California CT and GC Surveillance Overview

Trish McLendon, MPH

Surveillance and Data Management Unit Chief

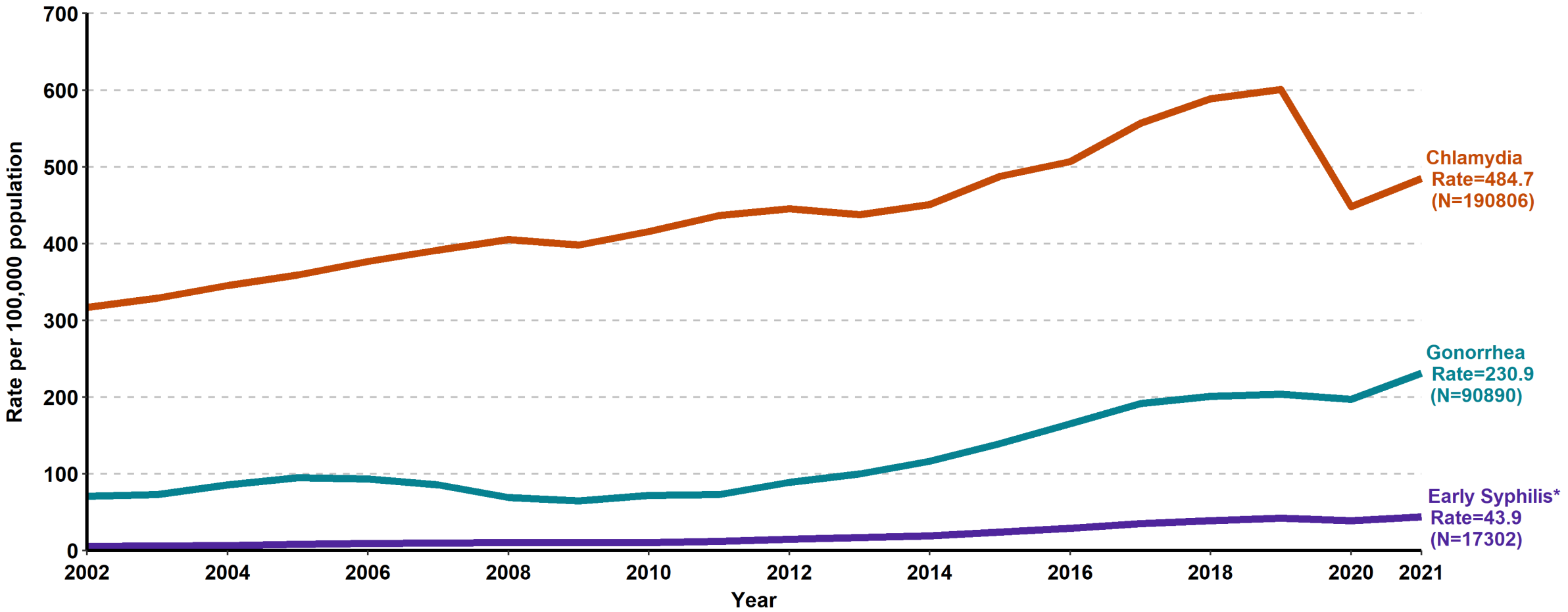
STD Control Branch, California Department of Public Health

California Department of PublicHealth

Chlamydia and Gonorrhea

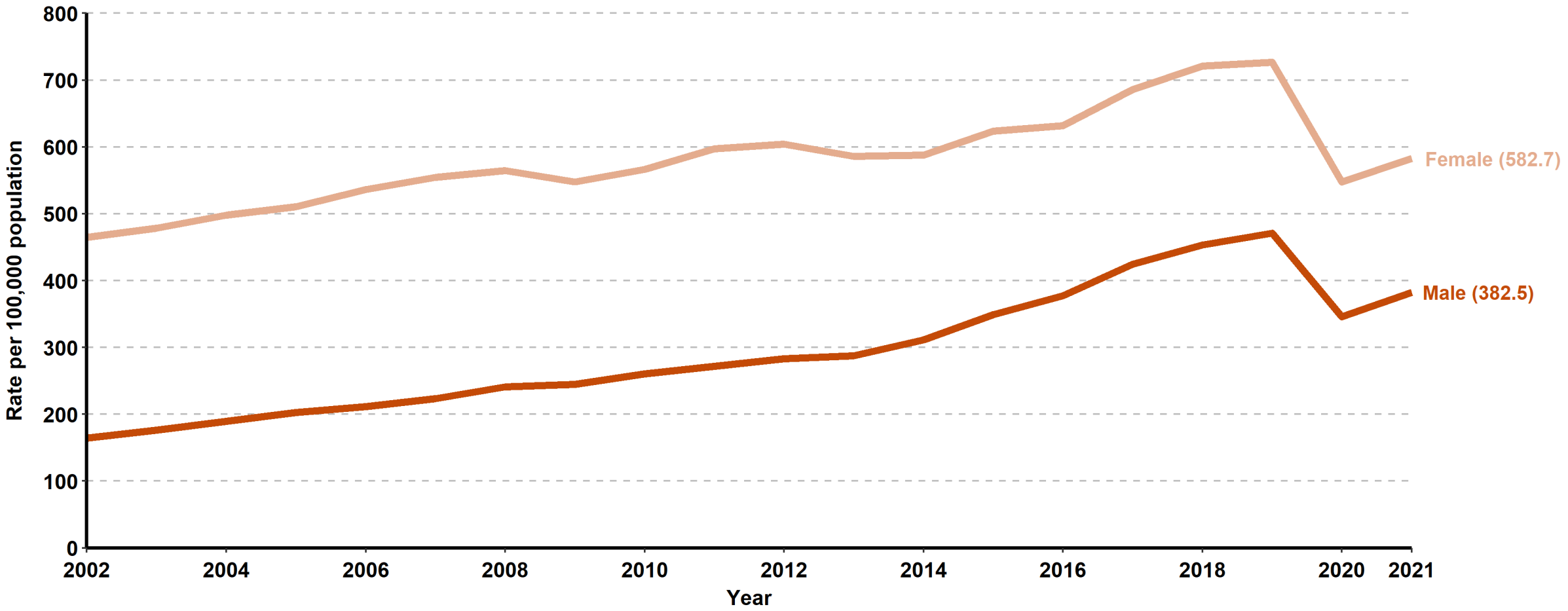
- Chlamydia
  - Most commonly reportable STI
  - Rates decreased due to Covid but have been increasing
  - Highest rates in young females
- Gonorrhea
  - Second most reported STI
  - Rates have continued to increase
  - Highest rates in males

Chlamydia, Gonorrhea, and Early Syphilis* California Incidence Rates, 2002–2021



* Early syphilis includes primary, secondary, and early non-primary non-secondary syphilis.

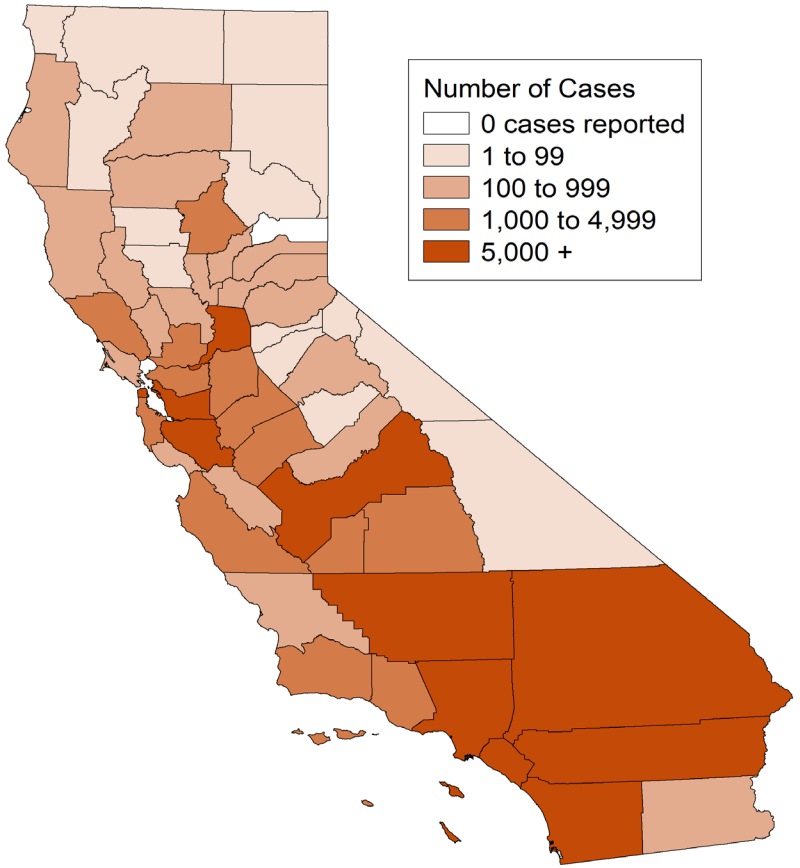
Chlamydia, Incidence Rates by Gender, California, 2002–2021



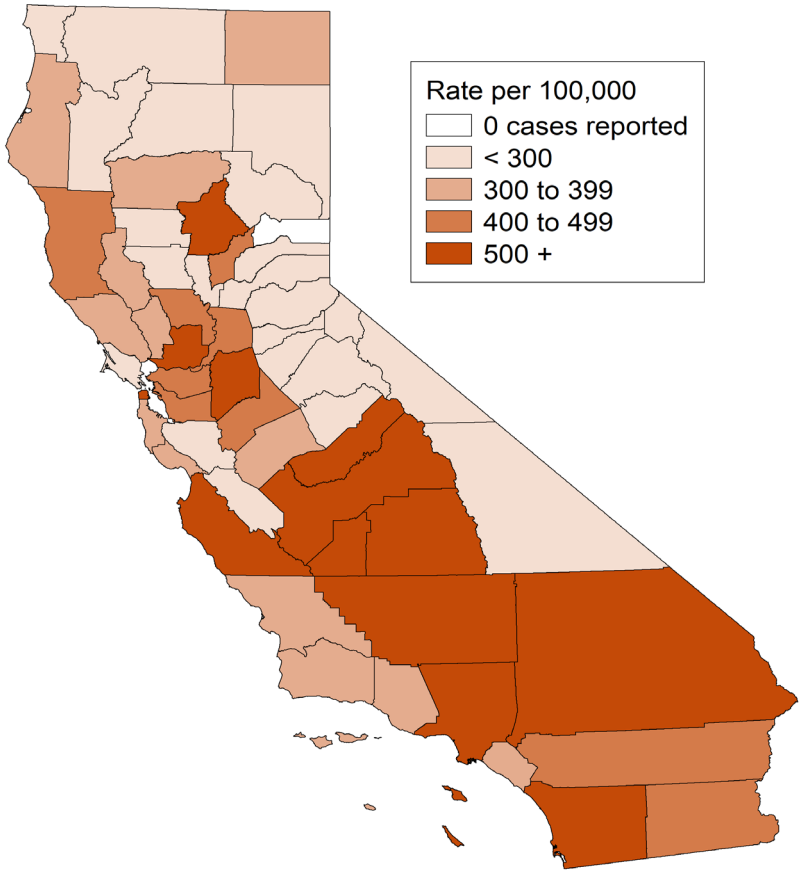
Screening guidelines recommend routine screening for specific populations, therefore higher rates of reported cases may in part reflect the targeted nature of screening programs.

Chlamydia, Case Counts and Incidence Rates by County, California, 2021

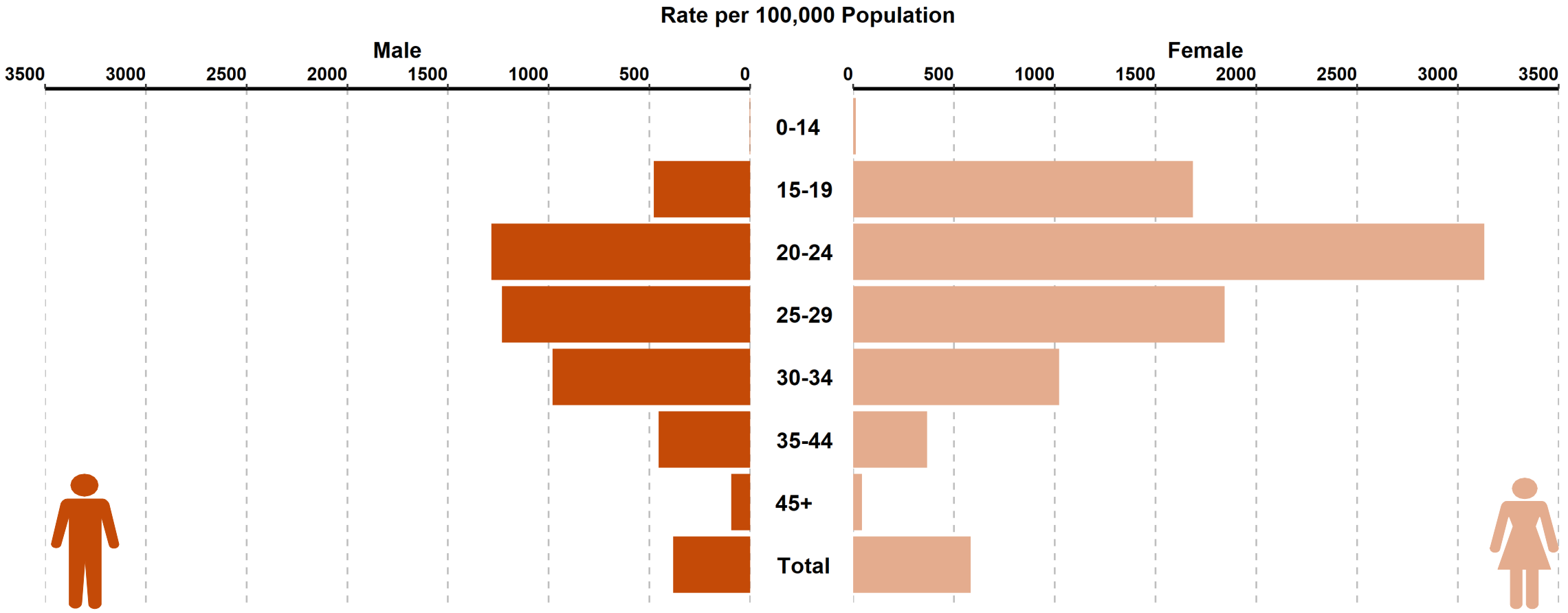
Chlamydia Cases



Chlamydia Rates

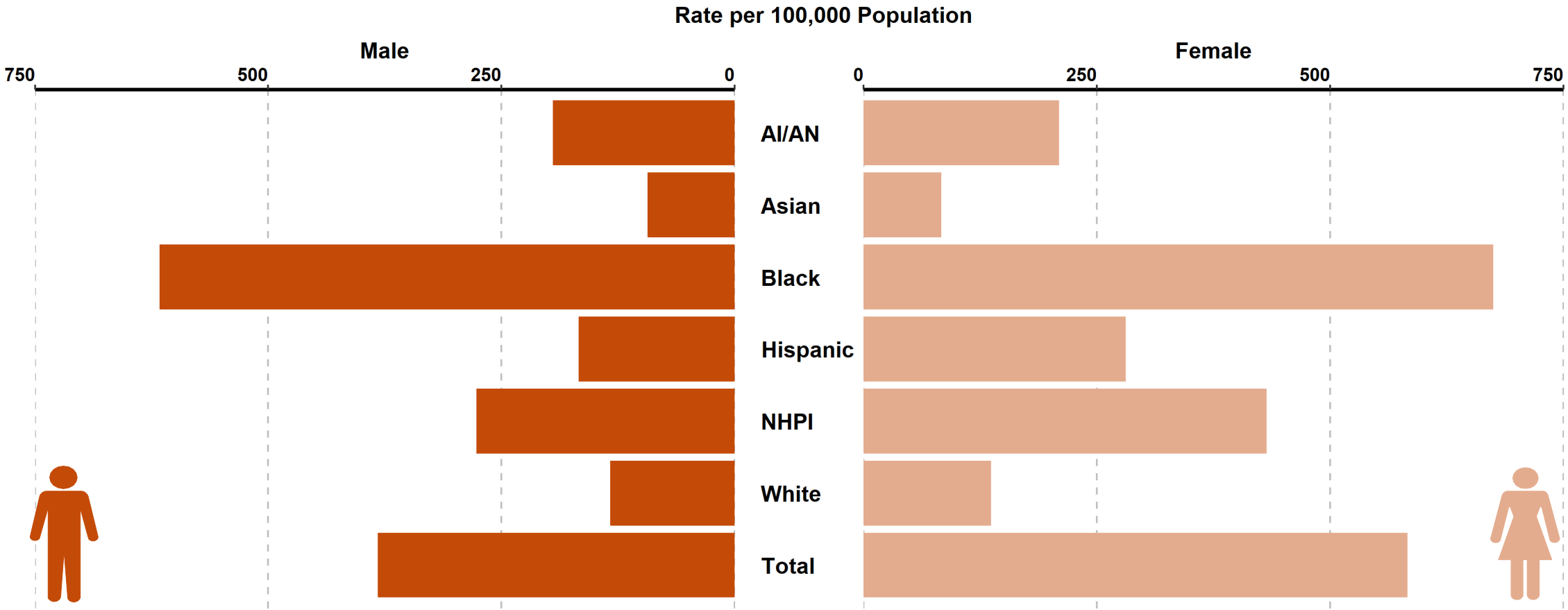


Chlamydia, Incidence Rates by Age Group (in years) and Gender, California, 2021



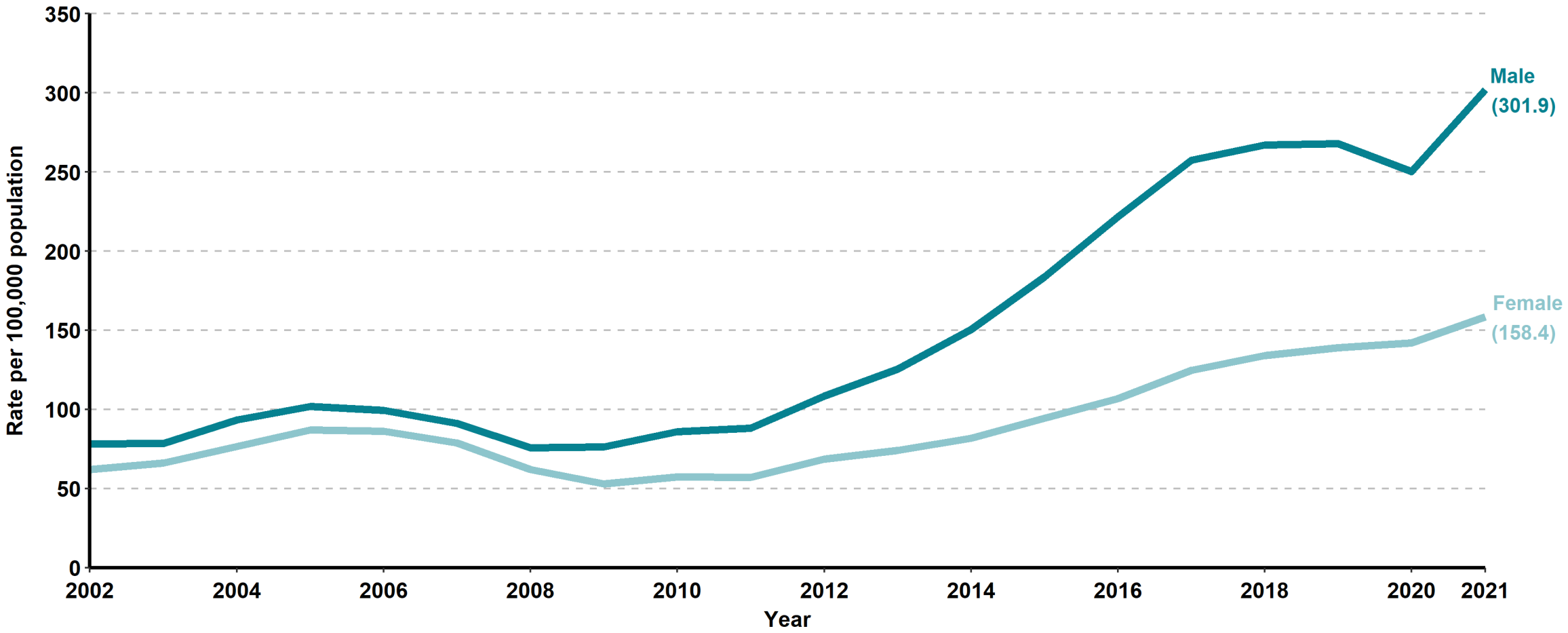
Age was “Not Specified” for 0.09% of female cases and 0.11% of male cases in 2021.
Screening guidelines recommend routine screening for specific populations, therefore higher rates of reported cases may in part reflect the targeted nature of screening programs.

Chlamydia, Incidence Rates by Race/Ethnicity and Gender, California, 2021



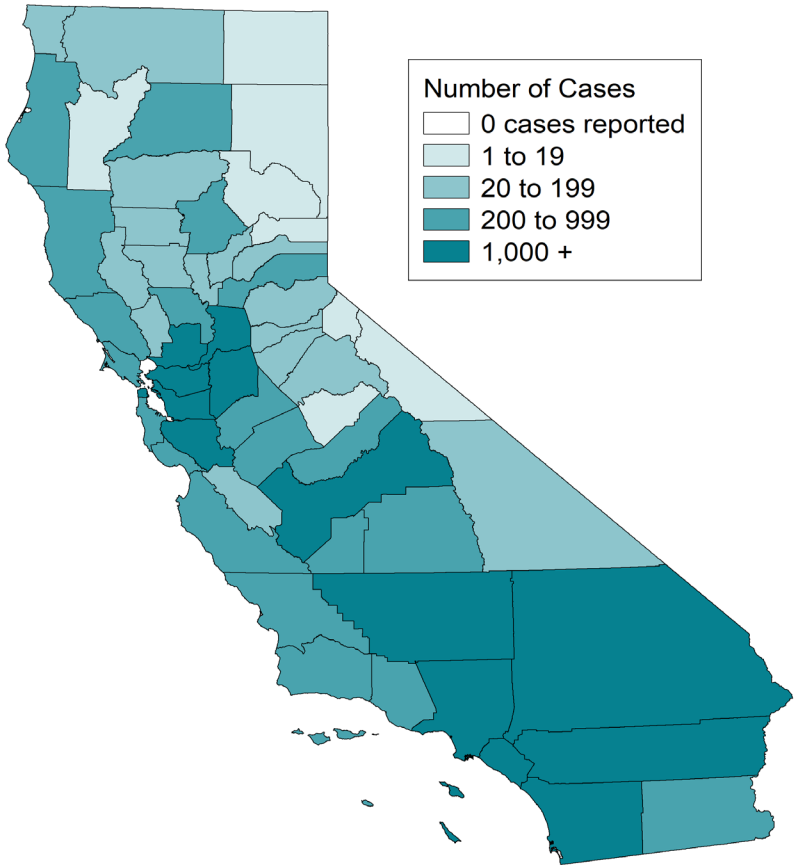
AI/AN = American Indian/Alaska Native, NHPI = Native Hawaiian/ Other Pacific Islander
Race/Ethnicity was "Not Specified" for 54.25% of female cases and 47.12% of male cases in 2021.
Screening guidelines recommend routine screening for specific populations, therefore higher rates of reported cases may in part reflect the targeted nature of screening programs.

Gonorrhea, Incidence Rates by Gender, California, 2002–2021

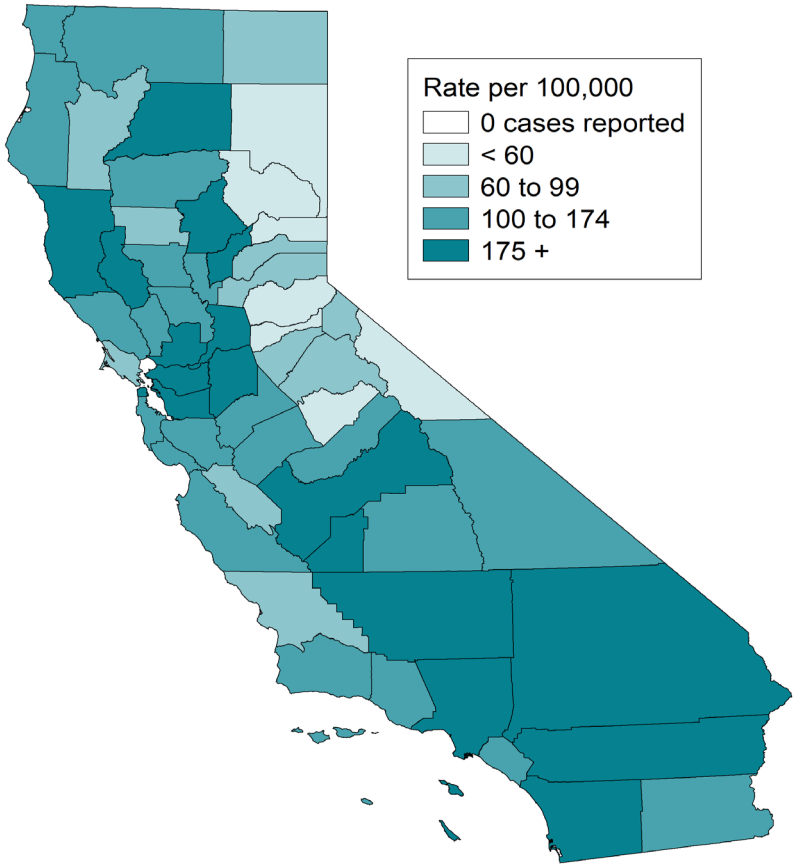


Gonorrhea, Case Counts and Incidence Rates by County, California, 2021

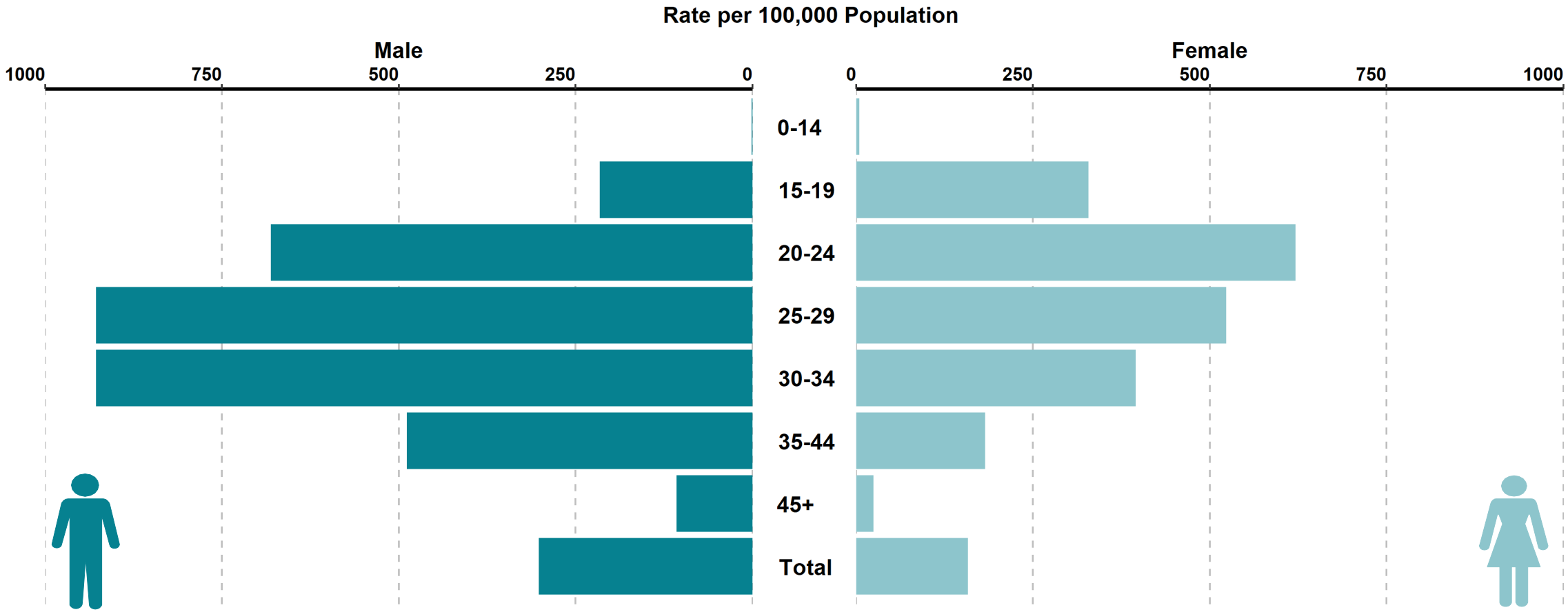
Gonorrhea Cases



Gonorrhea Rates

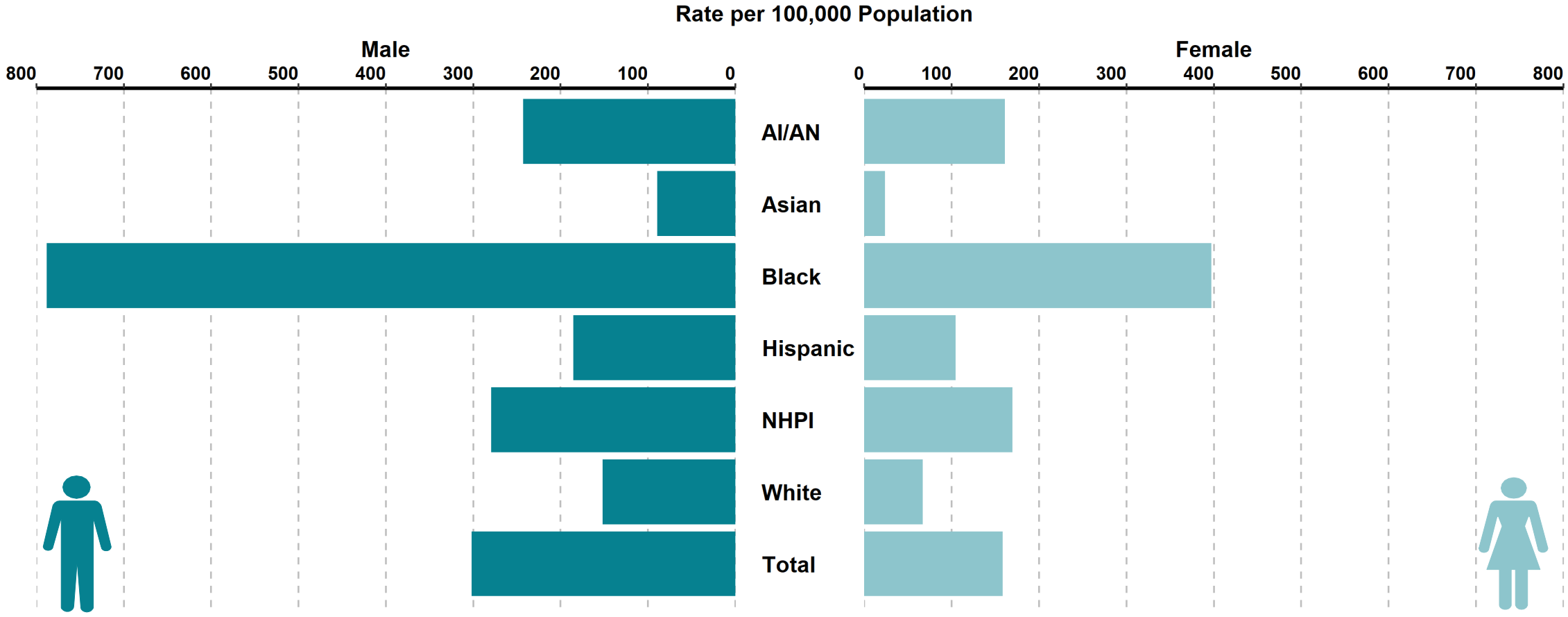


Gonorrhea, Incidence Rates by Age Group (in years) and Gender, California, 2021



Age was “Not Specified” for 0.2% of female cases and 0.15% of male cases in 2021.

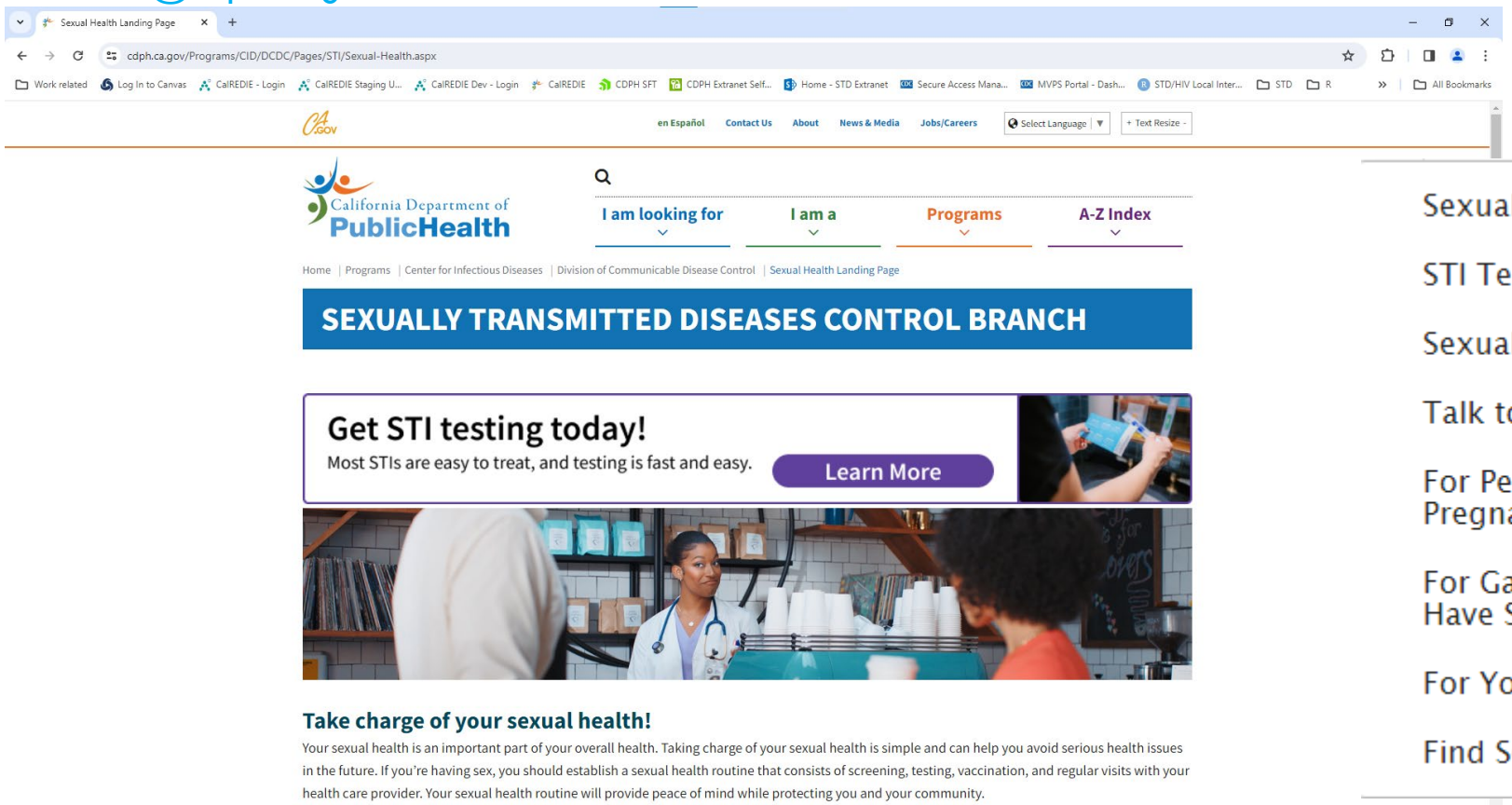
Gonorrhea, Incidence Rates by Race/Ethnicity and Gender, California, 2021



AI/AN = American Indian/Alaska Native, NHPI = Native Hawaiian/Other Pacific Islander.
Race/Ethnicity was “Not Specified” for 35.24% of female cases and 30.51% of male cases in 2021.

Information and Resources

- https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/std.aspx
- https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/STI/Sexual-Health.aspx
- STDCB@cdph.ca.gov



Thank you!

patricia.mclendon@cdph.ca.gov

STDEPI@cdph.ca.gov

Think STIs:
and Tools to Prevent Them

May 2024

Kurtis B. Mohr, MD, AAHIVS – CDPH STD Control Branch

Learning Objectives

1) Understand the importance of a good Sexual History and keeping sexually transmitted infections (STIs) on your differential.
2) Review resources for accurate information regarding STI screening and treatment guidelines.
3) Integrate biochemical prevention tools (e.g., doxyPEP, HIV PrEP) into your practice.

Slides courtesy of Dr. Lindley Barbee, MD, MPH; Wyatt Hanft, MD, MPH; Rosalyn Plotzker, MD, MPH; Akanksha Vaidya, MD, MPH; and Eric Tang, MD, MPH

Outline

Bacterial STIs

- ✓ California epidemiology & statistics – priority populations
- ✓ Case Scenario & Sexual Health History
- ✓ STI Screening & Treatment resources
- ✓ Partner Notification & Expedited Partner Therapy (EPT)
- ✓ Doxycycline post-exposure prophylaxis (doxyPEP)

HIV

- ✓ California statistics
- ✓ Biochemical HIV prevention: HIV Pre-Exposure Prophylaxis (HIV PrEP)

Social Determinants of Health (SDOH)

"Individual behaviors that **contribute to STIs** occur in a broad context that involves a complex interplay of factors such as **poverty**, **stigma**, **housing** and **food insecurity**, **discrimination**, **racism**, **medical mistrust**, **violence/trauma**, **access** to care, and **education**." – HHS STI National Strategic Plan 2021-2025

Priority populations

- Adolescents and young adults
- Gay, Bisexual Men who have sex with men (GBMSM)
- Geographic regions
- Pregnant women/women
- Racial/ethnic minorities
- Transgender persons

Priority Populations | HHS.gov

Case: Riley, 27 year-old cis-gender male

Presents with **rectal pain & rectal bleeding x3days**

- No diarrhea/abd cramping
- Denies f/c/n/v, no penile discharge/rashes/lesions/blood

Without *asking* more, Ddx:

- Hemorrhoids
- Anal fissure
- Pruritis Ani
- Perianal abscess/anal fistula
- Inflammatory bowel disease
- Malignancy

- Sexually Transmitted Infections

Sexual History

→ If we don't ask, we won't know what to do ←

CDC five Ps model:

Partners, **P**ractices, **P**rotection from STI,

Past history of STI, & **P**regnancy plans

- CA-PTC STD Expert Hour - Sexual History Taking 2021
  - https://www.youtube.com/watch?v=yNPTVg5ZCek
- AAFP Sexual Health History: Techniques and Tips
  - https://www.aafp.org/pubs/afp/issues/2020/0301/p286.html#afp2Back to Basics: Fundamentals of STI/HIV Prevention0200301p286-b9

Riley: Sexual History

In last 3 months, 2 female partners, 1 male partner

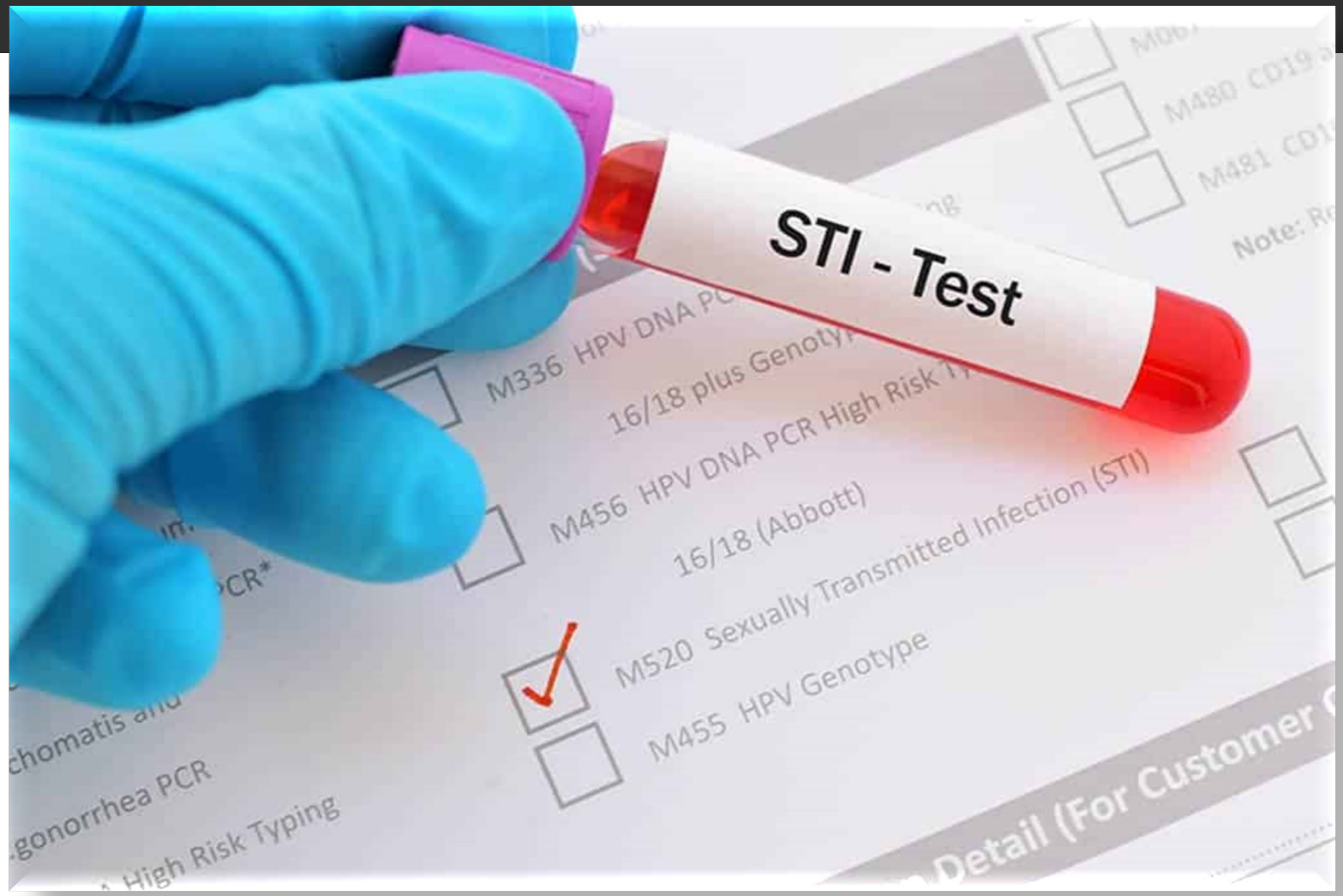
- Insertive penile-vaginal, penile-anal sex; intermittent condom use
- Receptive/insertive penile-oral sex
- Receptive penile-anal sex;
- Denies oral-anal sex ("rimming")

<u>STI Hx</u>

- Denies hx STIs or STI testing
- UTD - HPV, Hep A/B, Meningitis vaccines
- No JYNNEOS (mpox) vaccination

- (side bar on **Screening for STIs**)

STI Screening



STI Screening (CDPH)

- ✓ GC & CT – 3 pt @sites of exposure
- ✓ Syphilis
- ✓ HIV
- ✓ HBV & HCV

- ~~Trichomonas~~
- ~~HPV~~
- ~~LGV~~
- ~~HSV~~
- ~~Mgen~~

California STI Screening Recommendations

California-STI-Screening-Recommendations.pdf

Men who have sex with men (MSM) or with transgender women	Chlamydia & Gonorrhea	Annually at sites of sexual exposure (urethral [urine], rectum, pharynx) regardless of condom use; every 3-6 months if at increased risk	Increased risk includes patients on HIV PrEP (screen every 3-4 months) or living with HIV, if patient or sex partners has multiple partners, sex in conjunction with drug use
	Syphilis	Any age: annually, every 3-6 months if at increased risk	Screen every 3-4 months if on HIV PrEP
	HIV	Annually if patient/partner(s) have had >1 sex partner since last HIV test; every 3-6 months if at increased risk	Screen every 2 months (if on injectable HIV PrEP) or 3 months (if on oral HIV PrEP)
	Hepatitis B[7]	At least once	Test for HBsAg, HBV core antibody, and HBV surface antibody
	Hepatitis C[7]	≥18 years: at least once, repeat if at risk	Except in settings where the prevalence of HCV infection is <0.1%

STI Screening (CDC)

Screening Recommendations and Considerations Referenced in Treatment Guidelines and Original Sources

Print

By Disease | **By Population**

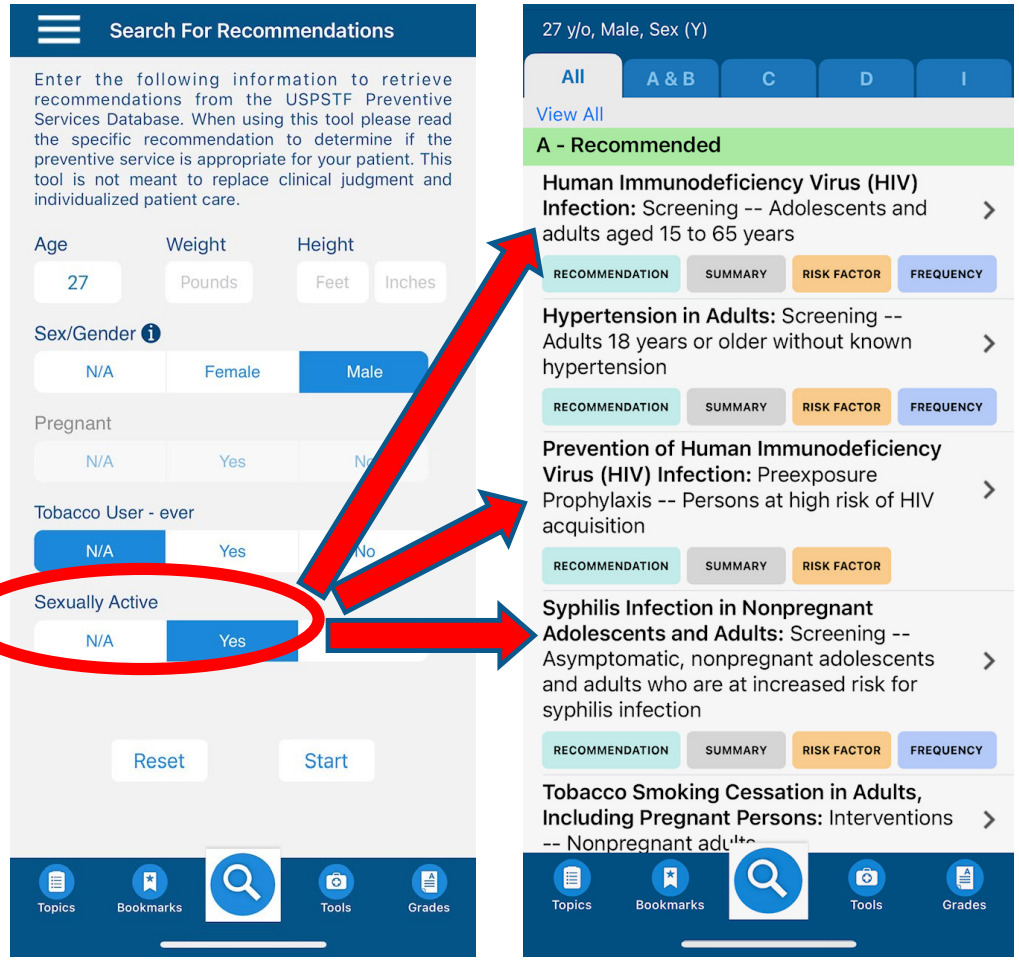
*In populations where no recommendations exist, screen based on risk factors and local STI prevalence

Men Who Have Sex with Men

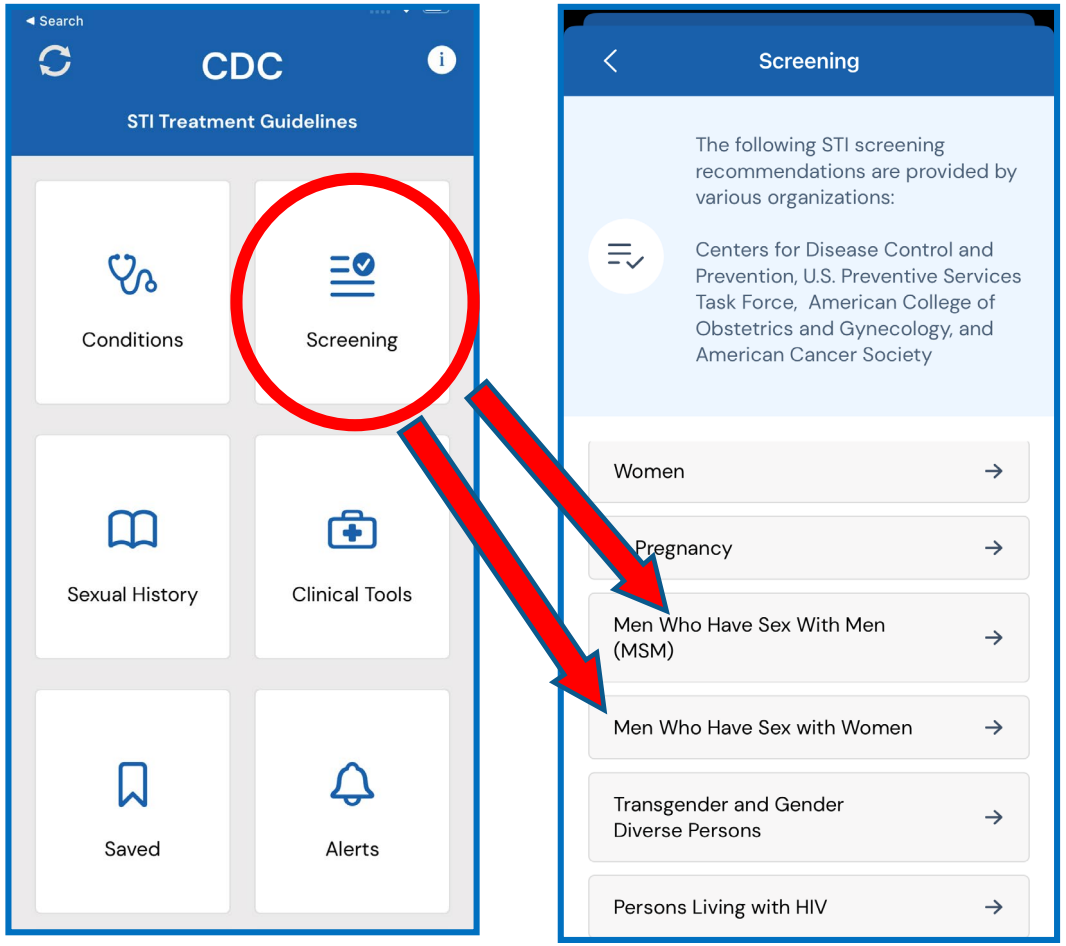
Chlamydia	• At least annually for sexually active MSM at sites of contact (urethra, rectum) regardless of condom use[2] • Every 3 to 6 months if at increased risk (i.e., MSM on PrEP, with HIV infection, or if they or their sex partners have multiple partners)[2]
Gonorrhea	• At least annually for sexually active MSM at sites of contact (urethra, rectum, pharynx) regardless of condom use[2] • Every 3 to 6 months if at increased risk[2]
Syphilis	• At least annually for sexually active MSM[2,5] • Every 3 to 6 months if at increased risk[2,5]
Herpes†	• Type-specific serologic tests can be considered if infection status is unknown in MSM with previously undiagnosed genital tract infection[2]
HIV	• At least annually for sexually active MSM if HIV status is unknown or negative and the patient or their sex partner(s) have had more than one sex partner since most recent HIV test[2, 7, 17] • Consider the benefits of offering more frequent HIV screening (e.g., every 3–6 months) to MSM at increased risk for acquiring HIV infection.[2]
HPV, Anal Cancer§	• Digital anorectal rectal exam[2] • Data is insufficient to recommend routine anal cancer screening with anal cytology[2]
Hepatitis B Screening	• All MSM should be tested for HBsAg, HBV core antibody, and HBV surface antibody[11]
Hepatitis C Screening	• All adults over age 18 years should be screened for hepatitis C except in settings where the hepatitis C infection (HCV) positivity is < 0.1%[12]

STI Screening Recommendations | CDC

USPSTF app



CDC STI app



Riley: Physical Exam

External Rectal Exam:

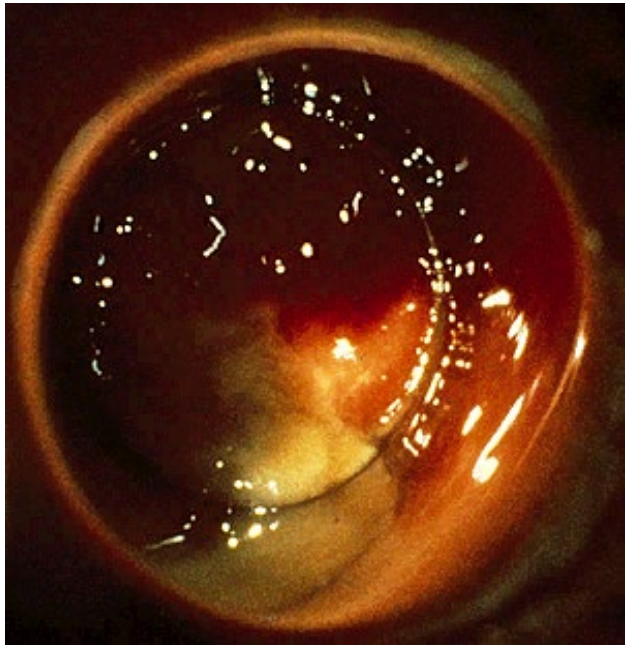
- No ulcers/lesions/rash

Digital Rectal Exam (DRE):

- Diffuse tenderness

Anoscopy:

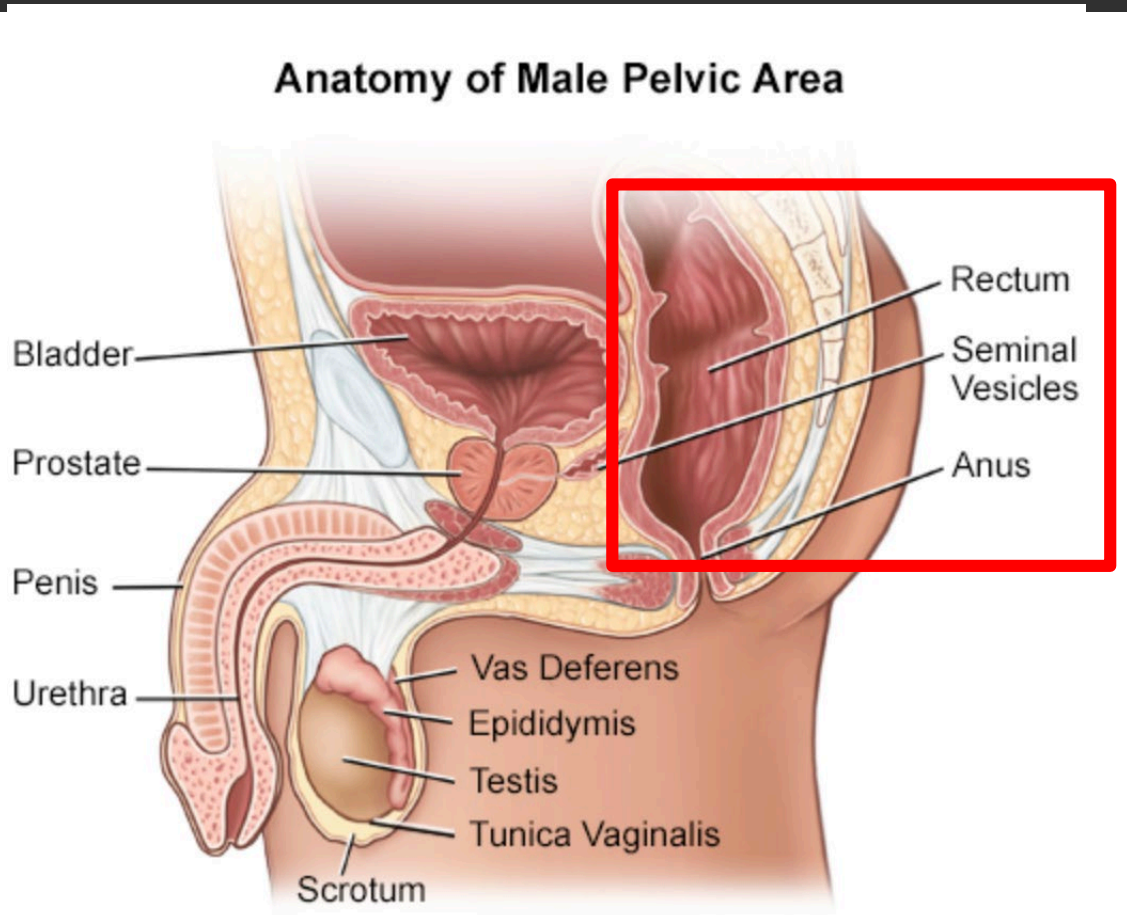
- Inflammed, friable mucosa, noted discharge; no ulcers/lesions



Mosby

STD Atlas, 1997

Sexually Transmitted Gastrointestinal Syndromes



Proctitis

Proctocolitis

Enteritis

Johns Hopkins Medicine. Overview of Male Anatomy: https://www.hopkinsmedicine.org/health/wellness-and-prevention/overview-of-the-male-anatomy

Sexually Transmitted Gastrointestinal Syndromes: Pathogens

Proctitis

Neisseria gonorrhoeae
Chlamydia trachomatis
(including **LGV serovars**)
Herpes Simplex Virus
***T. pallidum* (syphilis)**
Mpox (MPX)

Others:
M genitalium
N. meningitidis

Proctocolitis

Campylobacter species
Shigella species
E. Histolytic
LGV
T. pallidum (syphilis)

Enteritis

Giardia lamblia
Shigella species
Salmonella
E. Coli
Campylobacter species
Cryptosporidium

Immunosuppressed persons with HIV:
CMV

Proctitis: Diagnosis and Testing

- **Gonorrhea** (NAAT; GC culture and gram stain of rectal discharge if available)
- **Chlamydia** (NAAT; LGV PCR if available)
- **Syphilis** (serologic testing; darkfield of lesion if available)
- **HSV** (preferably PCR of rectal lesions)
- **MPX** (swab of lesions)

- Consider testing for *M genitalium* ("Mgen") with NAAT (and treat if positive) if *persistent* symptoms after standard treatment
- Test for HIV as well as GC/CT at other exposed sites for patients with acute proctitis

Riley's **test results**

- GC/CT – 3 pt testing negative
- **RPR reactive** → C-scope bx: path report +syphilis
- HSV-1 and HSV-2 PCR negative
- HIV negative
- Hep B immune; anti-Hep C non-reactive
- MPX test not done (no lesions present)
- (side bar on **Treatment for STIs**)

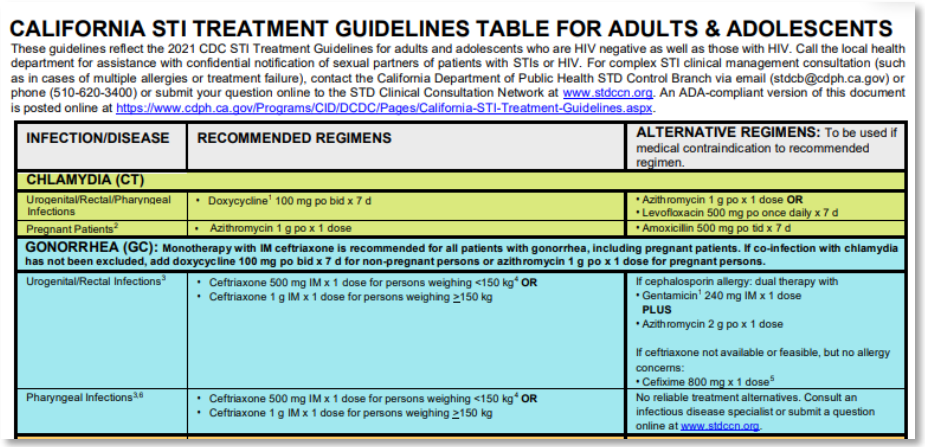
STI Treatment

STI Treatment – 2021 update

California STI Treatment Guidelines

CA-PTC STI Treatment Guidelines pdf →

CDPH Dear Colleague Letter (highlights changes)



CALIFORNIA STI TREATMENT GUIDELINES TABLE FOR ADULTS & ADOLESCENTS

These guidelines reflect the 2021 CDC STI Treatment Guidelines for adults and adolescents who are HIV negative as well as those with HIV. Call the local health department for assistance with confidential notification of sexual partners of patients with STIs or HIV. For complex STI clinical management consultation (such as in cases of multiple allergies or treatment failure), contact the California Department of Public Health STD Control Branch via email (stdcb@cdph.ca.gov) or phone (510-620-3400) or submit your question online to the STD Clinical Consultation Network at www.stdccn.org. An ADA-compliant version of this document is posted online at https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/California-STI-Treatment-Guidelines.aspx.

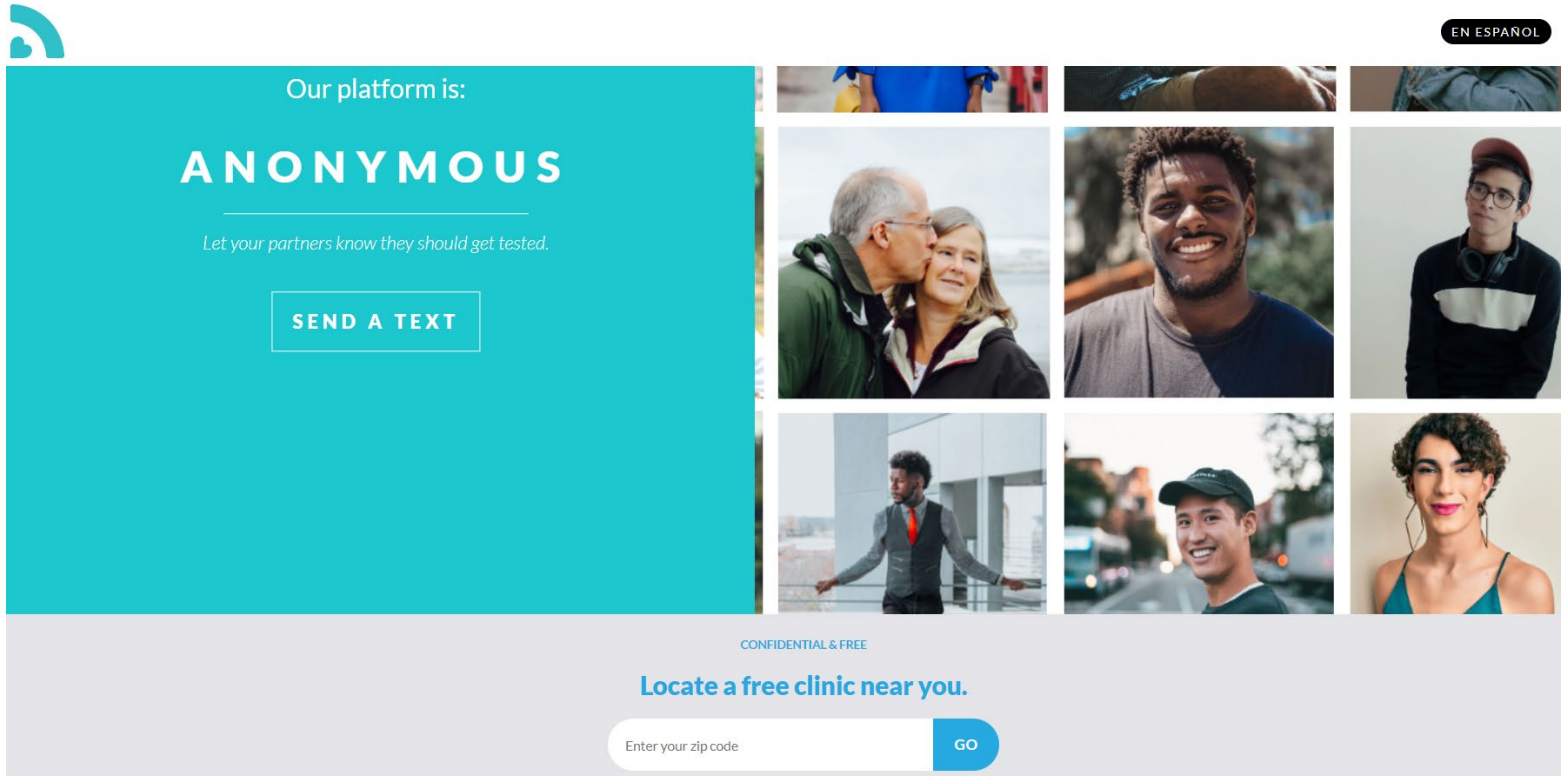
INFECTION/DISEASE	RECOMMENDED REGIMENS	ALTERNATIVE REGIMENS: To be used if medical contraindication to recommended regimen.
CHLAMYDIA (CT)		
Urogenital/Rectal/Pharyngeal Infections	• Doxycycline[1] 100 mg po bid x 7 d	• Azithromycin 1 g po x 1 dose **OR** • Levofloxacin 500 mg po once daily x 7 d
Pregnant Patients[2]	• Azithromycin 1 g po x 1 dose	• Amoxicillin 500 mg po tid x 7 d
GONORRHEA (GC): Monotherapy with IM ceftriaxone is recommended for all patients with gonorrhea, including pregnant patients. If co-infection with chlamydia has not been excluded, add doxycycline 100 mg po bid x 7 d for non-pregnant persons or azithromycin 1 g po x 1 dose for pregnant persons.		
Urogenital/Rectal Infections[3]	• Ceftriaxone 500 mg IM x 1 dose for persons weighing <150 kg[4] **OR** • Ceftriaxone 1 g IM x 1 dose for persons weighing ≥150 kg	If cephalosporin allergy: dual therapy with • Gentamicin[1] 240 mg IM x 1 dose **PLUS** • Azithromycin 2 g po x 1 dose If ceftriaxone not available or feasible, but no allergy concerns: • Cefixime 800 mg x 1 dose[5]
Pharyngeal Infections[3,6]	• Ceftriaxone 500 mg IM x 1 dose for persons weighing <150 kg[4] **OR** • Ceftriaxone 1 g IM x 1 dose for persons weighing ≥150 kg	No reliable treatment alternatives. Consult an infectious disease specialist or submit a question online at www.stdccn.org.

CA Family PACT webinar: *2021 Implementing the CDC STI Treatment Guidelines*

California PTC webinar: *2021 CDC STI Treatment Guidelines Update*

Sexual Partner Notification

- TellYourPartner.org anonymous notification



Expedited Partner Therapy (EPT)

*"the practice of a specified health care provider who diagnoses sexually transmitted **chlamydia**, **gonorrhea**, or another sexually transmitted infection (STI) and prescribes, dispenses, furnishes, or otherwise provides prescription antibiotic drugs to that patient's sexual partner or partners without examination of the sexual partner(s)."*

(California Health and Safety Code (HSC) 120582(a))

- **Presumptively treat all sexual partners from the last 60 days**
- **Decrease burden of STIs**
- **Improves accessibility & reduces barriers**
  - **work conflict**
  - **lack of transportation**
  - **lack of insurance/undocumented**
  - **prolonged time to next appt**

References: ▪ CDPH factsheet on SB 306 ▪ SB 306: Expanded Access to EPT for Prescribers webinar 2/9/2023

Acute Proctitis: Treatment

Ceftriaxone 500mg* IM in a single dose

PLUS

Doxycycline 100mg PO BID for 7 days**

*For persons weighing ≥150 kg, 1g of ceftriaxone in a single dose

**Extend to 100mg PO BID for 21 days in presence of bloody discharge, perianal or mucosal ulcers, or tenesmus and a positive rectal CT test to treat LGV

Add treatment for genital herpes if painful perianal or mucosal ulcers are present

Riley: Returns in 3 wks

- ✓Empirically tx'd for GC/CT with ceftriaxone IM x1/doxy x7 days
- ✓Bicillin L-A 2.4 MU x1
  - Sexual partners informed, treated
  - Denies any sexual activity since treatment

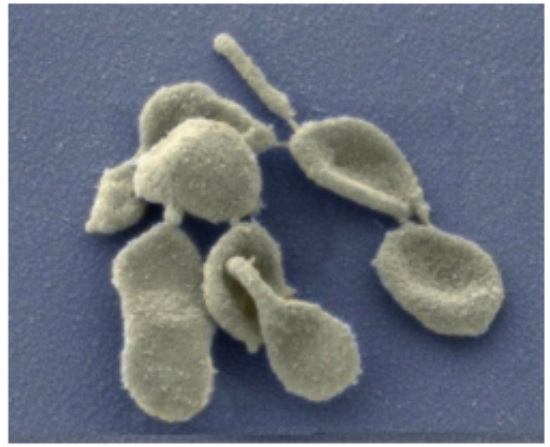
➢ **Continues w/some mild rectal discomfort/pain.** No d/c or bleeding

Now what??

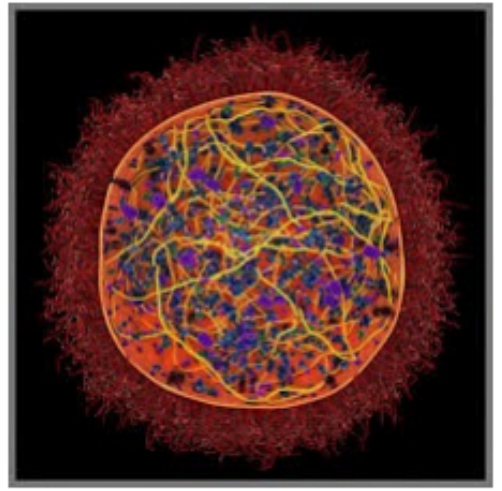
Gonococcal Infections Among Adolescents and Adults - STI Treatment Guidelines (cdc.gov)

Mycoplasma genitalium
The organism

- Mollicute
  - Lacks cell wall
- Second smallest known genome
  - 580 kb, translating to <500 genes
  - Subject of efforts to define minimal requirements for life[1] and to chemically synthesize bacteria[2]
- Very difficult to culture
  - Only achieved by ~3-4 laboratories worldwide
  - Takes ~6 months[3]
  - NAATs required for detection



Scanning electron micrograph



Computer generated 3D model

[1]Glass et al, PNAS 2006; [2]Gibson et al, Science 2008; [3]Jensen et al, J Clin Micro 1996

Mycoplasma genitalium ("Mgen") Webinars

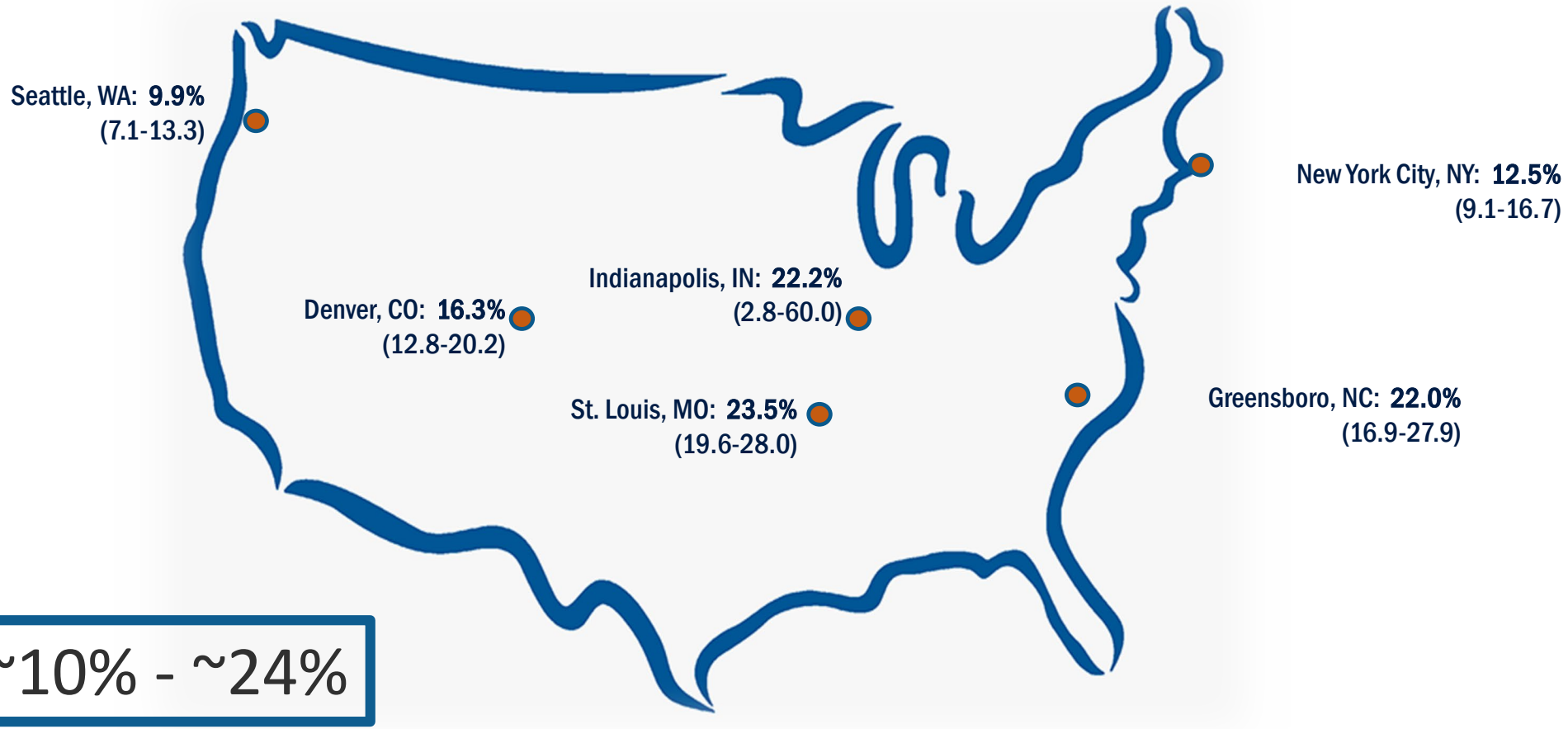
NCSD Learning Center

- "STI Awareness: Emergence of *Mycoplasma genitalium*"
- Dr. William Geisler, MD, MPH; Dr. Erik Munson, PhD., D(ABMM)

STI Expert Hour Webinar – CAPTC

- "Mycoplasma Genitalium - What's New?"
- Dr. Lindley Barbee, MD, MPH

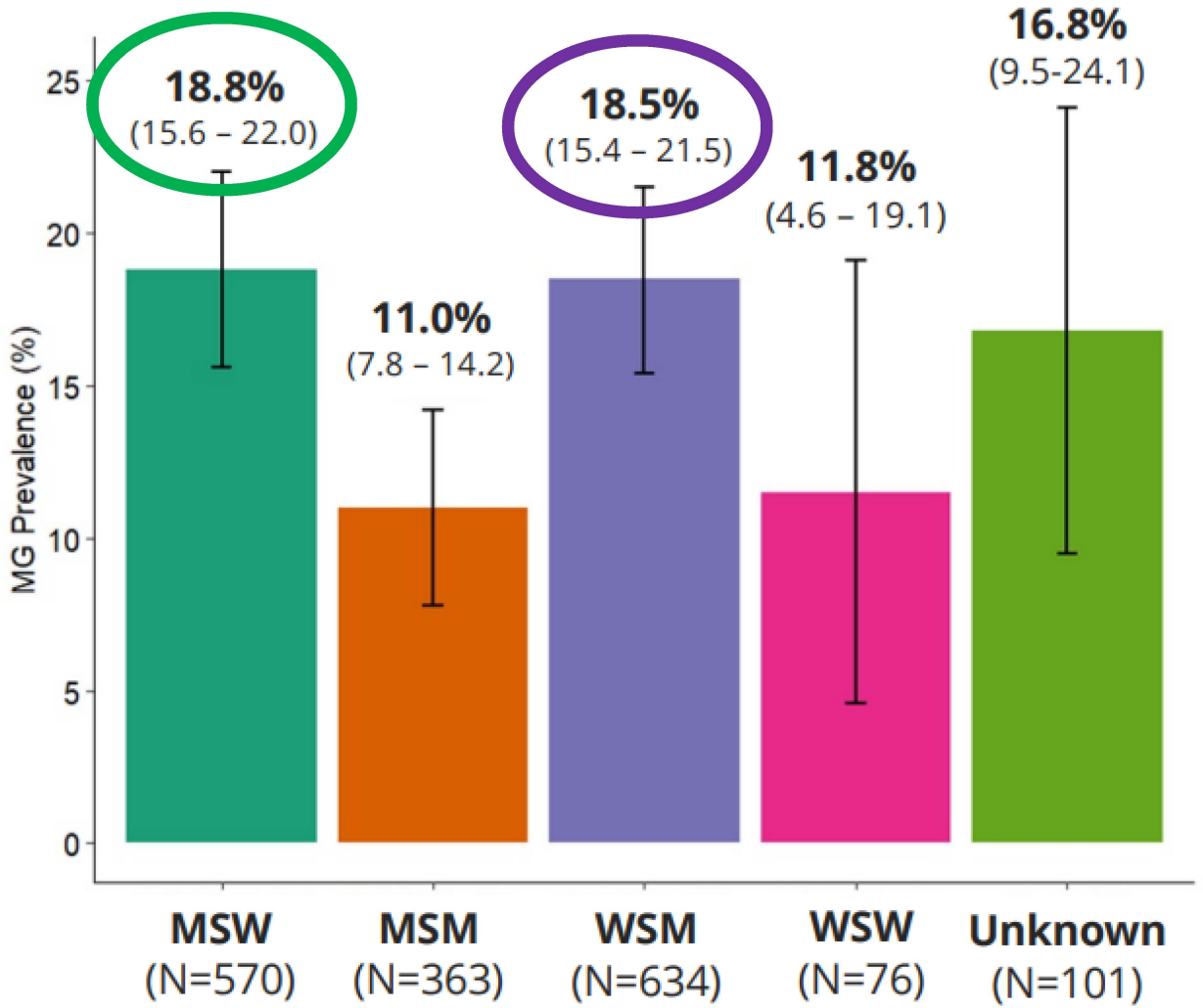
Mgen prevalence in STI clinics in U.S.



Range ~10% - ~24%

Manhart et al. 2023; Graphic from L. Barbee

MyGeniUS: Prevalence in sexual health clinic patients



Unknown=persons with unknown sex of sex partner (n=93), persons with unknown sex (n=1), MSW who also have sex with non-binary or transgender partners (n=6), and WSM who also have sex with non-binary or transgender partners (n=1)

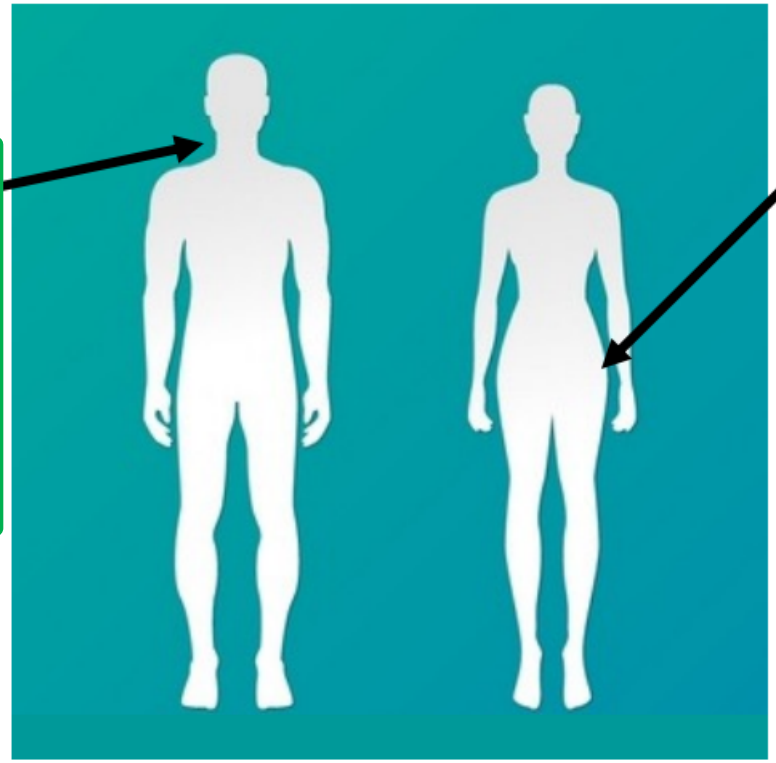
Manhart et al., STI & HIV World Congress 2021

Where do we find Mgen?

- Colonizes mucous membranes of human GU tract
- passed via Vaginal & **Anal sex**
- unclear **Oral** sex transmission

Oro-pharynx
- Rarely detected* (5/12 studies)
- Prevalence = **0.7 – 5.2%**

*no oropharyngeal infection detected in 6/12 studies



Rectum
- Frequently detected (19/20 studies)
- Prevalence = **1.6 – 17.4%**

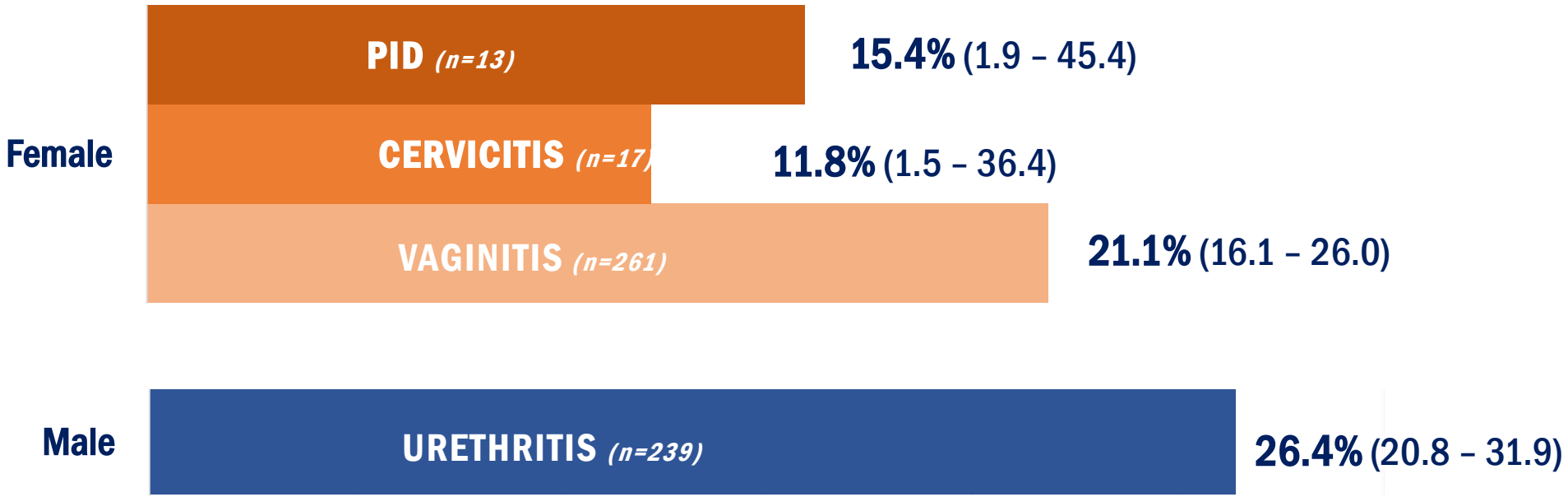
MSM - 1-26%
Women – 3%

Notes:

- Re-current infections possible thru antigenic variation
- Common co-infection with GC/CT/TV
- 3-fold incr risk of HIV among women & MSM

Barker et al. 2022; Manhart et al. 2008
CDC; Wood 2023; photo from Roche

Prevalence by illness type



** Among 700 persons with at least one recorded diagnosis*

Manhart et al. 2023; Graphic from L. Barbee

Who to test for Mgen?

Screening: *Asymptomatic* people NOT recommended

- Same for pregnant people, and extragenital testing

Rationale: Insufficient evidence of the consequences of asymptomatic infections nor that treatment prevents negative sequelae

Diagnostic testing: *Persistent* NGU/cervicitis/proctitis*

- NOT at initial presentation (consider in PID)

Rationale: Some cases clear w/doxy alone, which may slow dev. of moxifloxacin-resistant strains. *The pathogenic role of Mgen in proctitis is unclear

CDC

How is Mgen diagnosed?

Nucleic Acid Amplification Tests (NAATs)

FDA approved

- **Aptima®** MG (HOLOGIC)
- **Cobas®** TV/MG (ROCHE)
- **Alinity m®** CT/GC/TV/MG (Abbott)

Commercial labs - in-house;

- **NOT** FDA approved

Urogenital specimens:

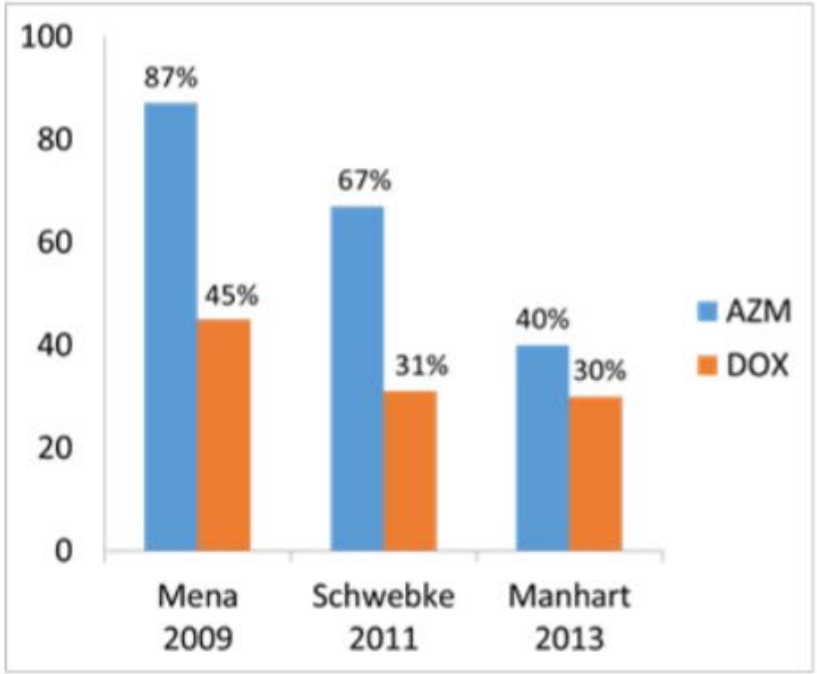
- females - vaginal swab
- males - 1st-catch urine

Hologic, Roche, SpeeDx

Efficacy of antibiotics for Mgen Urogenital infections

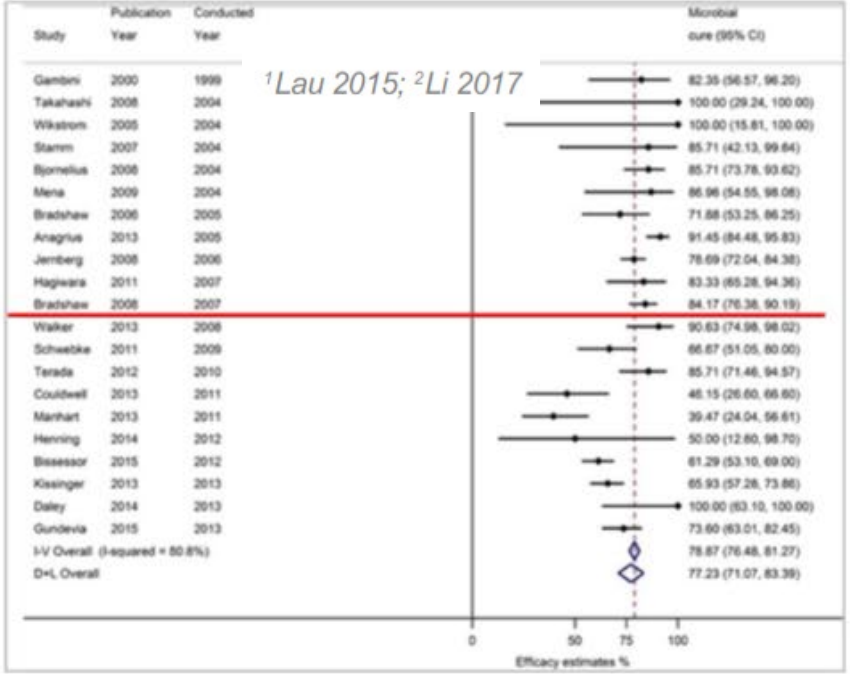
Doxycycline 100mg bid x 7d

30% to **45%** effective



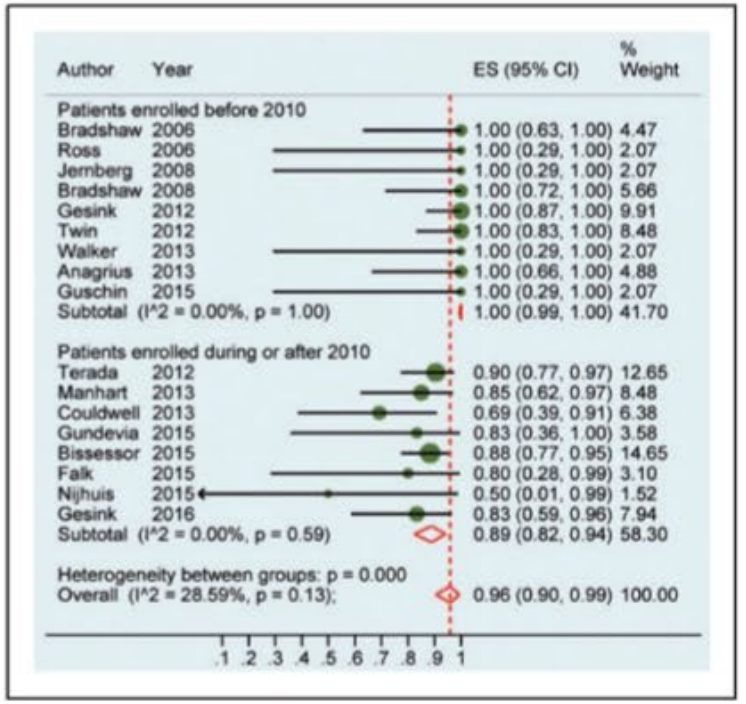
Azithromycin 1g

86% pre-2009 to **67%** post-2009[1]



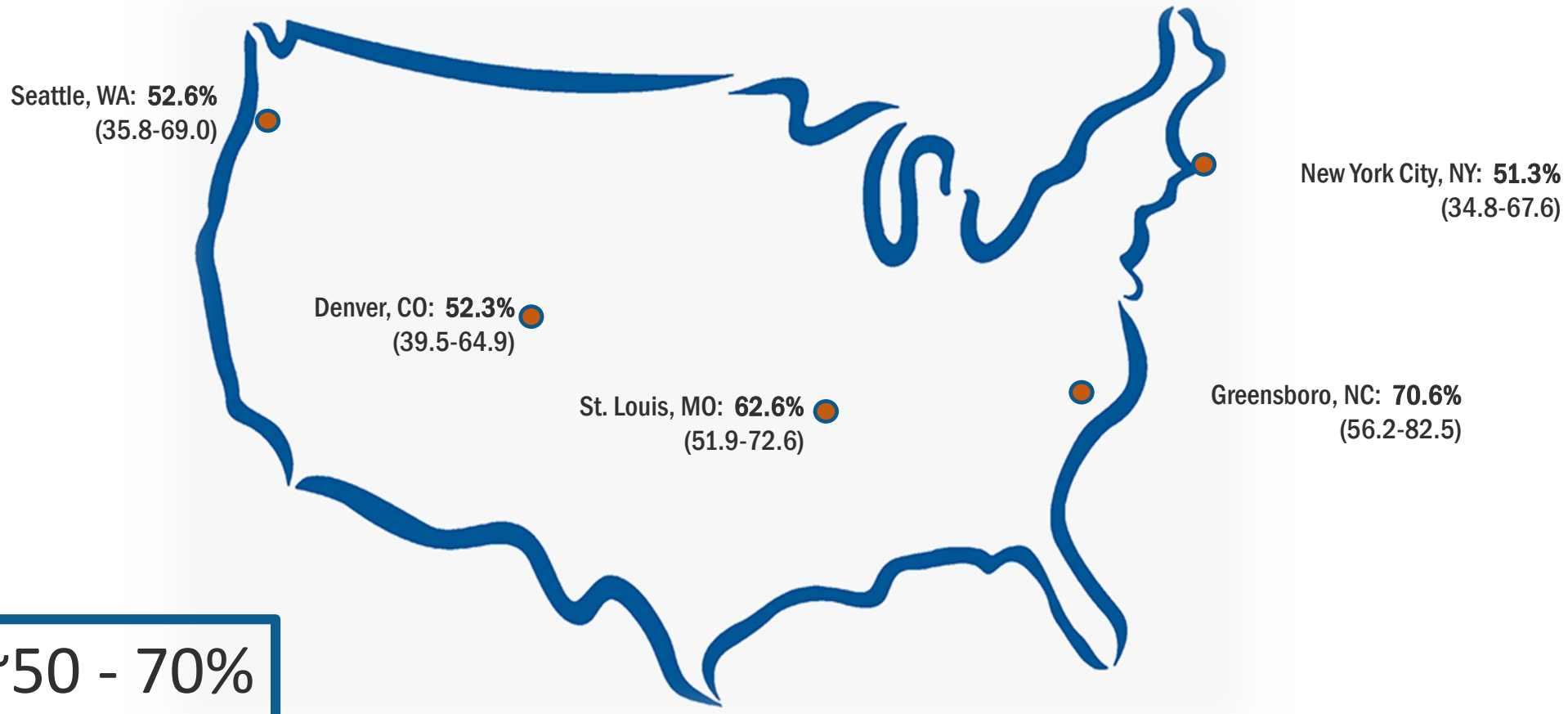
Moxifloxacin 400mg x 7-10d

100% pre-2010 to **89%** post-2010[2]



[1]Lau 2015; [2]Li 2017

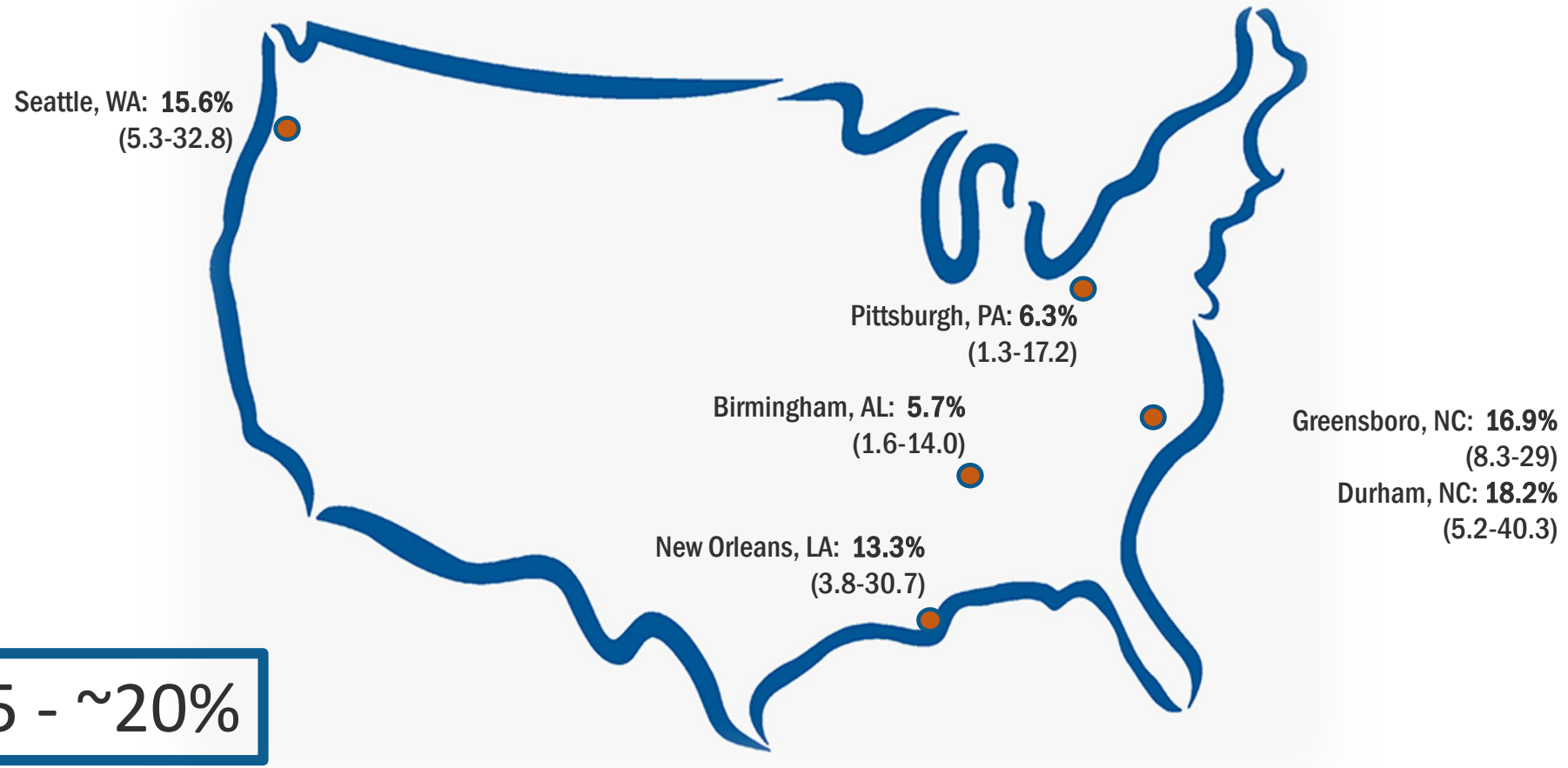
Macrolide (e.g., azithro) resistance in the U.S.



Range ~50 - 70%

Manhart et al. 2023

Fluoroquinolone (e.g., moxi) resistance in the U.S.



Range ~5 - ~20%

Bachmann et al. 2023

Resistance Testing - NOT FDA approved

1. ***Resistance*Plus® MG (SpeeDx)** – NAAT; incorporates macrolide resistance testing

2. **Labcorp** - Aptima NAAT (FDA approved) w/Hologic ASR for macrolide resistance testing (in-house lab developed test (LDT) validation)
   - 180092: Mycoplasma genitalium, NAA, Swab With Reflex to Macrolide Resistance Testing | Labcorp
   - 180084: Mycoplasma genitalium, NAA, Urine With Reflex to Macrolide Resistance Testing | Labcorp

3. **UAB – Univ Alabama**
   - Contact: Diagnostic Mycoplasma Lab
     - (205) 934-9142
   - Lab certified by:
     - College of American Pathologists (CAP)
     - Clinical Laboratory Improvement Amendment (CLIA)
     - State of Alabama
   - Questions?
     - Dr. Ken B. Waites, kwaites@uabmc.edu

How is M. genitalium treated?

Two-stage Therapy approach w/Resistance-Guided Therapy

Recommended Regimens if *M. genitalium* Resistance Testing is Available

If *macrolide sensitive:* Doxycycline 100 mg orally 2 times/day for 7 days, followed by **azithromycin** 1 g orally initial dose, followed by 500 mg orally once daily for 3 additional days (2.5 g total)

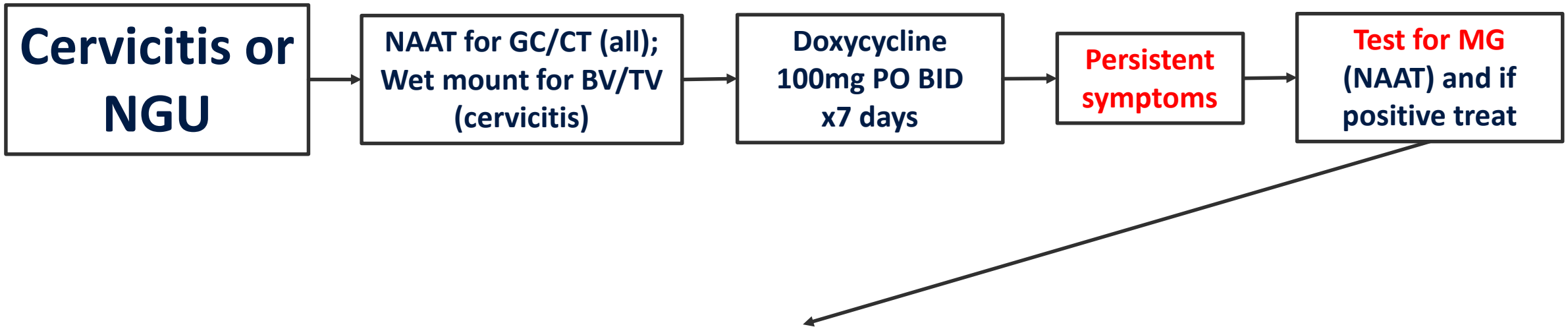
If macrolide resistant: Doxycycline 100 mg orally 2 times/day for 7 days followed by **moxifloxacin** 400 mg orally once daily for 7 days

Recommended Regimens if *M. genitalium* Resistance Testing is Not Available

If *M. genitalium* is detected by an FDA-cleared NAAT: Doxycycline 100 mg orally 2 times/day for 7 days, followed by **moxifloxacin** 400 mg orally once daily for 7 days

CDC

CDC guidelines for Mgen

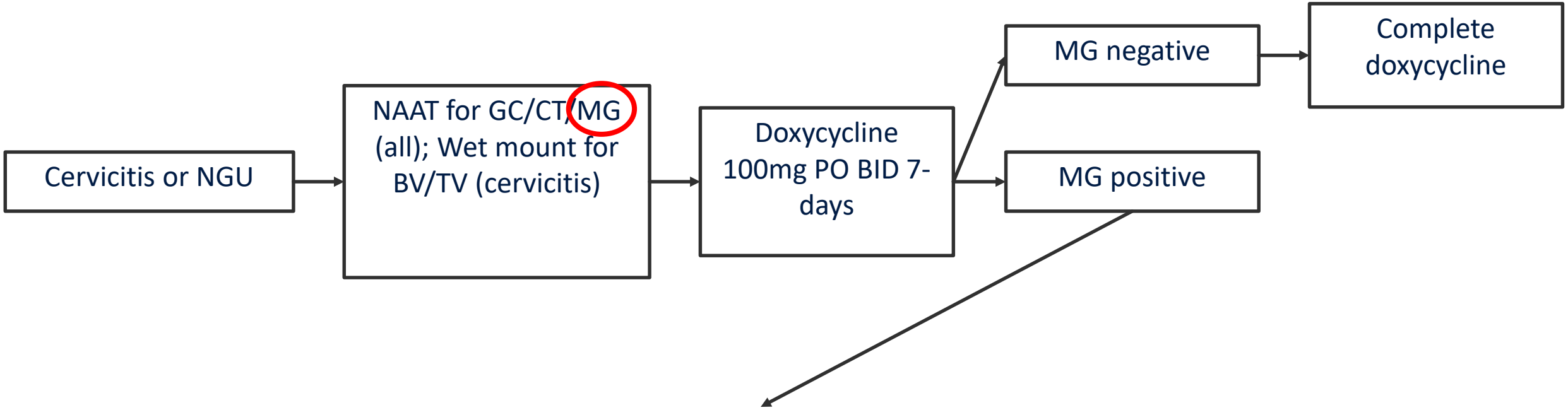


Recommended Regimens if *M. genitalium* Resistance Testing is Not Available

If *M. genitalium* is detected by an FDA-cleared NAAT: Doxycycline 100 mg orally 2 times/day for 7 days, followed by **moxifloxacin** 400 mg orally once daily for 7 days

CDC

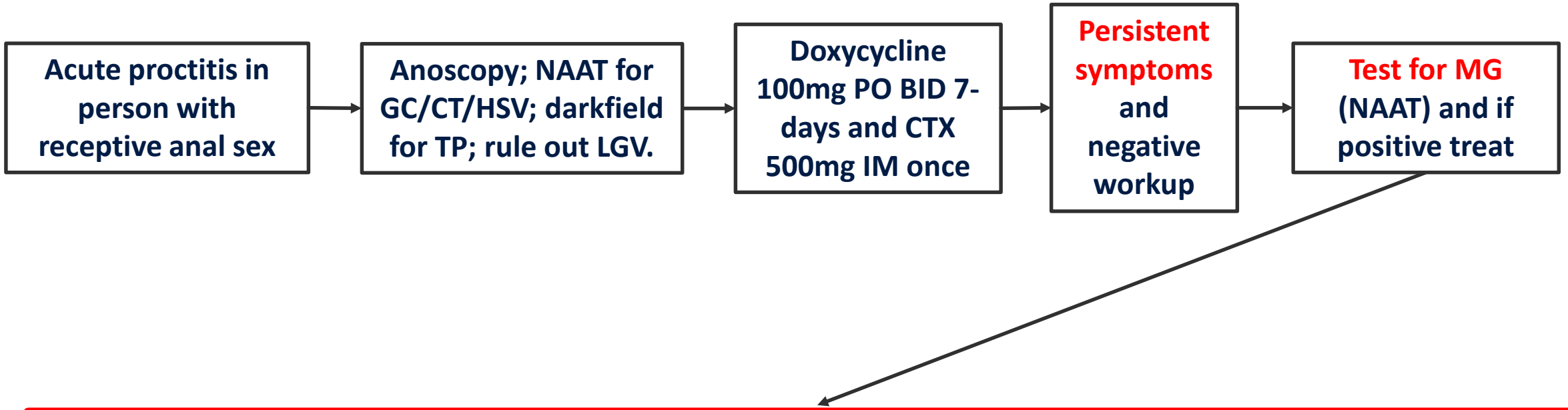
Can we test first?



Recommended Regimens if *M. genitalium* Resistance Testing is Not Available

If ***M. genitalium*** **is detected by an FDA-cleared NAAT: Doxycycline** 100 mg orally 2 times/day for 7 days, followed by **moxifloxacin** 400 mg orally once daily for 7 days

Mgen & proctitis?



Recommended Regimens if *M. genitalium* Resistance Testing is Not Available

If ***M. genitalium*** **is detected by an FDA-cleared NAAT: Doxycycline** 100 mg orally 2 times/day for 7 days, followed by **moxifloxacin** 400 mg orally once daily for 7 days

CDC

Alternative treatments?

Third-line - Salvage options:

- **Minocycline** 100mg PO BID x14d – 40-70% cure rate
- **Pristinamycin*** 1g PO QID for x10d – 75% cure rate; *Only available in Europe
- **Omadacycline** two 150mg tabs PO daily x ? days – no efficacy data
- **Tinidazole** 2g PO daily x ? days – no efficacy data
- **Lefamulin** two 150mg tabs PO daily x ? Days – not available

NCSD Learning Center; *Emergence of Mycoplasma genitalium;* Dr William Geisler, MD & Erik Munson, PhD; Apr 2024

Jensen et al. 2022

Testing & treatment in pregnancy

- First-line medications not safe in pregnancy:
  - **Doxycycline** – category D
  - **Moxifloxacin** – category C
- **Azithromycin** safe, but unable to target approp. tx when lacking resistance testing availability in US
- **Minocycline** – category D
- **Pristinamycin** – category B
  - active ag/st macrolide-resistant Mgen
  - not available in US (Europe & Australia)

Wood et al. 2023

Who else to test for Mgen?

Test of cure: ONLY when moxifloxacin cannot be used (e.g. pregnancy)
& pt *remains symptomatic* after tx

Rationale: Insufficient evidence asymptomatic colonization causes negative sequalae

Partner testing: Can be offered for *symptomatic* pts w/confirmed Mgen
No rec's for expedited partner treatment (EPT)

Rationale: High concordance of Mgen b/n partners. But no studies have determined whether reinfection is reduced w/partner tx.

Disease investigation: Mgen not a reportable infection
No rec's for contact tracing

Common questions: Gap in Abx & doxyPEP use

1. **Q:** ***How long of a "gap" can there be between doxycycline and moxifloxacin without having to restart the regimen*****?**

A: According to Expert Opinion, the recommendations are to RESTART doxy if it has been MORE THAN 7 days since the last dose.

2. **Q:** ***Will use of doxyPEP impact Mgen resistance*****?**

A: Studies at UAB have shown increased Tetracycline MICs but no doxycycline resistance. Therefore, one may expect initial tx w/doxy x7 days to lower the bacterial load may become ineffective – more likely to fail treatment regimen. But no large-scale data.

Bacterial STI Prevention

“I don’t like using condoms”

What is doxyPEP?

Doxycycline Post-Exposure Prophylaxis

Single, 200mg oral dose of **Doxycycline**, an antibiotic, taken within 72hrs after condomless sex (oral, anal, and/or insertive* vaginal sex) to reduce infections of gonorrhea (GC), chlamydia (CT), & syphilis

- Most efficacy data available in MSM & TGW
- no data in Transgender Men (TGM)
- *recent trial in Kenya for cis-gender women did NOT reduce incident STIs

CA-PTC STI Expert Hour Webinar: **doxy as PEP**, 4/28/2023

DoxyPEP AIDS 2022

Doxy-PEP: Day 1 of CROI 2023 | HIV.gov

Is doxy PEP effective?

3 major studies: Ipergay, DoxyPEP & Doxyvac:

- ✓ **Reduced new STIs by 65%**
- ✓ 71%-80% STIs were asymptomatic
- ✓ condomless sexual frequency didn't change
- ✓ Ceftriaxone use 50% LESS
- ✓ Meningitis vaccine, "MenB" (4CMenB, brand *Bexsero*): "halved" risk of GC

- ➢ LIMITATIONS…data only for **Men who have sex with men** (MSM) & **Transgender women** (TGW)
- ➢ no data in transgender men (TGM)

What about Cisgender Women (CGW)?

Kenya trial:

HIV Pre-Exposure Prophylaxis (PrEP) & dPEP

- 449 cis-females, age 18-30 on HIV PrEP
- Not pregnant* or breastfeeding

  (*doxycycline should NOT be used in pregnancy)

RESULTS:

→ **ineffective, ? adherence (by self report)**

→ **drug levels in endocervical tissue**

CDC Study – 20 participants
- measured doxycycline 200mg levels;

→ levels rise sooner vaginal (8hrs) vs rectal (48hrs)
→ levels sustained HIGHER rectal compared to vaginal

Doxycycline Use by Pregnant and Lactating Women | FDA

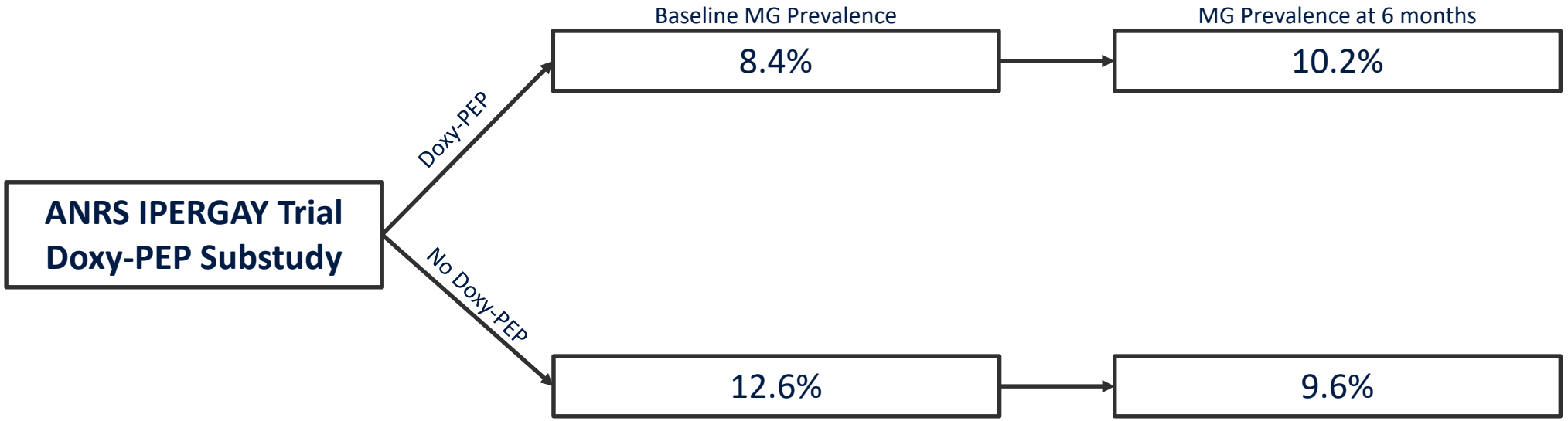
doxyPEP CDPH Recommendations

CDPH Doxy-PEP Recommendations for Prevention of STIs (ca.gov)

1. **Recommend doxy-PEP** to men who have sex with men (MSM) or transgender women (TGW) who have had ≥1 bacterial STI in the past 12 months.
2. **Offer doxy-PEP using shared decision-making** to all non-pregnant individuals at increased risk for bacterial STIs and to those requesting doxy-PEP, even if these individuals have not been previously diagnosed with an STI or have not disclosed their risk status.[i]
3. **Provide comprehensive preventative sexual health counseling and education** to all sexually-active individuals to include HIV/STI screening, doxy-PEP, HIV pre-exposure prophylaxis (PrEP)/HIV post-exposure prophylaxis (PEP), vaccinations (e.g. Hepatitis A/B, Human Papilloma Virus, Mpox, Meningococcal/MenACWY), expedited partner therapy, and/or contraception where warranted.

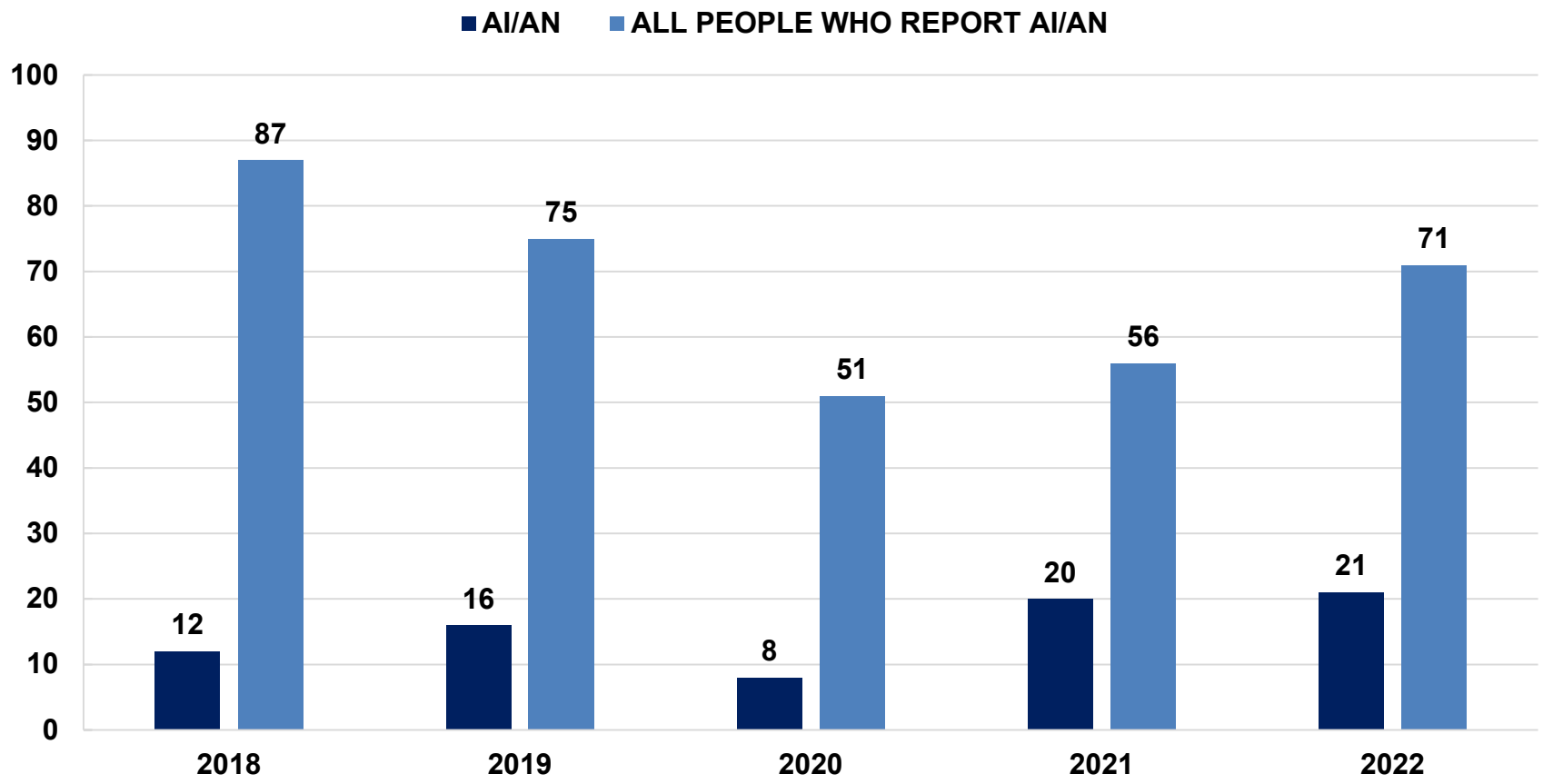
doxyPEP for Mgen prevention?

- Studies suggest doxy-PEP not effective for prevention of Mgen
- No difference in prevalence of macrolide & fluoroquinolone resistance in pre- and post-doxy groups



HIV and American Indian/Alaska Native, California 2018-2022: Data Overview

New HIV Diagnoses Among AI/AN and All People who report AI/AN, California 2018-2022

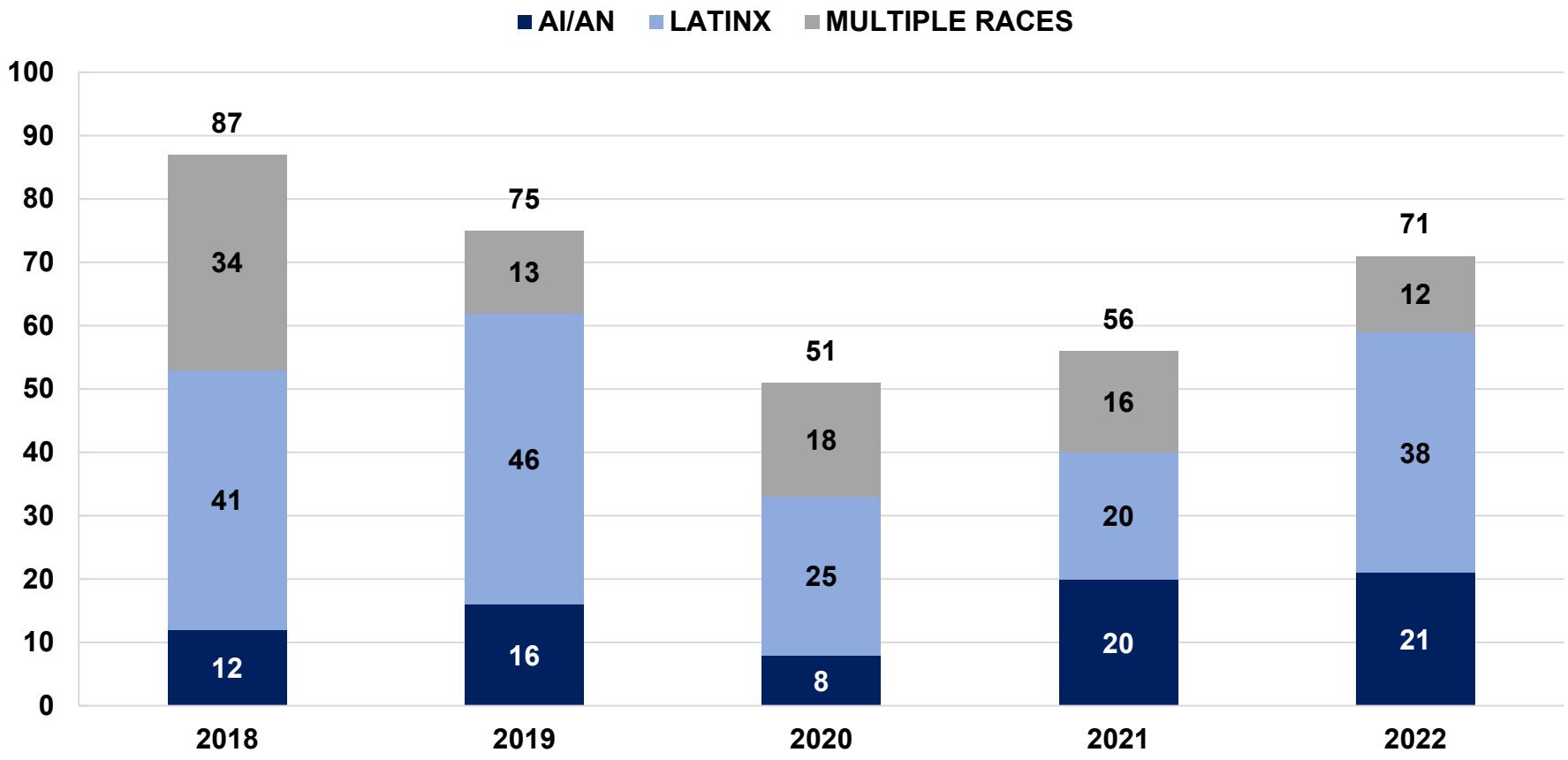


All people who report American Indian/Alaska Native (AI/AN) include those who are classified as Latinx or multiple race.

Source: HIV/AIDS Surveillance, eHARS data as of December 31, 2023

California Department of PublicHealth

Race/Ethnicity Classification of New HIV Diagnoses Among All People who report AI/AN, California 2018-2022



Source: HIV/AIDS Surveillance, eHARS data as of December 31, 2023

California Department of PublicHealth

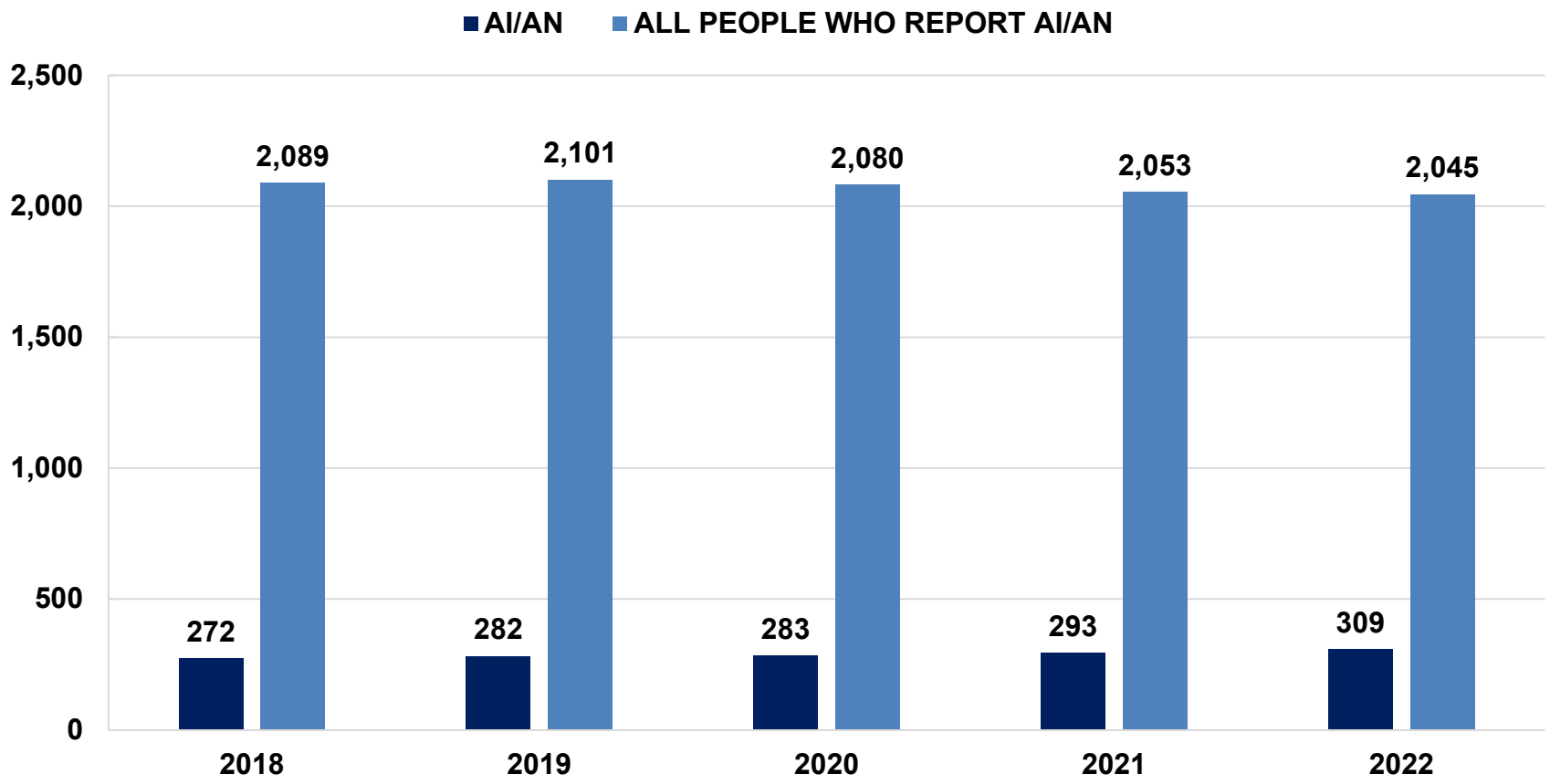
New HIV Diagnoses Among AI/AN and All People who report AI/AN by selected demographics, California 2022

Characteristic	AIAN #	AIAN % of Total	All People Who Report AIAN #	All People Who Report AIAN % of Total
Cisgender men	17	81%	54	76%
Cisgender women	4	19%	8	11%
Trans women	0	0%	9	13%
Trans men	0	0%	0	0%
Alternative gender identity	0	0%	0	0%
0 to 12	0	0%	0	0%
13 to 24	2	10%	14	20%
25 to 44	15	71%	46	65%
45 to 64	3	14%	10	14%
≥65	1	5%	1	1%
Transgender sexual contact (TGSC)	0	0%	9	13%
Male-to-male sexual contact (MMSC)	7	33%	34	48%
MMSCIDU	4	19%	7	10%
Injection drug use (IDU)	1	5%	4	6%
Heterosexual contact	4	19%	9	13%
Perinatal	0	0%	0	0%
Unknown risk/other risk	5	24%	8	11%
Bay Area	4	19%	11	15%
Central California	6	29%	9	13%
Greater Sierra Sacramento	2	10%	5	7%
Los Angeles	3	14%	30	42%
Rural North	3	14%	3	4%
Southern California	3	14%	13	18%
TOTAL	21		71	

Source: HIV/AIDS Surveillance, eHARS data as of December 31, 2023

California Department of PublicHealth

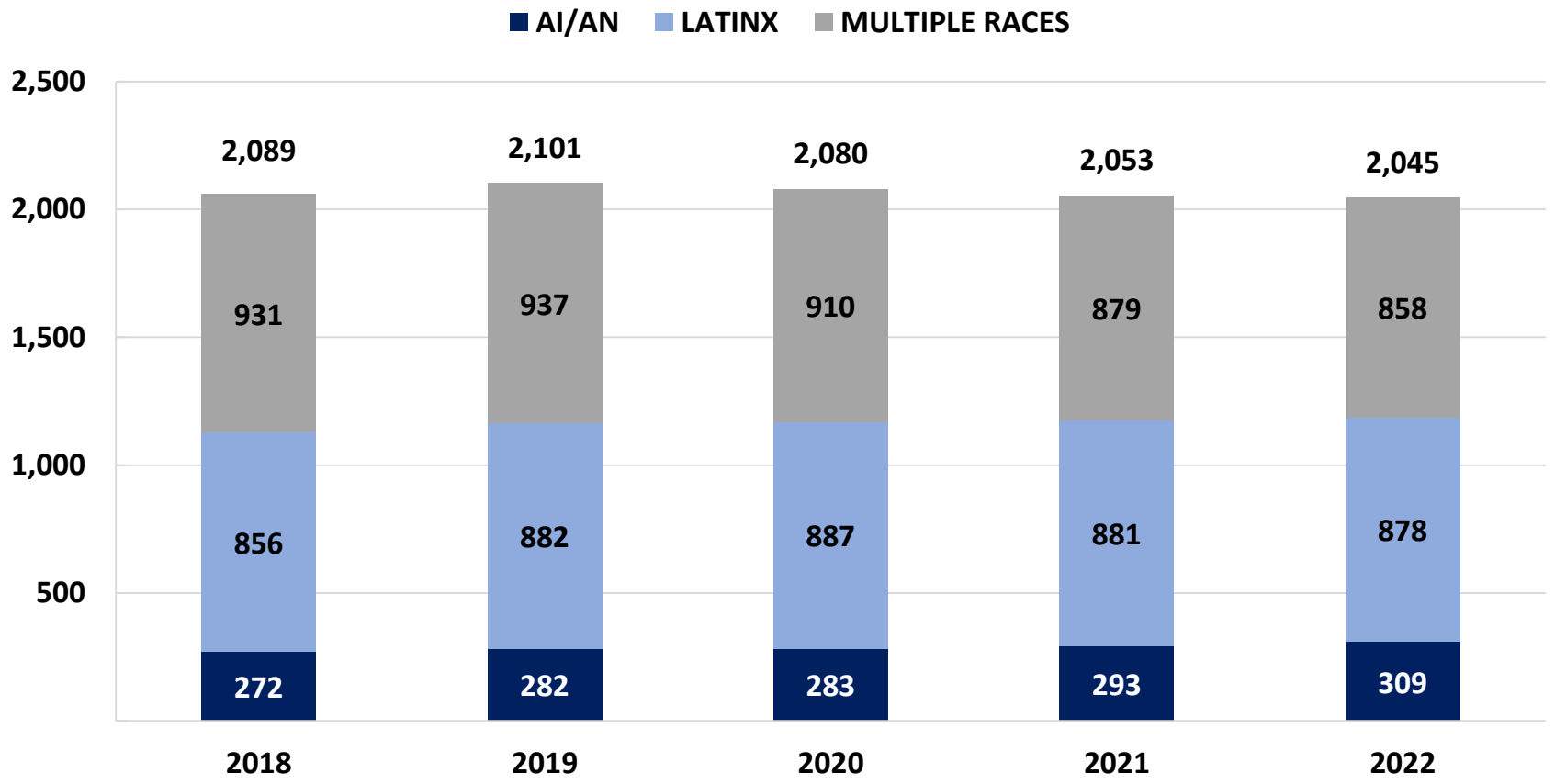
Persons Living with HIV Among AI/AN and All People who report AI/AN, California 2018-2022



Source: HIV/AIDS Surveillance, eHARS data as of December 31, 2023

California Department of PublicHealth

Race/Ethnicity Classification of People Living with HIV Among All People who report AI/AN, California 2018-2022



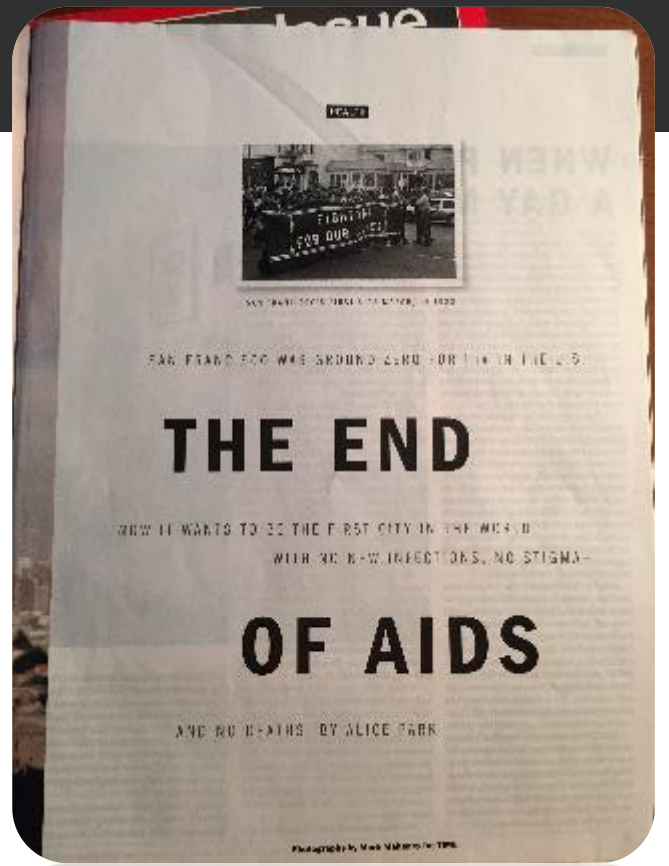
Source: HIV/AIDS Surveillance, eHARS data as of December 31, 2023

California Department of PublicHealth

HIV prevention strategies

- Structural/Behavior Interventions
  - Circumcision, Condoms, STI dx & tx, IDU safety
- HIV **T**reatment **as** **P**revention (TasP); U=U
- **HIV PrEP - Pre-Exposure Prophylaxis**
- PEP/nPEP – **P**ost-**E**xposure **P**rophylaxis/

  ***n**on-occupational* **P**ost-**E**xposure **P**rophylaxis



What is HIV PrEP?

Pre-Exposure Prophylaxis

- for HIV(-) individuals
- a biochemical therapy to *prevent* HIV acquisition
- part of comprehensive HIV prevention plan

USPSTF Aug 2023: "recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV"

Available options:

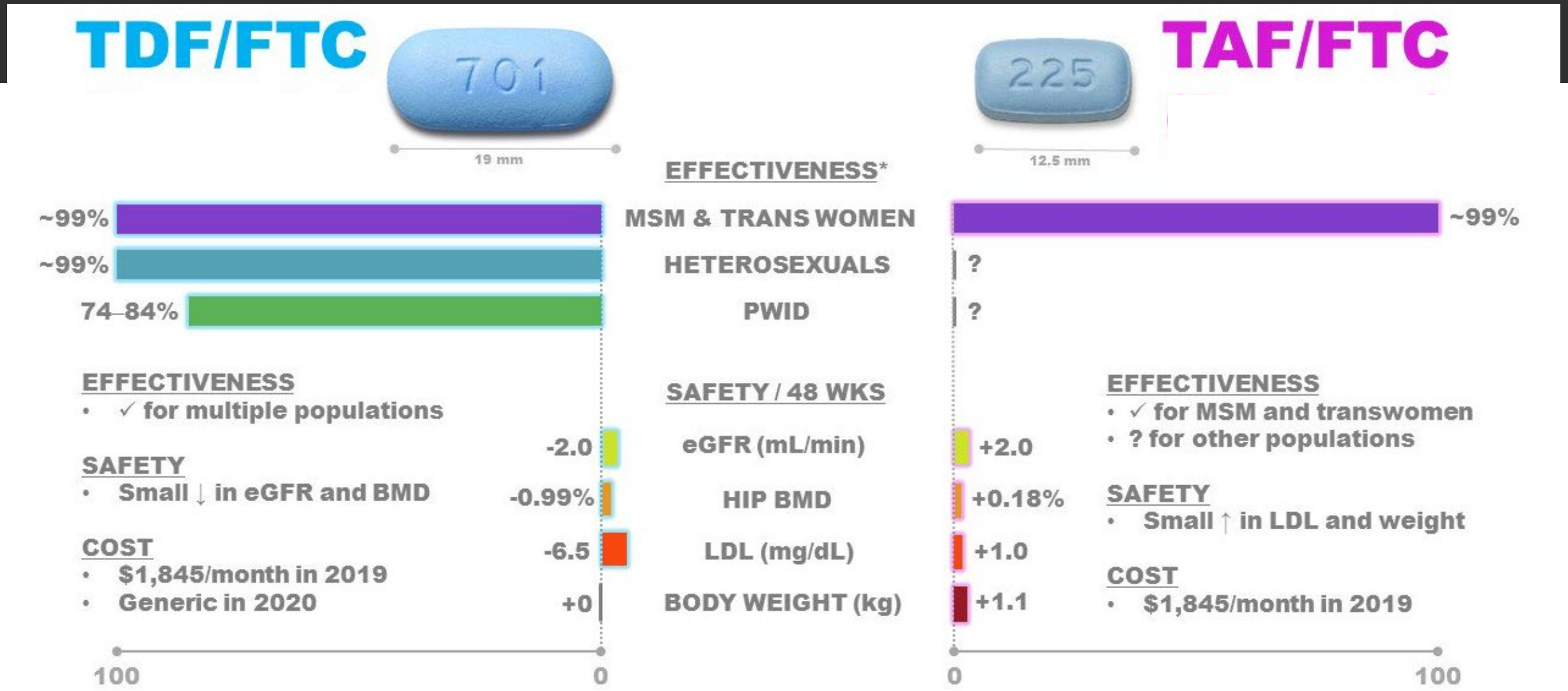
PO Emtricitabine (FTC) 200mg + Tenofovir *disoproxil fumarate (TDF) 300mg** (fixed dose **Truvada®**)

PO Emtricitabine (FTC) 200mg + Tenofovir *alafenamide (TAF) 25mg* (fixed dose **Descovy®**)

IM Cabotegravir (CAB-LA) 200mg/mL (**Apretude®**)

* Note: "In certain countries, TDF is labelled as **245 mg** rather than **300 mg** to reflect the amount of the prodrug (tenofovir disoproxil) rather than the fumarate salt (tenofovir disoproxil fumarate)" https://www.eacsociety.org/files/2019_guidelines-10.0_final.pdf

Oral HIV PrEP



2020 RWHAP Clinical Conference

*No data available for trans men. Sources: fda.gov/media/129607/download; fda.gov/media/129609/download; cdc.gov/hiv/risk/estimates/preventionstrategies.html Created by: @JuliaLMarcus

How long does oral HIV PrEP take to work?

- **7 days** daily PrEP → receptive anal sex (bottom)
- **21 days** daily PrEP → receptive vaginal sex and IDU*

- **No data** → insertive anal sex (top) or insertive vaginal sex

- **Unknown** → PrEP shots to reach maximum protection during sex

*not indicated for **FTC/TAF**

PrEP Effectiveness | PrEP | HIV Basics | HIV/AIDS | CDC

"On-Demand" PrEP (FTC/TDF only)

Aka: **2-1-1/**weekend/Event-Driven/Intermittent

"I don't want to take something every day"

IPERGAY (Feb 2012-Oct 2014)

*"**2-1-1**"* **FTC/TDF** for **MSM ONLY**

- **2** pills *before* encounter (2-24hrs)
- then **1** pill at 24 hrs
- then **1** pill at 48 hrs *after* 1st dose

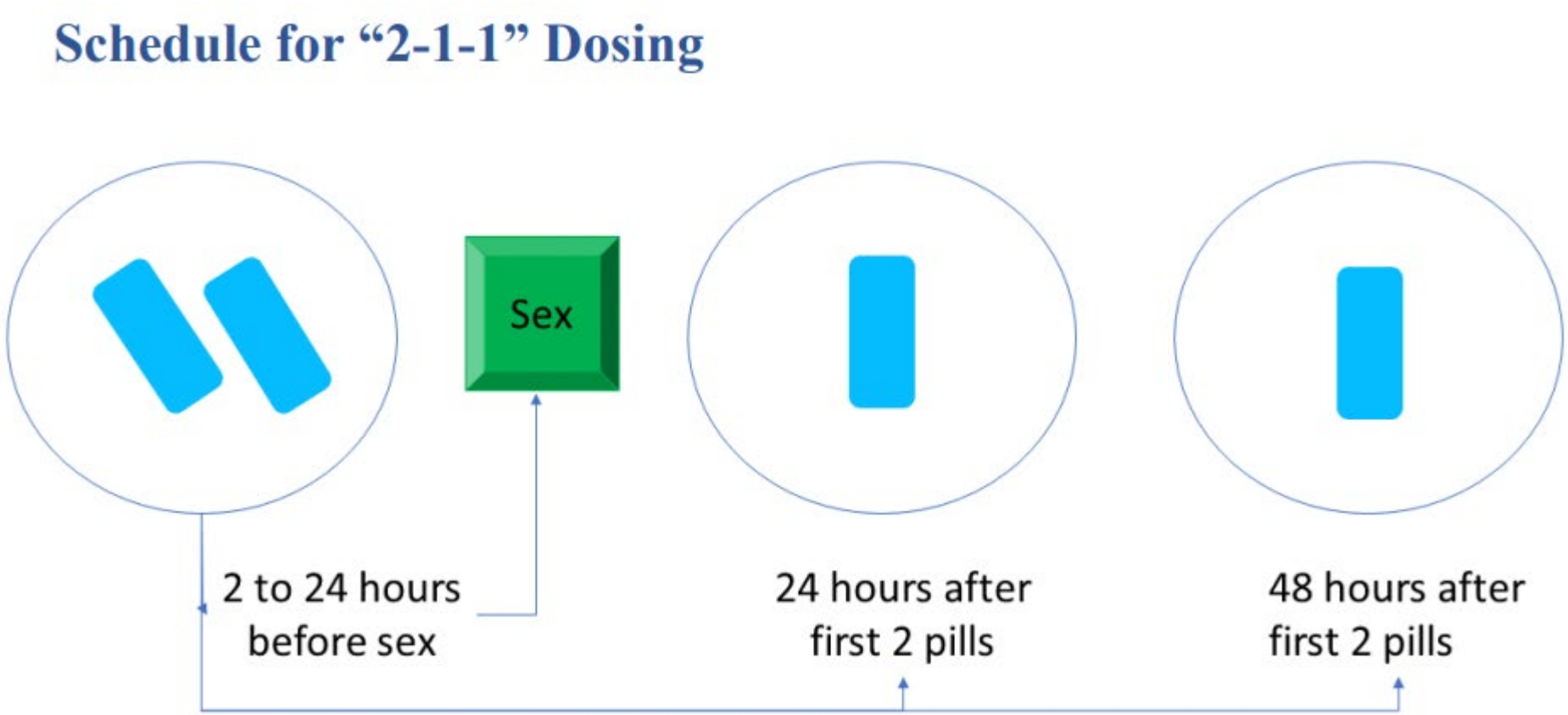
- avg ~4 pills/wk
- 1 seroconversion (no detectable drug levels)

→ **NOT** FDA approved; **NOT** CDC recommended

→ **"off-label" use**: some US Health Depts, Europe & Canada orgs, IAS-USA

CDC PrEP – 2021 UPDATE

“2-1-1” with FTC/TDF (MSM only)



CDC PrEP – 2021 UPDATE

Injectable HIV PrEP
Cabotegravir (CAB-LA)/Apretude®

"I forget my pills"

HPTN 083/084

- FDA: Adults & Adolescents weighing ≥35kg
- 1 HIV Integrase Inhibitor ***-vs-*** 2-non-nucleoside reverse transcriptase inhibitors
- IM ***-vs-*** PO
- Long half life (q1-2mo);
- Caveat: CAB-LA detectible >12mo after last injection
  - ✓ must cover w/PO PrEP if stop CAB-LA
- Screen HIV-RNA

CDC PrEP – 2021 UPDATE, A CLINICAL PRACTICE GUIDELINE; pg 16, Table 1b

Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o Initial dose o Second dose 4 weeks after first dose (month 1 follow-up visit) o Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)

HIV PrEP-associated **Labs** & **Follow Up**

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

*Assess for acute HIV infection

Oral & Injectable PrEP are not the same

- ✓ Adherence; ensure HIV negative
- ✓ screen STIs routinely
- ✓ monitor labs; kidneys, liver, lipids, weight
- ✓ Prophylactic vaccines

CDC PrEP – 2021 UPDATE, A CLINICAL PRACTICE GUIDELINE

HIV PEP/nPEP

To prevent HIV acquisition ***following exposure***

"I messed up."

- ✓ Begin w/in **72 hrs**
- ✓ **Rx x28 days**: 3-drug regimen
- ✓ **Baseline labs**: HIV, Hep B & C, GC/CT & syphilis
- ✓ **f/u labs**: 4-6 wks, 3- & 6-months (transition to PrEP!)
- ✓ Obtain Hx of sex partner (if known): ARV use, resistance, recent VL

PEPline 888.448.4911 9am – 2am EST, 7 days/wk

<<National Clinicians' Post-Exposure Prophylaxis **Hotline**>>

Updated Guidelines for nPEP —United States, 2016 (cdc.gov)

HIV PrEP Resources

CDPH Quick Clinical Guide: HIV PrEP

CDC:

- PrEP – 2021 Update - A Clinical Practice Guideline.
  https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- Let's Stop HIV Together Clinician Resources.
  https://www.cdc.gov/stophivtogether/clinician-resources/index.html
- PrEP Care System.
  https://www.cdc.gov/hiv/effective-interventions/prevent/prep/index.html
- Resources for Consumers.
  https://www.cdc.gov/hiv/risk/prep/index.html

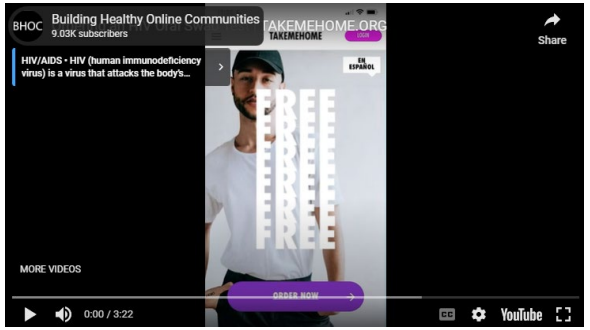
AETC National Clinician Consultation Center.

- PrEP Service (PrEPline): 855-HIV-PrEP (855-448-7737)

HIV Home Testing Kits (California)

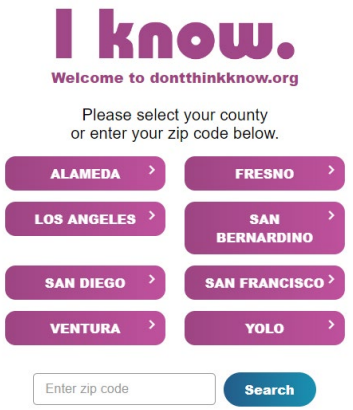
[Building Healthy Online Communities: Take Me Home program](#) (BHOC-TMH).

- **FREE** HIV oral self-testing with *OraQuick*
  - ✓ **All counties** in California (ages 17+); https://takemehome.org/ (English & Spanish)



Ordering an HIV Test, Patient Instruction video (3:22)
https://youtu.be/pBKl2B3SBDc

Don't Think, Know.org → HIV testing in select CA counties →



~

Thank You!

Questions?

~

Kurtis B. Mohr, MD, AAHIVS – CDPH STD Control Branch