SANTA CLARA COUNTY PUBLIC HEALTH DEPARTMENT

PrEP PROVIDER TOOLKIT

PRE-EXPOSURE PROPHYLAXIS (PrEP)
RESOURCES FOR HEALTHCARE PROVIDERS
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**FOR PROVIDERS**

**INTRODUCTION TO PrEP FOR HIV PREVENTION**

Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy in which antiretroviral drugs are used to protect HIV-negative people from HIV infection. PrEP (using once-daily Truvada®, the pill approved by the U.S. Food and Drug Administration for PrEP) has the potential to prevent HIV among individuals at very high risk for becoming infected with HIV, and provides individuals, clinicians, and HIV prevention workers with another option for HIV prevention. According to the Centers for Disease Control and Prevention (CDC), when taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by more than 90%. PrEP should be used as part of a comprehensive HIV prevention plan that includes adherence and risk counseling and prevention education.

STD/HIV Prevention & Control within the Santa Clara County Public Health Department is committed to enhancing HIV prevention and control strategies within Santa Clara County; among these strategies, PrEP has gained increasing attention locally and nationally. In August 2015, the California Department of Public Health, Office of AIDS issued a letter in support of the use of PrEP as a “critical first-line intervention” for individuals at high risk. Nationally, the White House released a 2015 update to the National HIV/AIDS Strategy, which includes full access to comprehensive PrEP services as one of the four key areas of critical focus.

**Efficacy**

Studies show that PrEP can reduce the risk of HIV infection in high-risk, HIV-negative people by up to 92% when taken consistently and as prescribed. This is true for both men and women, and for vaginal and anal sex. Adherence to PrEP is essential; clinical trials have shown a positive correlation between adherence and PrEP efficacy.

**Candidates for PrEP**

PrEP is appropriate for high-risk HIV-negative individuals, including men who have sex with men, heterosexual women and men, injection drug users, and transgender individuals. Among these populations, those who are at high risk for HIV infection include people with an HIV-positive sexual partner, a high number of sex partners, a history of inconsistent or no condom use, those who engage in commercial sex work, and those who share injection equipment. Taking a comprehensive sexual history is a useful tool for evaluating a patient’s eligibility for PrEP.

PrEP is not appropriate for individuals who are HIV-positive or do not know their HIV status. Because Truvada® alone is not sufficient to treat HIV, HIV-positive patients who inadvertently receive PrEP are at risk of developing drug-resistant HIV. Additionally, those who indicate that they are not able or ready to adhere to a daily oral treatment are not good candidates for PrEP, since efficacy is linked to adherence. Patients who have existing kidney disease or dysfunction, or don’t know their hepatitis B status, should not be prescribed PrEP, as Truvada® may worsen kidney health.

HOW CAN YOU DO YOUR PART TO SUPPORT PrEP SERVICES IN SANTA CLARA COUNTY?

1. **ADD YOUR NAME** to the PrEP provider directories: Contact the California Department of Public Health (www.cdph.ca.gov/programs/aids/Pages/OAPREP) and PleasePrEPMe.org to be included in directories of local PrEP providers.

2. **READ the guidelines/obtain training**

3. **PRESCRIBE PrEP to eligible patients**

For additional PrEP resources, please visit www.sccphd.org/rxprep or call (408) 792-3750
Prescribing and Supporting PrEP

Any licensed prescriber, including primary care providers, can prescribe PrEP to eligible patients. Before prescribing PrEP, providers should work with their patients to determine appropriate HIV prevention strategies based on sexual history, PrEP eligibility screening, and a clear understanding of PrEP recommendations. In addition to taking a comprehensive sexual history, health care providers should conduct tests for HIV, hepatitis B, STDs, and kidney function. Determining that a patient is HIV-negative is the most important part of a PrEP baseline assessment; as such, HIV testing should be conducted immediately prior to starting PrEP (ideally on the same day).

Individuals who decide to take PrEP will need to visit their providers regularly for routine care and testing. While a patient is using PrEP, visits should be scheduled every two to three months to assess blood work, side effects, adherence, and risk behaviors. Routine HIV tests and pregnancy tests (when applicable) should also be conducted every three months; STD tests can be done every six months if the risk for STDs is low.

If a patient becomes infected with HIV, PrEP should be discontinued immediately. Use of PrEP should also be stopped or reassessed if a patient is experiencing unmanageable side effects or symptoms, if risk of HIV exposure changes, or if adherence is low. If a patient becomes pregnant, PrEP should be discontinued but may be restarted during pregnancy if ongoing HIV transmission risk is sufficiently high. If an HIV-negative patient stops using PrEP for any reason, they should receive education on other ways to lower their risk of HIV infection.

Safety

When used in HIV-infected individuals, Truvada® has been found to cause renal toxicity and decreased bone mineral density. Although use of Truvada® for PrEP has not caused serious short-term safety concerns to date, further evidence is needed to determine PrEP’s effects on kidney health. PrEP is considered safe for women of child-bearing age. During pregnancy, the decision to use PrEP should be made on an individual basis, according to risk of ongoing HIV transmission.

Up-to-date clinical consultation on PrEP

For clinical consultation by phone, please call the Clinician Consultation Center:
CALL (855) 448-7737 or (855) HIV PrEP, available 9 am – 3 pm PST, Monday – Friday

Sources: Centers for Disease Control and Prevention; Project Inform; AIDS.gov
August 7, 2015

Dear Colleague:

Approximately 5,000 Californians become newly infected with HIV every year—almost 14 people every day. Although California has made significant progress in increasing the proportion of HIV-infected Californians who are receiving effective HIV treatment and are virally suppressed, which reduces HIV transmission by 96%, California has unfortunately not yet been successful in significantly reducing the annual number of new HIV infections.

HIV Pre-exposure Prophylaxis, or PrEP, is an important new HIV prevention option in which persons who are HIV uninfected but at significant risk for acquiring HIV take one pill a day to prevent acquiring HIV. The medication currently approved by the federal Food and Drug Administration for PrEP is co-formulated emtricitabine/tenofovir (Truvada®). The pill can reduce the risk of HIV infection by up to 92 percent¹ when consistently taken once a day as prescribed. PrEP does not replace other risk reduction options such as reducing the number of risk exposures, consistent use of condoms, and suppressing viral load through use of HIV medication among those who are HIV infected. However, this biomedical intervention will assist many for whom traditional risk reduction options may be insufficient to avoid infection.

With the advent of PrEP, we now have the opportunity to significantly lower the number of new infections. The California Department of Public Health, Office of AIDS (CDPH/OA) supports the use of PrEP as a critical first-line intervention for those individuals at greatest risk of HIV exposure, including gay men and other men who have sex with men, transgender persons, persons who inject drugs, and others at high risk for infection. The addition of PrEP to the toolbox of risk reduction options is a significant advancement in HIV prevention. The experience of California clinicians who are already providing PrEP confirms that it is feasible for PrEP to be provided by all health care providers as part of primary care.

Since the United States Public Health Service release of the Pre-exposure Prophylaxis for the Prevention of HIV Infection Clinical Practice Guidelines² in 2014, patient demand

¹ CDC PrEP Fact Sheet, May 2014
² PrEP Clinical Practice Guidelines
for PrEP has increased, and medical providers throughout the state are responding to the demand. PrEP medicine and clinical monitoring is covered by major private insurance programs, as well as Medicare, Medi-Cal and Covered California. Financial assistance may be available to individuals seeking PrEP, whether they have insurance or not. The Fair Pricing Coalition website has a concise summary of PrEP assistance programs.

In addition, there are several resources available to clinicians prescribing or considering prescribing PrEP:

- The PrEP Clinical Consultant telephone line at (855) 448-7737 or (855) HIV-PrEP is available Monday – Friday, 8 a.m. – 3 p.m. PST.

- The Pacific AIDS Education & Training Center (PAETC) offers free technical assistance and training related to PrEP and clinical practice: www.PAETC.org, e-mail: paetcmail@ucsf.edu or telephone (415) 476-6153.

- The San Francisco Department of Public Health offers free technical assistance and training related to PrEP, clinical practice and community engagement: www.getsfcba.org, e-mail: GET.SFCBA@SFDPH.ORG or telephone: (415) 437-6226

If you have questions or would like training or technical assistance to provide PrEP, CDPH OA is happy to assist you. Please e-mail: PrEP@cdph.ca.gov to arrange free training or technical assistance related to your PrEP requests.

In an effort to ensure access to PrEP is available throughout the state, CDPH/OA has developed a Directory of California PrEP Providers available on the CDPH/OA website: www.cdph.ca.gov/OAPrEP. The directory will be updated regularly in order to provide up-to-date accurate information to clients interested in PrEP. If you would like to add yourself and/or your clinic as a PrEP provider in the directory, please contact PrEP@cdph.ca.gov.

CDPH/OA is also working with partners throughout the state to write California PrEP treatment guidelines to address local provider needs and resources.

As the agency charged with coordinating state programs, services, and activities relating to HIV/AIDS, CDPH/OA is excited to see the the many responses to PrEP occurring throughout the state, including demonstration projects, development of PrEP
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clinics, community and clinician educational forums, and integration of PrEP into high-impact HIV prevention programs. We are committed to the expansion of PrEP availability in California, and will keep you informed of developments related to PrEP on an ongoing basis.

Sincerely,

Karen Mark, M.D., Ph.D., Chief
Office of AIDS
Center for Infectious Diseases
California Department of Public Health
People interested in **PrEP** are looking for your expertise. Help them find you!

Here are two PrEP provider directories that you can join:

Email **PrEP@cdph.ca.gov** for the California Department of Public Health, Office of AIDS PrEP directory

1. Clinical Guidelines

Resources Overview

Clinical Practice Guidelines, developed by the Centers for Disease Control and Prevention (CDC), provide comprehensive information on the use of PrEP for the prevention of HIV infection in the United States. The intended users of these guidelines include:

- Primary care clinicians who provide care to persons at risk of acquiring HIV infection;
- Clinicians who provide substance abuse treatment;
- Infectious disease and HIV treatment specialists who may provide PrEP or serve as consultants to primary care physicians about the use of antiretroviral medications;
- Health program policymakers.

The CDC also provides information on clinical trials that exhibited the effectiveness of PrEP.

Resources Included


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2. Identifying Candidates for PrEP: Conversation and Screening Tools

Resources Overview

The following resources are intended to help providers feel more comfortable talking to and screening potential candidates for PrEP. These tools offer suggestions for initiating conversations with patients who are unfamiliar with PrEP, and outline answers for common patient questions. Additionally, screening tools and checklists are available to streamline the screening process, including a Risk Index for men who have sex with men (MSM) to determine if PrEP is appropriate, and resources for taking a sexual history.

Resources Included

2. **Taking a Sexual History**; Santa Clara County Public Health Department; [www.sccphd.org/rxprep](http://www.sccphd.org/rxprep)
3. Billing, Insurance, and Other Administrative Procedures

Resources Overview

The resources included in this section aim to assist providers with keeping track of administrative protocols associated with providing PrEP. The following pages include information about billing, co-pay programs, and choosing insurance, as well as PrEP-related ICD, CPT, and LOINC codes. Some of the included resources, particularly those that are insurance related, may be useful to share with patients to help ensure that out-of-pocket costs are minimized.

Resources Included

1. PrEP Billing and Payment Assistance; Santa Clara County Public Health Department; www.sccphd.org/rxprep
4. Educational Materials for Patients

Resources Overview

In this section of the Toolkit, providers can find materials intended for distribution to patients. These resources can help patients understand proper PrEP use, how PrEP works, and answers to frequently asked questions. Additionally, resources that help patients understand the process of initiating PrEP, from questions to ask providers before beginning PrEP to choosing a well-suited insurance plan and getting payment assistance, are included.

Resources Included

1. **What You Need to Know about PrEP for HIV Prevention**; Santa Clara County Public Health Department; [www.sccphd.org/rxprep](http://www.sccphd.org/rxprep)


3. **One-pager with links for PrEP 101 for Patients**; Links to CDC, AIDS Map/NAM, AIDS.gov [www.sccphd.org/rxprep](http://www.sccphd.org/rxprep)


5. Additional Resources for Providers

Resources Overview

Links to additional resources are provided below, including UCSF’s Clinician Consultation Center PrEPline hotline for clinicians to consult about the use of PrEP, webinars on PrEP topics, and a database of PrEP educational materials for providers.

Resources Included

1. The CCC PrEPline; UCSF Consultation Center, funded by CDC; http://nccc.ucsf.edu/2014/09/29/introducing-the-ccc-prepline/

2. On-Demand Webinars; The Fenway Institute; http://www.lgbthealtheducation.org/lgbt-education/webinars/

3. Webinars & Modules; National Association of County & City Health Officials; http://www.naccho.org/topics/HPDP/hivsti/prep.cfm


6. Post-Exposure Prophylaxis (PEP); Santa Clara County Public Health Department; www.sccphd.org/rxprep