

ALAMEDA COUNTY HEALTH CARE SERVICES AGENCY PUBLIC HEALTH DEPARTMENT

Colleen Chawla, Director Kimi Watkins-Tartt, Director

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Dear Alameda County Healthcare Providers,

There is a new opportunity for prevention of sexual transmitted infections (STIs) for Alameda County residents called doxycycline post-exposure prophylaxis, or doxy-PEP. This letter provides provisional guidance regarding doxy-PEP. As new information becomes available this guidance may be modified. A recently completed randomized open-label clinical trial among 554 gay men and other men who have sex with men and transgender women who either were living with HIV (PLWH) or were taking HIV pre-exposure prophylaxis (PrEP) found a significant reduction in bacterial STIs (chlamydia, gonorrhea and syphilis) among participants taking oral doxy-PEP (200 mg doxycycline hyclate within 72 hours of sex) compared to those who did not; among participants randomized to doxy-PEP, there was a 62%-66% reduction in STIs per quarter of study follow-up, compared with participants randomized to standard of care (no doxy-PEP)[1,2]. In the study, doxycycline was found to be safe and well-tolerated, with no drug-related serious adverse events [1,2]. Other evaluations of doxy-PEP have demonstrated effectiveness of this strategy for reducing bacterial STIs in persons at high risk for STIs [3].

Bacterial STIs can cause significant morbidity and doxy-PEP offers a new strategy for prevention. It is important to note, this strategy has only been shown to be effective in adult gay men and other men who have sex with men, and transgender women at risk of STIs. There is currently no data on this strategy for cisgender women and adolescents. In addition, doxycycline has known side effects that may limit tolerability for some people.

Further study is needed to provide more information on doxy-PEP. Additional evaluations could help answer questions regarding acceptability and adherence, long-term effectiveness, if emergent antibiotic resistance in bacterial STIs and other organisms occurs, and impacts on the microbiome.

Doxy-PEP is currently an off-label indication. The SF City Clinic recently posted a Health Update with information on this strategy [4]. The Centers for Disease Control and Prevention (CDC) has released considerations for doxy-PEP as an STI prevention strategy, but there is no CDC guidance at this time [5]. The California Department of Public Health has not released guidance for doxy-PEP.

Recommendations:

- Healthcare providers should counsel gay men and other men who have sex with men,* and transgender women about doxy-PEP as part of <u>comprehensive</u> sexual health counseling [6, 7] with the following key points:
 - Efficacy of doxy-PEP: Reduced syphilis by 87%, chlamydia by 88% and gonorrhea by 55% in adult men who have sex with men and transgender women who were taking HIV PrEP. Reduced syphilis by 77%, chlamydia by 74% and gonorrhea by 57% among PLWH.
 - Safety of doxy-PEP: The medication was well tolerated in the trial and did not result in serious harms.
 Common side effects of doxy-PEP include headache, upset stomach, and rash/photosensitivity.
 - What doxy-PEP does not do: Doxy-PEP does not prevent HIV, monkeypox (mpox) or other viral infections, for example HPV and HSV.

* The term gay men and other men who have sex with men includes cis-gender men (individuals assigned male at birth), transgender men (individuals assigned female at birth), and non-binary persons who have sex with men.

- What we don't know about DoxyPEP: Long-term effectiveness, acceptability and impacts on bacterial infections and the microbiome are unknown. Efficacy against other bacterial STIs is not known.
- What makes doxy-PEP work: Taking a 200 mg dose within 72 hours of sex (preferably within 24 hrs), and not more than 200 mg doxycycline/day.
- HIV PrEP: Gay men and other men who have sex with men and transgender people who have had a
 recent STI and who are not taking HIV PrEP should also be <u>counseled</u> about HIV PrEP including new longacting formulations (cabotegravir).
- Adult gay men and other men who have sex with men, and transgender women who are interested in doxy-PEP and who have had a recent STI (chlamydia, gonorrhea or syphilis in the last 12 months), who are taking HIV PrEP, who have had more than 1 oral or anal condomless sex partner in the last year, or who are PLWH, should be offered doxy-PEP.
- Either doxycycline hyclate delayed release 200 mg (1 tab) OR doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs taken simultaneously) are acceptable. The 200 mg doxycycline should ideally be taken within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sex. Immediate release may be less expensive than delayed release and should be equivalently bioavailable. More information on doxy-PEP dosing has been shared by San Francisco City Clinic, referenced here.
- 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.
- For doxy-PEP initiation and follow-up, an ICD10 diagnosis code Z20.2 (Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission) can be used.
- Doxycycline can have drug interactions and side effects including sun sensitivity, esophagitis, and rarely a
 condition called benign intracranial hypertension. 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.
- Monitoring of people while taking doxy-PEP includes:
 - At least annual liver function tests, renal function tests, and a complete blood count. Screening every three months for gonorrhea and chlamydia at all anatomic sites of exposure, syphilis, and HIV (if not known to be living with HIV).
 - o If a person is diagnosed with an STI while using doxy-PEP, they should be treated according to standard CDC STI treatment guidelines [8].
 - Ongoing support for persons on doxy-PEP should include review of benefits and risks, with shared decision making on whether to continue doxy-PEP.

Alameda County Public Health Department (ACPHD) has a zero-tolerance stance to stigma and discrimination. ACPHD strongly recommends that all healthcare workers are <u>trained</u> to provide sensitive and evidence-based care, including care that is culturally/linguistically appropriate and gender affirming, to the following overlapping populations: low-income individuals; people of color; immigrants; and lesbian, gay, bisexual, transgender, gender queer and gender non-binary people.

Please contact the Alameda County Public Health Department STD Control and Prevention Unit with any questions at (510) 267-3220 or SexualHealth@acgov.org.

Sincerely,

Nicholas Moss, MD, MPH Alameda County Health Officer



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References

- 1."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:https://programme.aids2022.org/Abstract/Abstract/?abstractid=13231
- 2.Clinical Trial Registry accessed 01/18/2023: https://clinicaltrials.gov/ct2/show/NCT03980223
- 3. Grant, JS, Stafylis C, Celum C, Grennan T, Haire B, Kaldor J, Luetkemeyer AF, Saunders JM, Molina JM, Klausner D. Doxycycline prophylaxis for Bacterial STIs. Clin Infect Dis; 2020:70(6):1247-1253.
- 4.SF City Clinic Health Update: https://www.sfcityclinic.org/sites/default/files/2022-10/Health%20update DoxyPEP FINAL.1.pdf.
- 5. Doxycycline as STI PEP: Considerations for Individuals and Healthcare Providers of Gay or Bisexual Men or Transgender Women Primary Prevention Methods (cdc.gov)
- 6. Sexual Health | CDC | Health | Accessed January 30, 2023.
- 7. World Health Organization. (2015). Brief sexuality-related communication: recommendations for a public health approach. World Health Organization. https://apps.who.int/iris/handle/10665/170251.
- 8. CDC STI Treatment Guidelines https://www.cdc.gov/std/treatment-guidelines/toc.html