

**Chicago Department of Public Health Policy**



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Commissioner

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<b>SUBJECT:</b> CLINICAL PROTOCOL FOR PROVIDING DOXYCYCLINE AS STI POSTEXPOSURE PROPHYLAXIS AT CDPH STI SPECIALTY CLINICS		

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## Purpose

The purpose of this protocol is to provide clinical guidance for the initiation of doxycycline as sexually transmitted infection (STI) post-exposure prophylaxis (PEP), otherwise known as doxy-PEP, for individuals who are at behavioral or epidemiological risk of bacterial STIs at the Chicago Department of Public Health (CDPH) STI Specialty Clinics.

More than 2.5 million cases of chlamydia, gonorrhea, and syphilis were reported in 2021.<sup>1</sup> From 2020 to 2021, reported U.S. syphilis cases increased by 32%, gonorrhea (GC) rates increased more than 4%, and chlamydia (CT) increased nearly 4%.<sup>2</sup> An National Institutes of Health (NIH)-funded study published by the New England Journal of Medicine in April 2023 found that doxy-PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP.<sup>3</sup> Moreover, doxy-PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with human immunodeficiency virus (HIV) (PLWH).<sup>3</sup> Current efficacy data only applies to adult gay, bisexual, and other men who have sex with men (GBMSM), and transgender women (TGW). Studies among heterosexual cisgender women are ongoing.

## Policy

CDPH STI Specialty Clinics will screen for eligibility and offer doxy-PEP to patients assigned male sex at birth who have had condomless oral, anal, or vaginal sex in the past 72 hours.

## Definitions

CBC	Complete blood count
CDC	Centers for Disease Control and Prevention
CDPH	Chicago Department of Public Health
CMP	Comprehensive Metabolic Panel
CT	Chlamydia
GBMSM	Gay, bisexual, and other men who have sex with men
GC	Gonorrhea
HIV	Human immunodeficiency virus
LFT	Liver function test
MSM	Men who have sex with men
NAAT	Nucleic acid amplification testing
nPEP	Non-occupational post-exposure prophylaxis
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PLWH	People living with HIV
PN	Patient navigator
STI	Sexually transmitted infection
TGM	Transgender men
TGW	Transgender women

## Procedures

### I. Overview

Doxy-PEP is a targeted intervention for bacterial STIs that can potentially reduce STI acquisition

and transmission. 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 TGW, doxy-PEP has the potential to lessen health disparities. For those who meet clinical eligibility criteria and are willing to take doxy-PEP, CDPH STI Specialty Clinics will prescribe or dispense 60 days of doxycycline, ideally to be taken within 24 hours but no later than 72 hours after condomless oral, anal, or vaginal sex (See **Figure 1**). Doxycycline should not be taken more than once in 24 hours. Patients will undergo comprehensive STI screening as well as safety monitoring at routine 3-month intervals.

## **II. Eligibility criteria for doxy-PEP at CDPH STI Specialty Clinics**

Doxy-PEP will be recommended to cisgender men or TGW aged 18 years or older who have tested positive for gonorrhea, chlamydia, or syphilis in the previous 12 months and report condomless anal or oral sexual contact with one or more cisgender men or TGW partner in the past 12 months.

Doxy-PEP will be offered using shared decision making to cisgender men, transgender men (TGM), and TGW who report having multiple cisgender male or TGW sex partners in the past 12 months, even if they have not been previously diagnosed with an STI.

Patients who meet of ANY these criteria are ineligible for this clinical protocol:

- Syphilis diagnosed prior to inclusion into the clinical protocol without serologic evidence of cure (at least 4-fold decrease of RPR titer)
- Systemic treatment with retinoids (i.e., isotretinoin)
- Treatment with enzyme-inducing anti-epileptic drugs (i.e., carbamazepine, phenytoin, phenobarbital, primidone, fosphenytoin)
- Treatment with other enzyme-inducing medications (i.e., rifampin, warfarin)
- Documented tetracycline allergy
- Anticipated or ongoing use of tetracyclines for non-STI prevention (e.g., acne treatment)

At this time, there is insufficient evidence to recommend doxy-PEP for STI prevention for individuals who report receptive vaginal sex, as current efficacy data only applies to adult GBMSM as well as TGW. If used in people who are able to become pregnant, pregnancy testing should be conducted, as doxycycline use should generally be avoided during pregnancy.

## **III. Dosing guidelines for doxy-PEP**

- 120 capsules (60 days) of doxycycline hyclate or monohydrate immediate release 100 mg will be dispensed to the patient with no refills.
- 2 capsules of 100 mg of doxycycline should be taken simultaneously ideally within 24 hours, but no later than 72 hours after condomless oral, anal, or vaginal sex (See **Figure 1**).
- 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.

## **IV. STI testing for patients using doxy-PEP**

Patients enrolled in this clinical protocol should undergo comprehensive STI screening as well as safety monitoring at routine 3-month intervals. This will include serologic syphilis screening, 4th

generation HIV Ag/Ab screen for HIV-negative subjects, and site-specific GC and CT nucleic acid amplification testing (NAAT) of the oropharynx, urine, and anus.

Providers should follow standard of care in promptly treating any STIs screened during follow-up visits. Any confirmed STI exposure or infection should be treated according to the most recent [CDC STI Treatment Guidelines](#). Post-exposure prophylaxis can be continued even with the occurrence of one or more STIs. If doxycycline is used to treat an STI, post-exposure prophylaxis with doxycycline will be held and resumed after the end of treatment.

## V. Patient Counseling Points

People taking doxycycline should be counseled about how to best take the medication, lab monitoring, potential side effects, and how to appropriately store the medication. When counseling, clinicians should reiterate the doxy-PEP is used to prevent GC, CT, and syphilis but not HIV. Patients should also be counseled on HIV pre-exposure prophylaxis (PrEP) and non-occupational exposure (nPEP) for HIV to distinguish between doxy-PEP.

### i) How to best take the medication

- Take both capsules at the same time with a full glass of water.
- Avoid taking doxycycline at the same time as milk, dairy, or other products with calcium, as it may not work as well.
- Do not take bismuth (i.e., Pepto-Bismol), calcium, iron, magnesium, zinc, multivitamins with minerals, or antacids within 2 hours of taking doxycycline.
- Do not lie down for 30 minutes after taking doxycycline to lower the chance of esophageal and throat irritation.

### ii) Lab Monitoring

- Per the doxycycline package insert, liver function tests (LFTs), complete metabolic panel (CMP) for renal function, and a complete blood count (CBC) should be checked periodically in patients taking doxycycline for a prolonged period.
- LFTs and CBCs were monitored in the doxy-PEP study, and there were no laboratory-related severe adverse events. These laboratory parameters will be checked annually in individuals with a history of liver disease.

### iii) Side effects

Doxycycline is overall safe and well-tolerated, however counseling for patients should address the following potential side effects:

- Nausea, vomiting, diarrhea: Taking doxycycline with food may help with some of these symptoms.
- Loss of appetite
- Sensitivity to sunlight: Reduce time in the sun and/or wear sunscreen when exposed to sunlight.
- Esophageal ulceration is rare but may occur.<sup>4</sup>

### iv) Proper medication storage

- Store at room temperature protected with light.
- Store in a dry place. Do not store in the bathroom.

## v) Prevention

Behavioral interventions should be offered to provide information on STI transmission, educate about behaviors that can increase exposure to STIs, and aim to increase motivation to adjust behavior to reduce STI exposure.<sup>5</sup>

- Specific sexual practices that are important to highlight include condomless anal sex and sex with multiple partners, potentially amplified by concomitant use of alcohol or drugs.
- Proper condom use should be reviewed. Patients should be advised that condoms must be used consistently and correctly to be effective in preventing STIs.
  - (i) To prevent slippage, the penis should be withdrawn while erect and the condom should be held firmly against the base of the penis during withdrawal.
  - (ii) Latex condoms are the type most commonly used in studies of STI prevention. Polyurethane male condoms likely provide similar protection. Condoms made of other synthetic material and "natural membrane" condoms should not be used for STI prevention, as they are too porous.
  - (iii) Latex condoms should not be used five years after the manufacturing date or past the expiration date. A new condom should be used for each sex act, and it should be handled carefully to avoid tears or damage. The condom should be placed on after the penis is erect and prior to genital, oral, or anal contact with the partner.
- Women should be counseled that contraceptive methods that are not mechanical barriers offer no protection against HIV or other STIs.
- Vaccinations are available for the prevention of several infections that are sexually transmitted or associated with sexual activity; these include:
  - (i) Hepatitis A vaccine (see "Hepatitis A virus infection: Treatment and prevention", section on 'Vaccination')
  - (ii) Hepatitis B vaccine
  - (iii) Human papillomavirus (HPV)
  - (iv) N. meningitidis
  - (v) Mpox (formerly known as monkeypox) virus

## References:

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# Appendix A: Figures

Figure 1. How to take doxy-PEP

