CHAPTER

2

This is STUDY GUIDE 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:

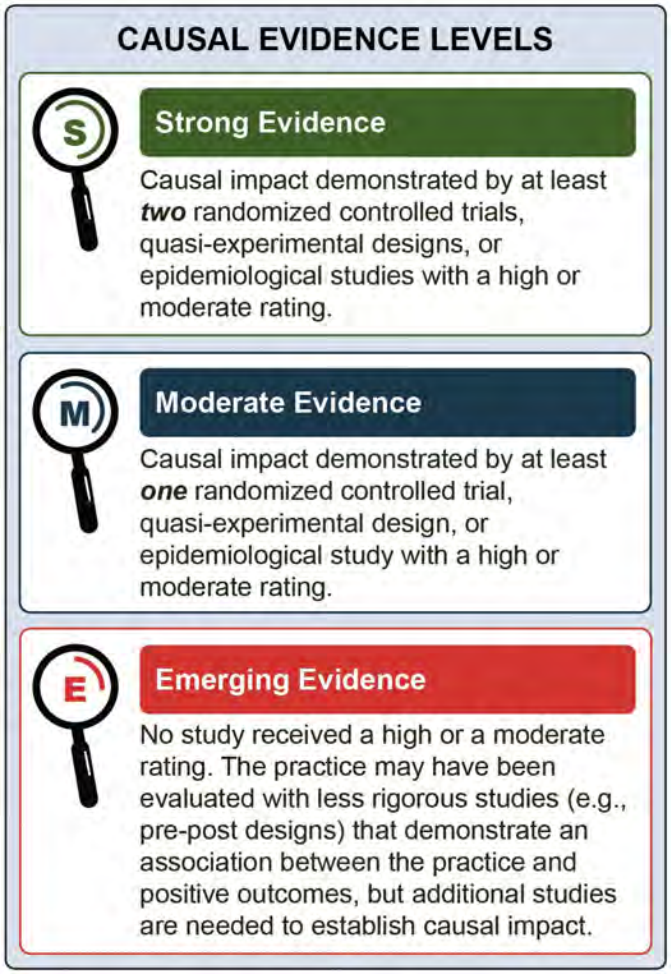
- Are experimental and comparison groups demographically equivalent, with the only difference being that participants in the experimental group received the intervention and those in the comparison group received treatment as usual or no/minimal intervention?
- Was baseline equivalence established between 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: The 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.



* 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)

Goal

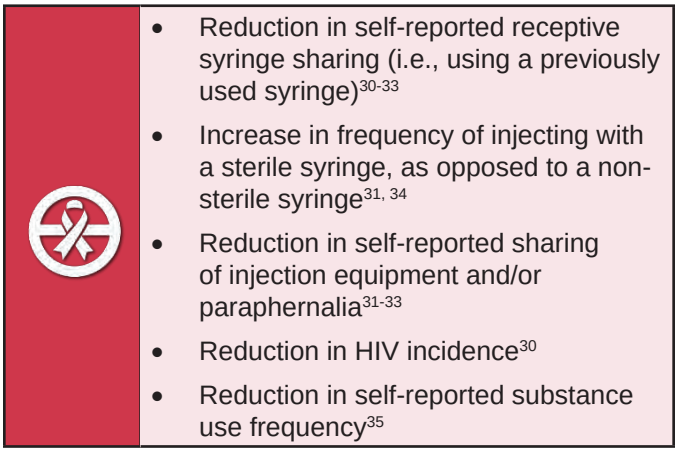
SSPs reduce the risk of infectious disease associated with injection drug use through preventive services, including provision of sterile syringes, injection drug equipment, and harm reduction education, as well as linkage to HIV and mental illness and/or SUD treatment.[21-23]

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)

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 & 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

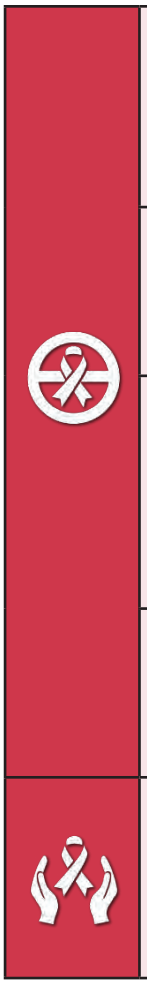
CBT can be implemented effectively by a variety of professionals including:

- 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

CHAPTER

3

You are still in Study Guide 2

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

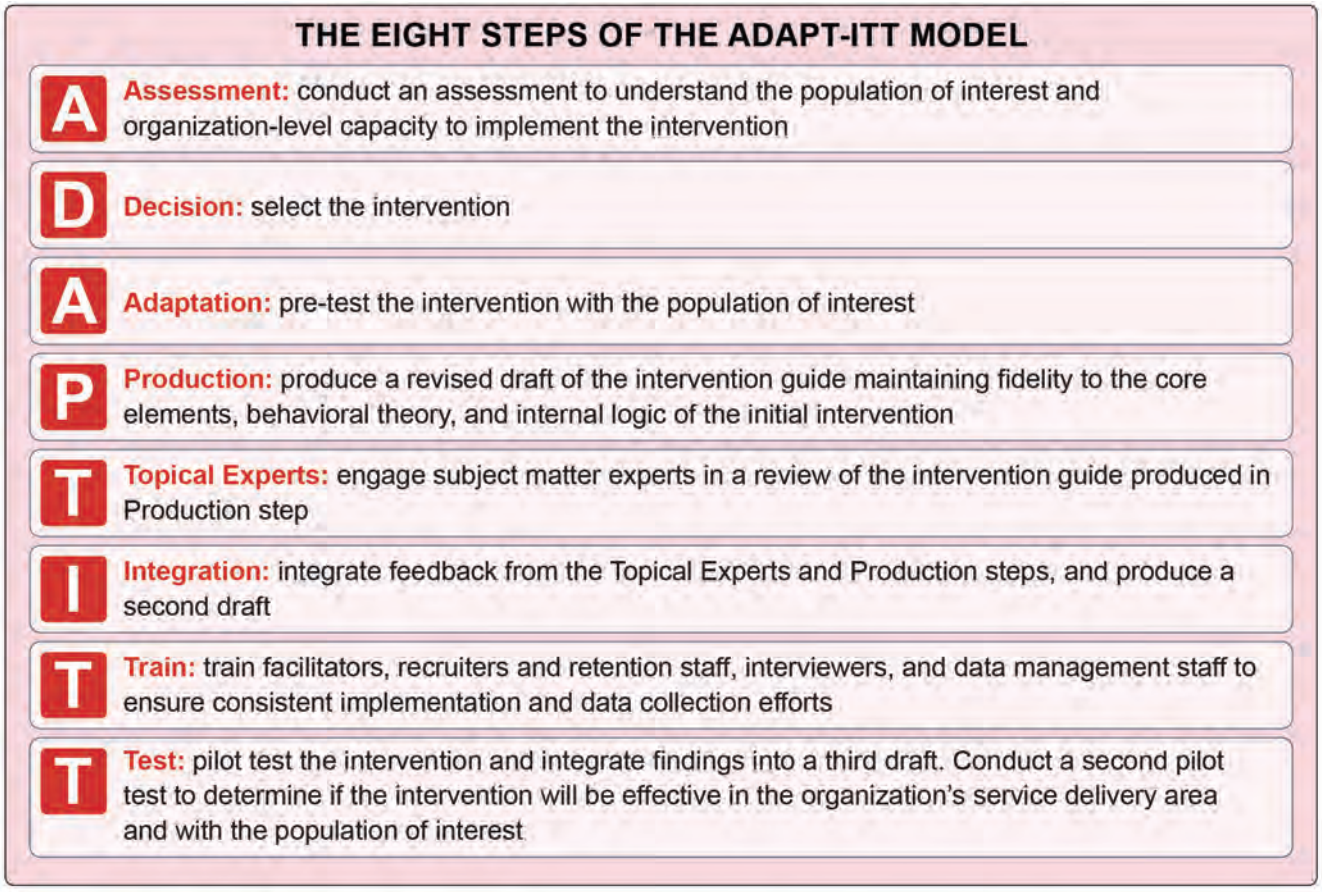
Practices implemented without adaptation may not be relevant to or acceptable for the client population.[5] Practices should be culturally relevant, available in the appropriate language, and produced at the appropriate reading level.[6-7]

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.



COORDINATING CARE

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. Oregon Health Authority Harm Reduction and SSP Planning Manual and Resource Library offers a manual and several resources on SSP planning and implementation.

Contingency Management

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 trainingcourses, newsletters, assistance with program implementation, and information on utilizing supervisors and consultants.

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. 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.

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. 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.***

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. 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]

This is the end of Study Guide 2. You may take Quiz 2 now or after you have finished reading Study Guide 3. Return to your My Home Page and click the name of the course, to take quiz 2.