

# STI Cases

Learning Community, March 26<sup>th</sup>

**Welcome! Please introduce yourself in the chat 😊**

# Welcome to our final LC session!

- **Please introduce yourself in the chat!**
- We're happy to have attendees here from the following clinics:
  - Bell Flower Clinic, Indianapolis, Indiana
  - Litoral Clinic, Migrant Health Center, Mayagüez, Puerto Rico
  - Mary Eliza Mahoney Health Center, Newark, New Jersey
  - Morrisania Clinic, Health & Hospitals, Bronx, New York
  - NYC Department of Health, NYC, New York
  - Take Care Down There Clinic, Columbus Public Health, Columbus, Ohio

# Group Agreements

- Keep cameras on, especially when talking
- All participants contribute to the discussion
- We're here to learn together
- Confidentiality: any patient information shared remains private

# STI Cases

# Ricky- Case 1



- 25 yo cis gender male,
- Presented August for PrEP but on screening found to be HIV + as well as Syphilis +
- Social/ Sexual history
  - Partner had HIV
  - From Venezuela- walked here thru Darien Gap to US
- Established care and started on Biktarvy (initial VL 62,000; follow up VL one month later 29 copies/ml)

# Approach: CDC 5 Ps

- Partners
  - One new partner (male) since last seen 3 months ago
  - 4 partners in last 6 months
- Practices
  - Oral and anal sex- top and bottom
- Prevention of Pregnancy
  - NA
- Protection from STIs
  - Some condoms, not for oral sex, about 50% for anal
- Past history of STIs
  - **History of rectal discharge September '23- treated ceftriaxone and doxy-7 days (STI tests negative)**
  - **History of syphilis: treated 28 days of doxycycline (shortage) August '23**

# Expanded Sexual Health History

Substance use

MJ daily

Mental health issues (depression, anxiety etc.)

PHQ2, PHQ9, GAD-7, ACES = 5

Evidence of depression- crying daily

Has pain from car accident he suffered a year ago, wants some medications to help with it

History of survival sex, sexual victimization, unwanted sex, intimate partner violence

Denies

Lives in shelter

# Action Steps

- HIV/STI screening- back for retesting- 3 months later
- Education
- Prevention
  - HPV vaccine
  - Doxy PEP discussion
- Social work referral



# Lab results...

- RPR

8/16/2023

9/12/2023

12/26/2023

2/27/2024

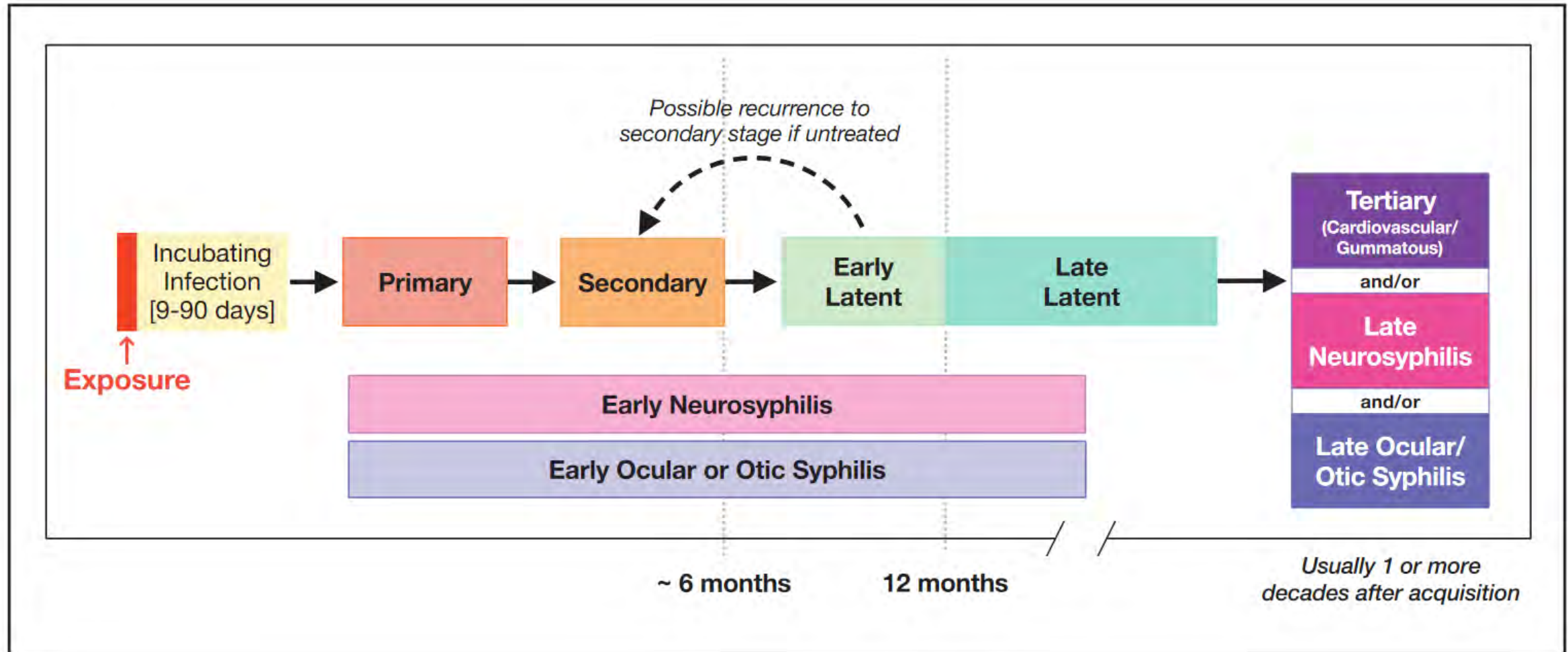
**Reactive 1:256 !**

**Reactive 1:128 !**

**Reactive 1:32 !**

**Reactive 1:64**

# Syphilis



# Enhanced Clinical Descriptions of Ocular and Otic Manifestations

## Ocular Syphilis

- Often presents as panuveitis
- Can involve any structure in the anterior and posterior segment of the eye including:
  - Conjunctivitis
    - Red eye/Pain
  - Anterior uveitis
  - Posterior interstitial keratitis
  - Optic neuropathy
  - Retinal vasculitis
- Can lead to **permanent** vision loss

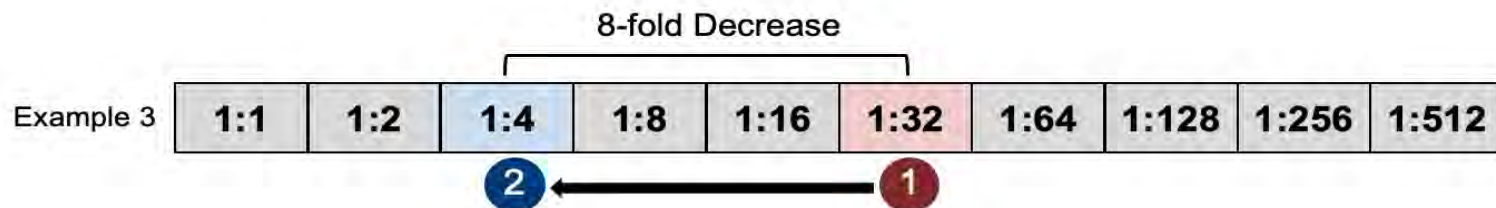
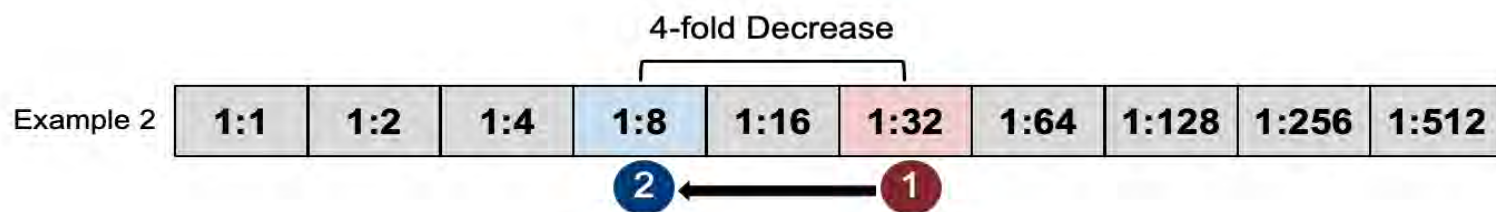
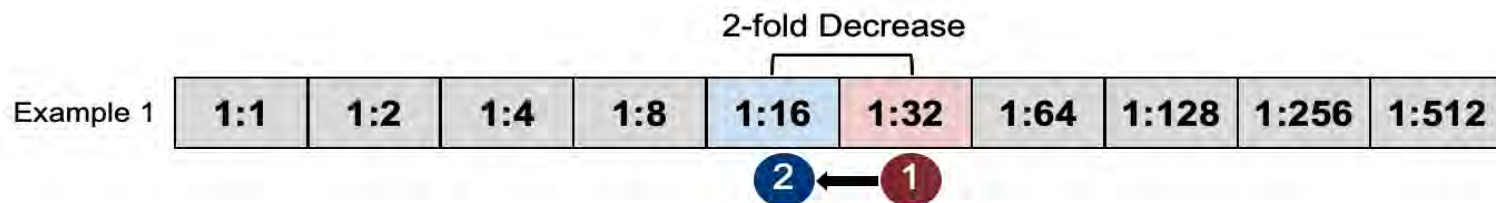
## Otosyphilis

- Typically presents with cochleo-vestibular symptoms including
  - Tinnitus
  - Vertigo
  - Sensorineural hearing loss
    - Unilateral/Bilateral
    - Have a sudden onset
    - Progress Rapidly
- Can result in **permanent** hearing loss

# Treatment

Stage	Treatment	Alternative
Incubation	Benzathine penicillin G 2.4 million units intramuscular injection once	Doxycycline 100mg twice daily for 14 days
Primary		
Secondary		
<b>Early latent</b>		
<b>Late latent</b>	Benzathine penicillin G 2.4 million units intramuscular injection 3 times at one week intervals	Doxycycline 100mg twice daily for 28 days
<b>Late of unknown duration</b>		
Tertiary (non-neuro)		
Neurosyphilis, Ocular, or Otic Syphilis	Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units intravenously every 4 hours, or by continuous infusion, for 10–14 days	Procaine penicillin G 2.4 million units IM once daily PLUS Probenecid 500mg 4 times daily for 10–14 days

# Interpreting titers: fold changes



Treatment Response:  
decreasing titers  
point 2 → 1

Our patient

8/16/2023

Reactive 1:256 !

9/12/2023

Reactive 1:128 !

12/26/2023

Reactive 1:32 !

2/27/2024

Reactive 1:64

# Syphilis treatment and Titers

Options: What would you do?

A. Retest in 3 months

B. Treat with IM bicillin 2.4 million units x 1

C. Re-treat with doxycycline 100mg BID x 14 days

# Treatment

Stage	Treatment	Alternative
Incubation	Benzathine penicillin G 2.4 million units intramuscular injection once	Doxycycline 100mg twice daily for 14 days
Primary		
Secondary		
<b>Early latent</b>		

# Mycoplasma genitalium – mollicute of ill repute

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Adult Infectious Diseases  
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NYC STD Prevention Training Center  
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# Dogged dysuria



- 29 year old male with dysuria and urethral discharge x 2 months
- Sexual history notable for male sexual partners, condomless oral and penetrative anal sex
- Reportedly tested positive for M genitalium, treated with doxycycline 100 mg BID x 7 days followed by moxifloxacin 400 mg daily x 7 days
- 3 weeks after treatment presents with ongoing dysuria/discharge. Notes condomless sex with 2 partners during/after his treatment
- GU exam unremarkable

# Round 2

- UA notable for 11-30 WBC
- Urine gonorrhea/chlamydia NAAT negative
- M genitalium NAAT +



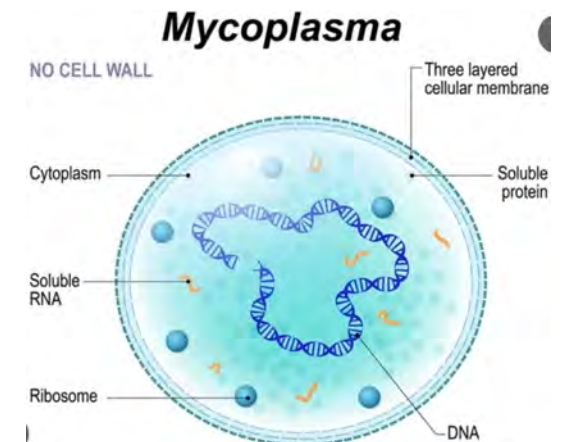
- Treated again with doxycycline 100 mg BID x 7 days followed by moxifloxacin 400 mg daily x 7 days
- Counseled to abstain from sex until he has completed treatment, and partners have been tested and/or treated



- Returns 3 weeks later with ongoing discharge and dysuria, unchanged since initial visit
- Notes no sexual contact since starting his second course of treatment

# Molli-not-so-cute

- Mollicutes: class of bacteria distinguished by lack of a peptidoglycan cell wall
  - medically significant genera include *Mycoplasma* and *Ureaplasma*
- Largely parasitic, with very small genome size—some of the smallest and simplest living things
- Difficult to culture, diagnosis often depends on molecular testing
- Simplicity (among other features) confers intrinsic resistance to many antibiotics
  - No peptidoglycan – no beta lactams, glycopeptides, or fosfomycin
  - No enzymes for folic acid metabolism – no TMP-SMX
  - Intracellular – poor activity of most aminoglycosides
  - Mutations in RNA polymerase – no rifampin



# M genitalium (Mgen) epidemiology

- From 2017-2018 NHANES, overall prevalence about 1.7% among people in the US aged 14-59
  - Prevalence 10.3% among sexually active people aged >14 presenting for routine care in one large multicenter study (with or without symptoms)
    - Associated with younger age, Black race, non-Hispanic ethnicity
    - Large multicenter study with a mix of sexual health and non-sexual health settings, funded by Hologic
  - Other series with prevalence in the general population closer to 5%
  - In series from US STI clinics, prevalence 26% among women, 28.7% among men
  - Higher prevalence among people with HIV
  - Prevalence not increased among MSM
    - In this group, M genitalium detected in rectal >urine >> pharyngeal specimens
  - Concordance among couples is high, approximately 40-50% in heterosexual couples. One Australian study showed concordance among MSM of 27%

Mycoplasma Genitalium - CDC Detailed Fact Sheet. Centers for Disease Control and Prevention. [https://www.cdc.gov/std/mgen/stdfact-Mgen-detailed.htm#\\_edn4](https://www.cdc.gov/std/mgen/stdfact-Mgen-detailed.htm#_edn4)

Cina M, Baumann L, Egli-Gany D, Halbeisen FS, Ali H, Scott P, Low N. *Mycoplasma genitalium* incidence, persistence, concordance between partners and progression: systematic review and meta-analysis. Sex Transm Infect. 2019 Aug;95(5):328-335. doi: 10.1136/sextrans-2018-053823. Epub 2019 May 4. PMID: 31055469; PMCID: PMC6678058.

# Syndromes associated with Mgen

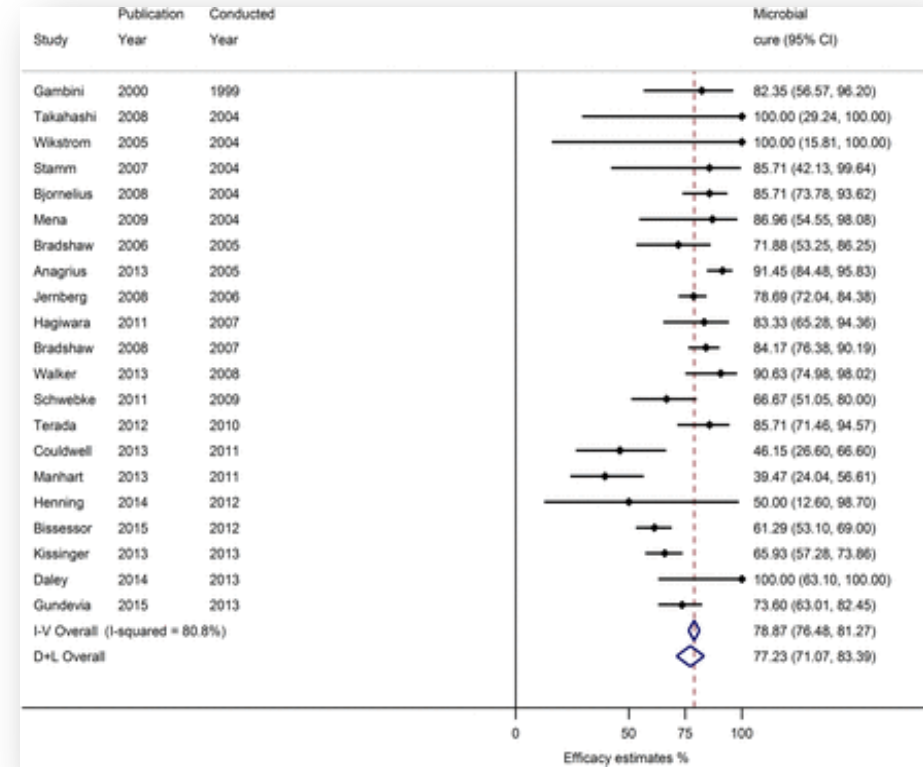
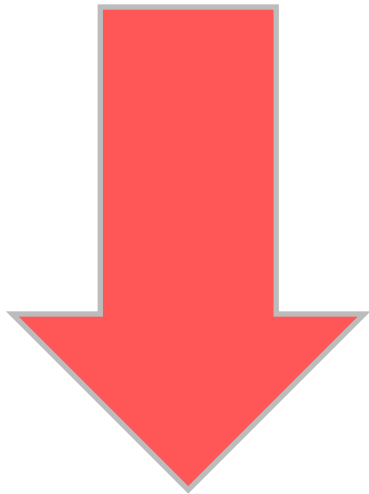
- Assigned male at birth:
  - Urethritis – conclusively causes 20-25% of non-gonococcal, non-chlamydial urethritis, and 40% of persistent or recurrent urethritis
  - Proctitis – conflicting association in MSM between rectal Mgen detection and symptoms -- weak or not present
  - Pharyngitis – Mgen has not been demonstrated as a cause
- Assigned female at birth
  - Cervicitis – Mgen detected in 10-30% of women with clinical cervicitis. Significant co-infection with other pathogens, but also studies showing cytokine normalization after treatment
  - PID – multiple studies demonstrate greater frequency of Mgen in women with PID, but generally cross-sectional. No clear prospective evidence of cause, or trial data showing that treatment of Mgen cervicitis prevents PID.
  - Pregnancy/fertility-related complications– to be discussed!



# Macrolide resistance in *M. genitalium*

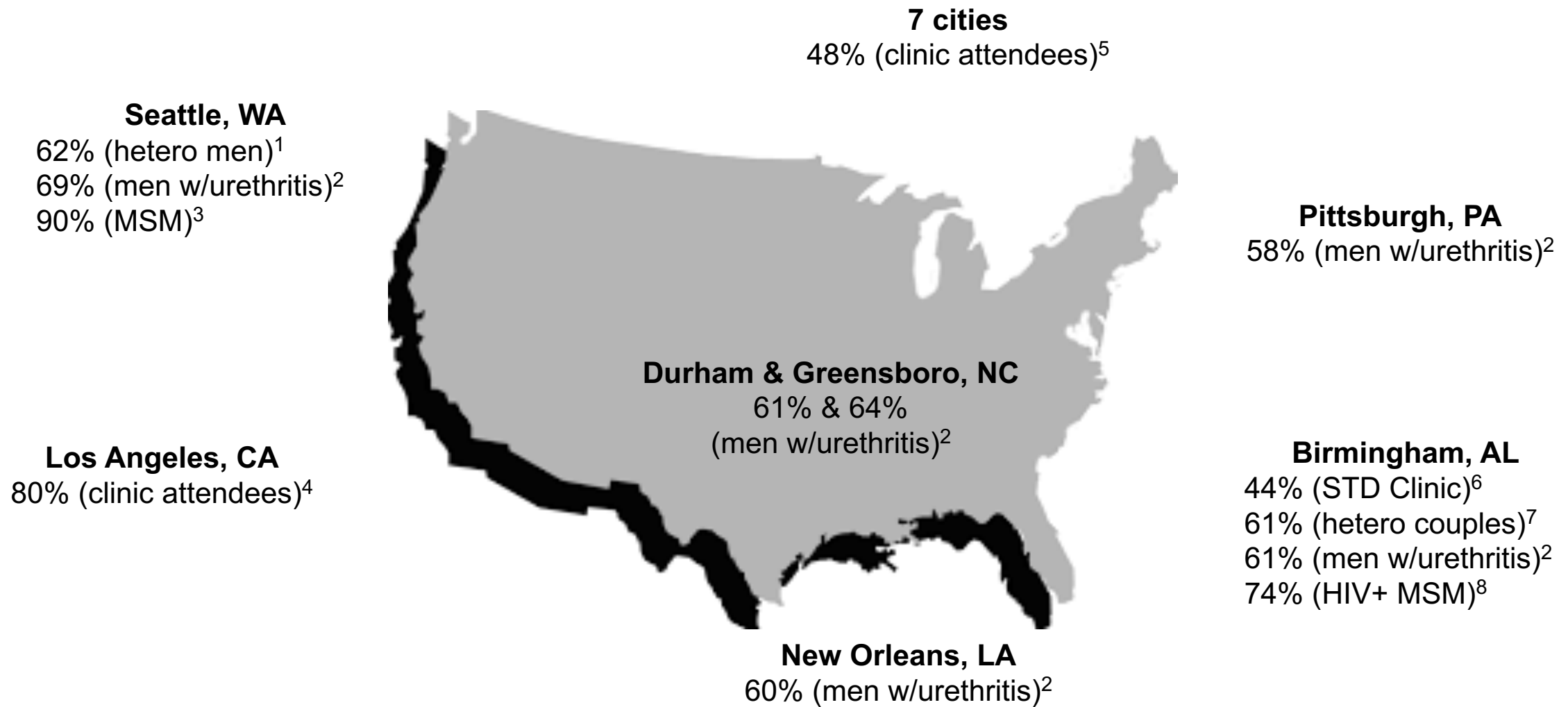
Driven by 5 SNP mutations in the 23S rRNA gene

- Pooled microbial cure rate 77.2%
  - Prior to 2009 – 85.3%
  - Since 2009 – 67%



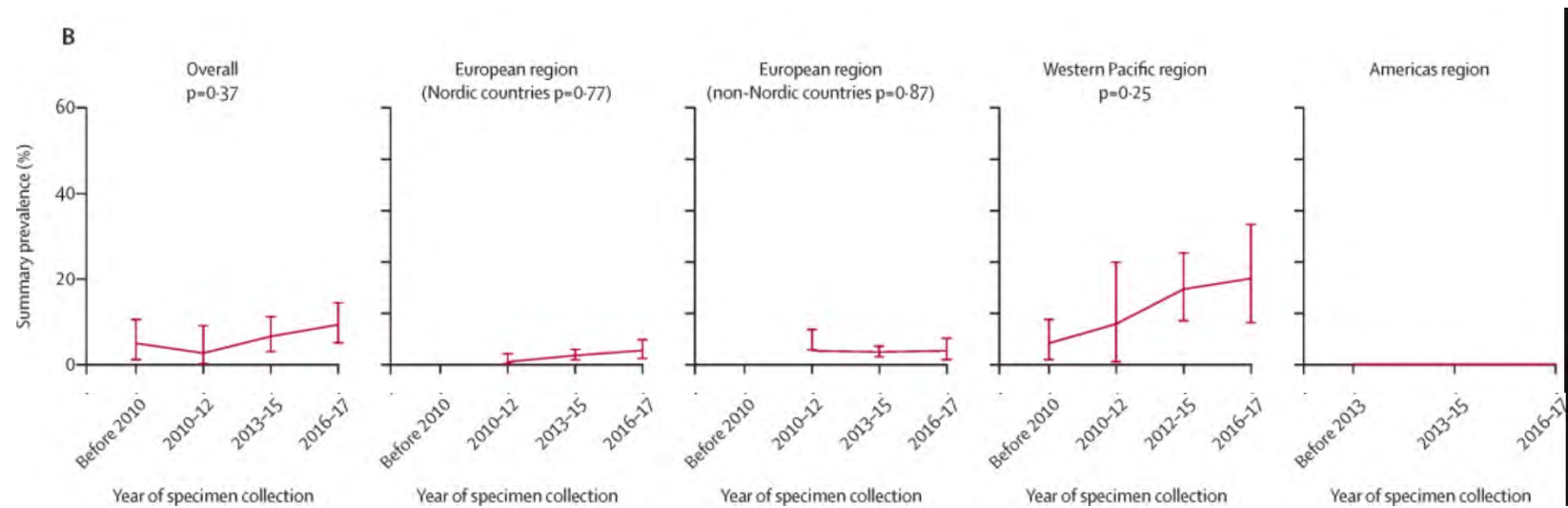
- Lau A, Bradshaw CS, Lewis D, Fairley CK, Chen MY, Kong FY, Hocking JS. The Efficacy of Azithromycin for the Treatment of Genital Mycoplasma genitalium: A Systematic Review and Meta-analysis. Clin Infect Dis. 2015 Nov 1;61(9):1389-99. doi: 10.1093/cid/civ644. Epub 2015 Aug 3. PMID: 26240201.

# Macrolide Resistance in *M. genitalium*



- Romano 2018; <sup>2</sup>Bachmann 2019; <sup>3</sup>Chambers 2019; <sup>4</sup>Allan-Blitz 2018; <sup>5</sup>Getman 2016; <sup>6</sup>Xiao 2018; <sup>7</sup>Xiao 2019; <sup>8</sup>Dionne-Odom 2018
- Slide credit: Lisa Manhart

# Quinolone resistance in *M genitalium*



- Meta-analysis included 25 studies reporting SNPs associated with quinolone resistance
- Global rate 2016-2017: 9.3%
- Americas region rate: 10.1% (insufficient data for temporal trend)

Dorothy A Machalek et al. Prevalence of mutations associated with resistance to macrolides and fluoroquinolones in *Mycoplasma genitalium*: a systematic review and meta-analysis, *The Lancet Infectious Diseases*, Volume 20, Issue 11, 2020, Pages 1302-1314



# Resistance-guided sequential therapy

Clinical Infectious Diseases

MAJOR ARTICLE



## Outcomes of Resistance-guided Sequential Treatment of *Mycoplasma genitalium* Infections: A Prospective Evaluation

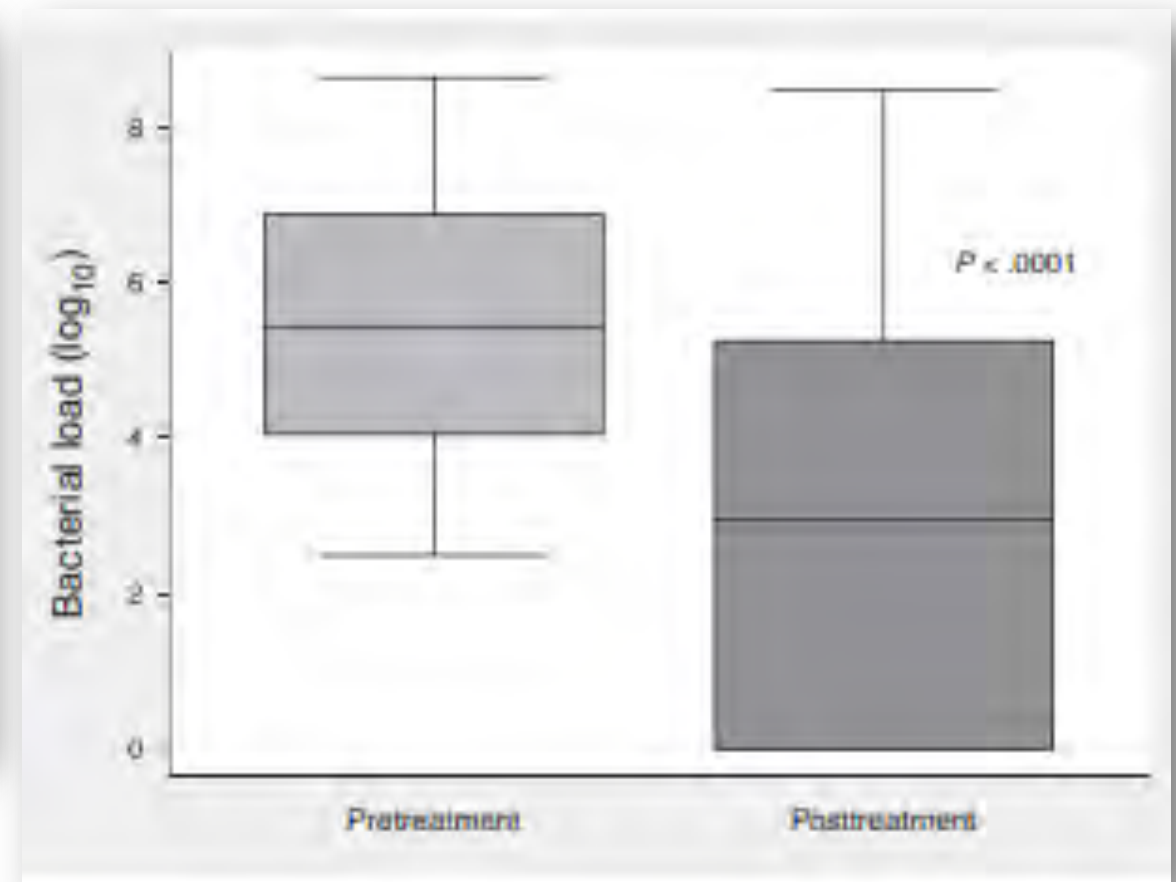
Tim R. H. Read,<sup>1,2</sup> Christopher K. Fairley,<sup>1,2</sup> Gerald L. Murray,<sup>3,4,5,6</sup> Jorgen S. Jensen,<sup>7</sup> Jennifer Danielewski,<sup>3,4</sup> Karen Worthington,<sup>2</sup> Michelle Doyle,<sup>2</sup> Elisa Mokany,<sup>8</sup> Litty Tan,<sup>8</sup> Eric P. F. Chow,<sup>1,2</sup> Suzanne M. Garland,<sup>3,4,6,9</sup> and Catriona S. Bradshaw<sup>1,2</sup>

<sup>1</sup>Central Clinical School, Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, <sup>2</sup>Melbourne Sexual Health Centre, Alfred Health, Carlton, <sup>3</sup>Murdoch Children's Research Institute, Parkville, <sup>4</sup>Department of Microbiology and Infectious Diseases, Royal Women's Hospital, Melbourne, <sup>5</sup>Infection and Immunity Program, Monash Biomedicine Discovery Institute, and <sup>6</sup>Royal Children's Hospital, Melbourne, Victoria, Australia; <sup>7</sup>Statens Serum Institut, Copenhagen, Denmark; <sup>8</sup>SpeeDx Pty Ltd, Eveleigh, New South Wales, and <sup>9</sup>Department of Obstetrics and Gynaecology, University of Melbourne, Victoria, Australia

(See the Major Article by Braun et al on pages 569-76 and Editorial commentary by Sulkowski on pages 577-9.)

**Background.** Rising macrolide and quinolone resistance in *Mycoplasma genitalium* necessitate new treatment approaches. We evaluated outcomes of sequential antimicrobial therapy for *M. genitalium* guided by a macrolide-resistance assay.

**Methods.** In mid-2016, Melbourne Sexual Health Centre switched from azithromycin to doxycycline (100 mg twice daily for 7 days) for nongonococcal urethritis, cervicitis, and proctitis. Cases were tested for *M. genitalium* and macrolide-resistance mutations (MRMs) by polymerase chain reaction. Directly after doxycycline, MRM-negative infections received 2.5 g azithromycin (1 g, then 500 mg daily for 3 days), and MRM-positive infections received sitafloxacin (100 mg twice daily for 7 days). Assessment of test of cure and reinfection risk occurred 14–90 days after the second antibiotic.



# Sounds good, but...



## *Mycoplasma genitalium*, NAA, Urine With Reflex to Macrolide Resistance Testing



Print



Share

TEST: 180084  CPT: 87563

### Special Instructions

This test is not approved for use in New York state due to reflexing to *Mycoplasma genitalium* Macrolide Resistance.

If reflex testing is performed, additional charges/CPT code(s) may apply.

# Roll tide

- One available option is sending specimens out to University of Alabama at Birmingham
  - Now with quinolone RAM testing!
  - <https://sites.uab.edu/dml/tests/>

Test Menu	Acceptable Specimens	Transport/Processing Details	Turnaround Time	CPT Code
<b>PCR- Mycoplasma genitalium</b> Includes detection of macrolide resistance	<ul style="list-style-type: none"><li>• Cervical swab</li><li>• Throat</li><li>• Urine</li><li>• Urogenital swab</li><li>• Vaginal swab</li></ul>	<b>Collection Device:</b> Sterile container (can also be used as transport if received with 48 hours of collection and kept 2-8C) <b>Transport Media:</b> Mycoplasma Ureaplasma transport media (examples: M4, M5, UTM, UVTM, eSwab)	1-4 days	87581

# Back to our patient

- Symptoms **from** Mgen, or symptoms **with** Mgen?
  - Remember that a significant proportion of sexually active people will test positive for Mgen, many of whom are asymptomatic
  - Consider other, less common pathogens that may cause dysuria: e.g. trichomonas, HSV
- Remember that reinfection is a common cause of symptom recurrence in all cases

# Treatment failure

## Open Forum Infectious Diseases

JOURNAL ARTICLE

### Efficacy of Minocycline for the Treatment of *Mycoplasma genitalium*

Emily J Clarke , Lenka A Vodstrcil, Erica L Plummer, Ivette Aguirre, Ranjit S Samra, Christopher K Fairley, Eric P F Chow, Catriona S Bradshaw  [Author Notes](#)

*Open Forum Infectious Diseases*, Volume 10, Issue 8, August 2023, ofad427,  
<https://doi.org/10.1093/ofid/ofad427>

Published: 11 August 2023 [Article history](#) ▼

- **Minocycline**
  - Slightly lower MICs than doxycycline observed
  - Largest case series of 90 patients with macrolide resistant M gen – 66.7% cure rate
    - 62 had failed tx with moxifloxacin
  - Regimen of 100 mg BID x 14 days





## **Mycoplasma genitalium Treatment Failure Registry**

**The purpose of this form is to collect clinical information on cases of *Mycoplasma genitalium* that fail antimicrobial therapy. All reported information will be maintained in the strictest confidence.**

# Other options?

- **Pristinamycin**
  - 50S ribosomal subunit inhibitor
  - 85/114 (75%) of patients with macrolide resistant M gen cured with 10 days treatment
  - Not available in the USA
  
- **Otherwise, mostly in vitro data available**
  - Tinidazole – at least one anecdotal cure!
  - Spectinomycin – one case report of treatment success
  - Omadacycline - how many new reasons can we find to use this?
  - Zoliflodacin – new topoisomerase inhibitor being studied for resistant gonorrhea

# But what about pregnancy?

- 26 woman G2P0 at 5 weeks gestation, seen in the ED for pelvic cramping in setting of positive home pregnancy test
- "STI screening" performed at that time, with positive result for M genitalium



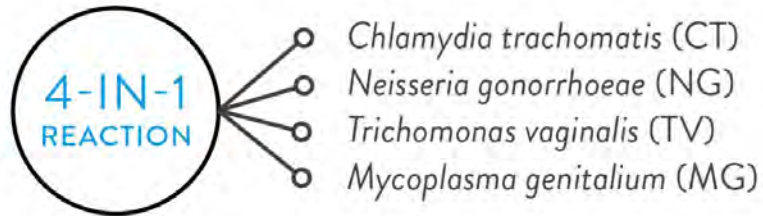
# Don't look and you shall not find

- 2022 meta-analysis assessed risk of adverse pregnancy and peri-natal outcomes
  - Pre-term birth: strongest evidence, OR of approximately 2
    - Oddly greater than OR for this outcome with gonorrhea/chlamydia/trichomonas
    - Unable to assess confounding due to lack of adjustment for variables other than age
  - Spontaneous abortion: OR = 1
  - PROM, low birth weight, perinatal death: minimal data
- Authors conclude that there is insufficient evidence to recommend screening for Mgen in asymptomatic pregnant people

Frenzer C, Egli-Gany D, Vallely LM, Vallely AJ, Low N. Adverse pregnancy and perinatal outcomes associated with *Mycoplasma genitalium*: systematic review and meta-analysis. Sex Transm Infect. 2022 May;98(3):222-227.

# And yet...

## ONE ASSAY, MULTIPLE POSSIBILITIES REDEFINING THE FUTURE OF STI TESTING WITH OPERATIONAL EFFICIENCY



Alinity m STI assay is a 4-in-1 multiplex assay to detect and differentiate CT, TV, MG, and NG to aid in the diagnosis of infection from these organisms.

## ANALYTES

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### Anyplex™ II STI-7e Detection

- *Chlamydia trachomatis* (CT)
- *Mycoplasma genitalium* (MG)
- *Mycoplasma hominis* (MH)
- *Neisseria gonorrhoeae* (NG)
- *Trichomonas vaginalis* (TV)
- *Ureaplasma parvum* (UP)
- *Ureaplasma urealyticum* (UU)
- Exogenous Internal Control

- Enter the multiplex PCR
- Used at some sites as part of routine prenatal screening rather than G/C alone

# Mgen in the pregnant patient

- Moxifloxacin and doxycycline not routinely recommended for use during pregnancy
- Given lack of clear evidence for harms, reasonable to defer therapy if no sxS
- For patients with symptoms, azithromycin is the only drug routinely recommended for use
  - In this group, reasonable to send resistance testing
    - If macrolide-susceptible, can treat with azithromycin 4-day course (1 gram x 1, followed by 500 mg daily x 3 days)
    - If resistant, risk-benefit conversation with patient, then potential treatment after delivery

# Take Home

- Mycoplasma genitalium is a relatively common inhabitant of the male and female GU tract, and can be asymptomatic colonizer
- In the absence of resistance guided therapy, tx is with doxycycline/moxifloxacin
- Cases of suspected failure following a recommended regimen should be evaluated for reinfection, incomplete adherence, and other causes of symptoms
- Resistance-guided testing may be helpful, but not always easy to get
- Minocycline has fair success rates with treating resistant Mgen
- Azithromycin is the only active drug routinely recommended in pregnancy
- Consider no treatment of asymptomatic pregnant people

# Case 2



- 24 yo HIV infected male, undetectable VL
- Sex only with current partner who is pregnant
- STI- no symptoms

# Approach: CDC 5 Ps

- Partners
  - One new partner (female) for the past year
- Practices
  - Vaginal sex- only
- Prevention of Pregnancy
  - **She is pregnant**
- Protection from STIs
  - Never
- Past history of STIs
  - **History of gonorrhea and chlamydia (urine August '23) follow up negative Dec 2023**
  - **History GC (rectal Jan 2023)**
  - **History of syphilis 2021 (treated)**

Date	Test Site Positive	Organism(s)	Treatment/ EPT	Symptoms
11/26/2020	Urine	Gonorrhea (GC)	Ceftriaxone	
11/9/2021	Urine/throat and rectal	negative		
3/8/2022	Urine	Gonorrhea	Ceftriaxone	Discharge and swollen testicle
5/4/2022	Urine/throat and rectal	negative		
7/19/2022	Urine	Chlamydia (CT)	Azithromycin (had already)	Partner CT + by report
11/15/2022	Urine	Chlamydia	Doxycycline	Discharge (partner with symptoms and GC/CT+)
1/31/2023	Urine	Gonorrhea	Ceftriaxone (partner treated)	Discharge and penile irritation
	Rectal	Gonorrhea		
5/30/23	Urine	CT and GC	Ceftriaxone and Doxy	Discharge
8/22/2023	Urine	CT and GC	Ceftriaxone and Doxy/ EPT partner	Testicular swelling
12/5/23	Urine/throat	negative	Empiric treatment Offered Doxy PEP	Mild discharge
1/23/24	Urine	GC	Ceftriaxone	

# Treatment Guidelines - Gonorrhea

Ceftriaxone 500 mg IM x 1  
for persons weighing <150kg\*

\*For persons weighing  $\geq 150$ kg, 1 g of IM  
ceftriaxone should be administered



# Treatment Guidelines - Gonorrhea

Ceftriaxone 500 mg IM x 1  
for persons weighing <150kg\*

\*For persons weighing  $\geq 150$ kg, 1 g of IM ceftriaxone should be administered

If chlamydia has **not** been excluded, treat for chlamydia with:

Doxycycline 100 mg PO twice daily x 7 days

\*For pregnancy, allergy, or concern for non-adherence 1g PO Azithromycin can be used

# PREGNANCY- STI guidelines

Ceftriaxone 500 mg IM x 1  
for persons weighing <150kg\*

\*For persons weighing  $\geq 150$ kg, 1 g of IM ceftriaxone should be administered

If chlamydia has **not** been excluded, treat for chlamydia with:

Doxycycline 100 mg PO twice daily x 7 days

\*For pregnancy, allergy, or concern for non-adherence 1g PO Azithromycin can be used

# Treatment Guidelines For Gonorrhea?

## Preferred Regimen

**Ceftriaxone 500mg intramuscularly once**

\*For persons weighing  $\geq 150$  kg (300 lb), 1g of IM ceftriaxone should be administered

**Doxycycline 100 mg orally twice daily for 7 days**

\*If chlamydial infection has not been excluded

## Alternative/Cephalosporin Allergy\*

**Gentamicin 240mg IM Plus Azithromycin 2g PO x1**

**Cefixime 800 mg orally as a single dose**

**gyrA testing – Ciprofloxacin 500mg PO x 1**

**\*No reliable alternatives for pharyngeal gonorrhea**

# Gonorrhea Follow-up

Abstain from sex until 7 days after completing treatment

Assess for treatment failure if persistent symptoms at 3-5 days with culture (with AST) and NAAT

Test of cure recommended for all pharyngeal infections at 7-14 days

Test of cure at 4 weeks if pregnant

Rescreen everyone at 3 months for re-infection

# What did we learn?

- Return sooner for test of re- infection
- Have partner EPT on site and document it in chart
  - EPT dot phrases for documentation and education for patients
  - Case management follow up
- Do resistance testing for GC
- Doxy PEP prescribed

# Implementation Questions

- Who should be given DoxyPEP?
- **What is the proper interval for STI testing for individuals on Doxy-PEP?**

Population	Recommendations
Men who have sex with men	At least annually, test at each site of exposure (urethra, rectum) for sexually active MSM regardless of condom use or every 3-6 months <b><u>if at increased risk</u></b> .
Patients taking PrEP	All patients starting and taking oral PrEP should have genitourinary and extra-genital testing performed at baseline and every 3 months.
Persons living with HIV	For sexually active individuals, screen at first HIV evaluation and at least annually thereafter. More frequent screening might be appropriate depending <b><u>on individual risk behaviors</u></b> and local epidemiology
Non-pregnant Women	Test at least annually for sexually active women under 25 years of age and those aged 25 years and older <b><u>if at increased risk</u></b> Rectal chlamydial testing can be considered in females <b><u>based on sexual behaviors and exposure</u></b> through shared clinical decision making.
Men who have sex with women***	Consider screening young men in high prevalence clinical settings (adolescent and STI clinics and correctional facilities)
Pregnant Women	All pregnant women under 25 years of age and those aged 25 years and older <b><u>if at increased risk</u></b> . retest during 3rd trimester if under 25 years of age or at risk.

• Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187. Published 2021 Jul 23. doi:10.15585/mmwr.rr7004a1

# CDC Preliminary Guidance

## Box. Population recommended for consideration for use of doxycycline as PEP for bacterial STI prevention

Considered

Recommendation	Strength of recommendation and quality of evidence
<ul style="list-style-type: none"><li>• Doxycycline 200mg <del>taken once orally</del> within 72 hours of oral, vaginal or anal sex <b>should be considered</b> for gay, bisexual, and other men who have sex with men, and for transgender women, with a history of at least one bacterial STI (i.e. gonorrhea, chlamydia or syphilis) in the last 12 months.</li></ul>	<b>AI</b>
<ul style="list-style-type: none"><li>• No recommendation can be given at this time on the use of doxycycline PEP for cisgender women, cisgender heterosexual men, transgender men, other queer and nonbinary individuals. If this intervention is offered, it should be implemented with considerations for ancillary services detailed below.</li></ul>	<b>There is insufficient evidence to assess the balance of benefits and harms of the use of doxycycline PEP</b>

# New York State Guidance

## RECOMMENDATIONS

### Biomedical Prevention of STIs

- Clinicians **should offer** doxy-PEP to cisgender men and transgender women who are taking HIV PrEP or receiving HIV care and 1) engage in condomless sex with partner(s) assigned male sex at birth and 2) have had a bacterial STI diagnosed within the past year and are at ongoing risk of STI exposure. (A1)
- Clinicians **should offer** doxy-PEP to cisgender men and transgender women who are *not* taking HIV PrEP or receiving HIV care and 1) engage in condomless sex with partner(s) assigned male sex at birth and 2) have had a bacterial STI diagnosed within the past year and are at ongoing risk of STI exposure. (A2†)
- Clinicians **should engage in shared decision-making with cisgender men** who 1) engage in condomless sex with multiple partners assigned female sex at birth and 2) have had a bacterial STI diagnosed within the past year, offering doxy-PEP on a case-by-case basis. (B3)
- When prescribing doxy-PEP, clinicians should use the dosing regimen of oral doxycycline 200 mg taken ideally within 24 to 72 hours of condomless sex (A1) and counsel patients (A\*) on the key points for patient education outlined in [Table 1: Considerations for Doxy-PEP Implementation](#).
- For individuals taking doxy-PEP, clinicians should screen for HIV, chlamydia, gonorrhea, and syphilis at least every 3 months. (A1)
- Clinicians should offer HIV PrEP to individuals who do not have HIV and are initiating or using doxy-PEP. (A\*)
- Clinicians should [offer HIV treatment](#) to individuals with HIV who are not on antiretroviral therapy and are initiating or using doxy-PEP. (A1)

Abbreviations: doxy-PEP, doxycycline post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

cis-men and TGW with an year and ongoing exposure on making with cis-MSW



# How Do I Prescribe Doxy-PEP?

FOR \_\_\_\_\_ DATE \_\_\_\_\_

ADDRESS \_\_\_\_\_

REFILL \_\_\_\_\_ TIMES

A generically equivalent drug product may be dispensed unless the practitioner hand writes the words "Brand Necessary" or "Brand Medically Necessary" on the face of the prescription.

**R<sub>x</sub>** Doxycycline Monohydrate 100mg tabs  
Take 2 tabs by mouth as needed every 24 hours  
Take 2 capsules by mouth, once daily as needed (take within 72 hours of condomless sex), Take no more than 2 capsules in any 24 hour period. Take with water and remain upright for 30 mins after taking

Dispense: #60 tabs  
Refills: 0

\_\_\_\_\_  
SIGNATURE

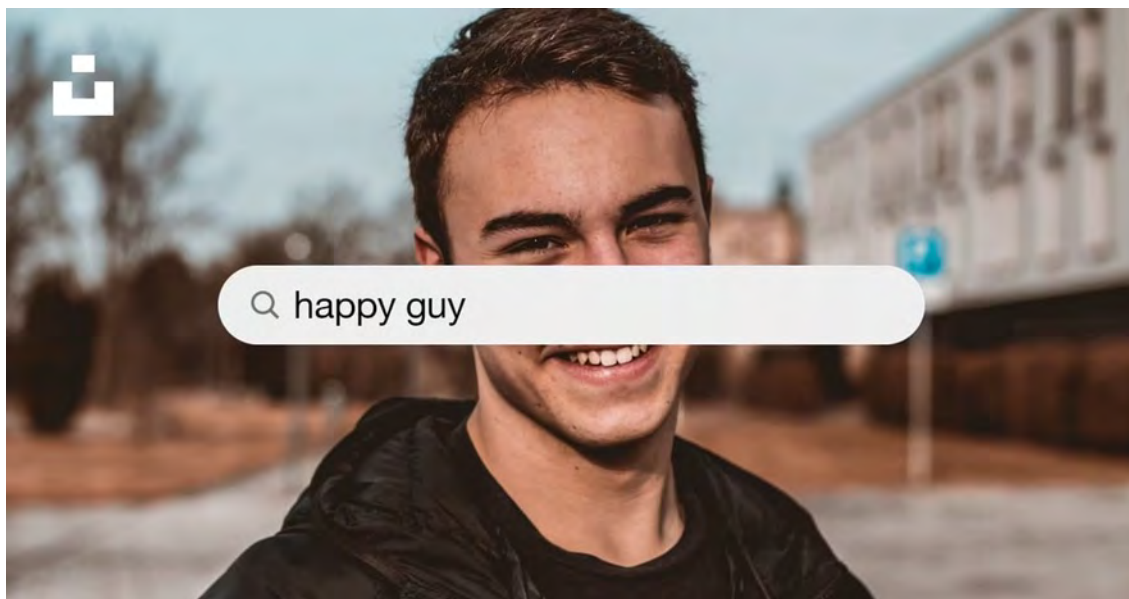
\_\_\_\_\_  
DEA NO.

ADDRESS \_\_\_\_\_

Reorder Item #6120 Total Pharmacy Supply, Inc. 1-800-878-2822

- Dispense and Refills
- 25% of patients used  $\geq$  10 doses per month

# Case 3- Happy Guy



- 24 yo male, HIV + on cabenuva every month injection for 5 months
- Last STI August had GC and CT (rectal)
  - Identified by 3 site screening
  - No symptoms
  - Treated with ceftriaxone 500mg IM and doxy 100mg BID x 7 days
- Returning, November, for test for re-infection
  - No new partners
  - No symptoms
  - Previous partners treated

# Test results

- Throat GC + NAAT (11/28/23 ) and RPR 1:32 (3 months prior was 1:2)
- Treated Ceftriaxone and 14 days of doxy 100mg BID (Bicillin shortage)

# Treatment Guidelines - Gonorrhea

Ceftriaxone 500 mg IM x 1  
for persons weighing <150kg\*

\*For persons weighing  $\geq 150$ kg, 1 g of IM  
ceftriaxone should be administered

# Test of Cure for Pharyngeal Infections

- Persistent nonviable organisms may cause a false positive NAAT
- Reinfection from re-exposure is a common cause of persistent positive GC tests

## RNA NAAT

TOC Pharynx*	N	Persistent RNA NAAT		OR (95% CI)
		N	(%)	
0-7 days	309	27	(8.7)	1 -----
8-14 days	367	8	(2.2)	0.23 (0.1-0.52)
<b>15-28 days</b>	<b>105</b>	<b>1</b>	<b>(1.0)</b>	<b>0.10 (0.01-0.75)</b>

- Hananta IPY, De Vries HJC, van Dam AP, van Rooijen MS, Soebono H, Schim van der Loeff MF. Persistence after treatment of pharyngeal gonococcal infections in patients of the STI clinic, Amsterdam, the Netherlands, 2012-2015: a retrospective cohort study. *Sex Transm Infect.* 2017 Nov;93(7):467-471. doi: 10.1136/sextrans-2017-053147. Epub 2017 Aug 19. PMID: 28822976; PMCID: PMC5739854.
- Bissessor M, Whiley DM, Fairley CK, Bradshaw CS, Lee DM, Snow AS, Lahra MM, Hocking JS, Chen MY. Persistence of *Neisseria gonorrhoeae* DNA following treatment for pharyngeal and rectal gonorrhea is influenced by antibiotic susceptibility and reinfection. *Clin Infect Dis.* 2015 Feb 15;60(4):557-63. doi: 10.1093/cid/ciu873. Epub 2014 Nov 3. PMID: 25371490.

# Follow up testing

- 3 month re-test → symptoms of rectal bleeding
  - No history of trauma. Partner tested and was negative for STIs but was treated.
- Results:
  - Rectal + CT NAAT
  - Throat and urine negative

# Treatment Guidelines - Chlamydia

## Preferred

Doxycycline 100 mg PO twice daily x 7 days

## Alternative

Azithromycin 1g orally once\*

\*Preferred during pregnancy

\*\*Pregnancy alternative: Amoxicillin 500mg orally 3 times per day for 7 days

**OR**

Levofloxacin 500mg orally x 7 days

# Guidelines – Chlamydia- PROCTOCOLITIS

## Preferred

Doxycycline 100 mg PO twice daily x 21 days

## Alternative

Azithromycin 1g orally weekly for 3 weeks

**OR**

Erythromycin base 500mg orally 4 times/day x 21 days



# Why Make This Change for Chlamydia

## Genitourinary infection

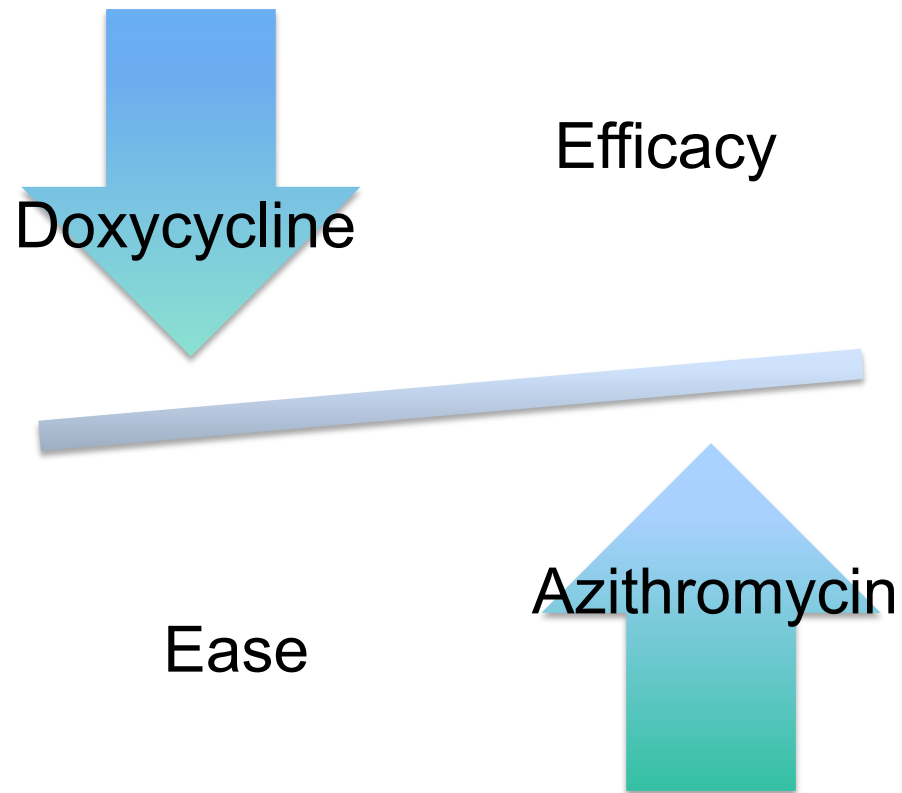
- Microbiologic failure higher among men

## Rectal infection

- Doxycycline superior to azithromycin (20%-26%)
- Rectal infection not uncommon among women with genitourinary infection (33%-83%)



# Azithromycin vs Doxycycline



## Indications for Azithromycin

- Pregnant or may be pregnant
- History of allergy or intolerance to doxycycline
- Unlikely to be adherent
- Unlikely to be able to obtain doxycycline and azithromycin is available at point of care

# Chlamydia Follow-up

Abstain from sex until partners have completed treatment or 7 days after single dose therapy

**Consider repeat testing at 4 weeks for rectal CT treated with Azithromycin due to lower efficacy**

Test of cure at 4 weeks if pregnant

Rescreen at 3 months for re-infection

# Cases: Question & Discussion

# Clinic Prompt

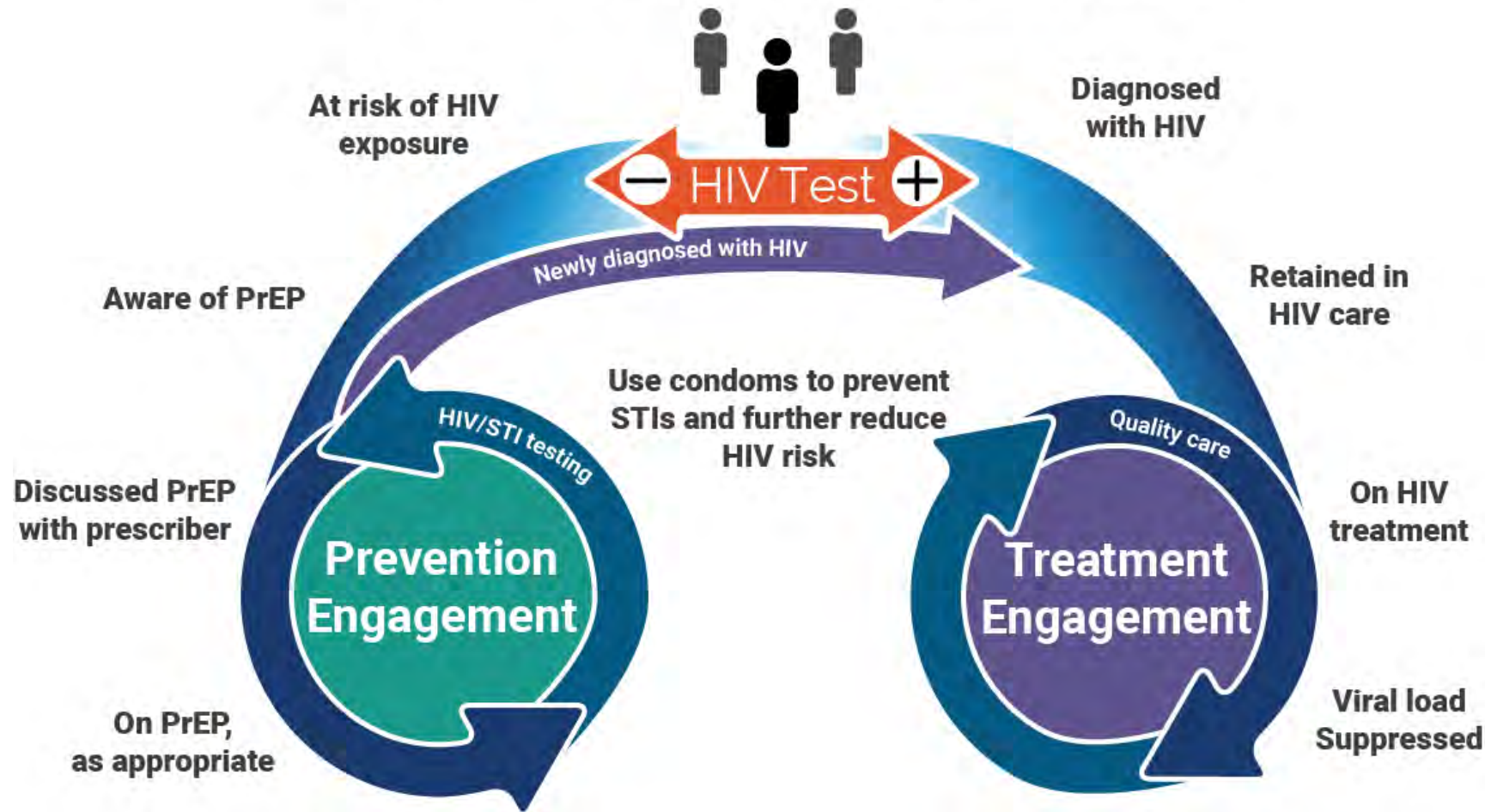
❖ What are 1-2 sexual health projects your clinic is working on in 2024?

# Quick Evaluation

1. How would you rate the value of today's discussion?
2. The level of the brief lecture was:
3. Attending the learning community is a good use of my time.
4. I felt comfortable contributing during the LC session.
5. As a result of today's session, are there any changes you would make in your practice?
6. Since the last LC, has your clinic made (or is in the process of making) any clinical practice changes related to HIV prevention services?

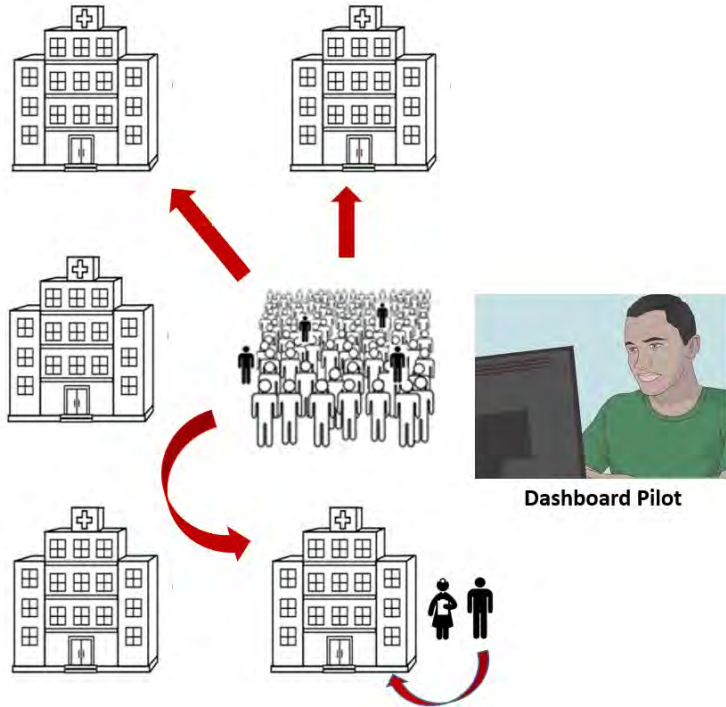
# Status-Neutral & Open-Access Service Delivery Model ~A Case Study~

## HIV Status-Neutral Service Delivery Model



Myers, J. E., Braunstein, S. L., Xia, Q., Scanlin, K., Edelstein, Z., Harriman, G., ... & Daskalakis, D. (2018, June). Redefining prevention and care: a status-neutral approach to HIV. In open forum infectious diseases (Vol. 5, No. 6, p. ofy097). US: Oxford University Press.

# Status-Neutral & Open-Access Service Delivery Model ~A Case Study~

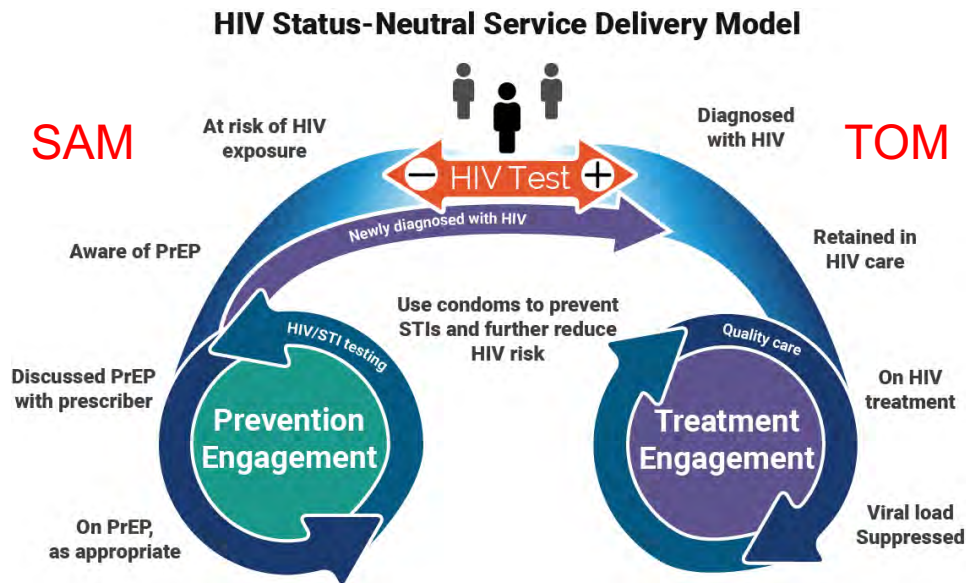


- October 24, 2023
  - Patient (Tom) identified on Dashboard after HIV testing conducted in CU/Emergency Room
  - HIV Antibody/Antigen Positive, Supplemental Pending
  - Tom was confused by results and relieved when our Coordinator reached out to offer an appointment for the next day
  - Patient's partner (Sam) was tested in ER as well and test results came back negative
  - The couple last had sex the day prior



# Status-Neutral & Open-Access Service Delivery Model ~A Case Study~

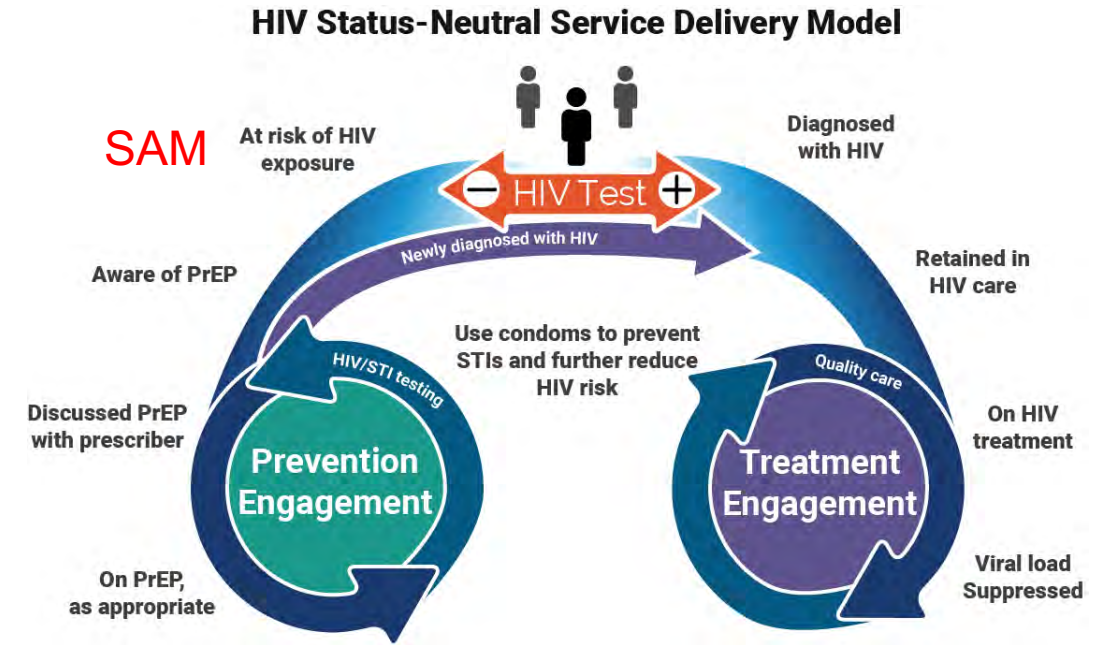
- October 25, 2023
  - Tom, accompanied by partner (Sam), came to VC3 and were greeted by team
  - Tom (presumed positive) and Sam (presumed negative) both moved through the Status Neutral Care Continuum while being supported by our staff members



# Status-Neutral & Open-Access Service Delivery Model

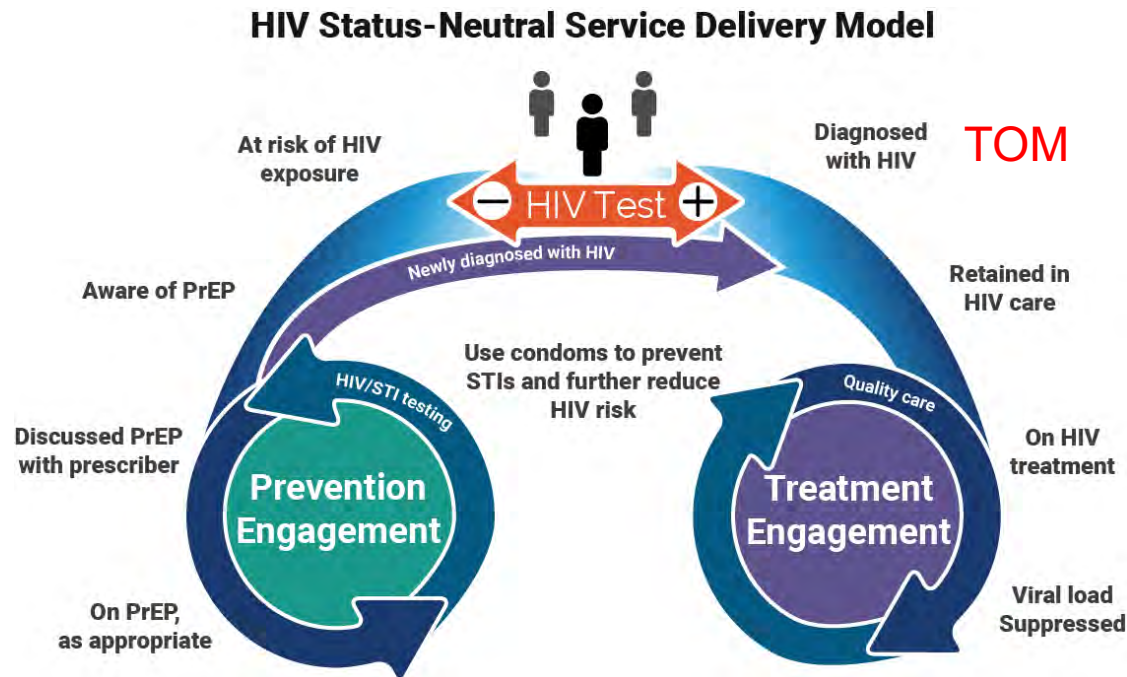
## ~A Case Study~

- Sam (presumed HIV negative)
  - Prevention Coordinator met with Sam and explained (post-exposure prophylaxis) PEP and discussed HIV testing significance.
  - Benefits Navigator met with Sam and activated Medicaid
  - Our provider met with patient and discussed HIV testing algorithm based on last exposure time. Provided PEP starter dose



# Status-Neutral & Open-Access Service Delivery Model

## ~A Case Study~



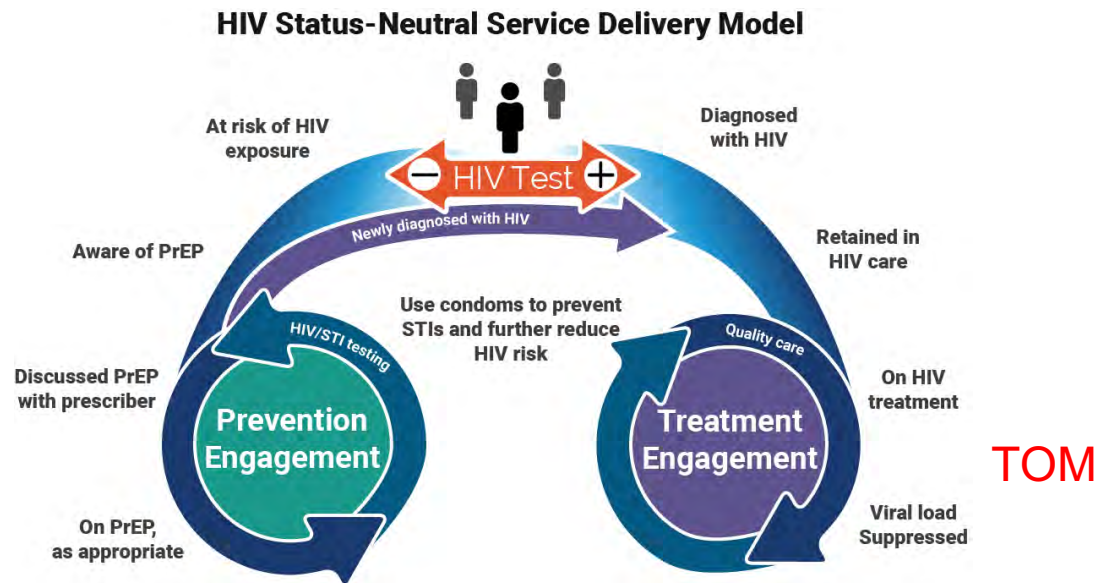
- Tom (presumed HIV Positive)
  - HIV Coordinator met with Tom and provided patient with comprehensive HIV education (prognosis, treatment, and transmission prevention methods)
  - Benefits Navigator met with Sam and activated Medicaid
  - A medical provider met with patient and discussed new diagnosis. ARV starter dose provided

- Our social worker met with Sam and Tom individually and then as a couple to discuss psychosocial concerns

# Status-Neutral & Open-Access Service Delivery Model

## ~A Case Study~

- November 2023 – February 2024
  - Tom (confirmed positive) engaged in care on r  
eached undetectable status, switched to Long  
Acting Injectable Cabenuva



# Status-Neutral & Open-Access Service Delivery Model ~A Case Study~

- November 2023 – February 2024
  - Sam (continuously negative) completed PEP and switched to PrEP. Sam is engaged in ongoing prevention care and engaged with mental health services.
  - This week Sam switched to Long Acting Injectable Cabotegravir

