



October 5, 2023

## CDC Issues DRAFT Guidelines for the Use of Doxy-PEP for Prevention of Bacterial Sexually Transmitted Infection

On October 2, 2023, the U.S. Centers for Disease Control and Prevention issued DRAFT guidelines for the use of doxycycline post-exposure prophylaxis (doxy-PEP) for bacterial sexually transmitted infection (STI) prevention.<sup>1</sup> Doxycycline as post-exposure prophylaxis should be considered for the prevention of STI, including gonorrhea, syphilis, and chlamydia among certain high-risk populations, including gay, bisexual and other men who have sex with men (MSM).

### DRAFT Guidelines:<sup>1, 2</sup>

Based on clinical trials, systematic reviews, and studies of populations who would likely benefit most from an intervention to reduce bacterial STIs, the following considerations are recommended:

1. Doxycycline 200mg taken once orally within 72 hours of oral, vaginal or anal sex should be considered for gay, bisexual, and other MSM, and others, with a history of at least one bacterial STI (i.e., gonorrhea, chlamydia or syphilis) in the last 12 months and who are at ongoing risk for acquisition of bacterial STIs.
2. Although not directly assessed in the trials included in these guidelines, doxy-PEP could be considered for MSM and others who have not been diagnosed with an STI in the prior year but will be participating in sexual activities that are known to increase likelihood of exposure to STIs (e.g., during weekend events, cruises, and festivals).

Although the pharmacokinetics of doxycycline and experience in treating bacterial STIs suggest that STI PEP with doxycycline should be effective in other populations, data to support doxy-PEP in other populations are limited.

If STI PEP with doxycycline is prescribed, **the recommended dose is 200mg once as soon as possible within 72 hours after having oral, vaginal or anal sex with a maximum dose of 200mg every 24 hours.** MSM and others who are prescribed doxy-PEP should undergo bacterial STI testing at anatomic sites of exposure at baseline and every 3-6 months thereafter. Human immunodeficiency virus (HIV) screening should be performed for HIV-negative MSM and others according to current recommendations.

### Additional considerations:<sup>2,3</sup>

In a recently published NIH-funded open label randomized study involving MSM and others who were taking pre-exposure prophylaxis (PrEP) against HIV infection or living with HIV infection and who had had *Neisseria gonorrhoeae* (gonorrhea), *Chlamydia trachomatis* (chlamydia), or syphilis in the past year, **the combined incidence of gonorrhea, chlamydia, and syphilis was lower by two thirds with doxy-PEP than with standard care.**

In a separate study using electronic health records of gay and bisexual men (GBM) and others assigned male sex at birth with  $\geq 2$  STI tests (chlamydia, gonorrhea, syphilis) at a specified health center during 2015–2020, using hypothetical doxy-PEP prescribing strategies, **prescribing doxy-PEP to all individuals would have averted 71% of STI diagnoses (number needed to treat for one year to avert one STI diagnosis [NNT] = 3.9).**

## Agency considerations:<sup>1</sup>

Given the impact of bacterial STIs among high-risk populations served by the IHS system of care, in consultation with agency subject matter experts, including the IHS Chief Clinical Consultant in Infectious Disease, we encourage implementation of doxy-PEP when clinically indicated for MSM and others to reduce the burden of STIs in tribal communities. To aid in the IHS implementation of doxy-PEP, an IHS [doxy-PEP Clinical Tool](#) has been developed. Additional resources to manage STIs can be found on the IHS [Sexually Transmitted Infections Initiative](#) webpage under the Strategic Initiatives tab of the IHS National Pharmacy and Therapeutics Committee (NPTC) website.

The [CDC DRAFT Guidelines](#) are open for [public comment](#) for 45 days and a final version is expected to be published during the first quarter of 2024. The NPTC has scheduled a clinical review of doxy-PEP during the [NPTC Spring 2024 Meeting](#) and will distribute a NPTC Formulary Brief summarizing the review, with appropriate recommendations.

### References:

1. U.S. Centers for Disease Control and Prevention, [DRAFT Guidelines for the Use of Doxy-PEP for Prevention of Bacterial STI](#). Accessed October 2, 2023.
2. Luetkemeyer AF, Donnell D, Dombrowski JC, et al. [Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections](#). *N Engl J Med* 2023; 388:1296-1306.
3. Traeger, MW, Mayer, K, Krakower, DS, et al. [Potential Impact of Doxycycline Post-exposure Prophylaxis Prescribing Strategies on Incidence of Bacterial Sexually Transmitted Infections](#). *Clin Infect Dis* 2023 Aug 18; ciad488.