

November 16, 2023

Division of STD Prevention Centers for Disease Control and Prevention 1600 Clifton Road NE, Mailstop US12–2 Atlanta, GA 30329

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

Dear Kathryn Wolff,

The National Association of County and City Health Officials (NACCHO) appreciates the opportunity to submit comments on the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention's (DSTDP) proposed guidance on the use of doxycycline as post-exposure prophylaxis (Doxy PEP) to prevent sexually transmitted infections (STIs). NACCHO represents the 3,000 local health departments across the country, which run a substantial proportion of the STI clinics across the country.

Broadly, NACCHO agrees with CDC that the research on which the guidelines are based show promise for the use of Doxy PEP and that it should be offered in the "context of a comprehensive sexual health approach including risk reduction counseling, STI screening and treatment, recommended vaccination, and linkage to HIV pre-exposure prophylaxis (PrEP), HIV care, or other services, as appropriate."

NACCHO's comments center on how the proposed guidelines can most effectively reach and be received by populations who would benefit from the intervention, as well as challenges presented by the current scope of the guidelines and what should be added.

Q: Are CDC's proposed guidelines for the use of post-exposure prophylaxis with doxycycline bacterial STI prevention clearly written?

NACCHO believes that the guidelines should be clear that the data shows successful use of Doxy PEP in those communities of men who have sex with men (MSM) and transgender women (TGW) that are *already* strong adherents of pre-exposure prophylaxis (PrEP) to prevent HIV. The three studies referenced as evidence of the efficacy of Doxy PEP were all conducted with individuals taking PrEP who were therefore already engaged in HIV/STI care and prevention activities and regularly interacting with the healthcare system. At the same time, the one study referenced that did not show changes in incidence of bacterial STI suggested that non-adherence was a likely explanation for lack of efficacy. NACCHO therefore recommends that the considerations for ancillary services included in the guidelines highlight the need for adherence counseling and support as a standard of care, particularly for non-PrEP users.





Additionally, users of HIV PrEP are disproportionately whiter and wealthier than those at highest risk for HIV and STIs.¹ Therefore, additional support should be considered for those who may need them based on social determinants that may impact adherence. Such factors may include perceived racism within the medical system, financial barriers (particularly around transportation), or food instability. Accounting for these factors is critical to learn from the equity challenges experienced through the HIV PrEP rollout, which has persisted for 10 years.

Considerations for ancillary services should also explicitly include recommendations to engage clients in conversations related to pregnancy intention of partners, as the U.S. is currently experiencing a congenital syphilis emergency related to surges in syphilis incidence. STI prevention conversations must include understanding the pregnancy intention of the client and all their partners.

Given ongoing research in this area, it is also important that a clear plan is laid out to update these guidelines quickly if/when new evidence becomes available that demonstrates efficacy of Doxy PEP in additional populations.

Q: If implemented as currently drafted, do you believe the proposed guidelines for the use of Doxy PEP would result in improved prevention of bacterial STIs in the United States?

While NACCHO supports efforts to develop guidelines for STI PEP, the current recommendation is not properly tailored to account for current and future evidence. The proposed recommendation for use of Doxy PEP is "doxycycline 200mg taken once orally within 72 hours of oral, vaginal, or anal sex should be considered for gay, bisexual, and other MSM, and for TGW, 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." However, the data only show efficacy of Doxy PEP among MSM and TGW who were also actively engaged with the healthcare system via daily PrEP use. This is a narrower scope than the recommendation and one that can be partially mitigated through the additional supports listed in our response above.

At the same time, the current recommendation may undermine efforts to expand the reach of the use of Doxy PEP in additional populations in the future. CDC should carefully consider how the proposed guidelines are distributed to ensure it is clear these guidelines are intended for a limited population at this time based on the available evidence, but future research could demonstrate promise.

In addition, given the promise of this intervention, high priority for such additional research should be among pregnancy-capable people, given the rising rates of syphilis and congenital syphilis and the shortages of Bicillin L-A with which to treat it which is the only way to treat during pregnancy. Determining if Doxy PEP is successful in pregnancy-capable individuals could lead to a decrease in pregnant people with syphilis, which would allow for fewer people in need of Bicillin L-A.

<sup>&</sup>lt;sup>1</sup> Harawa NT, Tan D, Leibowitz AA. Disparities In Uptake Of HIV Pre-Exposure Prophylaxis Among California Medicaid Enrollees. Health Aff (Millwood). 2022 Mar;41(3):360-367. doi: 10.1377/hlthaff.2021.01119. PMID: 35254941; PMCID: PMC9754721.





NACCHO also recommends the following to improve clarity 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 link patients to HIV PrEP services if not living with HIV, rather than merely counseling on access to HIV PrEP.
- Remove "reducing the number of sexual partners" from the counseling section.
- Specify the difference between Doxy PEP and doxy as STI PrEP and why Doxy PEP is the recommendation.

Finally, NACCHO cautions that media coverage referring to the use of Doxy PEP as "gamechanging" may lead to confusion as it is currently a targeted intervention for only a small group. Individuals reading this coverage may seek out Doxy PEP and be denied, deterring them from seeking it out in the future when they may qualify for it after subsequent research.

Q: How can the proposed guidelines most effectively reach and be received by populations who would benefit from the intervention?

An essential part of any rollout of Doxy PEP must include local health departments, STI clinics, and Ryan White clinics, as well as AIDS service organizations, federally qualified health centers, and programs providing integrated/syndemic services, such as syringe services programs. These entities interface directly with the communities that are most impacted by STIs as well as with those who are most likely to be interested in the use of Doxy PEP. Without a strong focus on those communities, CDC will miss the opportunity to make sure that those most in need for Doxy PEP and the most likely to adhere successfully to its use are served. Additionally, these entities, along with representatives from the communities they serve, should be engaged in design and roll-out of tailored Doxy PEP outreach strategies and messaging to ensure the most impacted individuals are reached in culturally and linguistically appropriate ways.

NACCHO also recommends the following to related to the above equity concerns:

- Support programs, providers, and individuals to understand implementation—including
  educational materials (in multiple languages) and promotional templates—before the final
  guidelines are published so that all providers are aware of and can provide Doxy PEP upon guideline
  release.
- Build outreach plans and education campaigns specifically for Black and Latino gay, bisexual, and
  other men who have sex with men and transgender women on Doxy PEP and how it can be used
  and requested.
- Support health departments to incorporate Doxy PEP 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 bacterial STIs to provide Doxy PEP community outreach, education, pop-up sites, telehealth, and other strategies.





• Encourage STI 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.

Thank you for the opportunity to provide comments. For any questions about these comments or to request further dialogue, please contact NACCHO's Chief of Government and Public Affairs, Adriane Casalotti, at <a href="mailto:acasalotti@naccho.org">acasalotti@naccho.org</a>.

Sincerely,

Lori Tremmel Freeman Chief Executive Officer