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Substance Use Screening, Risk Assessment, and Use Disorder Diagnosis in Adults

Updates, Authorship, and Related Resources

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Highlights of changes, additions, and updates in the May 30, 2024 edition	• Rated recommendations added in Patient Engagement and Interventions section • SIS-C (Single-Item Screen-Cannabis) added in Screening Tools section • Resources, citations, and references updated throughout this guideline
Intended users	Primary care clinicians and care providers in other adult outpatient care settings in New York State
Lead authors	Jennifer McNeely, MD, MS; Leah K. Hamilton, PhD; Susan D. Whitley, MD
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Committee: Substance Use Guidelines Committee
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Contents

Purpose of This Guideline

This guideline on screening and risk assessment for substance use in adults (≥18 years old) was developed by the New York State Department of Health AIDS Institute (NYSDOH AI) for use by primary care clinicians and in other adult outpatient care settings in New York State to achieve the following goals:

- Increase the identification of unhealthy substance use among New York State residents and increase access to evidence-based interventions for appropriate patients. “Unhealthy substance use” refers to a spectrum of use that increases the risk of health consequences and ranges from hazardous or risky patterns of use to severe substance use disorder (SUD).
- Increase the number of clinicians in New York State who perform substance use screening and risk assessment as an integral part of primary care.
- Provide clinicians with guidance on selecting validated substance use screening and risk assessment tools and on providing or referring for evidence-based interventions.
- Promote a harm reduction approach to the identification and treatment of substance use and SUDs, which involves practical strategies and ideas aimed at reducing the negative consequences associated with substance use.

Rationale: In the United States, the use of tobacco, alcohol, and drugs (illicitly manufactured and nonmedical prescription) are among the top 10 leading causes of preventable death, accounting for more than 500,000 deaths per year [White, et al. 2020; GBD 2018]. Alcohol-related deaths have doubled in the past 2 decades; in 2019, there were more than 140,000 alcohol-related deaths in the United States [CDC 2022]. Surging rates of drug overdose deaths (often opioid-related) are a public health crisis across the country. In the United States, drug overdose contributed to 1 in 22 deaths in 2021, and there were more than 100,000 drug overdose deaths in the 12 months ending August 2023 [CDC 2024; Gomes, et al. 2023].

Patient visits to healthcare settings are an opportunity for clinicians to identify substance use and related problems, offer timely interventions, and provide or link patients to treatment when indicated. Screening and treatment for tobacco use have been widely adopted as core clinical quality measures for primary care [CMS 2013], but alcohol and drug use screening is not as widely performed, and use is substantially under-recognized [Hallgren, et al. 2020; WHO 2016; Venkatesh and Davis 2000]. Screening for alcohol use has been a recommended practice in adult primary care since 1996 [Curry, et al. 2018]. In a study of 13 states and the District of Columbia in 2017, 81.4% of patients reported being asked about any alcohol use by a healthcare professional; however, only 37.8% reported being asked about binge drinking behavior [McKnight-Eily, et al. 2020].

Screening for substance use in primary care is generally well accepted by patients as a marker of quality care [Simonetti, et al. 2015; Miller, et al. 2006]. However, thoughtful implementation, with sensitivity to stigma and privacy concerns, is essential for patients and clinicians to be comfortable [Bradley, et al. 2020; McNeely, et al. 2018].

Substance Use Screening and Risk Assessment: Goals and Definitions

The goals of screening for and assessing substance use risk in primary care vary by practice setting and resources and may include:

- **Informing medical care:** Substance use is an important aspect of medical history because it can significantly affect disease processes, response to treatment, and exposure to health risks. Knowledge of a patient's substance use informs a clinician's diagnosis of other medical and psychiatric conditions and alerts them to associated health risks (e.g., overdose, liver disease) and common comorbid conditions (e.g., depression). Similar to knowledge about a patient's past medical history, family history, or social determinants of health, knowledge about a patient's substance use helps clinicians formulate effective patient-centered treatment plans.
- **Identifying the need for intervention:** A second goal is to identify patients who would benefit from interventions to limit harms related to use and/or reduce their consumption (see guideline section Patient Engagement and Interventions) or patients for whom treatment may be appropriate (see guideline section Diagnosis of Substance Use Disorder). Evidence-based interventions are available, including brief interventions for moderate-risk alcohol use, pharmacotherapy for opioid and alcohol use disorders, and treatment for smoking cessation [Patnode, et al. 2021; Patnode, et al. 2020; USPSTF(c) 2020; Curry, et al. 2018; Jonas, et al. 2014; Mattick, et al. 2014]. Such treatments can be delivered effectively in a primary care setting, but they remain underused.
- **Engaging patients:** Another goal is opening the conversation and engaging patients in discussion about substance use. If approached sensitively, a nonjudgmental discussion of a patient's substance use may reduce perceived stigma, improve the clinical relationship, and facilitate behavior change. Initiating such a discussion communicates to patients that substance use is a health issue that the clinician is concerned about and can offer help for.

Definitions of the terms used throughout this guideline are detailed below.

- **Unhealthy substance use:** Unhealthy substance use refers to a spectrum of use that increases the risk of health consequences and ranges from hazardous or risky patterns of use to severe substance use disorder. As defined in this guideline, unhealthy alcohol use is use that exceeds U.S. Department of Health and Human Services and Department of Agriculture 2015-2020 Dietary Guideline levels. For illicitly manufactured drugs, less information is available about dosage and health risks of specific substances and preparations, and any use is considered potentially unhealthy. For prescription medications with potential for misuse, any nonmedical use (use of prescribed medication at increased dose or frequency or for reasons other than prescribed) or use of medications that were not prescribed is considered unhealthy.
- **Screening:** Screening entails asking patients brief questions (or a single question) about substance use and can quickly identify patients with potentially unhealthy substance use. Many of these patients will not have substance use-related clinical signs or symptoms [Saitz(b), et al. 2014; Gordon, et al. 2013].
- **Risk assessment:** Risk assessment entails asking patients additional questions on the extent, duration, and pattern of substance use to determine the clinical significance and severity of use. Assessment tools determine the level of risk (i.e.,

low, moderate, or high) and thus the potential for negative consequences; see Box 1, below. As shown in Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions, risk level and other individual patient factors guide clinicians in recommending appropriate interventions and informing patients about the potential consequences of their substance use [McNeely(a), et al. 2016; Saitz 2005].

Box 1: Substance Use Levels of Risk [a]

- **Low risk:** Patient is abstinent or uses substances in a way that is not currently associated with negative health consequences or other problems (e.g., alcohol consumption that does not exceed levels recommended by U.S. Department of Health and Human Services and Department of Agriculture 2015-2020 Dietary Guidelines or occasional low-dose cannabis use).
- **Moderate risk:** Patient is at risk of and may already be experiencing negative health consequences or other problems, such as elevated blood pressure related to alcohol use, atypical chest pain related to cocaine use, or family problems or poor work performance related to opioid use.
- **High risk:** Patient likely has a substance use disorder, is likely experiencing substance-related health or other types of problems (e.g., alcohol use-related cirrhosis or consequences such as separation from family or loss of employment), and is engaging in continued or escalating use despite negative consequences.

Note:

a. Adapted from [Saitz 2005].

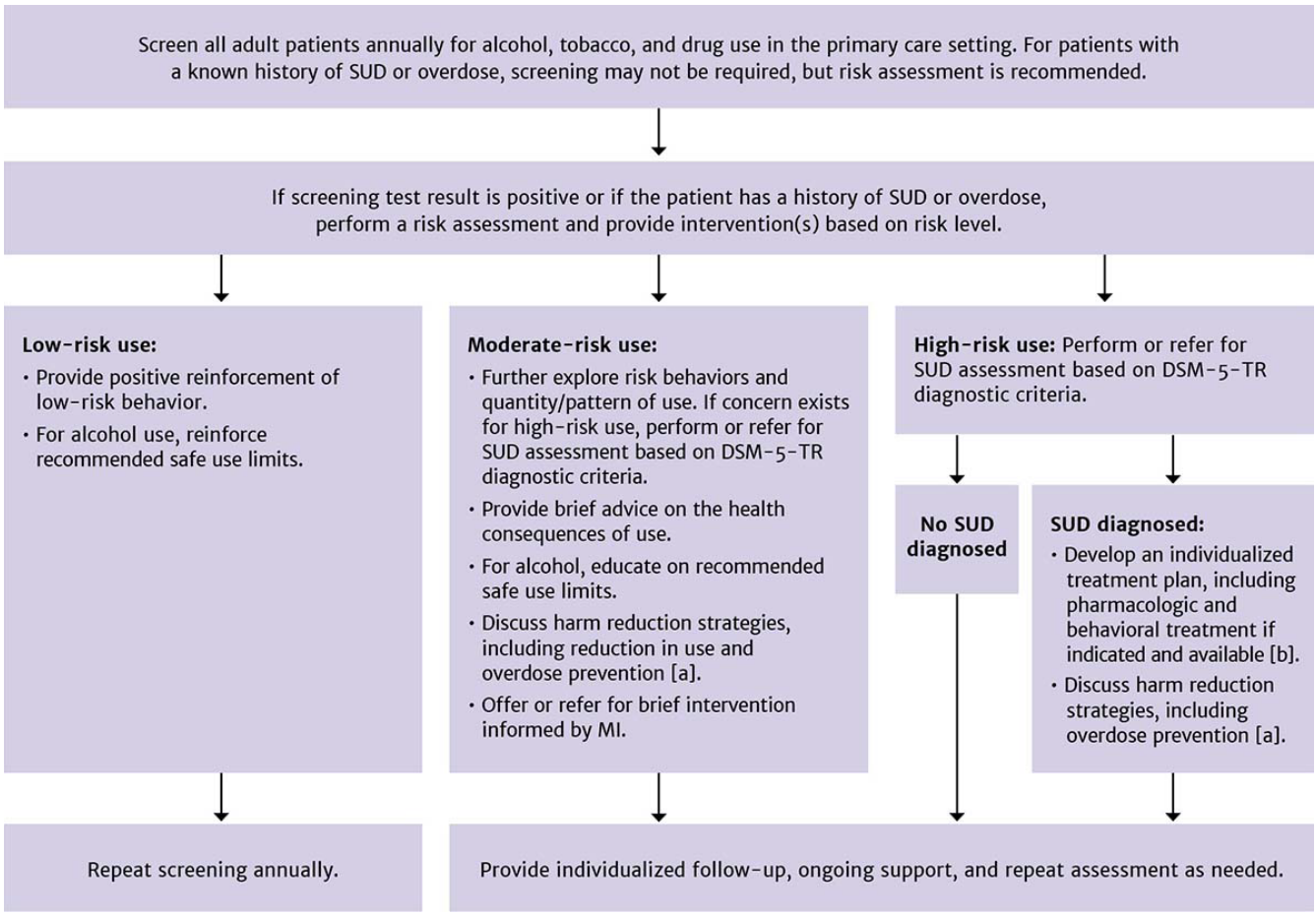
Screening

☑ RECOMMENDATIONS

Screening

- During the initial visit and once per year thereafter, primary care clinicians should screen for the following in adults ≥18 years old:
  - Alcohol use, and when unhealthy use is identified, assess the level of risk to the patient. (A1)
  - Tobacco use, and when use is identified, provide assessment and counseling. (A1)
  - Other drug use (B3), and when unhealthy use is identified, assess the level of risk to the patient. (A3)
  - See guideline section Risk Assessment and Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions.
- Before screening for substance use, clinicians should explain the benefits and risks of screening to all patients, especially those who are pregnant or planning to conceive; the discussion should include state reporting requirements and the potential for involvement of child protective services. (A3)
  - For information on the Child Abuse Prevention and Treatment Act (CAPTA) in New York State, see Plans of Safe Care for Infants and their Caregivers.
- Clinicians should also perform substance use screening to inform clinical care when:
  - Prescribing medication(s) that have adverse interactions with alcohol or drugs. (A2)
  - A patient has symptoms or medical conditions that could be caused or exacerbated by substance use. (A3)

Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions



Abbreviations: DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; MI, motivational interviewing; SUD, substance use disorder.

Notes:

a. See NYSDOH AI guideline Substance Use Harm Reduction in Medical Care.
b. See NYSDOH AI guidelines Treatment of Alcohol Use Disorder and Treatment of Opioid Use Disorder, NYSDOH AI Clinical Guidance: Stimulant Use, and U.S. Public Health Service: A Clinical Practice Guideline for Treating Tobacco Use and Dependence.

Alcohol

In primary care settings, clinicians should screen all adult patients ≥18 years old for alcohol use. A large body of evidence indicates that screening tools can accurately identify unhealthy alcohol use (see Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults) and that brief counseling interventions can reduce alcohol use, improve health, and be cost-effective [Patnode, et al. 2020; Kaner, et al. 2018; O'Connor, et al. 2018; O'Donnell, et al. 2014; McNeely, et al. 2008; Solberg, et al. 2008; Maciosek, et al. 2006]. The National Committee on Quality Assurance adopted alcohol screening and brief intervention as a quality indicator in 2018 and incorporated it into the widely used Healthcare Effectiveness Data and Information Set performance measures.

In the absence of systematic screening, unhealthy alcohol use typically goes unidentified [Hallgren, et al. 2022; McKnight-Eily, et al. 2020] or is identified by clinicians only when an individual has developed a severe alcohol use disorder or alcohol-related health problems, such as alcohol-related cirrhosis or pancreatitis.

→ KEY POINTS

- Ask patients about substance use during the initial visit and follow-up visits because patterns of use may change over time. Annual screening may be most appropriate, and most validated alcohol and drug screening questionnaires ask about use in the past year.
- Inform patients that information about their substance use is protected by the same privacy laws that apply to all other information in their medical records.

Tobacco

Clinicians should screen all patients for all types of tobacco use, and when use is identified, provide counseling, assessment, and treatment [Patnode, et al. 2021; USPSTF 2021]. Every visit with a care provider allows for identifying a patient's tobacco use and offering effective cessation interventions. Screening for tobacco use is often accomplished with 1 question: *"Have you ever smoked cigarettes or used any other kind of tobacco?"* Patients who answer "yes" should be asked about frequency and level of use in the past 30 days (e.g., number of cigarettes smoked per day) [DHHS 2008]. Despite concern about increasing rates of e-cigarette use, screening for electronic nicotine delivery systems is not currently a recommended practice [Krist, et al. 2021; USPSTF 2021].

Other Drugs

Based on clinical experience and expertise and federal recommendations [USPSTF(b) 2020], this committee recommends that clinicians screen for drug use other than alcohol and tobacco in adult patients ≥18 years old who present for primary care. Screening should be performed in settings where treatment or counseling resources are available on-site or by referral and should identify a patient's use of illicitly manufactured drugs and nonmedical use of prescription drugs that can be misused (e.g., opioids, benzodiazepines, and stimulants).

Evidence supports the accuracy of validated screening questionnaires in adults [Patnode, et al. 2020] and the benefits of pharmacologic treatment for opioid use disorder (OUD), which can be delivered effectively in primary care settings [Wartko, et al. 2023] and no longer requires a waiver for prescribing buprenorphine [Stringfellow, et al. 2021]. However, data on the effectiveness of drug screening plus brief intervention to reduce drug use and associated health consequences are currently limited, and this is an area of ongoing research. Randomized controlled clinical trials have generated mixed results regarding the efficacy of brief interventions in reducing drug use [Sahker, et al. 2022; Patnode, et al. 2020; Gelberg, et al. 2015; Roy-Byrne, et al. 2014; Saitz(a), et al. 2014; Humeniuk, et al. 2012]. Evidence supporting drug interventions delivered in primary care has primarily come from treatment-seeking populations, rather than patients identified only through screening [Saitz 2020; USPSTF(a) 2020].

No currently published studies demonstrate harms directly associated with screening adult primary care patients for drug use, although the potential for harm does exist [Saitz 2020]. For some patients, especially those who are pregnant or planning to conceive, positive results from a drug screening test could pose social or legal consequences, such as required reporting and the potential for involvement of child protective services (see discussion below). It is essential to respect the sensitivity of any substance use information documented in patients' health records and ensure that patients understand privacy protections for their health information.

Rationale for drug use screening: This committee's rationale for recommending drug use screening in adult patients, even with the potential for harm in some specific circumstances, is based on the following:

- Stigma is a significant barrier to identifying and treating unhealthy drug use or substance use disorders (SUDs). The exclusion of routine screening for drug use may perpetuate the perception that discussion of drug use with healthcare providers is taboo. This is especially the case if alcohol and tobacco use are discussed openly but drug use is not mentioned. Routine, matter-of-fact, nonjudgmental screening for drug use may help reduce stigma by normalizing this discussion.
- The social history that clinicians currently perform typically includes questions about alcohol, tobacco, and drug use but may not collect this information in a systematic and clinically useful manner. It is important that clinicians screen for drug use consistently, in a nonbiased manner, and use standardized, evidence-based screening tools.
- Fatal and non-fatal opioid overdose deaths can be reduced through increased identification of unhealthy opioid use and, when indicated, effective treatment with medications for OUD [Watts, et al. 2022; Wakeman, et al. 2020; Sordo, et al. 2017; Cousins, et al. 2016].

- Identifying and addressing unhealthy drug use, including drug use disorders, may positively affect other patient outcomes. For instance, identification of benzodiazepine use in a patient receiving opioids for chronic pain could inform overdose prevention counseling, opioid prescribing, and provision of naloxone to reduce the patient's overdose risk.
- Knowledge of a patient's drug use is essential for accurate diagnosis and treatment. For example, in a patient who uses cocaine, chest pain could be the result of drug use rather than a blocked coronary artery, but without knowledge of the drug use, the clinician will not have the information necessary to perform the appropriate diagnostic workup. In addition, knowledge of drug use may be essential for an accurate diagnosis of psychiatric disorders, and knowledge of injection drug use can help guide screening for infections.

→ KEY POINT

- Urine toxicology, measures of blood alcohol level, and other laboratory tests should not be relied on for identifying unhealthy drug use.

Drug use screening in individuals who are pregnant or planning to conceive: Because there are potential legal and social consequences of a positive drug use screening result in individuals who are pregnant or planning to conceive, this committee urges caution when performing drug use screening. It is essential to engage patients in shared and informed decision-making *before* screening is performed. Fully informed consent includes clear discussion and confirmed patient understanding of the benefits, potential harms, and consequences of screening. For patients who are pregnant or planning to conceive, the informed consent discussion should include:

- Description of drug screening processes and procedures
- Potential benefits of drug screening for the patient
- Discussion of how results are interpreted and likely next steps if the screening result is positive
- Confirmation of confidentiality of the patient's medical information
- Discussion of the risk of being reported to child protective services
- Discussion of the patient's ability to refuse drug screening without repercussions, except in cases in which screening is mandated by an employer or by the court
- Psychosocial support and counseling about the potential harms of drugs and treatment options for SUD, if patients decline to be screened for other drugs

Screening to Inform Clinical Care

Screening is recommended for patients who use medications that have adverse interactions with alcohol or drugs. Iatrogenic harm is possible if a patient's substance use is not identified, including adverse effects resulting from drug-medication interactions, overdose from combining prescribed medications with illicitly manufactured drugs, and withdrawal syndromes when a patient's drug use is undisclosed and they are unable to use, such as during hospitalization [Lindsey, et al. 2012; CDC 2007; Antoniou and Tseng 2002]. Patients taking prescription opioids or benzodiazepines should be screened for use of alcohol and for illicitly manufactured or nonmedical use of other sedating drugs (including other opioids or benzodiazepines) that can increase the risk of overdose. Patients taking any controlled substances should be assessed for co-occurring substance use that may increase the probability of engaging in risky use of prescribed medications or of having or developing an SUD.

Clinicians should be aware of potential interactions between alcohol or drugs and medications, such as antiretroviral, pain management, or neurologic medications (e.g., gabapentin and pregabalin) [Gomes, et al. 2017; Lyndon, et al. 2017; Lindsey, et al. 2012; Bruce, et al. 2008; Saitz 2005; Antoniou and Tseng 2002].

When counseling patients who use substances about drug-medication interactions, clinicians should be clear about the safety of their prescribed medications and be certain to encourage adherence to all critical medications, such as antiretroviral treatment [Kalichman, et al. 2015].

See the following resources for checking drug-drug interactions:

- Drugs.com > Drug Interactions Checker
- University of Liverpool HEP Drug Interactions
- University of Liverpool HIV Drug Interactions

Clinicians should also perform substance use screening in patients who have symptoms or other medical conditions that could be caused or exacerbated by substance use, such as chest pain, liver disease, or mood disorders [NIAAA 2024; Ries, et al. 2018; Kim, et al. 2017; Edelman and Fiellin 2016; Mertens, et al. 2005; Lock and Kaner 2004].

Box 2: Implementing Substance Use Screening in Primary Care Settings

- **Who to screen:** All adults seen by primary care clinicians should be screened for substance use. Some specific patient populations may have higher rates of unhealthy substance use [SAMHSA 2019; Schulden, et al. 2009], but no specific demographic characteristics reliably predict such use.
- **How often to screen:** Because substance use behavior changes over time, clinicians should repeat screening at regular intervals. However, evidence is lacking about the optimal frequency of screening [Moyer 2013]. Annual screening may strike the best balance between the need for frequent repetition of screening and time and resource constraints and has been recommended by an expert panel convened by the National Council for Behavioral Health and Substance Abuse and Mental Health Services Administration (SBIRT Change Guide 1.0, February 2018) [McNeely, et al. 2021].
- **Who should perform screening:** Most of the screening instruments discussed in Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults can be administered verbally by trained staff or can be self-administered by patients on paper or electronically. Primary care practices must choose the format that is most appropriate for their clinical workflow and patient population. Generally, self-administered screening facilitates more accurate reporting of stigmatized behavior, such as substance use [Wight, et al. 2000; Tourangeau and Smith 1996]. A self-administered approach may lead to higher rates of detected substance use by ensuring fidelity of administration [McNeely, et al. 2021; Williams, et al. 2015; Bradley, et al. 2011], increasing patient comfort [McNeely, et al. 2018; Spear, et al. 2016], and reducing staff burden. Electronic screening tools that can be self-administered can be completed online through a patient portal or an app made available with a tablet computer or kiosk in the clinic, with results uploaded to a patient's electronic health record.
- **How to introduce substance use screening to patients:** Explain the reasons for screening, the type of screening that will be performed, the potential benefits, and any potential harms. Make sure that patients understand how results will be interpreted and the likely response to screening results. Remind them of the privacy protections for the information being collected, including who will see the information; acknowledge the potential sensitivity of the information; and avoid judgmental or stigmatizing language [NIDA 2011].
- **Resources:**
  - National Institute on Drug Abuse: Implementing Drug and Alcohol Screening in Primary Care
  - National Committee for Quality Assurance: Screening and Follow-Up for Unhealthy Alcohol Use: Quality Improvement Change Package for Health Plans

Screening Tools

☑ RECOMMENDATION

Screening Tools

- Clinicians should use standardized and validated questionnaires for substance use screening (see Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults). (A3)

Successful substance use screening relies on accurate patient self-report. Although urine toxicology, measures of blood alcohol level, or other laboratory testing may detect the presence of substances used very recently (typically hours or ≤4 days after the last use), these tests are not appropriate for identifying unhealthy use, which may be intermittent and occur over time [Bosker and Huestis 2009; Cone and Huestis 2007; Verstraete 2004]. Laboratory screening tests for alcohol and drugs do not provide information about the severity or consequences of use and thus provide less information than questionnaires.

No reliable biomarker with sufficient sensitivity and specificity identifies the range of drinking behaviors that constitute unhealthy alcohol use [Afshar, et al. 2017; Jarvis, et al. 2017; Jatlow, et al. 2014; Stewart, et al. 2014; Verstraete 2004; Neumann and Spies 2003]. For drug use, urine, saliva, and blood testing are not recommended as replacements for questionnaire-based screening because laboratory tests have a brief window of detection (typically 1 to 4 days) [Bosker and

Huestis 2009; Cone and Huestis 2007; Verstraete 2004]. Although hair testing has a more extended detection period, the cost and lack of reliability for detecting occasional drug use decrease its utility in primary care [Verstraete 2004].

Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults [a]

Tool	Substance(s) Included	No. of Items, Approximate Time Required to Complete, and Format
AUDIT-C (Alcohol Use Disorders Identification Test-Concise) [Bradley, et al. 2007; Bush, et al. 1998] • Available in languages other than English	Alcohol	• 3 items; 1 to 2 minutes • Interviewer- or self-administered via electronic app or on paper
SISQ-Alc (Single-Item Screening Questions for Alcohol) [McNeely(c), et al. 2015; Smith, et al. 2009]	Alcohol	• 1 item; 1 minute • Interviewer- or self-administered via electronic app or on paper
SIS-C (Single-Item Screen-Cannabis) [Matson, et al. 2022]	Cannabis	• 1 item; 1 minute • Self-administered on paper
SISQ-Drug (Single-Item Screening Questions for Drug Use) [McNeely(c), et al. 2015; Smith, et al. 2010]	Prescription drugs, other drugs	• 1 item; 1 minute • Interviewer- or self-administered via electronic app or on paper
TAPS-1 (Tobacco, Alcohol, Prescription Medication, and Other Substance Use) [Gryczynski, et al. 2017]	Tobacco, alcohol, prescription drugs, other drugs	• 4 items; 2 minutes • Interviewer- or self-administered via electronic app
SUBS (Substance Use Brief Screen) [McNeely(b) and Saitz 2015]	Tobacco, alcohol, prescription drugs, other drugs	• 4 items; 2 minutes • Interviewer- or self-administered via electronic app or on paper

Note:

a. For information on the sensitivity and specificity of tools for drug screening, see U.S. Preventive Services Task Force: Unhealthy Drug Use: Screening; for information on the sensitivity and specificity of tools for alcohol screening, see Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: An Updated Systematic Review.

→ KEY POINT

- Whenever possible, it is best to have patients self-administer the screening and assessment questionnaires rather than having the clinician or staff ask the questions. In general, self-administered screening facilitates more accurate reporting of stigmatized behavior, such as substance use [McNeely, et al. 2021; Sayre, et al. 2020; McNeely, et al. 2018; Williams, et al. 2015; Tourangeau and Smith 1996].

An optimal screening instrument will quickly and accurately identify individuals with the full spectrum of unhealthy use, fit into the existing clinical workflow, and have flexible administration options (i.e., self- or interviewer-administered). To facilitate patient reports of substance use, the language used in any screening tool should be clear and nonjudgmental. Drug screening should capture nonmedical prescription drug use and illicitly manufactured drug use. Table 1, above, lists recommended substance use screening tools.

The briefest approach to screening may be to use the Single-Item Screening Questions (SISQ) for alcohol or drug use (SISQ-Alc and SISQ-Drug). SISQ tools are validated for interviewer administration or patient administration and have good sensitivity and specificity. A positive response on SISQ tools identifies unhealthy use in the past year but does not indicate the level of risk. Both the Substance Use Brief Screen (SUBS) tool and the first section of the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS-1) tool elicit information about use of tobacco, alcohol, illicitly manufactured drugs, and nonmedical prescription drugs through a single 4-item instrument. Like the SISQ-Alc and SISQ-Drug, the SUBS and TAPS-1 tools screen for any use in the past year, and a positive response indicates unhealthy use but does not identify level of risk. In states such as New York where cannabis is legal, asking about its use separately from that of illicitly manufactured drugs or nonmedical use of prescribed drugs may be preferable, and the Single-Item Screen-Cannabis, a validated single-item screening tool, is now available for this purpose [Matson, et al. 2022; Sayre, et al. 2020].

Risk Assessment

☑ RECOMMENDATIONS

Risk Assessment

- Clinicians should assess the level of substance use risk in individuals who have a positive substance use screening result or a history of substance use disorder (SUD) or overdose. (A3)
- Clinicians should use standardized and validated tools to assess the level of risk associated with substance use (see Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old). (A3)

Who to Assess

Clinicians should use validated tools to perform substance use assessments in individual patients who have any of the characteristics discussed below. The purpose of assessment is to identify the level of risk (low, moderate, or high) posed by a patient's substance use to guide clinical decisions about intervention, treatment, and follow-up (see Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions). Clinicians experienced in assessing and treating SUD may elect to use the Diagnostic and Statistical Manual of Mental Disorders-5-TR criteria as the initial assessment tool.

Positive substance use screening test: Given current levels of substance use in the general population and the negative effects of unhealthy substance use, any positive screening test result should prompt an efficient and accurate risk assessment [McNeely(a), et al. 2015; McNeely(c), et al. 2015].

Known history of SUD or overdose: Polysubstance use is common in people with SUD [Ellis, et al. 2023; Karamouzian, et al. 2022; Lin, et al. 2021; John, et al. 2018; Falk, et al. 2006]. For patients with a history of SUD, identification of all substances used, including tobacco, and assessment of the associated levels of risk are indicated for early intervention and clinical decision-making. SUDs are chronic conditions, and even patients with long periods of abstinence remain vulnerable to resuming previous patterns of use [McLellan, et al. 2000]. Patients with a history of SUD may reduce or stop use of one substance but develop unhealthy use of a different substance (e.g., alcohol) [Lin, et al. 2021; Callaghan, et al. 2018; Wang, et al. 2017; Falk, et al. 2006; Earleywine and Newcomb 1997]. Overdose is frequently the result of polysubstance use, and use of fentanyl and stimulants (methamphetamine, cocaine) is driving unprecedented rates of overdose death [Ciccarone 2021; Cicero, et al. 2020]. The use of opioids in combination with alcohol or benzodiazepines also puts individuals at high risk of overdose [Tori, et al. 2020]. In patients with a history of nonfatal overdose, it is critically important to conduct an assessment and identify all of the substances being used; the results will guide education and treatment to reduce the risk of another overdose.

The level of risk of associated with substance use in individuals who are planning to become pregnant should guide clinician counseling, particularly in light of the risk of fetal alcohol spectrum disorder that occurs early in pregnancy [May, et al. 2018; Moyer 2013; Stade, et al. 2009; Floyd, et al. 2008; Floyd, et al. 2006; DHHS 2005; CDC 2003]. In addition, it is reasonable to perform a substance use assessment in patients with chronic diseases who have difficulty following through with treatment recommendations or are not responding as expected to treatment of their medical condition [Garin, et al. 2017; Daskalopoulou, et al. 2014].

Risk Assessment Tools

Substance use assessment tools are designed to collect information on the quantity, frequency, and duration of substance use and to indicate a risk level (see Table 2, below).

Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old [a]

Tool	Substance(s) Included	No. of Items, Approximate Time Required to Complete, and Format
ASSIST (Alcohol, Smoking, and Substance Involvement Screening Test) [Humeniuk, et al. 2008] • Available in languages other than English	Tobacco, alcohol, prescription drugs, and other drugs; identifies specific drug classes	• 10 to 71 items; 5 to 15 minutes, depending on no. of substances used • Interviewer-administered
TAPS-2 (Tobacco, Alcohol, Prescription Medication, and Other Substance Use) [b] [Adam, et al. 2019; McNeely(a), et al. 2016]	Tobacco, alcohol, prescription drugs, other drugs; identifies specific drug classes	• 4 to 25 items; 2 to 4 minutes, depending on no. of substances used • Interviewer- or self-administered via electronic app on computer/tablet
ACASI-ASSIST (Audio Computer-Assisted Self-Interview-ASSIST) [Kumar, et al. 2016; McNeely(b), et al. 2016]	Tobacco, alcohol, prescription drugs, and other drugs; identifies specific drug classes	• 10 to 98 items; 5 to 15 minutes, depending on no. of substances used • Self-administered via electronic app on computer/tablet
Alcohol Symptom Checklist [Hallgren, et al. 2022]	Alcohol	• 11 items; 5 minutes • Self-administered on paper and documented in the electronic health record
AUDIT (Alcohol Use Disorders Identification Test) [c] [Reinert and Allen 2007] • Available in languages other than English	Alcohol	• 10 items; 3 minutes • Interviewer- or self-administered
DUDIT (Drug Use Disorders Identification Test) [Hildebrand 2015; Berman, et al. 2005] • Available in languages other than English	All drugs; does not identify drug classes	• 11 items; 5 minutes • Interviewer- or self-administered on paper
DAST-10 (Drug Abuse Screening Test) [Yudko, et al. 2007; Skinner 1982] • Available in languages other than English	All drugs; does not identify drug classes	• 10 items; 10 minutes or less • Interviewer- or self-administered on paper

Notes:

a. Clinicians with experience in treating patients with substance use and substance use disorder may choose to use the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision criteria as the initial assessment tool.
b. An online version of the TAPS tool with clinical guidance on interpreting the scores and resources for intervention is available at National Institute on Drug Abuse TAPS.
c. The 3-item AUDIT-C performs as well as the full 10-item AUDIT for identifying risky use and problem use in primary care [Bradley, et al. 2007]. However, use of the full AUDIT provides expanded information about problems related to alcohol use that may be helpful for clinicians offering brief interventions or other alcohol counseling.

Patient Engagement and Interventions

☑ RECOMMENDATIONS

Patient Engagement

- Clinicians should discern patients' perceptions of their substance use and adjust interventions using techniques informed by motivational interviewing. (A3)

Interventions

- For patients with low-risk substance use, clinicians should:
  - Provide positive reinforcement for minimizing risk. (B3)
  - Repeat screening annually. (A3)
- For patients with moderate-risk substance use, clinicians should further explore patients' risk level (risk behaviors, pattern and quantity of use); if concern exists about high-risk use, perform or refer for SUD assessment with DSM-5-TR criteria. (A3)
- For patients with high-risk substance use, clinicians should perform or refer for SUD assessment with DSM-5-TR criteria. (A2 for alcohol, A3 for other drugs).
- For patients with moderate- or high-risk substance use not diagnosed as a use disorder, clinicians should:
  - Offer brief advice on potential negative health consequences. (A3)
  - Discuss harm reduction strategies, including reducing use. (A3)
  - Provide or refer for a brief intervention informed by motivational interviewing. (A1 for alcohol, A3 for other drugs)
  - Provide individualized follow-up. (A3)

Abbreviations: DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; SUD, substance use disorder.

Many individuals with unhealthy alcohol use or other substance use regularly interact with the healthcare system, and primary care providers are optimally positioned to offer prevention, risk reduction, and treatment interventions. Routine screening and annual rescreening provide structure and opportunity to identify at-risk individuals, monitor for significant changes, and revisit identified concerns.

The Screening, Brief Intervention, and Referral to Treatment (SBIRT) framework provides a comprehensive approach to the delivery of early intervention and treatment services for patients with unhealthy substance use of various degrees of severity. The key elements include:

- Screening/risk assessment to quickly identify at-risk individuals
- Brief intervention focused on increasing awareness and motivation toward behavioral change
- Referral to treatment to facilitate access to care

For additional guidance on implementation and reimbursement based on this framework, see Substance Abuse and Mental Health Services Administration (SAMHSA): Screening, Brief Intervention, and Referral to Treatment (SBIRT) and Box 2: Implementing Substance Use Screening in Primary Care Settings.

Patient Engagement

A positive substance use screening result should trigger further risk assessment, including a detailed history and understanding of individual risk factors; see guideline section Risk Assessment. Assessment tools determine the level of risk (low-, moderate-, and high-risk use) and thus the potential for negative consequences and appropriate interventions. Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions outlines the sequence of steps for the clinician.

When administering a risk assessment tool or during patient evaluation after a self-administered risk assessment, clinicians should remain alert to the patient's perception of their substance use and readiness to change behaviors. Based on clinical experience, this interaction is an important opportunity to build rapport, dispel misconceptions, and engage patients in a

therapeutic relationship. Understanding a patient's readiness to change and identifying internal motivators for change provide important building blocks to shape the intervention strategy.

Motivational interviewing: Interventions tailored to match a patient's level of risk, perception of their substance use, and readiness to change can promote engagement and increase the probability of progress toward goals [VA/DoD 2015; SAMHSA 1997]. The principals of motivational interviewing (MI) provide a framework for this approach, and all clinicians can develop the skills to educate, advise, offer treatment, or refer patients for appropriate interventions [McLellan 2017; Edelman and Fiellin 2016]. The core skills of MI, as defined by Miller and Rollnick, can be remembered with the acronym OARS, which stands for: open-ended questioning, affirming, reflective listening, and summarizing [Miller and Rollnick 2013]. For more information, see Resources box, below.

Trauma-informed care: Individuals with SUD have a high prevalence of childhood trauma [Bartholow and Huffman 2023; Karsberg, et al. 2021; Zarse, et al. 2019], and substance use is a risk factor for repeated exposure to traumatic events [Aronowitz and Meisel 2022; Simon, et al. 2020]. Knowing that trauma contributes to challenges connecting to the healthcare system, clinicians and organizations with a trauma-informed approach can better overcome these barriers and improve outcomes. For more information on trauma-informed care, see the Resources box, below.

◊ RESOURCES

- SAMHSA: TIP 57: Trauma-Informed Care in Behavioral Health Services
- Centers for Disease Control and Prevention: 6 Guiding Principles to a Trauma-Informed Approach (infographic)
- New York State Trauma-Informed Network & Resource Center

Interventions

Positive reinforcement *(for patients with low-risk substance use)***:** For alcohol use, reinforce the benefits of staying below the U.S. Department of Health and Human Services and Department of Agriculture 2015-2020 Dietary Guidelines (1 drink or fewer per day for women and 2 drinks or fewer per day for men). Statements such as *"The amount that you are drinking falls within a level that is considered safe for most healthy adults and is unlikely to have a negative impact on your health"* and *"In general, the less you drink, the better it is for your health"* reinforce low-risk alcohol use. Be alert to pregnancy, older age (>65 years), and other health conditions that may warrant advice to drink less or not at all.

Brief advice *(for patients with moderate- or high-risk substance use)***:** Statements such as *"As your healthcare provider, I am concerned about your alcohol (or substance) use and the potential impact on your health"* and discussion of any related health effects (current or potential) should be integrated into the visit. This discussion can be supplemented by additional interventions as time and resources allow.

For individuals who use alcohol, clinicians can provide information on the recommended safe limits of use. Safe limits have not been established for older individuals or those with medical or psychiatric comorbidities. If a patient is hesitant, negotiate an individualized goal. Little information is available about the dose limits and associated health risks of cannabis and illicitly manufactured drugs.

Harm reduction strategies *(for patients with moderate- or high-risk substance use)***:** See the NYSDOH AI guideline Substance Use Harm Reduction in Medical Care for more information, including resources in New York State.

Overdose prevention strategies: Counsel patients to:

- Assume all illicitly manufactured opioids will contain fentanyl or other high-potency synthetic opioids and that stimulants and counterfeit pills may contain these agents.
- When possible, test drugs with fentanyl test strips or other drug-checking systems. Online sources include MATTERS (for New York State residents and programs, no charge), DanceSafe, and BTNX. Some NYS Authorized Syringe Exchange Sites may provide fentanyl test strips and other drug-checking systems.
- Try to avoid using drugs alone, and if they have to use alone, arrange for someone to check in or use phone- and web-based apps (e.g., Never Use Alone Inc. at 800-484-3731).
- When using any drug, start with a small amount.
- Carry naloxone (NLX), learn how to use it to reverse an opioid overdose, and encourage friends and contacts to do the same. The 4 mg NLX nasal spray formulation is available at pharmacies, at NYSDOH-Registered Opioid Overdose Prevention

Programs (no charge), and through online resources such as NEXT Distro. NLX is covered by NYS Medicaid and most private insurers.

Brief interventions *(for patients with moderate-risk substance use or high-risk substance use not diagnosed as a use disorder)***:** A brief intervention is a time-limited, patient-centered strategy that focuses on increasing insight and awareness about substance use and motivation toward behavioral change. Brief interventions can range from 5 to 20 minutes in duration, vary in frequency, and include a variety of components. Common elements of a brief intervention include discussion of the risks and rewards of substance use as perceived by the patient and individualized feedback about the level of risk.

Using these techniques, clinicians can encourage "change talk" by amplifying statements about a patient's desire, ability, and reasons for change [Rollnick, et al. 2022]. The amount of time spent in change talk is correlated with improved outcomes; the more a patient verbalizes their desire and reasons for change, the more likely it is to happen.

Robust evidence supports the efficacy of brief advice and other brief interventions in the primary care setting for reducing alcohol use among individuals with unhealthy use who do not meet the criteria for alcohol use disorder [Curry, et al. 2018; Kaner, et al. 2018; O'Connor, et al. 2018]. However, the optimal timing, dose, and order of interventions is unknown. A systematic review of the literature on brief alcohol intervention implementation in medical settings was unable to identify specific interventions that were clearly associated with improved outcomes [Curry, et al. 2018]. The most common component was the use of personalized feedback in which participants were shown how their alcohol use compared with that of others. Personalized feedback was often combined with MI or other strategies, such as drinking diaries, action plans, or alcohol use "prescriptions."

Randomized controlled clinical trials have generated mixed results regarding the efficacy of brief interventions in reducing drug use [Sahker, et al. 2022; Patnode, et al. 2020; Gelberg, et al. 2015; Roy-Byrne, et al. 2014; Saitz(a), et al. 2014; Humeniuk, et al. 2012]. Evidence supporting drug use interventions delivered in primary care has primarily come from treatment-seeking populations rather than patients identified only through screening [Saitz 2020; USPSTF(a) 2020]. However, brief interventions are recommended by SAMHSA and have been implemented in many healthcare settings with no evidence of harm [SAMHSA 2018].

In the absence of evidence to guide the choice of specific interventions, clinicians should engage in any strategies that are available and feasible. Clinician factors, including training and time restrictions, will guide strategy. Practice factors, including standard workflows, electronic health record decision support, and availability of integrated behavioral health specialists, can enhance the uptake and implementation of best practices [Loughran, et al. 2021].

Individualized Follow-Up

Because substance use behaviors can change over time, annual rescreening is recommended for individuals with low-risk substance use. For individuals with moderate- or high-risk substance use and those meeting criteria for an SUD, the frequency and type of follow-up will be individualized. As with other chronic diseases, the plan will vary based on the severity of the problem, presence of significant medical or psychiatric comorbidities, and the patient's perception and goals. When indicated, the plan should include referral for specialty services.

Diagnosis of Substance Use Disorder

☑ RECOMMENDATIONS

Diagnosis of SUD

- Clinicians should use the DSM-5-TR criteria to diagnose an SUD and determine its severity. (A3)
- If patients present with symptoms consistent with both an SUD and a mental health disorder, clinicians should assess for both types of disorder and refer for specialty behavioral healthcare when indicated. (A3)

Treatment

- Clinicians should engage in shared decision-making with patients diagnosed with an SUD to develop an individualized treatment plan that includes pharmacologic and behavioral treatment as indicated and available [a]. (A3)

Abbreviations: DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; SUD, substance use disorder.

Note:

a. See NYSDOH AI guidelines Treatment of Alcohol Use Disorder and Treatment of Opioid Use Disorder, NYSDOH AI Clinical Guidance: Stimulant Use, and U.S. Public Health Service: A Clinical Practice Guideline for Treating Tobacco Use and Dependence.

The diagnosis of an SUD and its severity is made by a clinical interview and based on DSM-5-TR diagnostic criteria (see Table 3, below) [APA 2022]. Diagnostic checklists incorporated into the health record can be helpful tools. Studies have confirmed that symptom checklists can reliably assess for alcohol use disorder criteria in patients who screen positive for high-risk drinking [Hallgren, et al. 2022]; a similar strategy may be useful for the diagnosis of other SUDs [Matson, et al. 2023].

Individuals with a diagnosis of SUD should be offered pharmacologic and behavioral treatment as indicated and available (see Note [a], above). Conversations about treatment options should be guided by precepts outlined in the guideline section Patient Engagement. When referral to specialty addiction treatment is necessary, primary care providers can support patients in selecting treatment resources, navigating potential barriers, and checking in about progress while continuing to address medical needs.

Patients often present with concurrent SUDs and mental health disorders [NIDA 2020]. Symptoms of one can mimic the other, making it challenging to arrive at a definitive diagnosis [SAMHSA 2019]. Clinicians should consider a diagnosis of SUD before establishing a primary psychiatric diagnosis (e.g., alcohol-induced depressive disorder vs. major depressive disorder). Symptoms of intoxication, such as mood changes or perceptual disturbances, and symptoms of withdrawal, such as depression, anxiety, irritability, and insomnia, can also mimic psychiatric disorders and should be carefully assessed. Care providers should consult with a mental health specialist when symptoms are severe and/or when a clear diagnosis is difficult to establish.

Table 3: DSM-5-TR Criteria for Diagnosing and Classifying Substance Use Disorders [a,b]

Criteria Type	Descriptions
Impaired control over substance use (DSM-5-TR criteria 1 to 4)	• Consuming the substance in larger amounts and for a longer amount of time than intended. • Persistent desire to cut down or regulate use. The individual may have unsuccessfully tried to stop in the past. • Spending a great deal of time obtaining, using, or recovering from the effects of substance use. • Experiencing craving, a pressing desire to use the substance.
Social impairment (DSM-5-TR criteria 5 to 7)	• Substance use impairs ability to fulfill major obligations at work, school, or home. • Continued use of the substance despite it causing significant social or interpersonal problems. • Reduction or discontinuation of recreational, social, or occupational activities because of substance use.

Table 3: DSM-5-TR Criteria for Diagnosing and Classifying Substance Use Disorders [a,b]	
Risky use (DSM-5-TR criteria 8 and 9)	• Recurrent substance use in physically unsafe environments. • Persistent substance use despite knowledge that it may cause or exacerbate physical or psychological problems.
Pharmacologic (DSM-5-TR criteria 10 and 11)	• **Tolerance:** Individual requires increasingly higher doses of the substance to achieve the desired effect, or the usual dose has a reduced effect; individuals may build tolerance to specific symptoms at different rates. • **Withdrawal:** A collection of signs and symptoms that occurs when blood and tissue levels of the substance decrease. Individuals are likely to seek the substance to relieve symptoms. No documented withdrawal symptoms from hallucinogens, PCP, or inhalants. • **Note:** Tolerance and withdrawal in the context of appropriate medical treatment (i.e., pain medication used as prescribed) do *not* count as criteria for an SUD.

Abbreviations: DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; SUD, substance use disorder.

Notes:

a. Adapted from [APA 2022]. Please consult the DSM-5-TR criteria for substance-specific diagnostic information.
b. SUDs are classified as mild, moderate, or severe based on how many of the 11 criteria are fulfilled: mild, any 2 or 3 criteria; moderate, any 4 or 5 criteria; severe, any 6 or more criteria.

All Recommendations

☑ ALL RECOMMENDATIONS: SUBSTANCE USE SCREENING, RISK ASSESSMENT, AND USE DISORDER DIAGNOSIS IN ADULTS

Screening

- During the initial visit and once per year thereafter, primary care clinicians should screen for the following in adults ≥18 years old:
  - Alcohol use, and when unhealthy use is identified, assess the level of risk to the patient. (A1)
  - Tobacco use, and when use is identified, provide assessment and counseling. (A1)
  - Other drug use (B3), and when unhealthy use is identified, assess the level of risk to the patient. (A3)
  - See guideline section Risk Assessment and Figure 1: Substance Use Screening, Risk Assessment, Diagnosis, and Interventions.
- Before screening for substance use, clinicians should explain the benefits and risks of screening to all patients, especially those who are pregnant or planning to conceive; the discussion should include state reporting requirements and the potential for involvement of child protective services. (A3)
  - For information on the Child Abuse Prevention and Treatment Act (CAPTA) in New York State, see Plans of Safe Care for Infants and their Caregivers.
- Clinicians should also perform substance use screening to inform clinical care when:
  - Prescribing medication(s) that have adverse interactions with alcohol or drugs. (A2)
  - A patient has symptoms or medical conditions that could be caused or exacerbated by substance use. (A3)

Screening Tools

- Clinicians should use standardized and validated questionnaires for substance use screening (see Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults). (A3)

Risk Assessment

- Clinicians should assess the level of substance use risk in individuals who have a positive substance use screening result or a history of SUD or overdose. (A3)
- Clinicians should use standardized and validated tools to assess the level of risk associated with substance use (see Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old). (A3)

Patient Engagement

- Clinicians should discern patients' perceptions of their substance use and adjust interventions using techniques informed by motivational interviewing. (A3)

Interventions

- For patients with low-risk substance use, clinicians should:
  - Provide positive reinforcement for minimizing risk. (B3)
  - Repeat screening annually. (A3)
- For patients with moderate-risk substance use, clinicians should further explore patients' risk level (risk behaviors, pattern and quantity of use); if concern exists about high-risk use, perform or refer for SUD assessment with DSM-5-TR criteria. (A3)
- For patients with high-risk substance use, clinicians should perform or refer for SUD assessment with DSM-5-TR criteria. (A2 for alcohol, A3 for other drugs).
- For patients with moderate- or high-risk substance use not diagnosed as a use disorder, clinicians should:
  - Offer brief advice on potential negative health consequences. (A3)
  - Discuss harm reduction strategies, including reducing use. (A3)
  - Provide or refer for a brief intervention informed by motivational interviewing. (A1 for alcohol, A3 for other drugs)
  - Provide individualized follow-up. (A3)

☑ ALL RECOMMENDATIONS: SUBSTANCE USE SCREENING, RISK ASSESSMENT, AND USE DISORDER DIAGNOSIS IN ADULTS

Diagnosis of SUD

- Clinicians should use the DSM-5-TR criteria to diagnose an SUD and determine its severity. (A3)
- If patients present with symptoms consistent with both an SUD and a mental health disorder, clinicians should assess for both types of disorder and refer for specialty behavioral healthcare when indicated. (A3)

Treatment

- Clinicians should engage in shared decision-making with patients diagnosed with an SUD to develop an individualized treatment plan that includes pharmacologic and behavioral treatment as indicated and available [a]. (A3)

Abbreviations: DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; SUD, substance use disorder.

Note:

a. See NYSDOH AI guidelines Treatment of Alcohol Use Disorder and Treatment of Opioid Use Disorder, NYSDOH AI Clinical Guidance: Stimulant Use, and U.S. Public Health Service: A Clinical Practice Guideline for Treating Tobacco Use and Dependence.

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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation. • The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.