



**2022**

# **Biomedical Prevention Manual of Procedures DPH – Sexual Health Clinics**



**COUNTY OF LOS ANGELES  
Public Health**

# ACKNOWLEDGEMENTS

Words cannot express our gratitude to everyone who contributed their knowledge and time to making this Biomedical Prevention Manual of Procedures for our County of Los Angeles Department of Public Health's Sexual Health Clinics. We wanted to dedicate this page to those individuals:

**Leo Moore, MD, MSHPM**

Medical Director

Clinic Services

**Sonali Kulkarni, MD, MPH**

Medical Director

Division of HIV and STD Programs

**Shobita Rajagopalan, MD, MS, MPH**

STD Clinical Chief, Associate Medical Director

Division of HIV and STD Programs

**Rebecca Cohen, MD, MPH**

Associate Medical Director

Division of HIV and STD Programs

**Ilish B. Pérez, MPH, CHES®, CPH**

Health Educator, Clinic Liaison

Division of HIV and STD Programs

# TABLE OF CONTENTS

<b>WHAT'S NEW IN THE BIOMEDICAL PREVENTION MOP</b>	<b>1</b>
<b>SECTION 1: PROGRAM OVERVIEW</b>	<b>3</b>
PrEP Overview	4
Identification of Patients Who May Benefit from PrEP	5
Delivery Sites	7
<b>SECTION 2: PREP/PEP SERVICE DELIVERY</b>	<b>8</b>
PrEP Panel Management	9
Staff and Clinic Specific Roles and Responsibilities	9
Laboratory and Pharmacy Services	10
PrEP Initiation Visit	11
1 Month Follow-up Visit	15
PrEP Referral/Transition to Primary Care	17
PrEP Schedule and Other Assessments	18
PrEP Service Delivery Checklist	19
PrEP On-Demand	20
PEP Schedule and Other Assessments	22
PEP Service Delivery Checklist	23
<b>SECTION 3: CLINICAL CONSIDERATIONS AND REFERRALS</b>	<b>26</b>
Management of Suspected Acute Seroconversion (Acute HIV)	27
Management of Patients with Recent High-Risk Exposure	28
Adverse Drug Reactions	29
Patients with Abnormal Kidney Functions	30
Patients with Chronic Active Hepatitis B Infection	31
Hepatitis C Treatment	31
Women's Health While on PrEP	31
Adolescent Minors	31
Mental Health Referral	32
Substance Use Treatment Referral	32
Adherence Counseling	33
Broken Appointments	33
<b>SECTION 4: CHARTING</b>	<b>34</b>
Forms	35
<b>SECTION 5: ON THE HORIZON – ADVANCES IN PREP DELIVERY</b>	<b>38</b>
Injectable PrEP	39
<b>LA COUNTY RESOURCES</b>	<b>40</b>
Division of HIV and STD Programs (Website)	41
Get Protected LA (Website)	42
Get PrEP LA (Website)	42
Rapid and Ready Program (Treatment as Prevention)	43
<b>REFERENCES</b>	<b>44</b>



# **What's New in the Biomedical Prevention MOP**

## What's New in the Biomedical Prevention Manual of Procedures (MOP)

### Identification of Patients Who May Benefit from PrEP:

- Persons who requested PrEP were added to all risk groups.
- All patients seen in the Sexual Health Clinic should be screened for PrEP and PEP in ORCHID. Providers must check the Sexual Health Form before or during the patient visit to determine if PrEP should be discussed with the patient.

### PrEP Delivery Sites:

- All sexual health clinics are now offering both PrEP and PEP.

### PrEP Initiation Visit:

- Clear guidance regarding initiation of PrEP at the initiation visit in patients in which there is not a recently documented HIV test has been added. If there are no contraindications, such as signs of acute HIV infection or history of kidney disease, we recommend **starting the patient on PrEP at the initiation visit** to decrease barriers to accessing PrEP and potentially prevent an HIV seroconversion.

### PrEP Referral/Transition to Primary Care:

- All DPH sexual health clinics should now be prescribing PrEP for **1-month** and actively referring patients to a PrEP Center of Excellence, DHS clinic (Rand Schrader or Maternal, Child, Adolescent Clinic at LAC-USC), or private primary care. Patients should only remain on PrEP in the DPH clinics in special circumstances, such as a patient with Medi-Cal who prefers receiving their PrEP prescription at a Sexual Health clinic. Patients who will need ongoing PrEP dispensed from the clinic's supply should be transitioned within 1-month.

### PEP

- All DPH sexual health clinics should now be prescribing PEP for **1-month**. Once the 1-month is completed, if the patient remains HIV negative, they can be transitioned to PrEP for 1 month in the DPH sexual health clinic before transitioning to PrEP Center of Excellence, DHS Clinic, or private primary care.

### Advances in PrEP Delivery

- New section added to keep providers abreast of new PrEP modalities and strategies.

# Section 1: Program Overview



## PrEP Overview

---

### Introduction

Antiretroviral drugs are an increasingly important component of HIV prevention, as they can reduce viral loads and infectiousness of persons living with HIV (i.e., “treatment as prevention”) and help prevent HIV acquisition in uninfected persons (i.e., “biomedical prevention”). Non-occupational Post-exposure prophylaxis (nPEP) and pre-exposure prophylaxis (PrEP) are two forms of HIV biomedical prevention. nPEP is a 30-day course of three antiretroviral drugs (Tenofovir/Emtricitabine + Dolutegravir or Raltegravir) that must be taken within 72 hours of a high-risk HIV exposure to prevent HIV seroconversion. PrEP involves the use of an antiretroviral medication taken by individuals who are HIV-negative and who are at ongoing, elevated risk for HIV infection before they are potentially exposed. PrEP has been shown to reduce the risk of HIV infection by up to 99% when taken consistently. There are two FDA-approved regimens for PrEP, both of which are fixed-dose combination tablets: 1) Tenofovir disoproxil fumarate (TDF) and Emtricitabine (FTC) and 2) Tenofovir disoproxil alafenamide (TDF) and Emtricitabine (FTC). Dosing of both regimens is one tablet by mouth once daily. The PEP regimen includes TDF/FTC once daily + Raltegravir twice daily. DPH currently offers TDF/FTC for PrEP and TDF/FTC + Raltegravir for PEP.

The Clinic Services PEP and PrEP program is designed for patients at high risk for HIV acquisition. In 2013, men who have sex with men (MSM) accounted for 85% of the new HIV cases in Los Angeles County (LAC). Heterosexual women accounted for the second biggest group, at 9%. Of note, the CDC guidelines do not mention transgender women, but in our local LAC statistics, transgender women (also referred to as transgender male-to-female persons) were included in the MSM group; other data sources have confirmed an HIV prevalence among transgender women in LAC of over 20%, so they are a population considered to be at very high risk for HIV and good potential candidates for PrEP.

## Identification of Patients Who May Benefit from PrEP

The Division of HIV and STD Programs (DHSP) recommends PrEP be considered for the following individuals:

Who is a Candidate for PrEP?	
Sexually Active Adults and Adolescents	Persons Who Inject Drugs
<ul style="list-style-type: none"> <li>Anal or vaginal sex in the past 6 months;</li> <li><b>and</b> sexual partner has HIV (especially if the partner has unknown or detectable viral load);</li> <li><b>or</b> recent bacterial STI;</li> <li><b>or</b> history of inconsistent or no condom use with sexual partner(s)</li> </ul>	<ul style="list-style-type: none"> <li>Injecting partner has HIV;</li> <li><b>or</b> shares drug preparation;</li> <li><b>or</b> injection equipment</li> </ul>

PrEP Guidelines for Los Angeles County that describe in more detail who should be considered for PrEP are available at: [http://publichealth.lacounty.gov/dhsp/Biomedical/LAC-HIVPrEP-Guidelines\\_FINAL\\_10212022.pdf](http://publichealth.lacounty.gov/dhsp/Biomedical/LAC-HIVPrEP-Guidelines_FINAL_10212022.pdf)

PrEP Screening should be completed for **every patient** that enters the Clinic Services Sexual Health Clinics. Nurses will complete the Sexual Health Form, and if one of the following screeners for heterosexual women, MSM/Transgender women, or Drug Users is checked, the provider **must** discuss PrEP with the patient. Alternatively, if the patient has a risk factor that is not included, the nurse may type a risk factor into the “Specify risk” field. **Providers must review the sexual health form to ensure appropriate screening and discussions about PrEP occur.**



Sexual Health - ZZZZTEST, ADULTPUMPSEVENTEEN

\*Performed on: 10/17/2018 1836 PDT

**PrEP Screening**

Yes  
 No

Yes  
 No

Yes  
 No

Yes  
 No

**Client ever taken PrEP:**  
 Yes  
 No

**Client ever taken PEP:**  
 Yes  
 No

**Client currently taking PrEP:**  
 Yes  
 No

**Patient referred to PrEP/PEP?**  
 Yes  
 No

**Heterosexual Women:**  
 Reports an HIV positive sex partner  
 Reported history of syphilis in past 12 months  
 Suspect her male partners may be having sex with men  
 Multiple partners (HIV status unknown)  
 Exchanged sex for money, drugs, or other goods

**MSM/Transgender Women:**  
 Reports an HIV positive sex partner  
 Anogenital STD in 12 months  
 Multiple partners (HIV status unknown)  
 Reports unprotected anal intercourse  
 Prescribed PEP previously and continued high risk behavior  
 Exchanged sex for money, drugs, or other goods

**Specify Risk:**

**Drug Users**  
 IDU (Intravenous Drug use or Injection Drug User) who sharing injection equipment >=1 time per day  
 Inject cocaine or methamphetamine  
 Use of stimulant drugs

## Delivery Sites

---

### PrEP Delivery Sites within Clinic Services

- Antelope Valley Health Center
- Central Health Center
- Curtis Tucker Health Center
- Hollywood-Wilshire Health Center
- Martin Luther King Jr. Health Center
- North Hollywood Health Center
- Pomona Health Center
- Ruth Temple Health Center
- Whittier Health Center

### Duration of PrEP at STD Clinics

The provision of PrEP at the STD clinics is of high public health importance given the high-risk patients seen in the clinics and the low use of PrEP in these patients. In addition, many patients in the community face barriers in accessing PrEP- financial barriers, poor access to health care, and difficulties obtaining PrEP with their provider.

After being initiated on PrEP at STD Clinics, patients will be actively assisted with finding a medical provider in the community who can continue to provide PrEP to the patient in the future. **The goal is to transition patients out of the STD clinics within 1 month or sooner.** Patients who have a primary care provider who can provide PrEP should be referred there. In 2020, PrEP received a Grade A recommendation from the United States Preventive Task Force, which **requires that all insurance providers cover PrEP without any additional costs to the patient, including co-pays, deductibles, and medication costs.** Patients who do not have a PCP and are Medi-Cal eligible can be referred to DHS primary care centers. Patients can also be referred to one of DPH's Division of HIV and STD Programs (DHSP) community health centers across LA County, called PrEP Centers of Excellence. These clinics provide an array of services, including PrEP, post-exposure prophylaxis (PEP), and a host of "navigation services," which include adherence counseling, insurance enrollment, and referrals for mental health and substance use services.

Extensions for PrEP for longer than 1 month through the DPH sexual health clinics may be accommodated in rare circumstances with the approval of Clinic Services' Director, Gema Morales-Meyer, DNP, MPH, RN, CNS.

# Section 2: PrEP/PEP Service Delivery



## PrEP Panel Management

The clinic staff will be responsible for re-engaging patients who have been lost to care as well as the continued treatment of PrEP patients. Patients should receive a reminder call for their appointment 1 – 2 days prior to their appointment to decrease the no-show rate.

PrEP ad-hoc forms should be completed in ORCHID during each patient visit.

## Staff and Clinic Specific Roles and Responsibilities

### Staff Roles and Responsibilities

Role	Responsibility
All Clinic MDs/NPs, RNs, PHIs	<ul style="list-style-type: none"> <li>• Screen STD clinic patients for potential PrEP eligibility</li> <li>• Refer appropriate patients for PrEP</li> <li>• Order appropriate lab work for PrEP visit</li> <li>• Patient education about PrEP</li> </ul>
PrEP clinic MDs/NPs	<ul style="list-style-type: none"> <li>• Determine suitability for PrEP</li> <li>• Medical evaluation and follow-up visits</li> <li>• PrEP prescription</li> <li>• Patient education and adherence counseling</li> <li>• Work with team to transition patient to primary care</li> </ul>

### Clinic Specific Roles and Responsibilities

Duty	Staff Name and Title
<b>Point of Contact for providers</b> wanting to make a referral for PrEP, ensuring warm hand-off (via phone) <ul style="list-style-type: none"> <li>• Referrals from Community Providers</li> <li>• Referrals from other DPH clinics</li> </ul>	Front desk
<b>Point of Contact for patients</b> self-referring for PrEP <ul style="list-style-type: none"> <li>• Answer patient’s questions</li> <li>• Assists in making appointments</li> </ul>	Front desk
<b>Panel Management</b> <ul style="list-style-type: none"> <li>• Patient Tracking</li> <li>• Calling patients with reminders and for broken appts</li> <li>• Serves as point person for questions from PrEP patients</li> </ul>	Front desk / Nurse
<b>Adherence Counseling</b>	Provider
<b>Risk Counseling</b>	Provider
<b>Patient Navigation</b> – lead to assist with the transition to primary care <ul style="list-style-type: none"> <li>• Works with patient to assess the best plan for transition (existing PCP vs. other)</li> <li>• Communicates with PCP or other providers (providers labs, other documentation as needed)</li> </ul>	Nurse / CHW

## Laboratory and Pharmacy Services

---

### Laboratory Services

Laboratory and/or program staff will order and collect specimens according to the schedule outlined in this manual. They will also ensure the specimens are sent to the appropriate laboratory. All labs, including creatinine, can be sent to PHL.

### Pharmacy Services

PrEP will be available through DPH Pharmacy and is restricted to PrEP services on the formulary. The clinics will maintain strong communication with DPH pharmacy to ensure a durable and sustainable antiretroviral medication supply, and appropriate medication preparation and dispensing, to adequately delivery the PrEP services.

- Patients can receive a 30-day supply upon initiation of PrEP.
- PrEP tablets should be taken from their manufacturer labeled bottled and poured into a brown vial with an ORCHID label.
- A medication guide should be given with all PrEP prescription fills and refills.
- The **Emtricitabine/Tenofovir disoproxil fumarate medication guide from Gilead** can be found at: [https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)
- The **Emtricitabine/Tenofovir alafenamide medication guide from Gilead** can be found at: [https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy\\_patient\\_pi.pdf](https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_patient_pi.pdf)
- A copy of the “Basics of PrEP” handout should be offered to the patient (available in English and Spanish) and can be found at: <http://publichealth.lacounty.gov/dhsp/HealthEducationLibrary.htm>

## PrEP Initiation Visit

---

### 1. Medical Assessment

- Obtain a general medical and social history, review of symptoms. Check specifically for:
  - Recent symptoms of a flu or mono-like illness consistent with acute HIV
  - Any history of renal or liver disease or osteoporosis
  - Any significant past medical history (e.g., diabetes, hypertension)
  - Other medications – check for serious drug-drug interactions
  - Ability to take daily medication
- Physical Examination
- All patients with positive screening tests for gonorrhea, chlamydia, and/or syphilis should be treated and followed up in accordance with routine clinic procedures.
- Vaccinations should be provided for clients based on prior vaccination history, vaccine availability, and indication:
  - Hepatitis B series – for all PrEP clients if not previously immunized
  - Meningococcal vaccine - all MSM and transgender women on PrEP
  - HPV Vaccine - MSM, transgender women, and women under 45 years old
- Patients can be dispensed or given a Rx for PrEP on the first appointment while labs are pending if they have a low likelihood of having acute HIV, have no significant past medical history, and no other high likelihood of contraindications (like a prior history of kidney or liver disease). Notify them that if any labs are abnormal, they should expect a phone call and may possibly need to come back for follow-up/discussion.

### 2. Documentation

- Provider to complete the PrEP provider ad-hoc form.
- Nurse to complete the PrEP nursing ad-hoc form.
- Nurse should complete the Sexual Health ad-hoc form if it has not been completed within the past 4 weeks; if there is no Sexual Health ad-hoc form or > 4 weeks since the last form was completed, complete again.

### 3. Patient Education: How to Take PrEP

- **Start the conversation:** Start with an open-ended question about PrEP: “What have you heard about PrEP?” or “What do you expect PrEP to do for you?”
  - Many patients will have heard something from friends or on the internet, so good to gauge their baseline level of knowledge and identify any particular questions.
- **How PrEP works**
  - Drug levels build up in your body so that if you are exposed to HIV, it can’t replicate and take hold.
  - Explain the two methods of PrEP offered in the sexual health clinic: daily PrEP and PrEP on-demand (for MSM only).
  - Takes 7 days for drug levels to reach protective levels for rectal exposures; data suggest for women or persons with vaginas anticipating vaginal exposure, it can take 21 days before adequate drug levels are reached in vaginal tissue.
- **Benefits and Risks of PrEP**
  - Common side effects:

- Nausea or loose stools usually improve after the first few weeks; counsel patients that if they can manage to get through those side effects, they should improve after a few weeks as the body adjusts.
- Less common: potential mild worsening of kidney function so that we will screen you now for kidney problems, and you need to have labs, including your kidney function, checked every few months while taking PrEP.
- Mildly decreased bone density but no increased use of fractures; there is good evidence that this is reversible, meaning that your bone density will return to its prior level after you stop the medication.
- For high-risk patients, you can safely counsel them that the benefits outweigh the potential risks.
- **Condoms:** Best to ask an open-ended question: “What have you heard about condoms and PrEP?”
  - Then explain that while PrEP is highly effective against HIV, it doesn't protect you from other sexually transmitted diseases. Also, PrEP and condoms are like seat belts and airbags. They work best together to provide the highest level of protection.
  - PrEP also doesn't prevent pregnancy (for women or persons who are able to get pregnant, discuss additional modes of contraception while on PrEP).
- **Adherence**
  - Ask the patient, “Do you currently take any medications daily?”
    - If yes, what helps you remember to take your pills?
    - If no, when you've taken medications in the past, how did you remember to take them?
  - Helpful strategies may include: using a pillbox, taking PrEP with other daily medications, using a phone alarm, marking doses taken on a calendar, and keeping bottles in a visible location associated with daily activity.
  - One common reason for medication non-adherence is due to unforeseen side effects. It is important to inform the patient of common side effects, such as mild nausea, diarrhea, stomach pain, headaches, and abnormal dreams, and work with them to address these side effects as they develop. Most side effects resolve within the first month of treatment.
  - Explain that PrEP is used to treat people who are HIV positive, but it's not strong enough alone and has to be combined with other HIV medications; if the patient isn't taking the medication regularly (i.e., missed several days in a row) and has a high-risk exposure, the patient shouldn't restart the medication without coming in for an HIV test to make sure they are negative to avoid developing HIV drug resistance
  - Explain what to do if a dose is missed: Inform patients to take the single missed dose as soon as they remember it unless it is almost time for the next dose. If it is time for the next dose, patients should skip the missed dose and continue with the regular dosing schedule. Doubling of dosing should not occur.
  - Teach patients to recognize symptoms of acute HIV infection. Instruct patients to report immediately to a clinic if they develop symptoms compatible with acute HIV infection (fever, fever with a sore throat, fever with a headache – Rash?).
- **Additional Risk-Reduction Counseling**
  - Ask the patient: What else are you doing to protect yourself from HIV?
  - Goals of this conversation should be to do the following:
    - Improve the patient's self-perception of risk.
    - Support behavior change previously accomplished or attempted by the patient;
    - Identify short-term and long-term risk reduction plans based on the patient's perceived ability to change their behavior; and

- Review the nexus between HIV/STD infections and alcohol and drug use.
  - For individuals who could benefit from more intensive risk reduction programming, intensive behavioral risk-reduction and substance use treatment programs within LAC can be found online at <http://publichealth.lacounty.gov/sapc/contactus.htm>.
- **Follow-up and transition in care**
  - Confirm a schedule for follow-up in 1 month to assess side effects, adherence, and transition plan.
  - Discuss the importance of regular visits and HIV/STD and safety lab testing on PrEP.
  - Transition out of STD clinic.
    - Develop a plan with the patient for when they can transition to primary care and determine the level of support the clinic needs to provide (calling the accepting PCP with the patient's permission, giving copies of labs, etc.).
    - If the patient has not had a regular PCP or is concerned that they cannot get PrEP from the PCP, provide the patient with at least three options of clinics that may be well suited to them.
    - DHSP will provide a list of DHSP-funded PrEP/PEP clinics accepting these patients.
    - Please document in the chart on the form which clinic the patient is likely to transition to.
  - Patients can come back for an additional month of medication but need to be linked to another clinic.

#### 4. Start Patient on PrEP

If there are no contraindications, such as signs of acute HIV infection or history of kidney disease, **start the patient on PrEP at the initiation visit**. Order HIV viral load and other tests (see Laboratory Results Review), obtain an updated cell phone number, and call the patient if HIV results are positive. As the provider will only be giving a 30-day prescription of PrEP, the risk of developing resistance to HIV is **extremely low**. It is essential to recognize that the patients you are seeing are at **high risk** of HIV infection, so crucial to start PrEP as quickly as possible to prevent a new HIV seroconversion.

#### 5. Laboratory Results Review

Review laboratory results and confirm medical eligibility for PrEP from intake visit. This can be done after the PrEP initiation visit or before starting PrEP. The following provides details guidance to consider when reviewing results.

Tests	Comments & Rationale
<b>HIV viral load</b>	If the patient is HIV-infected, PrEP is unsuitable because they must receive 3 active HIV medications for treatment. Refer them to HIV medical care.
<b>Creatinine</b>	Use the following online calculator for calculating CrCl: <a href="http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault">http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault</a> CrCl should be $\geq 60$ ml/min (Cockcroft Gault) to use tenofovir safely. Patients with CrCl < 60 should have the test repeated. Assess the use of potentially nephrotoxic medications (NSAIDs, acyclovir, valacyclovir) and bodybuilding substances (creatine, protein drinks). If repeat CrCl is $\geq 60$ , the patient may start PrEP. If not, the patient will probably need to access PrEP through their PCP. Creatinine should be documented on the PrEP Provider Ad-hoc form in ORCHID.



<p><b>Hepatitis B surface antigen</b></p>	<p>Because PrEP has anti-HBV properties, patients with a positive HBsAg should be encouraged to receive PrEP in a primary care setting, where the liver function can be monitored both during PrEP use and after any PrEP interruptions, and where comprehensive HBV management can occur.</p> <p>Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.</p>
<p><b>Hep C Antibody</b></p>	<p>If reactive hepatitis C Antibody, this does not affect PrEP administration. However, patients should be referred to primary care for additional testing to determine whether the patient has cleared infection (25-30% cases) or has chronic hepatitis C.</p>
<p><b>Pregnancy test for women and persons who are able to get pregnant</b></p>	<p>Women or persons who are able to get pregnant wishing to use PrEP during pregnancy should be encouraged to receive PrEP in a primary care or HIV specialty clinic (if used as part of an attempt to become pregnant with an HIV positive partner). Patient on PrEP should be counseled and referred for family planning services as an additional form of contraception, in addition to condoms, is highly recommended.</p>

# 1 Month Follow-up Visit

---

This is an **optional** visit for patients with difficulty transitioning to primary care. Ideally, this patient would have been transitioned to PrEP at an outside clinic after their initiation visit.

## 1. Medical Assessment

- Obtain a general medical and social history, review of symptoms. Check specifically for:
  - Any new medical issues or new medications
  - Assess side effects and symptoms of acute HIV.
  - Test for STDs if symptomatic.
- Conduct a 7-day recall medication adherence assessment
  - Document how many of the last seven doses they have taken (if no missed doses, you would document “7”).
  - Conversations regarding adherence should be conducted in a non-judgmental manner which will allow patients to openly express why they may be having challenges adhering to the medication.
  - If patients have missed more than one dose, then more counseling is recommended. See Medication Adherence below.
- Physical Examination
- Treat all patients with positive screening tests for gonorrhea, chlamydia, and/or syphilis. Should be treated and followed up in accordance with routine clinic procedures.
- Vaccinations should be provided for clients based on the indication.
- Respond to new questions and provide any new information about PrEP use.
- Provide a prescription or dispense medications for 30 days.
- Discuss a plan to transition to another medical provider for PrEP (see #6 below).

*For patients who experience any side effects, see section under Clinical Considerations for more information.*

## 2. Documentation

- Complete the PrEP-PEP Provider Ad-hoc form.
- Nurse to complete PrEP-PEP Nursing Ad-hoc form.

## 3. Medication Adherence Counseling

If more than one dose was missed in the past seven days, provide adherence counseling. It's important to discuss the following:

- How the patient has remembered to take the doses the patient did take (strengths-based approach).
  - “What helps you remember to take your pill?” and “What challenges do you experience in taking the pill?”
- Have the patient identify techniques for not missing future doses (timer on phone, pill box, incorporating it into another routine or at a particular time of day).
  - “What might help you take your pills more regularly?”
  - “What keeps you motivated to take the PrEP pills?”
  - “What, if anything, might help make taking PrEP even easier?”
- If a dose is missed, patients should be informed to take the single missed dose as soon as they remember it, unless it is almost time for the next dose. If it is time for the next dose, patients

should skip the missed dose and continue with the regular dosing schedule. Doubling of dosing should not occur.

#### 4. Risk Reduction Counseling – Engage in a strengths-based patient-centered counseling session.

Opener: “Let’s talk for a few minutes about what it’s been like taking PrEP since your last visit and your sexual health.”

Other prompts:

- What has been going on for you sexually since your last visit?
- In what ways has substance use impacted your risk activity?
- How does taking PrEP impact your risk activity?
- Has taking PrEP changed what you do to protect yourself from HIV/STIs?
  
- For example: topping (insertive anal intercourse) vs. bottoming (receptive anal intercourse)? Condom use?
- Discussions about HIV/STI status and/or testing with partners?

#### 5. Substance Use and Mental Health Referrals

If the patient screens positive for potential substance use disorder, refer the patient to services- (see [Referrals-Substance Use Resources](#)).

If the patient screens positive for potential mental health problems (reports “several days” on one or more of the questions), refer to mental health (see [Referrals-Mental Health](#)).

#### 6. Transition to Primary Care

- Develop a plan with the patient for when they can transition to primary care and determine the level of support the clinic needs to provide (calling the accepting PCP with the patient’s permission, giving copies of labs, etc.).
  - If the patient has not had a regular PCP or is concerned that they cannot get PrEP from the PCP, provide the patient with at least three options of clinics that may be well suited to them.
  - DHSP will provide a list of PrEP Centers of Excellence (DHSP-funded PrEP/PEP clinics) and DHS clinics that will accept these patients.
  - Complete the PrEP referral form and referral process, which includes CHS clinic staff contacting the referral site to provide them with the patient’s contact information and schedule an appointment. Patients will be given the clinic’s name, address, and phone number, which they should call to schedule an appointment. The patient appointment should be scheduled for no later than **2 weeks** from their last appointment at a sexual health clinic.

#### 7. Laboratory Testing – None at this visit.

#### 8. Medication

Patients will only receive a 14-day supply of PrEP at this visit and will be instructed to present to the clinic where they were referred within 2 weeks of the last visit to the sexual health clinic.

## PrEP Referral/Transition to Primary Care

---

Patients who do not have a primary care provider, are uninsured, or are underinsured (meaning that they have insurance, but their out-of-pocket costs for PrEP make it unaffordable) can be referred to a PrEP Center of Excellence, which can be found at <http://getprepla.com/centers-of-excellence/>. These clinics provide an array of services, including primary care, PrEP, post-exposure prophylaxis (PEP), adherence counseling, insurance enrollment, and referrals for mental health and substance use services. In addition to these clinics, the Los Angeles County Department of Health Services also provides PrEP services through the Rand Schrader and Maternal, Child, and Adolescent (MCA) clinics at the LAC-USC Medical Center.

During the PrEP New Patient Visit, **all** patients should be assessed for insurance status and informed that they will be referred to a PrEP Center of Excellence, DHS clinic, or their primary care provider to continue PrEP services within a primary care medical home. Patients will be provided a list of nearby clinics to discuss with the medical provider. Once a referral site has been chosen, a clinic team member will complete the PrEP referral form, schedule a follow-up appointment with the referral site, and provide the patient with a copy of the PrEP referral form with an appointment date and time of appointment listed.

## PrEP Schedule and Other Assessments

**Table 1. PrEP Schedule of Clinical and Laboratory Evaluations and Other**

	PrEP Initiation Visit	1 month Visit *
<b>Risk Assessment</b>		
HIV Risk Behaviors	X	X
<b>HIV Diagnostic</b>		
HIV Testing (4th gen or VL)	X	
<b>STD Diagnostic</b>		
Urine GC/CT	X	
Rectal GC/CT	X	
Pharynx GC	X	
Vaginal GC/CT	X	
Serum RPR	X	
HBsAg	X	
HBsAb	X	
HCV Antibody	X	
<b>Safety Labs</b>		
Creatinine	X	
Urine Pregnancy	X	
<b>Interventions</b>		
Meds Dispensed/Rx	X	X
Adherence Counseling	X	X
Risk-reduction Counseling (brief)	X	X
Referral to Services: (Intensive Risk-Reduction, Substance Use, Mental Health)	X <sup>a</sup>	X <sup>a</sup>
Vaccination (if indicated)	X	X
<sup>a</sup> if indicated based on risk assessment. * optional visit, only if additional time is needed to transition the patient		

## PrEP Service Delivery Checklist

---

### PrEP Initiation Visit Checklist

(Complete *PrEP Ad-hoc forms - and Sexual Health Form in ORCHID if not completed in past four weeks*)

- \_\_\_\_\_ Obtain past medical history. Query specifically about history of kidney and liver (e.g., hepatitis B) disease, bone disease, and fractures. For women or persons who are able to get pregnant and that are of childbearing age, assess pregnancy desires.
- \_\_\_\_\_ Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- \_\_\_\_\_ Order all laboratory results to assess for contraindications. If laboratory tests were performed, review at this visit.
  - HIV Viral Load
  - STD (GC/CT, RPR) (if not performed in the last month)
  - Serum Creatinine to calculate CrCl
  - HBsAg and HBsAb and HCV Ab
  - Check patient weight for CrCl
  - Pregnancy test (if applicable)
- \_\_\_\_\_ PrEP education/counseling with patient; ask questions to elicit patient understanding. Ensure all questions are answered regarding substance use and mental health needs and that referrals are made as appropriate.
- \_\_\_\_\_ Provide bottle of PrEP (#30 tabs) or write prescription for one-month supply.
- \_\_\_\_\_ Review the importance of regular clinic follow-up and ask the patient about the best method of communication for reminders (call, email, text). Schedule follow-up visit for 1-month and provide PrEP services appointment card PRN.
- \_\_\_\_\_ Start Hepatitis B vaccine series, administer meningococcal and HPV vaccinations, as indicated.
- \_\_\_\_\_ Review any lab results after the visit, as needed, and calculate CrCl. If the patient is HIV positive or CrCl<60, call the patient to tell them to stop the medication. Make appropriate arrangements for follow-up based on the patient's needs.
- \_\_\_\_\_ Discuss transition to non-STD clinic medical provider or PCP for ongoing PrEP. Share a list of PrEP providers with patients and tell them to schedule an appointment.

### 1 Month Follow-Up Appointment Checklist – OPTIONAL VISIT

(Complete *PrEP Ad-hoc Form and paper PrEP Referral Form*)

- \_\_\_\_\_ Assess the following at this visit
  - Patient's desire to continue PrEP
  - Side effects
  - Adherence
  - Signs/symptoms of acute HIV infection.
  - Possibility of pregnancy
- \_\_\_\_\_ Provide 14-day supply of PrEP (#14 tabs) or write prescription for one-month supply.
- \_\_\_\_\_ Transition patient to primary care for PrEP (see *PrEP Referral Form for more information*).

## PrEP On-Demand

---

### Also Known As PrEP 2-1-1 Regimen

Intermittent or “On Demand” PrEP, also known as the 2-1-1 regimen, is a non-daily PrEP regimen in which a person takes Tenofovir Disoproxil Fumarate (TDF)/Emtricitabine (FTC) prior to planned sexual intercourse. Specifically, this process requires that the patient take 2 pills of TDF/FTC within 2 – 24 hours prior to first sexual intercourse, then 1 pill every 24 hours during the period of sexual activity with one pill after the last sexual intercourse, and one last pill 24 hours later. This strategy has been studied in MSM in two key trials, IPERGAY and Prévenir, which showed high preventive efficacy of 86% and 99%, respectively. A recent study evaluating the use of 2-1-1 among patients in a clinical practice setting (Kaiser Permanente San Francisco) in 279 patients found no new HIV infections among patients using 2-1-1. The Centers for Disease Control and Prevention (CDC), International Antiviral Society-USA, and the World Health Organization have endorsed the use of 2-1-1 for MSM who engage in infrequent sexual intercourse. As the FDA has not approved this dosing, it is considered “off-label” dosing; however, CDC has issued clear guidance on its use, which is summarized below:

- Clinicians who elect to provide the 2-1-1 regimen should prescribe no more than **30** pills without follow-up and documentation of another negative HIV test. Patients having sex less than once weekly will have sufficient medication to cover up to 7 intermittent sexual events.
- 2-1-1 should be offered to **MSM only**, as this regimen has only been studied in MSM. There is also concern that masculinizing hormones (i.e., testosterone) and feminizing hormones (i.e., estradiol) may decrease levels of TDF/FTC in the bloodstream when it is given intermittently, so daily or injectable PrEP are the preferred strategies for transgender people.
- As TDF/FTC was studied for use as 2-1-1, it is the only medication that should be used for this purpose. Tenofovir alafenamide/Emtricitabine should **not** be prescribed for 2-1-1 due to the lack of published efficacy data regarding this regimen.
- 2-1-1 should not be prescribed to MSM with active hepatitis B due to concern for flare.

### Discussing 2-1-1

For MSM only, 2-1-1 should be discussed as an option. Particular emphasis should be placed on this option for MSM who meet at least one of the below criteria:




- Not having sex regularly
- Ability to plan when having sex (Ex. Long distance relationship, seeing a partner once a month, and not having sex with other partners in-between visits)
- Concern for long-term side effects of taking PrEP daily
  - NOTE: Although no data supports this concern, it has been raised in studies and real-world clinical settings.
- Concern for the ability to adhere to daily PrEP

## The “2-1-1” Schedule for Taking PrEP On-Demand






### How to take PrEP On-Demand?

If patient has sex **on one calendar day**, they should take:

- 2 pills at least 2 to 24 hours before sex.
- 1 pill 24 hours after the first dose.
- 1 pill 24 hours after the second dose.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		<b>SEX @ 8:00 PM</b>  Take no later than 6:00 pm.	 Take 24 hours after <u>first</u> dose.	 Take 24 hours after <u>second</u> dose.		

**If patient is going to have multiple sexual exposures**, they should continue to take a single PrEP pill every 24 hours until they have taken two additional doses, 24 hours apart, after their last sexual exposure. (See example below.)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
<b>SEX @ 9:00 PM</b>  Take no later than 7:00 pm.	<b>SEX (anytime)</b>  Take 24 hours after <u>first</u> dose.	<b>SEX (anytime)</b>  Take 24 hours after <u>second</u> dose.	 Continue to take 24 hours after <u>last</u> dose.	 Take <u>final</u> dose 24 hours after last dose.		

**Note:** PrEP On-Demand should only be used for spontaneous, planned sex. If patient is using PrEP On-Demand regularly, consider discussing Daily PrEP as an option to increase their protection against HIV.

For more information, see the [PrEP Options That Fit Your Sex Life](#) Fact Sheet (Aug 2022).



## PEP Schedule and Other Assessments

**Table 2. PEP Schedule of Clinical and Laboratory Evaluations and Other**

	PrEP Initiation Visit	1 month Visit
<b>Risk Assessment</b>		
HIV Risk Behaviors	X	X
<b>HIV Diagnostic</b>		
HIV Testing (4th gen or VL)	X	X
<b>STD Diagnostic</b>		
Urine GC/CT	X	
Rectal GC/CT	X	
Pharynx GC	X	
Vaginal GC/CT	X	
Serum RPR	X	
HBsAg	X	
HBsAb	X	
HCV Antibody	X	
<b>Safety Labs</b>		
Creatinine	X	
Urine Pregnancy	X	
<b>Interventions</b>		
Meds Dispensed/Rx	X	X
Adherence Counseling	X	X
Risk-reduction Counseling (brief)	X	X
Referral to Services: (Intensive Risk-Reduction, Substance Use, Mental Health)	X <sup>a</sup>	X <sup>a</sup>
Vaccination (if indicated)	X	X
Progress on Transition to Primary Care	X	X
<sup>a</sup> if indicated based on risk assessment.		

## PEP Service Delivery Checklist

---

### PEP Initiation Visit Checklist

- \_\_\_\_\_ Perform an HIV risk assessment to determine whether PEP is indicated for the patient. ( $\leq$  72 hours since substantial HIV exposure)
- \_\_\_\_\_ Provide basic education about PEP. (Refer to Basics of PEP document)
- \_\_\_\_\_ Obtain past medical history. Query specifically about history of kidney and liver (e.g., hepatitis B) disease, bone disease, and fractures. For women or persons who are able to get pregnant and are of childbearing age, assess pregnancy desires.
- \_\_\_\_\_ Review current and recent symptoms. Assess for symptoms of acute HIV infection.
- \_\_\_\_\_ Order all laboratory tests below:
  - HIV test: 4<sup>th</sup> generation Ag/Ab test
  - STD (GC/CT urine or vaginal, GC/CT rectum, GC pharynx, RPR)
  - BUN
  - Serum Creatinine to calculate CrCl
  - HBsAg, HBsAb, HBcAb, and HCV Ab
  - Check patient weight for CrCl
  - Pregnancy test (if applicable)
- \_\_\_\_\_ Order and dispense Tenofovir disoproxil fumarate (#30 tabs) + Raltegravir (#60 tabs)
- \_\_\_\_\_ Provide PEP education/counseling to patient; ask questions to elicit patient understanding.
- \_\_\_\_\_ Emphasize the importance of adherence to medication and return to the clinic at 1 month for a repeat HIV test. Inform the patient that they will be notified if their initial HIV test returns positive, which would require changing their medications from PEP to HIV treatment.
- \_\_\_\_\_ Order 1-month follow-up visit
- \_\_\_\_\_ Start Hepatitis B vaccine series, administer meningococcal and HPV vaccinations, as indicated.
- \_\_\_\_\_ Review any lab results after the visit, as needed, and calculate CrCl. If the patient is HIV positive or CrCl $<$ 60, call the patient to tell them to stop the medication. Make arrangements for follow-up based on the patient's needs. Work with DHSP and PHI to link patients to care ASAP.

### 1- and 3-Month Follow-Up Appointments

- \_\_\_\_\_ Assess the following at this visit:
  - Patient's risk behavior and desire to start PrEP
  - Medication adherence over the past month
  - Signs/symptoms of acute HIV
  - Possibility of pregnancy (if applicable)
- \_\_\_\_\_ Order all laboratory tests below:
  - HIV test: 4<sup>th</sup> generation Ag/Ab test
  - STD (GC/CT urine or vaginal, GC/CT rectum, GC pharynx, RPR)
  - Serum Creatinine (1 month only)

- \_\_\_\_\_ If the patient is interested in starting PrEP, provide basic education about PrEP (Refer to Basics of PrEP document).
- \_\_\_\_\_ Order and dispense Tenofovir disoproxil fumarate (#30 tabs)
- \_\_\_\_\_ Initiate referral to primary care or PrEP Center of Excellence.

## 6 Month Follow-Up Appointment

- \_\_\_\_\_ Assess the following at this visit:
  - Patient's risk behavior and, if not previously started on PrEP, desire to start PrEP
  - Medication adherence over the past month
  - Signs/symptoms of acute HIV
  - Possibility of pregnancy (if applicable)
- \_\_\_\_\_ Order all laboratory tests below:
  - HIV test: 4<sup>th</sup> generation Ag/Ab test – ***if patient is on PrEP OR if patient with + HCV Ab, as HCV can delay HIV seroconversion***
  - STD (GC/CT urine or vaginal, GC/CT rectum, GC pharynx, RPR) – based on risk
- \_\_\_\_\_ If patient is interested in starting PrEP, order and dispense Tenofovir disoproxil fumarate (#30 tabs)

## Initiate referral to primary care or PrEP Center of Excellence



# Section 3: Clinical Considerations and Referrals



## Management of Suspected Acute Seroconversion (Acute HIV)

Signs and symptoms of acute HIV are listed below in Table 2. Should a patient taking PrEP present with signs and symptoms consistent with acute HIV, this should trigger an immediate referral to HIV specialty care for appropriate evaluation. Providers should also order an HIV viral load at the time of the visit. PrEP medications should be continued pending the return of laboratory tests and expert clinician guidance.

Common Symptoms of Acute HIV
Fever
Fatigue
Rash
Headache
Lymphadenopathy
Pharyngitis
Myalgia or arthralgia
Nausea, vomiting, or diarrhea
Night sweats

During regular business hours, Monday - Friday, the *UCSF Clinician Consultation Center PrEPline (855-448-7737)* is available to answer a range of questions for clinicians regarding PrEP management. DHSP Medical Directors and Associate Medical Directors are also available for PrEP questions.

## Management of Patients with Recent High-Risk Exposure

---

Persons not currently on PrEP who seek care within 72 hours after an isolated sexual or injection-related HIV exposure should be evaluated for the potential need for non-occupational post-exposure prophylaxis (nPEP).

If such exposures occur on a regular basis, and the person is determined not to have HIV infection, clinicians should begin PrEP immediately because PrEP during the first 28 days is equivalent to a recommended PEP regimen. If the exposure is an isolated event, such as sexual assault or condom failure, PEP should be prescribed, but PrEP is not indicated after completing the 30-day PEP course.

If the patient presents to the clinic **within** 72 hours of their high-risk exposure and your clinic currently offers PEP\*, complete order the following labs:

- HIV Viral load
- STD (GC/CT, RPR)
- Serum Creatinine
- HBsAg, HBsAb, HBcAb
- HCV Ab
- Pregnancy test (if applicable)

- Prescribe a 30-day course of PrEP + Raltegravir while the labs are pending. **Administer the first dose of PEP while the patient is in the clinic.**
- When the labs return, check for any contraindications, including positive HIV test and renal dysfunction (CrCl < 60).
- Have the patient return in 1 month for evaluation. Complete the same tests as the 1 month PrEP visit.
- Discuss the potential need for PrEP.

If the patient presents to the clinic **outside** 72 hours of a high-risk exposure, complete a routine STD clinic visit and assess eligibility for PrEP.

Persons who repeatedly seek nPEP should be evaluated for possible PrEP use after confirming they have not acquired HIV infection. Because HIV infection has been reported in association with exposures soon after an nPEP course, daily PrEP may be more protective than repeated episodes of nPEP.

## Adverse Drug Reactions

---

Patients taking PrEP should be informed of side effects among HIV-uninfected participants in clinical trials. In these trials, side effects were uncommon and usually resolved within the first month of taking PrEP (“start-up syndrome”). Clinicians should discuss the use of over-the-counter medications for headaches, nausea, and flatulence should they occur. Patients should also be counseled about signs or symptoms that indicate a need for urgent evaluation (e.g., those suggesting possible acute renal injury or acute HIV infection).

In the event of intolerance, including but not limited to rash, nausea, vomiting, clinical jaundice, or abdominal pain, an “unscheduled visit” should be made in which a directed clinical assessment and laboratory evaluations including creatinine, liver function tests, and complete blood count with differential are performed.

If patients develop symptoms of intolerance after hours, they will be primarily addressed by the CHS clinician on-call. During regular business hours, the *UCSF Clinician Consultation Center PrEPline (855-448-7737)* is available to answer a range of questions for clinicians regarding PrEP management.



## Patients with Abnormal Kidney Functions

---

Patients initiating PrEP for the first time should have their creatinine tested after taking PrEP for 3 months and, if creatinine is stable, every 3-6 months after that. No patient receiving PrEP through CHS STD clinics should go longer than 6 months without having a creatinine test.

When checking kidney function, use the following online calculator for calculating CrCl: <http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault>

### Before PrEP Initiation

Before PrEP initiation, if CrCl < 60, Patients with CrCl < 60 should have the test repeated. Assess the use of potentially nephrotoxic medications (NSAIDs, acyclovir, valacyclovir) and bodybuilding substances (creatine, protein drinks). If repeat CrCl is  $\geq 60$ , the patient may start PrEP. If not, the patient will probably need to access PrEP through their PCP.

### After PrEP Initiation

If after initiation of PrEP, the CrCl < 60, PrEP should be discontinued immediately, and the creatinine should be repeated in 2-4 weeks. If the CrCl is  $\geq 60$ , may restart PrEP and check creatinine in 1 month.

If creatinine is greater than 1.5x baseline (but CrCl is still  $\geq 60$ ), discuss with the patient to see if there are any other potential causes for the creatinine elevation (e.g., dehydration, bodybuilding supplements, new medications, NSAIDs) and repeat creatinine in 2 weeks. If creatinine elevation is sustained, discontinue PrEP for 2-4 weeks and recheck creatinine. If creatinine has normalized, may restart PrEP and check creatinine in 1 month.

Patients who want to be on PrEP but have elevated creatinine should be referred to a nephrologist for further evaluation (usually done through the patient's PCP).

During regular business hours, the *UCSF Clinician Consultation Center PrEPline (855-448-7737)* is available to answer a range of questions for clinicians regarding PrEP management.

## Patients with Chronic Active Hepatitis B Infection

---

The two drugs in PrEP, TDF, and FTC, are each active against both HIV infection and HBV infection and thus may prevent the development of significant liver disease by suppressing the replication of HBV. Therefore, patients with chronic HBV infection should be encouraged to receive PrEP in a primary care setting, where liver function can be monitored both during PrEP use and after any PrEP interruptions, and where comprehensive HBV management can occur.

## Hepatitis C Treatment

---

For patients with hepatitis C, referral to a primary care provider is an essential first step so that the patient can get additional testing (including genotyping and ultrasound) to help determine the need for referral and treatment.

## Women's Health While on PrEP

---

### Referrals for Contraception

Per standard CHS procedure, women and persons who are able to get pregnant who need contraception should be referred either to their PCP, to DHS Family Planning through DHS, or other Title X family planning clinics. PrEP is permitted during pregnancy by the FDA and perinatal antiretroviral treatment guidelines<sup>2,3</sup>. No adverse effects have been found among infants exposed to TDF/FTC as part of a treatment regimen for pregnant women or pregnant persons with HIV or during breast(chest)feeding. However, the long-term safety of PrEP taken by women who are HIV negative after fetal (during pregnancy) or infant (during breast(chest)feeding) exposure is not yet determined. For this reason, patients who are pregnant or wish to become pregnant while taking PrEP should be encouraged to receive PrEP in a primary care or OB/GYN clinical setting, where more detailed evaluation and discussion about the potential benefits and risks of PrEP can occur.

## Adolescent Minors

---

As of May 25, 2018, Truvada as PrEP was FDA-approved for adolescent minors (youth under the age of 18). Although adolescents can consent for HIV and STD screening and treatment, including PrEP, we think it necessary to refer these youth to clinics specializing in pediatric and adolescent medicine. Please refer youth under 18 years old who may be suitable for PrEP and/or other youth-friendly and LGBT-friendly medical services to Children's Hospital LA or the Maternal, Child, and Adolescents Clinic at Los Angeles County – University of Southern California (see LAC PrEP Directory, available at [www.gretprepla.com](http://www.gretprepla.com)).

## **Mental Health Referral**

---

Ask patients about their health insurance status. If they are insured, their insurance likely provides some degree of mental health coverage, and their insurance card will include a number for them to call (which may be noted as behavioral health).

For other cases, including uninsured patients, call the LA County Department of Mental Health's Access Center, available 24/7 at 1-800-854-7771. You can also search their online service locator.

## **Substance Use Treatment Referral**

---

Ask patients about their health insurance status. If they are insured, their insurance likely provides some degree of substance use treatment coverage, and their insurance card will include a number for them to call (which may be noted as behavioral health).

For other cases, including uninsured patients, call LA County's Substance Abuse Prevention and Control Program's Number (800)-564-6600 and can find additional resources at <http://publichealth.lacounty.gov/sapc/findtreatment.htm>

## Adherence Counseling

Patients should be asked about adherence during each visit over the past four days. Regardless of the number of missed doses, the provider should first encourage the patient about the doses they did to remember to take (strengths-based approach) prior to asking additional questions about missed doses. Below is an example of this conversation:

<b>Provider:</b> Mr. Roberts, how many doses of PrEP have you missed in the past week?
<b>Patient:</b> I think I may have missed two doses last week.
<b>Provider:</b> So, you were able to take 5 doses over the past week. That’s definitely to be commended. Life happens, which can make it difficult to remember to take medication sometimes. How were you able to remember to take those doses?
<b>Patient:</b> I took the pill with breakfast each morning during the week, but on the weekends, I wake up much later and sometimes miss breakfast altogether.
<b>Provider:</b> I see, so the weekends are when you forget because of a change in your routine. How do you think you might be able to remember? ***
<b>Patient:</b> I will try setting an alarm on my phone.
<b>Provider:</b> Sounds good, I’ll check in with you again at our next visit.

Alternatively, the provider could offer recommendations of ways to remember, but allowing the patient to brainstorm ways to address the problem may increase “buy-in” through their own idea generation. Adherence plans should be a joint decision between providers and patients, ensuring that the plan fits into the patient’s everyday way of living.

## Broken Appointments

“Broken appointments” may take the form of the following:

- Patient misses any follow-up appointments and is unable to be reached for rescheduling.
- Patient does not pick up medications from a dispensary.
- Patient does not complete the required lab testing within 2 weeks of ordering.

For patients who meet one of the criteria above

- PrEP clinic staff to check-in, reschedule, and remind patients to obtain labs or medications or come in for their scheduled appointment.
- If a patient missed an appointment, ask them to come in for laboratory testing to be performed before their next appointment (if possible) to reduce delays in medication refill.
- One 30-day supply will be dispensed in the absence of labs or appointments, but if the patient fails to complete the scheduled task within 6 weeks, no additional refills will be dispensed.

# Section 4: Charting



# Forms

All patients seen for PrEP services should have the following forms completed:

## PrEP-PEP Ad-Hoc Form – Nursing – complete at every visit

The screenshot shows a medical charting interface for a patient named ZZZZTEST, ADULTPUMPSEVENTEEN. The form is titled "Pre Exposure Prophylaxis (PrEP)/Post Exposure Prophylaxis (PEP) History". It includes a navigation menu on the left with "PrEP History" and "PrEP Transition". The main form area contains several questions and checkboxes:

- Has client ever taken PrEP:** Radio buttons for Yes and No.
- How many times has the patient taken PrEP?** A text input field.
- Is patient interested in taking PrEP?** Radio buttons for Yes and No.
- If not interested in PrEP, why not:** Checkboxes for Don't need, Don't know about it, Concern about other's judgement, Afraid of side effects, and Other.
- How was PrEP administered?** Radio buttons for Prescribed, Dispensed, and No.
- How did you find out about PrEP?** Checkboxes for PrEP Advertisement, Social media, Community event, Online Dating app (Hook Up App) or Casual Encounter Dating App, Friend/word of mouth, and STD Clinic.
- Has client ever taken PEP:** Radio buttons for Yes and No.
- How many times has the patient taken PEP?** A text input field.
- Is patient interested in taking PEP?** Radio buttons for Yes and No.
- If not interested in PEP, why not:** Checkboxes for Don't need, Don't know about it, Concern about other's judgement, Afraid of side effects, and Other.
- Was PrEP discussed with any partner?** Radio buttons for Some, All, and None.

### PrEP Ad-Hoc Form – Provider – complete at every visit

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

\*Performed on: 10/17/2018 1846 PDT

**PrEP Contraindications/ Counseling**

**Possible Contraindication Checklist:**

	Yes	No
Signs of acute HIV	<input type="checkbox"/>	<input type="checkbox"/>
History of Liver Disease	<input type="checkbox"/>	<input type="checkbox"/>
History of Kidney Disease	<input type="checkbox"/>	<input type="checkbox"/>
Pregnant?	<input type="checkbox"/>	<input type="checkbox"/>

**PrEP Counseling Checklist:**

- Labs reviewed
- Vaccination history reviewed
- Awareness of Acute HIV Infection (AHI) symptoms and plan
- Importance of PrEP adherence
- Potential risk-side effect of PrEP
- Plan for follow up visits and labs
- PrEP clinic discontinuation procedures

**Reminder: Complete Clinic intake on this visit unless completed within the last 4 weeks**

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

\*Performed on: 10/17/2018 1846 PDT

**Transition to Primary Care Provider (PCP)**

**Referred:**

- PCP for PrEP
- PrEP "Center Of Excellence"

**Reason for not referred:**

- Uncomfortable with PCP
- No PCP established
- PCP will not prescribe
- Uninsured
- Discontinued use
- DHSP approved

**Reminder: All patients should be transitioned to PCP or Center of Excellence within 8 weeks**

PrEP-PEP Provider - ZZZZTEST, ADULTPUMPSEVENTEEN

\*Performed on: 10/17/2018 1846 PDT

PrEP Contraindica  
PrEP Transition  
**PrEP Treatment**

**PrEP Treatment**

**Date of Last PrEP Use:**

**Place Order: "Clinic Follow Up"**

**Side Effects**

**In the last 7 days, how many days did client take PrEP medication? \_\_dose(s) out 7 doses**

**How many pills left since last visit? \_\_pill(s)**

**Creatinine Clearance**

**Creatinine Clearance Date**

**Notes**



# Section 5: On the Horizon – Advances in PrEP Delivery



## **Injectable PrEP**

---

Cabotegravir, an integrase inhibitor that is currently used for HIV treatment, has been studied for use as PrEP monotherapy. Dr. Raphael Landovitz, Associate Professor of Medicine at UCLA, 2qw the principal investigator for these studies. Safety trials were completed and positive, showing that the gluteal injection (which is how the medication would be administered) caused injection site pain, but no major safety concerns. Safety trials also demonstrated that the medication remained above the threshold of maximum effectiveness for 8 weeks. The medication used every 8 weeks received [FDA approval in December 2021](#) as the first injectable option for the prevention of HIV.

# LA County Resources



## Division of HIV and STD Programs (Website)

---

Visit the Division of HIV and STD Programs (DHSP) website at [www.publichealth.lacounty.gov/dhsp/](http://www.publichealth.lacounty.gov/dhsp/) for program updates, health education materials, resources, and information on HIV, STDs, and PrEP/PEP.

### For You

This section is for patients/clients. They can find information on HIV and the most common STDs and associated diseases, including HIV and STD prevention information, frequently asked questions, help to talk to partners about HIV and STDs, information by population, information by disease, and more.

<http://publichealth.lacounty.gov/dhsp/InfoForYou.htm>

### For Health Care Providers

In this section, health care providers can find information on clinical practice alerts, health service alerts, and links that are designed to be helpful in the care and treatment of your patients.

<http://publichealth.lacounty.gov/dhsp/InfoForProviders.htm>

### For DPH Sexual Health Clinics

In this section, staff can find information and resources for the Los Angeles County Department of Public Health Sexual Health Services. Additionally, if you want to receive DHSP updates and access presentations/CMEs, please [click here to join our DHSP HIV/STD Clinical Updates Microsoft Teams Channel](#) or email contacts on the following link.

<http://publichealth.lacounty.gov/dhsp/DPHSexualHealthServices.htm>

### PrEP and PEP

In this section, health care providers and patients can find helpful information and resources pertaining to PrEP and PEP.

<http://publichealth.lacounty.gov/dhsp/PEP-PrEP.htm>

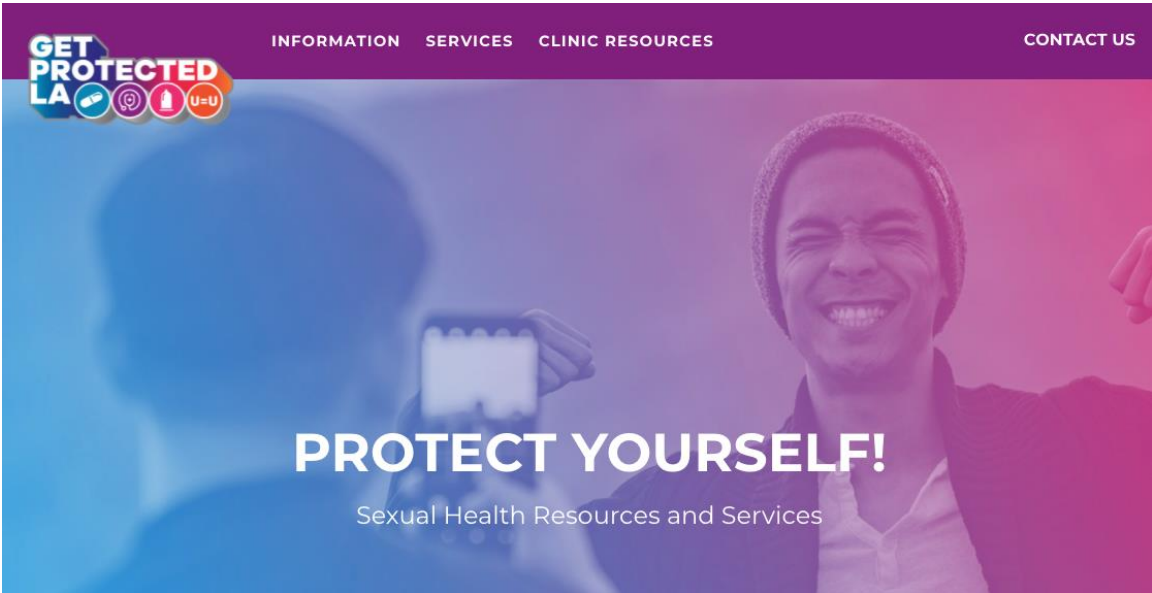
### DHSP Health Education Library

The DHSP Health Education Library is a central hub for DHSP health education materials and resources that are helpful for understanding a variety of HIV/STD topics. Materials and resources are categorized by topics.

<http://publichealth.lacounty.gov/dhsp/HealthEducationLibrary.htm>

## Get Protected LA (Website)

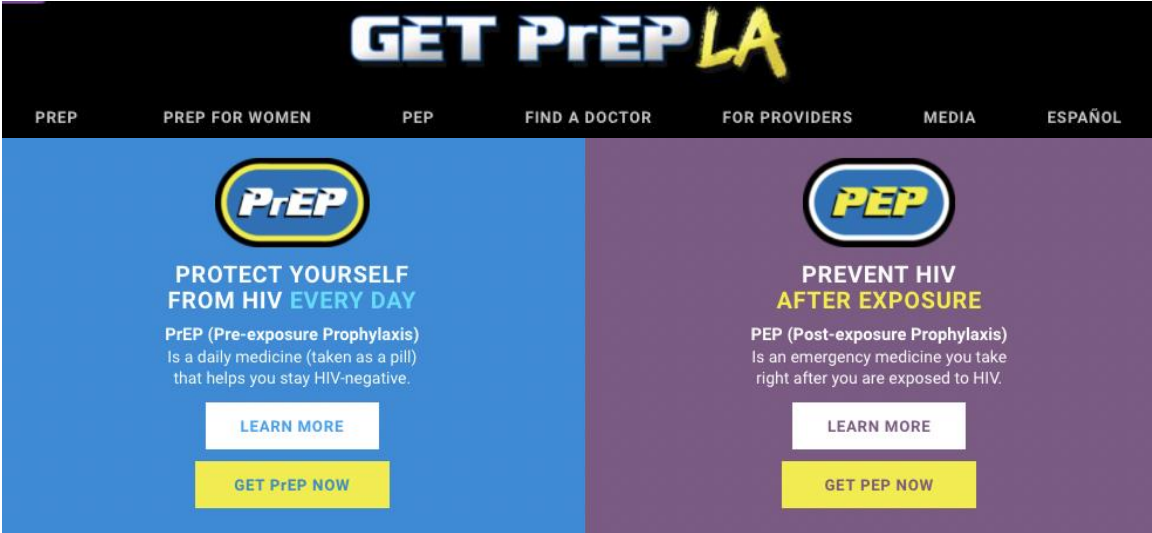
Visit [GetProtectedLA.com](http://GetProtectedLA.com) for more information, services, and resources on HIV and STDs.



## Get PrEP LA (Website)

Visit [GetPrEPLA.com](http://GetPrEPLA.com) for more information on PrEP and PEP.

For questions or concerns regarding PrEP and PEP, please email [prepinfo@ph.lacounty.gov](mailto:prepinfo@ph.lacounty.gov) or call (844) YEA-PREP.



## Rapid and Ready Program (Treatment as Prevention)

### Background

The national initiative, Ending the HIV Epidemic in the U.S. (EHE), focuses on 4 key pillars designed to help DHSP reach the goal of reducing new HIV transmissions in the U.S. by 75% in 5 years (by 2025) and by 90% in 10 years (by 2030).

The 4 EHE Pillars are: (1) Diagnose people living with HIV as early as possible; (2) Treat people living with HIV rapidly and effectively to achieve viral suppression; (3) Prevent new HIV transmissions using proven interventions, and; (4) Respond quickly to HIV outbreaks and deliver prevention and treatment services to people who need them.

The Treat Pillar focuses on treating people rapidly and effectively and includes a linkage to care indicator to measure progress: Increase the proportion of people diagnosed with HIV who are linked to HIV care within one month of diagnosis to 95%. While linkage to care data in LA County demonstrates increasing rates over the past 10 years, improvement is still needed to reach the EHE goal of 95% linkage within 1 month of diagnosis.

### Program Overview

The Rapid and Ready (RAR) Program is designed to promote and support linkage to care within 1 week of a positive HIV test or for persons who are ready to re-engage in care. Using a “status neutral” approach, individuals with a single, positive point of care HIV test are also considered candidates for the RAR Program. In this instance, providers can discuss the rapid ART option with clients and initiate it if appropriate while pending results. In the case that a client is not confirmed as HIV positive, then conversion to PrEP may be the next best step.

The RAR Program has 4 overarching objectives: (1) Reduce treatment delays; (2) Reduce loss to follow-up; (3) Improve health and wellness for people living with HIV; and (4) Reduce HIV transmission by helping people living with HIV achieve an undetectable viral load, known as undetectable equals untransmittable also known as “U=U” Program.

### Referrals from the Department of Public Health CS/CFS

CS/CFS referrals to the RAR Navigation team will be requested through the RAR toll-free number at 833-351-2298 (and follow-up can be done via email at [rapid@ph.lacounty.gov](mailto:rapid@ph.lacounty.gov)). The information below is required, and a representative will call the client once reviewed.

1. Staff name, agency name, and contact number
2. First and last name of the client
3. Client date of birth
4. Client phone number
5. Date of test
6. Date of results were disclosed (A result disclosure must be performed prior to a referral being made unless authorization is obtained)



**Need to see an HIV Provider?**  
**Call the Rapid and Ready Navigation Team**  
833-351-2298



Ending  
the  
HIV  
Epidemic

# References

1. Centers for Disease Control and Prevention (CDC). [Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline.](#)
2. CDC. [A Clinician's Quick Guide: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline.](#)
3. CDC. [Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States--2021 Update: Clinical Provider's Supplement.](#)
4. Clinical Care Options, LLC, March 6-10, 2021. [ANRS Prévenir: ANRS Prévenir: High Efficacy of Daily or On-Demand FTC/TDF PrEP Among Parisian MSM in Interim Analysis of Open-Label Prospective Cohort Study.](#)
5. Food and Drug Administration New Release, December 20, 2021: [FDA Approves First Injectable Treatment for HIV-Pre-Exposure Treatment.](#)
6. [Gilead Sciences. PrEP Package Insert. 2018](#)
7. HPTN 083. [A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine \(TDF/FTC\), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men.](#)
8. Landovitz R et al. New Eng J Med August 12, 2021: [Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women.](#)
9. Molina JM, Capitant C, Spire B, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. N Engl J Med **2015**; 373(23): 2237-46.
10. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. [Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States -- 2014.](#)
11. San Francisco City Clinic. [Pre-exposure Prophylaxis: A Primer for Primary Care Providers.](#)
12. The Body Pro. [PrEP Before and After Sex Worked as Well as Daily PrEP in Preventing HIV, New Study Finds.](#)
13. World Health Organization. [Guidance on oral pre-exposure prophylaxis \(PrEP\) for serodiscordant couples, men, and transgender women who have sex with men at high risk of HIV.](#)

Revised: October 2022