# Bacterial Infections

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# HRSA Disclaimer

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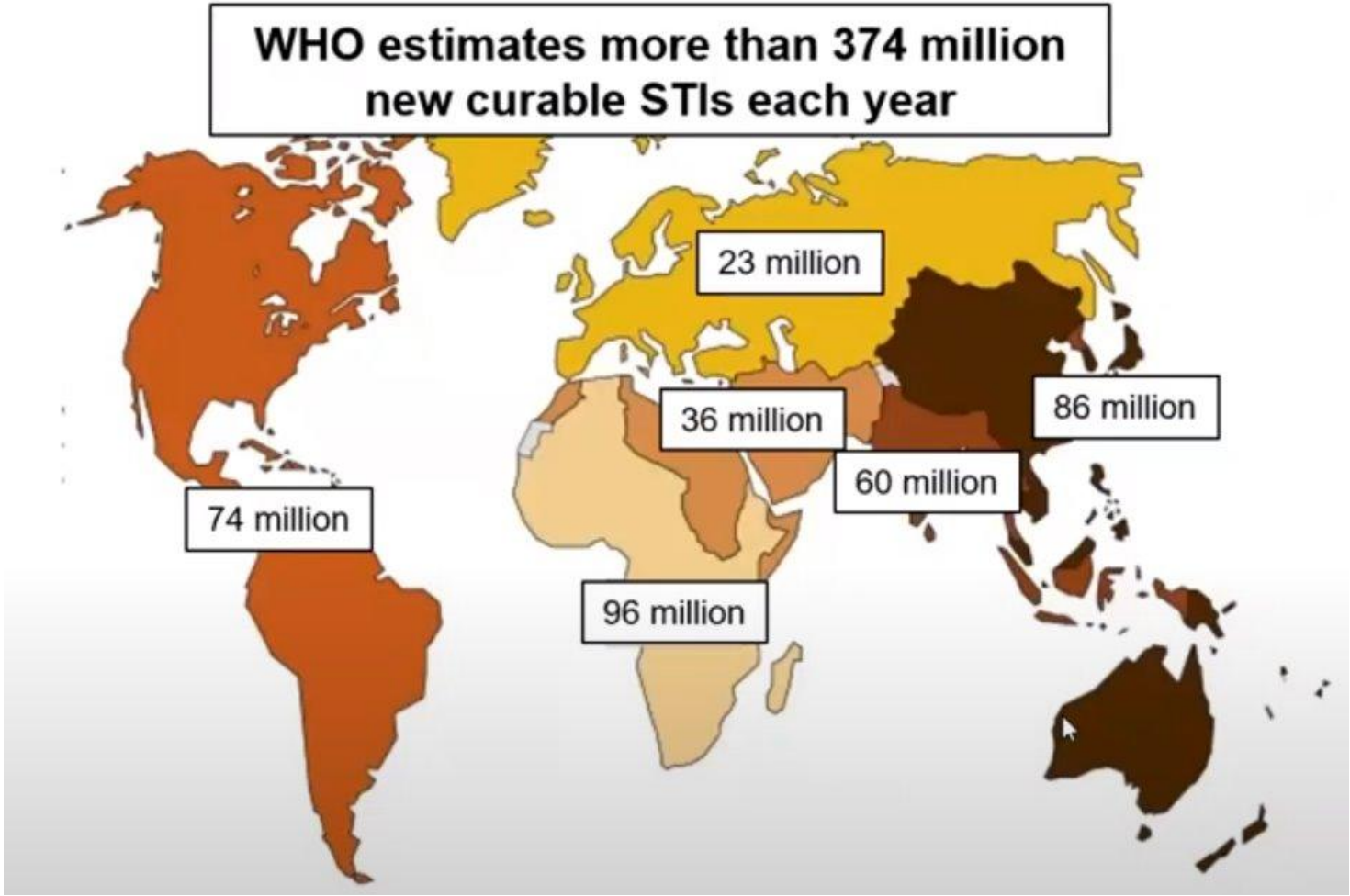
# Objectives

1. Describe current trends in bacterial STIs prevalence.
2. Explain how to screen for, interpret test results, and treat for syphilis, chlamydia, and gonorrhea.
3. Discuss options for prevention of bacterial STIs such as DoxyPEP.

# Agenda

1. The BIG 3: Gonorrhea/Chlamydia/Syphilis
    - Epidemiologic Trends
    - Clinical Presentations
    - Diagnostics
2. Cases/Break-Outs/Discussion
3. Treatment and Prevention
4. The Future of Bacterial STI (bSTI)
5. Questions/Comments

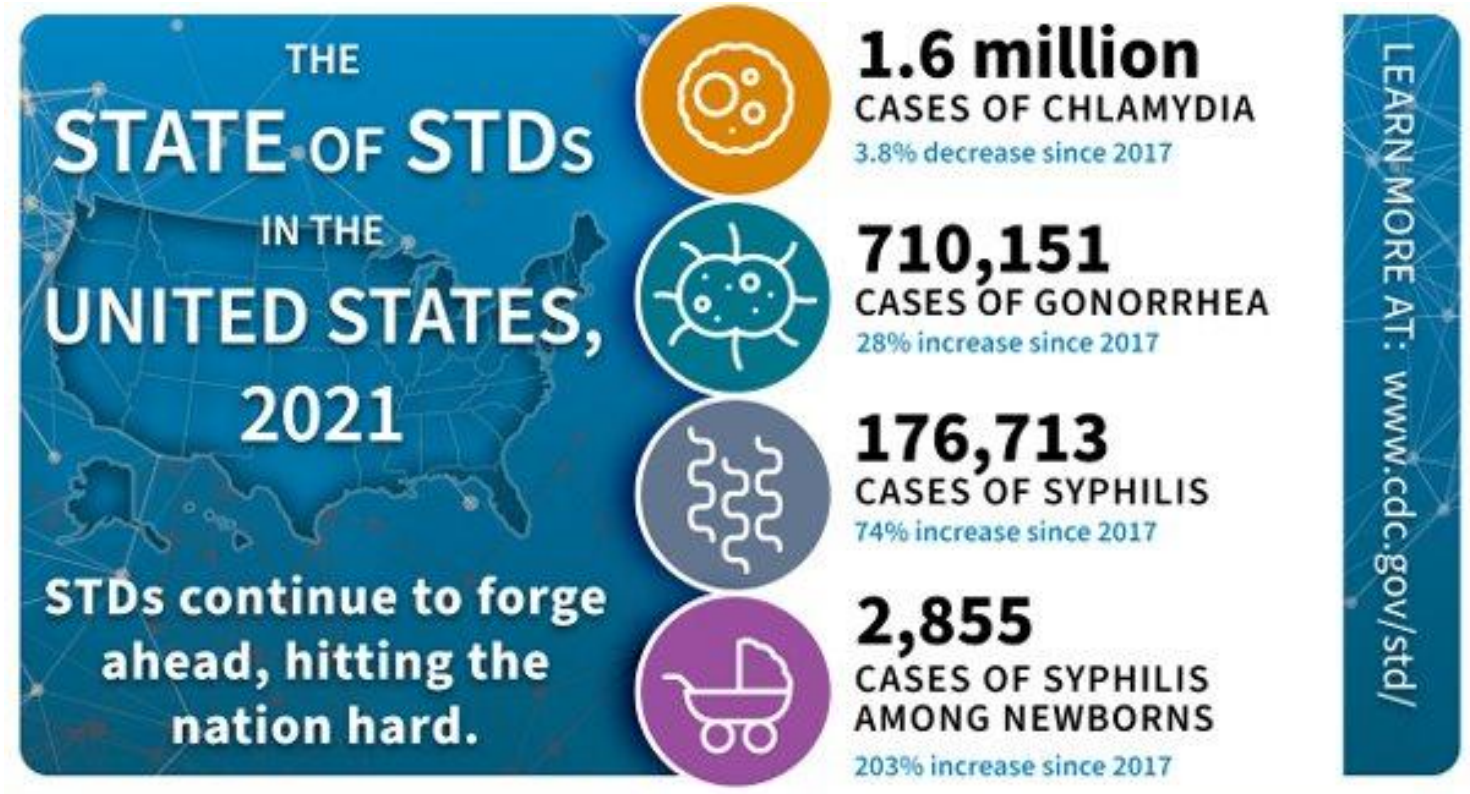
# Global STI Trends



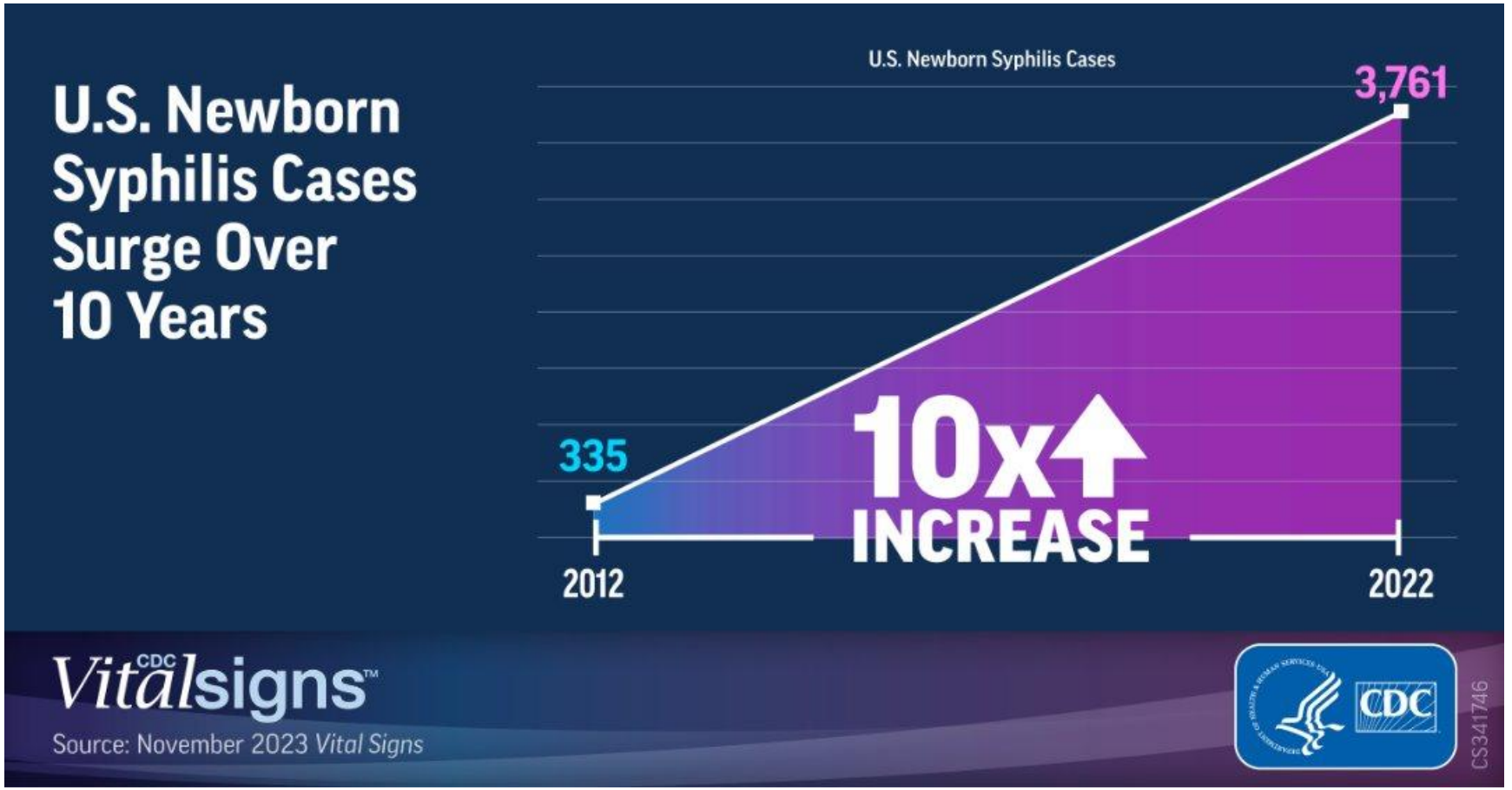

WHO Global Progress Report, 2021

# US STI Trends

Anyone who has sex could get an STI, but some groups are more affected.



# **STI Trends:** Congenital Syphilis

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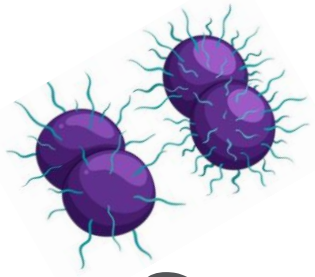
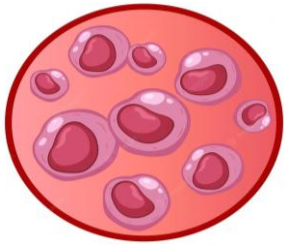
https://www.cdc.gov/mmwr/volumes/72/wr/mm7246e1.htm?s_cid=mm7246e1_w

Almost 9 in 10 cases of newborn syphilis in 2022 might have been prevented with timely testing and treatment during pregnancy.

One of the biggest risk factors for syphilis for some people is where they live. According to previous CDC data, in 2021, more than 70 percent of the U.S. population lived in counties considered to have high rates of syphilis among reproductive-age women (above the Healthy People 2030 target).



# Bacterial STIs



## Gonorrhea

- Causative Agent: *Neisseria gonorrhoeae* (bacterium)
- Infection Site: Genitourinary tract, throat, rectum
- Symptoms: Painful urination, discharge, asymptomatic in many cases
- Complications: PID, infertility, increased risk of HIV

## Chlamydia

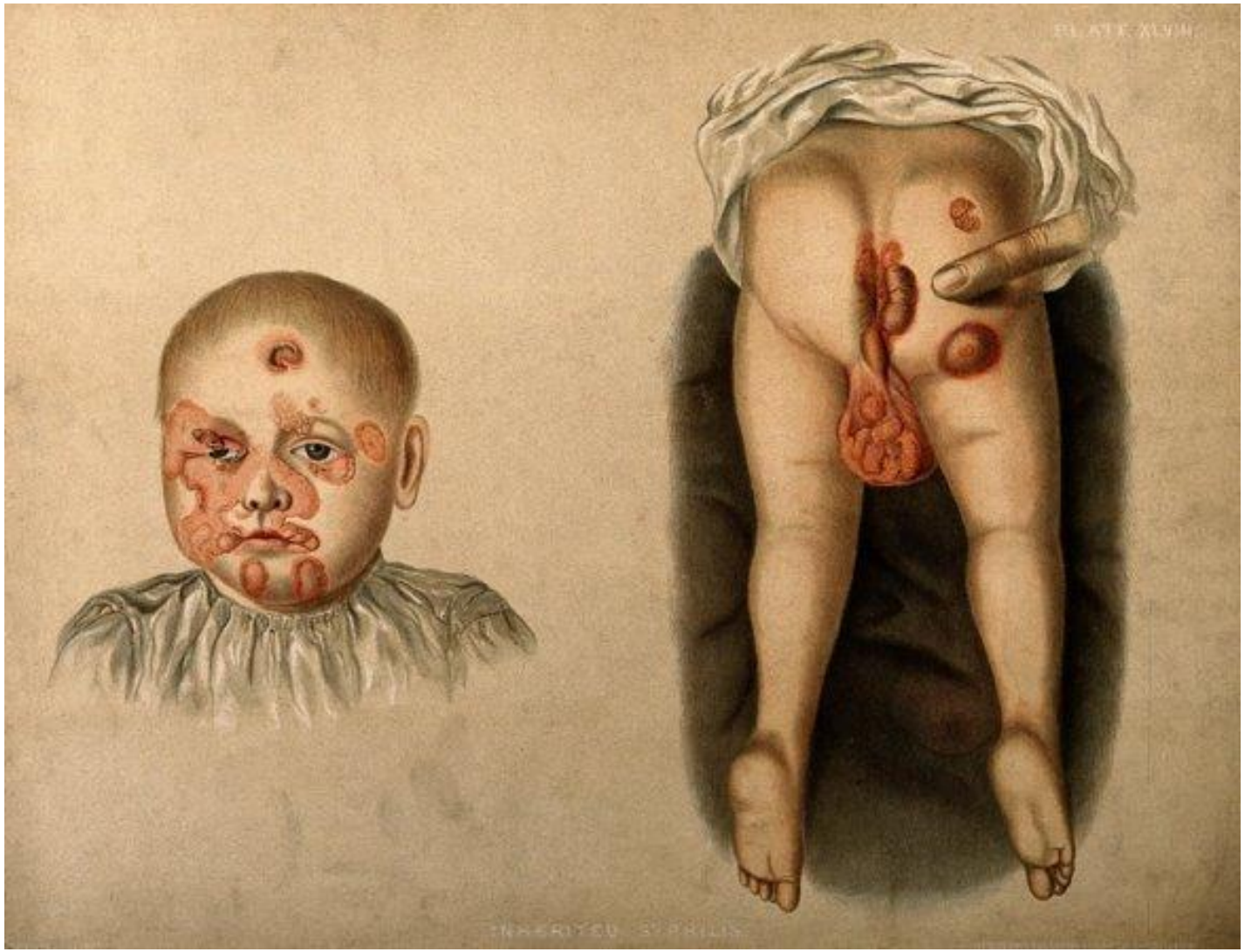
- Causative Agent: *Chlamydia trachomatis* (bacterium)
- Infection Site: Genitourinary tract
- Symptoms: Often asymptomatic, may have discharge or painful urination
- Complications: PID, ectopic pregnancy, infertility

# Bacterial STIs

## Syphilis

- Causative Agent:  (spirochete bacterium)
- Stages: Primary (ulcers), Secondary (rash), Latent, Tertiary (organ damage)
- Symptoms: Varies by stage, can be asymptomatic
- Complications: Neurological, cardiovascular issues, congenital syphilis

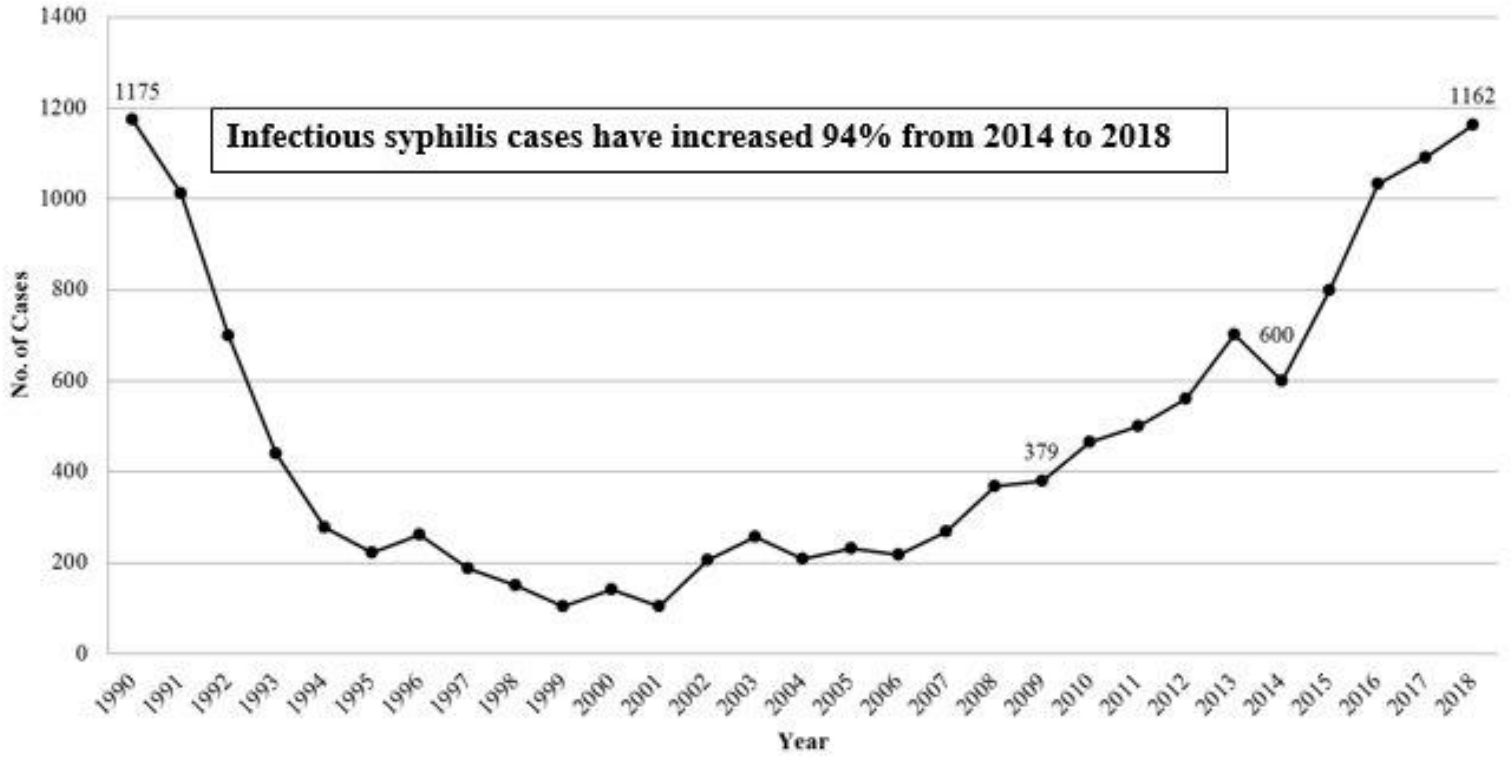
# Syphilis



https://commons.wikimedia.org/wiki/File:Hereditary_syphilis;_lesions_face,_buttocks,_genitals,_1850_Wellcome_V0010240.jpg

# Syphilis

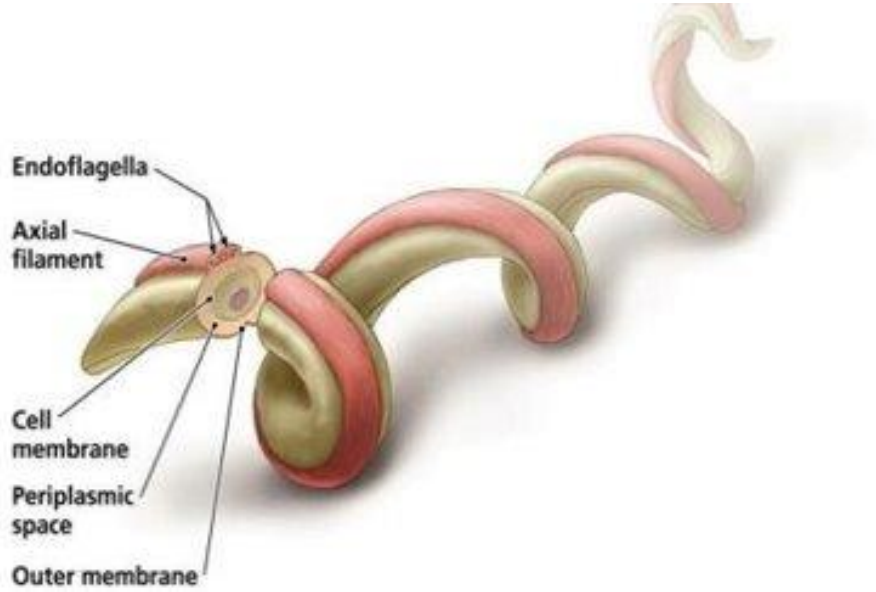
## Confirmed and Probable Infectious Syphilis* Cases, Massachusetts, 1990 to 2018

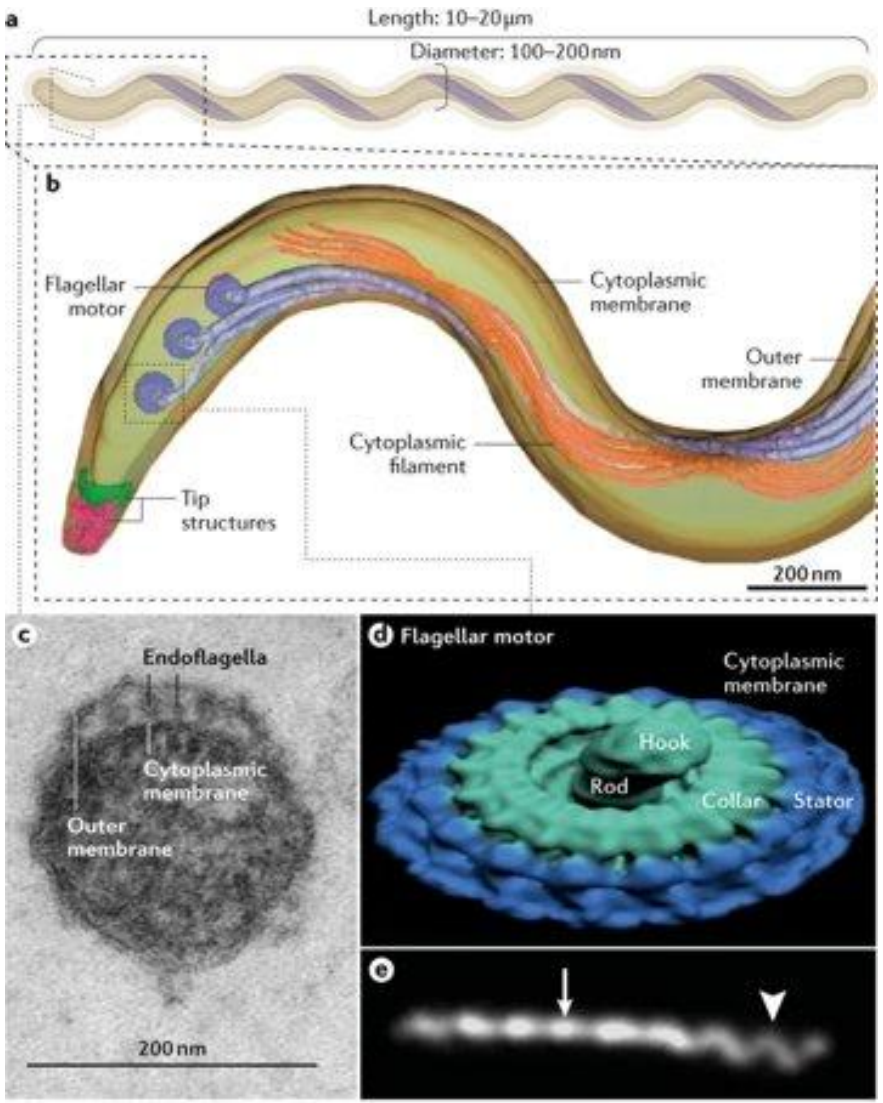



Data are current as of 4/5/2019 and are subject to change.
*Infectious syphilis is defined as primary, secondary and early latent stages of syphilis.
Data Source: Massachusetts Department of Public Health/Bureau of Infectious Disease and Laboratory Sciences/ Division STD Prevention

# Syphilis

- *Treponema pallidum*
  - Gram negative bacterium;
    - Obligate parasite
  - Spirochetes




Nature Reviews | Disease Primers

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# **Syphilis:** Transmission

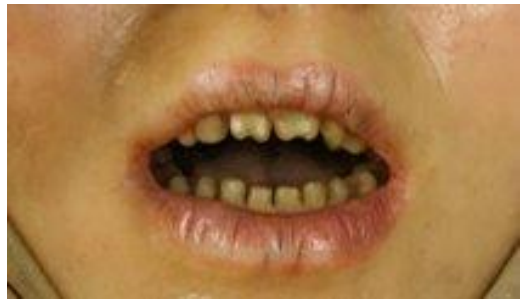
1. Acquired Syphilis: *T. pallidum* enters through bodily fluid
    - Cuts/Breaks in skin/mucosa
    - Sexual Contact
    - Contaminated needles
    - Direct contact with skin lesions (spirochetes)

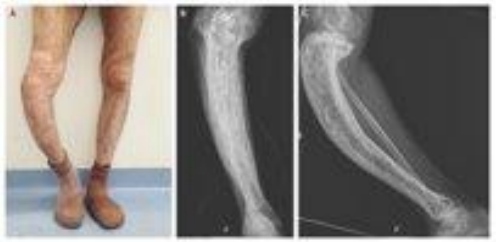
2. Congenital Syphilis
    - Infects baby *in utero* or while patient is being delivered

# **Syphilis:** Congenital Syphilis

Can cause early disease (first 2 years) or late disease, which includes:

- Still birth/miscarriage (early)
- Optic neuritis (early)
- Snuffles (early)
- Hepatosplenomegaly (early)



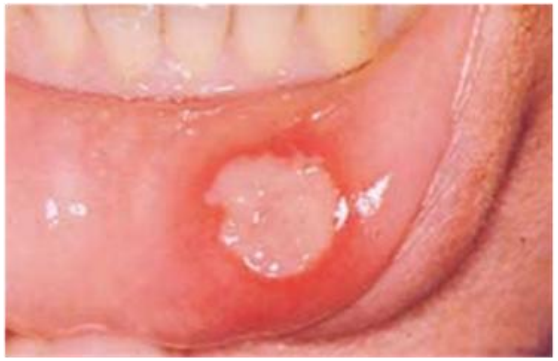


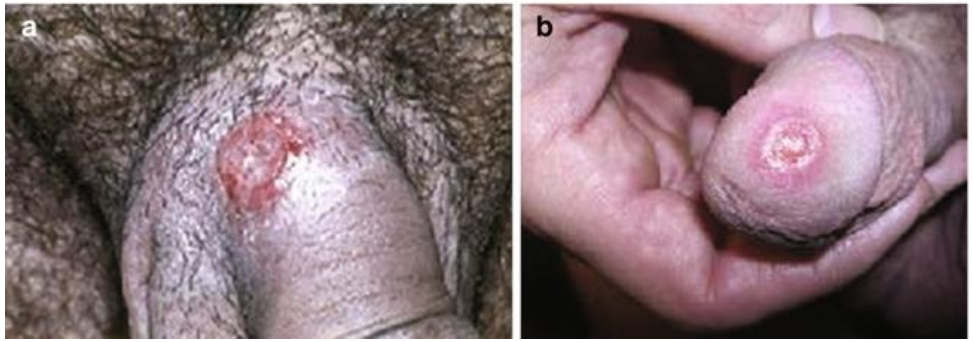
- Saddle nose (late)
- Saber shins (late)
- Hutchinson teeth (late)
- Hearing loss (late)

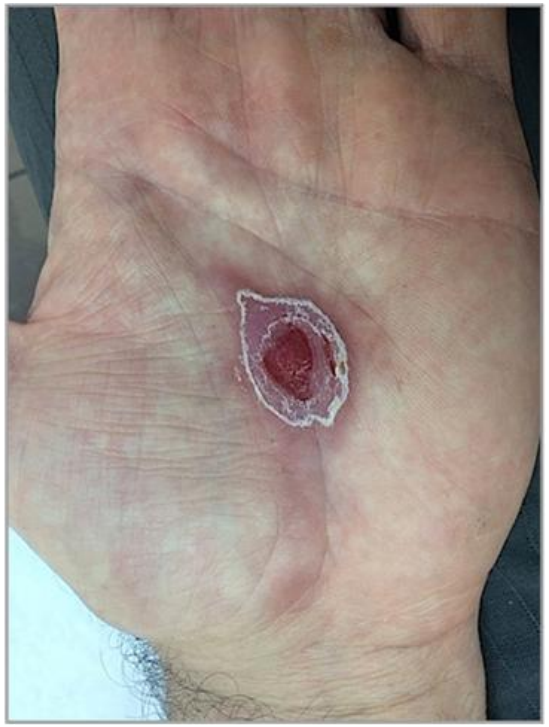
# Syphilis

**Three stages:**

**Primary** (Early localized)

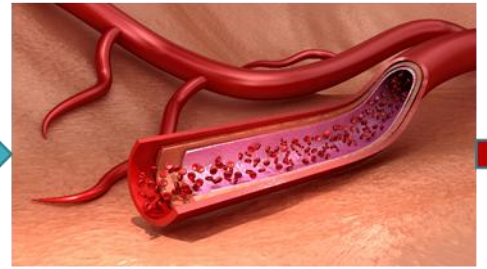


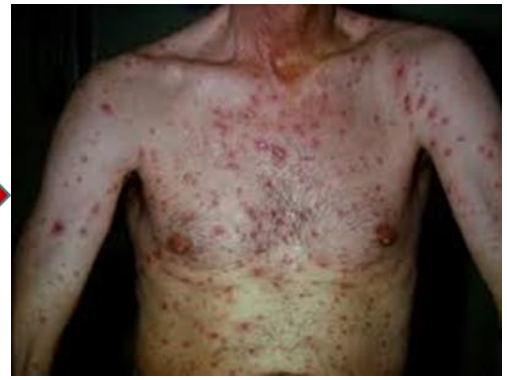


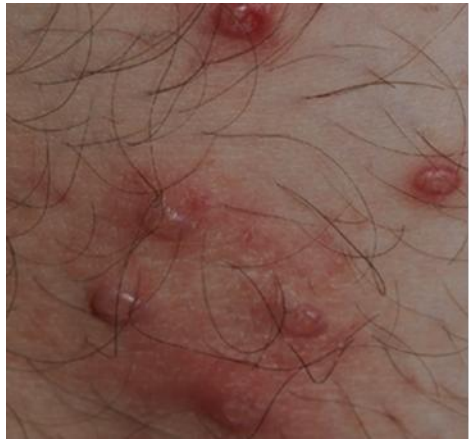



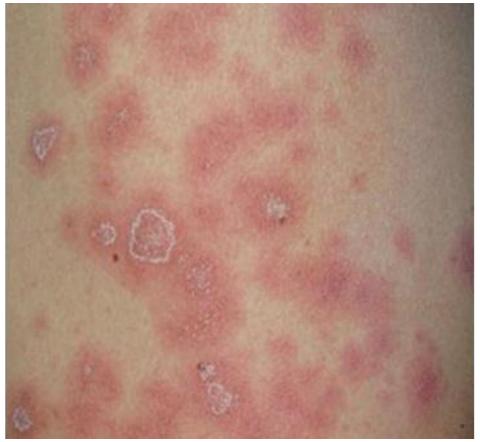
# Syphilis

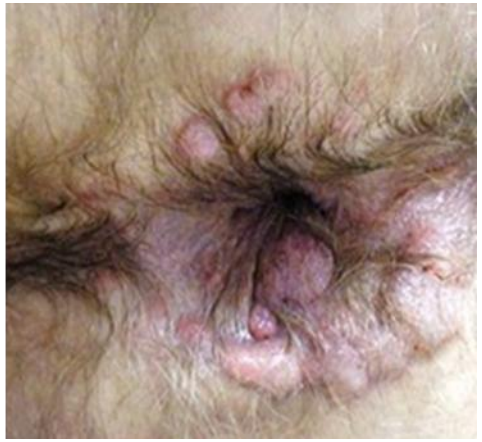
**Secondary** (Disseminated stage)
**Latent** (Dormant, asymptomatic)





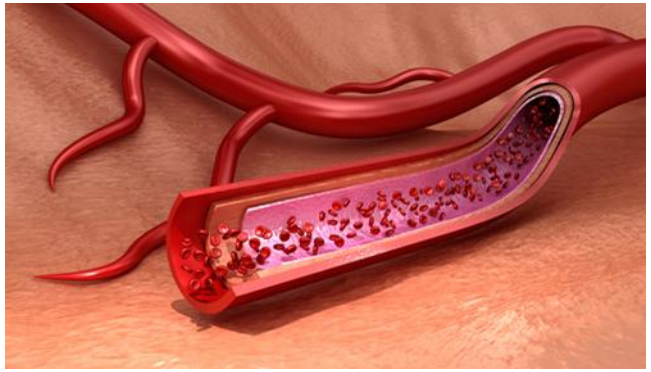




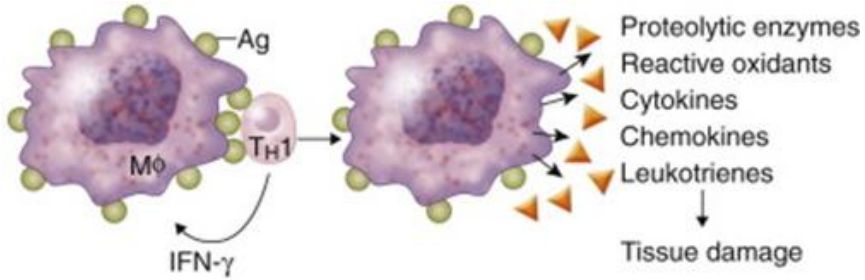


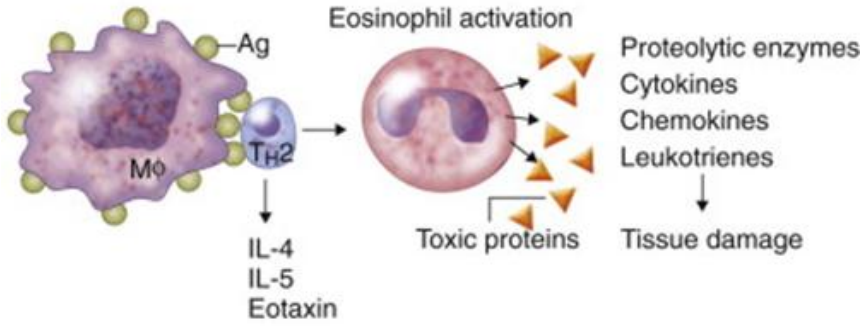
# **Syphilis:** Tertiary Stage

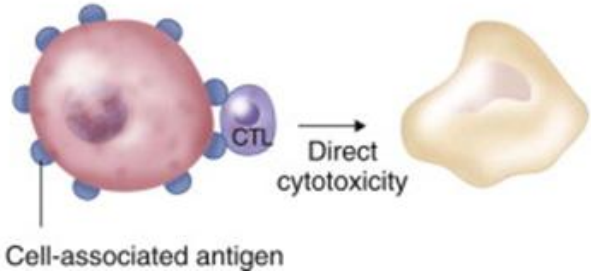
Few spirochetes → Lots of time → Lots inflammation due to impressive Type IV Hypersensitivity immune response



Delayed T-cell response
With TNF, IL-1, IL-6

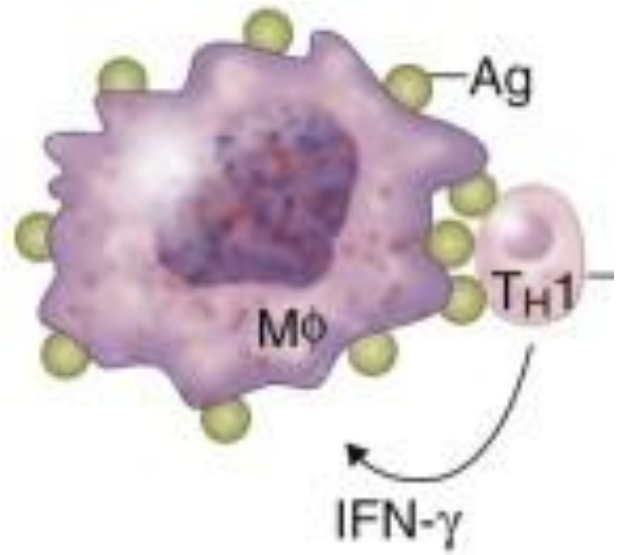


# **Syphilis:** Tertiary Stage

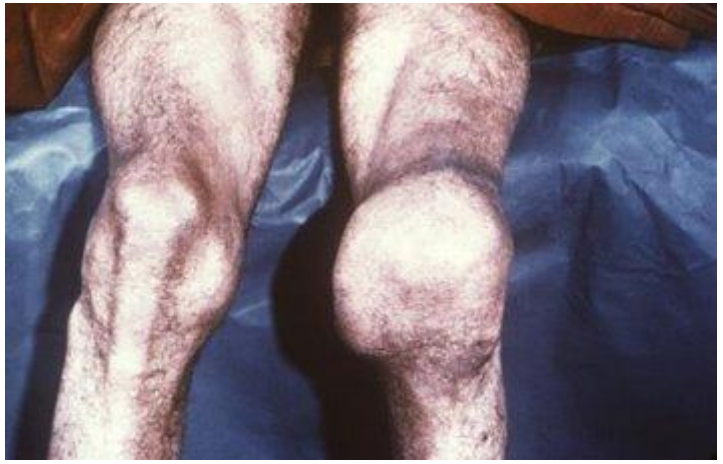
## Tertiary Syphilis – Immune Response

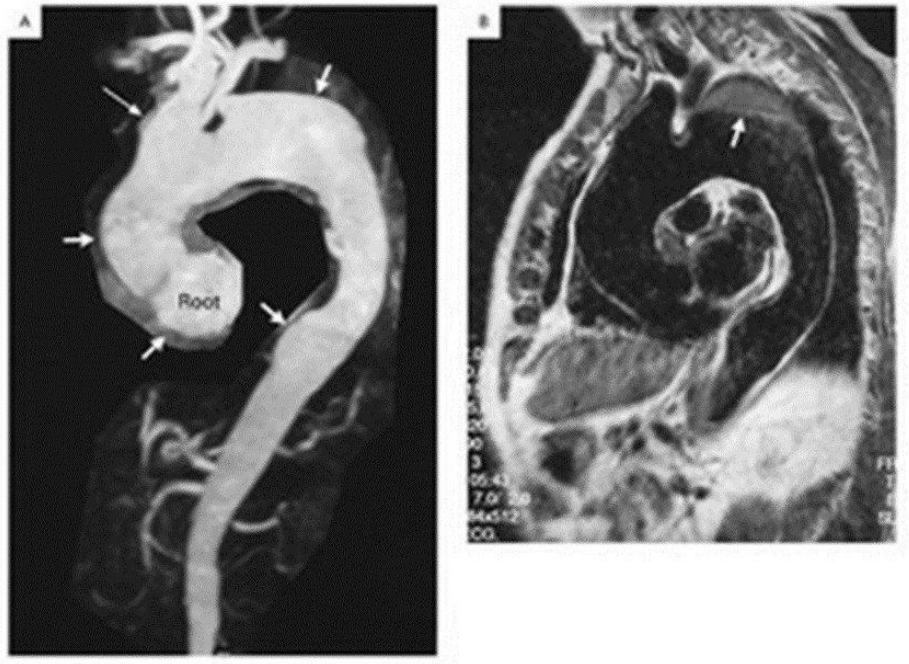


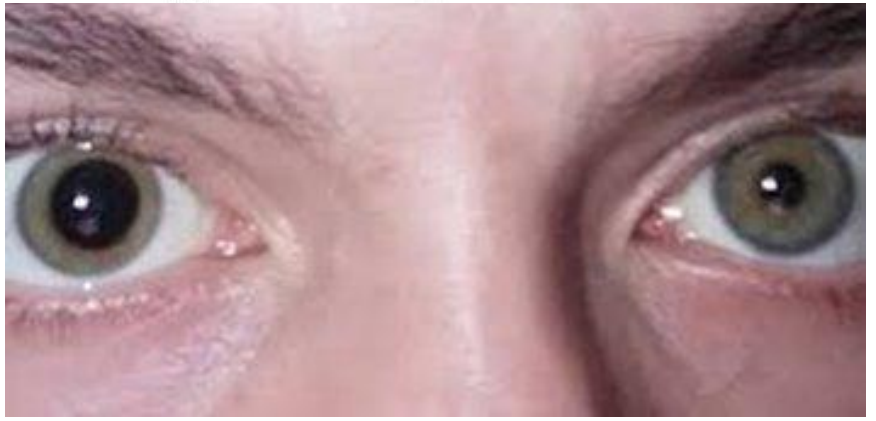

# **Syphilis:** Tertiary Stage

Tertiary Syphilis: Organ damage

- Cardiovascular syphilis
- Neurosyphilis
- Liver/joint/testes





# **Syphilis:** Diagnostics

**Serology** [antibody] **tests**:

- **Non-treponemal tests [NTT]** → Very sensitive, but not specific
- **Treponemal Tests** → Very specific

# **Syphilis:** Diagnostics

**Non-treponemal Tests:** May be negative in Latent Syphilis

1. Rapid Plasma Reagin (RPR) Test
2. Venereal Disease Research Laboratory Test (VDRL) ***

These detect anti-cardiolipin antibodies ("reagin").

These are not specific for T pallidum – as cardiolipin also seen elsewhere in damaged cells in our bodies.

*** CSF also

# **Syphilis:** Diagnostics

**Treponemal Tests:**

1. T. pallidum-particle agglutination (TPPA) ***
2. Fluorescent treponemal antibody absorbed (FTA-Abs) Specific for T pallidum ***
3. Syphilis Enzyme Immunoassay (EIA)

***CSF also

# **Syphilis:** Diagnostics

| Table 2: Screening and Diagnostic Tests for Syphilis | |
|---|---|
| **Serologic Tests** | **Description** |
| **Nontreponemal:**<br>• Rapid plasma reagin (RPR)<br>• Venereal disease research laboratory (VDRL) | • Nonspecific quantitative tests<br>• May be negative in 15% to 25% of cases presenting with primary chancre [Larsen, et al. 1995; CDC 2013]<br>• Near 100% sensitivity during secondary syphilis [Larsen, et al. 1995; CDC 2013]<br>• May be positive in the setting of medical conditions other than syphilis, including HIV infection; collagen vascular diseases; narcotic drug use; advanced age; pregnancy; chronic liver disease; some viral infections, such as Epstein-Barr virus; and other chronic inflammatory conditions |
| **Treponemal:**<br>• Fluorescent treponemal antibody absorbed (FTA-Abs)<br>• *pallidum* particle agglutination (TP-PA)<br>• *pallidum* IgG + IgM enzyme-linked immunosorbent assay (ELISA)<br>• Treponemal enzyme immunoassay (EIA)/chemiluminescence immunoassay (CIA) | • Measure antibody to surface protein of pallidum (antibodies will persist; they do not afford protective immunity and cannot be used to diagnose subsequent episodes or to monitor response to therapy)<br>• More specific than nontreponemal tests<br>• Become reactive approximately 7 to 10 days after the appearance of the chancre<br>• Rarely produce false-positive results [Hernandez-Aguado, et al. 1998; CDC 2011; Park, et al. 2011] |

https://cdn.hivguidelines.org/wp-content/uploads/20200506154740/NYSDOH-AI-Management-of-Syphilis-in-Patients-with-HIV_5-6-20_RL.pdf

# **Syphilis:** Diagnostics

| Table 1: Sensitivity of Serologic Tests in Untreated Syphilis*§ | | | | |
|---|---|---|---|---|
| Test | Stage of Disease (Percent Positive [Range]) | | | |
| | Primary | Secondary | Latent | Tertiary |
| VDRL | 78 (74-87) | 100 | 95 (88-100) | 71 (37-94) |
| RPR | 86 (77-99) | 100 | 98 (95-100) | 73 |
| FTA-Abs§ | 84 (70-100) | 100 | 97 (97-100) | 96 |
| Treponemal Agglutination§ | 76 (69-90) | 100 | 97 (97-100) | 94 |
| EIA | 93 | 100 | 100 | — |

EIA, enzyme immunoassay; FTA-Abs, fluorescent treponemal antibody test; RPR, rapid plasma reagin; VDRL, venereal disease research laboratory.

§FTA-Abs and *T. pallidum* particle agglutination are generally considered equally sensitive in the primary stage of disease.
*Reprinted from Centers for Disease Control and Prevention [CDC 2013].

https://cdn.hivguidelines.org/wp-content/uploads/20200506154740/NYSDOH-AI-Management-of-Syphilis-in-Patients-with-HIV_5-6-20_RL.pdf

# Cases

3 Breakout rooms

Unique cases in each room

- Open book/resources discussion about each case
- Select one person to come back and share highlights from discussion

Discussion of each question as a collective

# Case #1: PLWH & Syphilis

56-year-old male living with HIV (CD4 >600, VL undetectable) comes in for routine STI screen and is found to have the following labs:

HIV VL: <20 copies

CD4: 23%, 640

RPR: 1:4

Treponemal EIA: Positive

What do you do next? Additional information/labs…

# Case #1: PLWH & Syphilis

*What if…*

- He reports no prior infections with negative testing 6 months ago?
- He reports a remote history of an infection (initial RPR of 1:32, 5 years ago) with RPR titers between 1:2 and 1:4 for years with no new symptoms or findings?
- He reports no prior infection and now presents with headache and blurry vision?

# Case #2: Urethritis

27-year-old female presents with 5 days of urethral irritation and some discharge. She was treated with ceftriaxone 500mg IM x1 however GC/CT NAAT testing was negative. She returns with continued symptoms after 1 week.

What do you do next?

Additional information/labs/treatment…

# Case #2: Non-Gonococcal Urethritis (NGU)

**Definition:**
Urethral inflammation **not caused by Neisseria gonorrhoeae**

**Common Pathogens:**
- *Chlamydia trachomatis* (most common)
- *Mycoplasma genitalium*
- *Ureaplasma urealyticum*
- HSV, adenovirus
- Trichomonas vaginalis
- Idiopathic (~20–40%)

# Case #2: Non-Gonococcal Urethritis (NGU)

🔬 **Diagnostic Workup:**

- Urethral symptoms (discharge, irritation, dysuria)
- Urine NAAT: GC/CT ± M. gen (if available)
- Microscopy (≥5 WBC/HPF or leukocyte esterase on dipstick)
- Consider HSV PCR or trich testing if relevant

💊 **Management:**

- **Empiric:** Doxycycline 100 mg BID × 7 days
- **If *M. gen* positive:**
  - Start with doxy × 7 days → **Moxifloxacin** 400 mg daily × 7 days
- Abstain from sex × 7 days after treatment + partner treatment
- Reassess if symptoms persist: test-of-cure for M. gen, refer if needed

# Case #3: Painful Rectum

29 year old man who has sex with men presents with 1 week of rectal pain, tenesmus, and blood-tinged mucous discharge. He reports receptive anal sex with multiple partners over the past 2 months. He is HIV-negative and on daily PrEP.

He has mild abdominal tenderness, and rectal exam reveals severe tenderness, mucosal friability and purulent discharge.

Rectal NAAT: *Chlamydia trachomatis* positive

- What is the differential?
- How do distinguish treatment regimens?
- What follow up is needed?

# **Syphilis:** Treatment

**TABLE 2. FIRST-LINE AND ALTERNATIVE TREATMENTS BASED ON THE STAGE OF SYPHILIS INFECTION[8]**

| Stage of infection | First-line treatment | Alternative treatment |
|---|---|---|
| Primary | Benzathine benzylpenicillin 2.4 MU (1.8 g), single dose, intramuscular | Doxycycline 100 mg twice a day for 14 days, oral |
| Secondary | | |
| Early latent | | |
| Late latent or unknown duration | Benzathine benzylpenicillin 2.4 MU (1.8 g), weekly intervals for three weeks, intramuscular | Doxycycline 100 mg twice a day for 28 days, oral |
| Neurosyphilis, ocular syphilis, otosyphilis | Benzylpenicillin, 3 to 4 MU (1.8 to 2.4 g) every four hours for 14 days, intravenous | Doxycycline 200 mg twice a day for 28 days, oral |

# Doxycycline

**Bacterial Infections**

- Certain respiratory tract infections including pneumonia and sinusitis
- Skin and soft tissue infections
- Infections caused by *Mycoplasma pneumoniae*
- Chlamydial infections, including urethritis, proctitis, and pelvic inflammatory disease.
- Lyme disease caused by *Borrelia burgdorferi*
- Relapsing fever and other infections transmitted by ticks, lice, mites, and fleas.
- Brucellosis when combined with streptomycin
- Plague caused by *Yersinia pestis*
- Tularemia when used in combination with streptomycin
- Infections caused by Rickettsia, which include typhus fever, Rocky Mountain spotted fever, and Q fever.
- Syphilis in patients allergic to penicillins when used in multiple doses
- Leptospirosis
- For certain *Helicobacter pylori* infections in combination with other drugs

# Doxycycline

**Acne and Rosacea Treatment:**

- As an adjunctive therapy for severe acne and to treat rosacea.

**Malaria Prophylaxis:**

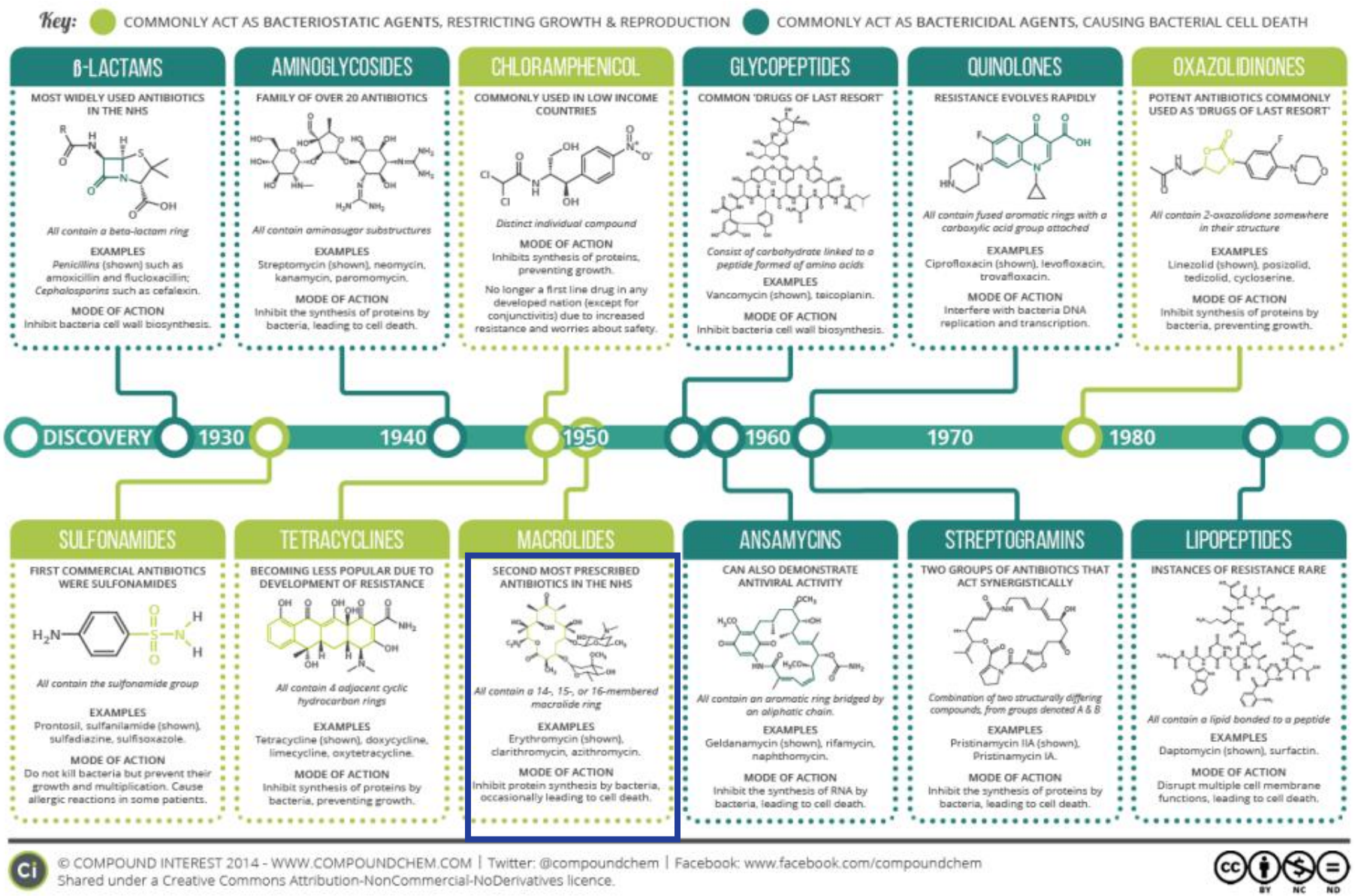
- Recommended for travelers to certain regions where malaria is endemic and strains are known to be resistant to other antimalarials.

**Anthrax Exposure**:

- For post-exposure prophylaxis and treatment of anthrax, including inhalational anthrax.

**As an anti-inflammatory:**

- Doxycycline has anti-inflammatory properties and may be prescribed for conditions like bullous pemphigoid and certain forms of arthritis.


Key: COMMONLY ACT AS BACTERIOSTATIC AGENTS, RESTRICTING GROWTH & REPRODUCTION
COMMONLY ACT AS BACTERICIDAL AGENTS, CAUSING BACTERIAL CELL DEATH
β-LACTAMS
MOST WIDELY USED ANTIBIOTICS IN THE NHS
All contain a beta-lactam ring
EXAMPLES
Penicillins (shown) such as amoxicillin and flucloxacillin; Cephalosporins such as cefalexin.
MODE OF ACTION
Inhibit bacteria cell wall biosynthesis.
AMINOGLYCOSIDES
FAMILY OF OVER 20 ANTIBIOTICS
All contain aminosugar substructures
EXAMPLES
Streptomycin (shown), neomycin, kanamycin, paromomycin.
MODE OF ACTION
Inhibit the synthesis of proteins by bacteria, leading to cell death.
CHLORAMPHENICOL
COMMONLY USED IN LOW INCOME COUNTRIES
Distinct individual compound
MODE OF ACTION
Inhibits synthesis of proteins, preventing growth.
No longer a first line drug in any developed nation (except for conjunctivitis) due to increased resistance and worries about safety.
GLYCOPEPTIDES
COMMON 'DRUGS OF LAST RESORT'
Consist of carbohydrate linked to a peptide formed of amino acids
EXAMPLES
Vancomycin (shown), teicoplanin.
MODE OF ACTION
Inhibit bacteria cell wall biosynthesis.
QUINOLONES
RESISTANCE EVOLVES RAPIDLY
All contain fused aromatic rings with a carboxylic acid group attached
EXAMPLES
Ciprofloxacin (shown), levofloxacin, trovafloxacin.
MODE OF ACTION
Interfere with bacteria DNA replication and transcription.
OXAZOLIDINONES
POTENT ANTIBIOTICS COMMONLY USED AS 'DRUGS OF LAST RESORT'
All contain 2-oxazolidone somewhere in their structure
EXAMPLES
Linezolid (shown), posizolid, tedizolid, cycloserine.
MODE OF ACTION
Inhibit synthesis of proteins by bacteria, preventing growth.
DISCOVERY
1930
1940
1950
1960
1970
1980
SULFONAMIDES
FIRST COMMERCIAL ANTIBIOTICS WERE SULFONAMIDES
All contain the sulfonamide group
EXAMPLES
Prontosil, sulfanilamide (shown), sulfadiazine, sulfisoxazole.
MODE OF ACTION
Do not kill bacteria but prevent their growth and multiplication. Cause allergic reactions in some patients.
TETRACYCLINES
BECOMING LESS POPULAR DUE TO DEVELOPMENT OF RESISTANCE
All contain 4 adjacent cyclic hydrocarbon rings
EXAMPLES
Tetracycline (shown), doxycycline, limecycline, oxytetracycline.
MODE OF ACTION
Inhibit synthesis of proteins by bacteria, preventing growth.
MACROLIDES
SECOND MOST PRESCRIBED ANTIBIOTICS IN THE NHS
All contain a 14-, 15-, or 16-membered macrolide ring
EXAMPLES
Erythromycin (shown), clarithromycin, azithromycin.
MODE OF ACTION
Inhibit protein synthesis by bacteria, occasionally leading to cell death.
ANSAMYCINS
CAN ALSO DEMONSTRATE ANTIVIRAL ACTIVITY
All contain an aromatic ring bridged by an aliphatic chain.
EXAMPLES
Geldanamycin (shown), rifamycin, naphthomycin.
MODE OF ACTION
Inhibit the synthesis of RNA by bacteria, leading to cell death.
STREPTOGRAMINS
TWO GROUPS OF ANTIBIOTICS THAT ACT SYNERGISTICALLY
Combination of two structurally differing compounds, from groups denoted A & B
EXAMPLES
Pristinamycin IIA (shown), Pristinamycin IA.
MODE OF ACTION
Inhibit the synthesis of proteins by bacteria, leading to cell death.
LIPOPEPTIDES
INSTANCES OF RESISTANCE RARE
All contain a lipid bonded to a peptide
EXAMPLES
Daptomycin (shown), surfactin.
MODE OF ACTION
Disrupt multiple cell membrane functions, leading to cell death.
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# Antibiotics for Treatment and Prevention

- The historical approach to STI prevention has focused on identifying infections and treating them to prevent transmission to others.
- This requires identification of confirmed or suspected infection.
- A new approach uses antibiotics after potential exposure to prevent development of infection.
- This approach is in addition to, not instead of identification of confirmed or suspected infections.

# DoxyPEP

**Doxycycline** as Post-Exposure Prophylaxis

- Safe, well tolerated, inexpensive
- Active against chlamydia (CT) and syphilis
- Some gonorrhea resistance (GC)
  - 20% of isolates in the US
  - Not 1st line treatment

# DoxyPEP

**2015 - 2018**

**IPERGAY** French PrEP-On-Demand Study includes Doxycycline as PEP, reveals 2/3 reduction in syphilis and chlamydia in MSM; but was not effective for gonorrhea.

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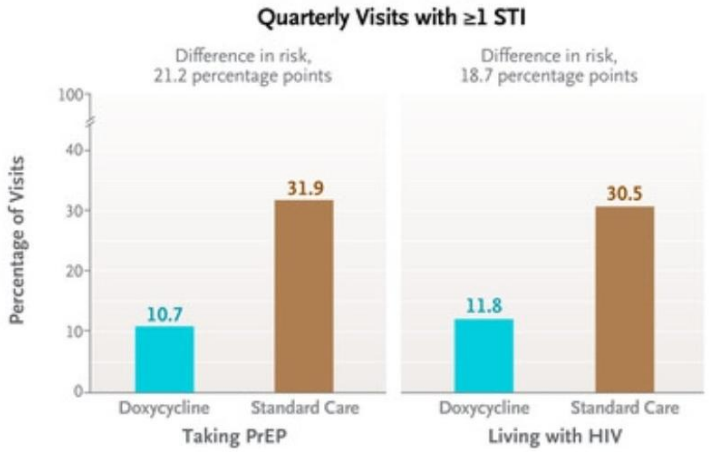


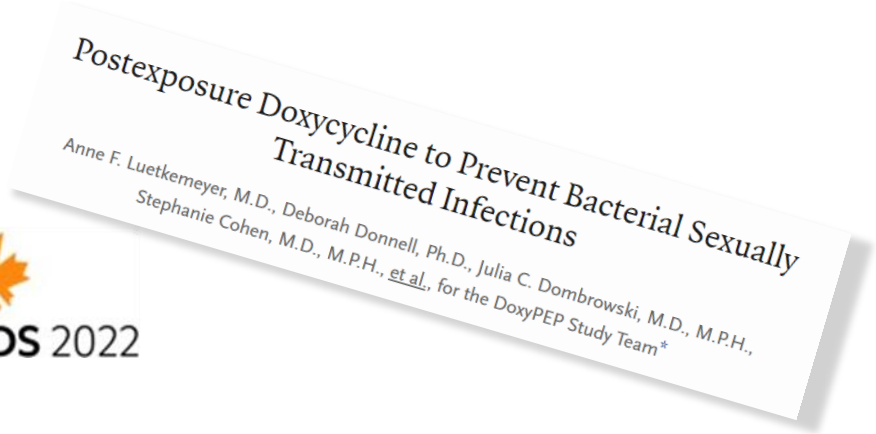


AIDS 2022

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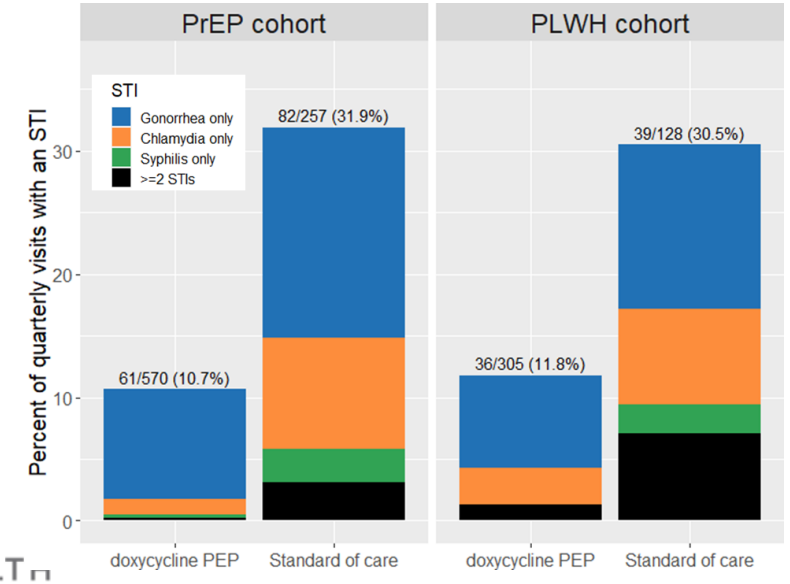


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**2023**
**DOXYVAC Study**, Molina *et al* CROI 2023

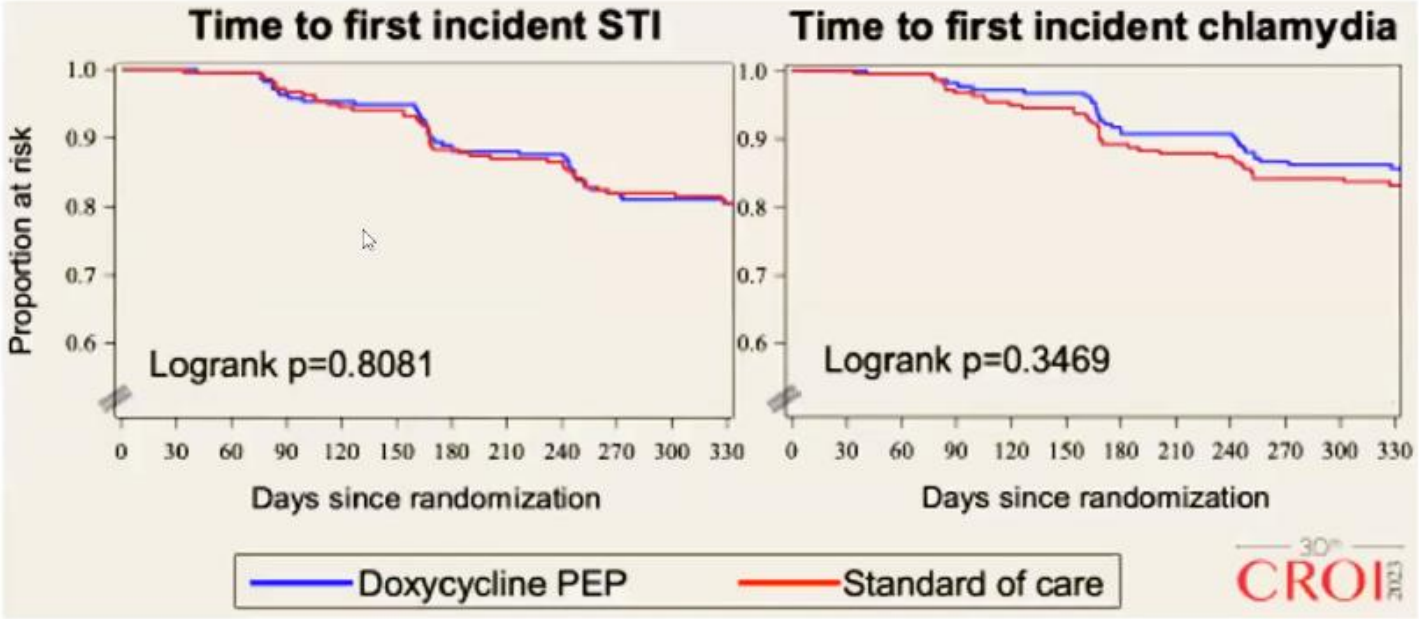
**DPEP Study**, Stewart *et al*, CROI 2023
Abstract [Mucosal Testing], Haaland, CROI 2023

# DoxyPEP

- 1:1 open-label randomized trial of dPEP (200mg doxycycline) taken within 72 hours after sex
- N=449 women taking PrEP, aged 18-30 (median age: 24 years)
- Quarterly follow-up for 12 months in Kisumu, Kenya

DPEP Study, CROI 2023

# DoxyPEP




NO difference between the two arms

DPEP Study, CROI 2023

# DoxyPEP

**High Self Reported adherence**

**Quarterly surveys**

- 77% (579/755) coverage of last sexual exposure

**Timeline follow-back calendar**

- In 72.8% of the quarterly surveys, >80% of sexual acts were covered

**Weekly SMS**

- 64% (134/211) participants reported full coverage in at least 80% of weeks
- 78% of weekly SMS reported full coverage

**Doxy Hair testing: 44% assigned to doxy-PEP never had doxycycline detected**

## **Results:** Hair drug testing

- In a randomly selected subset of 50 participants assigned to doxycycline PEP
  - 56.0% (28/50) of participants had doxycycline detected at least once
  - 29.0% (58/200) of all quarterly visits had doxycycline detected,
    - 32.6% (58/178) when medication holds excluded
- 6.7% (3/45) of enrollment visits had doxycycline detected
- 5.1% (2/39) of follow up visits among SOC group had doxycycline detected

Stewart et al DPEP ISSTDR 7.2023

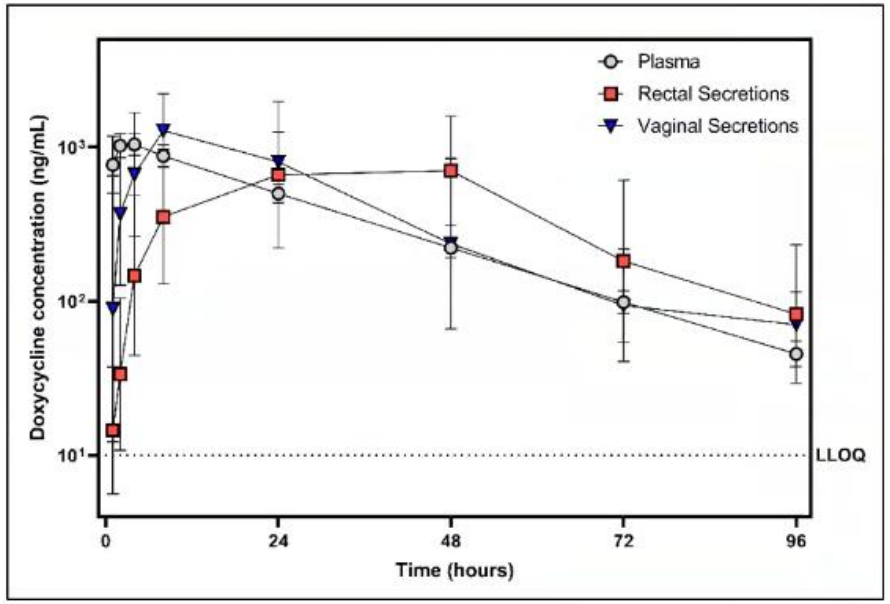




DPEP Study, CROI 2023

# DoxyPEP

## Mucosal Doxycycline Concentrations




| | *C trachomatis* | | *T pallidum* | | *N gonorrhoeae* | |
|---|---|---|---|---|---|---|
| | $C_{max}$* | Time >4x MIC | $C_{max}$* | Time >4x MIC | $C_{max}$* | Time >4x MIC |
| Plasma | 16x | 44h | 10x | 32h | 4x | 3h |
| Rectal Secretions | 11x | 62h | 7x | 51h | 3x | NA |
| Vaginal Secretions | 20x | 45h | 12x | 38h | 5x | 11h |

*Fold above MIC

Minimum Inhibitory Concentrations (MIC):

*N gonorrhoeae* (NG) MIC = 250 ng/mL CDC Antimicrob Resist Susc Test

*T pallidum* (TP) $MIC_{90}$ = 100 ng/mL Edmondson *Antimicrob Agents Chemother* 2020

*C trachomatis* (CT) $MIC_{90}$ = 64 ng/mL Zheng *Sex Transm Dis* 2015

Haaland CROI 2023, abstract 118

Slide 24

# DoxyPEP

## Gonococcal Antibiotic Resistance?

- Limited information in these studies given the low numbers of isolates in each cohort.
- There is no data thus far to suggest that DoxyPEP is a driving for worsening ABX resistance, as TCN-Resistance is already significant with GC
- It is challenging to tease out what TCN-Resistance is due to exposures outside of DoxyPEP

*Exposure to Ceftriaxone would decrease by 50%!*

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*Exposure to CTX would decrease by 50%!*

## Chlamydia & Syphilis Antibiotic Resistance?

- It has not clinically been documented. Testing for STI resistance is very difficult with these pathogens, and would be expensive and very involved

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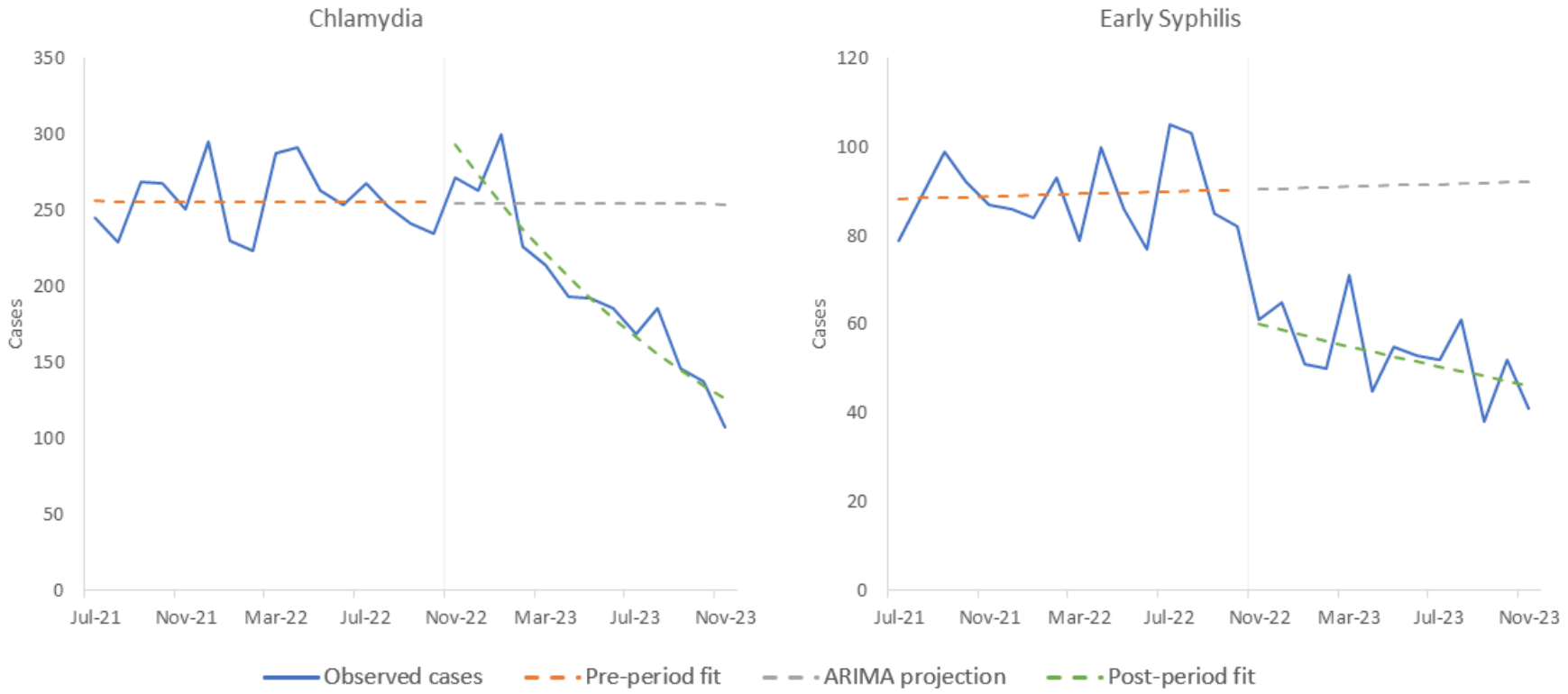
## Changes in Microbial Flora?

- Limited data on Staphylococcus and MRSA changes, no significant changes noted with the use of DoxyPEP at this time
- Gut Flora?

# Post-guideline Release Prevalence

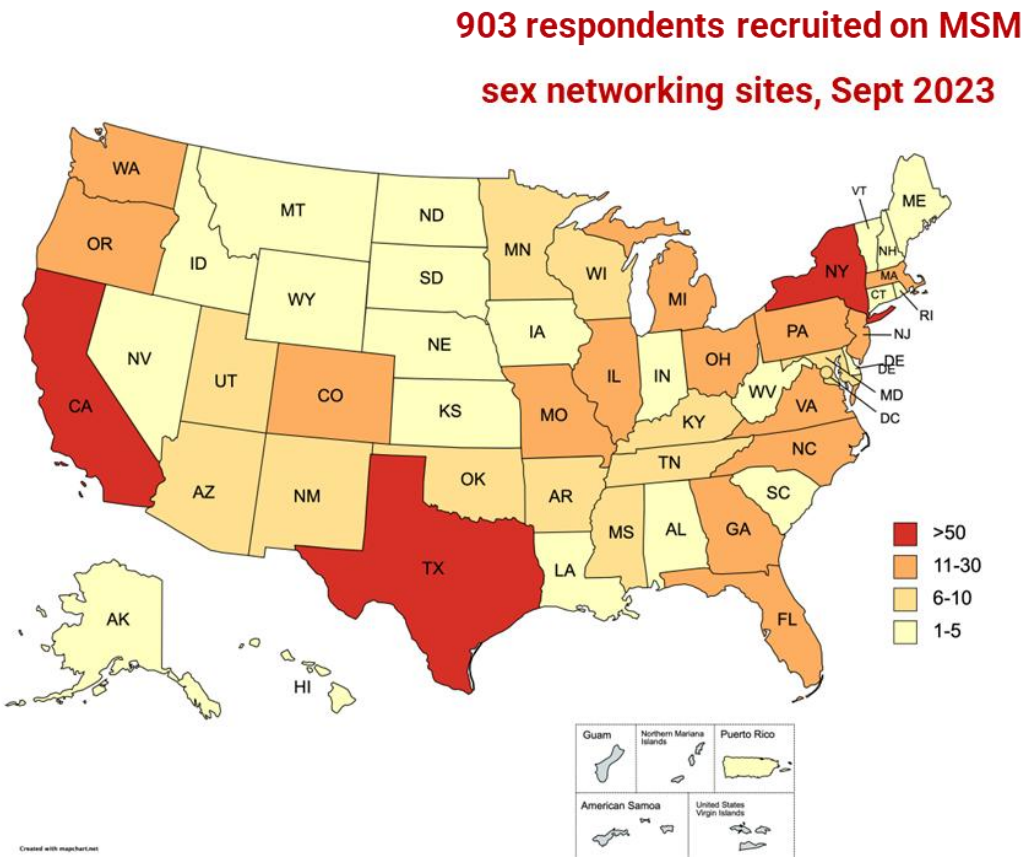



Madeline Sankaran et al.
San Francisco Department of Public Health

# Survey Data

## National Survey of Antibiotic Prophylaxis

Trager *et al*
Harvard, Department of Population Medicine




- Mean age = 42 years
- 19% living with HIV
- 42% using HIV PrEP

# Patient Awareness and Engagement

## National Survey of Antibiotic Prophylaxis

Trager *et al*
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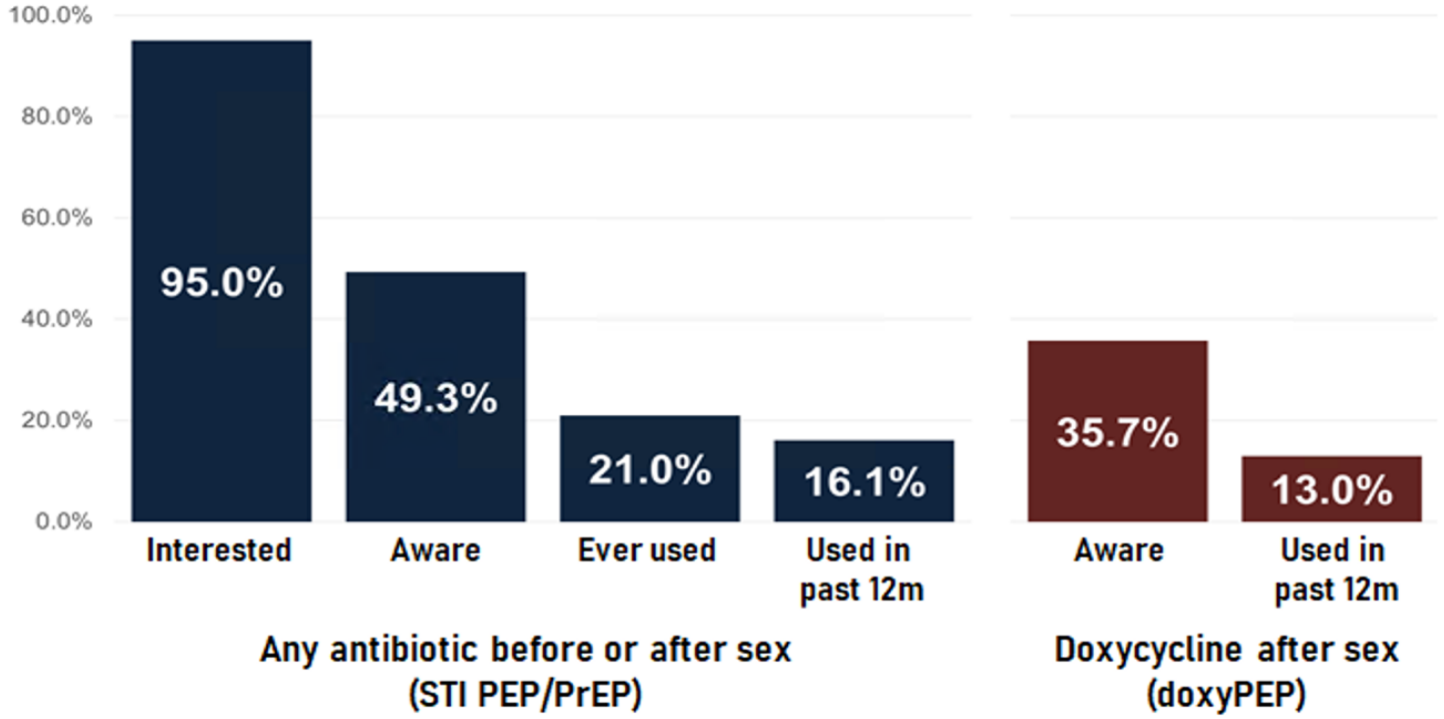

# Patient Responses

## National Survey of Antibiotic Prophylaxis

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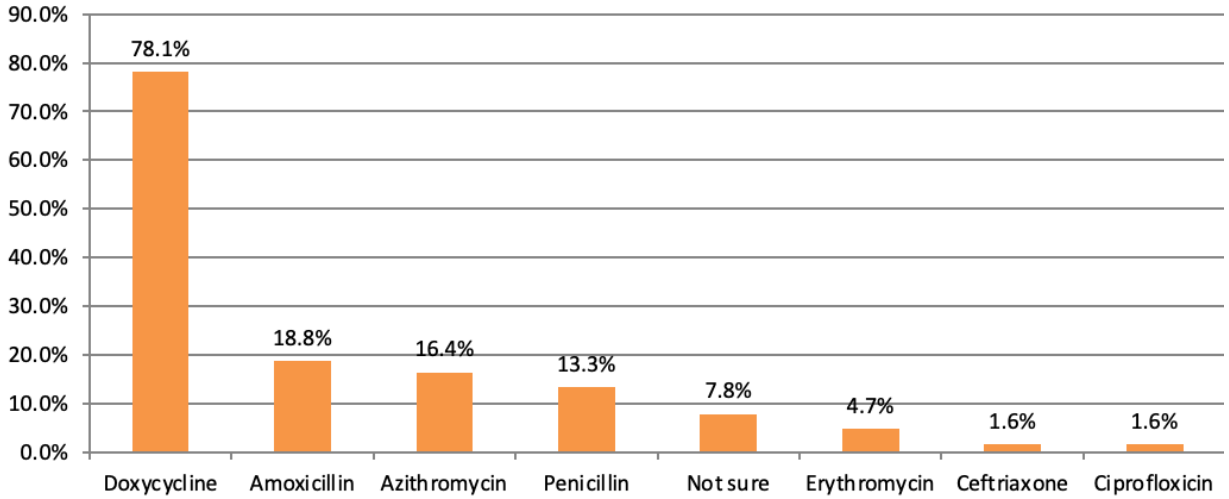
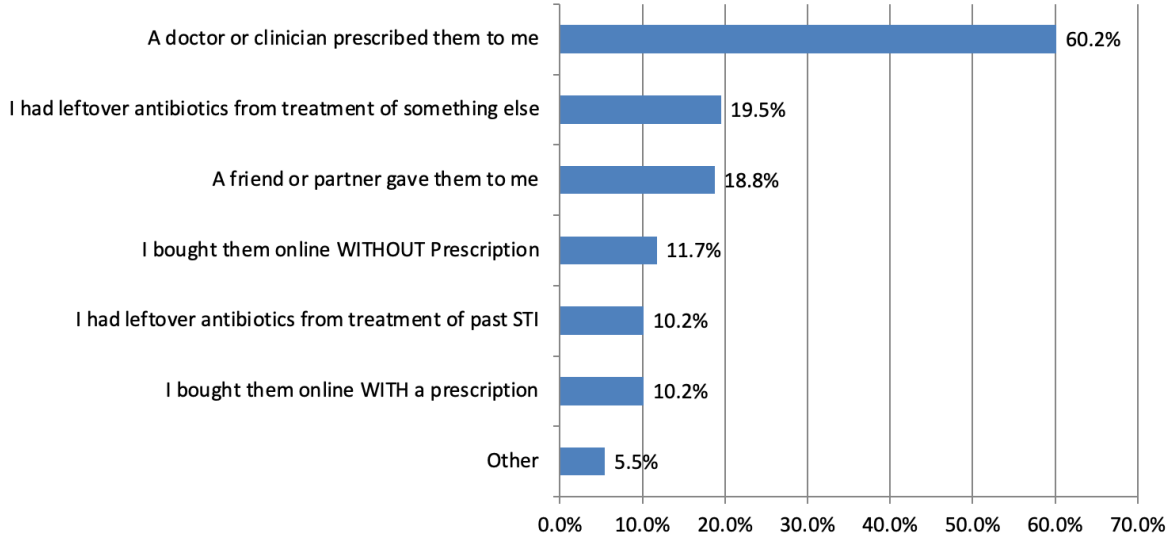



*When using antibiotics around the time of sex to prevent getting an STI, which antibiotics have you used?*

*Where did you get the antibiotics?*

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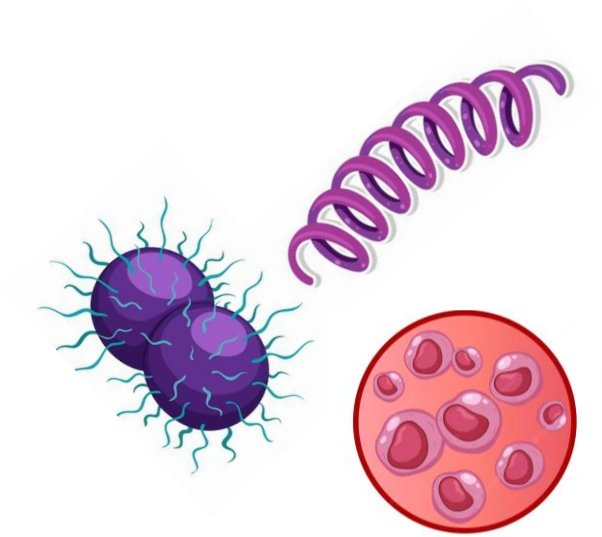
# **The Future of Sexual Health:** bSTI Treatment and Prevention

**DoxyPEP**

**Screening**



**Education**

**GC Vaccine**

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# **The Future of Sexual Health:** The Syndemic Approach

**Emerging Infections**

**DoxyPEP**

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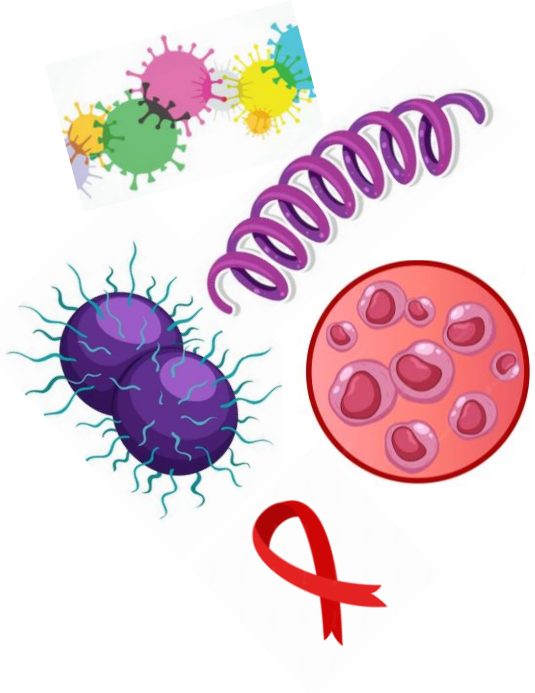

**HPV Vaccines**

**Education**

**GC Vaccine**

**HIV Management**

# **The Future of Sexual Health:** The Syndemic Approach


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Thank You!

# Questions/Comments?

# Request for Panel Questions

- Session 4 will include a panel discussion on ***A Whole Person Approach to STI Care***
- Panelists
  - **Victor Luna** – Founder & CEO of ProTech Care and previous manager of HIV prevention initiatives
  - **Dr. Taimur Khan** – Interim Co-Director of The Fenway Institute and Primary Care Provider at Fenway Health
  - **Dr. Kevin Ard** – Medical Director of the National LGBTQIA+ Health Education Center and Assistant Professor of Medicine at Harvard Medical School
- Please **submit questions** to Gavin Granitto at **ggranitto@fenwayhealth.org** by **Monday 6/23**
  - Questions can be theoretical or practical, be specific to Victor's work, be around specific barriers you are facing at your site, or anything else you can think of