Interim guidance for the use of doxycycline post-exposure prophylaxis (DoxyPEP) for bacterial sexually transmitted infection prevention

Purpose

To provide interim guidance on the use of oral doxycycline following condomless sexual encounters among cis-gender men or transgender women (TGW/birth gender male) to prevent bacterial sexually transmitted infections (STIs) including syphilis, gonorrhea, and chlamydia.

Intended Audience

Prescribing providers delivering clinical care to sexually active birth gender males, non-prescribing clinicians, and public health staff.

Population recommended for use of DoxyPEP for bacterial sexually transmitted infection (STI) prevention

Recommendation

Doxycycline 200mg taken orally within 72 hours of condomless sex should be considered for gay, bisexual, and other cis-gender men who have sex with other men (MSM) and transgender women (TGW) with a history of at least one bacterial STI (gonorrhea, chlamydia or syphilis) in the last 12 months.

CDC does not currently recommend Doxy-PEP for cisgender women (birth gender females). Current evidence does not show efficacy of DoxyPEP in cisgender women in preventing STIs. Further studies are needed to re-evaluate efficacy in this population.

The potential benefits and risks for transgender men (and other gender diverse patients assigned female sex at birth) who have anal sex with men are unknown. This population was not included in prior studies.

Doxycycline is contraindicated during the second and third trimesters of pregnancy because of risk for tooth discoloration.

Dosing and Prescribing Guidance

Recommendation

Doxycycline 200mg should be taken ideally within 24 hours but no later than 72 hours after condomless sex.

Doxycycline can be taken as often as once daily, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24-hour period.

Take doxycycline with fluids and remain upright for 30 minutes after the dose. Taking doxycycline with food may increase tolerability, avoiding potential GI side effects.

Either doxycycline hyclate OR doxycycline monohydrate immediate release 100 mg tabs (2 tabs taken simultaneously) are acceptable formulations for DoxyPEP.

Do not take concurrently with any antacids (e.g. H2 blockers, PPIs) or vitamin supplements (e.g. iron and calcium carbonate). Take doxycycline at least 1 hour before or 2 hours after antacids, calcium or iron containing products.

For ICD-10 diagnosis code, use Z20.2 (Contact with and [suspected] exposure to infections with a predominantly sexual mode of transmission).

Considerations when providing DoxyPEP for the prevention of bacterial STIs.

At initial PEP visit

Screen and treat as indicated for STIs (taking specimens for gonorrhea and chlamydia at all relevant anatomic sites of exposure, and blood for syphilis and HIV). Presumptively treat individuals that are having signs and symptoms of an STI(s), or have known exposure to an STI(s).

Counsel on risk reduction strategies including condom use, partner reduction, and accessing HIV PrEP, HIV PEP, or HIV treatment as indicated. Counseling should include a discussion of benefits and known and unknown harms of doxycycline as PEP, including reduction in bacterial STIs, a discussion of potential side effects such as phototoxicity, esophagitis and esophageal discomfort, gastrointestinal symptoms, and the potential for the development of resistance in other pathogens and commensal organisms.

If having signs and symptoms of an STI(s), regardless of taking DoxyPEP, one should immediately get tested and treated for that STI(s) and abstain from sex for seven days post-treatment. Conduct partner notification and expedited partner therapy as appropriate.

Provide enough doses of doxycycline to cover until next follow-up visit (3-6 months) based on individual's needs.

At follow-up visits

Screen for gonorrhea, chlamydia and syphilis every 3-6 months. As above, test for gonorrhea and chlamydia at all relevant anatomic sites of exposure.

For HIV negative individuals receiving HIV PrEP, screen per CDC HIV PrEP guidance (https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf). For HIV negative individuals not receiving HIV PrEP, consider screening every 3-6 months.

Re-assess need for doxycycline as PEP following similar guidelines for re-assessing need for HIV PrEP. (https://www.cdc.gov/hiv/basics/prep/starting-stopping-prep.html)

Provide risk reduction counseling and condoms.

Reiterate that if having signs and symptoms of an STI(s), regardless of taking DoxyPEP, individuals should immediately get tested and treated for that STI(s) and abstain from sex for seven days post-treatment. Conduct partner notification and expedited partner therapy as appropriate.

Provide enough doses of doxycycline to cover until next follow-up visit based on individual's needs.

Additional services to consider

Screen for hepatitis B and C infection; vaccinate against hepatitis B if non-immune. Administer other vaccines as indicated (MPOX, hepatitis A, HPV).

Recommend HIV PrEP for those at risk of HIV acquisition and linkage to HIV care and treatment for those who are newly diagnosed with HIV or not currently in care.

Recommend HIV PEP for those who have been exposed or may have been exposed to HIV within the past 72 hours. Consider bridging from HIV PEP to HIV PrEP upon completion of HIV PEP course if ongoing risk for HIV exposure remains.

Harm Reduction Messaging

Remember:

- While taking DoxyPEP, continue to get tested for STIs every 3-6 months and whenever you have symptoms.
- If symptomatic, also get treated and abstain from sex for at least seven days after treatment. Notify your partners to get tested and treated as well.
- DoxyPEP doesn't protect against MPOX (monkeypox), HIV, or other viral infections.
- Talk to your health care provider about HIV pre-exposure prophylaxis (HIV PrEP) and HIV post-exposure prophylaxis (HIV PEP) for HIV prevention.
- If you are living with HIV, continue to take your medications and see your health care provider regularly.
- Although DoxyPEP is highly effective, it doesn't provide 100% protection against STIs.
- Continue to consider condom use and other protective barriers as part of a comprehensive sexual health plan.
- Individuals who have concurrent substance use disorder should be referred to harm reduction services including syringe service programs if applicable, and medication assisted treatment programs.

References

- 1. U.S. Centers for Disease Control and Prevention, <u>DRAFT Guidelines for the Use of Doxy-PEP for Prevention of Bacterial STI</u>. Accessed October 2, 2023.
- 2. Workowski K, Bachman L, Chan P, Johnston C, Muzny C, Park I, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR. 2021;70:1–187.
- 3. Molina JM, Charreau I, Chidiac C, Pialoux G, Cua E, Delaugerre C, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial. Lancet Infect Dis. 2018 Mar;18(3):308–17.

4. Luetkemeyer AF, Donnell D, Dombrowski JC, Cohen S, Grabow C, Brown CE, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. N Engl J Med. 2023 Apr 6;388(14):1296–306.

- 5. Jean-Michel Molina, Beatrice Bercot, Lambert Assoumou, Algarte-Genin Michele, Emma Rubenstein, Gilles Pialoux, et al. ANRS 174 DOXYVAC: An Open-Label Randomized Trial to Prevent STIs in MSM on PrEP. CROI [Internet]. 2023 Feb 19;Seattle, Washington. Available from: https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/
- 6. Grant JS, Stafylis C, Celum C, Grennan T, Haire B, Kaldor J, et al. Doxycycline Prophylaxis for Bacterial Sexually Transmitted Infections. Clin Infect Dis. 2020 Mar 3;70(6):1247–53.
- 7. Zeggagh J, Bauer R, Delaugerre C, Carette D, Fressard L, Charreau I, et al. Incidence and risk factors for recurrent sexually transmitted infections among MSM on HIV pre-exposure prophylaxis. AIDS. 2022 Jul 1;36(8):1129–34.
- 8. Jenell Stewart, Kevin Oware, Deborah Donnell, Lauren R.Violette, Josephine Odoyo, Caitlin W.Scoville, et al. Doxycycline Post-Exposure Prophylaxis for Prevention of STIs among Cisgender Women. CROI. 2023 Feb 19;Seattle, Washington.
- 9. Primary Prevention Methods (cdc.gov)
- 10. <u>CDC Response to Doxy-PEP data presented at 2022 International AIDS Conference |</u>
 Newsroom | NCHHSTP | CDC