

PrEP and nPEP:

The Basics for Community-Based Organizations

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1. Introduction

Antiretroviral medications are changing not only the way that we do HIV treatment, but also the way that we do HIV prevention. Pre-exposure prophylaxis (PrEP) is the most recent biomedical addition to the HIV prevention toolbox. Currently, the only FDA-approved PrEP regimen is daily oral use of Truvada, the brand name for the combination of tenofovir disoproxil fumarate (TDF; brand name Viread) and emtricitabine (FTC; brand name Emtriva). There are other formulations of tenofovir in use for HIV treatment but only tenofovir disoproxil fumarate is used in PrEP. Many providers are wondering, “Is PrEP right for my clients?” “How could it change the epidemic in my community?” “How do I talk about it?” Although non-medical providers will not be making medical decisions for clients, it is important that we as community-based organization (CBO) providers have the information we need to discuss this exciting new prevention opportunity with our clients in a well-informed manner. This report answers these questions with a focus on the role that community-based organizations play in pre-exposure prophylaxis uptake and PrEP adherence, and on clarifying some of the key differences between PrEP and non-occupational post-exposure prophylaxis (nPEP), two antiretroviral weapons in the fight for “an AIDS-free generation.”¹

2. Using Antiretroviral Medications for Prevention

PrEP is the newest member in a group of strategies that use HIV medications for prevention.²

- Starting in 1996, when the first HIV highly active antiretroviral therapies (HAART) were released, these powerful new combinations of drugs expanded life expectancy in people living with HIV from months and years to decades.³
- Also in the mid-1990s, HIV treatments began to be used in pregnant, HIV-positive women to prevent HIV transmission to their unborn children, and that has resulted in a more than 90% decrease in mother-to-child transmission in the United States.^{3,4} Today, an HIV-positive woman on treatment has less than a 1% chance of transmitting HIV to her baby.⁴
- In the 2000s, researchers showed that antiretroviral treatment in HIV-positive people could help keep their HIV-negative partners uninfected. The 2011 HIV Prevention Trials Network (HPTN) 052 study found that HIV treatment in HIV-positive people reduced transmission to HIV-negative partners by 96%.⁵
- Post-exposure prophylaxis (PEP) has been in use since the 1990s. It has been used most often with health care providers who were exposed to HIV “occupationally,” for example, through an accidental needlestick while caring for an HIV-infected patient. However, evidence for its effectiveness has always been mixed.⁶ In 2005, the CDC released guidance recommending that anyone seeking care within 72 hours after a significant non-occupational exposure to potentially HIV-infected body fluids be given nPEP daily for four weeks (28 days). An nPEP regimen usually includes two or three HIV antiretroviral drugs, almost always including two from the class called non-nucleoside reverse transcriptase inhibitors.

- In 2010, the iPrEX study confirmed that HIV antiretroviral medication used before rather than after exposure, can reduce the risk of infection by up to 92%.⁷ PrEP, like PEP, is a way of using antiretroviral drugs to keep HIV-negative people HIV-negative. It is highly effective in preventing HIV infection when it is used properly. Unlike nPEP, PrEP is started before an exposure and continued during the exposure. Like nPEP, it continues after an exposure to HIV occurs in order to prevent infection.⁸

3. Summary of the Research on PrEP and nPEP

It's useful to understand the research data that supports nPEP and PrEP. The following research summary provides an overview of the evidence for PrEP, which is very strong, and for nPEP, which is more limited. (For more information on these and other studies, see Appendix C: PrEP Research Studies.) If you want to keep up on the latest information about PrEP clinical trials, some good resources are the [HIV Prevention Trials Network](#) and AVAC's PrEP Watch page called [PrEP Pipeline](#).⁹

3a. PrEP Research Summary

The strongest evidence for the safety and effectiveness of daily oral PrEP in preventing HIV infection comes from several large clinical trials conducted with participants from the major HIV transmission risk groups. In all the studies, all the participants received HIV risk reduction counseling and effective prevention tools. Those at sexual risk received free condoms, and free sexually transmitted disease (STD) testing and treatment; those at injection risk received access to drug treatment and clean injection equipment. In all of these studies, PrEP was found to be safe for participants in three populations: men who have sex with men, heterosexually active women and men, and people who inject drugs.

Men Who Have Sex with Men

Four key studies of men who have sex with men (MSM) support the strong evidence for PrEP efficacy: iPrEx, PROUD, a National Institutes of Health (NIH) demonstration study, and a Kaiser San Francisco study.

The iPrEx trial was conducted with almost 2,500 HIV-negative MSM in six countries on three continents. Half of the study participants received supplies of a PrEP pill (Truvada) and the other half received a placebo (a pill containing no medication). The researchers found that there were 44% fewer HIV infections among men randomly assigned to take daily Truvada compared to men assigned to take a placebo. However, not all the men assigned to take Truvada took it regularly as prescribed. The men who had measurable tenofovir disoproxil fumarate (TDF), a component of Truvada, in their blood had 92% fewer infections than men with no measurable TDF.⁷

In the follow-on study, called the open-label extension (or OLE) study, all men previously assigned to Truvada or placebo were offered daily Truvada for prevention. **iPrEx OLE** researchers continued to find a strong relationship among the number of PrEP pills a participant took (up to the maximum dosage of one pill per day), levels of drug in the blood, and prevention efficacy: taking fewer than two tablets weekly led to only a 44% reduction in HIV risk, while two to three tablets weekly led to

an 84% reduction, four to six tablets weekly led to up to 100% reduction, and seven tablets weekly led to a 100% reduction.¹⁰

In the **PROUD study**, researchers recruited more than 500 MSM at British sexual health clinics and randomized them into two groups, offering daily oral PrEP with Truvada to one group starting immediately and to the other starting after one year. Researchers stopped the study early after finding that the men who had started PrEP had 86% fewer HIV infections than those who were placed on the wait list, at which point they offered all wait-list participants the option of starting PrEP.¹¹

Following FDA approval of Truvada use for PrEP, NIH funded the **U.S. PrEP Demonstration Project** in three U.S. cities: San Francisco, Miami, and Washington, D.C. Researchers provided PrEP to more than 550 MSM who reported HIV risk behaviors. Two seroconversions occurred during the study. Both occurred in men whose blood level of TDF indicated that they had taken fewer than two doses per week. No HIV infections occurred in men with protective levels of TDF, that is, levels associated with at least four doses per week.¹²

The San-Francisco-based **Kaiser/Volk** study reviewed clinical data of more than 650 MSM who were part of the large Kaiser health care system. No HIV infections occurred among these men during 388 person-years of PrEP use.¹³ A person year is a measurement combining the number of people and their amount of time they participated in a study. Because it was not a research study, clinicians did not measure drug levels of individual patients.

Heterosexually Active Women and Men

Four key studies of heterosexually active women and men support the evidence for PrEP efficacy: Partners PrEP and Partners PrEP OLE, TDF2, VOICE, and Fem-PrEP.

The **Partners PrEP trial** in eastern Africa enrolled more than 5,700 men and women in serodiscordant (HIV mixed-status) heterosexual couples in which the partner with HIV infection did not meet immune system criteria for antiretroviral treatment. Researchers randomly assigned the HIV-negative partners to daily Truvada or placebo. Participants in the Truvada group had 75% fewer HIV seroconversions than those in the placebo group.¹⁴ There were no meaningful differences in PrEP effectiveness between men and women. Those who had measurable TDF in their blood had 90% fewer infection than those with no measurable TDF.

The **Partners PrEP OLE study** recruited serodiscordant couples and offered free antiretroviral treatment to the HIV-positive partner and free PrEP to the HIV-negative partner until the HIV-positive partner became fully virally suppressed. An early analysis at the near halfway point found that PrEP use reduced HIV infection by 96% compared to what would be expected based on the rate of infections in the original Partners PrEP trial placebo group. During the course of the study, only two new HIV infections occurred. Both participants had no measurable TDF in their blood: one was no longer with her original partner; the other had an HIV-positive partner who was not taking HIV antiretroviral treatments.

The **TDF2 trial** followed more than 1,200 heterosexually active male and female participants in Botswana. Researchers found a 62% to 78% reduction in the risk of getting HIV among participants taking PrEP as compared to the placebo group. Of the four participants in the PrEP group who

became infected, two had no measurable levels of TDF and two had levels that were far lower than others who did not become infected, suggesting that adherence was less than optimal.¹⁵

In two additional trials, PrEP adherence was too low to establish effectiveness. In the **VOICE trial**, researchers randomly assigned approximately 1,000 women from South Africa, Uganda, and Zimbabwe to each of three groups: daily oral Truvada, daily oral TDF alone, and daily oral placebo. Researchers found measurable TDF levels in only 29% of those assigned to Truvada and in only 30% of those assigned to TDF alone. Similarly, in the **Fem-PrEP trial**, researchers randomly assigned approximately 1,000 women from Kenya, South Africa, and Tanzania to either daily oral Truvada or placebo. As with VOICE, measurable TDF levels were low: just over 40% of HIV-uninfected women. Further, among women who became HIV-positive, only 21% had measurable TDF levels at the visit closest to their seroconversion.^{16,17,18} The researchers found that there were many participants who were not adherent for a variety of reasons: a doubt of the effectiveness of the medication, worries about side effects, and fear of the medication impacting fertility among them. These studies tell us that adherence can be challenging for some people, that participant education is important, and that adherence matters for PrEP to work as intended.

People Who Inject Drugs

During the **Bangkok Tenofovir Study**, researchers randomly assigned more than 2,400 people who were daily drug injectors to daily oral TDF or placebo. Participants in the TDF group were 49% less likely to contract HIV than those in the placebo group. Within the TDF group, participants who had any measurable TDF in their blood were 74% less likely than those with no measurable levels to become infected with HIV.^{19,20}

3b. nPEP Research Summary

One of the major obstacles that researchers face when studying nPEP is that they cannot conduct randomized trials. For a randomized trial of post-exposure prophylaxis to work, researchers would have to randomly assign some participants with a recent HIV exposure to receive a regime of nPEP and some to not receive it. This would obviously be unethical in addition to being logistically difficult.²¹ PEP for occupational exposures may be more effective than nPEP, in part because in an occupational setting, often a hospital, PEP is available within one to four hours of an exposure: the less time between exposure and PEP intervention, the more likely PEP will work.

In the 1997 **Case–Control Study of HIV Seroconversion in Health Care Workers After Percutaneous Exposure** for PEP, researchers found that health care workers who underwent a PEP regimen after a percutaneous (puncturing of the skin) exposure to HIV-infected blood were 81% less likely to become HIV infected than those who did not take PEP.²²

In the 2004 **Schechter MSM study**, researchers found fewer new HIV infections among MSM who took nPEP after a recent incident of transmission-related activity than among MSM who declined nPEP.²³

The New York State Department of AIDS Institute guidelines recommending nPEP are based on “existing published studies and best-practice evidence and constitute the considered opinion of a group of expert clinicians in the field of adult HIV medicine.”²⁴ And in 2016, the CDC stated that,

“Accumulated data from human clinical and observational studies, supported by data from animal studies, indicate that using antiretroviral medication initiated as soon as possible—that is, less than 72 hours after sexual, injection drug use, or other substantial non-occupational HIV exposure and continued for 28 days—might reduce the likelihood of HIV acquisition.”²⁵

4. PrEP and nPEP Medication Summaries for Non-Medical Providers

4a. PrEP Medication Summary

Dosing. As noted above, the only currently FDA-approved formulation for PrEP is Truvada. Truvada contains two drugs: tenofovir disoproxil fumarate (TDF) (300 milligrams) and emtricitabine (200 milligrams). For PrEP, the Truvada dosage is one pill per day.^{26,27}

Side Effects and Other Concerns. Most people do not have any side effects, but about 10% of people have mild ones. For most of these people, side effects go away after the first few weeks on Truvada.²⁸ The most common of the manufacturer-reported side effects of Truvada are: stomach area pain, headache, and weight loss.²⁹ Studies also noted some nausea and diarrhea.

The manufacturer also reports more serious effects, including: lactic acidosis, liver problems, bone problems (such as bone pain or weakening), and in a very small number of people, kidney problems.^{28,30} Although these effects do not happen often, armed with a patient’s history, health care providers can determine whether Truvada for PrEP is a good fit and whether some patients require careful monitoring of kidney or liver function, or bone density to make sure the medication causes no problems. So, one of the keys to success on PrEP is good communication with a well-informed medical provider. And the need for good communication continues even when a person decides to stop taking PrEP.²⁷

We don’t yet know what the long-term effects of taking Truvada for PrEP will be, because we have only a few years of experience on which to base these judgments. However, some Bangkok PrEP study participants were on TDF for five years without experiencing any health problems from the medication. It is important to remember that Truvada has been used by people living with HIV since the FDA approved it for treatment of HIV infection in 2004. The FDA approved Truvada for PrEP use in 2012. To limit the potential for negative effects of long-term use, HIV-negative people may decide to use PrEP only when they consider themselves to be at particularly high risk for HIV.

Adherence. The single most important message about Truvada for PrEP is that it is most effective at preventing HIV infection when the person takes it daily as prescribed. Some people think they can take a pill just before they expect to have sex. Others confuse PrEP with PEP and think that they can just take one pill *after* a sexual encounter. (In fact, PrEP pills are different from PEP, which requires additional medication; see below.) Still others take it inconsistently. As it stands, one of the findings that *all* the PrEP studies have had in common is that when people had no Truvada detectable in their blood, they were much more likely to get HIV than people who had detectable levels in their blood. PrEP can reduce the chances of getting HIV by more than 90% if it is taken the right way. The evidence today is that that means one pill *every day*.

It is also important to consider regular medical care before, during, and after using PrEP as part of

the process of being on a PrEP regimen. As safe and effective as PrEP can be, a medical provider must prescribe it and monitor its health effects. CBOs can play an important role not only in informing clients about PrEP and helping them maintain adherence if they choose to go on PrEP, but also helping them stay in contact with their medical providers. Some CBOs may even reach out to medical providers in their communities—to educate them about the need for PrEP prescribers, about the medical monitoring that makes PrEP usage safest, or both.

4b. nPEP Medication Summary

Dosing. According to the CDC’s 2016 guidelines, everyone who is offered nPEP should be prescribed a 28-day course of a three- or four-drug regimen. The preferred regimen for otherwise healthy adults and adolescents is tenofovir disoproxil fumarate (300 milligrams) and emtricitabine (200 milligrams) (the same drugs as in Truvada) *plus* an additional antiretroviral medication. However, different regimens are provided for children, pregnant women, and people with decreased renal function. Each of these drugs impedes a step the virus takes to enter a cell and replicate within the cell. If the patient knows the source of their exposure, the doctor may be able to identify the subtype of that person’s HIV and customize the nPEP combination that minimizes the likelihood of using a medication to which that subtype is resistant.^{25,31}

Side Effects and Other Concerns. Many people taking nPEP do experience side effects and report more side effects and of greater severity than people taking PrEP—which makes sense considering the dosage is higher and it involves three antiretrovirals instead of only two. The most commonly reported nPEP side effects are nausea, vomiting, diarrhea and other gastrointestinal complaints, fatigue, and headaches.²⁵

Adherence. Because no randomized, placebo-controlled studies have been conducted on nPEP, data on adherence and effectiveness is limited. However, the data we do have suggests that the more adherent participants were less likely to seroconvert. The message for clients is clear: Start nPEP as soon as possible within 72 hours and complete it as directed by your prescriber to maximize effectiveness.²⁵

5. Medical Care Before and During PrEP and nPEP

5a. PrEP-Related Medical Care and Testing Guidelines

HIV Testing. It is crucial that people who take PrEP are HIV-negative. The two medications in Truvada are not enough on their own, that is, without at least one other medication, to effectively treat an HIV infection. So at best, PrEP will be inadequate for HIV-positive people. But at worst, PrEP may harm a person living with HIV because the HIV that survives in their system might have the chance to become resistant to either or both of the drugs in Truvada, narrowing their treatment options later.

This could be a big problem, because Truvada is used in a lot of standard combination therapies for HIV treatment. For this reason, the [*CDC PrEP Clinical Practice Guidelines of 2014*](#) require that testing using blood should *always* be done within a week *before* a person either begins taking PrEP or restarts PrEP if they have stopped.³² The guidelines also state that people on PrEP should

be tested for HIV at least every three months. All of this means that people on PrEP should be in medical care—for their own safety.

To ensure that PrEP candidates are HIV-negative, medical providers should talk with patients to determine if they might have been recently exposed to HIV, have symptoms of a viral illness, and might be in the very earliest days of HIV infection when some HIV diagnostic tests will not be able to detect the virus. If the medical provider suspects this could be the case, they may decide to defer the decision about PrEP and offer follow-up antibody testing after another month has passed. It is even better if the provider sends a blood sample for an antigen/antibody lab test or for a viral load test, both of which could detect viral infection earlier in its course than a standard antibody test.²⁷

Kidney Function Testing. Decreased kidney function can be a safety issue for people on PrEP. Truvada may stress kidney function, which is usually measured by the kidney’s ability to remove creatinine (a bodily waste product) from the bloodstream and then get rid of in the urine. So before and during PrEP treatment, medical providers need to assess and monitor their patients’ kidney function by measuring creatinine clearance.²⁷

Hepatitis B and C Testing. People at risk for HIV are also often at risk for hepatitis B and hepatitis C, either through sex or through the sharing of injection equipment. It is safe for people with hepatitis B or hepatitis C infection to take Truvada for PrEP. The CDC guidelines state that all patients should be tested for hepatitis B before going on PrEP. If a person tests positive for hepatitis B or for active hepatitis C, they should consult their health care provider about appropriate treatment. If a person tests negative on all tests for hepatitis B, their health care provider should offer them a hepatitis B vaccination. There is no vaccine for hepatitis C.³²

Both of the drugs in Truvada help fight hepatitis B. (Only tenofovir disoproxil fumarate, however, is FDA-approved as a treatment for hepatitis B.) This means that if a person has an active infection with hepatitis B, and they go off PrEP, the infection can flare up severely when Truvada is stopped. Therefore, providers working with people living with hepatitis B who are taking PrEP should test their patients’ liver function to make sure that hepatitis B is under control before ceasing Truvada. It also means that people on Truvada who have not been vaccinated for hepatitis B may be less likely to get hepatitis B if exposed to the virus.²⁷

Other Monitoring and Information. Medical providers should assess PrEP-related drug side effects, ask patients about current HIV risk behaviors, test for STDs such as syphilis, gonorrhea, and chlamydia, and monitor for pregnancy. If patients have risk factors for osteoporosis or other bone problems, medical providers should refer them to specialists for consultation and management. The CDC guidelines also provide some information for medical providers about drug interactions with PrEP, and emphasize the importance of not using other drugs besides Truvada or tenofovir alone for PrEP, and *not* prescribing PrEP to people who are not the provider’s patients.²⁷

What About Condoms? The CDC recommends that people on PrEP still use condoms. PrEP offers “a lot of protection against HIV, but not 100%,” and PrEP does not protect against other STDs.⁵³ It is also true that many people are not currently using condoms consistently, and it may be that PrEP could hold the greatest benefit for those people.

5b. nPEP-Related Medical Care and Testing Guidelines

Health care providers should quickly evaluate a person’s potential HIV exposure to find out if it carries a substantial risk of HIV infection. They should also test patients for HIV to see if they have a pre-existing infection. If the exposure carries a substantial risk, and if the patient is HIV-negative, the health care provider should recommend that the three-drug nPEP treatment—most likely tenofovir disoproxil fumarate and emtricitabine plus an additional antiretroviral—begin less than 72 hours after the exposure. (Note that nPEP regimen’s components may vary somewhat for children, pregnant women, and people with decreased renal function.) Depending on the type of exposure, other testing may also be warranted, including testing for pregnancy, other STDs, and hepatitis B and C. When appropriate, providers should also refer patients for sexual assault counseling. It is important to note that CDC guidelines state that any patient who has taken more than one course of nPEP within the prior year should be offered PrEP as well.²⁵

Several resources can help medical providers evaluate the best candidates for nPEP, plus nPEP-related testing and monitoring considerations: the [CDC’s 2016 Guidelines on PEP](#),²⁵ [New York State Department of Health’s 2014 Guidelines](#),²⁴ the [National Institutes of Health’s 2014 Antiretroviral Therapy Guidelines](#),³⁴ and [Project Inform’s 2011 webpage on PEP](#).²⁵

6. Accessing PrEP and nPEP: Who Pays?

6a. Paying for PrEP

Fortunately, there are a variety of ways clients can pay for PrEP medications and associated health care, including Medicaid and Medicare, private or employer insurance, Medication Assistance Programs (MAPs), and, in some states, PrEP-specific Drug Assistance Programs called “PrEP DAPs.”

Medicaid pays for PrEP. The biggest challenge is that in states that did not choose to expand Medicaid,³⁵ many low-income people who would benefit from PrEP are not eligible for Medicaid because they are not disabled, pregnant, or single parents of eligible children. In addition, some Medicaid programs have difficult prior authorization processes or limit the number of drugs per month available to a beneficiary.

Medicare is a federal health insurance for those who are at least 65 years of age or who have qualifying long-term disabilities. It is sometimes delivered by private insurance plans. A Medicare rule states that six classes of drugs, including HIV drugs, must be included, or substantially included, in the Medicare formulary, but when it is delivered by private plans, coverage may vary.³⁶

Private Insurance usually pays for PrEP, but insurers may require prior authorization or co-payment fees paid by the client at each visit. For many people, a medical assistance program like one of those listed below may be able to help cover the cost of co-pays, co-insurance, or deductibles.

Even in non-Medicaid expansion states, people have increased access to private insurance through new options under the Affordable Care Act (ACA), because of the [Federal Health Insurance Marketplace](#).³⁷ Private health insurers are supposed to, and do, cover HIV-related medications. However, some insurers put HIV-related medications in the higher-cost tiers of their plans, meaning that these drugs are available to their enrollees only with higher co-pays, co-insurance, or annual deductibles.³⁸

Medication Assistance Programs and Co-Pay Programs. Gilead Sciences, the maker of Truvada, runs two MAPs: one provides medications to uninsured, low income clients for free; the other helps clients with paying their insurance company co-pay (the payment made by the patient in addition to the insurance) or co-insurance (a type of insurance in which the insured pays a share of the payment made against a claim). For information about Gilead and Patient Access Network Foundation³⁹ assistance programs, see the Fair Pricing Coalition’s fact sheet.⁴⁰ Currently, Gilead’s free PrEP Truvada program covers people who have household incomes up to five times the U.S. Federal Poverty level. For a single person, that is up to \$59,400 per year as of 2017.⁴¹ The Gilead co-pay program⁴² covers up to \$300 per month in deductible and co-insurance coverage.⁴³ To access the Gilead Medication Assistance Program,⁴⁴ call 1-855-330-5479, Monday through Friday between 9AM and 8PM EST. You can also download the application for the Gilead PrEP Medication Assistance Program from https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf and bring it to a PrEP clinical care provider to complete and submit for a patient.

PrEP DAP Programs. Some states have developed PrEP DAP programs; Washington State was the first to announce a PrEP DAP program in April 2014.⁴⁵ It requires applicants to be HIV-negative state residents and to have specified risk behaviors. For more information, see the following website: <http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP>.

New York announced a PrEP Assistance Program (PrEP-AP) in June 2014. At this time, this program does not cover Truvada itself, but it does cover the medical monitoring tests and clinical visits associated with PrEP care. Other states are considering establishing PrEP assistance programs as well.

6b. Paying for nPEP

The challenge in getting and paying for nPEP is that medication must start within 72 hours after possible HIV exposure. The medications that make up nPEP are usually covered by Medicaid, Medicare, or private health insurance.⁴⁶ Health care providers can also apply for free nPEP medicines through the medication assistance programs run by the manufacturers. Applications, which are available online, by fax, or sometimes through special phone lines, “can be handled urgently in many cases to avoid delay in getting medicine.”⁴⁷ Information for specific medications and manufacturers is available at http://www.pparx.org/en/prescription_assistance_programs/list_of_participating_programs. See also the Fair Pricing Coalition’s helpful guide to *Patient Assistance Programs and Co-Pay Programs for PEP*.⁴⁷

Crucially, state Crime Victim’s Compensation Programs, funded by the U.S. Department of Justice’s Office for Victims of Crime, may reimburse some or all nPEP medication and clinical care costs after a sexual assault. Contact information for each state is available at <http://www.ojp.usdoj.gov/ovc/map.html> or <http://www.nacvcb.org/index.asp?bid=16>.²⁵

7. PrEP-Related Psychosocial Issues

PrEP is not only a medical intervention, but also a psychological and social one. Since PrEP is a relatively new intervention, the current concerns covered here will continue to evolve over time:

Empowerment and Self-Esteem. PrEP offers women who have vaginal sex and men and women who have receptive anal sex the potential power to use an HIV prevention method without needing their partner's cooperation. Often the insertive partner in vaginal or anal sex has the final word on whether or not to wear a condom. Like other HIV prevention methods, taking PrEP requires a person to feel that their life and health are worth protecting, and medical and other service providers can emphasize this message when offering PrEP as one harm reduction option. In framing the client's role as the risk reduction decision maker, providers honor the client's strengths, including wisdom, autonomy, and individuality. Further, by offering clear information about PrEP's effectiveness and the importance of adherence, providers can help clients feel empowered to make an informed decision.

Stigma. A key problem facing many people considering or taking PrEP is stigma. Some people may have negative judgments of the sexual or injection behaviors that are associated with PrEP use. As Alex Garner, an openly HIV-positive Latino columnist, put it: "We've all experienced some form of stigma in our lives. As an HIV-positive gay Latino, I have experienced my fair share. When I seroconverted I encountered stigma for being 'stupid and slutty' enough to get HIV. Now negative men encounter stigma for being 'stupid and slutty' enough to *prevent* HIV."⁴⁸ Some have also suggested that men who are the receptive partners in anal sex are often the victims of "bottom shaming," which marginalizes them and suggests that they alone are responsible for their own HIV risk. Since receptive partners are at greatest risk for HIV, they are likely to benefit most from PrEP. So asking for PrEP may feel like a disclosure that a man is a sexually active bottom.⁴⁹ Of course, it is not only men who bottom who have had their sexuality (or other identities and behaviors) stigmatized. People of color, transgender people, women, and substance users are already marginalized, and the further stigma associated with PrEP might make many individuals feel less willing to consider this otherwise-viable HIV prevention option. To counter stigma, providers can create opportunities for community conversations about values, risk, choice, and responsibility, framing discussions in terms of overall sexual health and harm reduction.

Risk Compensation and Risk Tolerance. "Risk compensation" is the idea that as a person using a prevention tool—for example, PrEP—feels greater protection, they may compensate by increasing other behavioral risks. This idea raises a question: If people take PrEP, will they use condoms less and have unprotected sex with more people, possibly increasing their exposure to other STDs? And while it is certainly worth considering that some people who take PrEP may risk compensate, it is also important to note that in the iPrEX study, the researchers found no evidence of risk compensation among the participants.⁵⁰ The question of risk compensation should also be rooted in a broader conversation around adherence since the efficacy of PrEP is so closely tied to high rates of adherence. In addition, having a conversation around the topic of regular STD testing and treatment may also be appropriate for some PrEP users. In other words, risk reduction counseling and adherence supports were available to people on PrEP in most studies and may be a crucial part of helping to reinforce safer behaviors.

It is important for those counseling PrEP users to go back to the idea of client empowerment and individual choices. Testing and prevention counseling staff should share accurate information, for example, that condoms or PrEP is each, individually, a highly effective HIV prevention method, and that using both provides maximum protection. They should then ask the client what level of protection would be appropriate for them.

One factor in determining if PrEP is the right choice is an individual's risk tolerance. Some people may use condoms much of the time, but like having the idea of having PrEP as a backup layer of protection, especially if they "slip up" and don't use a condom. Some people may strongly dislike using condoms, and rarely do so. PrEP offers an alternative that can tremendously reduce their HIV risk. Some people feel very strongly that sexual health for them means preventing both HIV *and* other STDs. Since PrEP does nothing to prevent STDs like syphilis, gonorrhea, and chlamydia, those people would likely want to continue to use condoms, whether or not they choose to use PrEP. And someone who believes strongly that healthy people should not take drugs because the risk of side effects is too great would want to avoid medications like PrEP and use another method of protection. All of these choices provide some level of protection based on the sorts of risks and pleasures that are important to a particular client.

Communication, Connection, and Support. People need connection and support in order to make the decision about whether to try PrEP. If they do choose to use PrEP, they will need support to stay adherent to PrEP and regular medical care, and to decide how they want to talk about their PrEP choices with others. Communication, connection, and support is the opposite of isolation, silence, and stigma. Support is particularly important because PrEP is new and unknown for many, and, at the same time, is getting a lot of attention, not all of it complimentary, in the media.

HIV-negative clients may need support in talking with their doctors about PrEP, in linking to and navigating the primary care system, and in advocating for themselves within it. Further, clients may face particular psychosocial issues regarding adherence, and they may benefit as much from non-judgmental help addressing barriers as from reinforcement for success.

Even though one of the benefits of PrEP is that a person can implement it without disclosing their HIV status or PrEP use to sexual or injection equipment-sharing partners, there will be times when a client will want to communicate with their partners about their PrEP use or other means of harm reduction. Providers can help their clients decide what they feel comfortable sharing about their HIV status, testing history, risk tolerance, and preferred ways of protecting themselves. Further questions might be "What are my limits and how do I communicate them?" and "How comfortable do I feel asking my partners about their status and risk reduction methods?" Clear communication also reduces the possibility that some people may assume their partners are on PrEP when they are not, just as people can make incorrect assumptions about HIV status. Lastly, PrEP can play an important role in family planning between serodiscordant individuals who are considering or planning a pregnancy who may want to have similar conversations.

Anxiety or Intimacy? One of the most important "side effects" of PrEP could be reduced anxiety. When a person feels protected and safe, knowing that they are using an effective HIV-prevention method correctly, they may be able to enjoy the sexual side of their relationships—and life in general—more. Knowing that their negative partner is protected can also allay some of the fear and

stigma that HIV-positive sexual partners often feel. For people in serodiscordant relationships who occasionally or regularly have, or want to have, unprotected sex, PrEP, as well as HIV treatment for HIV-positive partners, can lead to more intimacy while retaining some levels of safety.

Another exciting consideration involves the use of PrEP among serodiscordant people who are trying to achieve pregnancy through sexual intercourse. In these cases, a combination of PrEP for the HIV-negative partner and antiretroviral treatment of the HIV-positive partner can vastly reduce the chance of HIV transmission without reducing the likelihood of pregnancy. The Partners Study also suggested that taking Truvada for PrEP as prescribed is not harmful for either pregnant women or their children.¹⁴

8. How Do Community-Based Organizations Fit In?

CBOs play a vital role in connecting HIV-negative people at high risk for HIV to PrEP. Here are a few of the ways that CBOs may be able to help:

Outreach and Education. Printed materials, such as pamphlets, brochures, and posters, both in a CBO's lobby as well as out in the community, can help increase awareness about PrEP. In addition, online resources, both on your website and distributed through social media, can help increase awareness and conversations around PrEP use. If you have funding to serve "High-Risk HIV-Negative" people, discuss with your CDC Project Officer how those dollars can be spent so as to encourage PrEP use in the community.

HIV Testing as a Way to Leverage a Discussion About PrEP. Most people who come in for HIV testing have two things in common: they have engaged in an unprotected sexual or needle-sharing risk at some point in the past, and they also care enough about their health to get tested. These attitudes offer an ideal starting point for discussions about PrEP. Make education and counseling about PrEP a part of your HIV test counseling protocol. Research and make available to counselors referrals to local providers who can prescribe PrEP and to websites that offer information that can help clients decide if PrEP is right for them. For example, one site that shares personal experiences of people who have decided to use PrEP is [My PrEP Experience](#).⁵¹ Use your clients as a resource: ask them if they know anyone on PrEP and what their or their friends' experiences have been. For clients who are already on PrEP, ask them how adherence has been for them and identify any successes or challenges they have had with adherence and address those during the counseling session.

Support for Decision Making. Create venues—live community forums, online discussion groups—where people can weigh and discuss the information available to help decide if PrEP is right for them. Train your staff so that they can offer both high-quality, up-to-date information and referrals without undermining the client's authority as the decision maker. On the one hand, PrEP is not the answer for everyone; on the other, it is a highly effective intervention when used correctly. The only "wrong" choice would be to use PrEP incorrectly: people who choose to use PrEP should do so under the care of a knowledgeable medical provider in order to maintain their health.

Support Connecting to Care. Fortunately, many CBOs already have programs to connect clients to care and support them in care. Extend these efforts to people who may want to access PrEP. Encourage ACA enrollment at your site or by referring clients to ACA navigators or community

Benefits Counselors. Learn about the Medication Assistance and Co-Pay Assistance Programs for Truvada, offered by Gilead and others, and share the message that clients often may have more options than they think for paying for PrEP. Talk with clients about the importance of finding the right provider, with whom they can have open conversations about things like sex and drug use. This is information medical providers will need to prescribe PrEP, monitor its use, screen and treat clients for any STDs, and ensure kidney and overall health. Consider reading—and offering to your clients—two publications: the Project Inform booklet [How to Get PrEP: A Publication for Understanding How to Navigate the American Healthcare System](#),⁵² and the CDC’s helpful brochure [Talk to Your Doctor About PrEP](#), which includes a list of questions to ask medical providers, a set of resources for providers and clients, and a list of suggested tasks for both before, during, and after the doctor’s visit.⁵³ Another excellent resource by Project Inform for clients who may have to advocate for themselves with their provider is [PrEP and Working Through a Difficult Doctor Visit](#).⁵⁴ For nPEP, there is also a document by Project Inform titled [Talking to your Doctor About PEP](#) that may be helpful for clients to know what to expect during nPEP medical visits.⁵⁵

Support for Adherence. We know that adherence is vitally important for both PrEP and nPEP to work effectively. How does your agency support adherence, both to medications and medical appointments, for people who are living with HIV? Are there methods you currently use that might also work among HIV-negative people taking PrEP and nPEP? Mobile apps and texting services, such as the one available at <https://www.care4today.com>, can help remind people to take medications on time. Remember also that insurance coverage as well as stable housing, food, mental health care, and other services support a person’s ability to adhere to PrEP regimens, increasing the importance of offering clients referrals to resources that support access to all of these services. These ideas, and many more can also be found in the CDC’s brochure [A Pill a Day Keeps HIV Away](#).⁵⁶

Work with Your Local or State Public Health Department. Your local public health department is your most important partner in the campaign to help clients at risk for HIV access PrEP. Public health departments can help you map the HIV epidemic in your community and your state. These data can help you to understand how to direct your prevention services efforts around PrEP, and to evaluate the success of these efforts. State and local public health departments are also key sources of training and technical expertise, and can help ensure that the efforts in your community are hitting the high-impact HIV prevention target you have set by replicating effective prevention strategies throughout your region or state. They are also often sources of funding and assistance with reimbursement for the services you provide.

Working with Community Medical Providers. Begin to build a network and resource list of local medical providers who prescribe PrEP, want to prescribe PrEP, and are knowledgeable about PrEP. This can be challenging at first, because it will likely require reaching out to a wider community of doctors beyond HIV specialists. HIV specialists, however, may be a big part of the way to building that bridge with their colleagues, and letting them know about PrEP and that they can safely prescribe it. Once you have identified a few PrEP-knowledgeable medical providers, consider hosting a community forum with them as one part of an effort to get the word out about PrEP. Several resources can help you find HIV- and PrEP-knowledgeable medical providers. Among these are <https://preplocator.org>, which lists prescribing doctors and agencies by ZIP code. A similar service is available at <https://aidsvu.org/locators/prep-locator/>. For prescribing medical providers

who need additional information regarding PrEP, UCSF offers a clinical consultation center for medical professionals, which is available at (855) 448-7737.

Finding nPEP can be more difficult in some locations. Since time is of the essence for nPEP treatment, knowing who is able and willing to prescribe nPEP and their hours of service is critical information for nPEP-eligible clients. In general, emergency rooms and urgent care facilities of any hospital should be able to prescribe nPEP. Failing that, local STD treatment centers or Planned Parenthood offices should also be able to assist. For prescribing medical providers who need additional information regarding nPEP, UCSF offers a clinical consultation center for medical professionals, which is available at (888) 448-4911.

Staying Connected to Information, Training, and Capacity Building. Use the resources highlighted in this document and listed below in the Resources section to stay connected to the latest information about PrEP. Talk with your CDC Project Officer about your further capacity building needs, and look at the CDC’s [Effective Interventions](#) website for information about ways to integrate PrEP referrals and support into high-impact prevention interventions such as Testing Together (a new public health strategy that occurs when two or more people who are in or planning to be in a sexual relationship receive HIV testing services together [including their HIV test results]) and Personalized Cognitive Counseling.

9. Questions and Answers About PrEP and nPEP

Several providers have expressed an interest in the possibilities that PrEP intervention offers:

- “It’s a way of preventing HIV that my clients may actually use.”
- “It gives my clients living with HIV the opportunity to engage in relationships without the fear of infecting their partners.”
- “PrEP doesn’t really change my prevention work—it’s just another option to provide to my clients.”

But they still have questions:

Question 1: Does PrEP prevent HIV?

Studies show that when people take PrEP the right way—consistently, as prescribed—it is very effective at preventing HIV.

Question 2: Does PrEP prevent sexually transmitted diseases?

No. PrEP can help people with hepatitis B, which can be sexually transmitted, keep their hepatitis B in check, but it does not prevent STDs other than HIV. Clients who want to use PrEP without condoms, which do prevent STDs, would have to weigh the pros and cons of condomless sex, including the increased risk of getting an STD.

Question 3: How can I start a conversation with clients about PrEP?

You'll feel a lot more at ease if you can trust in your knowledge about PrEP and if you feel comfortable with PrEP as a prevention option. Learn as much as you need to feel comfortable, but remember you can't learn everything.

Talking about PrEP with clients is a lot like talking about other ways they are protecting themselves from HIV. You can bring up PrEP at the same times that you would bring up other prevention options. PrEP won't be right for every client. But it's great to start a conversation about it in order to find out if your client is interested in learning more. Here are some ways that you might raise the issue:

- “What have you heard about PrEP?”
- “How are you protecting yourself right now from HIV? How is that working for you?”
- “There's a new way to prevent HIV—a pill you take every day called PrEP. Would you like to hear more about it?”
- “Some people are using a pill called PrEP every day to keep from getting HIV. What do you think about that?”

Sometimes a client might ask something that you don't know about PrEP. That's OK. Most people right now are just learning how to talk about PrEP. When faced with a question you can't answer, don't let it worry you. Let your clients know that you'll either find out the answer or find someone—or someplace—that can help them get the answer.

Question 4: What are the potential benefits of PrEP for clients?

For clients, PrEP is another tool in their health-maintenance toolkit. If your client decides that PrEP is the right choice, and if they understand how to take it and believe that they can take it every day, it can be a very effective way for them to avoid getting HIV. It can also reduce a client's anxiety about HIV and sometimes about sex. When an HIV-negative partner in a mixed-status relationship is taking PrEP regularly, each partner—HIV-negative and HIV-positive—may feel relief from the worries related to sexual intimacy. In addition, people on PrEP may feel good about themselves because they are being responsible in protecting themselves from HIV. Clients on PrEP can still use condoms and any other harm reduction methods they wish to. Finally, PrEP is something that people can do to protect themselves without having to ask their partners, who may not want to use condoms or even to talk about HIV.

Question 5: What's the right message to clients about PrEP and whether it is right for them?

Is the client:

- at risk for HIV (but HIV-negative)?
- willing to take a pill every day to prevent HIV?
- someone who doesn't have kidney problems?
- OK with being in follow-up care, including repeat HIV and STD testing?

If the answer to the above statements are all “Yes,” PrEP might be right for that person. A medical provider who understands the client’s medical history and is knowledgeable about PrEP can help the client decide. A doctor or other medical provider will run an HIV test to make sure that the person is HIV-negative before prescribing PrEP and will check other health-related issues such as kidney function. After the client begins PrEP, the provider will continue to monitor the client’s health and any side effects that come up.

Question 6: Does PrEP work for women as well as it does for men?

Yes. PrEP works as well for women as for men if taken regularly as prescribed. Daily doses of Truvada may take longer to reach protective levels in vaginal tissue and blood (about 20 days) than in rectal/anal tissue (about 7 days).^{32,57} Further, missing daily doses may cause faster loss of protection for vaginal sex than for rectal sex or injection exposures.⁵⁸ So, the effectiveness of PrEP for a woman may depend on the type of sex she is having, together with how consistently she is taking it.

Women who want to become pregnant or who might become pregnant should discuss potential PrEP use with their medical providers. Truvada is usually well-tolerated by pregnant women.⁵⁹ HIVE’s [Is PrEP right for me brochure](#) can help women answer some of their questions. PrEPWatch also has a helpful page about the [U.S Women and PrEP Working Group](#) that discusses PrEP access, effectiveness, and uptake, and the importance of expanding HIV-prevention options for women.⁶⁰ PrEP would also be appropriate for HIV-negative men who want to impregnate a female partner who is living with HIV.

Question 7: What about straight men? Or men who have sex with men but don’t identify as gay? What can I say to them?

PrEP is about preventing HIV no matter what your gender, sexual orientation, or identity is. As the Research Summary above demonstrates, PrEP works for men who have vaginal or anal sex with women, men who inject drugs and share injection equipment, as well as men who have anal sex with men. PrEP is like condoms in that it doesn’t care who you are having sex with: Used correctly, it protects you from getting HIV.

Question 8: How can I be culturally sensitive when I talk about PrEP?

Start by asking clients what their concerns are about HIV. How has HIV affected them? Their community? What kinds of prevention tools do they wish that they had? It’s helpful to start from a place of knowing what the epidemic looks like for the communities you work with—whether “community” is defined by a geographic area or by demographic groups like men who have sex with men or young MSM of color or Black women. The forces that can cause women, transgender people, and men who have sex with men to feel shame about their sexuality—as well as the shame and stigma, themselves—might create barriers to PrEP for individuals. This would also apply to other HIV-related behaviors, for example, substance use.

Many communities of color and LGBTQ people have also had negative experiences with the health care establishment in the past. It is important to validate those experiences, at the same time acknowledging that PrEP remains an important resource for these same communities. This history

of past negative experiences is an important reason to avoid “pushing” people to accept one medical intervention or another. Instead, focus on helping to empower your clients to make the health care decisions that are right for them. What information do they need, and do they have access to it? What other resources can help these clients optimize their health? Are these resources available in a written or spoken language clients can understand?

Transgender people and adolescents may be concerned about the lack of research studies regarding PrEP and their particular communities. Reassure these clients that more studies are being conducted right now in order to assess the effectiveness and safety of PrEP for a wider range of people.⁶¹ What we don’t know is whether or not PrEP is acceptable to trans people, because in clinical trials they were less likely to take it, and when they did take it, there were lower concentrations of tenofovir diphosphate, which might be a result of lower adherence or different pharmacokinetics.¹⁰ We need more information to know how best to deliver PrEP to trans people.

What we do know is that PrEP is safe and effective when it is taken on a daily basis. Further, let your clients know that Truvada has been used for many years as a part of a treatment regimen for people living with HIV, including adolescents and those on hormone therapy. Serious side effects are very rarely reported, occurring in less than 1% of those who take Truvada.

Not every client will choose PrEP. But even for the clients who ultimately decide PrEP is not for them, the decision to not use the intervention is not the end of the discussion. It’s the beginning of another conversation about how they *do* want to protect themselves going forward.

Question 9: How can we get doctors and other health care providers to talk with their clients about PrEP and nPEP?

Health care providers also need education and support to initiate PrEP and nPEP discussions with their patients who may benefit from its use. Many doctors who are not HIV specialists are being asked about PrEP or nPEP. Since these doctors most often provide health care for people without HIV infection, they may not have heard of PrEP or they may feel like prescribing it is outside of their scope of practice. Further, to offer medical care to a person on PrEP, providers need to be prepared to talk, at least briefly, not only about Truvada, but also about sex, drugs, and HIV and other STDs, as well as adherence. You may need to share the resources and information you have about PrEP and nPEP with them.

Many communities are beginning to form networks of providers: doctors, nurses, and other medical professionals, CBO providers, health department staff, and pharmacists are talking about how to make PrEP work where they are. Community-based providers and health department staff, as well as capacity-building assistance providers can help doctors learn how to determine which of their patients may need PrEP or nPEP. They can also help doctors access the CDC guidelines and tools for delivering PrEP or nPEP care, and understand the risk reduction and medication adherence issues to discuss with their PrEP or nPEP patients. Enlisting HIV specialists to talk to other doctors is useful because they often speak the same “language.”

Talk with your CDC Project Officer about capacity-building support for health care organizations in your area. Through technical assistance, for example, from a federally funded Prevention Training Center, doctors can learn more about HIV, PrEP, and nPEP, and grow to feel more comfortable

about offering, prescribing, and monitoring PrEP or nPEP.

There are many resources for medical providers considering prescribing PrEP or nPEP. UCSF offers expert consultation on guidance, laboratory monitoring, and follow up for both PrEP and nPEP. For prescribing medical providers who need additional information regarding PrEP, UCSF offers a clinical consultation center for medical professionals, which is available Monday–Friday, 11AM–6PM EST at (855) 448-7737. For prescribing medical providers who need additional information regarding nPEP, UCSF offers a clinical consultation center for medical professionals, which is available seven days a week, 9AM–12PM EST at (888) 448-4911. Other resources include the CDC’s *2014 Preexposure Prophylaxis for the Prevention of HIV infection in the United States and the 2016 Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV*.²⁵

Question 10: What if the doctor doesn’t bring it up? How can my client talk to his or her doctor about PrEP?

Talk with clients about the importance of finding a provider who they feel can support their health. Encourage them to seek someone with whom they feel comfortable having open conversations about behaviors like sex and drug use. Both Project Inform’s booklet *How to Get PrEP: A Publication for Understanding How to Navigate the American Healthcare System*⁵³ and the CDC’s brochure *Talk to Your Doctor About PrEP*⁵⁴ can help clients prepare for engaging in and initiating discussions with doctors. *Talk to Your Doctor About PrEP* includes a list of questions to ask a medical provider, a set of resources, and a list of suggested tasks for clients before, during, and after the doctor’s visit.

Some doctors may have a hard time supporting their patients in considering PrEP. For situations where a client might experience pushback from a doctor about a PrEP request, Project Inform has another helpful publication: *PrEP and Working Through a Difficult Doctor Visit*. This booklet helps clients address responses such as “Just use condoms,” “I’m not qualified to prescribe PrEP,” or “It won’t protect you against STDs.” People considering or on PrEP can also get tips and support from each other online, at places like *MyPrEPExperience* and *PrEP Facts FAQ*, which is an easily joined Facebook group that features both PrEP consumers and PrEP providing professionals.

Question 11: How will my clients pay for PrEP? What if they don’t have health insurance or enough money to pay out-of-pocket expenses? What if they aren’t already in care?

Check out the “Accessing PrEP and nPEP: Who Pays?” section above. Medicaid, Medicare, and most private or employer insurance policies pay for PrEP, although often with the requirement of prior authorization, co-pays, co-insurance, or deductibles. There are also MAPs and Co-Pay Assistance Programs that can help pay for either the cost of the drug or for the insurance co-payments. Some states are also developing their own PrEP Assistance Programs, often modeled in part on their state’s AIDS Drug Assistance Program. Medicare coverage varies by state. The CDC’s new brochure *Paying for PrEP* may also be helpful.⁶²

Question 12: Will PrEP increase unsafe sexual behavior? Aren't we really just promoting unprotected sex?

A lot of service providers are worried about this. Will people have more condomless sex because they are on PrEP and will this increase the likelihood that they will get infected? By presenting PrEP as an option, are we saying that “unsafe” sex is OK? There are a few ways to look at these questions.

- First, people can use condoms and also be on PrEP. In fact, that’s what the CDC recommends. While on PrEP, condoms are a way that people can keep themselves even safer.
- Second, PrEP doesn’t prevent pregnancy or STDs besides HIV—the way condoms do—so each client needs to decide if and how they want to protect themselves from those potential outcomes. In PrEP studies, even when STD rates were high, indicating low condom use, PrEP was highly effective in preventing HIV infection when taken regularly.
- Third, lots of people are already having condomless sex at least some of the time. PrEP gives these people, who may be unable to consistently use condoms for a variety of reasons, another option for staying HIV-negative.
- Fourth, PrEP is really effective when it is taken correctly, that is, consistently, every day. So it is unlikely that a person who is taking PrEP reliably will become infected with HIV—even if that person does not use a condom. PrEP doesn’t prevent pregnancy or STDs besides HIV—the way condoms do—so each client needs to decide if and how they want to protect themselves from those potential outcomes.

Conclusion

Using antiretroviral medication for prevention has the potential to dramatically decrease HIV rates in our communities. It is already resulting in reductions of new HIV infections. And PrEP is an especially important new tool for accelerating that drop. nPEP is another important tool for those clients for whom it is appropriate. Although PrEP is not the right strategy for everyone, it is an important option. By joining with other providers, including health departments and health care organizations, community-based organizations can fulfill a key leadership role around PrEP and nPEP in their communities.

Appendix A: PrEP Resources

Center for Disease Control and Prevention PrEP Page: <http://www.cdc.gov/hiv/prevention/research/prep/>. This webpage explains what PrEP is, discusses federal PrEP guidelines, and reviews PrEP clinical trials to date. It also has links to Basic PrEP Questions and Answers, the PrEP Support Hotline for Clinicians, and the CDC’s Fact Sheet on PrEP, as well as a host of other resources.

My PrEP Experience: <http://myprepexperience.blogspot.com>. This website features real stories from people who have chosen to use PrEP for HIV prevention.

NACCHO’s PrEP for HIV Prevention Webinars: <http://www.naccho.org/topics/HPDP/hivsti/prep.cfm>. The National Association of County & City Health Officials (NACCHO) has created a great series on PrEP with everything from an introduction to PrEP, to a guide to assessing individuals for PrEP, to incorporating PrEP into comprehensive HIV-prevention programs.

prepfacts.org: <http://prepfacts.org> This site is a partnership between the San Francisco AIDS Foundation, the San Francisco Department of Public Health, Gilead, and PrEP activists. It contains information on “PrEP Basics,” PrEP research, frequently asked questions on a number of important PrEP-related topics, and information on other biomedical interventions currently being studied. Also available in Spanish.

PrEP Watch: <http://www.prepwatch.org>. This site includes updates on research studies and other news about PrEP, and materials on understanding PrEP, how to access PrEP and what it can cost, and U.S. and worldwide advocacy efforts.

Project Inform: <http://www.projectinform.org/prep/>. This site includes educational booklets, four short educational videos, a portal where PrEP questions can be emailed, a PrEP Facts Flier, and a link to other PrEP websites.

Start.Truvada.com: <http://start.truvada.com> is a Gilead site that explains Truvada for PrEP in clinical/medical provider terms. It explains the safety/side effect information about Truvada for PrEP.

UCSF Clinical Consultation Center: available Monday to Friday, 11AM–6PM EST at (855) 448-7737 A hotline to provide clinical consultation to medical providers who are considering prescribing PrEP or have questions about the medications to their patients.

Appendix B: nPEP Resources

Center for Disease Control and Prevention PEP Page: <https://www.cdc.gov/hiv/risk/pep/>

This webpage explains what PEP and nPEP are, and discusses federal PEP and nPEP guidelines. It also has links to basic PEP Questions and Answers and the PEP Consultation Service for Clinicians, as well as a host of other resources.

Center for Disease Control and Prevention Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>. A guide for clinicians who may be prescribing PEP or nPEP.

National Institutes of Health PEP Page: <https://aidsinfo.nih.gov/education-materials/fact-sheets/20/87/post-exposure-prophylaxis--pep>. A webpage that offers basic questions and answers regarding PEP and nPEP.

taking PEP: <https://takingpostexposureprophylaxis.wordpress.com/blog/>. This website documents one user's experience through the 28 days of their nPEP experience.

UCSF Clinical Consultation Center: (888) 448-4911, open from 9AM–12PM EST, seven days a week. A hotline to provide clinical consultation to medical providers who are considering prescribing PEP or nPEP to their patients or have questions about the medications.

U.S. Department of Health & Human Services PEP Page: <https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/> A consumer-friendly webpage that offers basic questions and answers regarding PEP.

Appendix C: PrEP Research Studies

The following studies provided strong evidence for the safety and efficacy of daily oral PrEP use in different transmission groups.

iPrEX. Overall, participants assigned to the PrEP group were 44% less likely to become HIV-positive. **But participants who had detectable levels of PrEP drugs in their blood had a 92% reduction in their risk for getting HIV.**⁸ This illustrates one of the truths of PrEP as a strategy: you have to take it regularly for it to work.

Partners PrEP Study. This randomized controlled trial, published in 2012, found that among 4,758 mixed-HIV status heterosexual couples in Uganda and Kenya, participants who were assigned to the group that received PrEP were 75% less likely to become infected than those who received the placebo.^{6,14} **But among participants who actually took PrEP consistently enough to have had detectable levels of medicine in their blood when it was tested, PrEP reduced the risk of HIV infection by up to 90%.**⁶ The follow-up **Partners PrEP Demonstration Project** recruited new participants and combines both aspects of “treatment as prevention,” offering HIV-positive partners

antiretroviral treatment and HIV-negative partners PrEP until their HIV-positive partner has been on HIV treatment for at least six months. The idea is that PrEP serves as a “bridge” until the time when viral suppression in the partner living with HIV is achieved. **Data from 2012 to 2014 found 96% fewer HIV infections than what would have been otherwise expected.**⁶³

TDF2 Study. This randomized controlled trial, published in 2012, found **a reduction of the risk of getting HIV by 62% to 78% among more than 1,200 heterosexually active male and female participants in Botswana who took PrEP.**¹⁵ Of the four participants in the PrEP group who became infected, two had no detectable levels of Truvada, and two had levels that were far lower than other participants with similar characteristics who stayed uninfected.

Bangkok Tenofovir Study. This randomized controlled, double-blinded trial study of 2,413 injection drug users, published in 2013, found that **participants assigned to the tenofovir group were 49% less likely to contract HIV. However, participants who had any detectable tenofovir in their blood were 74% less likely to get HIV.** People over 40 years old were significantly more adherent than younger people, and women were significantly more adherent than men of the same age.^{6,19,64}

PROUD Study. This open-label randomized trial took place in England with 544 gay and other men who have sex with men from sexual health clinics. **The study found that PrEP gave a high level of protection, with an 86% reduction in HIV incidence.** The study also suggests that those who are most at risk for HIV infection are also the most interested in taking PrEP.¹¹

Kaiser/Volk Study. This study was an evaluation of patients accessing a specialized PrEP program through the Kaiser hospital system in San Francisco. **Of the patients who took PrEP, no new HIV infections occurred during 388 person years, despite high levels of STDs and reports of reduced condom use.**¹³ This is particularly striking since evidence from other studies (with similar populations, STD rates, and condom use), would lead one to expect an incidence as high as 8.9 new HIV infections per 100 person years. This also highlights the ongoing need for routine STD screening and treatment in clients who are utilizing PrEP, as treatment of STDs may act as an additional protective factor for HIV.¹³

US PrEP Demonstration Project. This was an open-label cohort study of MSM and transgender women from San Francisco, Washington, DC, and Miami. **This study found high levels of interest among MSM and transgender women at elevated risk for HIV infection when offered in STD clinics and community health centers, when proven efficacious to participants and provided to them at low or no cost.** They also found that hearing about PrEP from a friend or sexual partner was highly associated with a desire to go on PrEP. In addition, researchers found that increasing community awareness around PrEP and engaging MSM of color and transgender women can help increase PrEP uptake within these communities.¹²

IPERGAY Study. In addition to research into the effectiveness of daily oral PrEP use, the IPERGAY study sought to seek if intermittent dosing (taking PrEP only around the time before and after participants anticipated having sex) could be as effective. This randomized controlled study tested whether an “event-based” use of PrEP would be effective.⁶⁵ Researchers instructed MSM participants to take two pills between two and 24 hours before sex, plus two more single-pill

doses, one 24 and one 48 hours after the last pre-sex dose. The number of days participants took pills varied depending on how often participants had sex. Those having sex once a week would take four pills, but those having daily sex would be taking eight pills in a week, that is, even more than the Truvada dosing in the iPrEX study. **The researchers stopped the trial early, in October 2014, because it was so effective (86% reduction in HIV incidence in the treated group) that to continue the non-treatment condition would have been unethical.**^{66,67} Since, however, participants were taking PrEP an average of three to four days per week, CDC researchers caution it is unclear if this regimen will work among men who have sex less frequently.⁶⁵

Three other PrEP studies are worth mentioning because they highlight both the limitations and opportunities of the intervention and of the research so far:

iPrEX OLE Study. iPrEX OLE, published in 2014, was *not*, like iPrEX, a randomized controlled trial, which is the gold standard of research methodologies. Researchers sought to understand both, what influenced the decision to take PrEP, as well as how adherence affected protection. They uncovered three interesting findings.¹⁰ First, researchers found that sexually active people who were at the highest risk of getting HIV were attracted to taking PrEP. People who had more condomless receptive anal sex chose to start PrEP more often than those who had less condomless receptive anal sex. Second, researchers confirmed the iPrEX finding that the more PrEP pills subjects took (up to the maximum dosage of one pill per day), the more protection from HIV infection they got: **four to six tablets weekly led to up to 100% reduction and seven tablets weekly led to a 100% reduction.** Of the more than 1,200 participants who chose to start PrEP, only one-third took four or more doses per week, and just 12% took it every day. Third, researchers found that the following factors were associated with adherence: participants saying that they had receptive anal sex without condoms before the study started, being over the age of 24 (and especially those over 40), having more than five sex partners in the prior three months, having more than a high school education, knowing that they had an HIV-positive partner, not being transgender, and not having five or more alcoholic drinks per week.

Vaginal and Oral Interventions to Control the Epidemic (VOICE) Study. This randomized controlled trial of PrEP's effectiveness among 5,029 women in South Africa, Uganda, and Zimbabwe followed up on earlier promising research—the Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 trial²⁰—suggesting that tenofovir gel could substantially reduce HIV transmission to women. Participants were randomized into five groups: daily use of a tenofovir tablet, daily use of a Truvada tablet, daily use of a placebo tablet, daily use of a vaginal tenofovir gel, and daily use of a placebo gel. The first set of results, published in 2013, found none of the products effective. But it became clear that most participants did not use the products daily as recommended, and a large proportion had not used them at all in the recent past. There were several complicating factors, including the fact that subjects were paid to participate in the study. In addition, the intervention was unacceptable to many of the women in the study, perhaps because of rumors that Truvada would cause a variety of medical problems, including infertility.^{17,19} **The disappointing results of the VOICE Study, which had initially cast doubt on the effectiveness of PrEP in women, were later understood as problems with uptake, not effectiveness.**

FEM-PrEP Study. This randomized double-blind, placebo-controlled study sought to assess the effectiveness of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) in preventing HIV infection among a large cohort of Kenyan and South African women. The study was stopped early, however, in 2011, due to a lack of efficacy. The number of infections among the TDF-FTC group was not significantly different from those that occurred among the placebo group. However, researchers theorized that **low adherence (due to a low self-perception of HIV risk) might have been a contributing factor.**

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