



**STATE OF WEST VIRGINIA
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DoxyPEP: Doxycycline Post-Exposure Prophylaxis

Background

Research from the University of California, San Francisco published efficacy data¹ from 2022 in a randomized trial of doxycycline use for post-exposure prophylaxis (PEP) for sexually transmitted infections (STI). Study participants were men who have sex with men (MSM) and transgender women who were taking HIV pre-exposure prophylaxis (PrEP) or were people living with HIV (PLWH) and had been diagnosed with an STI in the past year. Among participants taking PrEP who took a single dose of doxycycline [200mg] within 24 to 72 hours after sex, the incidence of syphilis, chlamydia, and gonorrhea were reduced by 87%, 88%, and 55% respectively. Among PLWH who took a single dose of doxycycline [200mg] within 24 to 72 hours after sex, the incidence of syphilis, chlamydia, and gonorrhea were reduced by 77%, 74%, and 57% respectively. No significant adverse reactions attributable to doxycycline were observed among trial participants, and the trial ended early due to the high-efficacy observed.

Further research has been conducted with similar findings, such as an NIH-funded study² published in the spring of 2023 concluding that the combined incidence of syphilis, chlamydia, and gonorrhea was lower by two thirds with DoxyPEP when compared to standardized care for MSM.

Substantial increases in STI morbidity, including significant increases in congenital syphilis and syphilis diagnoses among women, and the threat posed by emerging antibiotic-resistant gonorrhea make the adoption of novel approaches to decrease new STI infections an urgent public health priority in West Virginia. DoxyPEP, while still an off-label indication, is the first biomedical prevention tool for STIs that has been shown to be effective and well-tolerated.

While the Centers for Disease Control and Prevention (CDC) has not yet released detailed guidance for DoxyPEP, it has published considerations for DoxyPEP³ as an STI prevention strategy.

Doxycycline is inexpensive and has a history of off-label long term use for conditions ranging from malaria to acne. The use of DoxyPEP for STI prevention is covered by Medicaid in West Virginia, and other insurance carriers are expected to pay for the medication as well.

Recommendations

- A. Discuss DoxyPEP with cisgender men and transgender women who meet the following eligibility criteria:
 - I. **Have had a bacterial STI in the past year** (in particular, those with syphilis history should be prioritized for DoxyPEP), AND/OR
 - II. **Report condomless anal or oral sexual contact** with at least one cisgender male or transgender female partner in the past year.
- B. Conduct a thorough sexual history⁴ with patients who are sexually active and offer DoxyPEP using shared decision-making to cisgender men and transgender women who report:
 - I. **Have had multiple sex partners in the prior year**, AND/OR
 - II. **Report having sex with anonymous partners** or under the influence of drugs or alcohol (even if not previously diagnosed with an STI).
- C. Support cisgender men and transgender women who request DoxyPEP, regardless of if they disclosed sexual behavior that puts them at risk for STIs. Stigma and/or shame may prevent patients from discussing sexual behaviors that may subject them to judgment even though those behaviors are threats to their sexual health.
- D. At this time, DoxyPEP has not been shown to be effective among cisgender women or transgender men. Given the lack of supporting data and the contraindications for doxycycline during pregnancy, there is not currently enough evidence to recommend DoxyPEP for individuals who report receptive vaginal sex, or who have the capacity to become pregnant.
- E. When initiating DoxyPEP, discuss the following points with patient:
 - I. Efficacy: DoxyPEP is not effective at preventing sexually acquired viral infections such as HIV, Mpox, Human Papillomavirus (HPV), or herpes simplex virus (HSV). It has only been shown to reduce the risk of syphilis, chlamydia, and gonorrhea.
 - II. Dosing and Prescribing: **200mg of doxycycline should be taken within 24 hours** (highest effectiveness) **but no later than 72 hours** after condomless oral, anal, or vaginal sex.
 - a) Either of the following doxycycline formulations are acceptable:
 - One doxycycline hyclate delayed release 200mg tablet, OR
 - Two doxycycline hyclate/monohydrate immediate release 100mg tablets (taken simultaneously), which is usually less expensive and likely to be preferred by insurance such as Medicaid.
 - b) **For ICD-10 diagnosis code, use Z20.2** (contact with and suspected exposure to infections with a predominantly sexual mode of transmission).
 - c) Consider prescribing 30 doses with a refill. This will increase the likelihood that a patient will have a dose available to take within 24 hours of potential exposure, reduce

the number of trips to (and potential questions from) their local pharmacy, and still allow opportunities for STI screening and follow-up.

- d) **DoxyPEP can be taken up to once per day**, depending on frequency of sexual activity. Patients should not take more than 200mg in a 24-hour period.

III. Monitoring: Consider scheduling the patient for routine blood work and STI testing.

- a) Based on the patient's predicted and actual frequency of use, periodic tests of the patient's renal function, liver function tests (LFTs), and complete blood count (CBC) may be considered.
- b) Persons taking DoxyPEP **should be screened and treated appropriately for gonorrhea and chlamydia (at all anatomic sites of exposure) and syphilis and HIV at the time of initiation and every three months thereafter** to identify and treat infections.
- Follow the most up to date STI Treatment Guidelines⁵ for patients that test positive.
 - DoxyPEP can then be used for prevention after adequate treatment is complete.

IV. Counseling Messages: Educate patients about possible drug interactions, increased risk of sunburn from photosensitivity, remaining upright for 30 minutes after taking doxycycline to reduce the risk of pill esophagitis, and the (rare) risk of benign intracranial hypertension.

- a) Encourage patients to take doxycycline with a glass of water, and to take with food if gastric upset occurs. Avoid co-administration with antacids.
- b) Studies are currently underway to evaluate the impact of DoxyPEP on antibiotic resistance and the gut microbiome.
- c) Impacts of long-term use of DoxyPEP for STI prevention for individual patients and for population-level rates of antimicrobial resistance are unknown. Doxycycline has been previously used safely for long-term prophylaxis of malaria and treatment for acne.

V. Comprehensive Sexual Health Recommendations: Screen for STIs at the first appointment and then every three to six months, regardless of HIV serostatus.

- a) Counsel HIV-negative patients on HIV PrEP options (daily oral PrEP or long-acting injectable PrEP).
- b) Ensure PLWH are in care and inform patients on Undetectable Equals Untransmittable (U=U) to help eliminate risk of transmitting HIV to partners.
- c) Order Extragenital Testing (EGT) for gonorrhea and chlamydia based on anatomic sites of exposure (urine/urogenital, pharyngeal, and rectal) based on sexual practices discussed in the patient's sexual history.
- d) Offer vaccines to protect against sexually transmitted or sexually associated infections according to current local eligibility and ACIP Guidance.⁶
- MPX Vaccine
 - Meningococcal Vaccine
 - Hepatitis A (HAV) Vaccine
 - Hepatitis B (HBV) Vaccine
 - HPV Vaccine

Resources

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 STIs in a randomized trial: <https://programme.aids2022.org/Abstract/Abstract/?abstractid=13231>.
2. Post-exposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections: <https://www.nejm.org/doi/full/10.1056/NEJMoa2211934>.
3. Doxycycline as STI PEP: Considerations for Individuals and Healthcare Providers of Gay or Bisexual Men or Transgender Women: <https://www.cdc.gov/std/treatment-guidelines/clinical-primary.htm#CautionsForDoxyPEP>.
4. A Guide to Taking a Sexual History: <https://www.cdc.gov/std/treatment/sexualhistory.htm>.
5. STI Treatment Guidelines: <https://www.cdc.gov/std/treatment-guidelines/default.htm>.
6. Advisory Committee on Immunization Practices (ACIP) Recommendations and Guidelines: <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.