

November 16, 2023

Department of Health and Human Services
Centers for Disease Control and Prevention

RE: Docket No. CDC–2023–0080; Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request for Comment and Informational Presentation

Submitted to Federal Rulemaking Portal: <http://www.regulations.gov>

Dear CDC colleagues,

The Fenway Institute at Fenway Health submits this comment in response to the request for comment on Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention. The Fenway Institute is the research, education and training, and health policy division of Fenway Health, a Federally Qualified Health Center and Ryan White Part C HIV Clinic, and one of the world's largest health centers focused on LGBTQIA+ communities. Since February 2023 we have prescribed doxycycline for STI post-exposure prophylaxis (DoxyPEP) to more than 1,000 Fenway Health patients. We also have about 3,500 patients on pre-exposure prophylaxis (PrEP) for HIV prevention, and more than 2,700 HIV patients. We conduct routine STI screening with many of our 35,000 unique patients every year. About half of our patients are LGBTQIA+, and more than 6,000 are transgender and gender diverse.

Over the past decade rates of chlamydia, gonorrhea and syphilis have increased dramatically around the world.^{1,2} In the U.S. over the past five years syphilis incidence is up sharply, gonorrhea incidence is up significantly, and chlamydia incidence has stayed steady at high rates.³ More than 2.5 million cases of chlamydia, gonorrhea and syphilis were reported in the U.S. in 2021.⁴ Congenital syphilis is up 755% over the past decade.⁵ The rising rate of STIs causes human suffering, stigma, and interferes with the goals of the Ending the HIV Epidemic initiative, as STI infection facilitates HIV infection. We need new tools to reduce STI incidence, especially among gay and bisexual men and other men who have sex with men (GBMSM) and among transgender women (TGW), who are disproportionately burdened by HIV, syphilis, gonorrhea, Hepatitis, and other STIs.^{6,7,8}

¹ O'Byrne P, Orser L, Kroch A. Rates of sexually transmitted infections are rising. *BMJ*. 2023 Jun 30;381:p1492. doi: 10.1136/bmj.p1492. PMID: 37391210.

² WHO. *Sexually Transmitted Infections. Fact sheet*. July 10, 2023. [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)) Accessed October 27, 2023.

³ CDC. *Sexually Transmitted Disease Surveillance 2021*. <https://www.cdc.gov/std/statistics/2021/default.htm>. Last updated April 11, 2023. Accessed October 27, 2023.

⁴ Ibid.

⁵ McDonald R, O'Callaghan K, Torrone E, et al. Vital Signs: Missed Opportunities for Preventing Congenital Syphilis – United States, 2022. *MMWR Morb Mortal Wkly Rep*. ePub: 7 November 2023. DOI: <http://dx.doi.org/10.15585/mmwr.mm7246e1>

⁶ MacGregor L, Speare N, Nicholls J, et al. Evidence of changing sexual behaviours and clinical attendance patterns, alongside increasing diagnoses of STIs in MSM and TPSM. *Sex Transm Infect*. 2021;97(7):507-513. doi:10.1136/sextrans-2020-054588

⁷ Lockart I, Matthews GV, Danta M. Sexually transmitted hepatitis C infection: the evolving epidemic in HIV-positive and HIV-negative MSM. *Curr Opin Infect Dis*. 2019;32(1):31-37. doi:10.1097/QCO.0000000000000515

⁸ CDC. *STD Facts – What Gay, Bisexual and Other Men Who Have Sex with Men Need to Know About Sexually Transmitted Diseases*. <https://www.cdc.gov/std/life-stages-populations/stdfact->

The Fenway Institute welcomes CDC's draft guidance on DoxyPEP for STI prevention. DoxyPEP has been shown to reduce the risk of bacterial STIs—syphilis, gonorrhea and chlamydia—among MSM and TW by two thirds.⁹ DoxyPEP has significant potential to reduce the incidence and transmission of bacterial STIs among GBMSM and TW. At Fenway Health, where about half of our 35,000 patients are LGBTQIA+, our ability to prescribe more than 1,000 DoxyPEP prescriptions already this year has allowed us to prevent STIs in these populations.

We agree that the evidence described in the CDC's draft *Guidelines for the use of doxycycline post-exposure 2 prophylaxis for bacterial sexually transmitted infection 3 prevention* warrant a strong AI rating. Based on our clinical experience providing sexual health care to thousands of sexual and gender minority patients, and conducting extensive research with these populations on HIV and STI prevention, we welcome and agree with the guidance that GBMSM and TGW diagnosed with a bacterial STI within the past 12 months should be offered DoxyPEP, as should those planning to engage in sexual behavior that could expose them to bacterial STIs. We also welcome the guidance calling for routine STI testing every 3 to 6 months for individuals taking DoxyPEP.

Risks associated with doxycycline use, including gastrointestinal issues and photosensitivity, should be communicated to patients.¹⁰ Concerns about potential antibiotic microbial resistance should also be addressed, although this is not a reason to withhold DoxyPEP for STI prevention. By preventing STIs, DoxyPEP may reduce overall antibiotic use among GBMSM and TGW disproportionately at risk for STIs.

We also encourage the CDC and other public health agencies to center racial and ethnic health equity in their roll-out of DoxyPEP. The CDC and local and state health departments should work closely with community-based organizations with long-standing relationships of trust with Black and Hispanic gay and bisexual men and transgender women to ensure equitable uptake of doxy-PEP. Staff at mainstream health centers serving Black and Hispanic communities should be trained in how to provide culturally responsive, trauma informed, and affirming care to LGBTQIA+ patients. Such care can reduce medical mistrust and reduce barriers to accessing care.

We thank you for the opportunity to provide this comment on the draft DoxyPEP guidance. Should you have questions or require more information, please contact Sean Cahill, Director of Health Policy Research, at scahill@fenwayhealth.org. Please consider The Fenway Institute, Fenway Health, and our National LGBTQIA+ Health Education Center as resources to assist you in rolling out DoxyPEP to reduce rising rates of STIs and racial and ethnic disparities within sexual health.

Sincerely,

Manny Lopes
Interim Chief Executive Officer

[msm.htm#:~:text=Am%20I%20at%20risk%20for,HIV%20infections%20occur%20among%20MSM](#). Last updated April 11, 2023. Accessed November 1, 2023.

⁹ Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N Engl J Med*. 2023;388(14):1296-1306. doi:10.1056/NEJMoa2211934

¹⁰ Medical News Today. *Doxycycline, oral tablet*. <https://www.medicalnewstoday.com/articles/doxycycline-oral-tablet>. Accessed November 1, 2023.

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