EVIDENCE-BASED RESOURCE GUIDE SERIES

Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders

SAMHSA
Substance Abuse and Mental Health Services Administration

Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders

Acknowledgments

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MESSAGE FROM THE ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

As the first U.S. Department of Health and Human Services Assistant Secretary for Mental Health and Substance Use at the Substance Abuse and Mental Health Services Administration (SAMHSA), I am pleased to present this new resource: *Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders.*

In response to the charge of the 21st Century Cures Act to disseminate information on evidence-based practices and service delivery models, the National Mental Health and Substance Use Policy Laboratory has developed the Evidence-Based Resource Guide Series focused on the prevention and treatment of substance use disorders (SUD) and mental illnesses. With this specific guide, SAMHSA's goal is to inform health care practitioners and administrators, policy makers, and community members about strategies to prevent and treat HIV among individuals who have mental illness and/or SUD.

Established in 2019, the federal initiative "Ending the HIV Epidemic: A Plan for America" aims to reduce new HIV infections in the United States by 90 percent by the year 2030. It encourages implementation of HIV prevention, diagnosis, treatment, and outbreak response through effective programs, practices, and resources. Supporting the needs of people at risk for and with HIV who have co-occurring mental illness and/or SUD is key to meeting the initiative's goals. People with mental illness and/or SUD are particularly vulnerable to HIV. SUD, in particular, can hasten the progress of HIV.[1] More specifically, injection drug use increases the risk of getting or transmitting the disease,[2] and the risk of getting HIV is 4 to 10 times greater for people with mental illness.[3]

This guide reviews effective programs and practices to prevent HIV and increase adherence to and retention in care. I encourage you to use this guide to become informed about the populations experiencing mental illness and/or SUD with or at risk for HIV; to review the current evidence on the effectiveness of programs and practices to prevent HIV among this population; and to develop and implement appropriate and effective programming in your communities. Ultimately, your efforts will help meet the goals of ending the HIV epidemic over the next decade.

Elinore F. McCance-Katz, MD, PhD
Assistant Secretary for Mental Health and Substance Use
U.S. Department of Health and Human Services

1 National Institute on Drug Abuse. (2020, April 10). *Common comorbidities with substance use disorders research report*. https://www.drugabuse.gov/publications/research-reports/common-comorbidities-substance-use-disorders/part-3-connection-between-substance-use-disorders-hiv

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FOREWORD

Evidence-Based Resource Guide Series Overview

The Substance Abuse and Mental Health Services Administration (SAMHSA), and specifically, the National Mental Health and Substance Use Policy Laboratory (Policy Lab), is pleased to fulfill the charge of the 21st Century Cures Act to disseminate information on evidence-based practices and service delivery models to prevent substance misuse and help people with substance use disorders (SUD), serious mental illnesses (SMI), and serious emotional disturbances (SED) get the treatment and support they need.

Treatment and recovery for SUD, SMI, and SED can vary based on a number of geographic, socio-economic, cultural, gender, race, ethnicity, and age-related factors, which can complicate evaluating the effectiveness of services, treatments, and supports. Despite these variations, however, there is substantial evidence to inform the types of resources that can help reduce substance use, lessen symptoms of mental illness, and improve quality of life.

This Evidence-Based Resource Guide Series contains a comprehensive set of modules with information to improve health outcomes for people at risk for developing, living with, or recovering from mental illness and/or SUD. It is designed for practitioners, administrators, community leaders, and others considering an intervention for their organization or community.

A priority topic for SAMHSA is preventing human immunodeficiency virus (HIV) among people with mental illness and/or SUD and linking people with HIV and co-occurring mental illness and/or SUD to HIV care. This guide reviews research findings and literature related to this issue, examines emerging and best practices, and identifies challenges and strategies for implementation.

SAMHSA's Policy Lab developed this guide between 2019 and 2020, prior to and during the COVID-19 pandemic. The practices and programs included in Chapter 2 were studied prior to the onset of COVID-19 and may require adaptation to accommodate the unique challenges of delivering health care during the pandemic. Implementation strategies, outlined in Chapter 3, may also need to account for COVID-19 conditions in each community, county, and state. Finally, the practices and programs highlighted in Chapter 4 are examples of implementation prior to and at early phases of the pandemic. It is possible these organizations and programs have modified their service delivery to include telehealth and other ways of providing services due to the COVID-19 public health emergency.

Expert panels of federal, state, and non-governmental participants provided input for each guide in this series. The panels included accomplished scientists, researchers, service providers, community administrators, federal and state policy makers, and people with lived experience. Members provided input based on their knowledge of healthcare systems, implementation strategies, evidence-based practices, provision of services, and policies that foster change.

Research shows that implementing evidence-based practices requires a comprehensive, multi-pronged approach. This guide is one piece of an overall approach to implement and sustain change. Readers are encouraged to visit the SAMHSA website for additional tools and technical assistance opportunities.

Content of the Guide

This guide contains a foreword and five chapters. The chapters stand alone and can be read in any order. Each chapter is designed to be brief and accessible to healthcare practitioners, healthcare system administrators, community members, policy makers, and others working to meet the needs of people at risk for developing, experiencing, or recovering from mental illness and/or SUD.

The goal of this guide is to review the literature on preventing and treating HIV for people with mental illness and/or SUD, distill the research into recommendations for practice, and provide examples of how practitioners use these practices in their programs.

FW	**Evidence-Based Resource Guide Series Overview** Introduction to the series.
1	**Issue Brief** Overview of current approaches and challenges to preventing and treating HIV for people with mental illness and/or SUD.
2	**What Research Tells Us** Current evidence on effectiveness of programs and strategies to prevent HIV among people with co-occurring mental illness and/or SUD and link them to HIV care: Practices to increase uptake of and improve adherence to Pre-Exposure Prophylaxis (PrEP), Syringe Services Programs, Contingency Management, Cognitive Behavioral Therapy, and Patient Navigation.
3	**Guidance for Selecting and Implementing Evidence-based Practices** Practical information to consider when selecting and implementing programs and practices to improve health outcomes for people with mental illness and/or SUD with or at risk for HIV.
4	**Examples of Effective Programs and Strategies** Descriptions of programs and practices to prevent HIV and link people with HIV and co-occurring mental illness and/or SUD to HIV care.
5	**Resources for Evaluation and Quality Improvement** Guidance and resources for implementing best practices, monitoring outcomes, and improving quality.

A NOTE ON MEDICATIONS FOR OPIOID USE DISORDER

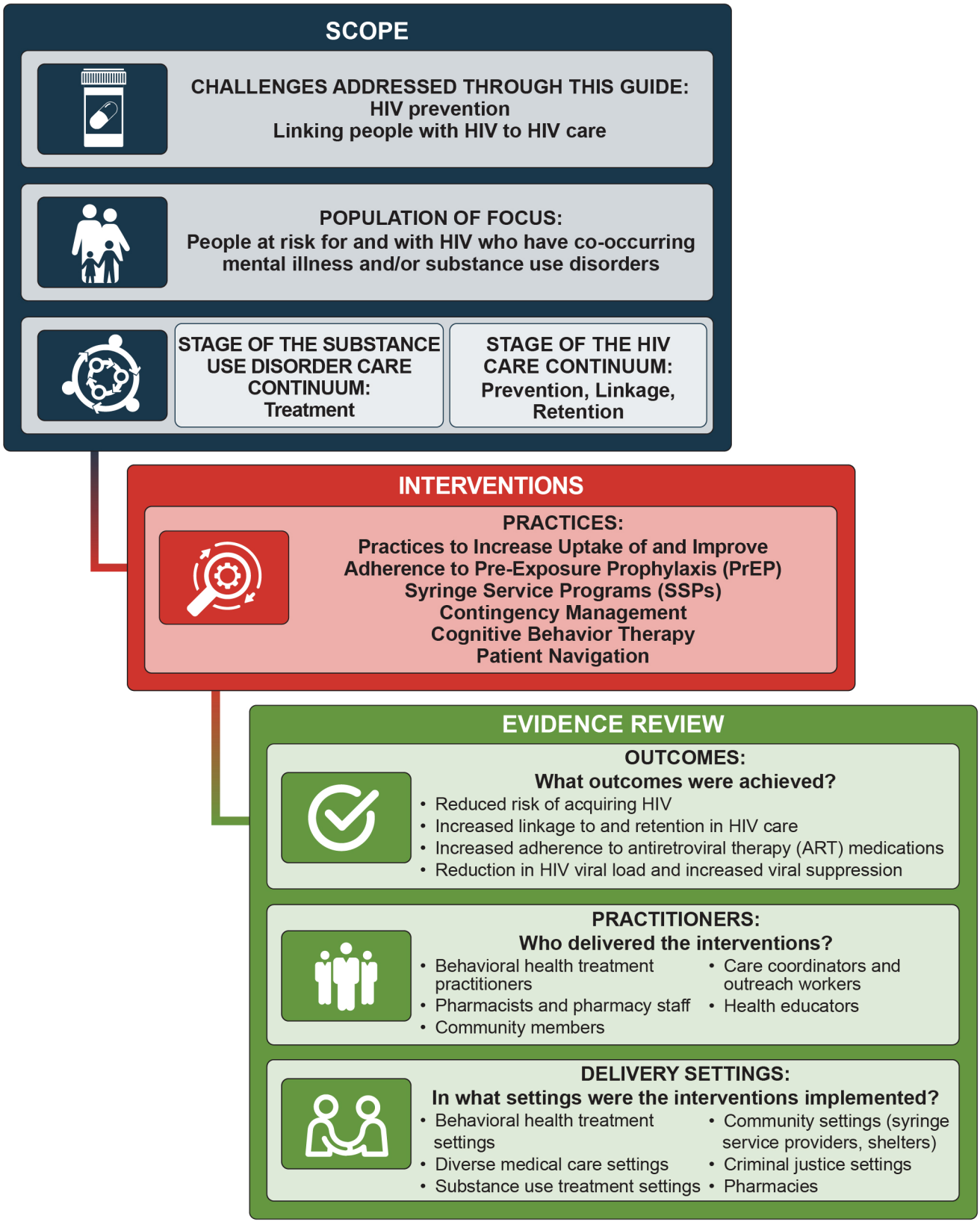
SAMHSA has an extensive online resource center with tools for use alongside this guide. For example, practitioners can use the current (2020) Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder together with practices recommended in this guide to support improved health outcomes for people with or at risk for HIV who are experiencing opioid use disorder. To avoid duplication, this guide does not discuss medications for opioid use disorder.

FOCUS OF THE GUIDE

People with mental illness and/or SUD are disproportionally affected by HIV. They may participate in behaviors that increase risk for contracting and transmitting HIV, such as sharing injection drug equipment or engaging in sexual behaviors that increase HIV risk. This guide addresses the co-occurrence of HIV and mental illness and/or SUD. It reviews effective programs and practices to prevent HIV and, for those with HIV, to increase linkage and retention in care in order to improve health outcomes.

The framework below provides an overview of this guide. The guide addresses the prevention and treatment of HIV among people with mental illness and/or SUD, and focuses on prevention and treatment practices that have been evaluated with adults. The review of these programs and practices in Chapter 2 of the guide includes specific outcomes, practitioner types, and delivery settings.

GUIDE FRAMEWORK



CHAPTER

1

Issue Brief

First detected in 1981,[1] human immunodeficiency virus (HIV) is a retrovirus that infects a type of white blood cells called CD4+ T-cells and puts people at increased risk for other infections. If left untreated, HIV can lead to acquired immunodeficiency syndrome (AIDS), which was once a fatal infection.

While there is no cure for HIV, it can be effectively managed as a chronic illness with antiretroviral therapy (ART), and prevented through harm reduction strategies (e.g., condoms and syringe services programs) and medical interventions (e.g., pre-exposure prophylaxis [PrEP] and post-exposure prophylaxis [PEP]).

Substantial progress has been made in preventing HIV and supporting people with HIV, however, there is still room for improvement in addressing linkage to treatment, ART initiation and adherence, and viral suppression, as well as engagement and retention along the HIV care continuum.

Challenges with client engagement across the HIV care continuum hinder the effectiveness of prevention and treatment efforts. These challenges increase the likelihood of HIV transmission and negative health outcomes for people with HIV.

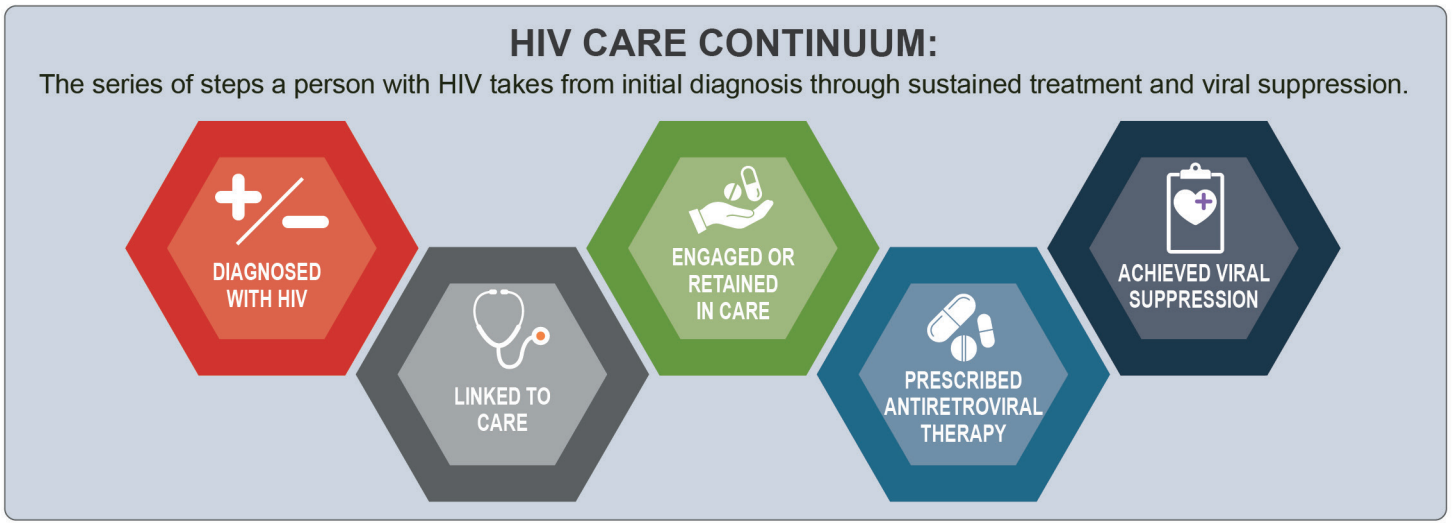
Established in 2019, the federal initiative "Ending the HIV Epidemic: A Plan for America" (EHE)[4] capitalizes on scientific discoveries and increased public awareness to prevent and treat HIV. As of 2020, there are 1 million people with HIV in the United States, and an estimated 38,000 new infections occur each year.[5] The goal of the EHE initiative is to reduce new infections by 75 percent by 2025 and by 90 percent by 2030.[6]

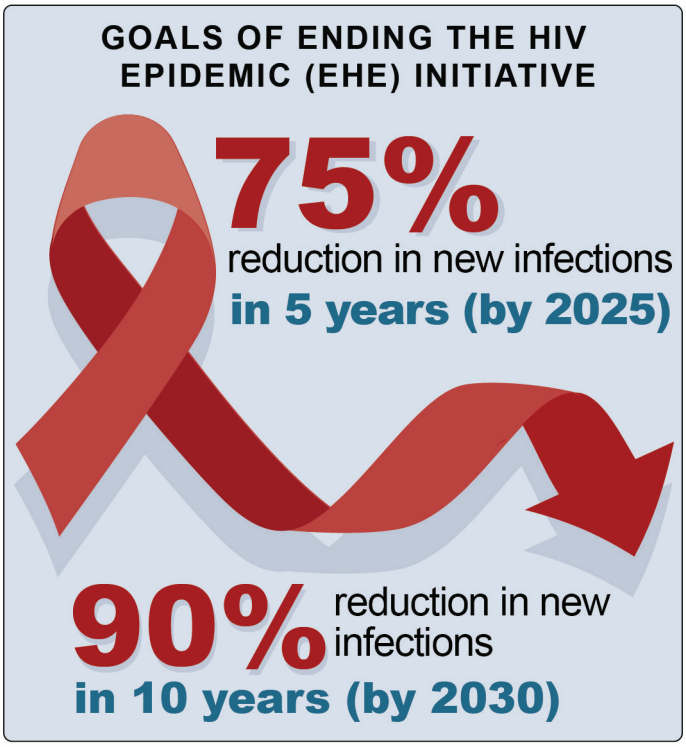
The success of the EHE initiative relies on identifying pathways to increase access to HIV prevention and treatment for those with complex needs.[7-8]

Biomedical Interventions for HIV Prevention and Treatment

Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) are medications that can be taken to prevent HIV transmission. PrEP has been shown to reduce the risk of contracting HIV from sex by 99 percent, and contracting HIV from injection drug use by 74 percent.[2] PEP, when taken within three days of possible exposure to the virus, has been shown to lower chances of HIV transmission by more than 80 percent.[3]

ART is a combination of medications used to treat HIV. ART blocks HIV replication, decreasing the amount of HIV in blood and bodily fluids. By reducing the HIV viral load (amount of virus) in the body, ART improves the health outcomes of people with HIV; decreases mortality; and, when treatment results in an undetectable viral load, reduces the chance of transmitting the disease to others to zero. The availability of and adherence to ART has changed HIV from a terminal diagnosis to a manageable chronic disease.





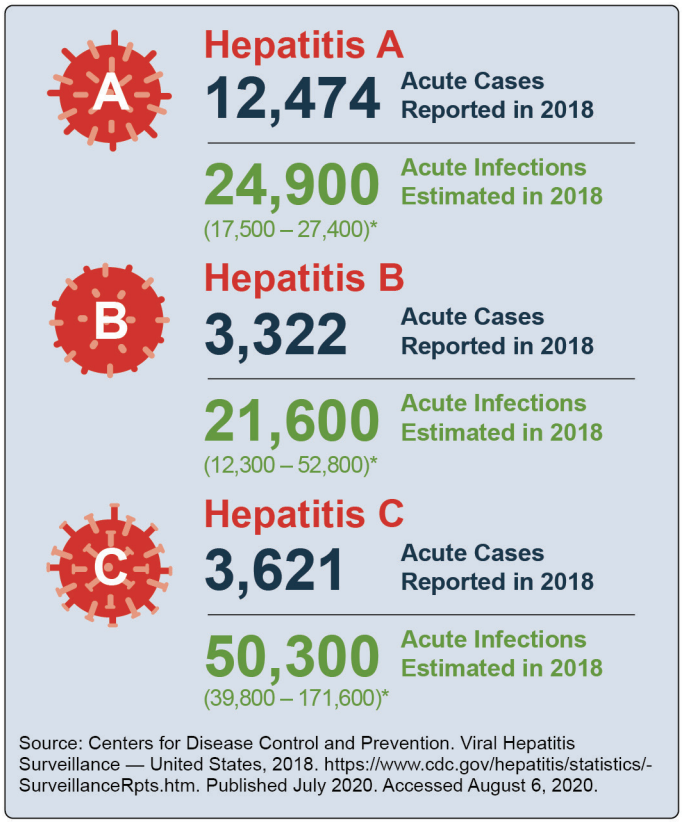
HIV Testing

In the United States, about 1 in 7 (14 percent) of the estimated 1 million people with HIV do not know they have the disease.[9] Testing identifies a person's HIV status and helps to link those who are newly diagnosed with HIV to care. Testing also helps to prevent HIV transmission and new infections.[10] Individuals who are undiagnosed or unaware of their HIV infection account for an estimated 30 to 40 percent of ongoing HIV transmissions.[11-12] The U.S. Preventive Services Task Force recommends that clinicians conduct screening for HIV infection among individuals aged 15 to 65, younger adolescents and older adults at increased risk, and all pregnant women, giving the recommendation an "A" rating, requiring HIV testing be provided free by health insurance companies.[13-15]

The EHE initiative recommends the following steps to increase the number of undiagnosed people with HIV who receive an HIV test, are diagnosed, and receive treatment: 1) make HIV testing simple, accessible, and routine in healthcare and non-healthcare settings using innovative technology, systems, and programs; and 2) conduct focused work to increase annual testing among people who are at substantial risk for HIV. HIV testing can be conducted in a range of clinical settings or at home (through rapid or mail-in self-tests).[16-17]

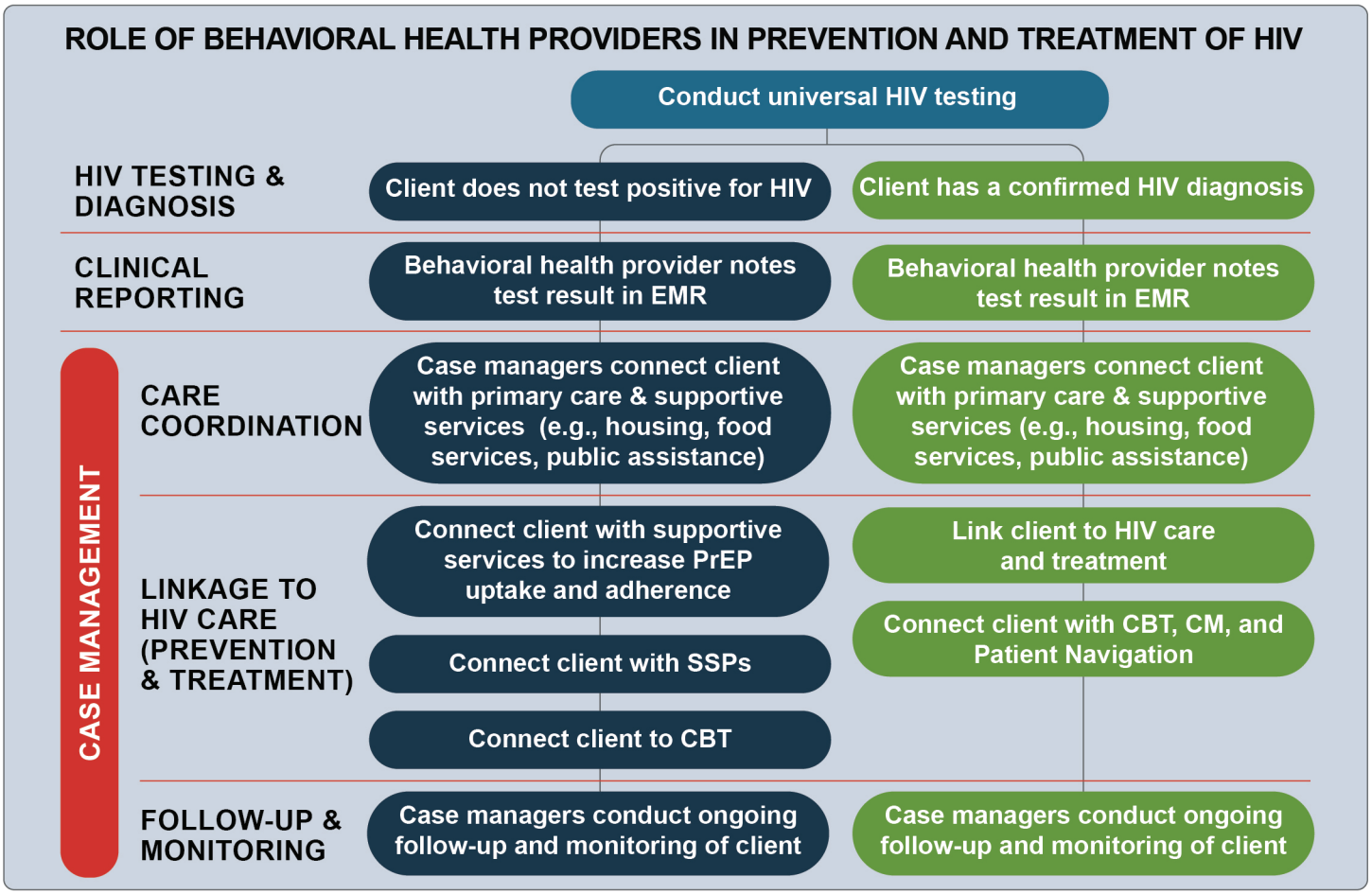
Behavioral health providers play an essential role in providing integrated HIV, viral hepatitis, mental health, and substance use screenings within the clinic setting. In a 2019 "Dear Colleague Letter," SAMHSA called on mental health and substance use providers to increase on-site, same-day oral fluid HIV testing efforts and include HIV testing as part of the standard of care.[19] Oral fluid testing can be self-administered and provides results within 20 minutes.[20] Settings that provide screening for many common co-occurring illnesses often include testing for viral hepatitis to address both hepatitis prevention and potentially serious co-occurring HIV and viral hepatitis infections.[21]

People with any mental illness diagnoses or symptoms were more likely to report being tested for HIV than those without mental illness diagnoses or symptoms.[22]



However, only 48.5 percent of people with a mental illness have had an HIV test.[23] Once diagnosed with HIV, persons with three or more psychosocial concerns were less likely to be adherent to HIV medications and persons with four or more problems were less likely to be virally suppressed.[24] People with mental illnesses were less likely to be prescribed ART and achieve viral suppression.[25]

Aligning with the EHE key strategy of diagnosing all individuals with HIV, universal testing in behavioral health settings can support rapid linkage to preventive services and HIV care including supportive services to increase PrEP uptake and adherence, syringe services programs (SSPs), cognitive behavioral therapy (CBT), contingency management (CM), and patient navigation (further discussed in Chapter 2).[26] The flow diagram (on page 4) shows the role of mental health and substance use providers in caring for clients who are at risk for or have been diagnosed with HIV.



Substance Use and HIV

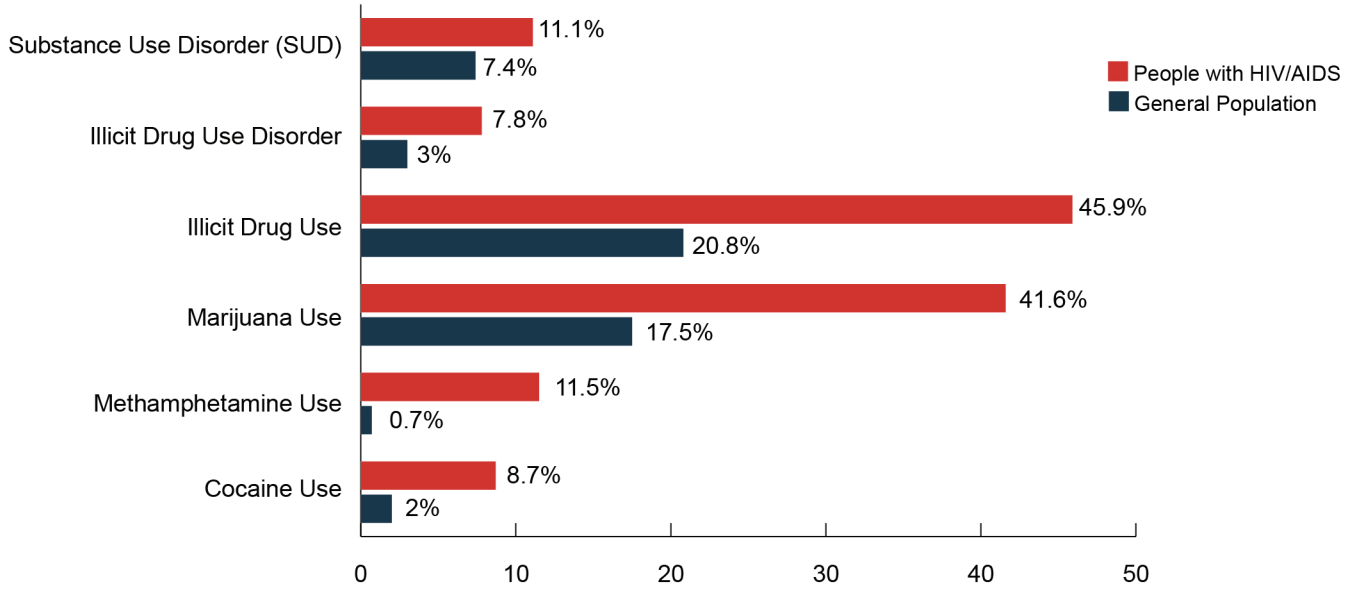
SUD can increase the risk of getting HIV and negatively impact HIV care, treatment, and related health outcomes. The prevalence of substance use among people with HIV is also higher than among the general population (as shown in the chart below). People who inject drugs (PWID) are at increased risk for blood borne pathogens, such as HIV and hepatitis B and C.[27] In 2017, 9 percent (or 3,641) of the 38,739 new HIV diagnoses in the United States and its territories were among PWID.[6, 28] Of that population, 2,625 were male and 1,016 were female.[28] Six percent (or 2,389) of new HIV diagnoses in the United States were directly attributed to PWID.[29] New HIV diagnoses are most prevalent among Whites, Blacks/African Americans, and individuals between the ages of 25 and 44.[28]

In addition, research suggests that substance use, including alcohol,[30-32] methamphetamine,[33-34] cocaine,[35] opioids, and inhalants, increases sexual behaviors that are associated with increased likelihood of getting HIV (e.g., condomless sex).[28, 36-38]

Mental Health and HIV

Mental illness can interfere with HIV prevention and adherence to treatment[48-49] and is linked to behaviors that increase likelihood of getting HIV.

PAST YEAR PREVALENCE OF SUBSTANCE USE AMONG PEOPLE WITH HIV/AIDS, AGED 12 OR OLDER

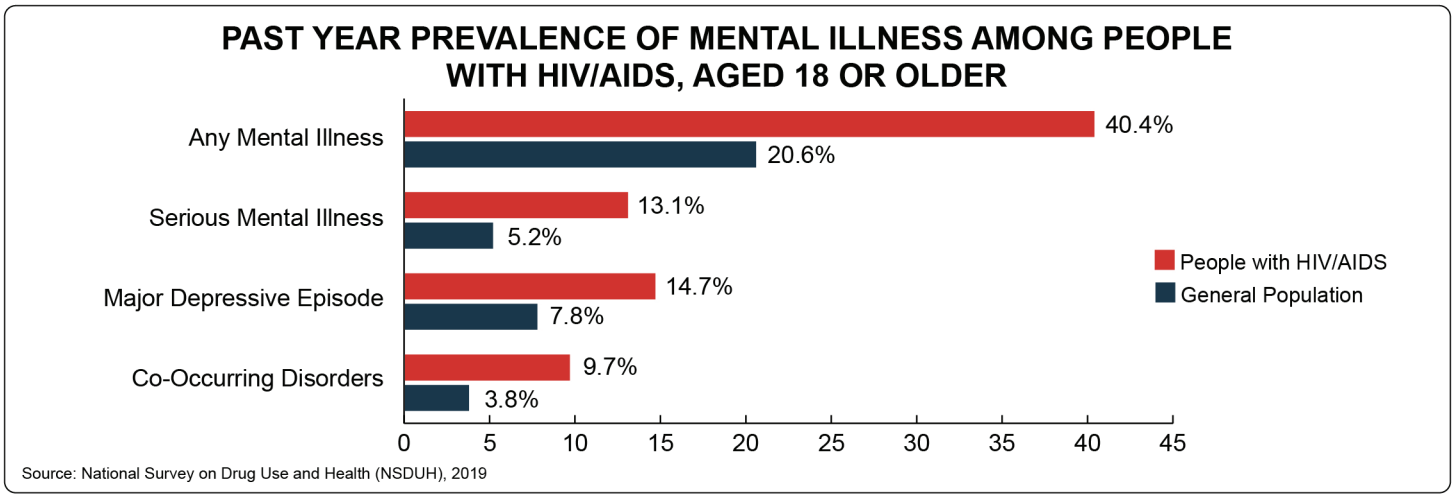


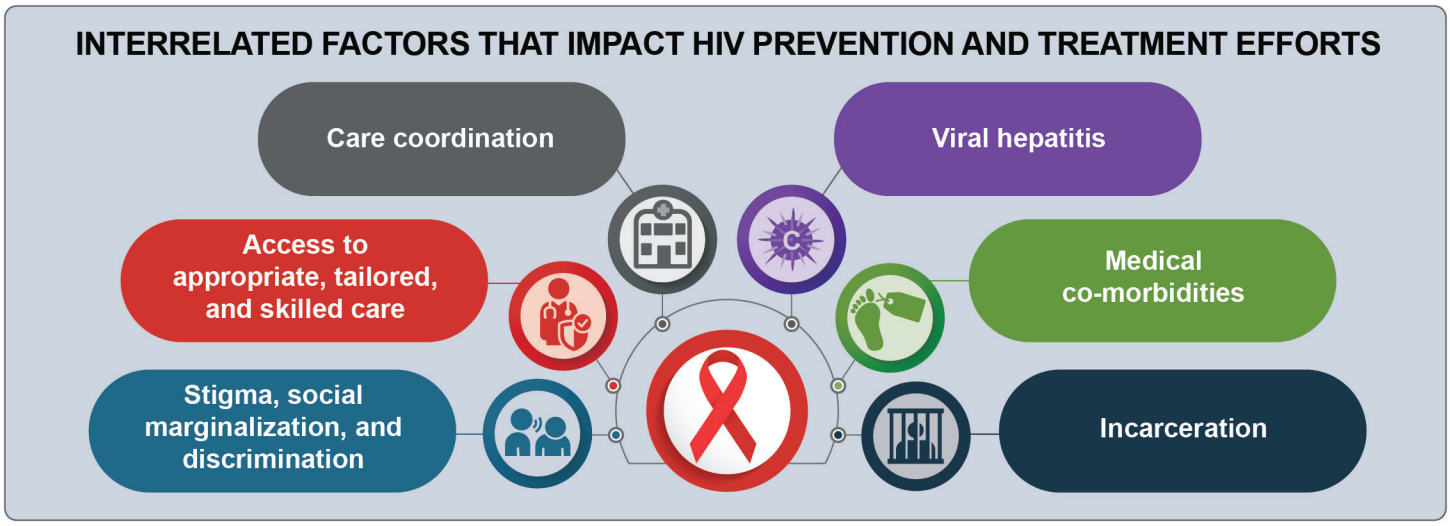
Source: National Survey on Drug Use and Health (NSDUH), 2019

Substances and HIV-Related Outcomes	
Alcohol	Heavy alcohol consumption is linked to sexual behaviors that increase likelihood of getting HIV and associated with delays in HIV diagnosis and lower rates of ART receipt and adherence.[39-40]
Opioids	Opioid use is associated with injection drug use equipment sharing and sexual behaviors that increase likelihood of getting HIV.[41-42] Injection drug use presents increased likelihood for HIV transmission, because the virus can survive in a used syringe for up to 42 days. A person without HIV has a 1 in 160 chance of getting HIV when using a syringe previously used by someone who has HIV.[38] Emerging evidence suggests that individuals who misuse prescription opioids are engaging in sexual behaviors that increase likelihood of getting HIV (e.g., condomless sex, sex with multiple partners).[42-43]
Methamphetamine	Methamphetamine use is associated with injection drug use equipment sharing and sexual behaviors that increase likelihood of getting HIV. People who actively use methamphetamines have lower rates of adherence to ART and medical follow-up (impacting both prevention and treatment).[44-45]
"Club drugs" [e.g., 3,4-methylenedioxymethamphetamine (MDMA, Ecstasy, Molly), Ketamine (Special K), Gamma Hydroxybutyric Acid (GHB, Liquid Ecstasy), alkyl nitrites (Poppers, TNT)][46]	"Club drugs" have been linked to sexual behaviors that increase likelihood of getting HIV. However, studies on these drugs are complicated, as it can be difficult to determine the timing of drug use and sexual behavior. Poly-drug use is also common among users of club drugs, complicating analyses.[47]

The prevalence of mental illness among people with HIV is also higher than among the general population (as shown in the chart below). People with HIV may experience high rates of depression, mood disorders, and generalized anxiety disorder.[50-55] An estimated 10 to 28 percent of people with HIV have co-occurring mental illness and/or SUD.[56] People with HIV who also experience depression report higher rates of other co-occurring mental health concerns such as anxiety disorders (78 percent) and SUD (61 percent), as well as increased viral loads.[54, 57-58] Depression in people with HIV can also negatively affect HIV treatment, as it is associated with discontinuation of and non-adherence to ART.[59-60]

In addition to depression and anxiety, trauma and post-traumatic stress disorder (PTSD) are strongly associated with HIV. Experiences of trauma among people with HIV can lead to behavior that increases likelihood of transmitting HIV, lower adherence to HIV care and ART, and higher likelihood of AIDS-related mortality.[61] Among women in the United States with HIV, 30 percent have PTSD (five times the national rate for women).[62]





Furthermore, women from low-income, high-HIV prevalence communities experience stressors that lead to the development of PTSD, such as high rates of child maltreatment and physical, emotional, and sexual abuse.[63]

Interrelated Factors that Impact HIV Prevention and Treatment Efforts

Understanding the complex relationship between social determinants of health, unmet needs, and HIV-related risk factors is key to addressing HIV and mental illness and/or SUD.[64] For example, it is difficult to engage people in HIV prevention or treatment programs when their basic ancillary needs (e.g., housing, child care, transportation, food, employment, health insurance) are not met.[65-68] In urban, high-poverty areas, higher HIV prevalence tends to be associated with socioeconomic status, including educational attainment, household income, employment status, structural racism, and housing status.[69-70] There are six key interrelated factors (identified below) that impact HIV prevention and treatment efforts addressed through the practices highlighted in this guide.

Stigma, social marginalization, and discrimination

Stigma is a "perennial problem,"[71] contributing to poor ART adherence, higher rates of depression,[72] and challenges related to HIV prevention (e.g., fear of disclosure impacting negotiation of condom use).[73] Stigmatizing beliefs (e.g., that HIV can be transmitted through coughing or sneezing) contribute to a culture of social discomfort, prejudice, violence, and discriminatory actions (e.g., avoiding interactions with a person they know has HIV).[73] Stigma and mistrust of medical systems may deter individuals from seeking care and from sharing with their healthcare providers details about behaviors that increase risk of getting HIV (e.g., injection drug use, condomless sex) and existing medical conditions (e.g., mental illness, SUD, HIV status, testing, and medication adherence).

Access to appropriate, tailored, and skilled care

Mental illness and SUD are conditions that present barriers to accessing and linking to HIV care, as well as initiating and adhering to medication (ART, PrEP, and PEP).[60, 74-80] Access to treatment is key to reaching viral suppression.[79] Individuals may experience challenges in finding providers that have expertise in HIV, mental health, and SUD. Mental illness and SUD treatment providers are well positioned to address some of the social determinants of health and unmet needs, but they may need additional training to address co-occurring HIV.[81]

Care coordination

Untreated or undertreated mental illness and/or SUD can create obstacles to initiating and continuing PrEP and ART, increasing the potential for HIV transmission. Integrated testing (as previously described) and service delivery (e.g., multi-disciplinary teams and one-stop-shop models that provide co-located or coordinated substance use, mental health, medical, and social services, further discussed in Chapter 3) are successful strategies for engaging and retaining in care people with or at risk for HIV who may have multiple co-occurring health and ancillary service needs.[82-85] Coordinated care, linkage to HIV care, and patient follow-up and monitoring within behavioral health settings (further discussed in Chapter 2) are also key to facilitating HIV prevention and treatment.

Medical co-morbidities

People with HIV have been shown to be at higher risk for cardiovascular disease, hepatic and renal disease, osteoporosis and fractures, metabolic disorders, skin and soft-tissue disorders, pulmonary disorders, central nervous system disorders, and various forms of cancer.[86-87] Cognitive difficulties can be caused by the impact of HIV on the brain (i.e., HIV-associated neurocognitive disorder).[88-89] Possible side effects and interactions from pharmacological therapy, including ART and medication for opioid use disorder, may further complicate health outcomes.[86-87, 90]

Viral hepatitis

People with HIV are disproportionately affected by viral hepatitis (hepatitis A virus [HAV], hepatitis B virus [HBV], and hepatitis C virus [HCV]). Of those with co-occurring HIV and viral hepatitis, about one third have both HBV and HCV. HBV and HCV are bloodborne pathogens, which can be spread through needle sharing associated with injection-drug use.[21] Nearly 75 percent of people with HIV who inject drugs also are infected with HCV.[91] Both HBV and HCV are also associated with sexual behaviors that increase risk of HIV (e.g., condomless sex). About half of people who have HCV do not display symptoms, so it is important that regular testing is done.[92] Co-occurring HIV and viral hepatitis present challenges in managing and treating HIV infection.[91, 94-95] Hepatitis A, B, and C are all associated with liver inflammation and liver damage. When the liver is inflamed, it is less able to process medications including anti-retroviral medications, which can cause worsened side effects of HIV medicine.[96] People with HIV who contract viral hepatitis are more likely to experience a faster progression of liver-related injury than people who do not have HIV.[21] Medications to treat hepatitis are similar to HIV in that they are anti-retroviral. However, some medications that treat HIV and HCV are not safe to use together, so it is important that people with HIV and HCV regularly consult with a doctor.[94]

Incarceration

While the extent of HIV transmission within jails and prisons is not fully understood,[97-99] the risk of HIV is heightened for incarcerated populations compared to non-incarcerated populations, namely due to high rates of HIV in prisons, inconsistent screening for HIV upon entry and release, condomless sex, injection drug use equipment sharing, and the labeling of condoms as contraband within prisons.[100-102] Release from incarceration is widely considered an especially vulnerable period for both opioid overdose[101-103] and discontinuation of HIV care and ART treatment provided during incarceration. The interruption in care can lead to reductions in treatment adherence[101, 104] and increases in viral loads.[101-102]

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CHAPTER

2

What Research Tells Us

This chapter presents five practices that healthcare practitioners can use to prevent and treat human immunodeficiency virus (HIV) among people living with mental illness and/or substance use disorders (SUD).

- Practices to increase uptake of and improve adherence to Pre-Exposure Prophylaxis (PrEP)
- Syringe Services Programs (SSPs)
- Contingency Management (CM)
- Cognitive Behavioral Therapy (CBT)
- Patient Navigation

Although selected practices are non-pharmacological, some are focused on improving uptake and adherence to medications. Each practice is described and given a rating to assist practitioners, clinic administrators, and policy makers in identifying ones that might serve their population of focus. This chapter also provides an overview of each practice, including a discussion of the typical implementation settings, populations that benefit from the practices, intensity of services, and practice outcomes.

Practice Selection

To be considered for inclusion in this guide, eligible practices had to meet the following criteria:

- Must be clearly defined and replicable
- Impact HIV prevention and treatment–related health outcomes among people with mental illness and/or SUD
- Are currently in use

- Have accessible technical assistance and support for implementation

Evidence Review and Rating

Authors completed a comprehensive review of published research for each selected practice to determine its strength as an evidence–based practice. Eligible research studies had to be published after the year 2000 and:

- Employ a randomized or quasi-experimental design, or
- Be a single sample pre-post design or an epidemiological study with a strong counterfactual (i.e., a study that analyzes what would have happened in the absence of the intervention).

Descriptive and implementation studies and meta-analyses were not included in the review, but were documented to provide context and identify implementation supports for the practices. Authors included systematic reviews when assessing SSPs, as an evidence base for SSPs was established pre-2000.*

Each eligible study was reviewed for evidence of measurable change in HIV and mental illness and/or SUD-related health outcomes. In addition, trained reviewers checked each study to ensure rigorous methodology, asking questions such as:

- Are experimental and comparison groups demographically equivalent, with the only difference being that participants in the experimental group received the intervention and those in the comparison group received treatment as usual or no/minimal intervention?
- Was baseline equivalence established between the treatment and comparison groups on outcome measures?
- Were missing data addressed appropriately?
- Were outcome measures reliable, valid, and collected consistently from all participants?

Using these criteria, each study's causal impact was assessed and given a rating of low, moderate, or high. Only randomized controlled trials, quasi-experimental designs, and epidemiological studies with a strong comparison were eligible to receive a high or moderate rating (see Appendix 2 for more information about the evidence review process).

Causal Impact: Evidence demonstrating that an intervention causes, or is responsible for, the outcome measured in the study's sample population.

After all studies for a practice were assessed and rated, each practice was placed into one of three categories based on its causal evidence:

- SSPs, CM, CBT, and Patient Navigation have strong evidence.
- Practices to Increase Uptake and Improve Adherence to PrEP have an emerging evidence base.

CAUSAL EVIDENCE LEVELS

Strong Evidence

Causal impact demonstrated by at least ***two*** randomized controlled trials, quasi-experimental designs, or epidemiological studies with a high or moderate rating.

Moderate Evidence

Causal impact demonstrated by at least ***one*** randomized controlled trial, quasi-experimental design, or epidemiological study with a high or moderate rating.

Emerging Evidence

No study received a high or a moderate rating. The practice may have been evaluated with less rigorous studies (e.g., pre-post designs) that demonstrate an association between the practice and positive outcomes, but additional studies are needed to establish causal impact.

* Due to concerns raised in the mid-1990s about the ethics of experimental design in SSP research,[1-3] researchers have had to rely on longitudinal and epidemiological approaches to understand the impact of regular use of an SSP on injection drug use behaviors, substance use frequency, substance use treatment enrollment, and HIV incidence, among people who inject drugs. Systematic reviews support strong evidence of effectiveness.[4-5]

Identification of Practices Associated with HIV Prevention and Treatment

In the discussion of selected practices, the following icons will be used to indicate ways in which the practice has been implemented to improve HIV prevention and treatment outcomes:

Practices to Increase Uptake of and Improve Adherence to PrEP

Goal

PrEP is a biomedical intervention in which people at risk of getting HIV adhere to a regimen of daily oral antiretroviral medications. The Food and Drug Administration has approved two forms of PrEP medication[6] that prevent HIV from multiplying within the body. Long-acting injectable forms of PrEP are currently being tested.[7]

Efficacy of PrEP as a biomedical intervention is **established**.

However, evidence for interventions that aim to increase PrEP uptake and adherence among people at risk of HIV who have mental illness and/or SUD is **emerging**.

The U.S. Preventive Services Task Force gave PrEP a Grade A recommendation.[8] It is an effective tool for reducing HIV transmission, including among populations behaviorally vulnerable to HIV, such as people who inject drugs (PWID)[9] and people who may be exposed to HIV through sexual contact.[10] PrEP is approximately 99 percent effective at preventing HIV when taken consistently and adhering to prescription guidelines.[9] PrEP is recommended for people who have had an increased risk of getting HIV in the past 6 months, and the risks/benefits of uptake and continuing should be an ongoing discussion between the client and provider.

While the efficacy of PrEP as a biomedical intervention is clear, people may face significant barriers to starting and adhering to PrEP, posing obstacles to reaching the goals of the Ending the HIV Epidemic (EHE) initiative. Barriers include, but are not limited to, the following:

- Stigma (both of HIV and of taking PrEP)
- Low awareness of the existence of PrEP among eligible PrEP users
- Low perception of risk of getting HIV
- Concern about possible side effects
- Lack of social support
- Perceived and actual cost
- Difficulty following the daily regimen[10]
- Health insurance coverage, or health insurance that does not cover laboratory and clinical visits[11-13]
- Limited access to care (e.g., transportation, hours of services)

Mental illness and/or SUD may compound these barriers.

Since the effectiveness of PrEP as a biomedical intervention has been established, this evidence review examines psychosocial supports to increase uptake and adherence to PrEP. These psychosocial interventions include the following:

- *PrEP Mate:* A bidirectional text-messaging program, grounded in the information, motivation, and behavioral (IMB) theory of behavior change, involving daily text reminders to take PrEP and weekly text check-ins.[18]
- *Bio-Behavioral Community Health Recovery Program (CHRP-BB):* A weekly group therapy and text-message reminder intervention encouraging PrEP adherence and teaching health management skills for people who are vulnerable to HIV (through injection drug use or condomless sex).[19]
- *Pharmacy-led PrEP (P-PrEP):* An integrated care intervention in which an in-clinic pharmacist consults with the client and prescribes PrEP the same day that the client tests negative for HIV.[15]

Outcomes Associated with Practices to Increase Uptake and Improve Adherence to PrEP

- Increased PrEP uptake, sustained for up to 9 months.[15-17]
- Increased PrEP adherence, sustained for up to 12 months.[15-19]

Typical Settings

Practitioners can implement practices designed to increase PrEP uptake and adherence in diverse mental illness, SUD, and HIV treatment settings, including the following:

- Safety net health clinics focused on HIV prevention and treatment[18]
- Mobile application that extends the reach of PrEP support[18]
- Methadone maintenance clinics[19]
- Non-clinical testing centers; pharmacies; community health centers[15-17]

Safety-net clinics provide care to individuals who have limited or no access to health care (as a result of financial circumstances, insurance status, or health conditions).[20]

Demographic Groups

Several categories of people can benefit from practices designed to increase PrEP uptake and adherence, including:

- Young men (mean age of 24) who have sex with men (MSM)[19]
- Individuals who reported recreational drug use[19]
- Individuals who reported binge drinking over the past 3 months[19]
- PWID[19]
- People who test negative for HIV[17]

PrEP should not be prescribed to people with HIV (as it is an inappropriate medical intervention for HIV) and/or people with severe renal insufficiency.[10]

Practitioner Types

A diverse range of behavioral health practitioners and clinical providers can implement practices to increase PrEP uptake and adherence, including:

- Clinic and research staff[18]
- Graduate-level trained facilitators[19]
- Pharmacists[15-17]

Intensity and Duration

While PrEP can be taken indefinitely, intensity and duration of individual practices to support PrEP uptake and adherence vary depending on the intervention.

- PrEPMate includes daily text reminders to take PrEP and weekly check-in texts about PrEP adherence, side effects, and attitudes around PrEP sent from clinicians[18-19]
- CHRP-BB includes four 50-minute weekly group meetings that address behaviors related to increased risk of getting HIV and increased PrEP adherence and daily text reminders to take PrEP[19]
- P-PrEP includes same-day PrEP referral by a pharmacist and follow-up appointment with a clinician within 6 weeks[17]

Syringe Services Programs (SSPs)

Strong Evidence

Goal

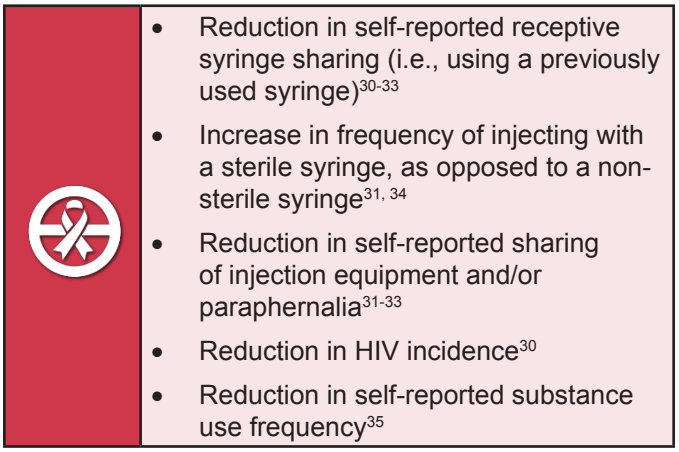
SSPs reduce the risk of infectious disease associated with injection drug use through preventive services, including provision of sterile syringes, injection drug equipment, and harm reduction education, as well as linkage to HIV and mental illness and/or SUD treatment.[21-23]

Decades of research demonstrate the efficacy and importance of SSPs in reducing the transmission of infectious diseases, including HIV and hepatitis C virus (HCV).[24] Due to concerns raised in the mid-1990s about the ethics of experimental design in SSP research,[1-3] researchers have had to rely on longitudinal and epidemiological approaches to understand the impact of regular use of an SSP on reductions in harm associated with injection drug use, substance use frequency and treatment enrollment, and HIV incidence among PWID.

SSPs have been shown to reduce HIV and HCV incidence by approximately 50 percent and are a key practice identified in the EHE initiative.[25-26] Additionally, SSPs have been effective in engaging hard to reach populations, as SSPs reduce typical barriers to entry

(e.g., clients do not need insurance coverage, pre-scheduled appointments, referrals)[7] and can adjust delivery venues to meet community needs (e.g., fixed-site or mobile exchange vans).[28] SSPs are also a prime setting for implementing combined interventions, including medication for opioid use disorder.[29]

Outcomes Associated with SSPs



- Reduction in self-reported receptive syringe sharing (i.e., using a previously used syringe)[30-33]
- Increase in frequency of injecting with a sterile syringe, as opposed to a non-sterile syringe[31, 34]
- Reduction in self-reported sharing of injection equipment and/or paraphernalia[31-33]
- Reduction in HIV incidence[30]
- Reduction in self-reported substance use frequency[35]

Typical Settings

SSPs are community-based interventions that vary significantly based on implementation setting, geographic location, scope, and services to meet local community needs.[26, 36] The eight studies in this evidence review showed that SSPs have been effective in both urban and rural settings and have operated successfully as both long-standing programs and temporary emergency public health responses to HIV outbreaks. SSPs have also been effective in both fixed-site and mobile settings.[30-31]

Demographic Groups

PWID, regardless of gender, age, education, marital status, income, or housing status, can benefit from consistent availability of sterile syringes provided through SSPs.[34] Access to sterile injection drug equipment, harm reduction education, and linkage to treatment through SSPs[22] can lead to reductions in harm associated with injection drug use, substance use frequency, and overall HIV incidence.[30-35]

Geographic proximity may also impact an individual's ability to access an SSP, suggesting that populations living near SSPs benefit most from their services.[32]

In this practice, individuals can acquire large numbers of syringes to distribute to their networks of others who also inject. As a result, SSPs can facilitate a larger number of sterile syringes available within a community.[33, 37]

Practitioner Types

SSP activities can be conducted by:

- Pharmacists, pharmacy managers, clerks, and technicians dispensing over-the-counter syringes[34, 38]
- Care service coordinators[31] and outreach workers[39]
- Professional staff and volunteers (including trained healthcare professionals)

These personnel are best equipped to take on these roles when provided with overdose prevention and response training and appropriate education about sterile syringe distribution and needle-stick injuries.[40-41]

Intensity and Duration

SSPs are structural interventions designed to impact population health.[38] Implementing an SSP is less about a specific number of interactions with PWID, and more about providing consistent, stable access to sterile syringes to increase the volume of sterile syringes available in a given community (benefiting both direct participants of SSPs and their networks).

However, the higher the number of interactions with SSPs, the more opportunities a provider has to offer additional harm reduction education materials (e.g., naloxone kits, PrEP, PEP) and SUD treatment.

Studies in this evidence review identified the following factors as affecting the success of service provision:

- **Operating hours:** Due to limited funding, SSPs may restrict their hours, potentially reducing interactions with clients and the number of syringes provided (at the individual and community levels).[34]
- **Location of the SSP:** The distance between an individual's home and the SSP has been identified as a barrier to accessing SSPs.[32, 34, 39]
- **Number of syringes provided:** SSPs can provide sterile syringes (not purchased using federal funding) in single or multiple day supplies, based on the number of syringes returned and reported injection frequency.[31]

Contingency Management (CM)

Strong Evidence

Goal

CM is a behavioral therapy that uses motivational incentives and tangible reinforcers to increase desirable behavior.[42-43] People in CM programs are given reinforcers—often vouchers that can be exchanged for money or goods, or chances to win prizes—when they consistently demonstrate positive behavior (e.g., negative urine drug screens, showing up for an appointment).[44]

Many state Medicaid, Medicare, and private insurance entities may not reimburse for CM reinforcers. Additionally, the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) has ruled that the Centers for Medicare and Medicaid Services (CMS) may not provide more than $75 annually (or $15 per individual appointment) in goods to beneficiaries, limiting CM enforcers to that amount.[45-47] Medicaid, Medicare, and private insurance agencies may reimburse for CM as a service, but any value of payment for the reinforcers is prohibited. Therefore, CM implementation requires careful coordination with HHS, the state health department, and other insurance providers. Providers wishing to implement CM may identify other funding for reinforcers (up to $75 per beneficiary annually), including federal, state, and private grants, as well as contributions from or opportunities to share costs with community partners.

Practitioners can implement CM along with individual or group counseling or in conjunction with scheduled medical visits, including urine drug screens, daily methadone dosing, or HIV-related appointments.[48-49]

Outcomes Associated with CM

CM is an effective psychosocial intervention for reducing substance use and maintaining substance use abstinence for periods of up to 1 year.[50] In 2006, researchers began testing CM principles in the prevention and treatment of HIV.[51] Behavior change takes time, and while CM has been shown to be effective for periods up to one year, it is important to note that these may be temporary changes for life-long disorders. HIV prevention and treatment outcomes attributed to CM are outlined below:

- Reduction in self-reported sexual behaviors that increase risk for HIV over the previous month (i.e., number of sexual partners, condomless sex, sex for money or nonmonetary items, and anal sex) sustained for up to 12 months.[42, 44, 48]
- Reduction in self-reported drug-use behaviors that increase likelihood for getting HIV over the previous month, (i.e., injection drug use, receptive syringe sharing, syringe lending, and using injection drug use equipment that has not been cleaned or sterilized) sustained for up to 12 months.[42, 48-49]

- Reduction in viral load, sustained for up to 6 months.[44, 52]
- Increase in adherence to antiretroviral therapy (ART), sustained for up to 4 months.[53]

Typical Settings

Practitioners can use CM across a variety of outpatient and inpatient settings and across urban, suburban, and rural settings, including:

- Outpatient treatment clinics[42, 44, 48-49, 52]
- SUD treatment settings (e.g., methadone clinics)[49]
- Counseling centers[42, 25]
- HIV-focused drop-in centers[44]

Demographic Groups

- CM has been effective in preventing HIV among adults aged 18 to 65, living in urban and suburban areas, who use cocaine and opioids and who are taking methadone. It has also been effective among adults who engage in sexual and drug use behaviors that increase likelihood of getting HIV.[42, 44, 48-49]

- CM is effective in increasing linkage to and retention in HIV care among people with co-occurring HIV and SUD including adults aged 18 to 65, living in urban and suburban settings, with HIV, and who use cocaine and opioids It has also shown efficacy among PWID and adults who take methadone.[42, 44, 48-49, 52]

Practitioner Types

CM can be implemented by a variety of practitioners, including:

- Counselors[42, 53]
- Post-doctoral fellows in psychology (who are provided with supervision from licensed psychologists)[44]
- Clinic staff with education levels ranging from no bachelor's degree to master's degree in social work [48-49]

Formal CM-specific training is not required, but training or coursework in behavioral analysis is available to support implementation of this practice.

Intensity and Duration

CM does not require a prescribed number of sessions or specified length of individual sessions, and has demonstrated efficacy when implemented in the following settings for the following durations:

- An intensive outpatient setting with daily counseling over 6 weeks[48]
- A methadone clinic with daily methadone dosing and weekly individual and group counseling over 12 weeks[42, 49]
- A counseling center with individual counseling over 16 weeks[52]
- A counseling center with weekly group counseling sessions over 24 weeks[44]

CM can also act as a "buy-in" for other behavioral interventions associated with longer-term benefits. For example, when combined with counseling, it may increase attendance at sessions, which in turn can have long-term therapeutic benefits.[48]

Cognitive Behavioral Therapy (CBT)

Goal

Providers in mental health settings are uniquely positioned to prevent HIV and support linkage and retention in HIV care and ART adherence for people with HIV. Through individual and group counseling such as CBT, providers can build "reciprocal, robust, and trusting relationships" by having consistent and confidential interactions with clients over time.[54]

CBT is a form of psychotherapy that seeks to modify problematic thinking, beliefs, or behavior through skill-building. CBT programs share three core principles. They are 1) goal-oriented; 2) time-limited; and 3) structured.[55] CBT helps individuals identify specific problems and gain the skills to manage and solve them.[56] All studies included in this evidence review employed the core components of CBT (basing individual and group work on thoughts, feelings, emotions, and skill-building).

This evidence review includes specific applications of CBT for mental health clinicians to use with clients living with mental illness and/or SUD with and at risk for HIV, detailed below:

	**Cognitive Behavioral Skill Building Intervention (E-CB)** E-CB facilitates HIV prevention through structured sessions on the following topics: • HIV education, including personalizing risk of getting HIV, condom use and negotiation skills and identifying situations with increased risk of getting HIV • developing and practicing problem solving, assertiveness, and communication training approaches.[57]
	Cognitive Behavioral Therapy for Trauma and Self Care (Project Thrive) Project Thrive addresses posttraumatic stress responses in MSM with histories of childhood sexual abuse who are at increased risk for HIV. This individual therapy model integrates counseling for sexual health with cognitive and behavioral strategies as a feasible and acceptable treatment among MSM to effectively reduce sexual risk for HIV and decrease post-traumatic stress disorder (PTSD) symptom severity.[58-59]
	Behavioral Activation for Methamphetamine Dependence (Project IMPACT) Project IMPACT is an individual therapy intervention that aims to reduce crystal methamphetamine use and condomless sex among MSM. This integrated treatment consists of behavioral activation, an evidence-based approach for depression that involves identifying and participating in pleasurable, goal-directed activities, and CBT with HIV sexual risk counseling.[60]
	Cognitive Behavioral Therapy for Social Anxiety and Sexual Health (Sexual Confidence) Sexual Confidence adapts the CBT framework for social anxiety to include substance use management in interpersonal situations and reducing sexual behaviors that increase likelihood of getting HIV through sessions on the following: • setting goals related to reducing risk of getting HIV and reducing social anxiety • the role of social anxiety and substance use in increasing risk of getting HIV • discussing and practicing coping skills for anxiety reduction[61-62]
	**Cognitive Behavioral Therapy for HIV Medication Adherence and Depression (CBT-AD)** CBT-AD integrates continued adherence counseling with traditional CBT techniques for the treatment of depression. CBT-AD uses proactive problem solving, action planning, and motivational interviewing to: • facilitate behavior change[63] • address the cognitive and behavioral patterns commonly experienced by adults with co-occurring depression and HIV[64] • improve ART adherence[63]

Outcomes Associated with CBT

	• Reduced sexual behaviors that increase likelihood of getting HIV, including improved attitudes towards condom use and greater condom use skills, sustained for up to 6 months[57,62, 65-66] • Reduced PTSD and depression symptom severity for up to 9 months[58, 60] • Reduction in crystal methamphetamine use for up to 6 months[66] • Increased perceived susceptibility to getting HIV, defined as perceptions of personal vulnerability to HIV disease, sustained for up to 6 months[57]
	• Reduction in viral load, sustained for up to 12 months[67] • Increase in adherence to ART, sustained for up to 15 months[63, 68-70]

Typical Settings

Practitioners can incorporate CBT in mental illness and/or SUD and social service settings including:

- Academic medical centers[65]
- Outpatient treatment centers[57]
- Methadone clinics[63]
- Homeless shelters[71]
- Community health clinics[69]

Demographic Groups

CBT is a well-established, effective treatment for people with mental illness and/or SUD who have or at risk for HIV. It is appropriate for anyone who can relate to the CBT core components, problem-solving approach, and structure, including:

- Men who have sex with men (MSM) who are at risk for HIV[61, 71]
- People with severe mental illness at risk for HIV[57]
- People with at least one HIV-related risk behavior, including self-reported injection drug use, two or more sex partners in the past 90 days, or having a partner with HIV[65]
- People with a history of child sexual abuse and at risk for getting HIV[58]

- People with co-occurring HIV and depression[68-69]
- People with co-occurring HIV and depression who inject drugs[63]

Practitioner Types

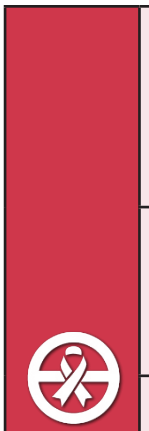
CBT can be implemented effectively by a variety of professionals including:

- Clinical psychologists[63]
- Master's level psychologists,[68] social workers, and counselors
- Case managers[72]
- Facilitators with an average of 10 years of experience leading group-based HIV prevention interventions with people who use drugs[65]

Practitioners do not need to be certified to practice CBT, but certifications are available.[73]

Intensity and Duration

CBT generally provides the tools for behavior change in 8 to 12 individual or group sessions, meeting once or twice weekly, with each session lasting between 60 and 90 minutes.[74] The length of treatment also varies depending on the individual's symptoms, resources, and preference. As highlighted below, studies included in this evidence review varied by time and number of sessions.



The E-CB intervention consists of six 90-minute sessions over the course of 6 weeks. Weekly sessions gave participants time to practice lessons between sessions, reinforcing content discussed during the sessions.[57]

Project Thrive consists of approximately 10 individual therapy sessions on integrated cognitive therapy strategies, behavioral techniques, and sexual risk reduction counseling.[58]

Project IMPACT consists of 10 weekly, 50-minute, in-person sessions that include HIV risk reduction sessions, sessions of cognitive behavioral therapy for reducing substance use, behavioral activation sessions, and preventing re-starting substance use.[60]

Sexual Confidence consists of 10 weekly 1 hour sessions using an integrated CBT model focusing on conversations between the client and facilitator (instead of a didactic learning session).[62]

CBT-AD consists of between nine and 12 50- to 60-minute sessions, with three "open sessions" (which allow for the individual and therapist to revisit the modules that are most relevant to the client's specific needs).[63, 64, 67, 69]

Patient Navigation

Goal

Patient navigation is a client-centered approach aimed at improving care engagement by addressing client and system barriers, and helps clients access medical and support services in an often complex healthcare system.[75] Originally developed as a strategy to improve timely access to cancer screening, diagnosis, and treatment,[76] patient navigation has been used to improve the health outcomes of multiple medical conditions, including HIV. During individual sessions, navigators work with participants to facilitate access to care, review health information, overcome personal or logistical challenges, and provide psychosocial support by promoting self-efficacy and problem-solving behaviors. In addition to the sessions, navigators accompany participants to HIV care and SUD treatment appointments.

In the context of the HIV-care continuum, patient navigation services typically focus on linkage to and retention in care, improving HIV treatment outcomes, client satisfaction, and client self-management.[77]

Outcomes Associated with Patient Navigation

- Viral suppression, sustained up to 12 months[78]
- Linkage to HIV care, with the greatest probability of linkage occurring within 6 months[53, 78]
- Retention in HIV care, sustained up to 12 months[78]
- Adherence to ART medications, sustained up to 12 months[53]

Typical Settings

Practitioners can provide patient navigation services in a wide range of treatment settings including:

- Correctional and criminal justice settings[78]
- Mental illness and/or SUD treatment programs[79]
- Primary health and HIV-specific care clinics[53]
- Hospitals[53]

PATIENT NAVIGATION: Supporting transition between jail and community

While incarcerated, people with HIV often achieve viral suppression due to the highly structured environment and consistent access to care. Post-release delays in linkage to and retention in care can cause declines in viral suppression.[74]

Peer patient navigators with shared lived experiences can play a key part in facilitating linkage to care by acting as role models. In the study included in this review, peer patient navigators established relationships with participants before they left jail, met them at the time of release, provided referrals for post-release housing and SUD treatment, and counseled them on retention and adherence behaviors in HIV care.

Demographic Groups

Patient navigation can be used with a variety of populations, but is often targeted for those at highest likelihood of not linking to or continuing in care[80] including:

- People with HIV, aged 18 or older, who report recent use of substances (i.e., opioids, stimulants, alcohol)[53]
- People with HIV (specifically men and transgender women) transitioning from jail to the community[78]

Practitioner Types

Patient navigation can be implemented effectively by a variety of professionals including:

- Medical professionals or clinical staff, community members, social workers, and other diverse professionals (e.g., case management, discharge planning, criminal justice system)[77]
- Peer patient navigators[78]

Patient navigators often share qualifications and skills with other support service providers in clinical settings, such as advocates, health educators, or case managers.[74] Matching peer patient navigators with individuals who have similar experiences is a successful approach for linking and retaining clients in HIV care[81] and can play a key role in building social networks and establishing trust, especially among stigmatized populations.[82]

Intensity and Duration

Patient navigation services are customized to the specific needs of clients, so there is no standard model for the intensity and duration of the program.[80] Typically, navigators meet regularly with clients for 11 to 12 individual sessions over 6 months, and their work continues through a predetermined endpoint (determined by the clinic model). In the case of HIV care, this endpoint is often linkage to care.[77]

Summary of Evidence-based Review

Practice	Practices to Increase Uptake of and Improve Adherence to PrEP	Syringe Services Programs (SSPs)	Contingency Management (CM)	Cognitive Behavioral Therapy (CBT)	Patient Navigation
Review Rating	Emerging Evidence	Strong Evidence	Strong Evidence	Strong Evidence	Strong Evidence
Focus of the practice	Practices designed to overcome barriers to initiating and sustaining PrEP use.	A harm reduction method for reducing the likelihood of HIV and HCV associated with injection drug use.	Focus on positively rewarding desired behaviors.	Focus on helping clients improve their quality of life not by changing their circumstances, but by altering their perceptions of those circumstances.	A client-centered approach aimed at improving engagement in HIV care by addressing client and system barriers.
Can be used in out-patient healthcare settings	✓	✓	✓	✓	✓
Can be used in in-patient healthcare settings	✓	-	✓	✓	✓
Specific training available	✓	✓	-	✓	✓
Can be practiced by peers	-	✓	-	-	✓
Special populations with whom the practice has been successfully implemented	Young MSM; PWID or recreationally use drugs	PWID	Individuals with co-occurring HIV and SUD; individuals who engage in sexual or drug use behaviors that increase likelihood of getting HIV	MSM; individuals with severe mental illness; individuals with co-occurring HIV, mental illness and/or SUD	Individuals with SUD; men and transgender women transitioning from jail to community
Intensity and duration	Indefinite	Indefinite	No prescribed intensity or duration; shown to be effective for between 6 to 24 weeks	Varies depending on specific CBT intervention implemented, ranges from 1 to 2 weekly sessions over the course of 8 to 12 weeks	No prescribed intensity or duration; typical range of 11 to 12 sessions over 6 months

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CHAPTER

3

Guidance for Selecting and Implementing Evidence-based Practices

This chapter discusses key implementation considerations to address the challenges of implementing programs for human immunodeficiency virus (HIV) prevention and treatment among people with mental illness and/or substance use disorders (SUD). It covers steps from practice selection and program funding through engaging and retaining people in care.

Prior to implementing practices identified in Chapter 2, each program or clinic should conduct a needs assessment to understand the following factors:

- Client population (e.g., the population of focus, their unique HIV-related risk factors,[1] cultures, challenges, and assets)
- Existing protocols and procedures that could facilitate or become barriers to implementation (e.g., intake procedures)
- Local factors that could impact service delivery (e.g., partnerships with community-based organizations and service providers, geography, transportation, and socio-political climate)[2]
- Program or organizational strengths, resources, and areas for development (e.g., organizational leaders and program champions, budget, available health insurance reimbursement to support planned activities, staffing and infrastructure, and information management support)[3]
- Training opportunities (program-specific and ongoing professional development)

Based on the needs assessment, practitioners can work with their clinical teams, administrators, leaders, and community members and partners to take the following steps to identify practices that are appropriate and feasible given available resources and local characteristics:

- Identify prevention and treatment priorities
- Identify desired short- and long-term outcomes
- Map resources (e.g., housing, employment, transportation, legal services) available within the local area to effectively connect clients with needed services
- Develop a logic model (a graphic depiction of the relationship between a program's activities and their intended outcomes)[4]

Implementation Challenges and Strategies

This chapter includes strategies to promote implementation and appropriate adaptation of practices to the population of focus, as well as specific implementation tools for the programs and practices described in Chapters 2 and 4. Key considerations described in this chapter include:

- Adapting and tailoring the practice to meet the needs of the client population
- Care coordination
- Workforce capacity and development
- Access to services
- Financing

Challenge

Practices implemented without adaptation may not be relevant to or acceptable for the client population.[5] Practices should be culturally relevant, available in the appropriate language, and produced at the appropriate reading level.[6-7]

Core components are defined by SAMHSA in the Strategic Prevention Framework as "those parts of a program or practice that are responsible for producing positive outcomes, and thus most essential and indispensable."[8]

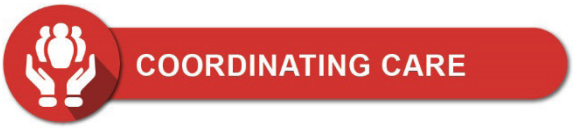
Strategies

Program administrators and clinic leadership can:

- Identify and consistently implement key characteristics (or core components) of each practice to generate anticipated outcomes.[1, 9] Outside of the core components, organizations can use their needs assessment to identify local-level adaptations that will improve service delivery to their client population.[10]
- When adapting a program, organizations should strive to preserve the setting (e.g., outpatient clinic, mobile health unit), maintain the prescribed dosage, and, if necessary, add rather than remove content.[11]
- Use a systematic process, such as the ADAPT-ITT model, to balance local program adaptation needs and adherence to the instructions provided in the original model.[5]
- Engage existing and potential clients in project planning, practice selection, and materials development. Members of the client community will have insight into ways to make programs culturally appropriate, reflecting a community's preferred language, attitudes, beliefs, values, and experiences.
- Assess and address staff and client health literacy,[12-13] and ensure materials meet federal plain language and National Standards for Culturally and Linguistically Appropriate Services guidelines.[14-15]
- Adapt and tailor client care plans and individualize case management approaches to meet the unique needs of the client. Effective case management is a client-driven process where the case manager and client collaborate on a care plan, including specific goals for prevention or treatment, and then continue to communicate to ensure the client is able to reach their goals.

THE EIGHT STEPS OF THE ADAPT-ITT MODEL

- **A** — **Assessment:** conduct an assessment to understand the population of interest and organization-level capacity to implement the intervention
- **D** — **Decision:** select the intervention
- **A** — **Adaptation:** pre-test the intervention with the population of interest
- **P** — **Production:** produce a revised draft of the intervention guide maintaining fidelity to the core elements, behavioral theory, and internal logic of the initial intervention
- **T** — **Topical Experts:** engage subject matter experts in a review of the intervention guide produced in Production step
- **I** — **Integration:** integrate feedback from the Topical Experts and Production steps, and produce a second draft
- **T** — **Train:** train facilitators, recruiters and retention staff, interviewers, and data management staff to ensure consistent implementation and data collection efforts
- **T** — **Test:** pilot test the intervention and integrate findings into a third draft. Conduct a second pilot test to determine if the intervention will be effective in the organization's service delivery area and with the population of interest



Challenge

People at risk for or with HIV who also have co-occurring mental illness and/or SUD experience complex medical comorbidities. Fragmented behavioral health and HIV primary care services make it difficult for practitioners to communicate with each other and their clients, potentially leading to poor HIV and mental illness and/or SUD outcomes.[16]

Moreover, fragmented care systems place a burden on the clients as they become the ones responsible for communicating sometimes complex health information among practitioners. Ancillary needs (e.g., housing, childcare, transportation, food insecurity, employment), which are critical to clients seeking or engaging in care, may also be difficult to address in a fragmented system.[17-20]

Strategies

Effectively addressing these interrelated conditions takes a coordinated approach[21] between mental illness and/or SUD and HIV care providers, and other agencies and stakeholders that are well-positioned to address the social determinants of health. Coordinated models may feature screening for mental illness and/or SUD using validated tools; team-based care, including both physician and non-physician staff; shared IT and electronic medical record systems to facilitate communication within care teams; and systematic measurement and review of patient outcomes.

When HIV clinics screen for mental illness and SUD and are able to provide coordinated care to address mental illness, SUD, and HIV, clients are more likely to reach viral suppression than their counterparts visiting HIV primary care services without coordinated mental health and substance use services.[32] Coordinated services help practitioners streamline service delivery to address unmet needs.

Collaborative Care involves increased collaboration between behavioral healthcare management, mental health, and primary care providers. This model includes taking a team-based, client-centered, collaborative approach to elements of client care, such as client registries, client education, screening or assessment tools, adherence monitoring, and evidence-based treatment guidelines.[22-23]

Integrated Care involves merging primary health care, mental illness and/or SUD screening and treatment, additional medical services (e.g., hepatology, dermatology), and social services (e.g., housing, employment) into one treatment plan. These linkages improve client outcomes by combining efforts such as referrals, case planning, and resources.[23-26]

The two terms are not interchangeable, and exist on a continuum.[27] For example, a system can collaborate while having separate EHR, billing, and scheduling systems. A system can also have integrated care with co-located services where practitioners collaborate and case-conference to discuss client care.

Examples of coordinated care models include patient centered medical homes,[28] primary care case management arrangements,[29] co-located or limited capacity primary care in behavioral health organizations,[29] SAMHSA's Primary Care and Behavioral Health Integration model,[30] and Certified Community Behavioral Health Clinic models.[31]

Practitioners can use the following strategies to determine the level of integration feasible and appropriate within their organization:

- Identify leaders within clinical networks and health systems who can champion integration and advocate for coordination, co-location, and integration over time.[21] Integration takes administrative, political, and financial investments, as well as cultural change and different ways of communicating among care teams and clinics.
- Modify funding structures, billing codes, and procedures to account for new coordinated models and consultation between practitioners.[21]
- Permit data sharing across AIDS-Service Organizations, social and health service practitioners, behavioral health specialists, and the department of corrections to increase service coordination.[33] When sharing data across organizations, review updated laws, policies, and regulations on confidentiality to maintain compliance and protect client information[34] and obtain consent from clients for data sharing during client assessment and intake.

Challenge

Behavioral health treatment practitioners and their clinical teams (e.g., case managers, clinical coordinators) are well positioned to address unmet needs (e.g., transportation, housing, employment, childcare), but may need additional training to address co-occurring infectious diseases.[35]

Practitioners who deliver services aimed at preventing and treating HIV among people experiencing co-occurring mental illness and/or SUD may need training and capacity building in the following areas:

- Practice-specific training to facilitate consistent implementation
- Working with clients who have co-occurring HIV and mental illness and/or SUD
- Creating a culturally appropriate, non-judgmental, and non-stigmatizing clinical environment supportive of both clients and staff[36-39]

Strategies

Provide intervention-specific training to implement the practices.

- Receiving customized, site-specific training can be resource intensive, and the provision of program-specific training and technical assistance may be dependent on grant awards. In recent years, federal funders have emphasized the need for replicable practice models that are easy to adapt, scale up, and implement in the absence of technical assistance, leading to an increase in robust training resources available online. These models include:
  - CDC's Effective Behavioral Intervention (EBIs) models
  - HRSA's Dissemination of Evidence Informed Interventions (DEII) model
  - HRSA's Evidence-Informed Interventions (E2i) models
- Program managers and practitioners should select implementation trainings that are not overly cumbersome or time consuming.[40]

Provide cross-disciplinary training and institutional support to practitioners to facilitate better understanding of different disciplines and ways to promote coordinated client care.

- Promote cross-training provided by the AIDS Education and Training Centers (AETCs) on HIV-related programs, policies, and practices to both Ryan White HIV/AIDS Program (RWHAP) and behavioral health practitioners. Similarly, promote training offered by SAMHSA's Prevention, Mental Health and Addiction Technology Transfer Centers for practitioners and volunteers providing care for persons with and at risk of HIV.
- Create mechanisms for staff to work and train across HIV and behavioral health service programs.[41]
- Identify in-house trainings (e.g., grand-rounds, in-service trainings), local trainings, online webinars, opportunities to attend conferences, and continuing education unit training opportunities to support cross-disciplinary learning.[9]
- Prevent vicarious trauma (i.e., work-related trauma due to continuous exposure to victims of trauma and violence),[42] burnout, and turnover by supporting manageable caseloads for staff and providing consistent clinical supervision. For example, peers and patient navigators may not have the formal clinical training their licensed mental health, substance use, and social work colleagues do, and may benefit from ongoing, structured clinical supervision.[43]

Provide ongoing trainings on ways to create welcoming, supportive environments for people with or at risk for HIV.

- Conduct and support staff training to enhance cultural competence and create a safe, supportive environment that improves client-staff relationships and reduces the risk of a client discontinuing treatment.[33]
- Include sessions on non-stigmatizing language[44] and trauma-informed practices[45-46] to improve client interactions with all staff (from the front desk, to their nurse, to the billing department).

Challenge

Linkage to and retention in care requires connection between the client and the provider. However, transportation and geographic barriers can make in-person, face-to-face connections challenging.

- Transportation-related challenges can include having to travel long distances to clinics,[39] inability to afford gas or fares for public transportation, and unreliable or lack of access to a personal vehicle or public transportation for travel to appointments.[38]
- People with HIV in rural areas are less likely to receive HIV care or be engaged in ART as a result of limited availability of HIV-specific practitioners, provider discrimination, confidentiality concerns, and lack of financial resources.[47] Geographic barriers can be compounded by HIV-related stigma where individuals may be reluctant to seek HIV prevention or treatment services in a small town or community for fear they may be "outed."[48]

Strategies

Program administrators and practitioners can overcome these challenges by employing the following strategies:

- *Telehealth* - Telehealth can connect clients with specialty practitioners and provide access to services without having to travel.[49] Telephone-based Cognitive Behavioral Therapy (CBT), as an example, has been shown to reduce depressive symptoms and improve ART adherence among people with HIV.[50]
- *Transportation assistance* - Vouchers for gas or public transportation can help eliminate worry about missing appointments due to transportation cost-related barriers.[51] In one model, peer navigators provided transportation to appointments for the first month to give clients sufficient time to establish a long-term transportation plan.[52] Ride share companies may also provide travel assistance. For example, Uber Health has partnered with an IT vendor, Cerner, in six states to get clients to and from their medical appointments. Lyft is also designated as a covered option for providing rides for eligible Medicaid beneficiaries.[53]
- *Combined healthcare visits* - Combining HIV care and other healthcare needs (e.g., routine check-up, behavioral health services) in one visit can limit the number of times a client needs to visit their healthcare provider, especially in settings where significant travel may be needed to attend appointments.[54] Practitioners should clarify if adequate reimbursement for these visits is available by confirming whether third party payers have the capacity to reimburse for same-day services.
- *Mobile health programs* - Mobile health programs have been used successfully to increase HIV screening among high-incidence populations in underserved areas.[55] Many syringe services programs (SSPs) utilize mobile sites due to their flexibility to respond to changing client needs and ability to provide a more informal, easily accessible location for clients who are unable to travel to a fixed site.[56]
- *Outreach* - Outreach activities, commonly used to link and retain people with HIV in care, can reduce barriers to accessing care. Patient navigation models specifically emphasize outreach, with navigation sessions often taking place in community settings where clients may feel more comfortable than in a clinic environment.[57] SSPs also expand their reach through secondary or peer-delivery models. SSPs provide people who inject drugs (PWID) with sterile injection drug use equipment to distribute to their networks and to inform them of disposal options.[56]

Challenge

Funding (including financing trainings, reimbursing staff, furnishing programs with needed materials) is essential to implementing and sustaining public health practices. Specific financing challenges for the recommended programs include:

- Insurance reimbursements for services
- Sustainable federal and state funding for service delivery not covered by insurance
- Restrictions on the use of federal funding for SSPs
- Lack of funding for reinforcers and vouchers necessary for Contingency Management (CM)
- Lack of funding for highly experienced clinicians to implement and facilitate programming

Strategies

Clinic administrators and leadership need to consider strategies for how to:

- Fund a practice
- Diversify funding streams across federal, state, local, and private initiatives[58]
- Counteract cost-prohibitive challenges to program implementation

When doing so, they should pay particular attention to:

- The specific resources available and needed to implement HIV and mental illness and/or SUD services, including number of staff, additional costs related to program materials, and anticipated duration of funding.[58]
- Potential collaborators that may have access to alternative funding sources. Community-based organizations, correctional facilities, community health centers, or mental illness and/or SUD

treatment settings can act as partners when applying for grants that may only be accessible to specific types of organizations. Partnerships can also be a way to offset the cost of program-related materials.

  - CM costs pose a unique challenge, as many state Medicaid, Medicare, and private insurance entities may not reimburse the reinforcers that are used in this practice, and programs are prohibited from reimbursing for more than $75 annually or $15 per individual appointment, regardless of the source of the funds. Additional funding sources, such as federal, state, and private grants, as well as contributions from or opportunities to share costs with partners, can help overcome barriers to funding CM reinforcers. SAMHSA suggests soliciting donations (which might prove particularly effective at providing CM reinforcers) and making use of volunteers or internships to cut costs.[60]

RYAN WHITE HIV/AIDS PROGRAM (RWHAP)

- RWHAP, a federal initiative started in 1990, can act as the "payer of last resort" for people with HIV, and be used to complete care for uninsured and underinsured individuals (for out of pocket costs, including medication copays or co-insurance for office visits). RWHAP complements and supplements other health programs such as Medicaid and commercial health insurance.
- RWHAP plays a critical role in improving health outcomes for people with HIV across the care continuum.
- This funding is only available for people with HIV, leaving a gap in coverage for preventive services.
- Each year over half a million people receive at least one service under the program.
- RWHAP is the third largest source of federal funding for HIV care in the United States, following Medicare and Medicaid, and was funded at $2.3 billion in FY 2019.[59]

- How the practice aligns with federal-level priorities and funding opportunities.
- The "Ending the HIV Epidemic: A Plan for America" initiative allocated $716 million in fiscal year (FY) 2021 to preventing, diagnosing, treating, and responding to HIV.[61]
- Potential insurance reimbursement strategies.
  - PrEP is included in Grade A preventive interventions by the U.S. Preventive Services Task Force. Therefore, most insurance plans are required to cover prescriptions for PrEP at no cost to the client. However, the task force recommendation does not extend to lab tests or other clinical services.[62]
    - The Centers for Medicare & Medicaid Services offer grant funding to reimburse patient navigators.[63]
- Opportunities to expand the types of trained facilitators leading behavioral health interventions, such as CBT and CM. Tapping graduate students and psychology or social work interns to facilitate these programs under clinical supervision can offset program costs as these practitioners are generally not paid.[64-65]

Special Funding Considerations for SSPs

The Consolidated Appropriations Act of 2016 allows the U.S. Department of Health and Human Services to fund SSP education and program evaluation.[66] Importantly, this legislation, as well as subsequent congressional appropriations acts, states that federal funds cannot be used to purchase needles or syringes.[67-68]

Practice Resources

Practices to Increase Uptake of and Improve Adherence to PrEP

- The AETC's "Prescribing PrEP for HIV Prevention: A Guide for Medical Providers" is a "pocket-guide" for practitioners considering prescribing PrEP. It includes an ideal timeline for screenings and visits, billing codes, and information about potential side effects.[69]
- The Harford County Health Department PrEP Resource Binder[70] and Michigan Department of Health & Human Services PrEP Provider Toolkit[71] are resources for providers (e.g., CDC consultation, prescribing guidelines, and summaries of PrEP efficacy trials) and clients considering PrEP (e.g., FAQs).
- The Fenway Institute's Implementing PrEP for HIV Prevention: State-wide Initiative and Provider Experiences presentation focuses on state-wide implementations of PrEP, provider feedback and experiences, and health communication materials to promote PrEP uptake.[72]

Syringe Services Programs (SSPs)

- The Harm Reduction Coalition Capacity Building Services provides free mentoring, training, and technical assistance, including the HIV Harm Reduction Navigator Core Competency Training and Skills-Building Training, to health departments, community-based organizations, and other community stakeholders seeking to establish, expand, or improve the effectiveness of their SSPs.[73]
- The CDC's Capacity Building Assistance Provider Network provides free training and technical assistance, continuous quality improvement, and marketing and administrative support for health departments, community-based organizations, and community partners looking to implement or improve HIV prevention programs and services.[74]
- The Harm Reduction Coalition's Guide to Developing and Managing Syringe Access Programs provides an overview of harm reduction principles and guidance on how to develop, implement, and manage a SSP.[75]
- The National Alliance of State and Territorial AIDS Directors (NASTAD) and Urban Coalition for HIV/AIDS Prevention Services (UCHAPS)

Syringe Services Programs (SSP) Development and Implementation Guidelines for State and Local Health Departments provides guidance on several aspects of SSP implementation, including how to conduct a community needs assessment, select a service delivery model, monitor outcomes, and build capacity of program staff.[56]

- Comer Family Foundation's Guide to Establishing Syringe Services Programs in Rural, At-Risk Areas provides an overview of the importance of SSPs in fighting the opioid epidemic. This resource offers guidance on considerations for SSP implementation and case studies of rural SSPs.[76]
- Oregon Health Authority Harm Reduction and SSP Planning Manual and Resource Library offers a manual and several resources on SSP planning and implementation.[77]

Contingency Management

- Contingency Management: Using Motivational Incentives to Improve Drug Abuse Treatment provides an overview of CM principles, a case study of a program using CM, and guidance regarding how to implement and supervise CM procedures.[78]
- The UCLA Integrated Substance Abuse Program's A Treatment Manual for Implementing Contingency Management: Using Incentives to Improve Parolee Enrollment and Attendance in Community Treatment is a guide for implementing CM for SUD treatment among parolees.[79]
- The Behavioral Health Recovery Management project A Clinician's Guide for Implementing Contingency Management Programs provides step-by-step guidance on CM implementation.[80]

Cognitive Behavioral Therapy

- National Association of Cognitive Behavioral Therapists CBT Onsite Training provides multiple resources for both administrators and clients, training, and certification for CBT administrators (i.e., professionals, educators, graduate students).[81]
- Beck Academy CBT training and certification offers training and certification for CBT administrators (i.e., professionals, educators, graduate students), online and in-person training courses, newsletters, assistance with program implementation, and information on utilizing supervisors and consultants.[82]
- The Evidence-Based Practice Institute's Intersecting Epidemics: Evidenced Based Approaches for Treating Depression and HIV/AIDS is an on-demand course (paid access), including a video recording, slides, and handouts.[83]
- Massachusetts General Hospital offers an online CBT program led by clinical experts (through paid access) for practitioners, including live chats with faculty and interactive discussion boards.[84]

Patient Navigation

- Texas Institute for Excellence in Mental Health Peer Specialist Training and Certification Programs: A National Overview is a compilation of information on existing peer specialist training and certification programs in the United States.[85]
- Best Practices for Integrating Peer Navigators into HIV Models of Care is an AIDS United publication that provides findings and lessons learned from diverse peer navigation models and grantee types.[86]
- As part of the National Minority AIDS Council's Organizational Effectiveness Series: Building Healthy Organizations, HIV Navigation Services: A Guide to Peer and Patient Navigation Programs provides information and tools to use in planning and implementing patient navigation programs.[87]
- The Peer Assisted Treatment of HIV and Substance (PATHS) Model guide describes the development, implementation, and evaluation of a navigation program that incorporates peers into a substance use treatment program for people with HIV.[88]
- Rural Health Information Hub's Rural HIV/AIDS Prevention and Treatment Toolkit contains resources and information focused on developing, implementing, evaluating, and sustaining rural HIV/AIDS programs, including a patient navigation model.[89]

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CHAPTER

4

Examples of Effective Programs and Strategies

The chapter describes how practitioners have implemented three prevention and treatment programs as part of a comprehensive strategy to prevent and treat HIV among people living with mental illness and/or substance use disorders (SUD):

- Faster Paths to Treatment: a SUD bridge clinic program implementing practices to Increase Uptake and Improve Adherence to Pre-Exposure Prophylaxis (PrEP)
- Louisville Metro Syringe Exchange Program (LMSEP): a Syringe Services Program (SSP)
- The Alexis Project: a HIV linkage and retention program implementing both Contingency Management (CM) and Patient Navigation

The three examples highlighted in this chapter were identified through an environmental scan and in consultation with experts. While there are additional programs that could have been featured in this chapter, those highlighted below were included to provide diverse examples of settings in which HIV and mental illness and/or SUD can be addressed.

To be included, the interventions had to:

- Include one or more of the practices identified in Chapter 2
- Be replicable (well-defined with guidance materials or a manual)
- Have research to support their impact on HIV and mental illness and/or SUD, or be identified as a promising practice
- Provide appropriate and effective interventions for varied geographic areas, practice settings, and diverse populations

Programs should implement practices with fidelity to evaluated models. Fidelity is the degree to which a program delivers a practice as intended and must be maintained for desired therapy outcomes. However, many programs adapt chosen practices to better serve their clients. As practitioners modify practices to address the needs and constraints of their population, budget, setting, and other local factors, they should strive to adhere to the practice's foundational principles.

Faster Paths to Treatment

Boston Medical Center (Boston, MA)

Faster Paths to Treatment is a low-barrier SUD bridge clinic that opened in 2016 to address the opioid use disorder (OUD) epidemic and overdose crisis. It is part of a network of SUD treatment programs at Boston Medical Center, and it uses a flexible, client-centered, harm-reduction model to provide rapid access to medications for OUD, outpatient medically-managed withdrawal, overdose and HIV prevention services, sexually transmitted infection testing and treatment, and linkage to long-term SUD treatment and primary/psychiatric care after stabilization. Faster Paths serves a population with high rates of prior drug overdose, polysubstance use, and homelessness. It is funded by the Massachusetts Department of Public Health Bureau of Substance Addiction Services.

Model Features and Elements

Recognizing the need for on-demand services, Faster Paths offers both scheduled and walk-in appointments and aims to provide same day access to buprenorphine (a form of medication for opioid use disorder) and HIV prevention services including testing, PrEP, and post-exposure prophylaxis (PEP). Same day services mitigate the chance of loss to follow-up and support client engagement.

Evidence-Based Practice Implemented by the Program

Practices to increase uptake of and improve adherence to PrEP

Population of Focus

People who use substances; 66 percent of clinic clients report injection drug behavior. Many clients have co-occurring psychiatric disorders and face significant psychosocial barriers to care, including housing instability.

Approximate Time Period (Duration)

Clients are typically followed in Faster Paths for weeks to months

Related Resources

Program Website

Taylor, J. L., Walley, A. Y., & Bazzi, A. R. (2019). Stuck in the window with you: HIV exposure prophylaxis in the highest risk people who inject drugs. Substance Abuse, 40(4), 441-443. https://pubmed.ncbi.nlm.nih.gov/31644387/

eReview of PrEP in PWID

Findings and Outcomes

- Because Faster Paths clients often report recent potential HIV exposures, "PEP-to-PrEP" (starting on PEP and transitioning to PrEP) has been the safest, most efficient, and effective way to start PrEP for this population.[1] If a client reports being exposed to HIV within the last 72 hours, Faster Paths emphasizes PEP as a bridge to PrEP, which can be started immediately at the end of a 28-day PEP course in clients who remain HIV negative. In April 2020, 22 percent of provider visit notes (including initial visits and follow up visits) addressed PEP or PrEP.

- To support practitioners in consistently evaluating HIV prevention needs, Faster Paths has a standardized intake laboratory panel and electronic medical record note templates to assess risk of getting HIV and PrEP eligibility.

Lessons Learned

- Many clients seen in Faster Paths have limited awareness about PrEP and its potential benefits as a result of not having had the opportunity to discuss PrEP with a provider in the past, limited information about PrEP within their social network, and marketing that has not been inclusive of people who inject drugs (PWID).
- The way a provider discusses PrEP can be crucial for uptake. For example, it can be important to emphasize that PrEP is recommended for preventing HIV for a wide range of populations (e.g., PWID, men who have sex with men, and heterosexual people) to reduce stigma related to PrEP.
- Faster Paths aims to educate clients about PrEP in a manner that is not overwhelming (e.g., at initial or follow-up visits, depending on client preference), highlighting the ways PrEP can benefit both the client and their networks (i.e., sexual and injection drug use equipment–sharing partners), and emphasizing that PrEP will not necessarily be a life-long medication.
- Faster Paths clients have an increased likelihood of acute HIV disease due to a current outbreak among PWID in Boston, MA. In April, 2020, 13 percent of HIV screening tests in Faster Paths resulted in a new diagnosis of HIV transmission associated with injection drug use. Providers have expressed concern about starting same-day PrEP while awaiting HIV test results due to potential barriers to reaching the client to stop PrEP if the test returns positive. However, providers realized when they asked the client to return to the clinic to begin PrEP at a later date, opportunities were missed due to loss to follow-up. Therefore, if a client has a reliable method of contact, providers consider starting PrEP while HIV test results are pending.
- Many SUD providers were not educated about PEP/PrEP during their clinical training, and the PEP/PrEP cases seen in Faster Paths are complex. To increase provider confidence prescribing PEP/PrEP in PWID, Faster Paths conducts didactic sessions with faculty, nurses, fellows, licensed drug and alcohol counselors, and administrative staff and provides real-time clinical support when PEP/PrEP questions arise.

Louisville Metro Syringe Exchange Program (LMSEP)

Louisville Metro Department of Public Health and Wellness (Louisville, KY)

The Louisville Metro Syringe Exchange Program (LMSEP) is a SSP that started in 2015. Established through the Louisville Department of Public Health and Wellness, LMSEP has two main goals:

- Prevent the spread of blood-borne infectious diseases transmitted through syringe sharing
- Link PWID to treatment

As a harm reduction program, LMSEP works with numerous community organizations and stakeholders to provide the following to PWID in the Louisville Metro area:

- Access to free and sterile syringes
- Safe syringe disposal (on site and at two mailbox disposals in the community)
- Fentanyl test strips
- Safe injection supplies
- HIV and hepatitis C virus (HCV) testing and referrals
- Referrals for mental illness and/or SUD treatment
- Counseling
- Harm reduction education on HCV, HIV, sexually transmitted infections, wound care, and overdose prevention (including providing naloxone)

LMSEP offers syringe exchange services at their main site inside the Louisville Metro Department of Public Health and Wellness. In addition, they offer mobile van exchange services at seven satellite locations during the week.

Model Features and Elements

- The primary pillar of LMSEP is trust. Through its outreach work, LMSEP emphasizes accepting participants where they are and not judging them or stigmatizing them further. Staff and volunteers also tell participants that pursuing SUD treatment is voluntary and not a requirement of the program.
- Underscoring the importance of mutual respect between participants and staff, LMSEP created a Participant Bill of Rights and Responsibilities to ensure the rights and expectations of participants, staff, and volunteers are clear to all individuals involved with the program.
- During their first visit, participants are asked to complete a voluntary intake form. Using the Program Staff Check List and this intake form, staff discuss LMSEP's numerous harm reduction and treatment services with participants.
- Within LMSEP's harm reduction model, certified alcohol and SUD counselors and HIV prevention specialists provide onsite support, testing, and linkage. LMSEP staff link participants who test positive for HIV to a Kentucky Care Coordination program case manager at the University of Louisville to facilitate HIV-specific care and treatment.

Evidence-based Practice Implemented by the Program

Syringe Services Program (SSP)

LMSEP is an outpatient SSP organized by the Louisville Department of Public Health and Wellness. LMSEP offers social and health services to PWID through fixed-site and mobile van settings.

Population of Focus

PWID, specifically adults aged 18 to 25.

Approximate Time Period (Duration)

Indefinite

Related Resources

- Program Website
- LMSEP Overview (slides)
- LMSEP Brochure of Services
- LMSEP Guidelines
- LMSEP Research Brief

Findings and Outcomes

- Since its establishment in 2015, LMSEP has served more than 20,000 unique participants, has had about 115,000 visits, and has distributed more than five million sterile syringes. LMSEP has also:
  - Tested more than 35,000 people for HIV and referred 29 for treatment
  - Tested more than 4,800 people for HCV and referred approximately 700 for treatment
  - Referred 719 people for SUD treatment
  - Connected more than 300 people to other community services
- Since LMSEP staff began distributing naloxone, 890 participants have reported almost 2,000 overdose reversals.
- Louisville has prevented a substantial rise in new HIV diagnoses, reporting a stable transmission rate while neighboring states have experienced increases. Before LMSEP opened, the rate of new HIV diagnoses in the Louisville metropolitan region was 15.3 per 100,000 in 2014. In 2017, the rate of new HIV diagnoses was 13.9 per 100,000.[2]

Lessons Learned

- Less restrictive dispensation policies (e.g., providing the number of supplies a client reports needing instead of offering one set of sterile supplies for every one set of used supplies) reduce syringe re-use and may benefit people who use injection drugs and may not directly attend a SSP.
- Build community collaboration and support to counter the stigma attached to the SSP practice. Engage partners from the start of program development throughout implementation. When assessing community readiness to start an SSP, LMSEP worked to build support with various partners and stakeholders, including political and social leaders, healthcare and social services providers, law enforcement, neighborhood associations, business owners, fire and rescue departments, the local media, and district and county attorneys.
- Building trust with program participants is often difficult but especially important. In LMSEP, this trust facilitated an increase of immunizations and treatment during a hepatitis A outbreak and the ability to educate participants on COVID-19 health and safety issues.

The Alexis Project

Friends Community Center, a Division of Friends Research Institute (Los Angeles County, CA)

The Alexis Project was developed under the Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color Initiative funded by the Health Resources and Services Administration's (HRSA) Special Programs of National Significance (SPNS). The project utilizes a multi-tiered approach to identify, engage, and retain in care transgender women of color with HIV.

The Alexis Project is named after Alexis Rivera who died on March 28, 2012, at the age of 34, from complications related to HIV. She was a proud Latina transgender woman, community activist, and peer advocate.

Model Features and Elements

The Alexis Project incorporates social network recruitment and engagement, peer health navigation, and contingency management to promote achievement of health outcomes along the HIV care continuum. Through social network recruitment, the Alexis Project recruits transgender women of color, who know they have HIV but are not in care, to the combined peer health navigation and contingency management intervention.

Peer Health Navigation (PHN):

- Peer health navigators work with participants to develop a client-centered treatment plan and link them to HIV care and/or other needed services (e.g., hormone therapy, mental health counseling, substance use treatment, legal services, transportation assistance).
- Participants receive unlimited PHN sessions and can contact peer health navigators any time.
- Participants complete a needs and barriers assessment at each session.
- The goals of sessions are to:
  - Identify barriers to care,
  - Identify and link participants to needed services, and
  - Increase participants' self-efficacy in working with HIV care providers and other treatment facilities.

Evidence-based Practice Implemented by the Program

Contingency Management (CM), Peer Health Navigation (PHN)

Friends Community Center is a non-clinical community research center that collaborates with two medical clinics that provide HIV primary care.

Population of Focus

Transgender women of color with HIV

Approximate Time Period (Duration)

18 months

Resources on the Program

- Program Website
- Alexis Project Implementation Manual
- SPNS Initiative: Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color, 2012-2017 background
- Reback, C.J., Kisler, K.A., & Fletcher, J.B. (2019). A novel adaptation of peer health navigation and contingency management for advancement along the HIV care continuum among transgender women of color. AIDS and Behavior. https://doi.org/10.1007/s10461-019-02554-0

- Participants receive increasingly valuable reinforcers in the form of CM reward points, which are redeemable for goods or services that promote a healthy, prosocial lifestyle (e.g., gift cards, bus tickets, payment of a utility bill, clothing).
- Increasingly valuable reinforcers serve as motivators for HIV care-seeking behavior and are specifically awarded to participants for attending HIV care visits and reaching and maintaining HIV milestones.

Findings and Outcomes

- Combined PHN and CM intervention was found to be effective in linking and retaining transgender women of color in HIV care.
- Average time from enrollment to linkage with HIV care was 67 days.
- 88 percent of participants attended at least two PHN sessions.
- 85 percent of participants attended a first HIV care visit, and 57 percent returned for a second HIV care visit.
- 14 percent of participants escalated through the entire CM schedule to achieve undetectable status.
- At intervention completion, 85 percent of participants were linked to care, and 44 percent had achieved and/or maintained viral load suppression.
- Increased attendance at PHN sessions was associated with increased probability of achieving behavioral and biomedical CM targets.

Lessons Learned

- Program administrators should support patient health navigators in setting boundaries to prevent burnout and vicarious trauma. Patient health navigators should receive ongoing training and support.
- Implementation teams will need to train HIV clinics on providing culturally competent health care to transgender women of color.
- Programs can promote retention in HIV care by providing unlimited PHN sessions, linking participants to other needed services, and providing an increasingly valuable reward schedule based on advancement through the HIV care continuum.
- PHN can be time consuming; for some participants, it may take multiple PHN sessions to feel ready to make a behavioral change. PHN should adopt a client-centered approach and build relationships first to develop a trusting partnership that facilitates lasting change for the client.

Coordination of Mental Health and HIV Care in a Mental Health Setting

Each of the case examples in this chapter illustrates how organizations have implemented one or more evidence-based practices in a clinical or community setting. While none of these examples highlights a program that is primarily focused on mental health, it is critical that programs primarily serving people with mental illness assess their clients for HIV risk, conduct HIV testing, and provide appropriate and integrated HIV prevention and treatment services and mental health treatment to address their client's complex needs.[3]

When first working with a potential client, mental health providers can conduct an intake and/or mental health assessment using screening tools such as the brief measure for assessing generalized anxiety disorder (GAD-7)[4] or the major depressive disorder module of the Patient Health Questionnaire (PHQ-9).[5] During this intake and screening, a mental health provider has an opportunity to discuss a client's overall health and wellbeing, including co-occurring medical conditions such as HIV.

- If a client has not had a recent HIV test, mental health providers can supply a self-administered oral fluids test which can provide results within 20 minutes.
  - If a client does not have HIV, a mental health provider can provide PrEP education, and support PrEP uptake and adherence (as described in Chapter 2); PrEP is highly effective in preventing HIV transmission from condomless sex and injection drug use.
  - If a client has HIV, a mental health provider can link a client to HIV primary care treatment, and provide the counseling necessary to support client mental health and ART uptake and adherence (including Cognitive Behavioral Therapy, as described in Chapter 2).
- For clients at risk for or with HIV, mental health providers can also connect the client to case management to address a client's unmet ancillary needs (e.g., housing, employment, transportation), which will help reduce barriers to PrEP and ART adherence.

Integrated behavioral health and infectious disease care can facilitate rapid screening, testing, and treatment, and improve health outcomes for people experiencing mental disorders and HIV. One example of effective mental health and HIV service integration is an infectious disease psychiatric consultation service embedded within the infectious disease outpatient department in a Boston hospital. Participants were offered a comprehensive approach to depression care that included pharmacologic and ancillary psychological therapies. When psychiatric consultation services were offered and linked to primary care, participants experienced benefits to both their mental health and HIV-related health outcomes. Participants had a statistically significant reduction in depression and viral load, and statistically significant increase in CD4 count. Additionally, a greater number of participants were prescribed anti-depressants and stimulants to treat their depression.[6]

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CHAPTER

5

Resources for Evaluation and Quality Improvement

Evaluating a practice or program answers critical questions about how well a practice has been implemented, and what is and is not working. Evaluation can also show how clients benefit from a program. This information can be helpful in making program adjustments, if necessary, and demonstrating the value of a program or practice to justify its continuation and secure additional funding. In addition, stakeholders can use information gathered through evaluation to encourage implementation of that practice in other programs or communities.

This chapter provides an overview of approaches to evaluate implementation of and results from practices to prevent and treat human immunodeficiency virus (HIV) among people with mental illness and/or substance use disorders (SUD).

This chapter also includes information on implementing a continuous quality improvement (CQI) process. Finally, the chapter concludes with specific evaluation resources, including potential outcomes to track.

EVALUATION PLAYS CRITICAL ROLES AT DIFFERENT TIMES IN INTERVENTION IMPLEMENTATION

During the development of the program, prior to full-scale implementation

Formative Evaluation

- Is the practice the right intervention for the population of interest?
- What resources does the organization have and need to implement and evaluate the practice?

As soon as the program implementation begins and during practice operation

Process/Implementation Evaluation

- Are practice activities being implemented as intended?
- What are the barriers and facilitators to implementation?

Continuous Quality Improvement

- What improvements could be made to the practice?
- What parts of implementation were working and should be unchanged?

After the practice is initiated with at least one client

Outcome/Effectiveness Evaluation

- Were the objectives of the practice achieved?
- Did client health, wellbeing, attitudes, beliefs, and behaviors change from the start of their participation in practice activities?

During operation of the practice, and at appropriate intervals at the end of a practice

Impact Evaluation

- To what extent can client outcomes be attributed to the practice activities?

Engage clinic community members, key populations, and behavioral health care consumers throughout all phases of evaluation planning, data collection, analysis, and dissemination.

Types of Evaluations

Evaluation is typically conducted before a practice is implemented to determine its feasibility (***formative evaluation***), during implementation (***process evaluation*** and ***CQI***), and after the intervention has been delivered to at least one client (***outcome and impact evaluations***). Each type of evaluation is necessary to assess an intervention's effectiveness. The graphic below illustrates these evaluation types in greater detail.

CONTINUOUS QUALITY IMPROVEMENT (CQI)

What is CQI?

CQI involves a systematic process of assessing program or practice implementation and short-term outcomes and then involving program staff in identifying and implementing improvements in service delivery and organizational systems to achieve better treatment outcomes. CQI helps assess practice fidelity, the degree to which a program delivers a practice as intended. There are many potential CQI models and approaches (see e.g., https://www.healthit.gov/faq/what-are-leading-continuous-quality-improvement-strategies-health-care-settings).

CQI differs from process evaluation in that it involves quick assessments of program performance, timely identification of problems and potential solutions, and implementation of small improvements to enhance treatment quality. CQI is usually conducted by internal staff. Process evaluation involves longer-term assessments and is best conducted by an external evaluator.

The Network for Improvement of Addiction Treatment (NIATx), a project originally funded by SAMHSA's Center for Substance Abuse Treatment, offers tools to conduct CQI and improve services in substance use disorder treatment settings. NIATx is based on the principle of program improvement through a series of small changes, tested and implemented one at a time, that in the end have a cumulative effect.

The Institute for Healthcare Improvement's PDSA Model for Improvement identifies a scientific method for testing small-scale changes in an action-oriented, cyclical manner. The stages are: planning it (Plan), trying it (Do), observing the results (Study), and acting on what is learned (Act).

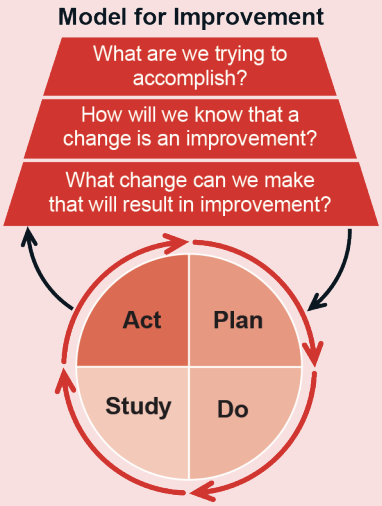
Why use CQI?

CQI takes a broader look at the systems in which programs or practices operate. Because of the pivotal role it plays in performance management, organizations preventing and treating HIV among people with mental illness and/or substance use disorders are encouraged to implement CQI procedures.

What are the steps involved in CQI?

Although steps in the CQI process may vary based on objectives, typical CQI steps are:

- Identify a program or practice issue needing improvement and a target improvement goal
- Analyze the issue and its root causes
- Develop an action plan to correct the root causes of the problem, including specific actions to be taken
- Implement the actions in the action plan
- Review the results to confirm that the issue and its root causes have been addressed and short-term and long-term treatment outcomes have improved
- Repeat these steps to identify and address other issues as they arise



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Preparing to Collect Data

The following steps can help clinics and practitioners prepare to collect and analyze data:

1. **Determine if the purpose of the data collection is evaluation or research.**

   Qualitative and quantitative evaluation and research enables managers and clinicians to learn from clients and obtain the perspective of those with lived experiences. Both evaluation and research can also involve collecting data from staff who deliver the new treatment to obtain their perspectives on facilitators and challenges to practice implementation.

   Program evaluation supports program improvement. Research contributes to generalizable knowledge by implementing study protocols and procedures approved by Institutional Review Boards (IRB) that adhere to human subject research protections. When designing program evaluations, researchers should consult with their institutions to ensure they are following appropriate data collection procedures.

2. **Identify team members to conduct evaluation activities.**

   Regardless of the type of evaluation conducted, collecting and analyzing data takes time. Programs need to identify team members who can conduct evaluation activities and secure funding to protect their time for evaluation trainings, data collection, and data analysis**.**

3. **Determine outcomes of interest.**

   A challenging step in the process of implementing new practices is to determine whether the practice has yielded desired outcomes. An outcome is the change a program hopes to accomplish through the implementation of a practice.

Qualitative and quantitative data are complementary. Each provides critical insight into if and how the intervention is operating and achieving the intended objectives.

Qualitative data include any non-numeric, text-based information, such as verbal, visual, or written data. Qualitative data collection methods include interviews, focus groups, clinical observations, gathering data from documents and images, and open-ended survey questions and polling responses.

Quantitative data are any numeric data that can be processed by mathematical or statistical analysis. Quantitative data collection includes close-ended survey questions and polling responses, services and utilization data, and claims and encounter data.

Outcomes

The table below provides a list of potential outcomes, example outcome indicators, and qualitative and quantitative data sources that program managers, clinicians, and others may use to evaluate practices identified in Chapter 2. Some of the short- and intermediate-term outcomes may be tracked at baseline and throughout the practice or program duration through an electronic health record, or through interviews with staff and clients. Longer-term outcomes may be obtained from administrative and survey data.

Outcome	Practice	Illustrative Indicators	Illustrative Data Sources
Short-term and intermediate outcomes			
Engagement in services	SSPs	• Access to SSP (number of sites, hours open) • Clients accessing SSP (visit numbers and dates) • Syringes distributed and returned for disposal	• Qualitative interviews (staff and clients) • Administrative data • Intake/enrollment data
	PrEP CBT CM PN	• Sessions and contacts scheduled and completed	• Administrative data
HIV education	CBT CM PN	• Change in knowledge, motivation, and skills to engage in HIV preventive acts (e.g., condom attitudes and use), • Perceptions of personal vulnerability to HIV	• Qualitative interviews (staff and clients) • Structured scales and assessments (e.g., Sexual Risk Behavior Assessment Schedule)
Knowledge of HIV and SUD harm reduction strategies	SSPs CBT	• Knowledge of safe injection practices • Knowledge about HIV transmission • Knowledge of overdose prevention strategies (e.g., naloxone access and trainings)	• Qualitative interviews (staff and clients) • Structured scales and assessments • Attendance/administrative data • Number of naloxone trainings and naloxone kits distributed
PrEP uptake	PrEP	• Number of PrEP prescriptions provided and filled	• Medical records • Pharmacy records
Linkage or re-linkage to HIV care	SSPs CM PN	• Number of HIV linkage-to-care visits scheduled and completed	• Administrative records • Medical records
Injection drug use behaviors	SSPs CBT CM	• Injecting with a sterile syringe • Sharing injection equipment	• Qualitative interviews (clients) • Staff logbooks • National Institute on Drug Abuse (NIDA) Risk Behavior Assessment
Ancillary service delivery	SSPs PN	• Referrals made and visits completed for specialty care and ancillary services (e.g., HIV/HCV/STI testing, medication-assisted treatment)	• Qualitative interviews (staff and client) • Administrative data • Medical records
Retention in HIV care	CM PN	• Number of medical visits that were at least 90 days apart (in the past year)	• Qualitative interviews (clients) • Medical records
Medication Adherence	PrEP	• Ongoing PrEP prescriptions provided and filled	• Medical records • Pharmacy records
	CBT CM PN	• ART prescriptions provided and filled	• Qualitative interviews (client) • Medical records • Medication Event Monitoring Systems (MEMS)

Outcome	Practice	Illustrative Indicators	Illustrative Data Sources
Short-term and intermediate outcomes			
Substance Use	PN	• SUD • Days of substance use in the prior 30 days	• Qualitative interviews (client) • Urine drug screen • Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) • Alcohol Use Disorders Identification Test (AUDIT) • Drug Abuse Screening Test (DAST-10)
Individual-level mental health	CBT	• Mental health score	• Structured scales and assessments (e.g., PHQ-9 for depression, Beck Depression Inventory, Hamilton Depression Scale, Montgomery-Asberg Depression Rating Scale, Generalized Anxiety Disorder (GAD-7) Scale)
	PN		• 12-item short form health survey (SF-12)
Changes in HIV risk associated with SUD	SSPs	• Frequency of substance use • Cessation of injection drug use	• Qualitative interviews (staff and clients) • NIDA Risk Behavior Assessment
Long-term and population-level outcomes and impacts			
Individual-level HIV outcomes	CBT CM PN	• CD4 cell count • Viral load	• Medical records • Lab test/blood sample
Population-level HIV outcomes	SSPs PrEP CBT CM PN	• Rate of new HIV diagnoses • Prevalence of HIV	• Administrative data • Medical records

SSPs PrEP CBT CM PN

Evaluation Resources

Evaluating Program Implementation

- A Framework for Program Evaluation, from the Program Performance and Evaluation Office at the Centers for Disease Control and Prevention, summarizes essential elements of program evaluation.
- The Community Toolbox, from the Center for Community Health and Development at the University of Kansas, includes a step-by-step guide to developing an evaluation of a community program, specific tools, and examples.

Quality Improvement and Continuous Performance Monitoring

- Institute for Healthcare Improvement's Quality Improvement Essentials Toolkit includes the tools and templates to launch a quality improvement project and manage performance improvement.

Evaluating Practices Specifically Addressing HIV and Mental Illness and/or SUD

- The Center for Innovation in Social Work and Health Community Health Worker toolkit includes best practices for evaluating peer programs.
- Rural Health Information Hub (RHIhub) has created HIV, Mental Health, SUD, and Telehealth specific Evidence-Based Toolkits for Rural Community Health (that can be broadly applied to both rural and urban health).
- The National Minority AIDS Council created a guide to program evaluation as part of their Organizational Effectiveness Series, defining types of evaluation, ways to assemble an evaluation team and design an evaluation plan, and steps to conducting an evaluation.

Appendix 1: Acknowledgments

This publication was developed with a significant contribution from Alexis Marbach, MPH, SAMHSA staff, a technical expert panel, and Abt Associates staff. The guidance is based on the thoughtful input of SAMHSA staff and the Expert Panel on the prevention and treatment of HIV among individuals experiencing co-occurring mental illness and/or substance use disorders (SUD) from October 2019 through August 2020. A series of guide development meetings was held virtually over a period of several months. Three expert panel meetings were convened during this time.

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Appendix 2: Evidence Review Methodology

The authors followed a rigorous, systematic evidence review process in the development of this guide. This appendix provides an overview of the evidence review methodology used to identify the ratings for the practices included in the guide: practices to increase uptake of and improve adherence to PrEP, syringe services programs, cognitive behavioral therapy, contingency management, and patient navigation. Reviewers, in coordination with SAMHSA and experts, conducted a four-step process to select practices, identify related studies, review and rate studies, and identify practice ratings.

Step 1: Practice Selection

The authors identified these five practices after a review of the literature and in consultation with experts. In an effort to include interventions that would be most useful to those seeking to prevent and treat HIV among people with mental illness and/or substance use disorders (SUD), eligible practices were required to meet the following criteria for evidence review:

- Be clearly defined and replicable
- Address the target outcome of preventing and treating HIV among people who use substances and/or have mental health concerns
- Be currently in use
- Have studies of their effectiveness
- Have accessible implementation and fidelity supports

At the conclusion of this step, SAMHSA and the guide's Expert Panel reviewed the proposed practices identified by the authors and agreed on five for inclusion in the evidence review and rating process.

Step 2: Study Identification

Once the practices were selected, the reviewers conducted a comprehensive review of published research on these practices to identify studies of the selected practices. This review only included studies from eligible sources (i.e., peer reviewed journals and government reports) that avoid clear conflicts of interest. The reviewers documented all potential studies identified through the literature search.

The studies identified in the literature search varied in type and rigor, so the reviewers assessed them further for inclusion in the evidence review. To be eligible for review and study rating, research studies had to:

- Employ a randomized or quasi-experimental design, or
- Be a single sample pre-post design or an epidemiological study with a strong counterfactual—a study that analyzes what would have happened in the absence of the intervention.

Literature reviews, descriptive studies, implementation studies, and meta-analyses were not included in the review, but were documented to provide context and identify implementation supports for the practices.

Additionally, to be eligible for further review and rating, studies had to:

- Be published or prepared in or after 2000
- Be a publicly available peer-reviewed paper or research report
- Be available in English
- Include at least one eligible outcome related to HIV prevention and/or treatment
- Have a comparison/control group that is treatment as usual or no/minimal intervention if using a randomized experimental or quasi-experimental design

Step 3: Study Review and Rating

Next, trained reviewers assessed each study to ensure the methodology was rigorous and therefore could demonstrate causation between the practice and the identified outcomes. Reviewers reviewed and documented each study to ensure that:

- Experimental and comparison groups were statistically equivalent, with the only difference being that participants in the experimental group received the intervention and those in the comparison group received treatment as usual or no/minimal intervention

- For randomized experiments with high attrition and for quasi-experimental designs, baseline equivalence was established between the treatment and comparison groups
- For randomized experiments, randomization was not compromised. For example, ensuring that reassignment of treatment status, usually made to balance the distribution of background variables between treatment and control groups, did not occur.
- Study did not have any confounding factors (factors that affect the outcome but are not accounted for by the study)
- Missing data were addressed appropriately
  - Imputation based on surrounding cases was considered valid
  - Complete case analysis was considered valid and accounted for as attrition
  - Using model with dummy for missing as a covariate was considered valid
  - Assuming all missing data points are either positive or negative was not considered valid
  - Regression-based imputation was considered valid; mean imputation was not considered valid.
- Outcome measures were reliable, valid, and collected consistently from all participants
- Valid statistical models were used to estimate impacts
- Practice demonstrated improved outcomes related to HIV prevention and treatment

Based on the study design and these study characteristics, reviewers **gave each study a rating** for causal impact. Reviewers used the following scoring metric for each study based on the eight factors above to determine if a study is rated:

- High support of causal evidence
- Moderate support of causal evidence
- Low support of causal evidence

Only randomized controlled trials, quasi-experimental designs, and epidemiological studies with a strong comparison were eligible to receive a high or moderate study rating.

Step 4: Practice Rating

After all studies for a practice were assessed for these criteria, the reviewers **gave each practice a rating** based on the number of studies with strong, moderate, or emerging support of causal impact. Causal impact is evidence demonstrating that an intervention causes, or is responsible for, the outcome measured in the study's sample population. The practice was placed into one of the following categories based on the level of causal evidence of its studies:

- **Strong Evidence**: Causal impact demonstrated by at least two randomized controlled trials, quasi-experimental designs, or epidemiological studies with a high or moderate rating.
- **Moderate Evidence:** Causal impact demonstrated by at least one randomized controlled trial, quasi-experimental design, or epidemiological study with a high or moderate rating.
- **Emerging Evidence:** No study received a high or a moderate rating. The practice may have been evaluated with less rigorous studies (e.g., pre-post designs) that demonstrate an association between the practice and positive outcomes, but additional studies are needed to establish causal impact.

The four-step process described above resulted in identification and rating of the five practices. The rating given to each practice is intended to inform decision making about adoption of new practices or clinical or system enhancements that will improve health outcomes for people with or at risk for HIV with co-occurring mental illness and/or SUD.

Photos are for illustrative purposes only.
Any person depicted in a photo is a model.

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