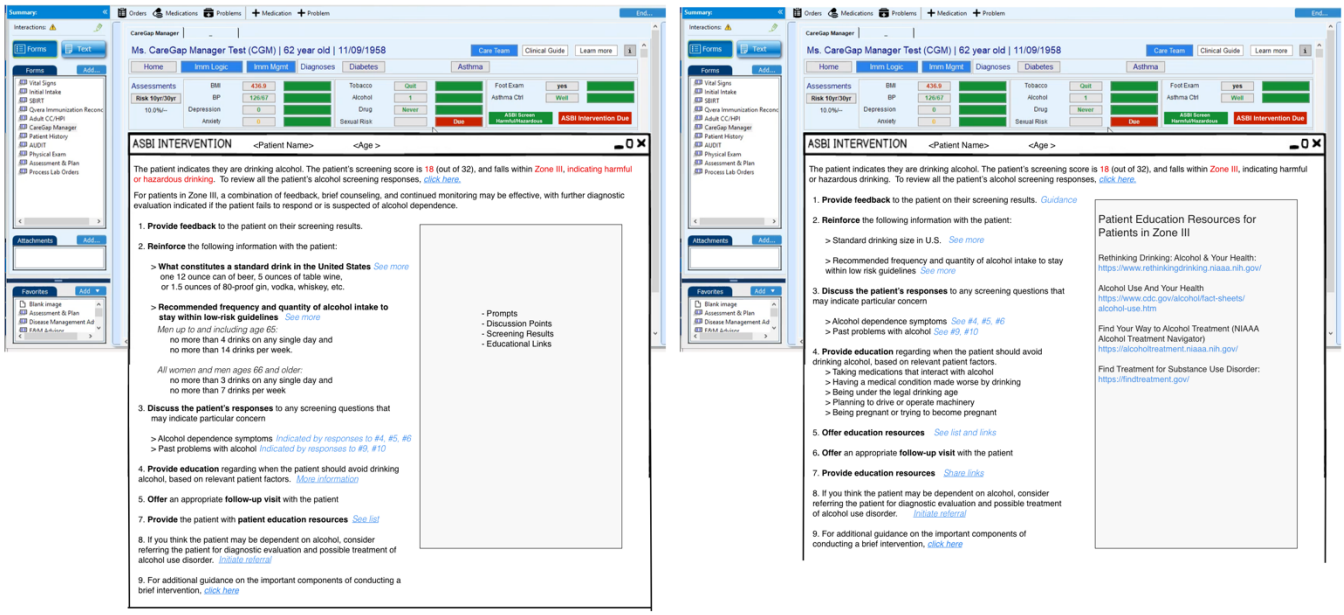


Figure 17. Brief Intervention App Design Progression: Two Panel Design

Next stage in design progression was incorporating additional content from the patient-facing CDS. Wireframes were generated with new graphical content, in both a one panel, scrollable layout, (Figure 18) and an alternative navigation format (Figure 19).

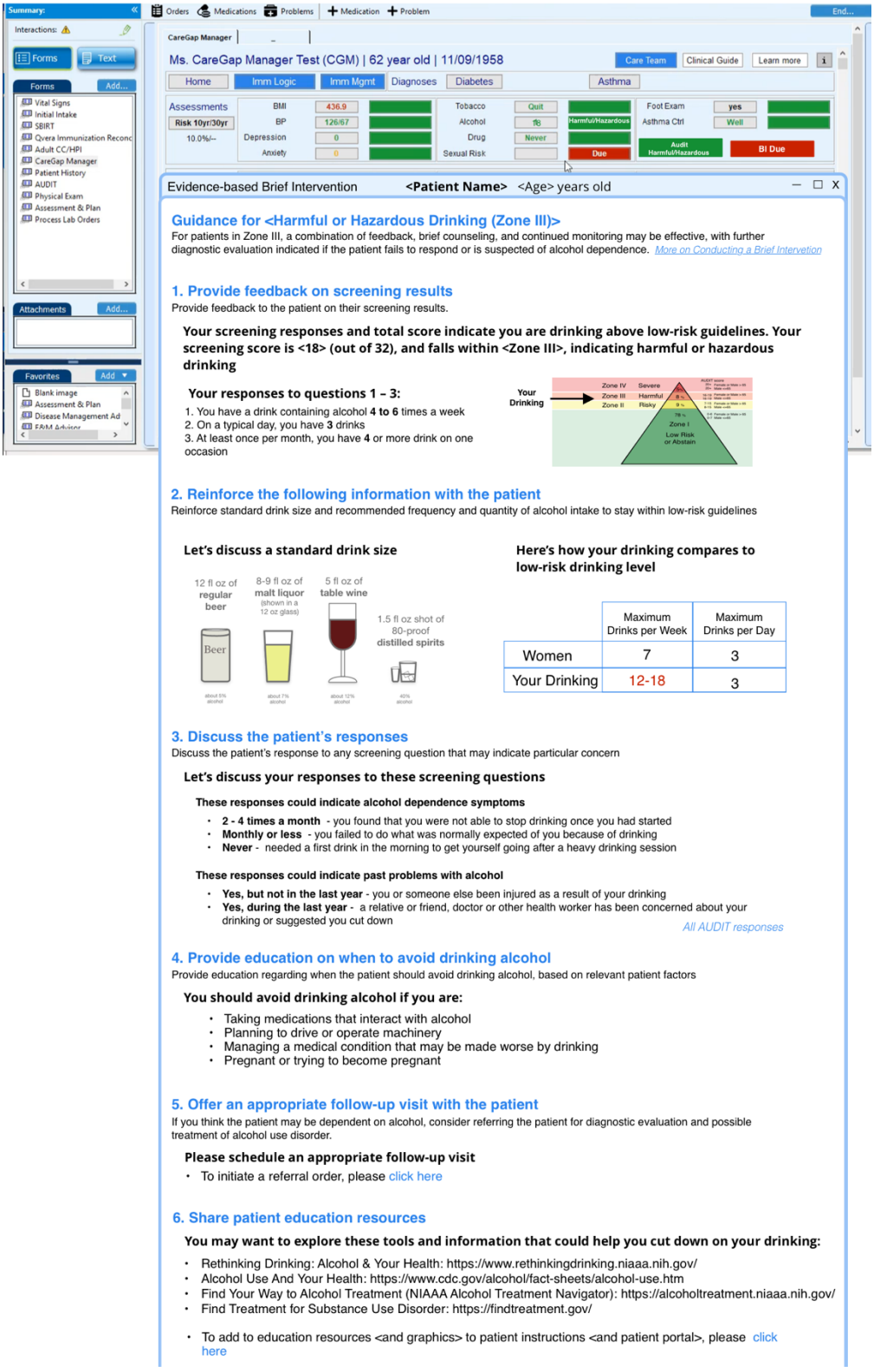


Figure 18. Brief Intervention App Design Progression: Scrollable Navigation

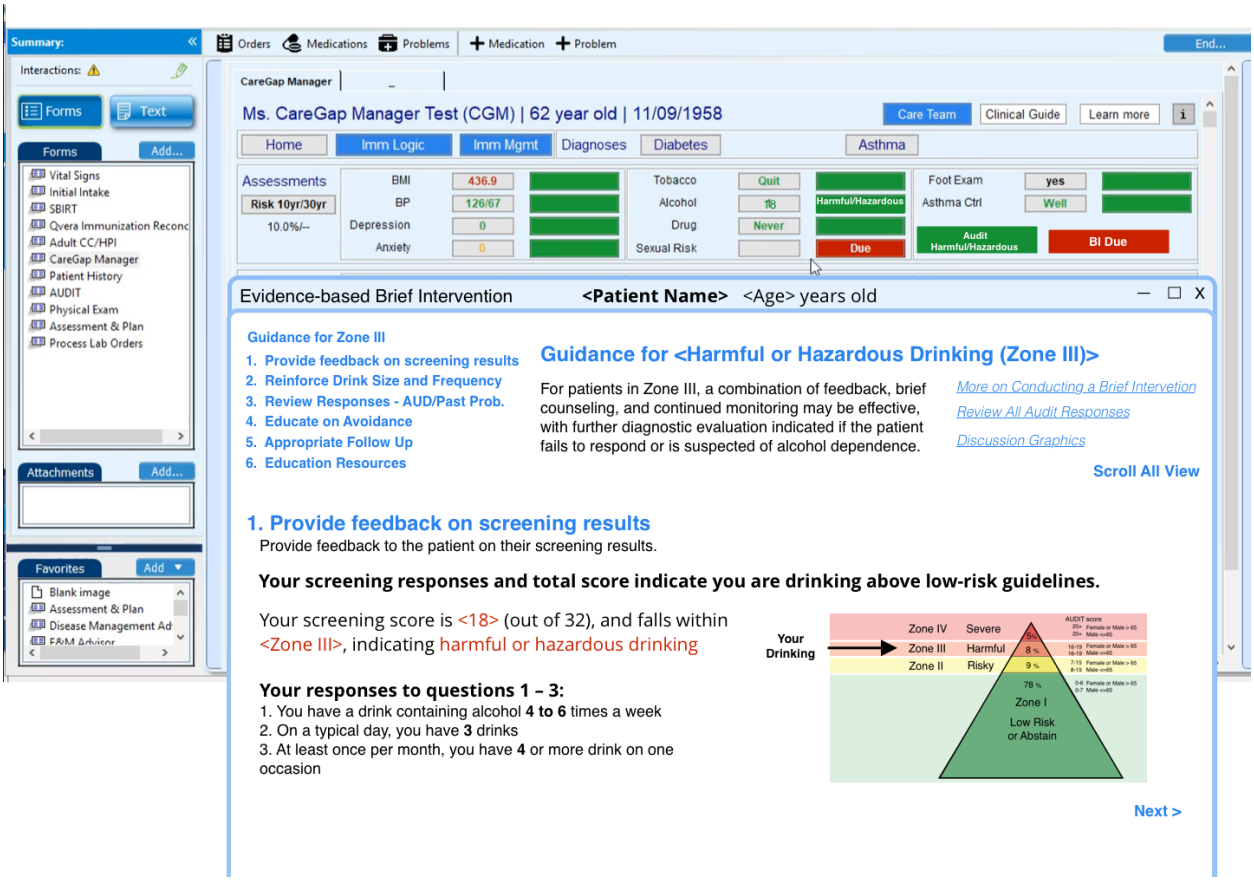


Figure 19. Brief Intervention App Design Progression: Alternative Navigation Through Hyperlinked Table of Contents

C.4 Brief Intervention Final Designs for Implementation

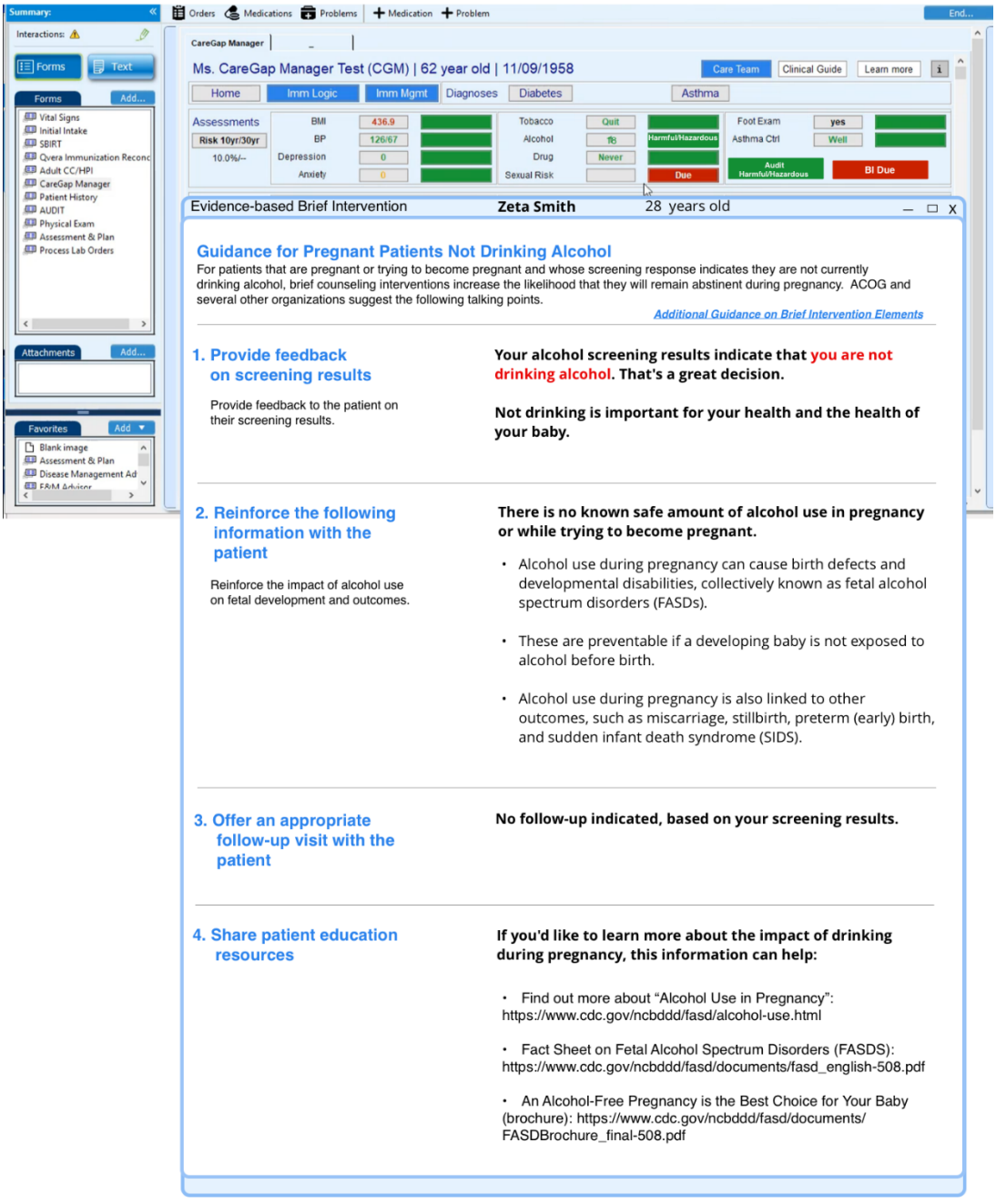


Figure 20. Brief Intervention App Design for a Pregnant Abstinent Patient

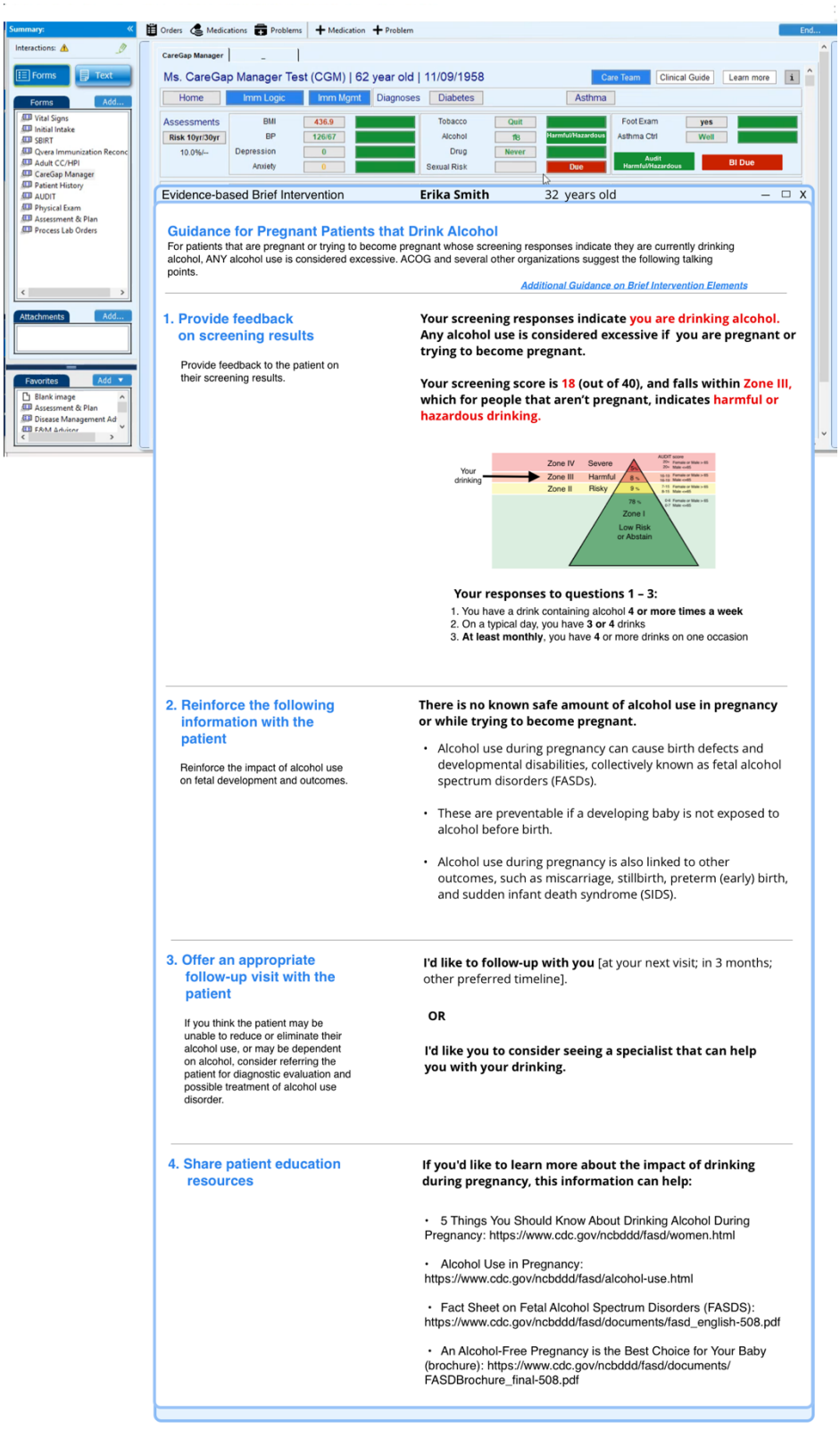


Figure 21. Brief Intervention App Design for a Pregnant Drinking Patient

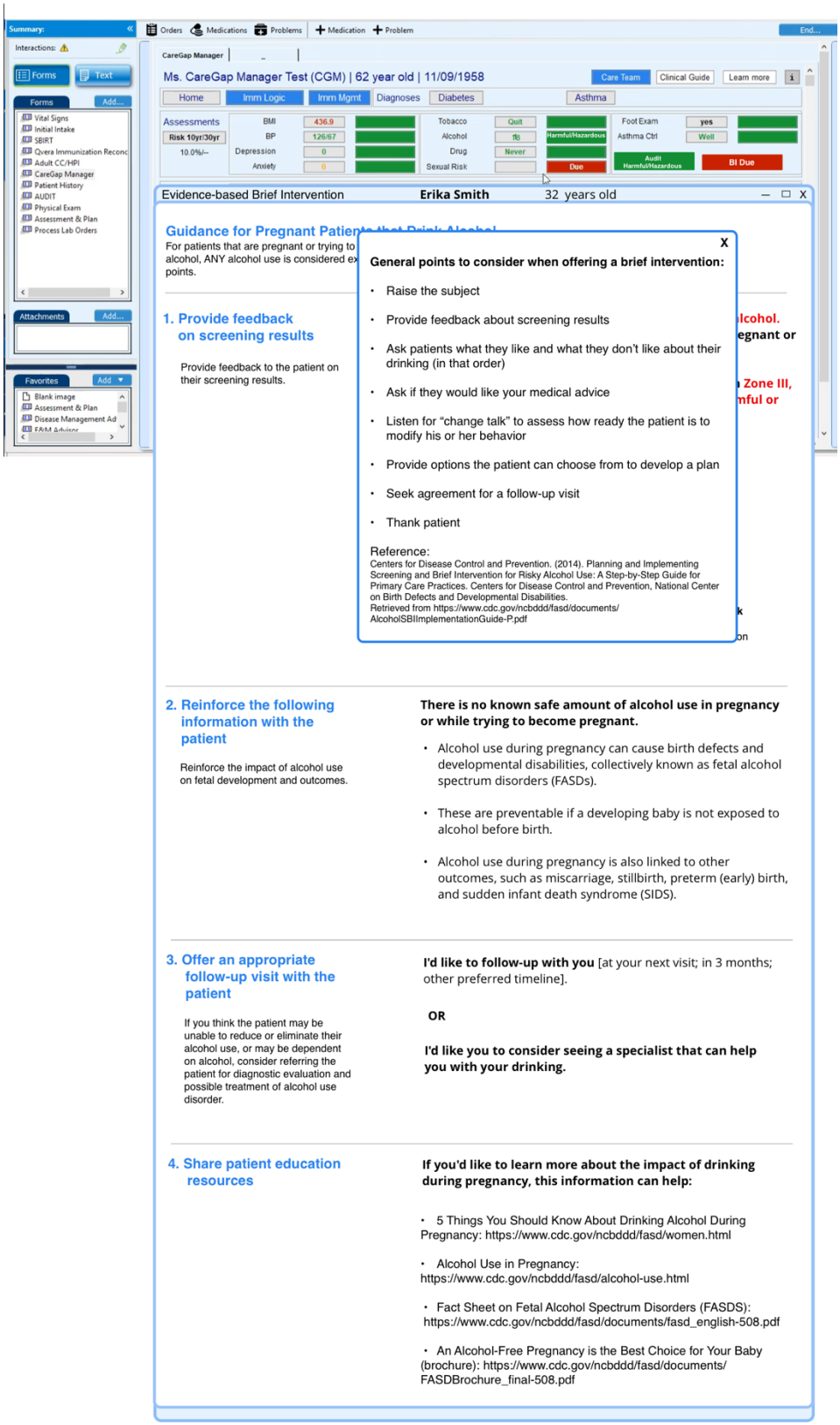


Figure 22. Brief Intervention App Design Showing Brief Intervention Guidance Pop-Up

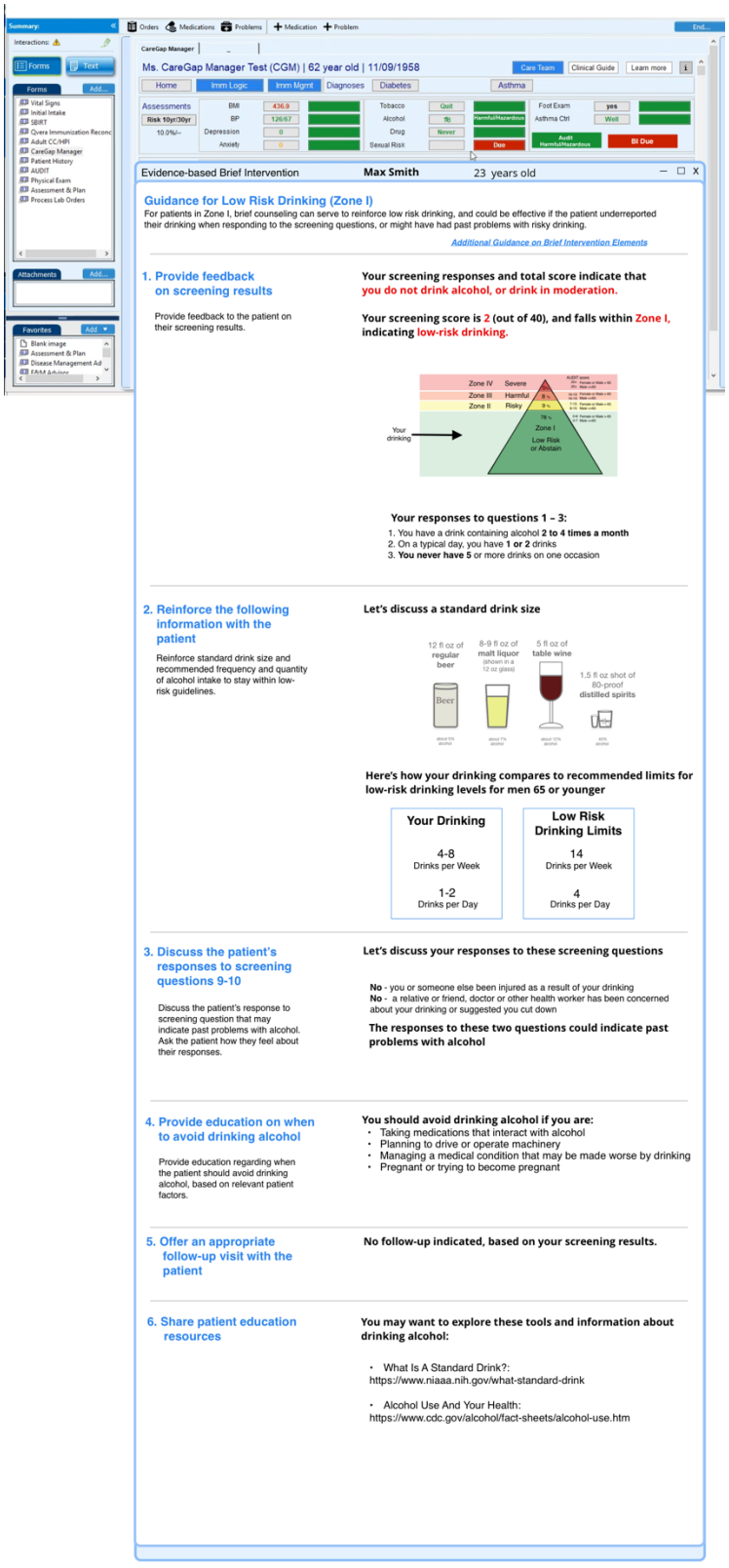


Figure 23. Brief Intervention App Design Showing Brief Intervention Guidance for a Male Patient With Low-Risk Drinking (Zone I) Results

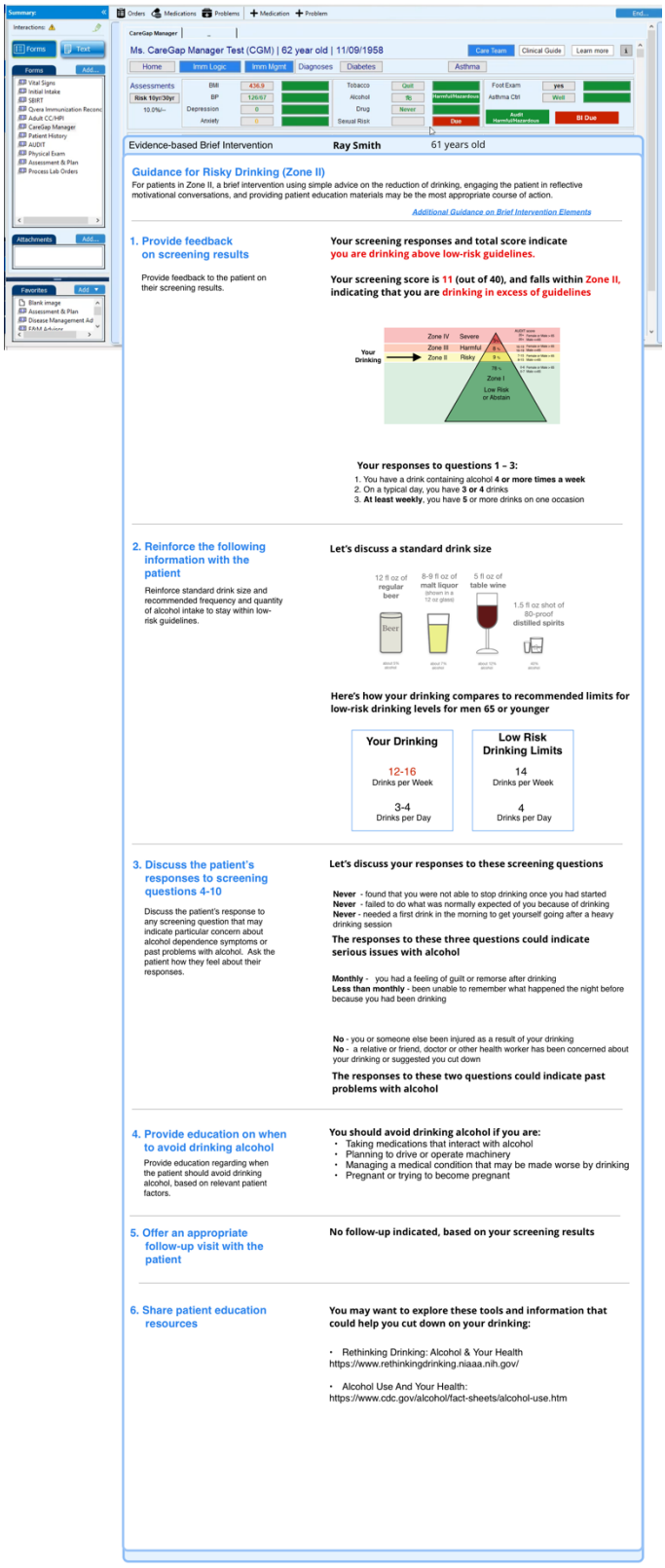


Figure 24. Brief Intervention App Design Showing Brief Intervention Guidance for a Male Patient With Excessive Drinking (Zone II) Results

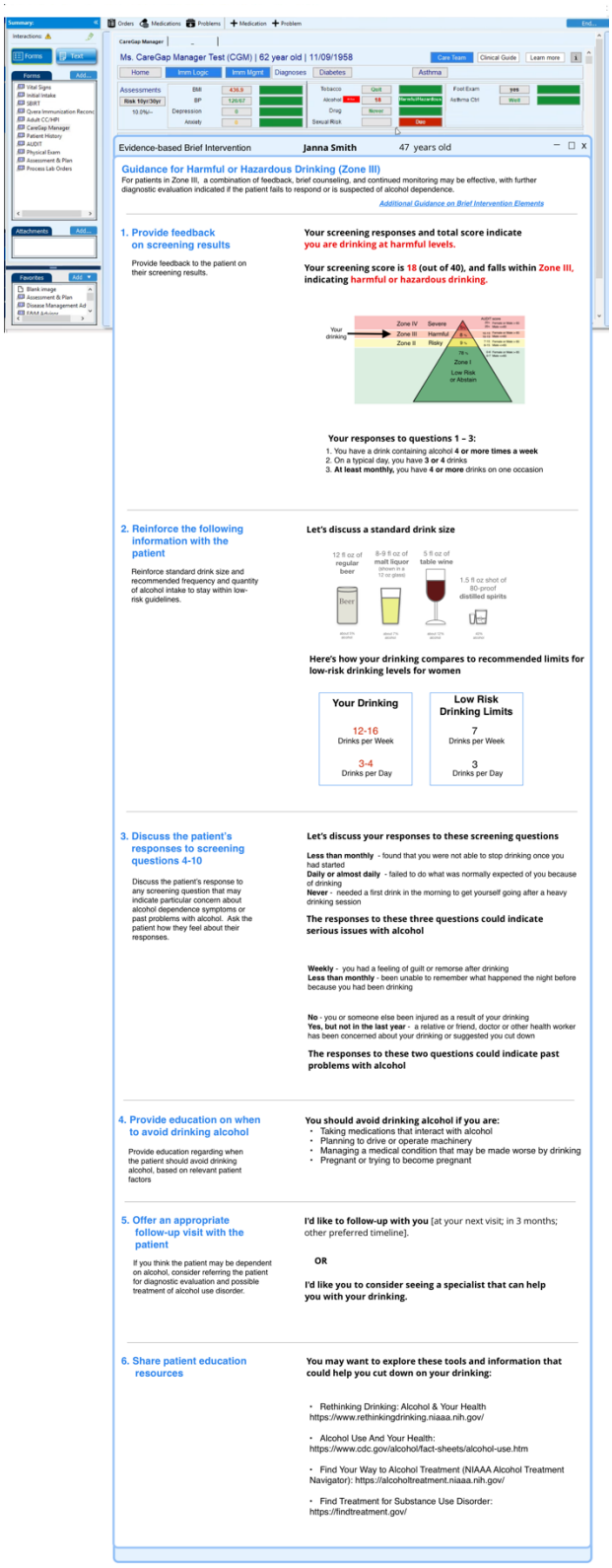


Figure 25. Brief Intervention App Design Showing Brief Intervention Guidance for a Female Patient With Excessive Drinking (Zone III) Results

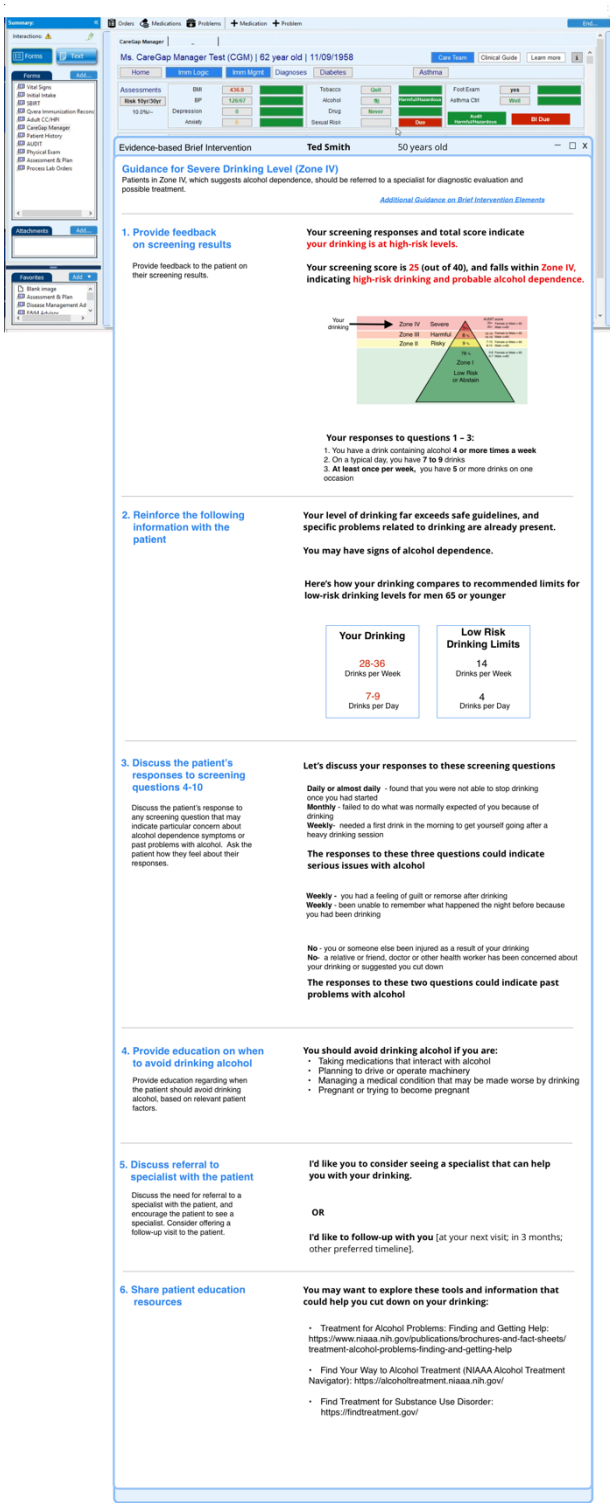


Figure 26. Brief Intervention App Design Showing Brief Intervention Guidance for a Male Patient With Harmful Drinking (Zone IV) Results

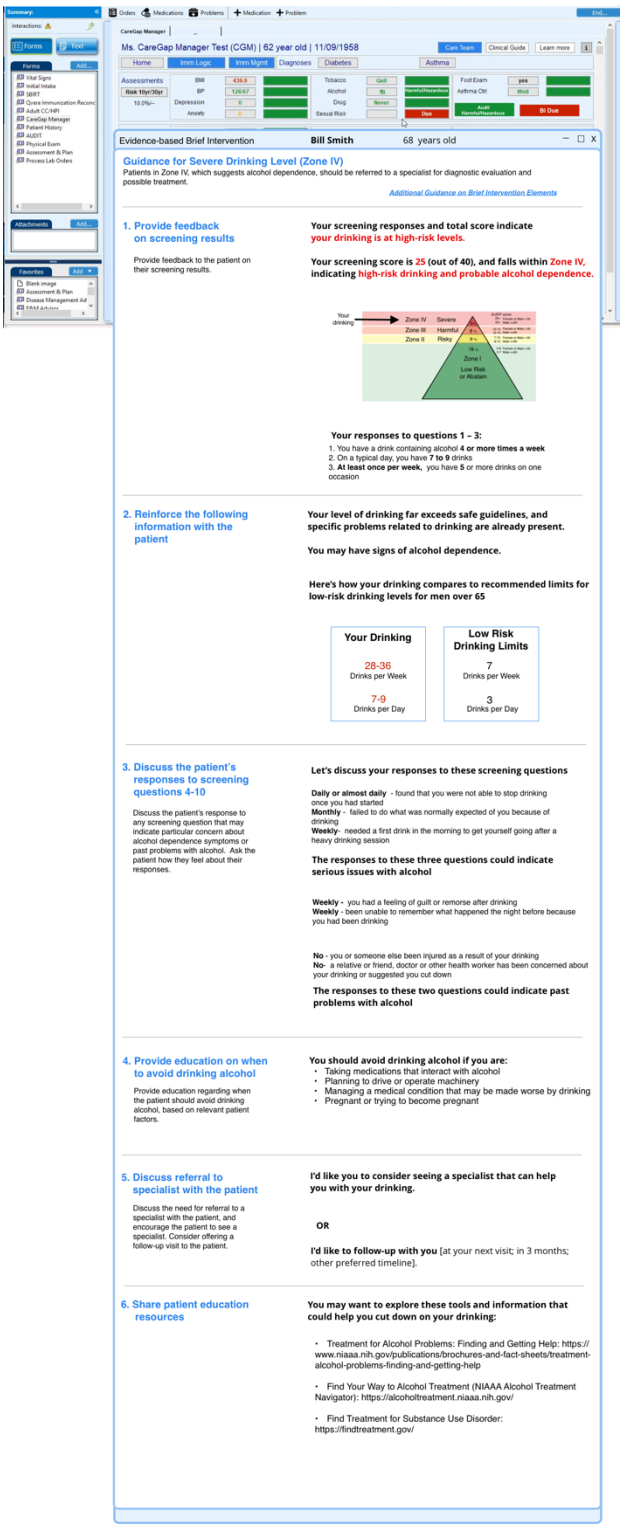


Figure 27. Brief Intervention App Design Showing Brief Intervention Guidance for a Male Patient, Over 65, With Harmful Drinking (Zone IV) Results

Appendix D Evaluation Interview Scripts

SCREENER APPLICATION QUESTIONS (Medical Assistants)

Screener-General Usage

Pattern of use of the screening application

These questions aim to give us a general overall impression of your use of the screening functions in CareGap Manager during the pilot and provide context for our discussion. The screening app refers to the application that opened when you clicked on the 'red' Audit button in CareGap Manager.

1. **How long have you been using CareGap Manager?**

1. **When was the last time you used the screening application, meaning clicked the 'Audit' button? Do you recall if the score required an intervention?**

1. **How frequently would you say you used the screening application?** Daily, weekly, other? Did that frequency change over the course of the pilot?

1. **Did you consistently use the screening application during every patient visit, as appropriate?** How did you make the intentional decision to use or not use, when screening was indicated? If intentional in not using, why? What were some of the considerations?

If not gathered previously:

Telehealth: Do you recall using the brief intervention during a telehealth visit?

Screener-Design and Content

Experience/impression of screening application

These questions aim to help us understand your impressions of using the screening application, specifically the design of the screens and its content.

1. **What were your overall impressions of using the screening application?** What did you find useful? What was not so useful? What did you like/not like?
    a. Graphic of standard drink sizes
    a. Conversational prompts
    a. Logic allowing step-thru of questions
    a. Other

Useful	Not Useful

1. **What changes might you suggest to the screener design, content, or interaction? How would that improve the tool for you?**

1. **How well does the functionality fit with your current workflow?** Were you able to complete the screening in the 5 minutes allotted to rooming a patient? Do you have any suggestions to make it fit better?

Screener-User and Patient Acceptance/Comfort

Impression of patient acceptance

These questions aim to help us understand your impression of patient acceptance of the clinical decision support, as well as your comfort with its content.

1. **How comfortable did patients seem in answering the screening questions with you?** Do you recall any patients pushing back on answering the screening questions? Were there specific questions that patients tended to push back on, or not answer?

1. **How comfortable were you going through the screening questions with the patient?** Were some questions more uncomfortable to ask than others?

1. **Do you have any suggestions to improve the patient experience?**

Screener-Conclusion

1. **How would you say using the screening application compared to your previous method of screening?**

1. **If the developers of the screening application could change one thing about the screening application and implement it next week, what would you recommend and why?**

    a. If **this was changed, how likely are you to want to continue to use the application, beyond the pilot?** If no, why not?

1. **Is there anything else you would like to share about the screening application or the pilot that I did not cover?**

BRIEF INTERVENTION APPLICATION QUESTIONS (Clinicians)

Brief Intervention-General Usage

Pattern of use of the intervention application

These questions aim to give us a general overall impression of your use of the intervention application during the pilot and provide context for our discussion. By brief intervention app, I am referring to the window that opened when you clicked on the "Intervention" button.

1. **How long have you been using CareGap Manager?**

1. **When would you say was the last time you used the intervention application, meaning clicked the 'Intervention" button?** Do you recall the risk level/zone of the intervention?

1. **How many times would you estimate you delivered an intervention over the course of the 15-week pilot?** - meaning, how many times you used the pop-up content to talk through the patient's drinking?

    a. *If not gathered previously:*
        i. **Were any of those higher risk (Zone 3 or Zone 4) interventions?**
        i. **Were any of those pregnant or trying to become pregnant intervention?**
            1. *"Yes" responses to these questions provide context for subsequent answers and highlight an opportunity to explore differences between intervention content.*

    a. ***Do you recall if you used the brief intervention app during a telehealth visit?***

1. ***We understand that time is limited, and visits can sometimes have multiple goals. How consistent were you in delivering an intervention when the Intervention button indicated an intervention was needed****?* Was it an intentional decision to use or not use when intervention was indicated? When intentional decision to not use, why? What were some of your considerations? What was the decision making around using it in an encounter?

1. ***Did having the intervention app available - embedded in CGM, flagging patient responses, and recommending an intervention, did you find it supportive of your clinical needs in doing evidence-based interventions with the patients?*** Was it more, or less, supportive than what you had before?

1. ***Did having the intervention app available with this information change your motivation or approach to conducting an intervention?*** Did it have an impact on your confidence or comfort in delivery an evidence-based intervention?

If not gathered during previously:

Telehealth: During the pilot, do you recall using the brief intervention during a telehealth visit?

Brief Intervention-Design and Content

Impressions/Experience with brief intervention application

These questions aim to help us understand your impressions of using the intervention application, specifically the design of the screens and its content..

1. **Imagine a new clinician has joined at your site. How would you describe the intervention app to them? What overall impressions would you share?**

1. ***How were you using the brief intervention application during visits?*** What did you find useful? What was not so useful to you? What did you like/not like?

Useful	Not Useful

General

1. **Follow-up, as needed: Which application content did you use regularly during the interventions?** Thinking about the information on the pop-up window, what do you recall using? There were several types of content - graphics, customized content based on patient responses and risk score, support for you as a clinician doing an intervention, and links to education information. Probe: *Do you have any feedback or specific experiences to share around using the: (select from those items not mentioned). Probe: Why was this content not of interest or helpful?*

a. **Graphics**
   i. Risk Zone Triangle (top image)
   i. Standard Drink Size (middle image)
   i. Customized table comparing 'Your drinking' to 'Low Risk Levels'

a. **Customization of content based on screening results**
   i. Patient individual responses to screening question (1-3) (top)
   i. Patient individual responses to full AUDIT (*Discuss Patient Responses* section)
   i. Customization of table comparing 'Your drinking' to 'Low Risk Levels'
   i. Pregnancy-specific brief intervention content

a. **Support for conducting a brief intervention**
   i. Outline of steps for conducting a brief intervention (left side of app)
   i. Conversational language prompts (right side of app)
   i. Supporting information/content as it relates to delivery of intervention
   i. Hyperlink to "Additional guidance on conducting a brief intervention"
   i. Prompting for referral or follow up visit step

a. **Educational materials**
   i. The selection of educational materials
   i. Hyperlinking to educational materials
   i. (Not implemented - Ability to print intervention material for patient)

1. ***Is there content you would recommend removing? Why? Do you have suggestion for additional content?***

1. ***What changes might you suggest to the intervention app? How would that improve the application for you?*** (If no changes suggested) Probe: *What are your thoughts on:*

a. **Ability to print intervention material for patient**

a. Integration with CGM - access to notes field, trigger button appearance
a. Formatting of content – use of color, spacing, fonts and overall appearance
a. Another interaction pattern/navigation – for example, a hyperlinked table of contents to support content navigation; content split across tabs; content divided by headers and accessed in expandable regions
a. Other areas for improvement

Brief Intervention-User and Patient Acceptance/Comfort

These questions aim to help us understand your impression of patient acceptance of the clinical decision support, as well as your comfort with its content.

1. ***How comfortable were you going through the AUDIT score and intervention questions with the patient?*** Were there sections that felt particularly awkward?

1. ***How comfortable did patients seem with you conducting the intervention with the tool?*** Do you recall any patients pushing back on the intervention content?

1. **Did you share your screen to show the application when conducting the brief intervention?** Do you regularly share your screen during visits?

    a. **Did you use the graphics to structure your conversation in any way?** If so, which ones?

        i. If used graphics, how comfortable did patients seem in engaging with the brief intervention tool? Do you recall any patients pushing back on the intervention content? Were there sections that felt particularly awkward?

1. ***Do you have any suggestions to improve the patient experience around the screening or intervention application?***

Brief Intervention-Conclusion

1. **How did using the intervention app compare to your previous method of conducting a brief intervention?** Did you do more interventions with app than with previous method?

1. ***If Heartland continues to make the clinical decision support available after the pilot, how likely or unlikely are you to continue to use it, and why?***

1. ***If the CDS developers could change any one thing about the intervention application, and implement next week, what would you recommend and why?***

    a. If answered 'not likely' or negatively on #2, *Probe: Would this change make it more likely for you to use the application, if available after the end of the pilot?*

1. ***Is there anything else you would like to share about the intervention application or the pilot that I did not cover?*** *Other thoughts or suggestions on clinical decision support?*

Appendix E Abbreviations and Acronyms

Acronym	Definition
API	Application Programming Interface
ASBI	Alcohol Screening and Brief Intervention
AUD	Alcohol Use Disorder
AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	AUDIT-Consumption
BI	Brief Intervention
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CMS	Centers for Medicare & Medicaid Services
CQL	Clinical Quality Language
EHR	Electronic Health Record
FASD	Fetal Alcohol Spectrum Disorders
FHIR	Fast Healthcare Interoperability Resources
FFRDC	Federally Funded Research and Development Center
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
NIDA QS	National Institute on Drug Abuse Quick Screen
ONC	U.S. Office of the National Coordinator for Health Information Technology
SMART	Sustainable Medical Applications, Reusable Technologies
USAUDIT	AUDIT, adapted for use in the United States
USAUDIT-C	USAUDIT-Consumption
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

NOTICE