



November 16, 2023

U.S. Centers for Disease Control and Prevention
Division of STD Prevention

Comments re: Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention [Docket No. CDC-2023-0080]

I write on behalf of the [Big Cities Health Coalition](#) (BCHC) to provide comment on the proposed guidelines for the use of Doxycycline Post-Exposure Prophylaxis for bacterial sexually transmitted infection (STI) prevention. BCHC is comprised of health officials leading 35 of the nation's largest metropolitan health departments, which together serve more than 61 million – or about one in five – Americans. We seek to advance a shared, equitable actionable vision to transform urban health, where all government agencies, healthcare providers and systems, and community-based organizations work together to promote and produce health, safety, and equity.

We strongly support these guidelines to offer doxycycline as sexually transmitted infection (STI) post-exposure prophylaxis (DoxyPEP), which will establish a public health intervention that will bring the nation's STI rates down and empower individuals to take charge of their health in a new and meaningful way. In full, the evidence presented in the guidelines document strongly supports the proposed recommendation.

We are particularly supportive of the following:

- The strength of recommendation and quality of evidence designation.
- The three criteria for the intervention: (1) taken within 72 hours of oral, vaginal, or anal sex; (2) for gay, bisexual, and other men who have sex with men, and for transgender women; (3) who have a history of at least one bacterial STI in the last 12 months.
- The specification of STI screening at anatomic sites of exposure.
- STI screening every 3-6 months (with clarifications requested below).
- Routine counseling on HIV preexposure prophylaxis (PrEP) for individuals not living with HIV who are not receiving HIV PrEP (with strengthened language requested below).
- The inclusion of transgender women in the recommendation.
- The inclusion of language instructing providers to “provide enough doses of doxy until next follow-up visit, based on individual assessment through shared decision making”.

Recommendations

This is a new intervention, which requires increased specificity and clarity. With the changes outlined below, the final guidelines will result in improved prevention of bacterial STIs in the United States.

1. Include additional clarity and specificity for providers.

- Specify how providers should determine how often to screen patients for STIs within the 3-to-6-month timeframe. Some patients will require screening more frequently, and others less frequently; screening frequency should be determined and reassessed as needed through a comprehensive sexual health history.
- Specify within the counseling section that providers should consider linking patients not living with HIV to HIV PrEP services, rather than just counseling on access to HIV PrEP.
- Specify within the counseling section that providers should take a history of adverse reactions to tetracycline.
- Specify within the counseling section that providers should counsel on available vaccines that protect against sexually transmitted or sexually associated infections, according to ACIP recommendations: mpox vaccine, Meningococcal vaccine, Hepatitis A, Hepatitis B, and HPV.
- Specify within the counseling section that patients should not lie down immediately after taking the medication.
- Remove “reducing the number of sexual partners” from the counseling section.
- Specify the difference between DoxyPEP and doxy as STI PrEP and why DoxyPEP is preferred over doxy as STI PrEP.

2. Add data on race, ethnicity, gender identity, and gender of sex partners and STIs to the section on who would benefit the most from DoxyPEP.

- Include evidence of the racial disparities in bacterial STIs. Among gay, bisexual, and other men who have sex with men, not all communities are impacted by STIs equally.
 - In 2020, the rate of reported chlamydia cases among Black men was 6.8 times the rate among White men.¹
 - In 2020, the overall rate of reported gonorrhea cases among Black men was 8.5 times the rate among their White counterparts.²

¹ “Health Disparities in HIV, Viral Hepatitis, STDs, and TB: African Americans/Blacks.” (2020, Sept. 14). CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. www.cdc.gov/nchhstp/healthdisparities/africanamericans.html.

² “Health Disparities in HIV, Viral Hepatitis, STDs, and TB: African Americans/Blacks.” (2020, Sept. 14). CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. www.cdc.gov/nchhstp/healthdisparities/africanamericans.html.

- In 2018, 34.7% of reported primary and secondary syphilis cases occurred among Black people.³
- In 2018, the rate of reported primary and secondary syphilis cases among Hispanic males was 2.2 times the rate among White males.⁴
- In 2018, Native Hawaiians and Other Pacific Islander men experienced 2.5 times the rate of gonorrhea than White males, and experienced 2.8 times the rate of primary and secondary syphilis.⁵
- Include STI Surveillance Data for gay, bisexual, and other men who have sex with men and transgender people that is further segmented by race and ethnicity.

3. Implementation Considerations: General

- Given that DoxyPEP is a new sexual health intervention for a population often burdened by discrimination and stigma, a thoughtful implementation is critical. Unfortunately, the guidelines provide no insight into the CDC’s implementation plan. The guidelines mention that “additional information about implementation and considerations for monitoring for antimicrobial resistance will be described in a separate document”, which will not be published until after the comment period closes (pg 2). In the future, we recommend that CDC publishes any supplementary materials mentioned in the guidelines for public comment simultaneously.
- Refer to doxy as STI PEP as “DoxyPEP” in all relevant work moving forward. References to “doxycycline as STI PEP” are out of step with how community and providers refer to DoxyPEP. The CDC should simplify language and align with how DoxyPEP is being messaged in practice.

4. Implementation Considerations: Equity

- Center equity from the start, do not wait for inequities to arise before addressing them.
- Apply lessons learned from the implementation of HIV PrEP:
 - 10 years into the implementation of HIV PrEP astounding inequities remain. DoxyPEP implementation should assume inequities will occur, rather than addressing them as they arise.
 - Racial disparities: In 2021, although most people who would benefit from HIV PrEP are Black or Hispanic/Latino, less than 25 percent of Black and

³ “Health Disparities in HIV, Viral Hepatitis, STDs, and TB: African Americans/Blacks.” (2020, Sept. 14). CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. www.cdc.gov/nchhstp/healthdisparities/africanamericans.html.

⁴ “Health Disparities in HIV, Viral Hepatitis, STDs, and TB: Hispanics/Latinos.” (2020, Sept. 14). CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. <https://www.cdc.gov/nchhstp/healthdisparities/hispanics.html>.

⁵ “Health Disparities in HIV, Viral Hepatitis, STDs, and TB: Native Hawaiians and Other Pacific Islanders.” (2020, Sept. 14) CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. <https://www.cdc.gov/nchhstp/healthdisparities/hawaiians.html>.

Hispanic/Latino people who were eligible for HIV PrEP were prescribed PrEP, compared to 78% of White people who were eligible and prescribed PrEP.⁶

- Geographic disparities: In 2021, the South accounted for 52% of new HIV diagnoses, but only 14% of people using PrEP.⁷
- Age disparities: In 2019, only 16% of 16 to 24 year olds who could benefit from HIV PrEP were prescribed PrEP.⁸
- Apply lessons learned from the 2022 mpox outbreak,
 - The mpox outbreak was impacted by and perpetuated racial and geographic health.⁹
 - During the 2022 mpox outbreak, public health officials learned that excessive vaccine restrictions based on sexual behavior deterred some people from getting the vaccine. Remember that patients may not be willing to divulge sensitive information about sexual behavior because of stigma.
 - Part of the initial resistance to the vaccine was the narrative that individuals had to be "extremely sexually active" to access it and the scarcity of supply, which created an incredibly high barrier to access and increased stigma through unintended shaming of sexual behavior. The messaging for doxy as PEP needs to be framed in the context of individuals being sexually active and therefore taking care of their sexual health.
- With the lessons learned from HIV PrEP and mpox in mind:
 - Complete plans to support programs, providers, and individuals—including educational materials (in multiple languages) and promotional templates—before the final guidelines are published so that all providers, regardless of who they serve, can provide DoxyPEP immediately.
 - Without federal guidance, templates, PSAs, posters, and other materials immediately available after the guidelines are finalized, providers and programs won't be working from the same starting point, which will lead to inequities.
 - Build education campaigns specifically for Black and Latino gay, bisexual, and other men who have sex with men and transgender women.
 - Support health departments to incorporate DoxyPEP in provider education and training, with an emphasis on serving Black and Latino gay, bisexual, and other men who have sex with men and transgender women.
 - Support local organizations serving Black and Latino gay, bisexual, and other men who have sex with men and transgender women more vulnerable to acquiring

⁶ "NCHHSTP Newsroom: PrEP for HIV Prevention in the U.S." (2023, Sept. 29). CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention. <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html>.

⁷ "AIDSVu Releases New Data Showing Significant Inequities in PrEP Use Among Black and Hispanic Americans." (2023, July 29). AIDSVu. <https://aidsvu.org/prep-use-race-ethnicity-launch-22/>.

⁸ "HIV: HIV by Age: PrEP Coverage." (2022, April 7) CDC Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention. <https://www.cdc.gov/hiv/group/age/prep-coverage.html>.

⁹ Kota, K. K., Hong, J., Zelaya, C., Riser, A. P., Rodriguez, A., Weller, D., Spicknall, I. H., Kriss, J. L., Lee, F., Boersma, P., Hurley, E., Hicks, P., Wilkins, C., Chesson, H. W., Concepción-Acevedo, J., Ellington, S., Belay, E. D., & Mermin, J. (2023). Racial and ethnic disparities in MPOX cases and vaccination among adult males — United States, May–December 2022. *Morbidity and Mortality Weekly Report*, 72(15), 398–403. <https://doi.org/10.15585/mmwr.mm7215a4>

bacterial STIs to provide DoxyPEP community outreach, education, pop-up sites, telehealth, and other strategies.

- Prevention Training Centers should be specifically dealing with black/brown community providers to support implementation from the start.
- Support programs and clinicians in their efforts to reduce unnecessary restrictions based on eligibility criteria. Inclusion criteria are important, but if a patient requests DoxyPEP, they should be eligible to receive it.
- Encourage community engagement in the early stages of program planning.
- Encourage programs to use their own surveillance data to identify priority areas to engage, and work with community-based organizations and community health centers within those areas.

5. Implementation Considerations: Patients

- Include thorough guidance about taking the medication within 72 hours of exposure and taking only one dose within a 24-hour period. We recommend including clear information for patients about the timeline that explicitly recognizes that there may be overlap among sexual encounters. For example, as the guidelines are currently written, a patient may have condomless sex with two people within 15 hours, take one dose of doxy 24 hours after the first encounter, and then mistakenly feel they must take a second dose to account for the sexual encounter another 24 hours later.
- Include thorough education on the difference between doxy for prevention and doxy for treatment. Since doxy is used as a treatment for chlamydia and syphilis, it's critical that patients understand the difference of the two regimens (treatment or prophylaxis) and that the regimens cannot be conflated.

6. Implementation Considerations: Integrate DoxyPEP into existing CDC initiatives and grants, beyond solely STI prevention.

- Support DoxyPEP as an allowable cost in the new CDC NOFOs for HIV Prevention and STI Prevention.
- Integrate DoxyPEP in CDC activities on HIV PrEP, for example, as the CDC prepares to launch a new social marketing campaign to increase HIV PrEP awareness among Black and Hispanic/Latino gay and bisexual men, it should include information in the campaign about DoxyPEP as well.

7. Implementation Considerations: Support workflow integration and provide education for health departments, providers, and pharmacies.

- Assist programs and providers with incorporating DoxyPEP into the status neutral approach. DoxyPEP fits neatly into status neutral work and should be incorporated into HIV prevention and treatment models and messaging accordingly.

- Advise providers on which ICD-10 codes can be used for DoxyPEP. When HIV PrEP was rolled out, providers used an ICD code that perpetuated stigma and itself was a barrier to access.

8. Monitor concerns about microbiome and antimicrobial resistance.

- Move forward with DoxyPEP, while monitoring interactions with the microbiome and antimicrobial resistance.
 - We support CDC’s decision to move forward with DoxyPEP while studies on the potential impacts on the microbiome and antimicrobial resistance are ongoing. While some comments may raise concerns in these areas, we must prioritize real evidence over theoretical risk.
 - Doxy has been used safely for sixty years as a daily medication for severe acne.¹⁰
 - Doxy was approved twenty-nine years ago to prevent malaria through daily use for up to four months.¹¹
 - STI PEP isn’t new; clinicians in sexual health clinics routinely treat patients (and their partners) as presumptive positives for bacterial STIs and provide STI PEP in the form of ceftriaxone and a seven-day course of doxy. A new DoxyPEP intervention will allow a more refined approach to STI PEP with a greater public health benefit.

9. Be prepared to update the guidelines quickly if/when evidence demonstrates that this intervention is effective in cisgender women, cisgender heterosexual men, transgender men, other queer and nonbinary individuals.

- Encourage shared decision making for populations for whom DoxyPEP is still being studied. Restricting access to a successful intervention can be discouraging for communities that feel they’ve been “left behind.” It’s important to make space for people to feel empowered to control their sexual health in conversation with their care providers.
 - Often, the way people see themselves and the way CDC sees them (e.g. gay, bisexual, etc.) aren’t aligned. Therefore, DoxyPEP should be offered to anyone who seeks it.
 - Although available evidence is inconclusive, jurisdictions have already implemented a shared decision-making model for offering DoxyPEP to heterosexual cisgender men, transgender men, or all non-pregnant individuals at increased risk for bacterial STIs, or to those requesting DoxyPEP.¹²

¹⁰ Baldwin, Hilary. (2020). “Oral Antibiotic Treatment Options for Acne Vulgaris.” *The Journal of clinical and aesthetic dermatology* vol. 13,9: 26-32.

¹¹ Styka, A. N., & Savitz, D. A. (2020). “Assessment of Long-Term Health Effects of Antimalarial Drugs When Used for Prophylaxis.” In *National Academies Press eBooks*. <https://doi.org/10.17226/25688>.

¹² The California Department of Public Health guidelines are available here: <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CDPH-Doxy-PEP-Recommendations-for-Prevention-of-STIs.pdf>; The San Francisco Department of Public Health guidelines are available here:

- Ensure a mechanism is in place to update these guidelines quickly if/when new evidence becomes available that demonstrates that DoxyPEP is an effective intervention for additional populations.
 - There are multiple ongoing studies examining the efficacy of DoxyPEP in additional populations. Please provide a timeline of those studies and when CDC will be prepared to reassess these guidelines.

Additional Questions for CDC to Clarify

- ⇒ As it pertains to the work of disease intervention specialists and providers, if a patient has been exposed to a bacterial STIs, and the provider or DIS learn the patient is on DoxyPEP, should that patient be processed as an exposure, and screened and treated accordingly?

- ⇒ Doxy often is not well tolerated due to gastrointestinal intolerance. Providers who already offer DoxyPEP counsel patients to take doxy with food, but not calcium or iron, to mitigate the negative effects. However, doxy's interaction label instructs patients not to take doxy with food. Can the CDC provide clarity in the guidelines to ensure that practice and protocols better align with current science? Any opportunity to make it easier for individuals to use and adhere to this intervention should be taken. If there is a way to support taking doxy with food, the CDC should include it in the counseling section of the guidelines. Current CDC guidelines on doxy for Malaria prevention state that "Doxycycline may also cause nausea and stomach pain. These side effects can often be lessened by taking doxycycline with food."¹³

Thank you for your work on this. Please do not hesitate to follow up with additional questions.

Sincerely,



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Executive Director

www.ncsddc.org/wp-content/uploads/2023/07/SFDPH-Health-Update-Doxycycline-Post-Exposure-Prophylaxis-Reduces-Incidence-of-Sexually-Transmitted-Infections-SFDPH-FINAL-10.20.2022.pdf

¹³ "Medicines for the Prevention of Malaria While Traveling: Doxycycline." CDC Global Health, Division of Parasitic Diseases and Malaria. Accessed Oct. 26, 2023.
https://www.cdc.gov/malaria/resources/pdf/fsp/drugs_2017/Doxycycline_2017.pdf