DOXYCYCLINE FOR STI PEP Implementation Toolkit



DOXYCYCLINE FOR STI PEP

IMPLEMENTATION TOOLKIT

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Find more resources and updates in the <u>Doxy as STI PEP Command Center</u>.



Introduction

As rates of sexually transmitted infections (STIs) in the United States continue to rise with a disproportionate impact on gay, bisexual, and other men who have sex with men (GBMSM) and transgender people, communities, clinics, and patients face an urgent need for new and accessible tools for prevention. A growing body of research shows that doxycycline as STI post-exposure prophylaxis (PEP) can be effective in preventing some of the most common STIs in cisgender GBMSM and transgender women when taken in the 72 hours after sex. Providing doxycycline as STI PEP offers new promise as a widely available and affordable option for STI prevention.

As soon as research demonstrated the significant positive impact of doxycycline as STI PEP, a handful of the nation's STD clinics started offering doxycycline as STI PEP to patients. Doxycycline is a widely available, inexpensive, and well-known drug and has been used for post-exposure prophylaxis for other health concerns, including Lyme disease. This toolkit combines existing lessons learned from those clinics already using doxycycline as STI PEP, as well as broader lessons learned from the implementation of other new sexual health biomedical tools, like PrEP for HIV and the Jynneos vaccine for Mpox.

The tools in this toolkit can help your community consider how to implement doxycycline as STI PEP in an equitable way. For questions, please contact Jenny Mahn at jmahn@ncsddc.org.



Doxycycline as STI PEP: An Overview for Pharmacists and Providers

What is Doxycycline as STI PEP?

Doxycycline as STI PEP is a targeted intervention for bacterial STIs that can potentially reduce STI acquisition and transmission. It involves taking 200 mg of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex.

Is there clinical trial data to support the efficacy of Doxycycline as STI PEP?

An NIH-funded study <u>published</u> by the New England Journal of Medicine in April 2023 found that doxycycline as STI PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP. Moreover, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH). (Source: <u>N Engl J Med 2023; 388:1296-1306</u>)

Is Doxycycline as STI PEP for everyone?

Current efficacy data only applies to adult gay, bisexual, and other men who have sex with men (GBMSM), as well as transgender women. Studies among heterosexual cisgender women and adolescents are ongoing.

What are the dosing guidelines for Doxycycline as STI PEP?

- 200 mg of doxycycline should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sex
- Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24-hour period.
- Either doxycycline hyclate delayed release 200 mg (1 tab) OR doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs taken simultaneously) are acceptable.



What about STI testing for patients using Doxycycline as PEP?

Patients using doxycycline as STI PEP should still engage in regular sexual health testing, including being screened for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV) every three months. If a person utilizing doxycycline as STI PEP is diagnosed with an STI, they should be treated according to the <u>2021 CDC</u> <u>STI treatment guidelines</u>.

What about doxycycline's potential side effects?

In addition to informing patients about the potential STI prevention benefits of doxycycline as STI PEP, providers should also counsel patients about potential adverse side effects of doxycycline including phototoxicity, gastrointestinal symptoms, and more rarely esophageal ulceration.



Quick Start Guide for Doxycycline as STI PEP

Use this Quick Start Guide to navigate considerations for offering doxycycline as STI PEP in your community.

Workflow Integration of Doxycycline as STI PEP

Consider building in the following internal resources to routinely and equitably offer doxycycline as STI PEP:

- Protocols/Standard of Procedures (SOPs)
- Administrative capacity
 - Offer in-service training to build provider and staff awareness and buyin
 - D Optimize your Electronic Health Record (EHR) system
 - □ Integrate proactive counseling on doxycycline as STI PEP during routine care visits, including PrEP visits, HIV care visits, and STI visits.
- Medication provision
 - Determine what prescriptions you will provide for doxycycline as STI PEP
 - Reach out to local pharmacies about doxycycline as STI PEP. See the Doxycycline as STI PEP Quick Reference Guide for Pharmacists and Providers and Pharmacy Letter in this toolkit.
 - Understand the benefits of doxycycline as a relatively inexpensive drug,
 approximately \$.06 per each 100 mg pill under 340b and \$.08/pill with
 a GoodRX card but remember that patients may still need information
 on how to access doxycycline at lower costs and on how to access it.

Community Input

Community Planning Do not wait until the program is implemented to engage the community! Engage them in program planning, messaging, and workflows.

Community Guidance Create a doxycycline as STI PEP community advisory board which meets at regular intervals.



Community Feedback Create infrastructure to gather community feedback and integrate feedback into your program. Develop and use an accountability framework to govern how and when the community will receive updates on how their feedback is being incorporated.

Develop and Use Culturally Reflective Patient Education and Awareness Materials

Prepare Staff Ensure all staff – from front desk and clerical staff to providers – are trained and on the same page about doxycycline as STI PEP. Patients should be able to clearly understand how they can access doxycycline as STI PEP and not encounter barriers when making appointments or interacting with staff.

Collaborate on Communications Engage community-based organizations and local representatives from populations experiencing sexual health disparities in the development of messaging and communications tools.

Be Transparent with Providers and Patients Being transparent with providers and patients about what we know and what we don't know about doxycycline as STI PEP will help increase trust and build comfort. These conversations might include the limitations of current research, including the lack of supportive data on cisgender women, or concerns about antimicrobial resistance (AMR).

Program Evaluation

Consider developing an evaluation plan to benchmark the effectiveness of your efforts that examines the following questions:

- How will you assess the effectiveness of your doxycycline as STI PEP program? What benchmarks will you use?
- What is the time frame and frequency of assessment and data collection?
- How will your program evaluation data be shared, in what frequency, and with whom?
- How will you determine if your doxycycline as STI PEP program is equitable and reaching populations disparately impacted by STIs?



Template: Guidelines for Doxycycline as STI PEP

Background/Efficacy

More than 2.5 million cases of chlamydia, gonorrhea, and syphilis were reported in 2021. (Sexually Transmitted Disease Surveillance 2021; CDC) From 2020 to 2021, reported U.S. syphilis cases increased by 32%, gonorrhea rates increased more than 4%, and chlamydia increased nearly 4%. (Sexually Transmitted Disease Surveillance 2021; CDC) An NIH-funded study published by the New England Journal of Medicine in April 2023 found that doxycycline as post-exposure prophylaxis (PEP) reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP. Moreover, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH). (N Engl J Med 2023; 388:1296-1306) Current Efficacy data only applies to adult gay and bisexual men and transgender women. Studies among heterosexual cisgender women are ongoing.

Dosing

- 200 mg of doxycycline should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex.
- Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24-hour period.
- Either doxycycline hyclate delayed release 200 mg (1 tab) OR doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs taken simultaneously) are acceptable.
- Immediate release may be less expensive than delayed release and should be equivalently bioavailable.
- For ICD10 diagnosis code, use Z20.2 (Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission).

Implementation Protocol

Insert implementation protocols for your clinic, health department, or communitybased organization here.



Health Equity Considerations for Doxycycline as STI PEP

Gay, bisexual, and other men who have sex with men (GBMSM) and transgender people experience higher rates of STIs than other populations, and the disparities are even larger for GBMSM and trans people of color. As an effective new prevention tool for cisgender GBMSM and transgender women, doxycycline as STI PEP has the potential to lessen health disparities. However, lessons learned from the introduction of PrEP for HIV and Jynneos as the Mpox vaccine demonstrate that an effective introduction of doxycycline as STI PEP will require careful attention to health equity.

The following are ways you can ensure your doxycycline as STI PEP program is equitable and prepared to serve your community.

Develop Equitable Criteria for Offering Doxycycline as STI PEP

Develop organization-wide criteria for when you will proactively offer doxycycline as STI PEP. For example, you may offer doxycycline as STI PEP to every GBMSM or transgender woman who has tested positive for syphilis or for a bacterial STI in the past six months. You may want to build counseling about doxycycline as STI PEP into certain routine visits.

Reduce Unnecessary Restrictions Based on Eligibility Criteria

During the 2022 Mpox Outbreak, public health officials learned that excessive vaccine restrictions based on sexual behavior deterred some people from getting the mpox vaccine. Remember that patients may not be willing to divulge sensitive information about sexual behavior because of stigma.

Proactively Offer Information about Doxycycline as STI PEP

Doxycycline as STI PEP is a new intervention. Some patients may have heard about it in the news while others may not know about it. Proactively informing patients rather than waiting for them to request it can facilitate more equitable distribution of doxycycline as STI PEP.

Address Existing Barriers to STI Services

Existing barriers to sexual health services – barriers that often increase disparities in STI rates and care – may also impact equitable access to doxycycline as STI PEP if you do not take steps to address them. Adopting certain health equity strategies can make your doxycycline as STI PEP program more equitable for patients in your community, including:



- Offering flexible clinic hours, including weekends, evenings, and accommodation of walk-in appointments
- Incorporating telehealth visits and non-clinic-based, self-collect STI testing for follow-up
- Engaging in shared decision-making with patients who may benefit from doxycycline as STI PEP

Be Transparent in Your Messaging and Consider Patients' Information Needs

Clearly explain to patients what is known and what is still unknown about doxycycline as STI PEP. In counseling patients and in your consumer-facing materials, you should be sure to include potential side effects of doxycycline, the need for periodic STI testing, and that STI PEP is an off-label use for doxycycline.

Your patients may also be interested in more context about doxycycline as STI PEP, including:

- Doxycycline has been used as PEP for other medical uses, like in the prevention of Lyme disease.
- Doxycycline is not a new drug. Black, Latino, and other patients of color who may be aware of the history of unethical drug testing on people of color and medical racism may want to know that doxycycline is an older, well-known antibiotic.
- While doxycycline isn't a new drug, doxycycline as STI PEP is a new use for an existing drug. Other providers and pharmacists may not be aware of doxycycline as STI PEP.

Educate Other Medical Providers and Pharmacies in Your Area

As a leader on STI prevention and treatment in your community, you can support your patients by taking an active role in increasing awareness, training, and education among area providers, including pharmacies, as well as to community-based organizations that serve GBMSM, transgender women, and people of color. Update these key stakeholders as new information is available. Be intentional about reaching out to rural, underfunded, and smaller community-based organizations and clinics in your region.

Engage the Local Community

Developing partnerships and building trust with community-based organizations is essential for equitable STI prevention, treatment, and care, and those relationships



can provide a powerful source of feedback as you introduce doxycycline as STI PEP to patients in your community. Invite multiple community-based organizations to listen-and-learn sessions where they are provided with information on studies, protocols, and other key information on doxycycline as STI PEP. Hold space for listening as well as an opportunity to receive feedback on implementation protocols, patient and community materials, and messaging. Create a doxycycline as STI PEP community advisory group or engage existing advisory groups to provide regular feedback on your program and how it can be improved.

Communicating About Doxycycline as STI PEP

Doxycycline as STI PEP is an empowering way individuals can have agency to prevent new bacterial STIs. You can partner with patients and community members to develop and test culturally reflective consumer messages that build awareness, create transparency, and clearly inform your community about doxycycline as STI PEP. Key information you may want to include in marketing materials and patient materials include:

- What doxycycline as STI PEP is and the benefits
- How to access doxycycline as STI PEP
- Side effects and safety information
- Costs of doxycycline as STI PEP and how to access it at low cost
- STI testing recommendations

Work with your community to make sure materials reflect patients who could benefit from doxycycline as STI PEP – GBMSM and transgender women – and that materials reflect the population in your area. Be sure your materials communicate in plain language and the language(s) your patients use most comfortably.



Sample Letter on Doxycycline as PEP to Local Pharmacies

[DATE]

Dear [pharmacist or pharmacy name],

Thank you for being a valued pharmacy partner in our community. I am writing to inform you that our organization has recently implemented doxycycline as STI PEP, a targeted intervention for bacterial STIs that can potentially reduce STI acquisition and transmission. Doxycycline as STI PEP involves taking 200 mg of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex.

An NIH-funded study <u>published</u> by the New England Journal of Medicine in April 2023 found that doxycycline as STI PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP. Moreover, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH). More information on the study can be found <u>here</u>. (Source: <u>N Engl</u> <u>J Med 2023; 388:1296-1306</u>) This current efficacy data only applies to gay and bisexual men and other men who have sex with men (GBMSM) and transgender women; studies among heterosexual cis-gender women are ongoing.

You may begin to see doxycycline as STI PEP prescriptions from providers at our clinic for [insert dosing here; i.e., 30 doses of 200 mg doxycycline with two refills]. Our providers are monitoring these patients closely and will continue to follow-up with them as clinically necessary, including regular STI testing every three months. If you have any questions about doxycycline as STI PEP or the prescription, please see the enclosed "Doxycycline as STI PEP: An Overview for Pharmacists and Providers" or contact me at [insert email address here] or [insert phone number here] or the ordering provider at [clinic phone number] rather than asking the patient about their reason for the prescription.

Thank you in advance for ensuring that our patients continue to have a sex-positive and affirming experience at [name of pharmacy].

Sincerely,

[medical director/clinic manager]



Resource Links: Doxycycline as STI PEP

- <u>CDC: Doxycycline as STI PEP: Considerations for Individuals and Healthcare</u> <u>Providers of Gay or Bisexual Men or Transgender Women</u>
- <u>California PTC STI Expert Hour doxyPEP: Promise, Opportunities, and</u> <u>Considerations for Implementation. Featuring Stephanie Cohen, MD, MPH,</u> <u>Medical Director, San Francisco City Clinic & Director, STI Prevention and</u> <u>Control Section, San Francisco Department of Public Health</u>
- <u>SF City Clinic doxyPEP Info Sheet</u>
- <u>STD Engage 2023 Plenary: DoxyPEP Takes Center Stage</u>
- <u>doxyPEP and Anti-Microbial Resistance featuring Dr. Annie Luetkemeyer at</u> <u>CROI 2023</u>
- <u>StopHIVATL on Twitter: "What are your thoughts on Doxy for Pep? Comment below! https://t.co/Iuene43ltg #StopHIVATL #SaferSex #UequalsU</u> #HIVAwareness #KnowYourStatus #PrEP #HIVPrevention #Atlanta #SexPositivity #HarmReduction #DrugUserHealth https://t.co/sEvxPNybDP" / <u>Twitter</u>
- SF City Clinic Graphic: How to Take doxyPEP
- <u>SF City Clinic doxyPEP Patient FAQ English/Spanish</u>

Find more resources and updates in the <u>Doxy as STI PEP Command Center</u>.