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Substance Use Screening and Risk Assessment in Adults

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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 (NYS) Department of Health (DOH) AIDS Institute (AI) for use by primary care providers and in other adult outpatient care settings in NYS to achieve the following goals:

Increase the identification of unhealthy substance use among NYS 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 NYS 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.

Role of primary care providers in New York State: Primary care providers in NYS play an essential role in identifying and addressing unhealthy substance use in their patients. In light of the potential consequences of alcohol and drug use for individuals, communities, and healthcare systems, this committee recommends that all primary care providers in NYS be prepared to perform or provide substance use screening, assessment of risk level, and brief interventions as appropriate.

Definition of Terms

Screening

Screening entails asking patients brief questions about substance use and should be routinely performed by care providers for all patients seen in medical settings. This guideline recommends substance use screening for all adults seen by primary care providers. Screening can quickly identify patients with potentially *unhealthy substance use* (see Box 1, below), many of whom will not have substance use–related clinical signs or symptoms [Saitz(b), et al. 2014; Gordon, et al. 2013]. Most screening instruments are brief and may be as short as a single question; therefore, they do not collect detailed information on the risk level, duration, or specific pattern of substance use.

- See the guideline section Substance Use Screening for All Adult Patients in the Primary Care Setting
- See Table 1: Recommended Validated Tools for Use in Medical Settings to Screen for Alcohol and Drug Use in Adults

Box 1: 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 (SUD).
- As defined here, unhealthy alcohol use is use that exceeds guideline-recommended levels; for illicit drugs, 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.
- Brief screening tools can identify potentially unhealthy use and can be followed by a risk assessment to determine the clinical significance and severity of use.

Risk Assessment

Risk assessment is performed using brief assessment tools to collect information on the extent, duration, and pattern of an individual patient's substance use. Assessment tools determine the level of risk (i.e., low, moderate, or high) and thus the potential for negative consequences (see Box 2, below). This guideline recommends that clinicians use only validated questionnaires for risk assessment in patients who have a positive screening result or a history of SUD or overdose. As shown in Figure 1, below, 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].

- See Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old
- See the guideline section Diagnosis of Substance Use Disorder

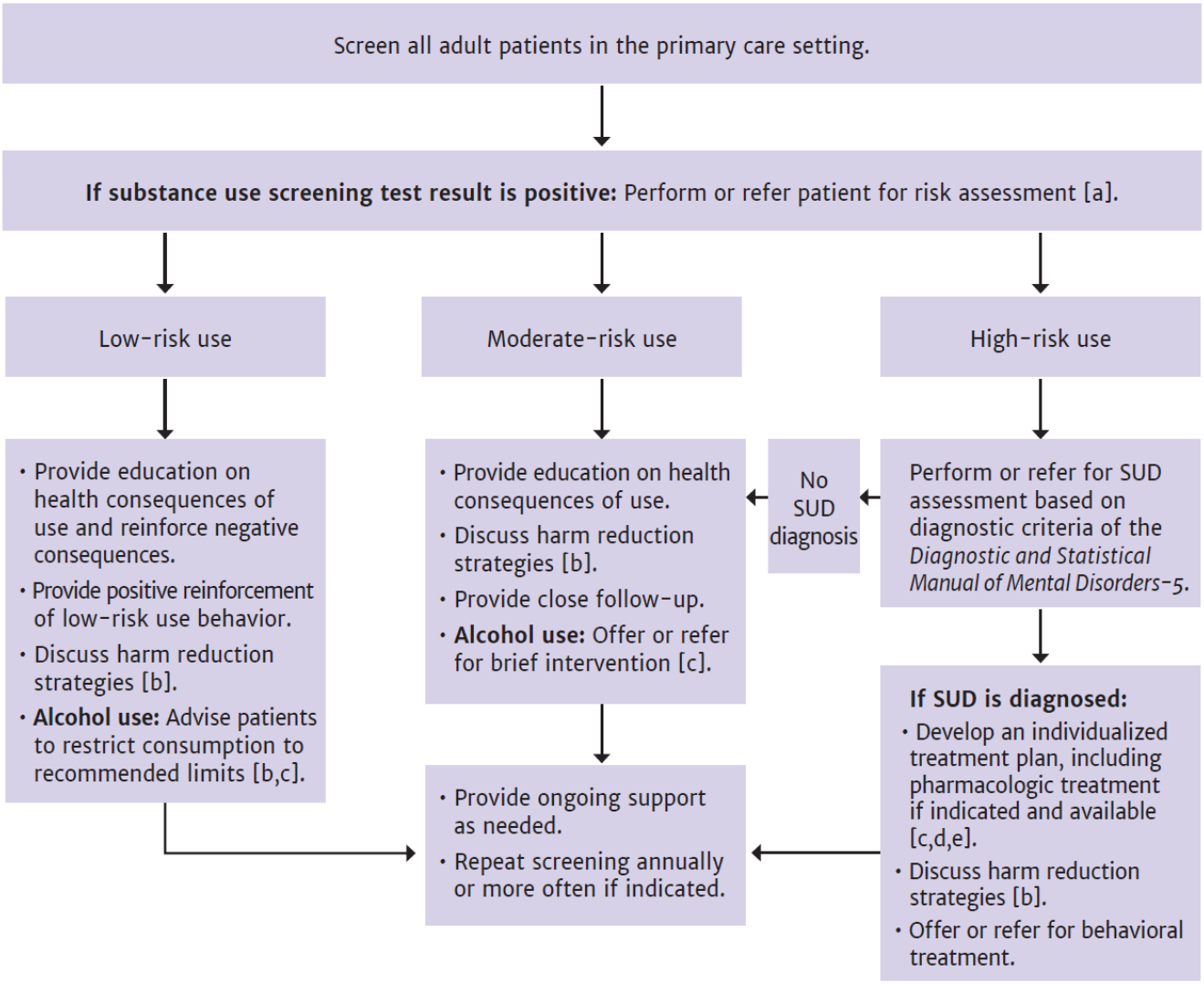
Box 2: Substance Use Levels of Risk [a]

- **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 guideline-recommended levels or occasional cannabis use).
- **Moderate risk:** Patient is at risk for 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 an SUD, 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].

Figure 1: Substance Use Identification and Risk Assessment in Primary Care



Notes:

a. For patients with a known history of SUD or overdose, screening may not be required by assessment is recommended.
b. See NYSDOH AI guideline Substance Use Harm Reduction in Medical Care.
c. See NYSDOH AI guideline Treatment of Alcohol Use Disorder and National Institute on Alcohol Abuse and Alcoholism: Helping Patients Who Drink Too Much: A Clinician's Guide.
d. See NYSDOH AI guideline Treatment of Opioid Use Disorder.
e. See U.S. Public Health Service: A Clinical Practice Guideline for Treating Tobacco Use and Dependence.

Goals of Screening and Risk Assessment

In the United States, tobacco, alcohol, and other (e.g., illicit, nonmedical prescription) drug use 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 2017, there were more than 72,500 alcohol-related deaths in the United States [White, et al. 2020]. Increases in opioid use disorder and skyrocketing rates of drug overdose deaths (often opioid-related) are a public health crisis across the country [Wilson, et al. 2020; Dowell, et al. 2017; Rudd, et al. 2016; SAMHSA 2016].

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 [WHO 2016; Venkatesh and Davis 2000]. Although screening

for alcohol use has been a recommended practice in adult primary care since 1996 [Curry, et al. 2018], only 1 in 6 adults in the United States report ever discussing alcohol use with a healthcare professional [McKnight-Eily, et al. 2014].

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, for patients and care providers to be comfortable, thoughtful implementation, with sensitivity to stigma and privacy concerns, is essential [Bradley, et al. 2020; McNeely, et al. 2018] (see the NYSDOH AI guideline Substance Use Harm Reduction in Medical Care > Avoiding Substance Use-Associated Discrimination).

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

- **Informing medical care:** One goal is to inform a patient's 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 care provider'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 knowing about a patient's past medical history, family history, or social determinants of health, knowing about a patient's substance use helps care providers formulate effective patient-centered treatment plans.
- **Identifying the need for intervention:** A second goal is to identify patients who would benefit from interventions to reduce their consumption (see guideline section Management of Low-, Moderate-, and High-Risk Substance Use) or patients who are candidates for substance use disorder treatment (see Figure 1: Substance Use Identification and Risk Assessment in Primary Care). 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. 2020; Curry, et al. 2018; Jonas, et al. 2014; Mattick, et al. 2014; USPHS 2008]. 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 done with knowledge and sensitivity, this may reduce stigma, improve the patient–care provider relationship, and lead to behavior change. Initiating a discussion about substance use communicates to patients that it is a health issue, not a moral failing, and that their care provider is concerned enough about substance use to address it and offer help.

→ KEY POINT

- It is essential that clinicians are aware of their own biases and try to set them aside when screening and evaluating patients for drug and alcohol use.

Substance Use Screening for All Adult Patients in the Primary Care Setting

☑ RECOMMENDATIONS

Primary Care Screening for Adults

- During the initial visit and during annual follow-up visits, 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 it is identified, provide assessment and counseling. (A1)
  - Drug use (B3), and when unhealthy use is identified, assess the level of risk to the patient. (A3)
  - See the guideline section Risk Assessment.
- Before screening for drug use, clinicians should explain the risks and benefits 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 repeat 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)

→ KEY POINTS

- It is important to ask patients about substance use during an initial visit and during 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.
- It is important to 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.

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; O'Connor, et al. 2018; O'Donnell, et al. 2014; Kaner, et al. 2009; 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 (HEDIS) performance measures.

In the absence of systematic screening, unhealthy alcohol use typically goes unidentified [McKnight-Eily, et al. 2017] or is identified by healthcare providers only when an individual has developed a severe alcohol use disorder or alcohol-related health problems, such as alcohol-related cirrhosis or pancreatitis. In a study among individuals reporting current alcohol use, only 17.4% reported ever discussing their use with a health professional, and the rate was only modestly higher (25.4%) for those who reported binge drinking [McKnight-Eily, et al. 2017].

Tobacco

Clinicians should screen all patients for all types of tobacco use, and when it is identified, provide counseling, assessment, and treatment [USPHS 2008]. Every visit with a healthcare provider affords the opportunity to identify a patient's tobacco use and offer 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) [AHRQ 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].

Drugs

Based on clinical experience and expertise, this committee recommends that clinicians screen for drug use in adult patients ≥18 years old who present for primary care. The decision to screen should consider the rationale and specific circumstances discussed below and should only be performed for the purpose of informing clinical care. Screening should identify a patient's use of illicit 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]; 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 active research. Randomized controlled clinical trials have generated mixed results regarding the efficacy of brief interventions in reducing drug use [Patnode, et al. 2020; Gelberg, et al. 2015; Roy-Byrne, et al. 2014; Saitz(a), et al. 2014; Humeniuk, et al. 2012].

Evidence supports the benefits of pharmacologic treatment for opioid use disorder, which can be delivered effectively in primary care settings. However, no pharmacotherapy is currently approved by the U.S. Food and Drug Administration for other types of drug use disorders. Some patients with unhealthy use of drugs other than opioids will benefit from referral to addiction treatment or from psychosocial interventions integrated into primary care, but data on long-term outcomes of interventions in primary care settings are scarce, and many patients may not have access to evidence-based services [USPSTF 2020].

No currently published studies demonstrate harms 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 that care providers 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 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.
- Opioid overdose deaths can be reduced through increased identification of unhealthy opioid use and, when indicated, effective treatment with medications for opioid use disorder [SAMHSA 2019; 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 nonmedical 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 healthcare provider will not have the information necessary to perform the appropriate diagnostic work-up. 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.

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 potential harms, consequences, and benefits 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.
- Description of the CAPTA law and legal requirements for healthcare providers when screening results are positive.
- 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 potential harms of drugs and treatment options for SUD, if patients decline to be screened for other drugs.

Repeat screening to inform clinical care in individual patient circumstances: Iatrogenic harm is possible if a patient's drug use is not identified, including adverse effects resulting from drug-medication interactions, overdose from combining prescribed medications with illicit 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].

Clinicians should repeat 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 [Kim, et al. 2017; Edelman and Fiellin 2016; NIAAA 2016; Ries, et al. 2014; Mertens, et al. 2005; Lock and Kaner 2004].

Screening is also recommended for patients who use medications that have adverse interactions with alcohol or drugs and for patients who engage in known risk behaviors, such as unprotected sex, that may co-occur with substance use [Maxwell, et al. 2019; McKetin, et al. 2018; Scott-Sheldon, et al. 2016; Rehm, et al. 2012]. Patients taking prescription opioids or benzodiazepines should be screened for use of alcohol and for illicit 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. Specific assessment tools (e.g., Opioid Risk Tool, Current Opioid Misuse Measure) have been developed to predict and evaluate prescription opioid misuse among patients receiving chronic opioid therapy, but discussion of these tools is beyond the scope of this guideline. Care providers 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, care providers 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 interactions:

- Drugs.com > Drug Interactions Checker
- University of Liverpool HEP Drug Interactions Checker
- University of Liverpool HIV Drug Interactions Checker
- Consensus validation of the POSAMINO (POtentially Serious Alcohol–Medication INteractions in Older adults) criteria [Holton, et al. 2017]
- NYSDOH AI Resource: ART Drug-Drug Interactions
- For patients: National Institute on Alcohol Abuse and Alcoholism > Harmful Interactions: Mixing Alcohol With Medicines

Implementing Substance Use Screening in Primary Care Settings

- **Who to screen:** All adults seen by primary care providers 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 there are no specific demographic characteristics that reliably predict such use.
- **How often to screen:** Because substance use behavior changes over time, care providers 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, February 2018) [SAMHSA 2018].
- **Who should perform the 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 on a computer. 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 ensure fidelity of administration [Williams, et al. 2015; Bradley, et al. 2011], increase patient comfort [McNeely, et al. 2018; Spear, et al. 2016], and reduce the burden on staff. 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 2012].

Screening Tools

☑ RECOMMENDATION

Screening Tools

- Healthcare providers 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.

There is no reliable biomarker with sufficient sensitivity and specificity to identify 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

Tool [a]	**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(b), et al. 2015; Smith, et al. 2009]	Alcohol	• 1 item; 1 minute • Interviewer or self-administered via electronic app or on paper
SISQ-Drug (Single-Item Screening Questions for Drug Use) [McNeely(b), 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
SoDU (Screen of Drug Use) [Tiet, et al. 2015]	Prescription drugs, other drugs	• 2 items; 1 minute • Interviewer
SUBS (Substance Use Brief Screen) [McNeely and Saitz 2015]	Tobacco, alcohol, prescription drugs, other drugs	• 4 items; 2 minutes • 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

Note:

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

→ 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. 2018; Spear, et al. 2016; Williams, et al. 2015; Bradley, et al. 2011; Wight, et al. 2000; 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 report of substance use, the language used in any screening tool should be clear and nonjudgmental. Drug screening should capture nonmedical prescription drug use and illicit 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 -Drug). SISQ tools are validated for interviewer administration or self-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) and the first section of the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS-1) tool elicit information about use of tobacco, alcohol, illicit drugs, and nonmedical prescription drugs through a single 4-item instrument. Like the SISQ-Alc and -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 some circumstances, the purpose of screening may be to diagnose substance use disorder rather than identify unhealthy drug use. For example, if the clinical setting cannot offer early intervention or preventive care, screening may be used to identify individuals in need of referral to addiction treatment. In such cases, the Screen of Drug Use (SoDU) tool, which specifically identifies drug use disorders, may be used. The SoDU was validated using Diagnostic and Statistical Manual of Mental Disorders–IV (DSM-IV) criteria, and a positive screen corresponds to a DSM-IV diagnosis of "drug abuse or dependence."

Alcohol: The briefest alcohol screening questionnaires (SISQ-Alc, TAPS-1, SUBS) use a single question about binge drinking in the past year to identify unhealthy alcohol use. Although it is possible for patients to use more alcohol than the recommended limits in the U.S. Department of Health and Human Services and Department of Agriculture Dietary Guidelines (14 drinks/week for men ≤65 years old, 7 drinks/week for women and men ≥65 years old), even in the absence of binge drinking, validation studies have demonstrated good sensitivity [NIAAA 2016; DHHS 2015]. The 3-item Alcohol Use Disorders Identification Test–Concise (AUDIT-C) is a widely used and recommended brief screening tool for alcohol use in medical settings [Moyer 2013; Frank, et al. 2008; Bradley, et al. 2007; Reinert and Allen 2007; Bradley, et al. 2003; Bush, et al. 1998]. Unlike the other brief screening tools, the AUDIT-C identifies the level of risk to patients with problem use and high-risk use. The AUDIT-C does not screen for tobacco or drugs.

Tobacco: Tobacco use is incorporated into some of the brief screening instruments (SUBS, TAPS-1) included in Table 1, above. The accuracy of SUBS and TAPS-1 tools for identifying tobacco use is high, with a sensitivity of 98% and a specificity ranging from 80% to 96% [Gryczynski, et al. 2017; McNeely(a), et al. 2015]. Use of a single instrument that concurrently screens for tobacco and alcohol use will streamline the screening process.

Drugs: Screening for drug use can be performed with the SISQ-Drug, SUBS, or TAPS-1 tools, all of which perform well in validation studies of adults in primary care settings [Gryczynski, et al. 2017; McNeely(a), et al. 2016; McNeely(a), et al. 2015; McNeely(b), et al. 2015]. With changes in the legal status of cannabis and shifting attitudes toward cannabis use, clinics should provide patients and staff with clear instructions about reporting cannabis use on questionnaires that categorize cannabis as an illicit drug [Lapham, et al. 2017]. In states where cannabis is legal, it may be best to ask about its use separately from illicit drugs [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)

Candidates for Risk Assessment

Clinicians should use validated tools to perform substance use assessment 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 Identification and Risk Assessment in Primary Care).

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(b), et al. 2015].

Known history of SUD or overdose: Polysubstance use is common in people with SUD [Callaghan, et al. 2018; Falk, et al. 2006; McLellan, et al. 2000; Earleywine and Newcomb 1997]. 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]. Furthermore, overdose is frequently the result of polysubstance use, often involving use of opioids in combination with alcohol and other drugs [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 inform 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 poor adherence to 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 [a]	**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, other drugs; identifies specific drug classes	• 10 to 71 items; 5 to 15 minutes, depending on no. of substances used • Interviewer administered

Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old [a]		
Tool [a]	**Substance(s) Included**	**No. of Items, Approximate Time Required to Complete, and Format**
ACASI-ASSIST (Audio Computer-Assisted Self-Interview–ASSIST) [Kumar, et al. 2016; McNeely(b), et al. 2016]	Tobacco, alcohol, prescription drugs, other drugs; identifies specific drug classes	• 10 to 98 items; 5 to 15 minutes, depending on no. of substances used • Self-administered on computer/tablet
AUDIT (Alcohol Use Disorders Identification Test) [Reinert and Allen 2007] • Available in languages other than English	Alcohol	• 10 items; 3 minutes • Interviewer- or self-administered
DUDIT (Drug Disorders Identification Test) [Hildebrand 2015; DUDIT 2003] • 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
TAPS (Tobacco, Alcohol, Prescription Medication, and Other Substance Use) [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 on computer/tablet

Note:

a. Clinicians with experience in treating patients with substance use and substance use disorder may choose to use Diagnostic and Statistical Manual of Mental Disorders–5 diagnostic criteria as the initial assessment tool.

Alcohol use: To assess level of risk in patients who use alcohol, clinicians can use the Alcohol Use Disorders Identification Test (AUDIT) or the AUDIT-Concise (AUDIT-C) tool, both of which have been widely adopted in medical settings [NIAAA 2016; Bradley, et al. 2007; Reinert and Allen 2007; Bradley, et al. 2003]. The AUDIT is a 10-item questionnaire developed by the World Health Organization (WHO) for alcohol use screening in medical settings. The AUDIT-C consists of the first 3 items of the AUDIT, which asks only about alcohol consumption. Although the full AUDIT is still widely used, the 3-item AUDIT-C performs as well as the full 10-item AUDIT instrument for identifying risky use and problem use in studies conducted among primary care patients in the United States [Bradley, et al. 2007]. However, use of the full AUDIT provides expanded information about problems related to alcohol use that may be helpful for care providers offering brief interventions or other alcohol counseling.

Tobacco use: For patients who use tobacco, assessment of health risks is typically accomplished by asking about the number of cigarettes smoked per day. The 2-item Heaviness of Smoking Index, which asks about total cigarettes per day and the timing of the first cigarette, can determine the level of dependence for daily smokers.

Drug use: For assessment of drug use, which can involve multiple substance classes with varying levels of risk, the instruments are by necessity more complex. The WHO Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) was one of the first screening tools designed for use in healthcare settings to provide substance-specific risk stratification for drugs. Its length and complexity have hindered its implementation in primary care settings [Ali, et al. 2013; Babor, et al. 2007], but a self-administered electronic version may be more feasible [McNeely(b), et al. 2016].

The more recently developed Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS) tool streamlines the ASSIST to perform this assessment relatively quickly and still supply substance-specific information about the level of risk. Scores range from 0 to 4, with higher scores indicating greater severity. The TAPS tool was specifically developed for adult primary care and is recommended for use in general medical settings to screen for opioid and other substance use [SAMHSA 2018]. It is validated in an electronic, patient self-administered format (myTAPS) [Adam, et al. 2019] and a more traditional interviewer-administered questionnaire. An online version of the TAPS tool with clinical guidance on interpreting the scores and resources for intervention is available on the National Institute on Drug Abuse TAPS website.

Management of Low-, Moderate-, and High-Risk Substance Use

Assessment with validated tools can characterize the level of risk as low, moderate, or high (see Figure 1: Substance Use Identification and Risk Assessment in Primary Care and Table 2: Brief, Validated Risk Assessment Tools for Use in Medical Settings With Adults ≥18 Years Old). Intervention options for substance use are determined by the level of risk identified in the assessment process, an individual's perception of the problem, and time restrictions, among other factors. Individuals with unhealthy substance use regularly interact with the healthcare system, and primary care settings are optimally positioned to offer prevention and treatment interventions. All clinicians can develop the skills to offer treatment or refer patients for appropriate interventions [McLellan 2017; Edelman and Fiellin 2016].

Harm reduction strategies should be discussed with individuals who engage in substance use at all risk levels.

Clinical resources for addressing tobacco use include the NYSDOH Information about Tobacco Use, Smoking and Secondhand Smoke, the New York City Department of Health and Mental Hygiene publication Treating Tobacco Addiction, and the American Academy of Family Physicians table of FDA-Approved Medications for Smoking Cessation. For patients who use any type of tobacco, the U.S. Public Health Service Clinical Practice Guideline for Treating Tobacco Use and Dependence: 2008 Update recommends the "5 As" approach as an intervention:

1. **Ask** patients about tobacco use.
2. **Advise** tobacco users to quit.
3. **Assess** willingness to quit.
4. **Assist** in a quit attempt.
5. **Arrange** for follow-up.

For individuals with low-risk use of any substance, clinicians can offer positive reinforcement and reminders of the negative consequences of use. For individuals who use alcohol, clinicians can provide information on the recommended limits of use; see the U.S. Department of Health and Human Services and Department of Agriculture Dietary Guidelines. Robust evidence supports the efficacy of screening and brief interventions in the primary care setting for reducing alcohol use among individuals with unhealthy use who do not meet criteria for alcohol use disorder [Curry, et al. 2018; Jonas, et al. 2012]. Studies on the efficacy of brief interventions in reducing drug use have found mixed results [Gelberg, et al. 2015; Roy-Byrne, et al. 2014; Saitz(a), et al. 2014; Humeniuk, et al. 2012]; however, brief interventions are recommended by the Substance Abuse and Mental Health Services Administration and have been implemented in many healthcare settings with no evidence of harm [SAMHSA 2018]. If an individual has high-risk substance use, it is essential to perform or refer for a full diagnostic substance use disorder assessment using the Diagnostic and Statistical Manual of Mental Disorders–5 criteria (see guideline section Diagnosis of Substance Use Disorder).

Brief interventions: Brief interventions range from 5 to 20 minutes in duration, vary in frequency, and include a variety of components based on different psychological and motivational approaches. Common elements of a brief intervention include discussion of the risks and benefits of substance use as perceived by the patient, individualized feedback regarding level of risk, advice on reducing use to within recommended safe limits, discussion of any related health effects, and motivational support (see Figure 2, below). A commonly used acronym is FRAMES: Feedback, Responsibility, Advice, Menu Options, Empathy, and Self-Efficacy. The time available for an intervention and the individual's level of engagement and motivation for change often determine the duration, type, and frequency of brief interventions.

For further information and resources, see the NYSDOH AI guideline Treatment of Alcohol Use Disorder > Behavioral Treatment.

Figure 2: Brief Intervention: "Can We Spend a Few Minutes Talking About Your Substance Use?"

Adapted from [Project ASSERT 2019].

Diagnosis of Substance Use Disorder

☑ RECOMMENDATIONS

Diagnosis of Substance Use Disorder

- For accurate diagnosis of a substance use disorder (SUD) and its severity, clinicians should perform or refer patients for a full assessment based on Diagnostic and Statistical Manual of Mental Disorders–5 (DSM-5) criteria. (A3)
- Clinicians should assess patients' perceptions of their substance use and readiness to change substance use behaviors. (A3)
- If individuals present with symptoms consistent with both an SUD and a mental health disorder, clinicians should assess for both types of disorder before making a diagnosis and should refer for specialty behavioral healthcare when indicated. (A3)

Healthcare providers should perform or refer patients for a full assessment based on DSM-5 diagnostic criteria to accurately diagnose an SUD (see Table 3, below) [APA 2013]). The DSM-5 criteria can accurately diagnose the SUD and its severity—mild, moderate, or severe—and the assessment can be performed by the clinician or experienced staff. If expertise or resources are limited, then clinicians may refer the patient to a care provider who can perform the full assessment. Clinicians experienced in assessing and treating SUD may elect to use the DSM-5 criteria as the initial assessment tool.

To enhance patient engagement and increase the possibility that a patient will follow through with the care plan, interventions must be tailored to match an individual's perception of the problem and their readiness to change [NIAAA 2016; VA/DoD 2015; SAMHSA 1997]. Based on clinical experience, the diagnostic process is an opportunity to build rapport; explore a patient's attitudes toward substance use and treatment; dispel any misconceptions about treatment, particularly pharmacologic treatment; and engage patients in care.

Patients often present with concurrent substance use and mental health disorders, and symptoms of one can mimic the other, which can complicate diagnosis and make it more challenging [SAMHSA 2019]. Clinicians should consider a diagnosis of SUD before establishing a primary psychiatric diagnosis (e.g., consider alcohol-induced depressive disorder before diagnosing a major depressive disorder). Symptoms of intoxication, such as depressed or elevated mood or perceptual disturbances, and symptoms of withdrawal, such as depression, anxiety, and insomnia, can also mimic psychiatric symptoms and should be carefully assessed.

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

Criteria Type	Descriptions
Impaired control over substance use (DSM-5 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 attempted 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.

Table 3: DSM-5 Diagnostic Criteria for Diagnosing and Classifying Substance Use Disorders [a,b,c]	
Criteria Type	**Descriptions**
Social impairment (DSM-5 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.
Risky use (DSM-5 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 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:** Individuals can have an SUD with prescription medications, so tolerance and withdrawal (criteria 10 and 11) in the context of appropriate medical treatment do *not* count as criteria for an SUD.

Abbreviations: DSM-5, Diagnostic and Statistical Manual of Mental Disorders–5; PCP, phencyclidine; SUD, substance use disorder.

Notes:

a. Adapted from [APA 2013].
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.
c. Please consult the DSM-5 for substance-specific diagnostic information.

All Recommendations

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

Primary Care Screening for Adults

- During the initial visit and during annual follow-up visits, 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 it is identified, provide assessment and counseling. (A1)
  - Drug use (B3), and when unhealthy use is identified, assess the level of risk to the patient. (A3)
  - See the guideline section Risk Assessment.
- Before screening for drug use, clinicians should explain the risks and benefits 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 repeat 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

- Healthcare providers 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 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)

Diagnosis of Substance Use Disorder

- For accurate diagnosis of a substance use disorder (SUD) and its severity, clinicians should perform or refer patients for a full assessment based on Diagnostic and Statistical Manual of Mental Disorders–5 (DSM-5) criteria. (A3)
- Clinicians should assess patients' perceptions of their substance use and readiness to change substance use behaviors. (A3)
- If individuals present with symptoms consistent with both an SUD and a mental health disorder, clinicians should assess for both types of disorder before making a diagnosis and should refer for specialty behavioral healthcare when indicated. (A3)

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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.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
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.
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.