



November 16, 2023

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

RE: Public comment in response to the draft *guidelines for the use of doxycycline post-exposure prophylaxis for bacterial sexually transmitted infection prevention* (Docket No. CDC-2023-0080)

On behalf of the Syndemics Working Group, a work group of the Federal AIDS Policy Partnership (FAPP), and the thirty-five undersigned organizations, we write to provide comments on the draft guidelines for the use of doxycycline post-exposure prophylaxis (DoxyPEP) for bacterial sexually transmitted infection (STI) prevention.

FAPP is a coalition of local, regional, and national organizations advocating for federal legislation and policy seeking to ultimately end the HIV epidemic in the United States. In pursuit of this outcome, FAPP has formed a Syndemics Working Group with a mission to advance interlocking approaches to federal infectious disease policy to more effectively and comprehensively intervene in the many epidemics that intersect with HIV. These intersecting epidemics include, but are not limited to, sexually transmitted infections, viral hepatitis, drug overdose, tuberculosis, and COVID-19 (including long COVID).

The draft guidelines published by the Centers for Disease Control and Prevention (CDC) on October 2, 2023 will ultimately provide the country with a public health intervention that will bring down the STI rates and empower individuals to take charge of their health in a new and meaningful way. In full, the evidence presented in the draft guidelines—including the IPERGAY study, DoxyPEP study, and the ANRS DOXYVAC study—strongly supports the proposed recommendation.

We are particularly supportive of the strength of recommendation and quality of evidence designation; the three criteria for the intervention; the specification of STI screening at anatomic sites of exposure every three to six months; the inclusion of transgender women in the recommendation; and routine counseling on HIV PEP, PrEP, or HIV treatment, with the stronger language recommended below.

The syndemic consequences of STIs are well documented and this new intervention will have a positive impact on more than bacterial STI rates in the U.S. Having an STI makes someone three to five times more likely to acquire HIV and makes someone more likely to transmit HIV.¹ In 2018, 2489 HIV infections among gay, bisexual, and other men who have sex with men were attributed to gonorrhea and chlamydia, with a lifetime direct medical cost of \$1.05 billion.² Furthermore, having an STI may increase a person's likelihood of acquiring hepatitis C.

With these syndemics in mind, we make the following recommendations:

¹ Wasserheit JN. (1992). Epidemiologic synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. *Sexually Transmitted Diseases* 9: 61-77. Fleming, D. T., & Wasserheit, J. N. 1999. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. *Sexually transmitted infections*, 75(1), 3-17. <https://doi.org/10.1136/sti.75.1.3>

² Chesson, H. W., Spicknall, I. H., Bingham, A., Brisson, M., Eppink, S. T., Farnham, P. G., Kreisel, K., Kumar, S., Laprise, J., Peterman, T. A., Roberts, H., & Gift, T. L. (2021). The estimated direct lifetime medical costs of sexually transmitted infections acquired in the United States in 2018. *Sexually Transmitted Diseases*, 48(4), 215-221. <https://doi.org/10.1097/olq.0000000000001380>

1. Prioritize a syndemic approach in the implementation of DoxyPEP.

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). Without the additional information provided in that document, we offer broad recommendations on implementation.

Studies have indicated that over the course of a year, nearly half of people on PrEP will be diagnosed with an STI.³ The syndemic benefits of DoxyPEP will be hampered if this effective intervention is siloed solely within the CDC's Division of STD Prevention (DSTDP). On the programmatic level, the CDC should support DoxyPEP as an allowable cost within existing CDC initiatives and grants beyond STI prevention and alongside HIV PrEP activities and other syndemic work.

For providers, the CDC should provide implementation guidance, educational materials, and other support in the form of templates, PSAs, posters, etc.—in multiple languages—that mutually support HIV PrEP and DoxyPEP for cisgender gay, bisexual, and other men who have sex with men and transgender women.

2. Prioritize a syndemic approach within the considerations for ancillary services to provide individuals receiving doxycycline PEP for the prevention of bacterial STIs.

The targeted population for whom DoxyPEP is recommended is part of the same population for whom HIV PrEP, hepatitis vaccination, and other interventions are indicated, and the counseling section should take advantage of a cross-cutting approach.

The counseling section should include stronger language intended to connect patients to HIV PrEP; it should specify that providers should "consider linking patients not living with HIV to HIV PrEP services, rather than merely "counseling on access to HIV PrEP". Additionally, the counseling section should specify 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. Lastly, the counseling section should also include counseling on HCV testing, as the CDC recommends one-time HCV testing for all adults and routine testing for people who currently inject drugs and share needles, syringes, or other drug preparation equipment, and people with select medical conditions.

3. Center equity and mitigate stigma at the outset.

Ten years into the implementation of HIV PrEP, astounding racial and geographic inequities remain: In 2021, although most people who would benefit from HIV PrEP are Black or Hispanic/Latino, less than 25 percent of Black and Hispanic/Latino people who were eligible for HIV PrEP were prescribed PrEP, compared to 78% of White people who were eligible and prescribed PrEP.⁴ In 2021, the South accounted for 52% of new HIV diagnoses, but only 14% of people using PrEP.⁵ And in 2019, only 16% of 16- to 24-year olds who could benefit from HIV PrEP were prescribed PrEP.⁶

³ Traeger MW, Cornelisse VJ, Asselin J, Price B, Roth NJ, Willcox J, Tee BK, Fairley CK, Chang CC, Armishaw J, Vujovic O, Penn M, Cundill P, Forgan-Smith G, Gall J, Pickett C, Lal L, Mak A, Spelman TD, Nguyen L, Murphy DA, Ryan KE, EL-Hayek C, West M, Ruth S, Batrouney C, Lockwood JT, Hoy JF, Hellard ME, Stoové MA, Wright EJ; PrEPX Study Team. Association of HIV Preexposure Prophylaxis With Incidence of Sexually Transmitted Infections Among Individuals at High Risk of HIV Infection. *JAMA*. 2019 Apr 9;321(14):1380-1390. doi: 10.1001/jama.2019.2947. PMID: 30964528; PMCID: PMC6459111. McManus H, Grulich AE, Amin J, et al. Comparison of Trends in Rates of Sexually Transmitted Infections Before vs After Initiation of HIV Preexposure Prophylaxis Among Men Who Have Sex With Men. *JAMA Netw Open*. 2020;3(12):e2030806. doi:10.1001/jamanetworkopen.2020.30806

⁴ "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>.

⁵ "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/>.

⁶ "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>.

DoxyPEP implementation should assume inequities (racial, geographic, gender, age, socioeconomic, etc.) will occur, rather than addressing them as they arise. Therefore, plans to support programs, providers, and individuals—including educational materials (in multiple languages) and promotional templates—should be completed 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.

Furthermore, the CDC should build education campaigns specifically for Black and Latino cisgender gay, bisexual, and other men who have sex with men and transgender women ahead of finalizing the guidelines; support health departments to incorporate DoxyPEP in provider education and training, with an emphasis on serving Black and Latino cisgender gay, bisexual, and other men who have sex with men and transgender women; and support local organizations serving Black and Latino cisgender gay, bisexual, and other men who have sex with men and transgender women more vulnerable to acquiring bacterial STIs to provide DoxyPEP community outreach, education, pop-up sites, telehealth, and other strategies. And Prevention Training Centers should specifically work with Black and Latino community providers to support implementation from the start.

Additionally, the CDC must support programs and clinicians in their efforts to reduce unnecessary restrictions based on eligibility criteria.

Throughout implementation, the CDC should encourage community engagement in the early stages of program planning and 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.

Lastly, to mitigate stigma, the CDC should remove “reducing the number of sexual partners” from the counseling section.

4. 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 LGBTQ and nonbinary individuals.

The CDC should 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.

In the interim, the CDC should encourage shared decision making for populations for whom DoxyPEP is still being studied. Taking lessons from the inequitable implementation of HIV PrEP, if a patient requests DoxyPEP, they should be eligible to receive it while the CDC continues to assess the benefits of DoxyPEP in cisgender women, cisgender heterosexual men, transgender men, transmasculine people, and other populations. 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.

Thank you for your consideration.

Signed,

Act Now: End AIDS (ANEA) Coalition
Advocates for Youth
AIDS Action Baltimore
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
AIDS United
APLA Health
AVAC

Berkeley Free Clinic
Big Cities Health Coalition
Chicago Black Gay Men's Caucus
Clary Strategies
Essential Access Health
Five Horizons Health Services
Getting to Zero San Francisco
GLMA: Health Professionals Advancing LGBTQ+ Equality
HealthHIV
Healthy Teen Network
HIV+Hepatitis Policy Institute
JSI
NASTAD
National Coalition of STD Directors
National Association of County and City Health Officials
NMAC
PrEP4All
Pride Action Tank
Religious Coalition for Reproductive Choice
SAGE
Strategies for High Impact
The AIDS Institute
The Reunion Project
Treatment Action Group (TAG)
U=U plus
UCSF Alliance Health Project
Vivent Health