

Optimizing PrEP Adherence:

A Toolkit for PrEP Programs in the United States



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OVERVIEW

In this publication, we present information from current and emerging clinical projects around adherence for people who start and use PrEP over time. Although this guide is focused on daily oral PrEP, we have included resources that may apply to non-daily dosing and other formulations.

Frontline workers—such as public health, clinical, and navigation staff—can utilize this information to adapt PrEP services in support of their

clients' patterns of adherence and persistence.

As you review the presented PrEP adherence strategies, consider how they could be tailored to an individual's ongoing needs. We first offer a “basic” adherence template that can be used to establish baseline information and support for all PrEP users. We then present additional strategies that can further optimize PrEP adherence as needed.

We define **adherence** as taking PrEP medication as prescribed, while **persistence** focuses on continuing PrEP over time. The objectives for this publication are:

● To review the importance of PrEP adherence in reaching high levels of protection from HIV infection,

● To describe facilitators and barriers to PrEP adherence and persistence, and

● To provide various evidence-based strategies that support PrEP adherence and persistence.

** The majority of the literature reviewed for this publication used the daily oral PrEP medications FTC/TDF (Truvada) or FTC/TAF (Descovy).*

WHY IS PREP ADHERENCE IMPORTANT?

PrEP is a highly effective bio-behavioral strategy used to prevent HIV infection. The FDA approved and the CDC currently recommends daily oral medication (FTC/TDF or FTC/TAF fixed-dose combination pills) and injectable medication (cabotegravir) every two months for prevention of HIV through sexual exposure.¹ This guide is focused on interventions to support adherence and persistence with daily oral PrEP. Research is ongoing to evaluate supporting adherence with other forms of PrEP. Regardless of the form of PrEP they use, individuals must take PrEP consistently to ensure high levels of protection.

Drug levels and PrEP efficacy

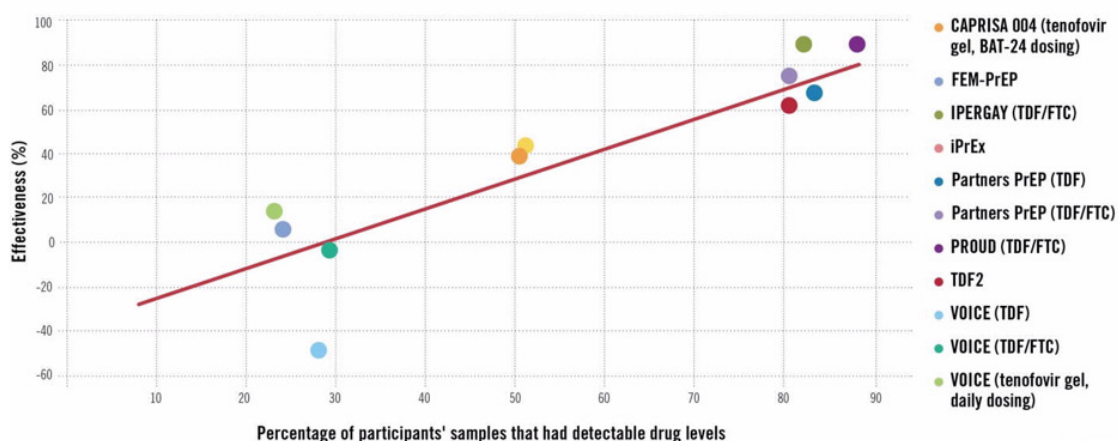
Randomized controlled trials (RCTs) of PrEP show a strong relationship between adherence (taking medication as prescribed) and efficacy (how well PrEP prevents HIV infection).²⁻⁵ As seen in Figure 1, the efficacy of PrEP corresponds highly with detectable levels of drug(s) in blood or other tissues. These drug levels are then used to estimate adherence.

In these studies, adherence was a critical factor in efficacy. In contrast, the non-adherence seen in several studies raised concerns that PrEP may not reduce HIV infections to the same degree for some populations. We continue to learn more about how best to support real-world PrEP use from how participants are supported in implementation studies.

continued

FIGURE 1

PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



AVAC
February 2016

Reproduced with permission from AVAC. TDF = tenofovir disoproxil fumarate, FTC = emtricitabine.

New forms of PrEP are in clinical study⁶ that are using different drugs and different methods of taking them, such as implants, films, and gels. An injected form of PrEP called cabotegravir that is taken every two months was recently found to be as safe and effective⁷.

Drug levels and exposure routes

In studies where condomless anal sex was the main route of HIV transmission, no infections were seen among men and transgender women who have sex with men who took at least four doses of oral F/TDF medication per week.^{8,9} This suggests some ‘forgiveness’ when daily doses are sometimes missed for people having anal sex.

In contrast, studies of cisgender women show that at least six to seven doses per week are needed to reach high levels of protection from vaginal exposures.¹⁰ Similar adherence to daily PrEP is also needed for exposures through injection drug use. Studies continue to seek the optimal dosing of daily PrEP for certain individuals, including transgender and pregnant people. Some transgender populations and pregnant women have not been included in studies of PrEP efficacy.

Non-daily oral PrEP

A non-daily use of PrEP for anal sex using tenofovir DF (TDF)/emtricitabine (FTC)—called “on-demand” PrEP—was shown to be effective in the IPERGAY study of men who have sex with men (MSM)¹¹. Individuals who use on-demand PrEP take 2 pills at least 2 to 24 hours before anal sex, a third pill 24 hours after the first dose, and then a fourth pill 24 hours later. As a result, many call this 2-1-1 PrEP. In contrast, the ADAPT study that compared daily to non-daily PrEP regimens found that daily dosing was more feasible for some people.¹²

While added “forgiveness” may exist for missing doses of daily PrEP for anal sex, this may not be the case with on-demand dosing. Except in cases when sex did not happen, ensuring that every dose is taken for on-demand PrEP is key.

The efficacy of this dosing has not been studied for vaginal sex or injection drug use. On-demand PrEP (for men and transgender women who have sex with men) is supported by the CDC,¹ by various health departments,^{13, 14, 15} and by the World Health Organization.¹⁶

WHAT HAVE DEMONSTRATION PROJECTS TAUGHT US ABOUT USING PREP?

Once the RCTs had shown the safety and efficacy of PrEP, several groups conducted demonstration projects. These studies investigated to understand what adherence and retention in PrEP care would look like in “real-world” settings.

Participants in the early RCTs did not know if they were taking PrEP or a placebo nor whether PrEP even prevented HIV. In contrast, the demonstration projects offered PrEP to everyone, and no one took a placebo.

These newer studies found substantially higher rates of PrEP adherence than in the RCTs. As suspected early on,³ those in the RCTs may not have believed that the study drugs could prevent HIV or may have been concerned that the drugs posed safety issues.¹⁷⁻²⁰

The National Institutes of Health conducted its first demonstration project in the U.S. in one community health center and two STI clinics. Adherence was high among MSM and transgender women soon after they started PrEP: 85% of 294 people had drug concentrations at or above effective levels at follow-up visits.²¹ However, adherence declined over the year of follow-up. Another PrEP study among youth also showed adherence dropped off over time, when moving from monthly to quarterly visits.²²

Outside of demonstration projects, other studies showed that many people do not return after the first prescribing visit for PrEP. One study reported 62% of people who started PrEP followed up at three months while 38% returned at six months.²³

Another study showed follow-up visits dropped by 11% at three months and dropped 27% at six months.²⁴ Recent work using pharmacy refill data

suggests that about half of those who started PrEP had stopped within the first year.²⁵ The average time to stopping PrEP may be as short as four months after starting PrEP.²⁶

Despite the high adherence seen in early demonstration projects, the reasons behind loss to follow-up in more diverse settings are now becoming better understood. Factors associated with stopping PrEP include younger age, cost of PrEP services, gaps in insurance coverage, medical mistrust, substance use, and mental health issues.²⁵⁻²⁷

Individuals may stop PrEP because they no longer believe they are at risk for HIV. Alternatively, they may rely on other strategies such as using condoms regularly or monogamously coupling with persons who are HIV negative or who are living with HIV and are virally suppressed. In these cases, stopping PrEP does not necessarily suggest a lack of persistence.

One study proposed prevention-effective adherence as a way to use PrEP over periods of possible exposures to HIV where using PrEP is indicated.²⁸ In these cases, PrEP providers can carefully follow individuals who may still be at risk but who do not continue PrEP due to issues such as loss of health insurance, change in benefits, or personal preference.²⁹

Discerning why adherence and persistence may change over time is a key aim for PrEP demonstration projects. These projects continue to evaluate a range of strategies (see Table 1 below) to optimize adherence in diverse populations (e.g., transgender persons, MSM of color, cisgender women, youth). Lessons learned can guide community programs that carefully monitor uptake, adherence, and retention in PrEP care.

TABLE 1: PrEP Initiation, Adherence, and Persistence from Demonstration and Real-world PrEP Programs

SAMPLE/POPULATION	PRESCRIBED/ INITIATED	ADHERENCE	PERSISTED WITH PREP
Young Black MSM in EleMENT study (Atlanta) 2015-2016 ³⁰	34%		83%
Medicaid insurance database Females 2017 ³¹	0.15-0.26%		
Miami Pride 2018 ³² (majority MSM)	32%	56% (SR adherent)	82%
CA PrIDE prevention project 2015-2018 ³³ Overall of eligible	38%		
CA PrIDE prevention project 2015-2018 ³³ MSM of eligible participants	36%		
CA PrIDE prevention project 2015-2018 ³³ TGW of eligible	56%		
Los Angeles (CA) <i>AssistanceServicesKnowledge-PrEP</i> Program Sept 2016 to March 2018 ³⁴ (TGW)		87% (SR perfect past 4 days)	80% SR 81 90 days
Los Angeles (CA) <i>AssistanceServicesKnowledge-PrEP</i> Program Sept 2016 to March 2018 ³⁴ (MSM)		83% (SR perfect past 4 days)	70% SR at 90 days
Los Angeles (CA) <i>AssistanceServicesKnowledge-PrEP</i> Program Sept 2016 to March 2018 ³⁴ (TGW and MSM)		49% (SR perfect past 30 days)	73% SR at 90 days
San Francisco CA Stay Study TGW 2017-2019 ³⁵ at 3 months on PrEP, at 6 months on PrEP		84% (SR near perfect past week at 3 mos.)	21% (SR at 3 mos.)
		88% (SR near perfect past week at 6 mos.)	35% (SR at 6 mos.)
Philadelphia PA SHE project cis-gender women in syringe program 2018-2019 ³⁶ at week 12 and week 24		47% (SR consistent adherence at 3 mos.)	
		51% (SR consistent adherence at 6 mos.)	
Philadelphia PA SHE project cis-gender women in syringe program 2018-2019 ³⁶ at week 12 and week 24		5% (Urinalysis consistent adherence at 3 mos.)	62% at 3 months with 48% of these continuing through month 6
		8% (Urinalysis consistent adherence at 3 mos.)	

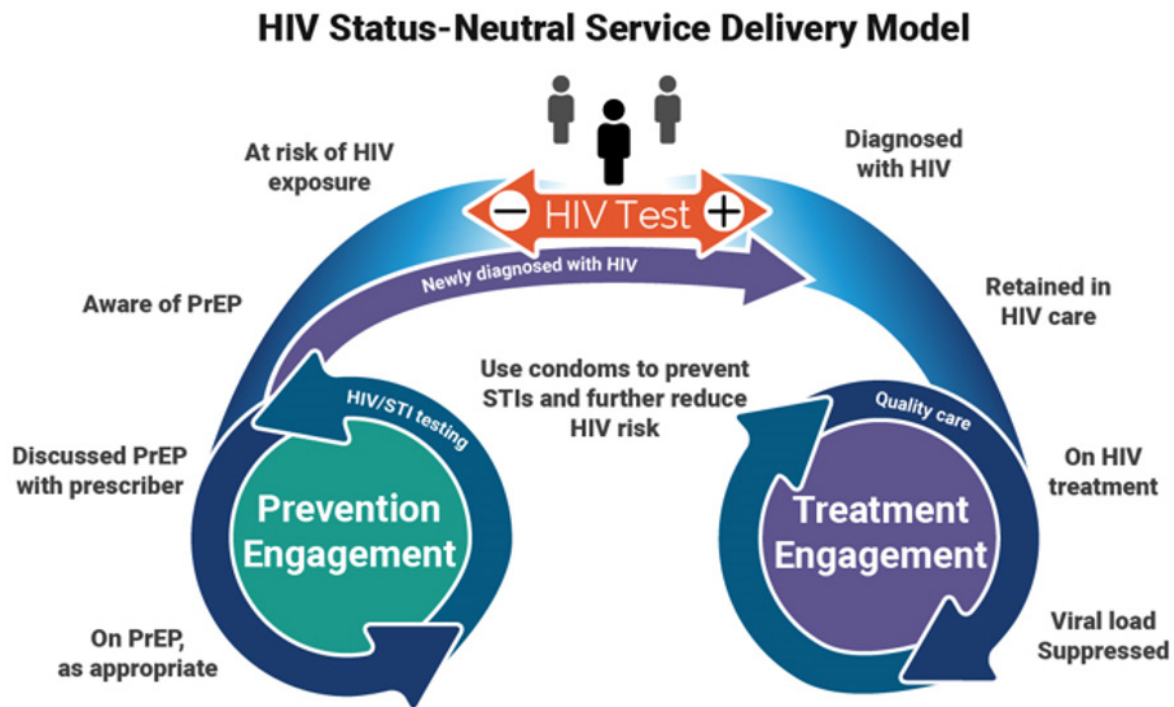
continued

TABLE 1: PrEP Initiation, Adherence, and Persistence from Demonstration and Real-world PrEP Programs, *continued*

SAMPLE/POPULATION	PRESCRIBED/ INITIATED	ADHERENCE	PERSISTED WITH PREP
CA AEGIS project cisgender women 2016-2018 ³⁷ week 12, 24 and 48		33% (DBS near perfect adherence at 3 mos.) 21% (DBS near perfect adherence at 6 mos.) 18% (DBS near perfect adherence at 12 mos.)	62% (at 1 year)
Chicago EPIC project young MSM 2015-2016 ³⁸ week 12, 24, and 36		>70% (drug concentration 4-7 doses per week at 3 mos.) 60% (drug concentration 4-7 doses per week at 6 mos.) 50% (drug concentration 4-7 doses per week at 9 mos.)	
PrEP initiations in 2015 – 2017 national pharmacy chain data ³⁹			56% at 1 year 41% at 2 years
San Francisco CA sexual health clinic 2014-2015 ⁴⁰ (largely MSM)	78%		47% at ~12 mos.
San Francisco CA Public Health Clinic registry 2012-2017 ⁴¹ MSM and TGW			76% (did not have gap >90 days in PrEP doses)
Southern CA Kaiser Permanente pharmacy refill based data 2014-2018 ⁴² of those prescribed PrEP	99%		47% ^A
New York City cis-gender women 2015-2016			67% at 3 mos. 38% at 6 months
Atlanta GA Grady Health System PrEP program 2015-2017 ⁴³ largely MSM			32% at 12 months
Atlanta GA Grady Health System PrEP program 2018-2020 ⁴⁴ TGW			52% at 6 mos.
Northern CA Kaiser Permanente pharmacy refill based data 2012-2019 ⁴⁵	98%		48% over observation period 69% of those who stopped at any point restarted again

SR = Self Report; Perfect = 0 missed doses; near perfect = missed 0-3 doses per week; DBS = drug concentrations from dried blood spot analysis; A = Had 80% of more medication on hand to cover daily dosing for 12-month period.

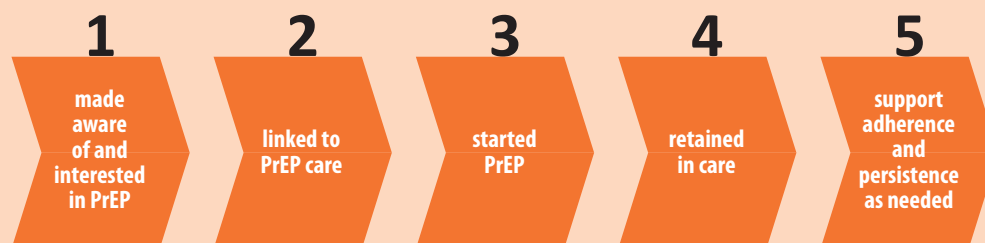
FIGURE 2: Steps to Effective PrEP Use



- This figure demonstrates how PrEP care and persistence fit within a status-neutral care delivery model. Note that prevention engagement is ongoing, including during periods when clients may stop or re-start PrEP as their HIV risk changes over time.

Source: New York City Department of Health and Mental Hygiene

FIGURE 3: Steps to Effective PrEP Use



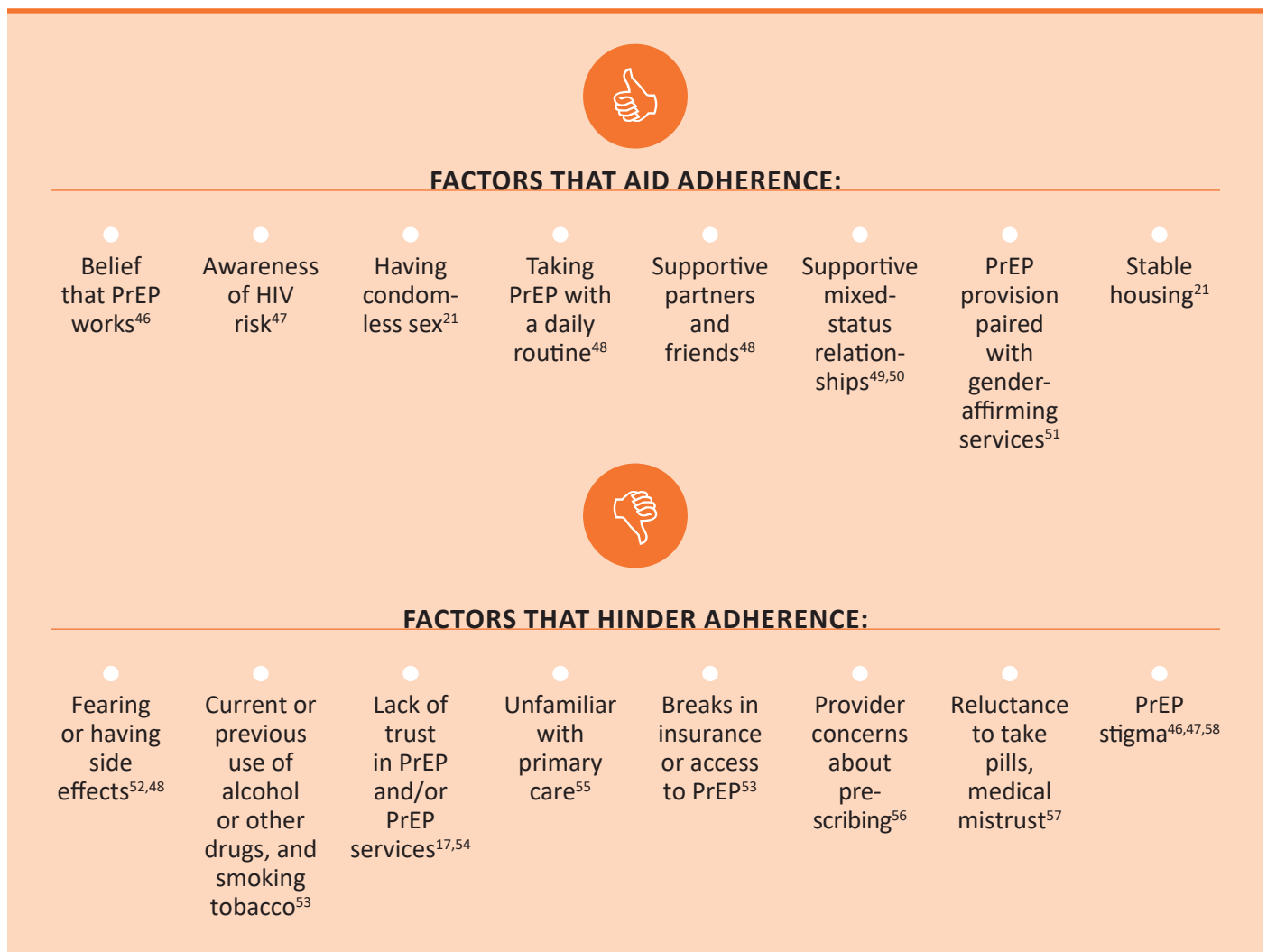
- As shown in the PrEP continuum¹, adhering to PrEP—along with regular HIV and STI screening, clinical monitoring, prescription refills, and referrals for other services—represent effective engagement in a PrEP program.
- This toolkit focuses on Steps 3-5 of the continuum. However, it is likely that the education that individuals receive at earlier steps have downstream effects on adherence.

WHAT INFLUENCES PREP ADHERENCE?

Several studies have identified factors that can help or hinder adherence to PrEP. (A summary is found in Figure 4.) A person's lack of adherence may be due to unintentional reasons, such as forgetting to take their pills or having their pill routines interrupted. Conversely, some PrEP users may intentionally not take PrEP because they fear others might see them taking it or they want to avoid side effects.



FIGURE 4: Facilitators and Challenges to PrEP Use and Adherence



Facilitators and challenges to PrEP adherence can be considered using two well-studied social and behavioral models:

- 1) the Information-Motivation-Behavioral (IMB) model⁵⁹
- 2) the socio-ecological model⁶⁰



IMB MODEL

This model suggests that three factors can affect adherence:

- ▶ understanding information about the use of PrEP;
- ▶ being motivated to take PrEP as prescribed; and
- ▶ having behavioral skills to take PrEP consistently.

For example, feeling protected and less anxious about having sex may motivate someone to take PrEP consistently. In contrast, a person with little to no experience interacting with the health care system—a reality for many young, healthy individuals—may be a behavioral challenge to adherence and ongoing engagement in PrEP care. The IMB model can help explain the use of PrEP⁵⁹⁻⁶¹, and it underlies several methods that can support adherence to PrEP.^{62,63}

SOCIO-ECOLOGICAL MODEL

(See also Appendix B, figure 4.)

The socio-ecological model describes factors that affect adherence at several levels:

- ▶ individual (such as personal beliefs about PrEP efficacy),
- ▶ inter-personal (such as how PrEP is viewed by partners or social networks),
- ▶ community/group (such as cultural beliefs or impacts of racism, homophobia, or transphobia on health-seeking behaviors),
- ▶ institutional/organizational (such as experiences with health systems, quality of care, or access to covered PrEP services), and
- ▶ macro/policy levels (such as insurance regulations or patient assistance benefits).

Each step of the PrEP continuum can be explored in terms of these factors and how they may apply to individuals or populations. Drop-off during stages of the continuum may point to the need for using individual or clinical interventions that support adherence.⁶⁴ For example, clinic staff could acknowledge doubt and mistrust about PrEP,^{17,19,20} even among those who eventually start it.

Providers and agencies that offer PrEP may benefit from applying these models to explain adherence and ‘non-adherence’ to those they serve and select targeted strategies to improve their quality of care. For example, some PrEP-focused telehealth programs initiated with COVID-19 may have reduced barriers to ongoing PrEP use through pharmacy-delivered PrEP and home-based HIV/STI screening^{65,66}.

HOW CAN PREP PROGRAMS SUPPORT ADHERENCE AND PERSISTENCE?

PrEP programs can integrate basic services as part of standard of care that support patients to start and maintain PrEP. These programs can also consider enhancing strategies for those who struggle with staying on PrEP. We present two “packages” of options for programs to consider: **basic** and **enhanced**.

Lower PrEP adherence rates have been seen in various studies with trans women, cis women, adolescents/youth, MSM of color, and people who inject drugs.⁶⁷ PrEP programs could offer enhanced adherence support to these individuals while carefully considering population-specific needs.

The **basic adherence support package** includes a minimum of education, pill-taking planning, check-in, and provider support that are suitable for most patients who start PrEP. This basic package should be easily understood by patients and minimally burdensome on both patients and clinic staff.

An **enhanced adherence support package** can be created for those who need additional support. This can include offering specific tools and strategies that address common barriers to adherence. It can also include adopting interventions used in PrEP demonstration projects and clinical practice and/or adapting interventions that have improved adherence to HIV treatment.

DEVELOPING THE BASIC PREP ADHERENCE SUPPORT PACKAGE

Valuable adherence tools have emerged from open-label PrEP studies and clinical practice that are now available online (see *Resources for Basic PrEP Education Discussions*, p33). Essential points to cover in initial and ongoing PrEP visits are highlighted in Table 2 (page 12). See Appendix C for more information on patient-centered medication management discussions.

Table 3 contains recent strategies for PrEP adherence as well as adherence strategies in HIV treatment⁶⁸ that can be adapted to PrEP services. Integrating these core areas into a comprehensive plan can help clients reach high levels of adherence and persistence.

The information in Tables 2 & 3 can be shared with clients during visits with clinical or non-clinical providers and/or offered through printed or digital materials. Sharing information and then asking individuals about its relevance and importance may foster adherence.



TABLE 2: Basics to Share Throughout PrEP Care^{1, 5, 6}

INFORMATION AREAS	KEY MESSAGES
What is PrEP?	Explain what PrEP is and how it is believed to prevent HIV infection.
Efficacy and Adherence	Explain that people who take PrEP regularly reach high levels of protection, and protection may be lower for those who cannot. It is important to take PrEP as prescribed.
Cautions	Describe the time needed to reach full protection for a daily PrEP regimen (e.g., for FTC/TDF, 7 daily doses for rectal and 20 days for vaginal exposures). While extremely rare, breakthrough infections—including those with drug-resistant virus—have occurred. State that PrEP does not prevent other STIs.
Regimen	Clearly explain how to take PrEP, including what to do in case of a missed dose (i.e., take when you remember); to avoid taking more than prescribed; and to reassure that PrEP can be taken while using alcohol or other substances.
Persistence	Discuss missing doses and when protection may decline. Advise clients to return to PrEP care to re-start PrEP after periods of non-use.
Stopping PrEP	Advise clients to check with their provider if they stop or want to stop a daily PrEP regimen for more than 7 days. For those living with chronic hepatitis B, close monitoring is recommended but hepatitis B flares have not been seen when stopping PrEP. ⁶⁹
Safe restarts	Reinforce how to restart PrEP safely after a break and the need for a new HIV test to confirm their status before restarting.
Side effects	Describe possible side effects: start-up syndrome with gastrointestinal symptoms (1 in 10 people) can occur, usually resolve within 1 month; symptoms often respond with taking PrEP with food or before bed. For FTC/TDF: kidney dysfunction, as measured by elevated serum creatinine (1 in 200, typically reversible when PrEP is stopped); 1% average loss of bone tissue, reversible when PrEP is stopped with no increase in fracture risk. Tenofovir AF (FTC/TAF): small increase in weight and cholesterol, reversible when PrEP is stopped.
Concomitant medications or treatments	Discuss the client's use of gender-affirming hormones, fertility intentions, and other medications or supplements. Discuss drug interactions, if any.
Substance use	Describe safety of PrEP even when using drugs, regardless of reported use or non-use. ⁷⁰ Reinforce that people who use methamphetamines or other substances can take PrEP. ⁷¹
Access to medication and clinical services	Offer to link clients to staff who can help with insurance navigation or patient assistance programs to cover the costs of PrEP, lab monitoring, and provider visits. Ensure visit times align with patient schedules. Offer referrals to other clinics as needed. Revisit changes in insurance coverage and finances to prevent unwanted breaks in PrEP.
Comprehensive plans for HIV prevention and sexual health	Discuss other strategies that prevent HIV and reinforce PrEP as part of a comprehensive HIV prevention and sexual health package including regular STI screening, access to condoms, and clinical monitoring.
Contact information to pose questions or share concerns	Provide responsive staff contacts for clients to access reliable and culturally responsive care during their PrEP journeys.

TABLE 3: Using ART Adherence Strategies to Support PrEP Adherence

CORE AREA	ART ADHERENCE STRATEGIES RETOOLED FOR PREP CARE
Deliver respectful care	- Facilitate positive provider-patient interactions at point of care. Ensure all staff offer culturally responsive service. Provide additional staff training as needed. - Avoid judgmental reactions to reported adherence challenges.
Create individualized plans	- Assess potential barriers to adherence and tailor strategies to address them. - Address misconceptions and other beliefs that deter adherence. - Plan to take doses around routine, daily events, and cues; develop medication schedules. - Prepare users for changes in their routines, missing doses, and concerns that may impede adherence, such as disclosing PrEP use to others.
Navigation support	- Establish, monitor, and assist clients in navigating insurance coverage and/or coverage of PrEP services using patient assistance programs. - Provide additional support, reminders, 2-way communication between visits - Identify and address barriers to adherence over time, including cost coverage issues - Track pharmacy fills and appointments to identify and support clients who struggle with adherence
Monitor PrEP Adherence	- Ask about adherence at each visit - Routinely collect self-report and medication refill data - Establish contact/outreach when visits are missed
Low barrier PrEP care	- Flexible scheduling and options for different types of visits (drop-in, telephone, video), extended hours - On-site lab and/or medication availability - Same-day PrEP starts
Offer tools or resources	- Encourage use of pillboxes, diaries, cell phone alarms, or other tools. - Utilize smartphone apps or other services such as 2-way text messaging or phone calls. - Connect with others on PrEP for peer support (e.g., use of social network or peer health navigators). - Facilitate referrals/access to wrap-around services to address unmet needs that hinder adherence, such as housing, food insecurity, education.

Advances in PrEP Delivery Models to Improve PrEP Adherence and Persistence

The adherence strategies in Table 3 have been adapted in various real-world community programs. Below are examples of emerging models of PrEP care that use these strategies to optimize adherence.

PREP THROUGH PHARMACIES

Kelly-Ross Pharmacy in Seattle, WA offered a PrEP program in a community pharmacy called “One-Step PrEP”. A protocol was developed with an HIV specialist medical director who was approved by the state’s pharmacy quality assurance commission.

Pharmacists were trained for PrEP care and recruited patients through local CBOs and health department. At baseline, patients received point-of-care and laboratory testing in a private space and an on-site 30-day prescription of TDF/FTC.

Staff provided insurance navigation activities. Patients enrolled in the pharmacy’s refill program with text or phone reminders, with follow-up visits every three months.

From 2015 through 2018, 714 patients were evaluated and 97% started PrEP, while staying for a mean of 241 days. Among those who received PrEP, 50% remained in care at the end of three years, 18% transferred care to a PCP, 21% were lost to follow-up, 6% stopped due to perceived lower risk, and 5% moved.⁷²

EXPRESS CLINIC VISITS

The sexual health clinic in London, 56 Dean Street, used their existing express clinic service model for STI care to expand their PrEP care services. The “PrEPxpress” service used nurses to lead initial PrEP visits, allowed patients to drop in every 3 months for visits, and conducted follow-up monitoring with questionnaires on a touch-screen computer. STI testing was done through self-swabbing, and blood tests were completed by clinic staff.

Adherence support was provided by health advisors, and physicians were available for complex medical history, potential drug interactions, or adverse events outside the scope of the protocol. In just four months, PrEP services expanded to 1700 patients that were enrolled in the implementation study, PrEP Impact.⁷³

SAME-DAY PREP STARTS

The Denver Metro Health STD Clinic conducted a feasibility study of a same-day start of PrEP for interested patients. Participants completed point-of-care HIV testing, and results were reviewed at this visit. Other lab tests were also drawn on site.

A clinic pharmacist dispensed a 30-day supply of free PrEP and provided adherence counseling. Participants also met with a navigator to help enroll in insurance or assistance programs and to set up a 1-month follow-up visit at a local clinic.

A total of 131 people were screened and 100 enrolled: 98% were MSM, median age was 28 years, 39% identified as Hispanic, and 8% identified as Black. Only 62% had insurance and 26% had a primary health provider. No one had abnormal baseline laboratory results. Seventy-eight percent attended at least one follow-up visit, and 57% attended at least two appointments within 180 days of enrollment.⁷⁴

TELEHEALTH PREP VISITS

In 2017, the Iowa Department of Public Health, University of Iowa, and community representatives developed the Iowa TelePrEP program. This telehealth model was designed to overcome access barriers in rural areas, including long distances to PrEP providers and stigma.

People were identified through STI clinics or referred themselves from advertising. Initial and follow-up video visits were conducted by TelePrEP pharmacists through collaborative agreements. Clients completed testing at local laboratories and were linked to STI treatment through local partner services staff. In the first year, 103 clients were referred; 81% completed a first tele-visit; 79% started PrEP; and 87% were retained in the program at six months.⁷⁵

PrEP is a Preventive Service

In June, 2019, the US Preventive Services Task Force (USPSTF) gave PrEP an “A” grade recommendation. The Affordable Care Act (ACA) requires commercial health plans and Medicaid expansion programs to cover select preventive services, including any service with a Grade A or B from the USPSTF—without cost-sharing, which means that these services must be covered before any deductible and without coinsurance or a copayment. With this Grade A recommendation, most commercial health plans and Medicaid expansion programs must cover PrEP without cost sharing as of January 1, 2021. [This brief developed by NASTAD](#) includes more information about the USPSTF Grade A recommendations and PrEP coverage considerations.⁷⁶



Health plan and PrEP navigators can follow steps outlined in this infographic to verify PrEP is being covered as a preventive service.⁷⁷ More information on reimbursement for PrEP adherence services can be found in Appendix A.

Program Adherence Support Continuous Quality Improvement

Providers can use each question below to assess their programs’ approach to optimize PrEP adherence for the populations they serve.

What is the standard of care to support adherence?

- ▶ Comprehensive education throughout PrEP use
- ▶ Navigation services that support access to insurance and health care
- ▶ Referrals for behavioral health and other support services
- ▶ Monitoring self-reported adherence
- ▶ Monitoring safe stops and re-starts

How do we support people who struggle with adherence?

- ▶ Specific strategies and tools such as enhanced counseling, navigation services, mHealth, panel management
- ▶ Adapt evidence based interventions

Are interventions working?

Are they valued by PrEP users?

- ▶ Monitoring adherence and retention in PrEP programs
- ▶ Patient surveys, advisory group feedback

See the next section of this toolkit for more on specific strategies to enhance PrEP adherence support.

ENHANCING THE BASIC PREP ADHERENCE SUPPORT PACKAGE

For people living with HIV who take treatment, monitoring viral load offers an objective way to determine who may need more adherence support. However, at this time—outside of clinical studies—we lack a routine, objective biomarker of PrEP exposure (such as drug levels in blood, urine, or hair) to predict who could benefit from enhanced PrEP adherence support.

PrEP programs can track gaps in PrEP care or delays in refills to identify clients who may be experiencing adherence challenges. Further, frequent check-ins with clients about their experiences and desire to stay on PrEP can help programs find people who may benefit from additional support. When choosing an approach, it is recommended that PrEP providers carefully consider population-specific needs, such as youth.

PREP ADHERENCE INTERVENTIONS

Interventions developed in the context of PrEP delivery are presented in Table 4, pages 20–21.

Several U.S. demonstration projects and clinical studies have blended conversations about PrEP adherence within larger discussions of how PrEP fits within promoting overall sexual health. This approach engages PrEP users in problem solving, planning, and prioritizing their sexual health. Discussions around using condoms and/or other prevention methods may also be relevant. While some strategies continue to be studied and developed, PrEP programs may want to incorporate them into planning for future adherence interventions.

Providing non-judgmental care and having open conversations about sexual decision making may enhance connections with the care team, which may increase trust and persistence in a PrEP program. Future studies are needed to explore this assertion.



There is growing recognition that PrEP services engage individuals in systems of preventive care and links to needed mental⁷⁸ and medical health services⁷⁹. Failing to evaluate these needs and/or offer support may represent missed opportunities and may ultimately lead to stopping PrEP.

ENHANCING THE BASIC PREP ADHERENCE SUPPORT PACKAGE

Discussion-Based Interventions

Supporting PrEP through discussion or counseling-based approaches can engage PrEP users on all levels of the socio-ecological context of PrEP use. Increasingly, the impact of PrEP use on sexual health, wellness, and well-being is being recognized: using PrEP decreases anxiety and fear, and it fosters closer relationships for some PrEP users.^{80,81}

PrEP providers can discuss with patients the social, psychological, structural, and cultural factors that may influence their PrEP adherence and persistence. Several discussion-based approaches have been proposed. Whether used as the basic package or together with e-Health or other strategies as an enhanced package, having positive, affirming discussions with PrEP patients is recommended.

NSC and iNSC

Next-step counseling (NSC) and integrated next-step counseling (iNSC) were developed for iPrEx and iPrEx OLE^{43,44,82}. iNSC involves brief discussions at each clinic visit focused on exploring experiences with sexual health protection, identi-

fying relevant needs, and problem-solving strategies to strengthen sexual health. The basic idea is to use motivational interviewing to help people take small steps towards achieving sexual health and by prioritizing PrEP adherence.

The approach is feasible and acceptable, but it has not been rigorously evaluated for efficacy. It likely will not be evaluated given that iNSC has been adopted by several demonstration projects and roll-out programs as part of their “basic package”. Other approaches are available and have observational support^{83,21} with the common features being process-oriented, sex-positive discussions.

C4 (client-centered coordinated care)

There is a significant need for using culturally tailored HIV prevention and PrEP services for Black MSM in the U.S.⁸⁴ The HPTN 073 trial implemented a theoretically principled, culturally informed, and client-centered model to promote PrEP uptake and adherence among black MSM. It also incorporated navigation to employment, education, and housing services.^{85,86} We anticipate that C4 will be adapted to support PrEP scale-up in this highly affected community.



Importantly, most discussion-based approaches were first implemented in a context of providing PrEP in a client-centered, gender-affirming, non-judgmental environment. Creating care environments that are welcoming and sex-positive enhance PrEP services.

ENHANCING THE BASIC PREP ADHERENCE SUPPORT PACKAGE

PrEP-Steps

Structured discussions over several sessions that cover specific content and exercises may also help in working with those who struggle with optimal adherence. An adaptation of Life-Steps, an ART adherence intervention in Partners PrEP⁸⁷, has been retooled as ‘PrEP-Steps’ and is being implemented in the U.S.⁴⁹

Targeted-iNSC

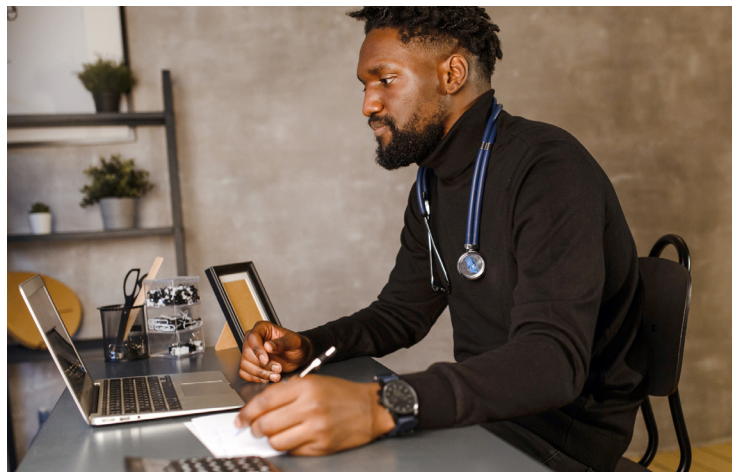
An approach called targeted-iNSC⁴⁸ has been developed as a companion piece to providing drug concentration test results to patients. Here, PrEP users problem solve around improving adherence after being presented with data such as drug levels that show low rates of adherence.

mHEALTH INTERVENTIONS

Various adherence support strategies for PrEP have been evaluated that use mobile health, or mHealth. Several have been developed for engaging adolescents and youth. Text messaging interventions are promising, highly scalable interventions to support PrEP adherence and retention in PrEP care.

PrEPmate

PrEPmate is a CDC-supported evidence-based intervention (EBI) that uses bidirectional text messaging, daily pill taking reminders, informational videos, and an online forum. The intervention was piloted (iText)⁸⁸ and then evaluated for efficacy in a randomized controlled trial (the EPIC study)³⁸ among 121 young MSM and transgender women in Chicago. Compared to controls, those who received PrEPmate had higher PrEP adherence and retention in PrEP care. PrEPmate has been adapted for use in a PrEP demonstration project enrolling transgender persons in Northern California.



ENHANCING THE BASIC PREP ADHERENCE SUPPORT PACKAGE

iTAB (Individualized Texting for Adherence Building)

iTAB used daily texts with personalized reminders for PrEP dosing.⁸⁸ Among 398 MSM and transgender women, the intervention did not significantly impact the generally high adherence across groups. (87% at week 12 and 83% at week 48 had concentrations suggesting 4 or more doses per week.) However, very high adherence (equal to 7 doses per week) was more common in the intervention arm (34% versus 25%). This approach is now being used to support adherence among cisgender women in a PrEP demonstration project.



Drug Level Feedback

PrEP programs have been interested in using objective measures of drug detection (yes/no) or the level of drug in dried blood spots, hair, plasma, or urine. While promising, this approach has been largely limited to clinical research projects in the US as a way to provide feedback to clients about PrEP use^{63,89-92} as a strategy to increase adherence support.⁶³ However, this approach has not yet been rigorously evaluated as an intervention tool.

In one large study of young women in South Africa, incentives tied to drug levels did not improve adherence. About half the women in both the incentives and control groups had high adherence per drug levels.⁹³ As drug level tests become more affordable, using them to guide adherence support may become more common.

Panel Management

Panel management focuses on a clinic's patient base by coordinating preventive care strategies for groups or "panels" of patients. Staff routinely

monitor and discuss care data in efforts to identify possible service issues, such as gaps in care, that lead to enhancing outcomes.

Panel management is a type of patient care coordination that has been used at different steps of the PrEP continuum. For example, the San Francisco Department of Public Health used a web-based tool called PrEP-Rx in primary care clinics. The program used HIV risk assessments completed by patients, automated reminders to clinicians to conduct follow-up procedures, and a timeline for clinicians to see how long a patient was on PrEP.⁹¹ An evaluation showed the program helped with efficiency and capacity in prescribing and managing PrEP.⁹⁴

Panel management efforts that include clinical and non-clinical staff such as PrEP coordinators and navigators can support PrEP users throughout their journeys. Many programs already collect utilization data that predict subsequent loss to care, such as missed visits.⁹⁵ Routine tracking of missed visit data can alert PrEP care staff about clients who may require more adherence and retention support.

TABLE 4: Select U.S.-based PrEP Adherence Interventions

INTERVENTION	DESCRIPTION
Integrated and Targeted Next Step Counseling (iNCS⁶², t-iNCS⁶³)	<i>Brief discussion at each prescribing visit</i> - Developed originally in iPrEx OLE - Focused on sexual health promotion at each visit - Several studies are using targeted versions of iNCS to locate non-adherence based on drug concentrations
PrEP-Steps⁴⁹	<i>Five-session, semi-structured intervention</i> - Developed in Partners PrEP - Series of up to five 30–50-minute sessions with a counselor focused on improving adherence and sexual health in response to non-adherence event/criteria
PrEP Demo Patient Centered Support²¹	<i>Brief discussion at each prescribing visit</i> - Developed as part of standard of PrEP care for men and transgender women who have sex with men - Delivered by trained counselors
C4^{85,86}	<i>Theory-based navigation and support for linkage to wrap-around resources</i> - Developed by and for Black MSM (BMSM) in the US as part of HPTN 073 - Comprehensive care visits offered to those thinking about or taking PrEP to optimize linkage to services for unmet needs from peer (from BMSM community) counselors
SPARK Counseling⁸³	<i>Brief discussion at each prescribing PrEP visit</i> - Developed as part of an RCT looking at the impact of discussions on adherence specifically or sexual well-being more broadly - Peer counselors implemented sessions
iText, PrEPmate^{88,38}	<i>Weekly text message outreach with follow-up for those requesting it in response to text</i> Developed for a pilot nested within iPrEx OLE at 2 U.S. sites that used text-based (SMS or email), weekly outreach with follow-up by phone (as needed or requested) by trained counselors who also provided support face-to-face during PrEP visits. An RCT in young MSM and transgender women in Chicago showed improved adherence and retention in PrEP care compared to controls
iTAB⁹⁶	<i>Daily text reminders with tailored messages</i> Developed as part of a demonstration project that examined effects of daily reminder, customized messages received via SMS text among MSM

continued

TABLE 4: Select U.S.-based PrEP Adherence Interventions, *continued*

INTERVENTION	DESCRIPTION
Drug monitoring with feedback⁶²	<i>Dried blood spot (DBS), plasma, urine, hair</i> - iPrEx OLE and other studies shared drug detection and drug level information with participants at their next PrEP visits or by contacting them directly with test results - Used as opportunity to explore experiences, and to problem-solve challenges.
Drug monitoring to step-up⁶³	<i>Use of monitoring to escalate and direct intensified adherence approach</i> Demonstration projects used drug monitoring data (drug detection or drug levels) to determine who might benefit from intensified adherence support
mSMART (smartphone monitored incentivized adherence⁹⁷)	<i>Use of smartphone video with incentives for dose monitoring</i> - Pilot project provided support for feasibility and acceptability - Video DOT may be possible in clinical practice but requires resources - Incentives included \$2/timely dose for a max of \$56 USD over 4 weeks - App-based features sought to improve information, motivation, and behavioral skills

ADAPTING EVIDENCE BASED INTERVENTION PACKAGES

While individualized adherence plans may draw from one or more strategies, several comprehensive, structured interventions could be adapted to PrEP. These interventions combine several evidence-based strategies into a single program. Evidence suggests that interventions using several strategies may offer unique advantages.⁹⁸

The [CDC offers various interventions](#) to health care providers through an e-learning platform, including Partnership for Health—Medication Adherence. Additional interventions previously developed for ART adherence may be considered for adaptation to PrEP programs. [These interventions](#) are delivered in different ways and rely on various staff to provide support.



For example, clinicians or peers can facilitate discussions or provide support over the phone and can work closely with the PrEP user or couples. Uniquely, these interventions improve adherence to ART, and each is based on an underlying theory for what drives adherence behavior.

CONCLUSIONS

As PrEP continues to be rolled out, there is clear need for sustainable, culturally relevant strategies to support adherence and persistence in diverse communities and programs. Although newer approaches continue emerging in the scientific literature, other strategies can be used to bridge research gaps. The strategies outlined in this toolkit draw from providing PrEP education, sexual health counseling, and adherence support during research trials, demonstration projects, and clinical care.

PrEP programs should consider promoting adherence by providing a basic support package as detailed on pp 11–15. Core elements include educating clients about PrEP, identifying a personalized pill taking regimen, and offering regular check-ins with clients about key contextual issues timed with quarterly HIV/STI screening. Gaps in insurance coverage, unmet behavioral health needs, and challenges with social determinants of health, like housing insecurity, can negatively impact PrEP adherence and persistence. PrEP programs should be prepared to help clients navigate these issues, including offering referrals to community resources.

Monitoring adherence is also critical, and programs should anticipate that a client's desire to use PrEP will change over time. Stopping or restarting PrEP can be influenced by partner status, perceived risk, and/or other interpersonal or structural factors.

Programs can also tailor strategies and tools through an enhanced package of support for those who face adherence challenges. In this regard, this publication has highlighted both



adopting proven PrEP adherence interventions such as mobile health strategies (pp 18–19) and adapting interventions originally designed to support ART adherence (pp 26–27).

Programs should carefully consider provider and client burden when considering these enhanced strategies, particularly when considering more time-intensive counseling approaches or mHealth interventions. Client and program needs are also likely change over time, as new PrEP technologies and delivery systems become available.

Finally, PrEP projects that enrolled transgender people, black MSM, youth, and heterosexual cisgender women will continue to inform how best to deliver culturally responsive services for these populations. Voices of communities disproportionately affected by HIV should be guiding the development of new ways to optimize PrEP adherence and persistence over time. PrEP providers from urban and rural settings should also inform how to scale feasible programs that support the clients they serve.

For more information about PrEP and other helpful resources, please refer to the [CDC website](#).

APPENDIX A: Reimbursements for Adherence Counseling

▶▶ Adherence Counseling Coverage Considerations

Health plans must cover PrEP ancillary services in addition to the medication without cost sharing. These services include: HIV testing, hepatitis B and C testing, evaluation of kidney function (creatinine and creatine clearance), pregnancy testing, STI screening and counseling, and adherence counseling. Persons taking PrEP must be offered regular counseling for assessment of behavior and adherence consistent with CDC guidelines to ensure that PrEP is used as prescribed and to maxi-

mize PrEP's effectiveness. Components of adherence support also include patient education, reminder systems for taking medication, and developing a plan to address medication adverse effects.

Importantly, these services must be covered at the intervals recommended by CDC guidelines, and plans cannot use medical management techniques to cover these services at other intervals.⁷⁶

▶▶ Billing and Coding Considerations for Adherence Counseling

PrEP adherence counseling, both basic and enhanced counseling, performed in a physician's office by a licensed provider may be billed with the same codes as PrEP initiation.⁹⁹

With appropriate documentation, a physician, advanced practice registered nurse (APRN) or physician assistant (PA) could provide time-based counseling for a patient using office visit codes or preventive medicine counseling codes.

Adding modifier 33 ensures that commercial plans will pay the claim without a patient due amount for patients.

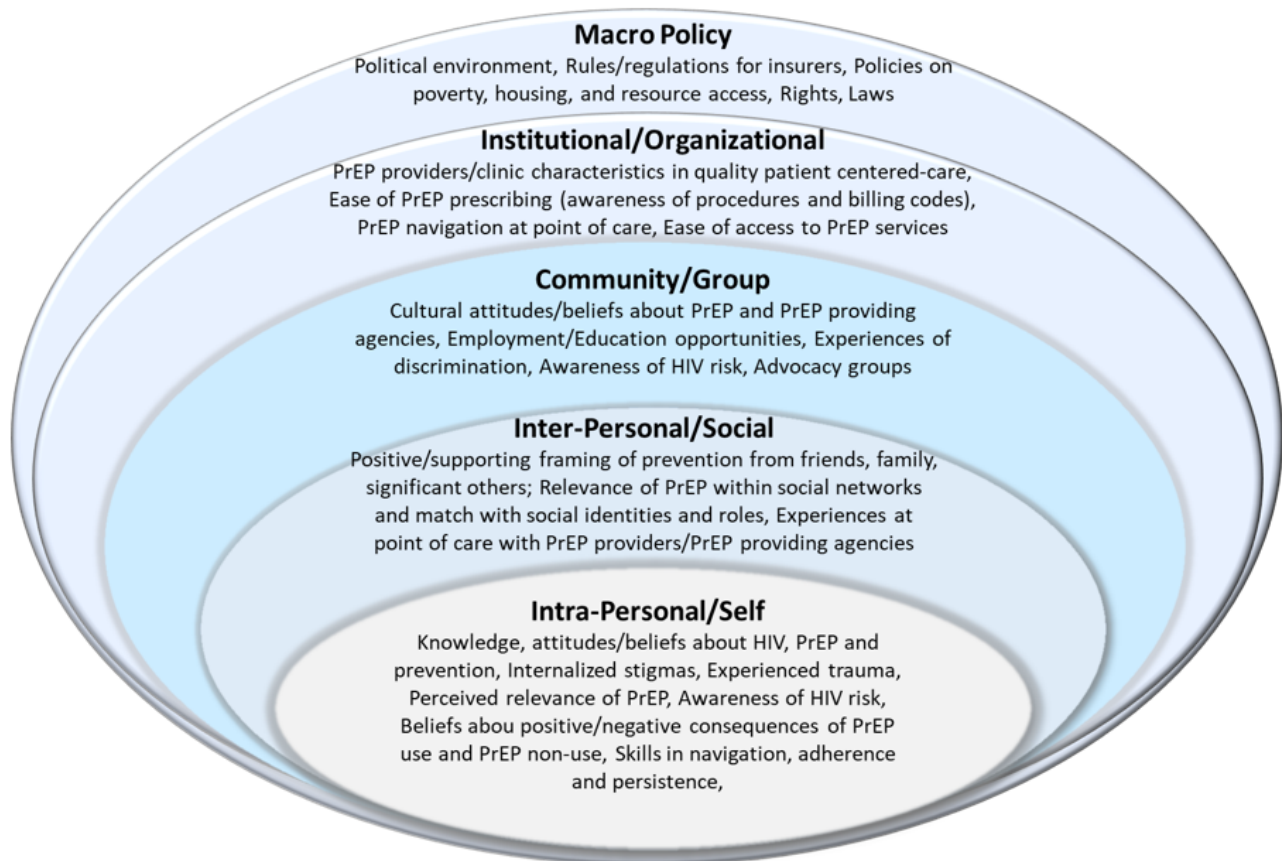
When the primary purpose of the service is

the delivery of an evidence-based service in accordance with a US Preventive Services Task Force A or B rating in effect and other preventive services identified in preventive services mandates (legislative or regulatory), the service may be identified by adding 33 to the procedure. For separately reported services specifically identified as preventive, the modifier should not be used.¹⁰⁰

PrEP initiation codes and additional information on billing and coding for PrEP can be accessed in NASTAD's Billing Coding Guide for HIV Prevention and Illinois Public Health Association's Billing Manual for HIV Testing and Related Services.

APPENDIX B: Socioecological Model

FIGURE 4: Example of Socioecological Framing of PrEP Uptake and Adherence (adapted from ^{46,64,101})

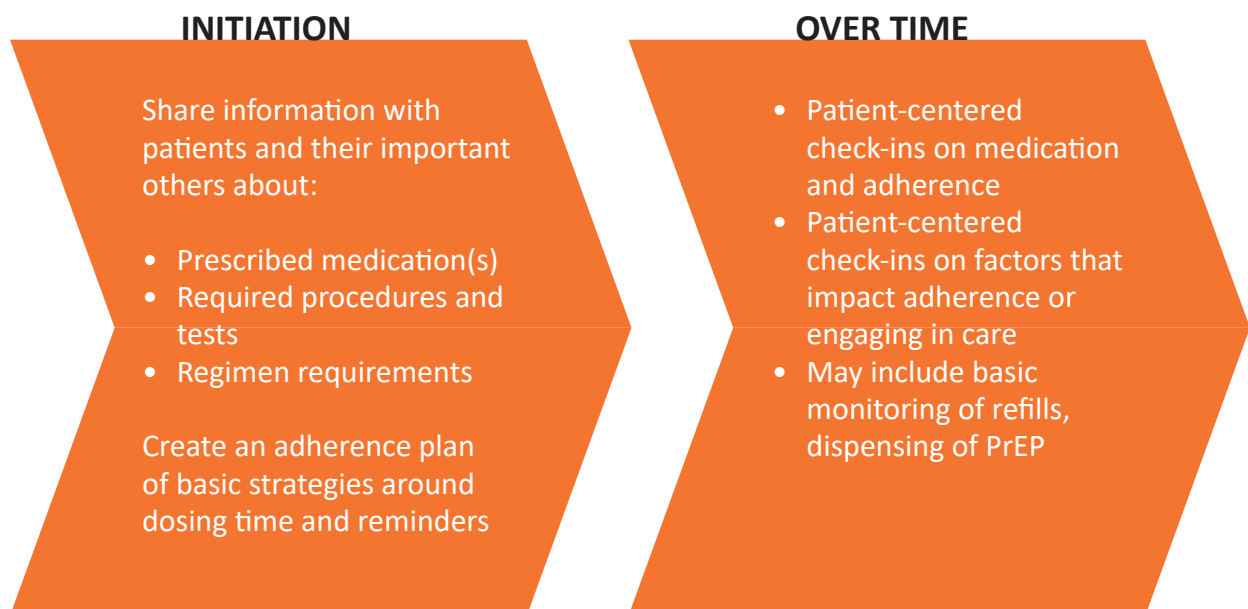


APPENDIX C: Medication Management

Helping PrEP users develop an adherence plan is a critical part of medication management (see Figure 5). This requires asking about adherence in a non-judgmental manner at each visit. This also creates opportunities to consider more tailored interventions when needed.

Given that “forgetting” is the most common reason why people with HIV report missing doses of their medicines,^{102,103} providers can use strategies to reduce forgetting (see Table 2). Since changes in insurance are common while people take PrEP, clinic staff can advise PrEP users what they can do in these situations and reassure them that various programs can cover the costs of PrEP care.

FIGURE 5: Features of Medication Management¹⁰⁴



APPENDIX D: Adapting ART Adherence Interventions to PrEP

Project HEART: Helping Enhance Adherence to Antiretroviral Therapy ¹⁰⁵		
INTERVENTION	DESCRIPTION	IMPLICATIONS
Social support/problem-solving, individual/dyadic intervention delivered before and in first 2 months after patient starts ART. A support partner chosen by the patient must attend at least 2 of the first 4 sessions. Includes activities to identify and address barriers, which is used to develop an individualized adherence plan (IAP) for the patient.	Health educator, medical provider, case manager, social worker in Community Health Centers (CHCs), community-based organizations (CBOs), or Care clinics who deliver five 1-1/2 to 2-hour sessions with five phone calls over six months.	IAPs apply to PrEP, and could be adapted to include planning for the duration of PrEP use and safe re-starts. Dyadic focus can readily apply to couples using PrEP. Problem-solving around adherence challenges is an essential component of most effective adherence approaches. Calls between clinical care visits may enhance engagement in PrEP care.

Partnership for Health—Medication Adherence ¹⁰⁶		
INTERVENTION	DESCRIPTION	IMPLICATIONS
Brief (3–5 minute), clinic-based, provider-directed intervention emphasizing the patient-provider relationship to promote healthy behaviors. Includes patient adherence messages during medical visits and the use of posters and brochures that convey the partnership theme and ART adherence messages.	Medical provider in CHCs and Care clinics who delivers 3- to 5-minute sessions at each clinical care visit.	PrEP use may be optimized by making adherence a common discussion point at each care visit. For HIV-positive people in care with sero-different partners on PrEP, adherence also can be highlighted. An emphasis on overall client health and wellness would fit well with providing comprehensive support and attending to unmet needs. No additional staff are needed.

continued

APPENDIX D: Adapting ART Adherence Interventions to PrEP, *continued*

Peer Support ¹⁰⁷		
INTERVENTION	DESCRIPTION	IMPLICATIONS
Individual- and group-level intervention, where HIV-positive individuals—currently adherent to ART—serve as peers, who provide medication-related social support through group meetings and weekly telephone calls to patients on ART. Trained peers in CHCs, CBOs,	Care clinics delivering six, twice-a-month, 1-hour group meetings and weekly phone calls over 3 months.	Programs using PrEP ‘ambassadors’ or ‘experts’ as peers or near-peers has had high appeal in community mobilization efforts around PrEP. Social support may be particularly meaningful for those using PrEP who feel stigmatized and isolated. Events and calls between clinical care visits may enhance engagement in PrEP care. Relatively time-intensive.

SMART Couples: Sharing Medical Adherence Responsibilities Together ¹⁰⁸		
INTERVENTION	DESCRIPTION	IMPLICATIONS
A couples-level intervention provided to sero-different couples that addresses adherence to ART and safe sex behaviors within the couple, fostering active support of both people.	Health educator, medical provider, social worker in CHCs, CBOs, and Care clinics delivering four, 45–60-minute sessions over 5 weeks.	Couples using PrEP together, or using PrEP and ART, could engage in this focused intervention. May be particularly helpful to prepare couples for adherence during the first month of PrEP and ART.

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GLOSSARY

Adherence	The extent to which an individual is able to follow dosing regimen of a prescribed medication
ART	Antiretroviral therapy
CDC	Centers for Disease Control and Prevention
Cis-gender	Term for individuals whose gender identity matches the sex assigned to them at birth
Creatinine	A serum blood test commonly used to monitor kidney function
DBS	Dried blood spots (DBS) refer to a biological sampling method where blood samples from patients are blotted and dried on filter paper and analyzed. This method has been used extensively in PrEP research to monitor for PrEP adherence.
Efficacy	The degree to which an intervention accomplishes the desired or projected outcomes (i.e., whether it works)
FTC/TDF	A combination pill with emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF).
FTC/TAF	A combination pill with emtricitabine (FTC) and tenofovir alafenamide (TAF).
Gender-affirming services	An array of services (clinical, social, etc.) that help support one's gender identity and wellness.
HPTN	HIV Prevention Trials Network
IMB	Information motivation behavioral skills model of adherence—a framework that suggests that adherence is a function of being well informed, motivated and having skills and confidence.
iNSC	Integrated next-step counseling
Intentional non-adherence	An intentional decision not to dose for a number of reasons including fear of stigma or avoidance of real or perceived side-effects
mHealth	mobile health
MSM	Men who have sex with men
NIH	National Institutes of Health
Non-intentional non-adherence	Inadvertently not taking a medication due to several reasons including forgetting to take a dose or disruptions in routine
NSC	Next-step counseling
PEP	Post-exposure prophylaxis
Persistence	The duration of time that an individual is on a medication; from initiation to discontinuation
PLWHIV	People living with HIV/AIDS
PrEP	Pre-exposure prophylaxis
PWID	Person(s) who inject drugs
RCT	The randomized controlled trial (RCT) is a clinical research study design that randomly assigns study participants to receive an active intervention compared to a control condition. It provides the highest level of evidence about the safety and efficacy of a new treatment or prevention strategy
Sero-different Partnership	Referring to a partnership/relationship where one partner is sero-positive (HIV+) and the other is sero-negative (HIV-)
Socio-ecological Model	A framework that places individual health behavior within a larger system that also includes relationships, community, systems of care, and policies.
STI	Sexually transmitted infection

RESOURCES FOR BASIC PREP EDUCATION DISCUSSIONS

RESOURCE	LINK
AIDSinfo website with basic information on PrEP and fact sheets that can be printed	https://hivinfo.nih.gov/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep <i>see also</i> http://www.hiv.va.gov/pdf/prep-patient-overview.pdf
CDC provides resources for consumers and providers, including English and Spanish user-friendly documents and infographics that can be printed	https://www.cdc.gov/hiv/risk/prep/index.html https://www.cdc.gov/actagainstaids/campaigns/starttalking/materials/prepresources.html
PrEP Facts provides resources tailored to specific groups accessing PrEP that can serve as a client resource (best viewed from website but can also be downloaded)	http://prepfacts.org https://www.who.int/tools/prep-implementation-tool
AVAC and AVERT provide basic fact sheets that can be printed	http://www.avac.org/prep/basics https://www.avert.org/professionals/hiv-programming/prevention/pre-exposure-prophylaxis
HIV.gov provides an overview of PrEP education with graphics that can also be printed	https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis
Overview of PrEP basics and specific questions that clients may have	https://www.unaids.org/sites/default/files/media_asset/UNAIDS_JC2765_en.pdf
Information about women and PrEP	https://www.thewellproject.org/hiv-information/prep-women https://apps.who.int/iris/bitstream/handle/10665/255866/WHO-HIV-2017.09-eng.pdf
Questions providers can use to discuss PrEP with clients	https://aidsunited.org/prep-kit https://www.cdc.gov/hiv/pdf/basics/prep/cdc-hiv-stsh-prep-brochure-english.pdf
Videos	http://www.whatisprep.org/ https://www.youtube.com/watch?v=-Xx92whZS0o https://www.youtube.com/watch?v=TR8-3uAuZGo
Other (interactive webpages focused on PrEP and experiences with use of PrEP geared towards consumers)	http://www.prepwatch.org/ https://aidsvu.org/services/#/prep
Other tools for prescribers	https://www.ashm.org.au/products/product/3000100092 https://www.cdc.gov/hiv/clinicians/prevention/index.html

Optimizing PrEP Adherence: A Toolkit for PrEP Programs in the United States



getSFcba.org/resources/prep-adherence-toolkit
get.sfcba@SFDPH.org

San Francisco Department of Public Health
US Centers for Disease Control and Prevention (CDC)