

Provider Health Alert Update 3/21/2023

Doxycycline Post-Exposure Prophylaxis (Doxy-PEP) For Adult cisgender men who have sex with men and transgender women living with HIV or taking/eligible for HIV pre-exposure prophylaxis (PrEP)

Given the potential benefit of doxy-PEP on the study population (adult cisgender men who have sex with men and transgender women who are living with HIV or taking PrEP), Contra Costa Public Health is asking providers to take the following actions:

As part of comprehensive sexual health counseling, health care providers should review the following with adult cisgender men who have sex with men and transgender women:

- Offering doxy-PEP, using shared decision making, to adult cisgender men who have sex with men and transgender women who are:
 - Living with HIV, or taking or [eligible for HIV](#) PrEP, **AND**
 - have had a recent STI (chlamydia, gonorrhea, or syphilis in the last 12 months), **OR**
 - report condomless anal or oral sexual contact in the past year.
- Counseling around HIV PrEP for those who are [eligible](#) and not taking.
- Screening for gonorrhea and chlamydia at all anatomic sites of exposure and testing for syphilis and HIV (if not known to be living with HIV) every 3 months.
- Treating according to [standards](#) of any STI diagnosed.

Introduction:

There is an increasing burden of gonorrhea, chlamydia, and syphilis infections in the United States, and some groups, including gay men, bisexual men, and transgender women, experience higher burden of these Sexually Transmitted Infections (STIs). Data from a recent study on the off-label use of doxycycline post-exposure prophylaxis (doxy-PEP), 200 mg of doxycycline taken within 72 hours of condomless sex, demonstrated significant effectiveness and tolerability against these common STIs in adult cisgender men who have sex with men and transgender women who are living with HIV or taking HIV pre-exposure prophylaxis (PrEP). More data is needed to fully understand acceptability, adherence, long-term effectiveness, whether doxy-PEP causes any changes to resistance patterns, and potential benefits for other populations. At this time, given the potential benefit of doxy-PEP on the study population (adult cisgender men who have sex with men and transgender women who are living with HIV or taking PrEP), Contra Costa Public Health is asking providers to include doxy-PEP counseling as part of the comprehensive sexual health counseling for men who have sex with men and transgender women.



The Study:

A recently completed [randomized open-label clinical trial](#) among 554 gay men and other men who have sex with men and transgender women who were living with HIV or were taking HIV PrEP found a significant reduction in bacterial STIs (chlamydia, gonorrhea, and syphilis) among participants taking oral doxy-pep (200 mg doxycycline within 72 hours of condomless sex) compared to those who did not. [The study](#) found a 62%-66% reduction in STIs among participants per quarter of study follow-up, compared with participants randomized to standard care (no doxy-PEP). In the study, doxycycline was found to be safe and well-tolerated with no drug-related adverse events. In this study, this strategy showed effectiveness for reducing bacterial STIs in persons high risk for STIs and can offer a new strategy for prevention for this group.

Currently, this strategy has only been shown to be effective in adult cisgender men who have sex with men and transgender women at risk of STIs. **There is no data for the use of doxy-PEP for heterosexual cisgender women and adolescents.** Additionally, doxycycline has known side effects that may limit tolerability for some.

Additionally, other studies are needed to provide more information on doxy-PEP for other populations along with aiding in answering questions relating to acceptability and adherence, long-term effectiveness, if any changes to resistances in bacterial STIs and other organisms occurs, and if any impacts to the microbiome.

Recommendations:

As part of comprehensive sexual health counseling, health care providers should review doxy-PEP with adult cisgender men who have sex with men and transgender women who are living with HIV or taking/eligible for HIV PrEP. Comprehensive sexual health counseling should include the following key points:

- Counseling around doxy-PEP and offering doxy-PEP, using shared decision making, to individuals if:
 - Interested in doxy-PEP.
 - Living with HIV, or taking or [eligible](#) for HIV PrEP, **AND**
 - have had a recent STD (chlamydia, gonorrhea, or syphilis in the last 12 months), **OR**
 - report condomless anal or oral sexual contact in the past year.
- Counseling around HIV PrEP for those who are [eligible](#) and not taking.
- Screening for gonorrhea and chlamydia at all anatomic sites of exposure and testing for syphilis and HIV (if not know to be living with HIV) every 3 months.
- Treatment according to [standards](#) of any STI diagnosed, even if using doxy-PEP.

Counseling around doxy-PEP should include:

- **Efficacy and Safety of doxy-PEP:**
 - In studies that included men who have sex with men and transgender women living with HIV or taking HIV PrEP, doxy-PEP reduced bacterial STIs overall by 66% (among people taking PrEP) and 62% (among people living with HIV).
 - In in adult men who have sex with men and transgender women taking HIV PrEP, doxy-PEP reduced syphilis by 87%, chlamydia by 88% and gonorrhea by 55%.



- In in adult men who have sex with men and transgender women living with HIV, doxy-PEP reduced syphilis by 77%, chlamydia by 74% and gonorrhea by 57%.
 - The medication was well tolerated in the trial and did not result in serious harms during the study. Common side effects of doxy-PEP include headache, upset stomach, and rash/photosensitivity.
- **How to take doxy-PEP:**
 - Take 200 mg of doxycycline within 72 hours of sex (preferably within 24 hrs) after condomless oral, anal or vaginal sex, and not more than 200 mg doxycycline/day.
 - Either doxycycline hyclate delayed release 200 mg (1 tab) OR doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs taken simultaneously) are acceptable.
 - Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24-hour period.
- **What doxy-PEP does not do:**
 - Doxy-PEP does not prevent HIV, monkeypox (mpox) or other viral infections, for example HPV and HSV.
- **What we don't know about doxy-PEP:**
 - Long-term effectiveness, acceptability and impacts on bacterial infections and the microbiome are unknown. Efficacy against other bacterial STIs is not known.
- **Side effects of Doxycycline and monitoring needs if taking doxy-PEP:**
 - Doxycycline can have drug interactions and side effects including sun sensitivity, gastrointestinal symptoms, esophagitis, and rarely a condition called benign intracranial hypertension. **Doxycycline should be taken with plenty of water and persons should remain upright for 30 minutes after taking doxycycline to reduce to risk of esophagitis. Additionally, persons should use sunscreen and stay out of direct sunlight when on the medication.** If there are any symptoms such as headache, diarrhea, decrease in appetite, jaundice, symptoms of esophagitis, or skin rash/photosensitivity this should be reported immediately to a provider.
 - Persons should also avoid dairy, calcium, antacids, or multivitamins within 2 hours before or after Doxy PEP. These can reduce absorption in the stomach.
 - Monitoring of people while taking doxy-PEP includes:
 - Consideration of at least annual liver function tests, renal function tests, and a complete blood count, particularly in individuals with a history of liver or renal disease.
 - The [doxycycline package insert](#) recommends liver function tests, renal function tests, and CBC to be checked annually in patient taking doxycycline for a prolonged period of time. CBC and liver function tests were monitored during the study and there were no laboratory adverse effects during the study period, but providers should consider annual monitoring labs in patients taking doxy-PEP.

Resources:

- [Evaluation of Doxycycline Post-exposure Prophylaxis to Reduce Sexually Transmitted Infections in PrEP Users and HIV-infected Men Who Have Sex With Men - Full Text View - ClinicalTrials.gov](#)



- “Doxycycline post-exposure prophylaxis for STI prevention among MSM and transgender women on HIV PrEP or living with HIV: high efficacy to reduce incident STI's in a randomized trial.” AIDS 2022 (**Aids 2022 Program abstract with session links**): <https://programme.aids2022.org/Abstract/Abstract/?abstractid=13231>
- [Health-Update-Doxycycline-Post-Exposure-Prophylaxis-Reduces-Incidence-of-Sexually-Transmitted-Infections-SFDPH-FINAL-10.20.2022.pdf \(sfcdcp.org\)](#)
- [CDC Response to Doxy-PEP data presented at 2022 International AIDS Conference | Newsroom | NCHHSTP | CDC](#)
- **CDC Doxy-PEP considerations and Primary Prevention methods:** <https://www.cdc.gov/std/treatment-guidelines/clinical-primary.htm#CautionsForDoxyPEP>
- **Doxycycline FDA package insert:** https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/050795s005lbl.pdf
- **CDC treatment guidelines:** [CDC’s STI Treatment Guidelines](#) and <https://www.cdc.gov/std/treatment-guidelines/default.htm>
- [CDC’s PrEP for the Prevention of HIV guidelines](#)
- AETC Prescribing PrEP Guide for Healthcare Providers: <https://aidsetc.org/prep>

