

Biomedical Prevention

Manual of Procedures

DPH - Sexual Health Clinics



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### 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 request PrEP was 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 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 <u>1-month</u>. Once the 1-month is completed, if patient remains HIV negative, can be transitioned to PrEP for 1 month in the DPH sexual health clinic before transition 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 sero-conversion. PrEP involves the use of an antiretroviral pill 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 sometimes, 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:

### **MSM** and Transgender Persons

- Reports an HIV positive sex partner
- Has a history of anogenital bacterial STD diagnosed in the past 12 months
- Has a history of multiple sex partners of unknown HIV status
- Engages in unprotected anal intercourse
- Black and Latino MSM
- Has other risk factors that increase HIV risk
- Has been prescribed post-exposure prophylaxis (PEP) and demonstrates continued high-risk behavior or multiple courses of PEP
- Has other risk factors that increase HIV risk, including transactional sex (such as sex for money, drugs, housing)
- Reports sharing injection equipment such as those used to inject hormones
- Reports intimate partner violence
- Persons who request PrEP

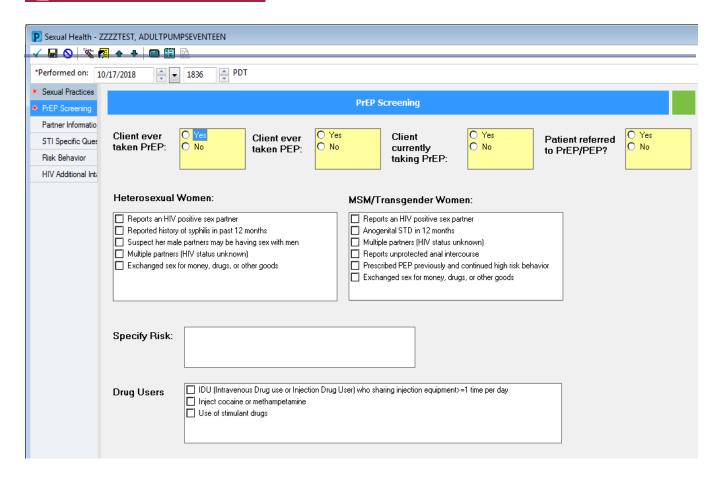
Heterosexual Women	Drug Users
<ul> <li>Reports an HIV positive sex partner</li> <li>History of syphilis diagnosed in the past 12 months</li> <li>Has a male partner who she suspects may be having sex with men or with other women</li> <li>Has other risk factors that increase HIV risk, including transactional sex (such as sex for money, drugs, housing)</li> <li>Persons who request PrEP</li> <li>Reports intimate partner violence</li> </ul>	<ul> <li>Injection drug users who share injection equipment, inject one or more times per day, inject cocaine or methamphetamine, or engage in high-risk sexual behaviors</li> <li>Use of stimulant drugs associated with high risk behaviors, such as methamphetamine</li> <li>Persons who request PrEP</li> <li>Reports intimate partner violence</li> </ul>

PrEP Guidelines for Los Angeles County that describe in more detail who should be considered for PrEP are available at:

http://ph.lacounty.gov/dhsp/Biomedical/LAC\_PrEP\_Guidelines\_2021.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 that appropriate screening and discussions about PrEP occur.

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### **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
- Ruth Temple 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, the 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 for 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 cost. 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 abuse 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> <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> <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
Point of Contact for providers wanting to make referral for PrEP, ensuring warm	Front desk
hand off (via phone)	
Referrals from Community Providers	
Referrals from other DPH clinics	
Point of Contact for patients self-referring for PrEP	Front desk
Answer patient's questions	
Assists in making appointments	
Panel Management	Front desk / Nurse
Patient Tracking	
Calling patients with reminders and for broken appts	
Services as point person for question for PrEP patients	
Adherence Counseling	Provider
Risk Counseling	Provider
Patient Navigation – lead to assist with transition to primary care	Nurse / CHW
Works with patient to assess best plan for transition (existing PCP vs other)	
Communicates with PCP or other provider (providers labs, other	
documentation as needed)	

### **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 on the formulary restricted to PrEP services only. 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 out of 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: <a href="https://www.gilead.com/-">https://www.gilead.com/-</a> /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
- A copy of the <u>"Basics of PrEP"</u> handout should be offered to the patient (available in English and Spanish).

### **PrEP Initiation Visit**

### 1. Medical Assessment

- Obtain a general medical and social history, review of symptoms. Check specifically for:
  - o 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 normal clinic procedures.
- Vaccinations should be provided for clients based on prior vaccination history, vaccine availability and indication:
  - o 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 low likelihood of having acute HIV, have no significant past medical history,
  and no other high likelihood of contraindications (like 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 no Sexual Health ad-hoc form or > 4 weeks since last form completed,
  complete again.

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

- **Start the conversation:** Start with 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 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 that only studies of daily dosing have proven the efficacy of PrEP.
- Takes 7 days for drug levels to reach protective levels for rectal exposures; data suggest for women anticipating vaginal exposure, 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 improves after 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 we will screen you now for kidney problems and you need to have labs including your kidney function checked every few months while you're 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 go back 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 for 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, discuss additional modes of contraception while on PrEP).

### Adherence

- Ask 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, keeping bottles in a visible location associated with a 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,
  and stomach pain as well as 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 (ie, missed several days in a row) and has a high risk exposure, he/she shouldn't restart the medication without coming in for an HIV test to make sure he/she is negative so as 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 patient to recognize symptoms of acute HIV infection. Instruct patient to report immediately to clinic if they develop symptoms compatible with acute HIV infection (fever, fever with sore throat, fever with headache – Rash?).

### Additional Risk-Reduction Counseling

- o 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 patient;
  - Identify short-term and long-term risk reduction plan based on the patient's perceived ability to change his or her 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 <a href="http://publichealth.lacounty.gov/sapc/contactus.htm">http://publichealth.lacounty.gov/sapc/contactus.htm</a>.

### • Follow-up and transition in care

- Confirm a schedule for follow-up in 1 month to assess side effects, adherence, and transition plan.
- o Discuss 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 he/she can transition to primary care and determine the level of support the clinic needs to provide (calling the accepting PCP with patient's permission, giving copies of labs, etc).
  - If the patient has not had a regular PCP or is concerned that he/she cannot get PrEP from the PCP, provide the patient with at least three options of clinics that may be well suited to him/her.
  - DHSP will provide a list of DHSP-funded PrEP/PEP clinics that will accept 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 then 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 patient on PrEP at the initiation visit**. Order HIV viral load and other tests (see Laboratory Results Review) obtain updated cell phone number, and call 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 important to recognize that the patients you are seeing are at **high risk** of HIV infection, so important 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
HIV viral load	If the patient is HIV-infected, PrEP is not right for them because they must receive 3 active HIV medications for treatment. Refer them to HIV medical care.
Creatinine	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 ≥ 60 ml/min (Cockcroft Gault) to safely use tenofovir.  Patients with CrCl<60 should have the test repeated. Assess use of potentially nephrotoxic medications (NSAIDS, acyclovir, valacyclovir) and body building substances (creatine, protein drinks). If repeat CrCl is ≥ 60, patient may start PrEP. If not, patient will probably need to access PrEP through his/her PCP. Creatinine should be documented on the PrEP Provider Ad-hoc form in ORCHID.
Hepatitis B surface antigen	Because PrEP has anti-HBV properties, patients with a positive HBsAg 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.  Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
Hep C Antibody	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 patient has cleared infection (25-30% cases) or has chronic hepatitis C.
Pregnancy test for women	Women wishing to use PrEP during pregnancy should be encouraged to receive PrEP in a primary care or HIV specialty clinic (if being used as part of attempt to become pregnant with an HIV positive partner). Women on PrEP should be counseled and referred for family planning services as an additional form of contraception, in addition to condoms, is highly recommended.

### 1 Month Follow-up Visit

This is an <u>optional</u> 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 normal clinic procedures.
- Vaccinations should be provided for clients based on indication.
- Respond to new questions and provide any new information about PrEP use.
- Provide a prescription or dispense medications for 30 days.
- Discuss plan to transition to another medical provider for PrEP (see #6 below).

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

### 2. Documentation

- Complete 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).
  - o "What might help you take your pills more regularly?"
  - "What keeps you motivated in taking 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 stregnths-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 getting 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 patient screens positive for potential substance use disorder, refer patient to services-(see Referrals-Substance Use Resources).

If patient screens positive for potential mental health problem (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 he/she can transition to primary care and determine
  the level of support the clinic needs to provide (calling the accepting PCP with patient's
  permission, giving copies of labs, etc).
  - If the patient has not had a regular PCP or is concerned that he/she cannot get PrEP from the PCP, provide the patient with at least three options of clinics that may be well suited to him/her.
  - DHSP will provide a list of PrEP Centers of Excellence (DHSP-funded PrEP/PEP clinics) and DHS clinics that will accept these patients.
  - Complete PrEP referral form and referral process which includes CHS clinic staff contacting the referral site to provide them with patient's contact information and schedule an appointment. Patient will be given name, address, and phone number of the clinic which they should call to schedule an appointment. Patient appointment should be scheduled for no later than <u>2 weeks</u> from their last appointment at a sexual health clinic.
- 7. Laboratory Testing None at this visit.

### 8. Medication

Patient 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 last visit at sexual health clinic.

### **Prep Referral/Transition to Primary Care**

Patients who do not have a primary care provider, are uninsured, or 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 <a href="http://getprepla.com/centers-of-excellence/">http://getprepla.com/centers-of-excellence/</a>. 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 abuse 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 which they will 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 a copy of the PrEP referral form with 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 *
Risk Assessment		
HIV Risk Behaviors	Х	Х
HIV Diagnostic		
HIV Testing (4th gen or VL)	Х	
STD Diagnostic		
Urine GC/CT	X	
Rectal GC/CT	X	
Pharynx GC	Х	
Vaginal GC/CT	Х	
Serum RPR	Х	
HBsAg	Х	
HBsAb	Х	
HCV Antibody	Х	
Safety Labs		
Creatinine	Х	
Urine Pregnancy	Х	
Interventions		
Meds Dispensed/Rx	Х	Х
Adherence Counseling	Х	Х
Risk-reduction Counseling (brief)	Х	Х
Referral to Services: (Intensive Risk-Reduction, Substance Abuse, Mental Health)	Xa	Хa
Vaccination (if indicated)	Х	Х
<sup>a</sup> if indicated based on risk assessm * optional visit, only if additional tim		the patient

COUNTY OF LOS ANGELES, DEPARTMENT OF PUBLIC HEALTH 2022 BIOMEDICAL PREVENTION MOP

### **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 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 answered regarding substance abuse 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 importance of regular clinic follow-up and ask 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 vaccine and HPV vaccination, as indicated. Review, as needed, any lab results after the visit, and calculate CrCl. If patient is HIV positive or CrCl<60, call patient to tell him/her to stop the medication. Make appropriate arrangements for follow-up based on patient's needs. Discuss transition to non-STD clinic medical provider or PCP for ongoing PrEP. Share list of PrEP providers with patient and tell them to schedule 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).

### **PEP Schedule and Other Assessments**

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

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

### **PEP Service Delivery Checklist**

<b>PEP Initia</b>	ation Visit Checklist
Per 72 h Pro Obt hep ass Rev Ord	form an HIV risk assessment to determine whether PEP is indicated for patient. (≤ hours since substantial HIV exposure)  vide basic education about PEP. (Refer to Basics of PEP document)  tain past medical history. Query specifically about history of kidney and liver (e.g., patitis B) disease, bone disease, and fractures. For women of childbearing age, ess pregnancy desires.  view current and recent symptoms. Assess for symptoms of acute HIV infection. der all laboratory tests below:  HIV test: 4th 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)  Iter and dispense Tenofovir disoproxil fumarate (#30 tabs) + Raltegravir (#60 tabs)  vide PEP education/counseling to patient; ask questions to elicit patient  Iterstanding.  phasize importance of adherence to medication and return to clinic at 1-month for eat HIV test. Inform patient that they will be notified if their initial HIV test returns initive, which would require changing their medications from PEP to HIV treatment. Iter 1-month follow-up visit rt Hepatitis B vaccine series, administer meningococcal vaccine and HPV cination, as indicated.  view, as needed, any lab results after the visit, and calculate CrCl. If patient is HIV bitive or CrCl<60, call patient to tell them to stop the medication. Make arrangements follow-up based on patient's needs. Work with DHSP and PHI to link patient to care
1- and 3-	Month Follow-Up Appointments
Ord	Patient's risk behavior and desire to start PrEP Medication adherence over past month Signs/symptoms of acute HIV Possibility of pregnancy (if applicable) der 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) atient interested in starting PrEP, provide basic education about PrEP (Refer to sics of PrEP document).

Return to Table of Contents	PrEP/PEP Service Delivery
Order and dispense Tenofovir disoproxil fumarate ( Initiate referral to primary care or PrEP Center of E	·
6 Month Follow-Up Appointment	
Assess the following at this visit:	
☐ Patient's risk behavior and, if not previously started of	on PrEP, desire to start PrEP
☐ Medication adherence over past month	
☐ Signs/symptoms of acute HIV	
☐ Possibility of pregnancy (if applicable)	
Order all laboratory tests below:	
<ul> <li>HIV test: 4<sup>th</sup> generation Ag/Ab test – if patient on Patient on Patient on HCV can delay HIV seroconversion</li> </ul>	rEP OR if patient with + HCV Ab, as
□ STD (GC/CT urine or vaginal, GC/CT rectum, GC pt	harynx, RPR) – based on risk
If patient interested in starting PrEP, order and disp (#30 tabs)	pense Tenofovir disoproxil fumarate
Initiate referral to primary care or PrEP Cei	nter 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 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 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 with 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 completion of 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 clinic.
- When the labs return, check for any contraindications, including positive HIV test and renal dysfunction (CrCl < 60).</li>
- Have patient return in 1 month for evaluation. Complete the same tests as the 1-month PrEP visit.
- Discuss 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 headache, 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 month thereafter. 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 CrCI: <a href="http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault">http://reference.medscape.com/calculator/creatinine-clearance-cockcroft-gault</a>

### **Before PrEP Initiation**

Before PrEP initiation, if CrCl < 60, Patients with CrCl < 60 should have the test repeated. Assess use of potentially nephrotoxic medications (NSAIDS, acyclovir, valacyclovir) and body building substances (creatine, protein drinks). If repeat CrCl is ≥ 60, patient may start PrEP. If not, patient will probably need to access PrEP through his/her 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 ≥ 60, may restart PrEP and check creatinine in 1 month.

If creatinine is greater than 1.5x baseline (but CrCl is still ≥ 60), discuss with the patient to see if there are any other potential causes for the creatinine elevation (e.g., dehydration, body building 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 (this would usually be 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 important 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**

Women who need contraception should be referred either to their PCP, to DHS Family Planning through DHS, or other Title X family planning clinics, per standard CHS procedure. Use of PrEP is permitted during pregnancy by both 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 HIV infected pregnant women or during breastfeeding. However, the long-term safety of PrEP taken by HIV-uninfected women after fetal (during pregnancy) or infant (during breastfeeding) 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 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 important to refer these youth to clinics that specialize 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 <a href="https://www.gretprepla.com">www.gretprepla.com</a>).

### **Mental Health Referral**

Ask patient 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 (may be noted as behavioral health).

For other cases, including uninsured patients, call 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 patient about their health insurance status. If they are insured, their insurance likely provides some degree of substance abuse treatment coverage and their insurance card will include a number for them to call (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 other resources at <a href="http://publichealth.lacounty.gov/sapc/findtreatment.htm">http://publichealth.lacounty.gov/sapc/findtreatment.htm</a>

### **Adherence Counseling**

During each visit, patients should be asked about adherence over the past four days. Regardless of the number of doses missed, 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:

**Provider:** Mr. Roberts, how many doses of PrEP have you missed in the past week?

Patient: I think I may have missed two doses last week.

**Provider:** 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?

**Patient:** 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.

**Provider:** 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?\*\*\*

Patient: I will try setting an alarm on my phone.

Provider: 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 their own 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, as this will ensure 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 appointment and is unable to be reached for rescheduling.
- Patient does not pick up medications from dispensary.
- Patient does not complete 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 patient to obtain labs or medications or come in for their scheduled appointment.
- If patient missed appointment, ask patient 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 absence of labs or appointment, but if the patient fails to complete the scheduled task within 6 weeks, no additional refills will be dispensed.

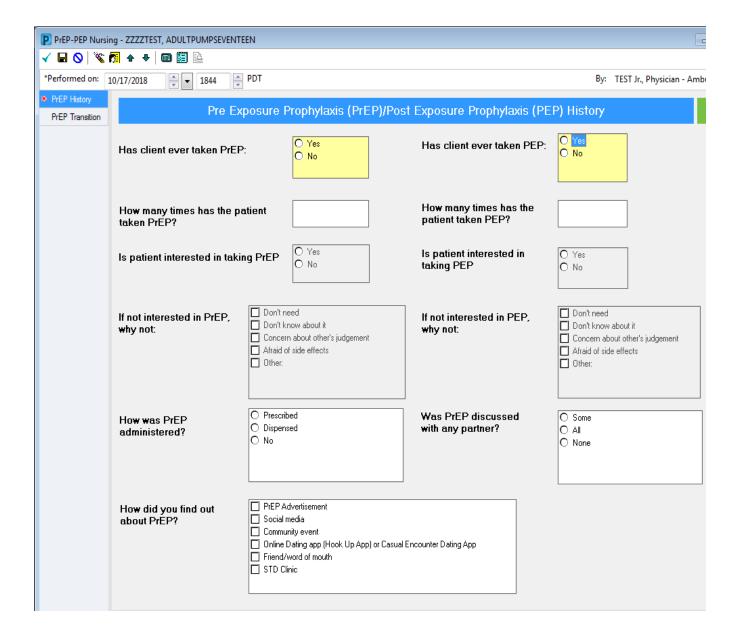
### **Section 4: Charting**



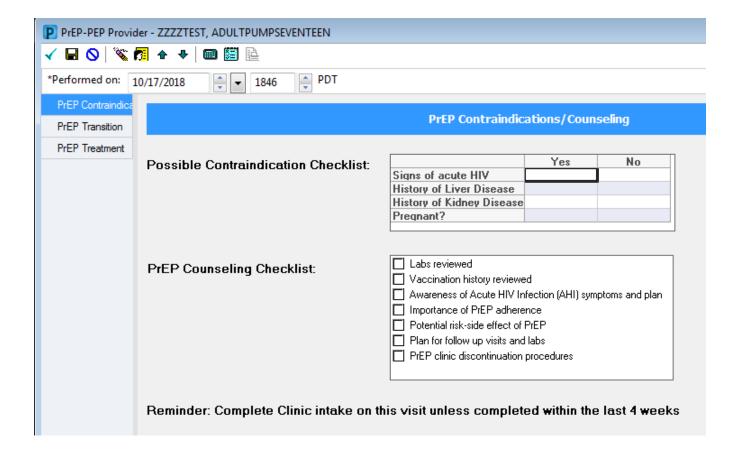
### **Forms**

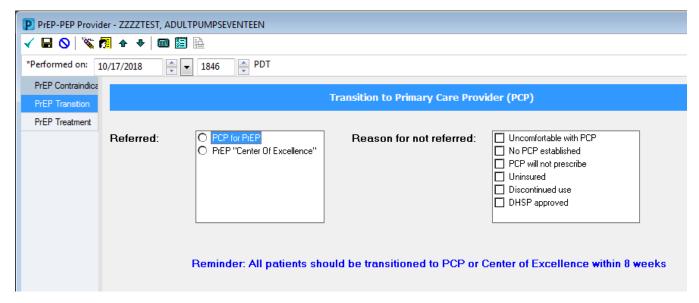
All patients seen for PrEP services should have the following forms completed:

### Prep-Pep Ad-Hoc Form - Nursing - complete at every visit

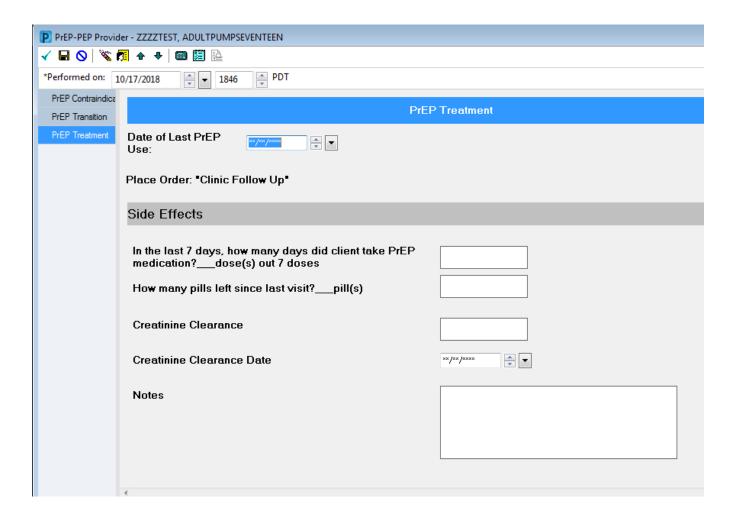


### PrEP Ad-Hoc Form - Provider - complete at every visit





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

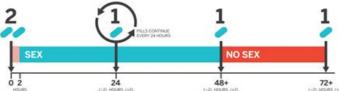


### **Intermittent PrEP**

### Also Known As "On Demand" PrEP (2-1-1) Regimen

Intermittent or "On Demand" PrEP also known as the 2-1-1 regimen, is the process of a person taking Tenofovir/Emtricitabine prior to planned sexual intercourse. Specifically, this process requires that the patient take 2 pills of Tenofovir/Emtricitabine 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 is currently being studied by Jean-Michel Molina, a professor of infectious diseases at University of Paris Diderot. The study period is from May 2017 – May 2020. Dr. Molina provided an update on findings thus far in July 2018 during which he reported that over the entire trial period, among people who adhered to this regimen, there have been 0 new HIV infections and over the study period approximately 85 new cases of HIV have been averted. Currently, on demand PrEP is not approved by the FDA, likely due to the studies still being ongoing, so patients should be encouraged to take PrEP daily for maximum protection against HIV.

## SEX WITHIN 24 HOURS OF THE FIRST DOSE 2 1 1 SEX NO SEX NO SEX SEX BEYOND 24 HOURS AFTER THE FIRST DOSE



For more information, see the <u>San Francisco AIDS Foundations "Taking PrEP 2-1-1 for Anal Sex" flyer.</u>

### Injectable PrEP

Cabotegravir, an integrase inhibitor which 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 have been completed and were 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 has received FDA approval in December 2021 as the first injectable option to for the prevention of HIV.

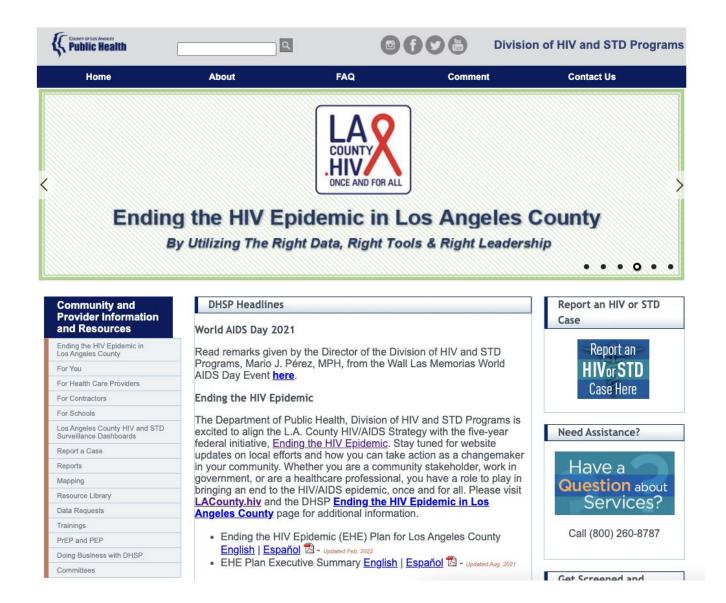
### **LA County Resources**





### **DHSP** (Website)

Visit the DHSP website at <a href="www.publichealth.lacounty.gov/dhsp/">www.publichealth.lacounty.gov/dhsp/</a> for program updates, health education materials, resources, and information on HIV, STDs, and PrEP/PEP.



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### **Get Protected LA (Website)**

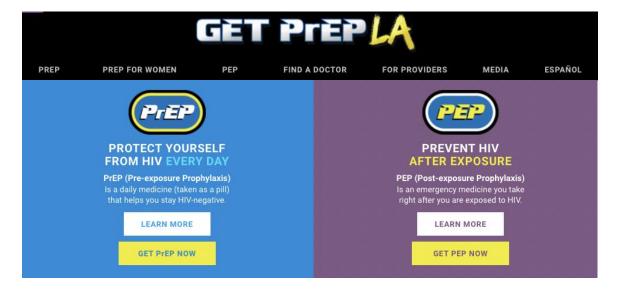
Visit GetProtectedLA.com for more information, services, and resources on HIV and STDs.



### **Get PrEP LA (Website)**

Visit GetPrEPLA.com for more information on PrEP and PEP.

For questions or concerns regarding PrEP and PEP, please email <a href="mailto:prepinfo@ph.lacounty.gov">prepinfo@ph.lacounty.gov</a> 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) <u>Diagnose</u> people living with HIV as early as possible; (2) <u>Treat</u> people living with HIV rapidly and effectively to achieve viral suppression; (3) <u>Prevent</u> new HIV transmissions using proven interventions, and; (4) <u>Respond</u> 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 reengage 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 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, also known as undetectable equals untransmittable also known as "U=U" Program.

### **Referrals from 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 <a href="mailto:rapid@ph.lacounty.gov">rapid@ph.lacounty.gov</a>. The below information is required, and once reviewed, a representative will call the client.

- 1. Staff name, agency name, and contact number
- 2. First and last name of 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





### References

- 1. Centers for Disease Control and Prevention. <a href="Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline">Prevention of HIV Infection in the United States---2021 Update: A Clinical Practice Guideline</a>
- 2. Centers for Disease Control and Prevention. <u>Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States 2017 Update. March 2018</u>.
- 3. Centers for Disease Control and Prevention. <a href="Prevention of HIV Infection in the United States-2014 A Clinical Providers">Prevention of HIV Infection in the United States-2014 A Clinical Providers</a> Supplement. May 2014.
- 4. World Health Organization. <u>Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men, and transgender women who have sex with men at high risk of HIV.</u>
- 5. Gilead Sciences. PrEP Package Insert. 2018;
- 6. 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.
- 7. San Francisco City Clinic. <u>Pre-exposure Prophylaxis: A Primer for Primary Care</u> Providers.
- 8. The Body Pro. <u>PrEP Before and After Sex Worked as Well as Daily PrEP in Preventing HIV, New Study Finds</u>.
- 9. 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.
- 10. Landovitz R et. al. New Eng J Med August 12, 2021: <u>Cabotegravir for HIV Prevention in</u> Cisgender Men and Transgender Women;
- 11. Food and Drug Administration New Release, December 20, 2021: <u>FDA Approves First Injectable Treatment for HIV-Pre-Exposure Treatment.</u>

Revised: April 2022