

## So Much STI Data: Information to Help You Stay Current and Informed



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## Disclosures

Dr. Giroto is a consultant for Wolters Kluwer. She will provide information based on the evidence and national recommendations, which may be off-label in nature.

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## Objectives

Describe	Review	Explain	Outline
Describe updated screening recommendations and epidemiological trends of sexually transmitted infections (STIs).	Review the Centers for Disease Control and Prevention's STIs recommendations.	Explain latest evidence based STI updates.	Given medication shortages, outline the pharmacist's role in delivering targeted patient education and implementing strategies for responsible medication stewardship for STIs.

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## Sexually Transmitted Infections (STI) and Screening Recommendations

Centers for Disease Control and Prevention (CDC)  
United States Preventative Services Task Force (USPSTF)

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## Questions to Think About

Which STIs are routinely recommended to be screened for in sexually active young women (e.g., < 25 years of age)?

Which STIs are routinely recommended to be screened for in specific populations (e.g., pregnancy, MSM)?

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## Tests Recommended for Screenings

- **Nucleic acid amplification test (NAAT)** testing is recommended for **gonorrhea and chlamydia**
- For **syphilis**, an initial test followed by a confirmatory test, if positive. There are two categories of tests.
  - **Non-treponemal tests** such as Rapid Plasma Reagin (RPR) or Venereal Disease Research Laboratory (VDRL)
  - **Treponemal serologic tests** such as chemiluminescence immunoassay (CIA) or enzyme immunoassay (EIA)
- **Antibody/antigen** test is frequently used to test for **HIV**
- **Serologic tests** are used to test for **Hepatitis B and C**

Papp JR, et al. MMWR Recomm Rep 2024;73(No. RR-1):1-32. doi: <https://dx.doi.org/10.15585/mmwr.r7301a1>  
Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.r7004a1

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## Risk Factors for STI

The risk factors vary a bit based on the specific STI. This is a general overview.

- New or multiple sex partners
- Sex partner having sex with other partners concurrently
- Inconsistent condom use in non monogamous relationship
- History of an STI themselves or in their partner
- History of sex for money or drugs
- History of imprisonment or incarceration
- Injection drug use (for those also transmitted via blood exposure)
- Men who have sex with men (MSM)

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## STI Screening Recommendations

All

- HIV testing recommended once for those 13 - 64 years, and more frequently if demonstrating risk factors.

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## STI Screening Recommendations

### Asymptomatic Non-Pregnant Women

#### Gonorrhea and chlamydia

- **Annual screening** in sexually active women  $\leq 24$  years and in those 25 years or older with risk factors.
  - Risk factors: multiple partners, inconsistent condom use, or prior history of a STI

#### Syphilis

- Screening in those with risk factors

#### Human papillomavirus

- Testing for cervical cancer beginning at age 21 years. USPSTF considering adding stopping at age 65 years in low-risk persons.

USPSTF. Chlamydia and gonorrhea: Screening Recommendation. September 2021; USPSTF JAMA. 2022;328(12):1243-1249. doi:10.1001/jama.2022.15322; USPSTF Cervical Cancer Screening in Adults and Adolescent Draft. Dec 2024. Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi:10.15585/mmwr.r7004a1.

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## STI Screening Recommendations

### Pregnant Women

#### Gonorrhea and chlamydia

- **Initial testing in first trimester based on age/risk**, with repeat testing during 3<sup>rd</sup> trimester in those who continue to meet risk.

#### Syphilis

- Initial screening in first trimester, repeat testing at 28 weeks, with additional testing at birth (ACOG recommends all, CDC recommends the testing at birth if at higher risk).

#### HIV, Hepatitis B and C

- HIV should have screening at 1<sup>st</sup> pregnancy visit and again in 3<sup>rd</sup> trimester.
- Hepatitis B and C should be screened at 1<sup>st</sup> pregnancy visit.

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. USPSTF. Syphilis infection screening in pregnant persons draft recommendation. November 2024. CT State Law <https://www.acog.org/news/news-releases/2024/04/acog-recommends-obstetrician-gynecologists-increase-syphilis-screening-for-pregnant-individuals> ~ Tech-Buzzsky. ACOG's 2024 recommendation for 2025 obstetrician-gynecologist screening of 2025 pregnant individuals, and 2025 health of 2025 and 2025 quality.

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## STI Screening Recommendations

### Men

Insufficient evidence to make routine recommendations for men. Instead, recommendations are based on risk factors.

#### Gonorrhea, chlamydia, and syphilis

- **Annual screening**
  - Considered in those sexually active and visiting clinic settings serving high risk patients.
  - Recommended for MSM, additional testing (e.g., Q3-6 months) if high risk.
    - Risk factors: receiving PrEP, living with HIV, or multiple sex partners

#### Other screening

- MSM should have baseline Hepatitis B screening and annual Hepatitis C screening.

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi:10.15585/mmwr.r7004a1.

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## STI Retesting

Those who screened positive for chlamydia and gonorrhea should be retested 3 months after treatment.

Those with a syphilis diagnosis should have follow-up testing with the RPR or VRDL.

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## Learning Assessment

A 19-year-old female is at the clinic. It is noted that she had recent unprotected sexual intercourse with her partner. She has not had any previous STI screenings. Which STIs are indicated for screening at this time? (select all that apply)

- A. HIV, Gonorrhea, and Chlamydia
- B. Gonorrhea, Chlamydia, and Syphilis
- C. Chlamydia, Syphilis, and HPV

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## Epidemiology of Common STIs

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### Epidemiology of STIs

2023 Centers for Disease Control and Prevention – Incidence of STI's

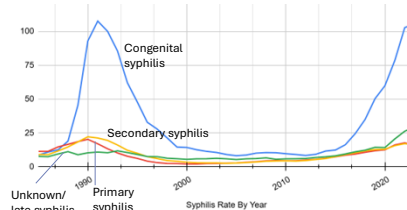
48% of diagnoses of syphilis, gonorrhea, and chlamydia were in **persons 15 – 24 years old**

32% of diagnoses of syphilis, gonorrhea, and chlamydia were in **non-Hispanic Black or African American persons**

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### Syphilis

Rate of Congenital, Primary, Secondary, and Unknown/Late Syphilis by Year in the US



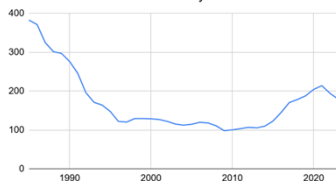
- ❑ 2023 highest overall cases of syphilis in over 70 years
- ❑ Continued increase in rates from 2022 to 2023
  - ❑ Increases primarily in 2 categories
- 1. Persons who had syphilis of unknown duration or late syphilis (>10% increase)
- 2. Congenital syphilis (> 100% increase since 2019, but from 22-23 3% increase)

CDC STI Statistics Available at: <https://www.cdc.gov/sti/statistics/data-via/table-sti-cases-rates.html>  
 CDC National Overview of STIs in 2023 Available at: <https://www.cdc.gov/sti/statistics/annual-summary.html>

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### Gonorrhea

Rate of Gonorrhea in the US by Year



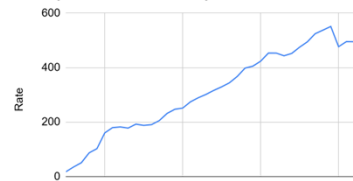
- ❑ Decreases throughout the 1990s and early 2000s
- ❑ Recent peak in 2021, followed by declines in 2022 and 2023
- ❑ Half of cases in 2023 occurred in MSM

CDC STI Statistics Available at: <https://www.cdc.gov/sti/statistics/data-via/table-sti-cases-rates.html>  
 CDC National Overview of STIs in 2023 Available at: <https://www.cdc.gov/sti/statistics/annual-summary.html>

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### Chlamydia

Chlamydia Rates in the US by Year



- ❑ Most cases diagnosed due to screening
- ❑ 56% cases in adolescents and young adults
- ❑ Rates in the past 3 years have been similar
- ❑ From 2022-2023 slight increases in cases in women and decreases in cases in men

CDC STI Statistics Available at: <https://www.cdc.gov/sti/statistics/data-via/table-sti-cases-rates.html>  
 CDC National Overview of STIs in 2023 Available at: <https://www.cdc.gov/sti/statistics/annual-summary.html>

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## Centers for Disease Control and Prevention's STI Treatment Recommendations

- ☒ Syphilis
- ☐ Gonorrhea
- ☒ Chlamydia
- ☒ Other (pelvic inflammatory disease, trichomoniasis, bacterial vaginosis, genital warts & genital herpes simplex)

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## Things to Think About

What are the first line treatment options for each type of STI?

If there are changes, why did they change?

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## Syphilis Basics

**Primary syphilis:** single chancre or multiple painful lesions

**Secondary syphilis:** rash often on palms or soles, mouth/genital sores, swollen lymph nodes

**Early latent:** infection within the past year, but asymptomatic

**Unknown or late latent:** infection more than a year duration or unknown duration without symptoms

**Organ specific manifestations:** neurosyphilis, ocular syphilis, otosyphilis

**Congenital syphilis:** Infection acquired by the fetus

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Syphilis Treatment

- **Primary, Secondary, and early latent infection**
  - 2.4 million units benzathine penicillin G (Bicillin-LA) IM x 1
- **Unknown or late latent infection**
  - 2.4 million units benzathine penicillin G (Bicillin LA) IM x 3 weekly doses
- **Neurosyphilis, ocular syphilis, otosyphilis**
  - 3-4 million units aqueous penicillin G IV every 4 hours OR as a continuous infusion of 18-24 million units/day. Continued for 10-14 days

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Congenital Syphilis Treatment

- **If confirmed or highly probable congenital syphilis**
  - 50,000 units/kg of aqueous penicillin G IV every 12 hours for the first 7 days of life then every 8 hours from day 8 through 10.
  - Alternative: 50,000 units/kg of procaine penicillin G IM daily x 10 days
- The above regimens can also be used if **possible congenital syphilis** or a single dose of 50,000 units per/kg IM of benzathine penicillin G x 1 (Bicillin LA) can be considered in some less likely situations where follow-up is assured.

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Treatment of Gonococcal Infections

### Uncomplicated infections

- Infections of the **cervix, urethra, rectum, pharynx**
  - < 150 kg: Ceftriaxone 500 mg IM x 1
  - ≥ 150 kg: Ceftriaxone 1000 mg IM x 1
- In **pregnancy**
  - Ceftriaxone 500 mg IM x 1

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## Treatment of Gonococcal Infections

### Eyes

- **Infections of the eye**
  - Neonates and infants: Ceftriaxone 25-50 mg/kg IM/IV x 1 (max 250 mg)
  - Adolescents and adults: Ceftriaxone 1000 mg IM x 1
- Ocular **prophylaxis** in neonates: erythromycin 0.5% ointment in each eye x 1 at birth



<https://phil.cdc.gov/details.aspx?pid=3766>  
public domain

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Treatment of Gonococcal Infections

### Disseminated infections

- **Arthritis:** Ceftriaxone 1000 mg IM/IV Q24h x 7 days
- **Endocarditis:** Ceftriaxone 1000 – 2000 mg IV Q12-24h > 4 weeks
- **Meningitis:** Ceftriaxone 1000 – 2000 mg IV Q12-24h x 10-14 days

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Chlamydia Treatment

### Non-pregnant adolescents/adults:

- **Doxycycline** 100 mg PO BID x 7 days
- **Pregnancy: Azithromycin** 1000 mg PO x 1
- **Neonates** (i.e., eye infection, pneumonia):
  - **Erythromycin** (i.e., base or ethyl succinate) 50 mg/kg/day PO div four times daily x 14 days OR
  - **Azithromycin** 20 mg/kg/day once daily PO x 3 days

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Other: Pelvic Inflammatory Disease, Trichomoniasis, Bacterial Vaginosis Treatments

### • Pelvic Inflammatory Disease (PID)

- **IV therapy Ceftriaxone** 1000 mg IV Q24h + **Doxycycline** 100 mg PO/IV Q12h + **Metronidazole** 500 mg PO/IV Q12h. (Can also use doxycycline with either cefotetan or ceftiofur) transitioned to oral therapy once able to complete 14 total days of therapy.

### • Trichomoniasis

- **Metronidazole** for treatment. Females 500 mg PO BID x 7 days, while males currently only a single dose of 2 grams orally is recommended. Pregnant individuals should be treated.

### • Bacterial vaginosis

- **Metronidazole** 500 mg PO BID x 7 days or as 0.75% gel daily x 5 days OR **clindamycin** 2% cream nightly x 7 days

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Other: Genital Warts, Genital Herpes

### • Therapies to anogenital warts\*

- Patient applied: **Imiquimod** 3.75% or 5% cream, **Podofilox** 0.5% solution or gel, or **Sinecatechins** 15% ointment
- Provider managed: cryotherapy, surgical removal, application of trichloroacetic acid or tichloroacetic acid)

### • Genital Herpes (Herpes Simplex Virus - HSV)

- Important for molecular testing to determine HSV1 vs HSV2
- All 1<sup>st</sup> episodes treated with antiviral for 7-10 days (i.e., acyclovir 400 mg PO TID, famciclovir 250 mg PO TID, valacyclovir 1000 mg PO BID)
- **Suppressive therapy** for HSV2 or in those with recurrent HSV1 (i.e., acyclovir 400 mg BID, famciclovir 250 mg BID, valacyclovir 500 mg – 1000 mg once daily). These may also reduce transmission of the virus.
- Recurrent or severe HSV should be treated as well (see guidelines for specifics)

Workowski KA, et al. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.

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## Learning Assessment

What are the guideline-based treatment recommendations for a 200 lb male patient with a confirmed co-infection of gonorrhea and chlamydia?

- Ceftriaxone 500 mg IM x 1 and Azithromycin 1000 mg PO x 1
- Ceftriaxone 250 mg IM x 1 and Doxycycline 100 mg PO BID x 7 days
- Ceftriaxone 500 mg IM x 1 and Doxycycline 100 mg PO BID x 7 days

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## New at Home OTC Screening Tests for STIs

<https://www.fda.gov/news-events/press-announcements/fda-marketing-authorizations-enables-increased-access-first-step-syphilis-diagnosis>  
<https://www.visbymedical.com/sexual-health-test/>  
<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorizations-first-test-chlamydia-and-gonorrhea-home-sample-collection>

- Part 1 antibody **blood syphilis test** (NOWDiagnostics) FDA authorized for at home OTC use - August 2024
- Home collection kit and at home test for **women** to test for **chlamydia, gonorrhea, and trichomoniasis** (VisbyMedical)– March 2025.
- In Nov 2023 FDA authorized an at home sample collection for **chlamydia and gonorrhea** (required sample to be sent in).

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## DOXY PEP

- New! “Guidelines on the use of doxycycline postexposure prophylaxis for bacterial sexually transmitted infection prevention”**
- Doxy PEP is postexposure prophylaxis of **200 mg of doxycycline once within 72 hours of having sex** (i.e., oral, vaginal, anal) (max 200 mg/24 hours) .

Bachmann LH, et al. MMWR Recomm Rep 2024;73(No. RR-2):1-8. DOI: <http://dx.doi.org/10.15585/mmwr.rr7302a1>.

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## DOXY PEP

- Is recommended to counsel gay, bisexual, and other **MSM and transgender women** with a **history of syphilis, chlamydia, or gonorrhea** in the past 12 months about **benefits and risks of DOXY PEP**. Insufficient current evidence to provide a recommendation for other populations.
- DOXY PEP is recommended to be used **after the individuals have been evaluated for STIs and HIV**. They are recommended to be seen every **3 to 6 months for continued screening and monitoring**.

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## DOXY PEP

### Data to support DOXY PEP recommendation

- Multiple studies have shown in primarily MSM with prior history of STI in past year. Both controlled clinical trials and real-world evaluations.
- Demonstrated statistical reductions in new onset cases of syphilis, chlamydia and in some cases gonorrhea.
- Studies showed median usage of 4-5 doses per month.
- Area to be watched, antibiotic resistance. In the 2 studies that have looked at resistance, visual increases in the percent tetracycline resistant gonorrhea have been observed (NS).

Molina JM, et al. Lancet Infect Dis. 2018 Mar;18(3):308-317. doi: 10.1016/S1473-3099(17)30725-9.  
Molina JM, et al. Lancet Infect Dis. 2024 Oct;24(10):1093-1104. doi: 10.1016/S1473-3099(24)00239-6.  
Lustigmeier AF, et al. N Engl J Med. 2023 Apr 6;389(14):1295-1306. doi: 10.1056/NEJMoa2211934.  
Osmundson J, et al. Open Forum Infect Dis. 2025 Feb 15;12(3):ofae089. doi: 10.1093/ofid/ofae089.

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## Learning Assessment

What is one concern regarding the implementation of DOXY PEP that should be monitored?

- Impact of HIV cases
- Adverse effects from the frequent use of the medication
- Antimicrobial resistance

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## STI Medication Stewardship in an Era of Shortages

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### Process for Stewardship

- Review shortage
- Consider what alternatives are available
- Determine what populations may need the medication on shortage
  - Include ASP principles of narrowest effective antibiotic for the shorted needed duration
- Work to define alternatives when possible
  - Include ASP principles of narrowest effective antibiotic for the shorted needed duration
- Update pathways
- Provide education to providers and in resources
- Provide prospective review and feedback to ensure appropriate use of the medications

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### Recent Shortage Example

- Bicillin LA (benzathine penicillin G)
  - In 2024 all formulations were on shortage.
  - Recommended dosage form for multiple types of Syphilis.
  - Currently, adult dosage forms of 1.2 and 2.4 million units are available. Pediatric dosage of 600,000 units expected in Aug/Sept 2025. Some imports have become available for use.

<https://www.accessdata.fda.gov/scripts/cdrh/cdrhfiles/newstudies/ART/ArticulatingDetails.cfm?AID=Penicillin%20G%20Benzathine%20LA&id=2024-0001>

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### Stewardship

- **Determined possible alternatives:** doxycycline, tetracycline, and ceftriaxone
- **Concerns with alternatives**
  - **Doxycycline and tetracycline** – uncertain effectiveness and potential toxicity in pregnant individuals and newborns. Uncertain effectiveness in those living with HIV and in those with organ system involvement.
    - **Recommend for non-pregnant primary, secondary, and latent syphilis treatment in those without HIV infection.**
  - **Ceftriaxone** – uncertain dose, duration, and effectiveness.
    - **Not generally recommended.**
- When **either alternative** is used **confirmatory testing is recommended** to demonstrate effectiveness.

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### Stewardship

- Groups **not** recommended to receive alternatives
  - Pregnant individuals and congenital syphilis – **Prioritize Bicillin LA for these groups.**

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### Stewardship

- Obtain support for specific updates to local recommendations.
- Update education.
- Review orders, usage, and provide continued feedback.
- When it resolves, educate and go back to optimal recommendations.

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## Learning Assessment

You are working with ED physicians to manage a shortage of ceftriaxone. One of the areas that is a concern is the treatment on gonorrhea. Which of the following would be a stewardship principle applied to this STI management choice?

- A. Use the most recent antibiotic approved for the indication
- B. Use alternative based on narrowest effect spectrum and incorporating local resistance data, if known
- C. Choose alternative that will also cover other STIs just in case

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## Questions?

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