

clients who have no identified challenges to adherence, the interventionist can use the booster session to review and ensure that the existing adherence plan is working, and help the client identify potential future barriers to adherence that have yet to present themselves (e.g., travel, changes in work schedule).

Session 1: Introduction, Assessment, Education, and Dosing Scheduling

Session 1 provides the foundation for the subsequent intervention content, and begins with the interventionist working to establish an alliance with the client. Qualitative data from the individuals who took PrEP in the context of an efficacy trial suggested that a strong, positive relationship with the adherence interventionist was key to successful adherence counseling (Taylor et al., 2014). Because it can be challenging to balance the need for the client to express his concerns about safer sex, with the interventionist's need to gather background information and cover the required intervention content, we suggest setting the tone of the session as follows:

I am happy to be working with you as your adherence counselor for PrEP. I have a lot to learn about you, so that I can be as helpful to you as possible during our work together. I would like to begin by telling you a little about the counseling. I will then ask you some questions about yourself, so that I can begin to get to know you better and learn about what your life is like these days. We have a lot to cover today, so we are going to do our best to limit that part of our visit to about 15 minutes. Does this sound okay? [wait for response] What questions do you have so far?

After providing an overview of the adherence intervention, the interventionist conducts a brief psychosocial assessment (e.g., living situation, health status, substance use, sexual partnerships) to determine potential facilitators of and barriers to daily PrEP adherence. Next, the interventionist introduces the client to the PrEP education that provides the client with a foundation of knowledge about PrEP. This component allows the client to learn more about PrEP and to clarify questions or misconceptions that he might have about PrEP use. Based on Centers for Disease Control (2011, 2014b) guidelines for PrEP use in sexual-minority men, educational topics include the importance and rationale of daily dosing, long-term safety and tolerability, common side effects and side-effect management, substance using behaviors that can impact adherence to PrEP, and the importance of not sharing PrEP medication with others.

To introduce clients to taking PrEP on a daily basis, we provide a "Starting PrEP" introductory video that addresses motivation for taking PrEP, understanding PrEP effectiveness, and what to expect in terms of side effects. "Brett" is a 23-year-old gay man who has been

taking PrEP for 8 months (see Video Clip 1). He describes his motivation to take PrEP, some mild side effects, and his own strategy to eliminate these side effects. Brett takes PrEP because it makes him feel safer when he has sex with his partner who is HIV positive. For him, PrEP is added protection to condoms and lubricant, particularly if a condom falls off or breaks, or if he decides not to use condoms during sex.

Deciding to take a daily medication to help prevent HIV is a significant commitment that may require ongoing motivation. One component of the intervention is the use of some MI techniques that are designed to help clients identify their motivations to adhere to PrEP on a daily basis. For the purposes of this intervention, motivation to adhere to PrEP should be viewed as fluid. Motivation may change over time in response to a variety of events (e.g., medication side effects, the end of a partnered relationship, introduction of new partners, or an increase or decrease in overall sexual activity). To facilitate this discussion, the interventionist introduces a "Pros and Cons" worksheet to better understand clients' possible reasons to maintain high PrEP adherence versus not adhering regularly to PrEP. This can be a basis for different problem-solving approaches to take later in the intervention. Sometimes clients have a difficult time identifying their own pros and cons, so the interventionist may need to help guide this discussion based on his or her experience working with other PrEP users. Table 2 shows an example of a completed worksheet.

Assessing motivation frequently can assist the interventionist and client to identify periods in which lowered motivation may result in decreased adherence to PrEP and, thus, increased risk for HIV acquisition. The following video shows how the interventionist assesses "Cody's" motivation to take PrEP as part of his HIV risk-reduction strategy. In this case, the interventionist wonders if Cody, a 20-year-old gay man, understands the degree to which taking a daily medication to help prevent



Video 1. Starting PrEP. Video Clip 1. Music by Josh Woodward.

Table 2
Possible Pros and Cons to Taking PrEP

Topic	Pros	Cons
Maintaining high PrEP adherence	<p>PrEP may afford me additional protection from HIV</p> <p>Allows me to achieve a greater sense of intimacy while feeling safer</p> <p>Counseling sessions may be helpful in supporting high adherence and making healthier lifestyle choices more generally</p>	<p>Possibility of side effects</p> <p>Have to take a pill every day</p> <p>Taking a pill every day reminds me that I am risky</p> <p>Not sexually active every day, so I wonder if I really need to take a pill every day</p> <p>May not get anything out of the counseling sessions</p>
Not adhering to PrEP	<p>Would be easier to take PrEP in a way that was consistent with sexual activity rather than every day</p> <p>It is easier not to take PrEP or attend study visits</p> <p>No medications mean no side effects</p> <p>Fewer reminders of my HIV risk</p>	<p>I remain at risk/high risk for acquiring HIV</p> <p>Not taking PrEP as prescribed may make me vulnerable to HIV</p> <p>I may need the support of the counseling sessions, at least in the beginning, to make sure I am taking PrEP properly</p>

HIV may require a bit of a commitment, and he is interested in understanding what is guiding or motivating Cody to begin this change in his life.

In Video Clip 2, after Cody generated pros and cons, the interventionist assessed his motivation to take PrEP every day by introducing a numerical scale from 0 (*not at all motivated*) to 10 (*highly motivated*). Cody rated his motivation as a 7, which is moderate-high on the motivation scale. Then, the interventionist inquired about why Cody chose a 7, noting that motivation changes over time. Last, the interventionist summarized the discussion and noted how, over the course of the intervention, they will continue to discuss Cody's motivation. Because motivation naturally changes over time, an interventionist should assess the client's motivation at the start of every session and explicitly discuss steps to increase motivation when necessary.



Video 2. Assessing motivation to take PrEP. Assessing motivation to take PrEP

While it may be possible in the future that PrEP will not need to be taken daily, current FDA guidelines call for daily dosing (Centers for Disease Control, 2014b). Upon completion of the educational component and introductory video, the interventionist and client work together to establish a daily dosing time, based on the client's preferences, and discuss when and how PrEP dosing can be linked to an already established, daily-occurring behavior. The goal of this conversation is to obtain a sense of when the client would like to take his PrEP medication, and how he spends his time on a weekly basis—to see if there might be any problems with the preferred dosing time. Questions and comments to consider could be:

- “You may already have a time of day in mind, but before we talk about that time, please tell me a little about a typical day for you.”
- “Does this schedule vary at all, for example, were you thinking about a weekday or a weekend?”
- “What are some activities that you do every single day, no matter what else is going on, no matter where you are?”
- “What are you thinking would be the ideal time to take your PrEP? Why then and not earlier or later?”

Next, the interventionist guides the client to plan ahead to develop reminder strategies, as a backup plan for his established dosing time. Reminders could include cell phone reminders, calendar reminders, watch alarms, reminder stickers placed in visible locations, and friend/partner reminders. If possible, the interventionist works with the client to set the reminder during the session (e.g., setting an alarm on a watch or smartphone). For clients who are unable to set a reminder while in the session, the interventionist works with the client to develop a concrete

plan of when and how he will set the reminder after the session is over.

Although many people who take PrEP do not experience any short-term side effects, it is important to create a plan if side effects do occur. The most common side effects with PrEP are gastrointestinal in nature (e.g., increased gas, diarrhea, changes in bowel habits, or nausea). The interventionist can explain that each of these side effects is relatively uncommon (Centers for Disease Control, 2011) and tend to be limited in duration to the early period of adjustment to the medication, and typically resolve within days to weeks of medication initiation without the need for additional intervention. If any of those side effects occur, the interventionist and client develop a plan to overcome those side effects. Examples of side-effect managing solutions include eating multiple small meals instead of fewer larger meals, using over-the-counter medication for symptom relief, or calling a trained medical professional if the symptoms persist for multiple days. The interventionist then gives the client an opportunity to ask questions, summarizes the content of the session, reviews the adherence plan for the week, reviews the plan of what to do if side effects occur, and informs the client about what will be covered at the next session.

Session 2: Focus on PrEP Adherence and Ongoing PrEP Education

The purpose of this session is to understand the client's experiences taking PrEP since the last visit with the interventionist, identify any side effects, monitor any missed doses through self-report, engage in problem solving barriers to adherence, and provide further psychoeducation when needed. If the client has experienced any side effects, the interventionist should review the plan (established in Session 1) to make sure that the client feels confident about managing those side effects before moving forward with the Session 2 content. The interventionist may review PrEP education for an explanation of ways to manage common side effects such as using over-the-counter medications, adjusting dietary habits, or changing the dosing time. The client should consult a provider if there is concern about side effects or if there might be serious medication interactions; the interventionist and client can work as a team to develop a plan for this consultation if it arises.

It may be difficult for clients to talk to interventionists about missed doses as a result of social desirability bias, or even the clients' forgetting that they missed a dose. Because talking about missed doses is integral to effective adherence counseling, the interventionist should normalize nonadherence, and adopt a nonjudgmental attitude. For example, the interventionist could say:

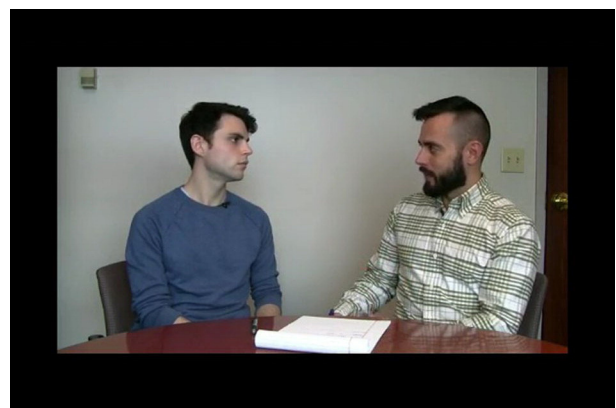
- “It’s been a week since we last met and I’m curious to hear about how the past week has gone. Taking

PrEP can be difficult and I don’t expect things to have gone perfectly this week. That is why we are here together!”

- “I want you to feel open about sharing your experiences this week with PrEP, even if things did not go perfectly. In fact, sharing that information will give us specific things to work on and make our time together most effective.”
- “How many doses did you miss? What got in the way? Tell me about any times where you almost missed a dose.”

The interventionist should identify and discuss *each* missed dose—rather than talking about them in general, which typically would result in not having the kind of detailed information that would be most helpful for the interventionist to use for CBT-consistent problem solving. Then they can work together to identify real or potential adherence barriers, and implement a problem-solving plan to overcome those barriers. Some common barriers clients may face when taking PrEP consist of forgetting, unexpected travel or overnight travel, staying at someone else’s (could be a sex partner) place, experiencing side effects, mental health concerns, substance use, or actual or perceived stigma (e.g., that the client is sexually promiscuous).

In the following video, we return to Cody whose self-reported adherence indicated he did not miss a daily dose the first week. However, in Week 4, he reports missing a weekend dose and we provide a video example of how to problem solve and address his nonadherence. At this point in their work, Cody and his interventionist did not need to problem solve any barriers to adherence (although his adherence changes in Session 4). For clients who have 100% adherence, and who cannot articulate any barriers that may arise over the next week,



Video 3. Problem solving and addressing nonadherence.

reinforce their use of any of the strategies for maintaining adequate adherence, review their adherence plan as developed in Session 1, then flexibly move to another module that might meet the client's needs. However, after reviewing adherence and discussing in-depth the importance of daily dosing, Cody presented two questions commonly asked by PrEP users that focus on daily adherence (see Video Clip 3). While the first question broaches the importance of daily PrEP use to prevent HIV infection and resistance, the second question relates to the risk of HIV infection from a partner who is HIV positive with a suppressed viral load.

During discussions of adherence to PrEP, some clients might state a common misconception that the body can build up a "tolerance" to the medications used in PrEP. This may be due to all the information about resistance to antiretrovirals, which can happen as a result of low adherence in the context of treatment. Thus, clients might believe that Truvada may not work to treat HIV should they become infected in the future. Clients should be provided with the correct information that the body does not build up tolerance to these medications. "Resistance" can only occur if as person has HIV, and there is the opportunity for the virus to mutate to a version that is resistant to one's medications. However, if a person does not have HIV, then there is no virus in the bloodstream, and it cannot therefore mutate to be resistant to PrEP.

Session 3: Follow-Up on Adherence and Focus on Sexual Risk Behavior

For clients who are experiencing little difficulty adhering to daily dosing, the sexual risk-reduction component is usually introduced at the third weekly visit. It is important to recognize that consistent condom use may not be a goal that clients have and, irrespective of their intentions, may not be attainable for all individuals at all times and in all contexts. In fact, this may be what drives some individuals to seek out PrEP. Thus, the goal of this module is to help individuals recognize any areas of vulnerability for HIV risk, as well as to minimize their risk of acquiring other STIs, and to help formulate a plan for behavior change, should the client wish to change any of the behaviors that may place him at risk.

The aim of this session is to help clients make informed decisions about sex and sexual risk, and involves a detailed review of sexual behavior (e.g., condomless sex), including a discussion about how individuals may still be vulnerable to HIV exposure and/or other STIs. To facilitate this discussion, the following questions may be helpful when completing the worksheet:

- "When it comes to sex, what do you do that is okay and what is not okay for you?"

- "How happy are you with your current sexual behaviors? What, if any, changes are you considering?"
- "What factors (e.g., your mood, where you have sex, partner type) make you step outside of your sexual comfort zone?"
- "Everyone who is sexually active with other people is at some risk of acquiring HIV or other STIs. Given your sexual comfort zone, and what you know about HIV transmission, which behaviors put yourself, or others, at risk for HIV and STIs?"

Upon completing the Sexual Comfort Zone exercise, the interventionist introduces the client to HIV knowledge and transmission risk behaviors. Topics in this educational component include understanding the highest risk activities for HIV acquisition (e.g., receptive anal sex without condoms), factors that increase risk of HIV infection (e.g., having a concurrent STI), understanding the HIV viral load of HIV-infected partners, identifying the lowest risk activities (e.g., oral sex), and noting ways to reduce the risk of acquiring HIV and STIs. Next, the interventionist assesses what, if anything, the client wants to change, then asks if there are behaviors he is considering moving inside or outside of the comfort zone. If so, problem solving and MI may be used to change and formulate a plan for behavioral change in sexual behavior; if not, then the interventionist and client may move on to another module or end the session. An overarching framework is that the interventionist is not guiding the depiction of the sexual risk limits, nor having a preconceived judgment about risky behaviors, but instead is helping the client generate his own goals.

Another important feature of the sexual risk-reduction component, however, may be the assessment of the client's pros and cons of relying solely on PrEP for HIV prevention, versus using PrEP in combination with additional methods such as condoms or other behavioral risk-reduction practices like serosorting (choosing partners of the same serostatus), strategic positioning (choosing sexual positions



Video 4. Incorporating safer-sex practices.

that are less likely to acquire HIV), or withdrawal without ejaculation (Parsons et al., 2005). For clients who choose to rely solely on PrEP, interventionists may use MI techniques, nonjudgmentally as always in MI, to identify the pros and cons of this strategy, and can make sure that clients have a realistic understanding of the health risks to condomless sex. To introduce clients to incorporating safer-sex practices, we provide them with a video of a PrEP user named “Brett,” who describes how he uses condoms and discusses HIV status and PrEP use with his sexual partners (see Video Clip 4).

Many clients may view PrEP as part of a “sexual risk-reduction package” to be used in addition to condoms, testing, and other risk-reduction strategies. For these clients, problem solving and MI techniques may further create plans for developing and maintaining ongoing safer-sex practices. Booster sessions (see below) offer opportunities to reassess the comfort zone and evaluate any changes the client may be interested in making as his motivation to take PrEP changes.

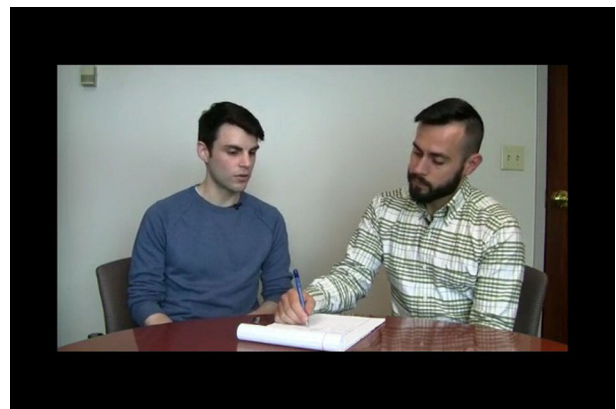
Session 4: Follow-Up on Adherence and Problem Solving Barriers to PrEP Adherence

When the interventionist and client have identified barriers or potential barriers to PrEP adherence, they work together using a problem-solving approach (D’Zurilla, 1986; Nezu & D’Zurilla, 1989; Psaros et al., 2014; Safren et al., 1999) to generate a plan and a backup plan to overcome those barriers. This involves listing all (or potential) barriers to adherence, such as forgetting, unexpected travel (e.g., overnight), side effects, change in sexual risk activity, mental health concerns, substance use, or actual or perceived stigma associated with taking PrEP (e.g., stigma from partner or from another health care or non-health care professional). Next, the interventionist and client generate as many solutions to each problem as possible, via brainstorming. Then, the interventionist helps the client evaluate the pros and cons of each potential solution, with the goal of assigning each potential solution a rating from 1 (*least desirable*) to 10 (*most desirable*; rankings are not mutually exclusive). The best solution, and one potential backup solution, should be identified based on participant acceptability, likelihood of success, and ease of implementation. Some barriers may require the merging of two solutions (e.g., for forgetting, a participant may wish to store his medication in an obvious place as well as to set a cell phone reminder).

We now return to Cody, who during Session 2 reported not missing any daily doses of PrEP, but for the past couple of weeks a pattern had emerged in which he has missed doses on Friday and Saturday nights. The client identified the potential barrier of forgetting, but the interventionist probed deeper and an assessment revealed that Cody’s alcohol use was the precipitating

barrier to adherence. Identifying the correct barrier is essential for the success of problem solving. Video Clip 5 provides an example of problem solving barriers to adherence. Problem solving involves identifying the problem (listing barriers to adherence), generating as many possible solutions to that problem as possible (i.e., brainstorming), and then picking one or two solutions and a backup plan for that problem.

After identifying the barrier, Cody and his interventionist brainstorm several potential solutions (see Video Clip 5). Brainstorming should occur without judgment. Even an idea that seems pretty outrageous at first, upon reflection, may be the key to an idea that works. During this time, it is important to be creative and to focus on quantity over quality of potential solutions. Next, the interventionist and client evaluate each of them by weighing the pros and cons of each potential solution, and scoring the potential solutions (with 1 = *least desirable* and 10 = *most desirable*; rankings are not mutually exclusive). Based on the rating, the interventionist and client work together to create a plan to ensure or enhance adherence. While the interventionist may offer potential solutions, it is important to remain nonjudgmental and allow the client to score each solution. Cody decided that taking his PrEP dose before he goes out with friends on Friday and Saturday nights, when drinking alcohol might later lead to forgetting to take a dose, would be the best possible solution. Finally, Cody developed a plan for implementation, identified when and how it will be implemented, and set up an alarm on his cell phone to remind him to take his medication. It is important to note that *problem solving* is a process that continues over time. If the plan or the backup plan does not work, then the client and interventionist can try again over the next week. If new problems arise, the interventionist and client can address those too, but treat each barrier as an individual problem to be solved.



Video 5. Problem solving barriers to adherence.