



This webinar is sponsored by
visby medical™



**We make
healthcare
run better.™**

Point-of-Care PCR Testing for STIs: Advancing Urgent Care Diagnostics

Guest Speaker : Glenn Harnett, MD, FCUCM, CEO

July 13, 2023

Glenn Harnett,
MD, FCUCM, CEO
glenn@no-resistance.com

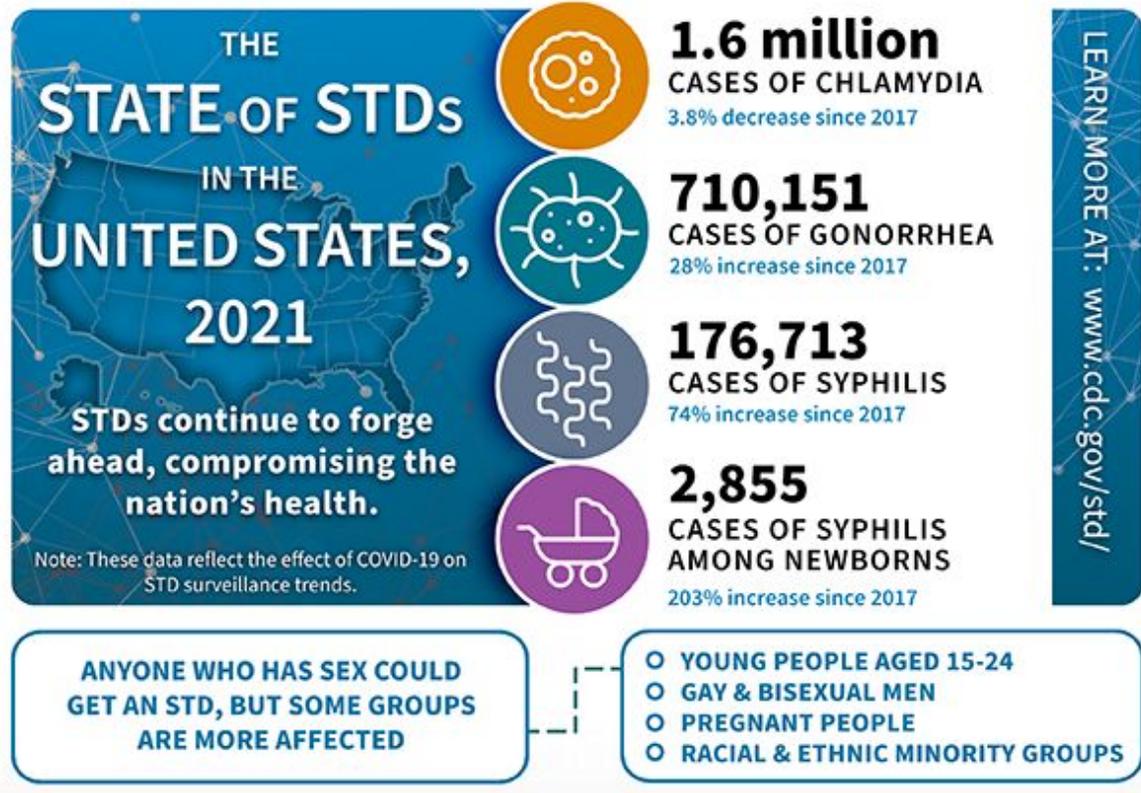


- Chief Executive Officer, No Resistance Clinical Trial Site Management
- JUCM Editorial Board Member
- Author: Harnett G. *“The rising importance of urgent care in the fight against the STI epidemic”*. J Urgent Care Med. 2022;16(3):15-20
- Principal Investigator in in-vitro diagnostic clinical trials for lab device manufacturers including Abbott, Roche, Becton Dickinson, Cepheid, Alveo, Talis, Anavasi, and Visby Medical
- Funding from Visby Medical and BioMérieux for marketing consulting services

Learning Objectives

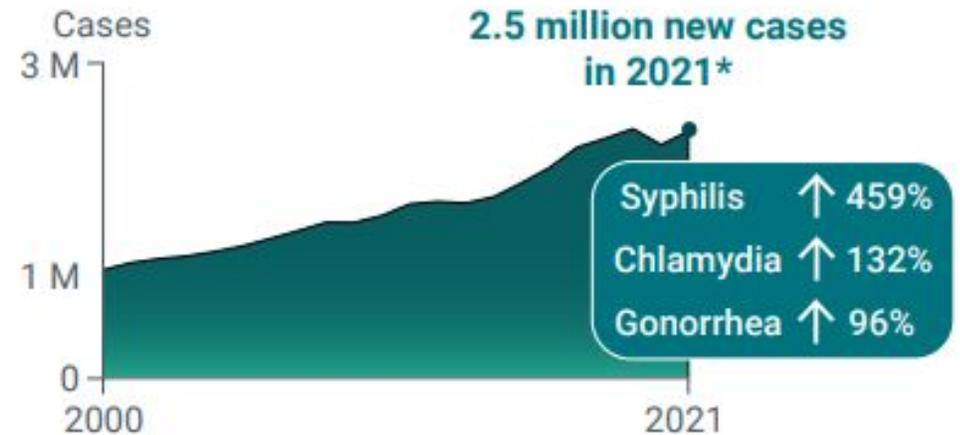
- Review applicable CDC STI Treatment & Screening Guidelines
- Discuss sexual health education strategies for STIs in young people
- Examine the importance of timely STI diagnosis and appropriate treatment
- Discuss definitive/directed antibiotic therapy vs empiric/presumptive treatment
- Review the advantages of rapid, point-of-care STI testing in urgent care

STIs at all time high



STI Overview

Chlamydia, gonorrhea, and syphilis cases have been increasing for years.



Nomenclature for discussion

Chlamydia trachomatis: CT
Neisseria gonorrhoea: NG



Together = CTNG

Complications of CTNG Infections

- Pelvic inflammatory disease
- Ectopic pregnancy
- Infertility
- Chronic pelvic pain
- Increased risk for HIV transmission and acquisition

Because so many infections are initially asymptomatic, some women don't exhibit recognizable symptoms until complications (eg, PID) have occurred

A Role for Urgent Care

- In the 1980s and 1990s, most STI care was provided in dedicated STI clinics. Funding cuts have led to a decrease in these clinics, with almost 80% of STI cases now diagnosed in non-STI clinics
- Nearly half of Millennials and Gen Z (aged 10-41) do not have a PCP

Take-Home Message

80% of STI cases are now diagnosed in non-STI clinics

Patient/Provider Challenges in STI Testing

- Until recently there have been no FDA approved rapid POC tests for STIs, forcing Providers to make treatment decisions without benefit of test results
- Missed opportunity for patient education without definitive diagnosis
- Poor follow-up rates – as high as 33% in some studies (unable to contact, no access to portal, socioeconomic factors, etc.)
- Provider continuity issues
- Relaying positive STI testing results over the phone is not ideal
- TV testing often via wet mount -- 40% of positive patients were missed when comparing PCR to wet mount

Operational Challenges in STI Testing

- Potential for notification errors with delayed results
- Delayed results can go missing...
- Due to delayed testing results (48hrs+), staff must notify patients when results return
- Time burden of results notification (multiple calls, certified letters, etc)
- Time burden of scheduling follow-up appointments for Tx if/when patient is contacted (Don't forget - ceftriaxone is IM – can't call in an Rx)
- Multiple providers may become involved in follow up and treatment decisions
- Time spent on documentation

Public Health Challenges in STI Testing

- Delay in treatment for eventual lab positive patients while awaiting test results who are not treated presumptively can lead to disease progression and complications
- Transmission may continue while waiting for test results
- Missed opportunity for expedited partner(s) treatment (EPT)
- Patients treated presumptively with antibiotics are placed at risk for antibiotic complications unnecessarily
- Unnecessary antibiotics may contribute to antibiotic resistance

Case Study 1

- 18-year-old female college freshman
- CC: vaginal discharge
- HPI: Symptoms started one week prior and include vaginal discharge and itching. No dysuria, abdominal pain, or pelvic pain
- Sexual history: No prior history of STI. Has had two sexual partners in the past 6 months
- LMP: 3 weeks ago
- Allergies: tetracycline

Poll Questions

You order send out tests for CT and NG. How would the testing samples be collected at your clinic?

- A) Urine sample
- B) Patient self-collected vaginal swab (SCVS)
- C) I would perform a pelvic exam and collect an endocervical swab

What if this were a male patient?

- A) Urine sample
- B) Provider collected urethral swab
- C) Patient provides self collected urethral swabs

Urine vs SCVS vs Provider-Collected Cervical or Urethral Swab for CTNG Testing

- SCVS vs Cervical (CT and NG in women)
 - Sensitivity: 92%–98%
 - Specificity: 99%

- Urine vs Cervical (CT and NG in women)
 - Sensitivity: 79%–87%
 - Specificity: 99%

- Urine vs PC urethral (CT and NG in men)
 - Sensitivity: 88% –92%
 - Specificity: 99%

Bottom line...

- CDC considers SCVS equivalent to provider-collected
- Urine screening in women has poor sensitivity
- Urine screening is considered acceptable for CTNG screening in men

Case Study 1 (continued)

- Vaginal swab is sent to an external lab for NAAT testing

- Chlamydia: Positive
- Gonorrhea: Negative
- Trichomonas: Negative
- BV: Negative
- Candida: Negative

- Diagnosis: Cervicitis
- Provider reviews results and prescribes treatment

Poll Question

What antibiotic treatment would you prescribe for this patient?

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

CDC Treatment Guidelines: Chlamydia

Chlamydial Infections

Risk Category	Recommended Regimen	Alternatives
Adults and adolescents	doxycycline 100 mg orally 2x/day for 7 days	azithromycin 1 gm orally in a single dose OR levofloxacin 500 mg orally 1x/day for 7 days
Pregnancy	azithromycin 1 gm orally in a single dose	amoxicillin 500 mg orally 3x/day for 7 days

CT Important Change

- *Azithromycin removed as first-line therapy*

Presumptive treatment for CTNG should be provided for men and women at increased risk, in areas with a high prevalence of CTNG, if follow-up cannot be ensured, or if testing with NAAT is not possible.

Case Study 2

- 27-year-old female, recently married and actively trying to conceive
- CC: vaginal discharge and irritation
- HPI: 2 weeks vaginal discharge, reports regular menses
- Sexual history: No prior history of STI. Has had one sexual partner in the past 1.5 years
- Pelvic exam:
 - Presence of white/off-white discharge in and around the vaginal vestibule
 - Mild CMT, no adnexal pain or masses

Case Study 2 (continued)

In-house laboratory assessments:

- Urine pregnancy: Negative
- UA normal
- Wet mount microscopy: Negative for trichomonas

External lab NAAT assessments:

- Chlamydia: Negative
- Gonorrhea: Positive

Poll Question

Patient is diagnosed with gonorrhea. What treatment would you order?

- A) Ceftriaxone (Rocephin) 250mg IM
- B) Azithromycin 1gm PO
- C) Ceftriaxone (Rocephin) 250mg IM and Azithromycin 1gm PO
- D) Ceftriaxone (Rocephin) 500mg IM
- E) Azithromycin 1gm PO
- F) Ceftriaxone (Rocephin) 500mg and Azithromycin 500mg PO

CDC Treatment Guidelines: Gonorrhea

Gonococcal Infections

Risk Category	Recommended Regimen	Alternatives
Uncomplicated infections of the cervix, urethra, and rectum: adults and adolescents <150 kg ⁶	ceftriaxone 500 mg IM in a single dose ¹⁷	If cephalosporin allergy: gentamicin 240 mg IM in a single dose PLUS azithromycin 2 gm orally in a single dose If ceftriaxone administration is not available or not feasible: cefixime 800 mg orally in a single dose ¹⁷
Uncomplicated infections of the pharynx: adults and adolescents <150 kg ⁶	ceftriaxone 500 mg IM in a single dose ¹⁷	
Pregnancy	ceftriaxone 500 mg IM in a single dose ¹⁷	

NG Important Changes

- Higher-dose ceftriaxone recommended
- Azithromycin no longer recommended as dual therapy

For persons weighing ≥ 150 kg, 1 gm of ceftriaxone should be administered.

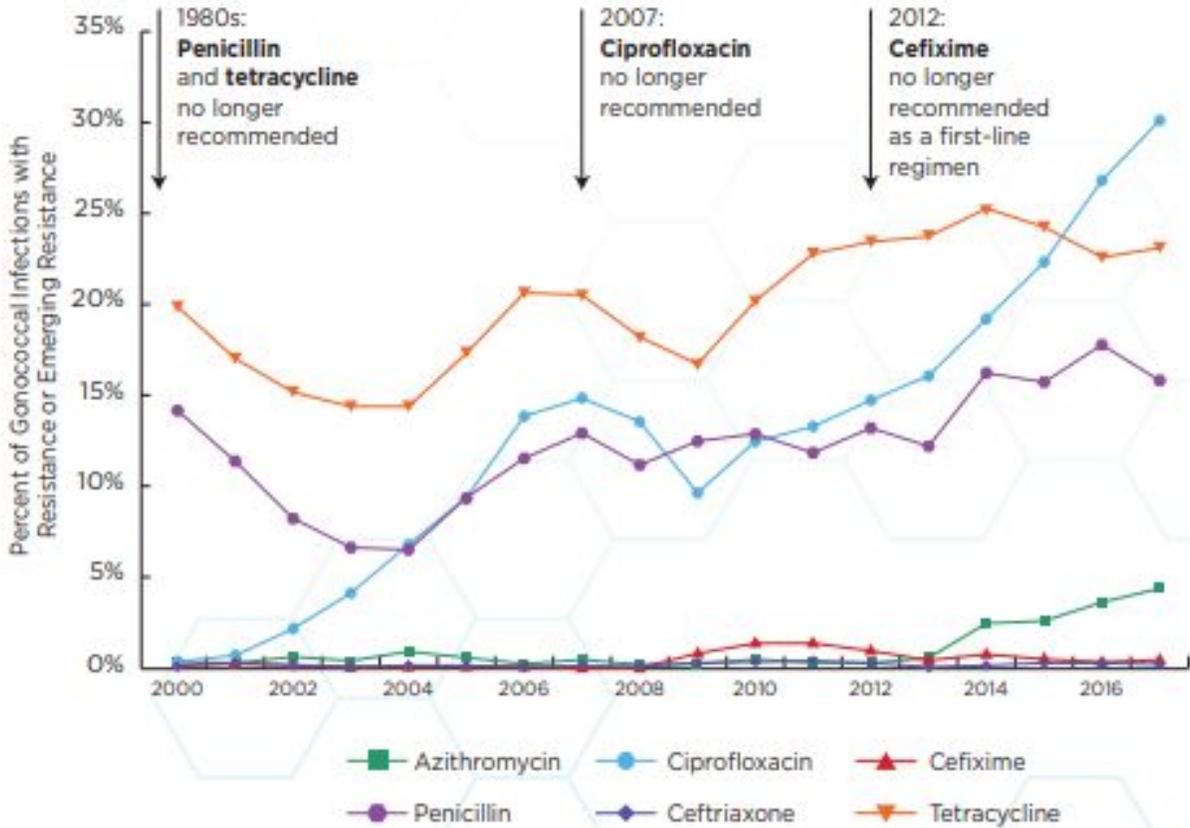
DRUG-RESISTANT *NEISSERIA GONORRHOEAE*

THREAT LEVEL **URGENT**



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Gonorrhea rapidly develops resistance to antibiotics—ceftriaxone is the last recommended treatment.



Stewardship Tip!

The advent of new and more rapid point-of-care CT and NG testing will make it easier to exclude co-infection with both pathogens.

Stick to monotherapy if either CT or NG has been excluded by testing.

Azithromycin Resistance Rising!

Follow-Up Considerations

- Other Tests:** All persons who receive a diagnosis of gonorrhea should be tested for other STIs, including chlamydia, syphilis, and HIV
- Retest in 3 months:** Due to high rates of reinfection (regardless of whether their sex partners were treated), both men and women should be instructed to return in 3 months after treatment for repeat testing—even if asymptomatic
- Partner testing:** All sex partners during the previous 60 days should be referred for evaluation, testing, and presumptive treatment
- Avoiding reinfection:** To minimize disease transmission, persons treated for gonorrhea should be instructed to abstain from sexual activity for 7 days after treatment and until all sex partners are treated (7 days after receiving treatment and resolution of symptoms, if present)
- Expedited partner therapy:** See following Slide

Expedited Partner Therapy

<https://www.cdc.gov/std/ept/legal/default.htm>

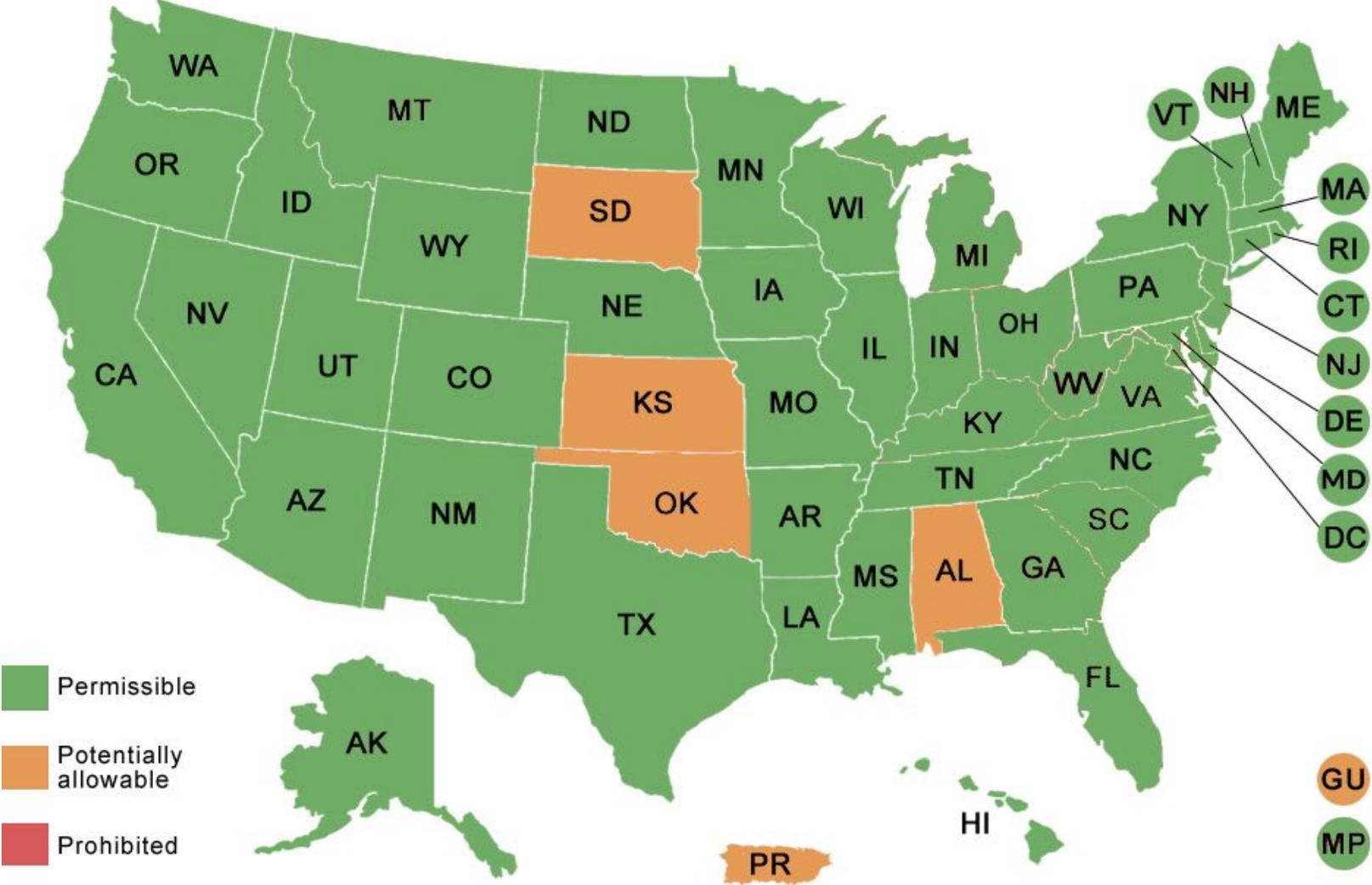
What is EPT?

- Expedited Partner Therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with chlamydia or gonorrhea by providing prescriptions or medications to the patient to take to his/her partner **without** the health care provider first examining the partner
- Effective management requires treatment of the patients' current sex partners to prevent reinfection and curtail further transmission
- Clinicians provide patients with sufficient medications directly or via prescription for the patients and their partners
- EPT can be delivered to the partner by the patient, or a collaborating pharmacy as permitted by state law

Treatment:

- Treating sexual partner with **cefixime 800 mg orally as a single dose** is recommended, provided that concurrent chlamydial infection has been excluded.
- If a chlamydia test result has not been documented, the partner may be treated with a single dose of oral cefixime 800 mg plus oral **doxycycline 100 mg 2 times/day for 7 days**
- If adherence with multiday dosing is a considerable concern, **azithromycin 1 g orally as a single dose** can be considered - but has lower treatment efficacy among persons with rectal chlamydia

Legal Status of Expedited Partner Therapy (EPT)



Poll Question

Do you routinely offer asymptomatic sexually active women with *non*-STI complaints screening for chlamydia and gonorrhea?

- A) No, I am too busy - we are an urgent care center, not a primary care office
- B) I probably should, but I am afraid their insurance won't cover the cost
- C) Yes, they should be offered screening

Why Is Screening So Important??

Bottom line – Most patients are unaware they even have an infection!

Even when a woman has symptoms, they are often so mild and nonspecific that they are mistaken for a bladder or vaginal infection

**Asymptomatic
Chlamydia**

75%

**Asymptomatic
Gonorrhea**

50%

**Asymptomatic
Trichomonas**

80%

CDC Screening Guidelines for CTNG in Women

Screening Compliance with CDC Recommendations is Dismal in the US!!

- Routine screening for chlamydia and gonorrhea infection on an annual basis is recommended for all sexually active females aged 15–24
- A national survey of youth aged 15–25 years found that most had never received an STI test; only 16.6% of females and 6.6% of males had been tested in the past 12 months

Take-home message

This population accounts for almost half of all new STD infections yearly!

Screening for Other Women at Increased Risk of CTNG

Risk factors for women 25 years or older (who should also be screened annually):

- They have a new partner
- More than one sex partner
- A sex partner with concurrent partners
- A sex partner who has an STI
- Practice inconsistent condom use
- Have a previous or coexisting STI
- Have a history of exchanging sex for money or drugs
- Have a history of incarceration

Take-home Reminder!

- Screen based on age and risk factors, not just symptoms or exposure!
- Chlamydia infections are asymptomatic in 70-75% of females
- Gonorrhea infections are asymptomatic in 50% of females

CDC CTNG Screening Guidelines for Men

Men Who Have Sex with Women

There is insufficient evidence for routine CTNG screening among heterosexual men who are at low risk for infection, however, screening young men should be considered in high prevalence clinical settings such as:

- Communities with high prevalence rates of CTNG
- Adolescent clinics
- Correctional facilities
- STI/sexual health clinics
- Recent travel history with sexual contacts outside of the US

Men Who Have Sex with Men

- Chlamydia and gonorrhea testing at least annually for sexually active MSM at sites of contact (urethra, rectum), regardless of condom use
- Add Pharyngeal Gonorrhea testing at least annually for sexually active MSM with pharyngeal sites of contact
- Every 3 to 6 months if at increased risk (i.e., MSM on PrEP, with HIV infection, or if they or their sex partners have multiple partners)

How can we improve Screening Rates?

- Standing orders for the registration/triage staff
- Express visits
- EMR clinical decision tools
- Specimen panels
- Reflex testing
- Designate a clinical champion!
- Carve out payments for CDC recommended screenings
- Because of a high likelihood of reinfection, the CDC also recommends re-testing all patients diagnosed with chlamydial or gonococcal infection **3 months after** treatment, regardless of whether they believe their partners have been treated

Education is Key to Slowing Transmission

THE LOWDOWN ON HOW TO PREVENT SEXUALLY TRANSMITTED DISEASES

Practice Abstinence
The surest way to avoid STDs is to not have sex.

This means not having vaginal, oral, or anal sex.

Have Fewer Partners
Agree to only have sex with one person who agrees to only have sex with you.

Make sure you both get tested to know for sure that neither of you has an STD. This is one of the most reliable ways to avoid STDs.

Talk With Your Partner
Talk with your sex partner(s) about STDs and staying safe before having sex.

It might be uncomfortable to start the conversation, but protecting your health is your responsibility.

Use Condoms
Using a condom correctly every time you have sex can help you avoid STDs.

Condoms lessen the risk of infection for all STDs. You still can get certain STD infections, like herpes or HPV, from contact with your partner's skin even when using a condom.

Get Vaccinated
The most common STD can be prevented by a vaccine.
The HPV vaccine is safe, effective, and can help you avoid HPV-related health problems like genital warts and some cancers.
Who should get the HPV vaccine?

All boys and girls ages 11 to 12, but the vaccine can start at age 9

Everyone through age 26 years, if not vaccinated already

Get Tested
Many STDs don't have symptoms, but they can still cause health problems.

Talk with your health care provider | Search for CDC recommended tests | Find a location to get tested for STDs
The only way to know for sure if you have an STD is to get tested.

The Good News
STDs **ARE** preventable. There are steps you can take to keep yourself and your partner(s) healthy.
Here's How You Can Avoid Giving or Getting an STD: 

If You Test Positive...
Getting an STD is not the end!
Many STDs are curable and all are treatable.
If either you or your partner is infected with an STD that can be cured, both of you need to start treatment immediately to avoid getting re-infected.

View Infographic Online at: www.cdc.gov/std/prevention/lowdown/

- Adolescents are also especially vulnerable to sexual risk because they are undergoing rapid cognitive, behavioral, emotional, and social development.

The CDC's website is an excellent source of information for both patients and providers and provides numerous free educational documents and posters for download. <https://www.cdc.gov/std/prevention/default.htm>

Taking a Sexual History

The Five “P”s

To further guide your dialogue with your patient, the 5 “Ps” may be a useful way to help you remember the major aspects of a sexual history.

1. Partners
2. Practices
3. Protection from STIs
4. Past History of STIs
5. Pregnancy Intention

These are the areas that you should openly discuss with your patients. You probably will need to ask additional questions that are appropriate to each patient’s special situation or circumstances, but the goal of the 5Ps is to improve patient health, not simply to solicit full disclosure of sexual practices, especially if patients are not comfortable.

Dialogue With Patient

- **May I ask you a few questions about your sexual health and sexual practices? I understand that these questions are personal, but they are important for your overall health.**
- **At this point in the visit I generally ask some questions regarding your sexual life. Will that be ok?**
- **I ask these questions to all my patients, regardless of age, gender, or marital status. These questions are as important as the questions about other areas of your physical and mental health. Like the rest of our visits, this information is kept in strict confidence unless you or someone else is being hurt or is in danger. Do you have any questions before we get started?**
- **Do you have any questions or concerns about your sexual health?**

“Presumptive” and “Empiric” Treatment of STIs

Long delays in test results for samples sent to central labs, as well as poor follow-up, often lead clinicians to treat before a lab result is obtained

Empiric Treatment



Treatment for patients who have a proven or suspected infection, but the responsible organism(s) has or have not yet been identified

Presumptive Treatment



Treatment begun on the basis of an educated guess and in the absence of laboratory confirmation of disease

Syndromic Treatment



Treatment occurs before confirmation of a definitive diagnosis

Problem: NG and CT infections in women are often asymptomatic. Relying on signs and symptom to treat NG and CT often leads to under-treatment in women

By contrast: result- or data-driven treatment is treatment guided by, or informed by, a test result

A Real Conundrum...

SETTING	LOCATION	% OVER-treated	% UNDER-treated
Emergency Dept 	Chicago, IL	21.6%	43.4%
	Inner city	86%	4%
	Urban academic	46.7%	43.8%
	St. Louis, MO (pregnant women)	15.6%	80%
	St. Louis, MO (women)	67.5%	87.5%
Urgent Care	Baton Rouge, LA	87%	12%

33%

undertreated patients
lost to follow up

54%

Under-treated patients
contacted did NOT return for
treatment

Catch-22

To treat or not to treat???

Consequences of Under-Treatment of STI

- **Public health concern**, creating a pool of untreated patients at risk of spreading the infection
- **Delayed** treatment may result in complications of an untreated progressive infection (details on next slide)
- **Delayed** expedited partner treatment
- **Reduced** opportunity for result-enabled, face-to-face clinician—patient dialogue

Consequences of Over-Treatment of STI

- Unnecessary exposure of the patient to a medication leading to possible adverse effects
- Selection of antibiotic-resistant microorganisms thus contributing to the further emergence of antibiotic-resistant infections
- Ineffective or misleading clinician-patient dialogue because discussion will be biased by an incorrect diagnosis
- Inefficient clinic workflow: staff needs to contact patient by phone (often problematic) and schedule return appointment for the correct treatment
- Reduced patient-satisfaction
- Reduced clinician-satisfaction

New Research Evaluating Rapid POC CTNG Testing

- May, et al, found a significant reduction in unnecessary antibiotic treatment (overtreatment) for CT/NG in subjects tested on a rapid molecular test compared with those tested with delayed NAAT
- Gaydos, et al, also compared rapid CT/NG testing vs delayed CT and NG testing
 - In this study, none of the patients in the rapid testing group were undertreated compared with 56% who were undertreated in the routine testing group
 - Overtreatment was reduced, as well, with only 25% unnecessarily treated in the rapid testing group vs 47% in the routine testing group

Take Home Message:

*Recent studies have shown that rapid CTNG testing has the potential to **significantly reduce** over- and under-treatment with antibiotics*

A New FDA Cleared, CLIA-Waived, POC Device for CT/NG/TV Detection

Performance of a single-use, rapid, point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: a cross-sectional study



Authors: Sheldon R Morris, MD Claire C Bristow, PhD Michael R Wierzbicki, PhD Mark Sarno, eJD Lenore Asbel, MD Audrey French, MD Charlotte A Gaydos, DrPH Lydie Hazan, MD Leandro Mena, MD Purnima Madhivanan, MD Susan Philip, MD Saara Schwartz, MD Constance Brown, MD David Styers, BS Toni Waymer, BA Jeffrey D Klausner, MD

Published November 23, 2020

[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30734-9/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30734-9/fulltext)

A study on the Performance of the Visby Medical Sexual Health Test Findings

Between Feb 25, 2019, and Jan 6, 2020, 1585 participants aged between 14 years and 80 years (mean 34·8 [SD 14·2]) were enrolled. 1555 participants had tests run with the investigational device, of whom 1532 (98·5%) had a valid result on either the first or repeat test. Among the patients with evaluable results (including a determinate patient-infected status), the device had

***C trachomatis* (n=1457):**
sensitivity of 97·6% (95% CI 93·2–99·2)
specificity of 98·3% (97·5–98·9)

***N gonorrhoeae* (n=1468):**
sensitivity of 97·4% (86·5–99·5)
specificity of 99·4% (98·9–99·7)

***T vaginalis* (n=1449):**
sensitivity of 99·2% (95·5–99·9)
specificity of 96·9% (95·8–97·7)

HIV & Syphilis on the rise

- Individuals with an active syphilis infection have an estimated 2-5x increased risk of contracting HIV if exposed to that virus
- Untreated syphilis in pregnant women who acquired the disease during the four years before delivery can lead to infection of the fetus in up to 80% of cases and may result in stillbirth or infant death in up to 40% of cases
- One in eight people living with HIV in the United States are unaware of their infection
- The CDC recommends that individuals at higher risk of HIV infection be tested at least annually

Syphilis Increasing in MSM and Heterosexuals

- In 2018, MSM accounted for the majority (53.5%) of all reported cases of syphilis
 - 41.6% were known to be living with diagnosed HIV
- Rates of syphilis among women increased 30.4% during 2017–2018 and 172.7% during 2014–2018, suggesting a rapidly growing heterosexual epidemic
- STDs reached an all time high in 2018, marking the fifth consecutive year of increases
 - Syphilis cases increased 185% from 2014-2018
- It is recommended that PrEP patients are **tested quarterly** for STI
<https://www.cdc.gov/hiv/risk/prep/index.html>



Congenital Syphilis

- Untreated syphilis in pregnant women **results in stillbirth or infant death in up to 40% of cases**
- There were a total of **1,306 congenital syphilis** cases reported in 2018; the most since 1995
- Cases of congenital syphilis **increased by 87%** from 2012 to 2016, from 8.4 to 15.7 cases per 100,000 live births
- 70% of infants with congenital syphilis are born to mothers who received prenatal care, but detection/treatment of maternal syphilis often occurs too late to prevent congenital syphilis.



CDC Recommendations

PATIENT POPULATION	SYPHILIS	HIV
Pregnant Women	1. Retest early third trimester and at delivery if high risk	<ol style="list-style-type: none"> 1. All on first prenatal visit 2. Retest early third trimester and at delivery if high risk
MSM (Men who have sex with men)	<ol style="list-style-type: none"> 1. Minimum annual testing if sexually active 2. Every 3 - 6 months if at increased risk. 	At least annually for sexually active MSM if HIV status is unknown or negative and the patients himself or his sex partners(s) have had more than one sex partner since their most recent HIV test)
Persons with HIV	For sexually active individuals, screen at first HIV evaluation and at least annually thereafter. More frequent screening may be appropriate depending on individual risk behaviors and local epidemiology.	N/A
Men	N/A	<ol style="list-style-type: none"> 1. All men aged 13 - 64 (opt out) 2. All men who seek evaluation or treatment for STDs
Women	N/A	<ol style="list-style-type: none"> 1. All women aged 13 - 64 (opt out) 2. All women who seek evaluation or treatment for STDs

This equates to 1 to 3 Tests Per Pregnant Women for both HIV and Syphilis and 1 to 4 tests for MSM at high risk

Published Studies

HIV-Syphilis Antibody rapid detection at POC

- A New Generation of Rapid Assays: Detection of HIV and Syphilis Simultaneously by Niel Constantine, Univ. of Maryland

DPP HIV-Syphilis System: Summary of Overall *T. pallidum* Sensitivity and Specificity (n=791)

Sample Matrix	Syphilis Sensitivity (95% CI)	Syphilis Specificity (95% CI)
Fingerstick Blood	111/119 = 93.3% (87.3% - 96.6%)	646/668 ¹ = 96.7% (95.1% - 97.8%)
Venous Whole Blood	115/119 = 96.6% (91.7% - 98.7%)	646/672 = 96.1% (94.4% - 97.3%)
Plasma	116/119 = 97.5% (92.9% - 99.1%)	647/672 = 96.3% (94.6% - 97.5%)

¹Fingerstick Whole Blood Results not collected from four (4) subjects.

HIV:

Sensitivity = 99.4%

Specificity = 99.6%

Treponema pallidum:

Positive Percent Agreement = 94.7%

Negative Percent Agreement = 95.5%

- A CARTRIDGE-BASED RAPID IMMUNOASSAY FOR THE DETECTION OF HIV AND SYPHILIS by Charlotte Gaydos, Johns Hopkins

Summary of Overall Syphilis Sensitivity and Specificity (n=341)

Sample Matrix	Syphilis Sensitivity (95% CI)	Syphilis Specificity (95% CI)
<u>Fingerstick Blood</u>	33/33= 100% (89.6% - 100%)	297/308= 96.4% (93.7% - 98.0%)
Venous Whole Blood	33/33= 100% (89.6% - 100%)	295/308= 95.8% (92.9% - 97.5%)
Plasma	33/33= 100% (89.6% - 100%)	294/308= 95.5% (92.5% - 97.3%)

Poll Questions

Do you believe that a rapid, point-of-care STI test would be clinically and operationally useful in your clinic?

- A) Yes
- B) No
- C) Unsure

What is the probability that you would adopt and utilize a rapid, point-of-care STI test at your clinic in the next year? Scale: 1=lowest, 5=highest

- A) 5 (highly probable)
- B) 4
- C) 3
- D) 2
- E) 1 (highly improbable)

Advantages of Rapid STI Point-Of-Care Tests

CLINICAL advantages

- Enables result-driven, appropriate treatment within the span of a single clinic visit
- Reduces probability of untreated STI infection progression
- Reduces probability of onward transmission
- Facilitates patient education by providing an accurate diagnosis before the patient leaves the clinic
- Enables the prompt treatment of the diagnosed person's sexual partner(s) via the CDC-sanctioned EPT program (Expedited Partner Treatment)

OPERATIONAL advantages

- Improves clinic workflow - increases the efficiency of clinic staff
- Likely positively impacts clinic's cost effectiveness
- Increases patient and physician satisfaction by providing a clinician with an accurate diagnosis during the initial visit

FINANCIAL advantages

- Time = Money
- Patient treated immediately without need for 2nd clinic visit - free up schedule to see other patients
- Increased E/M level office visit
- Will a second visit for the same diagnosis be reimbursed?
- Sexual partner(s) may be referred to clinic for testing/treatment
- No more follow up calls

Take-Home Points

1. 80% of STI cases are now diagnosed in non-STI clinics (Hello Urgent Care!)
2. Chlamydia is asymptomatic in 75% of women, Gonorrhea is asymptomatic in 50% of women
3. Half of all new STDs are in young people aged 15-24
4. Self-collected vaginal swabs are sufficient for CTNG screening
5. Doxycycline treatment of choice for chlamydia— Azithromycin removed as first-line therapy
6. Ceftriaxone 500 mg now recommended for gonorrhea treatment – azithromycin removed
7. Compliance rates with CDC CTNG screening recommendations in the United States are dismal!
8. Most states have provisions allowing for Expedited Partner Therapy without requiring provider see the partner in person
9. A Rapid, POC test for STIs can reduce over and under treatment of STIs and become a new tool for antibiotic stewardship