

# Sexually Transmitted Infections in Adolescents & Pre-Exposure Prophylaxis (PrEP)

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**JOHNS HOPKINS**  
M E D I C I N E

# Objectives

- Review the Centers for Disease and Control and Prevention recommendations for screening, prevention and treatment of sexually transmitted infections (STIs) in adolescents
- Identify adolescent populations at risk for HIV and the recommendations around pre-exposure prophylaxis (PrEP)
- Discuss barriers needed to address youth seeking PrEP in school based health settings

# The STATE of STDs in the United States



in 2017

THE NATION EXPERIENCES  
STEEP AND SUSTAINED STD  
INCREASES.



**1.7 million**  
CASES OF CHLAMYDIA  
22% increase since 2013



**555,608**  
CASES OF GONORRHEA  
67% increase since 2013



**30,644**  
CASES OF SYPHILIS  
76% increase since 2013

LEARN MORE AT: [www.cdc.gov/std/](http://www.cdc.gov/std/)

Anyone who has sex is  
at risk, but some groups  
are more affected



- YOUNG PEOPLE AGED 15-24
- GAY & BISEXUAL MEN
- PREGNANT WOMEN

# SEXUALLY TRANSMITTED INFECTIONS AMONG YOUNG AMERICANS

## Youth bear disproportionate share of STIs

Americans ages 15-24 make up just **27%** of the sexually active population



But account for **50%** of the **20M** new STIs in the U.S. each year



Consequences are particularly severe for young women



Ages 15-24

Ages 25+

## Young people account for a substantial proportion of new STIs



Many do not know they're infected because STIs often have no symptoms

Data are cases among youth ages 15-24



## Unique factors place youth at risk



**Insufficient Screening**  
Many young women don't receive the chlamydia screening CDC recommends



**Confidentiality Concerns**  
Many are reluctant to disclose risk behaviors to doctors



**Biology**  
Young women's bodies are biologically more susceptible to STIs



**Lack of Access to Healthcare**  
Youth often lack insurance or transportation needed to access prevention services



**Multiple Sex Partners**  
Many young people have multiple partners, which increases STI risk

# Case: Erica

- Erica is a 16-year-old sexually active female who presents with vaginal discharge.
- How do you approach Erica?



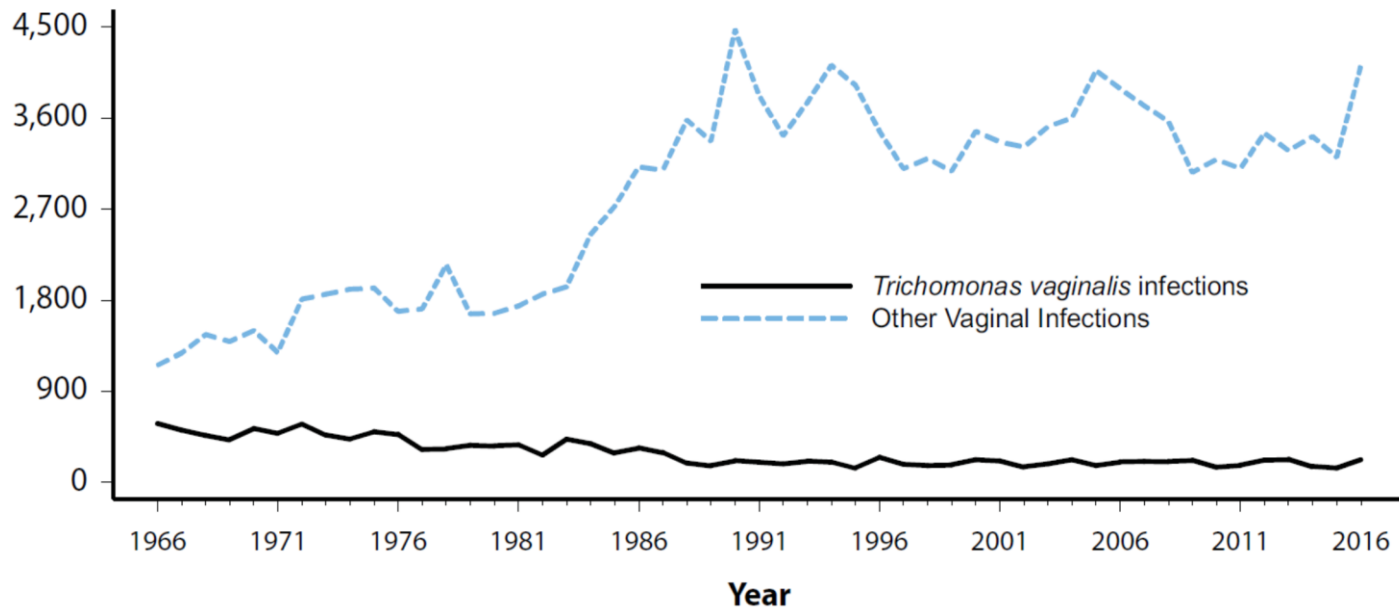
# Case: Erica

- Do you need to perform a pelvic exam?
  - Erica is symptomatic and sexually active.
  - A pelvic exam in this case is a diagnostic exam not an asymptomatic screening.
  - If Erica had been asymptomatic, would you perform a speculum exam?



# Trichomonas vaginalis and Other Vaginal Infections Among Females — Initial Visits to Physicians' Offices, United States, 1966–2016

Visits (in thousands)



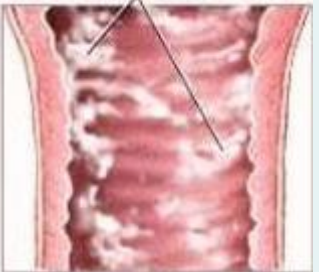

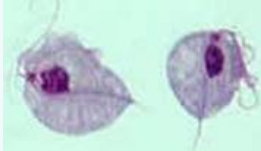


**NOTE:** The relative standard errors for *Trichomonas vaginalis* infection estimates range from 23% to 17% and for other vaginal infection estimates range from 13% to 8%. See Section A2.5 in the Appendix and Table 44.

**SOURCE:** National Disease and Therapeutic Index, IMS Health, Integrated Promotional Services™, IMS Health Report, 1966–2016. The 2017 data were not obtained in time to include them in this report.


# Vaginitis Differential Diagnosis



Diagnosis	Bacterial Vaginosis ( <i>Gardnerella vaginalis</i> )	Trichomoniasis ( <i>Trichomonas vaginalis</i> )	Candida vaginitis ( <i>Candida albicans</i> )
Examination	 <ul style="list-style-type: none"> <li>- Thin, off-white discharge with fishy odor</li> <li>- No vaginal inflammation</li> </ul>	 <ul style="list-style-type: none"> <li>- Thin, yellow-green, malodorous, frothy discharge</li> <li>- Vaginal inflammation</li> </ul>	 <ul style="list-style-type: none"> <li>- Thick, “cottage cheese” discharge</li> <li>- Vaginal inflammation</li> </ul>
Microbiology	<p>Overgrowth of bacteria species normally present in vagina with anaerobic bacteria</p> 	<p><i>T vaginalis</i> is single-celled, flagellated, anaerobic protozoan parasite. Only protozoan that infects genital tract.</p> 	<p>Candida species are normal flora of the skin and vagina.</p> <p>VVC is caused by overgrowth of <i>C. albicans</i> and other non-albicans species.</p>
Sequelae	<ul style="list-style-type: none"> <li>- Pregnancy complications; Pelvic Inflammatory Disease (PID)</li> <li>- Susceptibility to other STDs (HIV, HSV, CT/GC)</li> </ul>	<ul style="list-style-type: none"> <li>-Pregnancy Complications (pre-term delivery, low birth weight)</li> <li>-Increased HIV risk</li> <li>*Women: Vaginitis</li> <li>*Men: Urethritis</li> </ul>	<ul style="list-style-type: none"> <li>-Pregnancy Complications (pre-term delivery, low birth weight)</li> <li>-Increased HIV risk</li> </ul>



# Vaginitis Treatment

Diagnosis	Bacterial Vaginosis (Gardnerella vaginalis)	Trichomoniasis (Trichomonas vaginalis)	Candida vaginitis (Candida albicans)																
Diagnosis	<ul style="list-style-type: none"> <li>- <u>Amsel's criteria:</u></li> <li>- Positive Whiff</li> <li>- pH&gt;4.5</li> <li>- Thin, white discharge</li> <li>- Clue cells (&gt;20% of the cells)</li> </ul>	<p><b>Newer Trichomonas Diagnostics</b></p> <table border="1"> <thead> <tr> <th>Test</th> <th>Sensitivity</th> <th>Specificity</th> <th></th> </tr> </thead> <tbody> <tr> <td>OSOM</td> <td>&gt;83%</td> <td>&gt;97%</td> <td>10 min POC</td> </tr> <tr> <td>Affirm VPIII</td> <td>&gt;83%</td> <td>&gt;97%</td> <td>45 min POC</td> </tr> <tr> <td>Aptima* (NAAT)</td> <td>74-98%</td> <td>87-98%</td> <td><b>FDA approved April 2011 (women)</b></td> </tr> </tbody> </table> <p> Roche Amplicor FDA cleared PCR testing for GC/CT has been modified for T.Vag detection, ok for male urine.</p> <p><i>CDC 2010 STD Treatment Guidelines</i></p> <p><small>*APTIMA Trichomonas vaginalis Assay (package insert).</small></p>	Test	Sensitivity	Specificity		OSOM	>83%	>97%	10 min POC	Affirm VPIII	>83%	>97%	45 min POC	Aptima* (NAAT)	74-98%	87-98%	<b>FDA approved April 2011 (women)</b>	<ul style="list-style-type: none"> <li>- Clinically by the presence of external dysuria and vulvar pruritus, pain, swelling, and redness.</li> <li>- Wet Prep (10% KOH)</li> <li>- Culture</li> </ul>
Test	Sensitivity	Specificity																	
OSOM	>83%	>97%	10 min POC																
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Aptima* (NAAT)	74-98%	87-98%	<b>FDA approved April 2011 (women)</b>																
Treatment	<ul style="list-style-type: none"> <li>- Metronidazole 500 mg PO BID x 7 days</li> <li>- Metronidazole gel 0.75% OD x 5</li> <li>- Clindamycin cream or 7 days</li> </ul>	<ul style="list-style-type: none"> <li>- 2 grams Metronidazole</li> <li>- 2 grams Tinidazole</li> <li>- Alternative: Metronidazole 500 mg PO BID x 7 days</li> </ul>	<ul style="list-style-type: none"> <li>- Diflucan 150 mg PO X 1</li> <li>- Topically applied azole drugs are more effective than nystatin.</li> </ul>																
Treatment Failure/ Alternative	<ul style="list-style-type: none"> <li>- Tinidazole 2 gm PO X 2 days</li> <li>- Tinidazole 1 gm PO X 5 days</li> <li>- Clindamycin 300 mg PO BID X 7 days</li> <li>- Clindamycin ovules 100 mg OD, QHS X 3 days</li> </ul>	<ul style="list-style-type: none"> <li>- Re-treat with metronidazole 500 mg PO BID x 7 days</li> <li>- If repeat failure, treat w/ tinidazole or metronidazole 2 gm PO x 5 days</li> </ul>	<ul style="list-style-type: none"> <li>- Culture*</li> <li>- 7–14 days of topical therapy or a 100-mg, 150-mg, or 200-mg oral dose of fluconazole every third day for a total of 3 doses [day 1, 4, and 7]</li> <li>- Weekly for 6 months</li> </ul>																

# Screening Recommendations

AAP	NOT routinely recommended for asymptomatic Consider screening ♀ if individual or population-based risk factors
ACOG	NOT routinely recommended Consider screening ♀ based on local prevalence
CDC*	NOT routinely recommended: HIV+ ♀ Consider Trichomonas screening persons receiving care in high-prevalence settings, i.e., STD clinics, correctional facilities or if high risk (e.g., multiple sex partners, or h/o STD)

# Management of Sex Partners

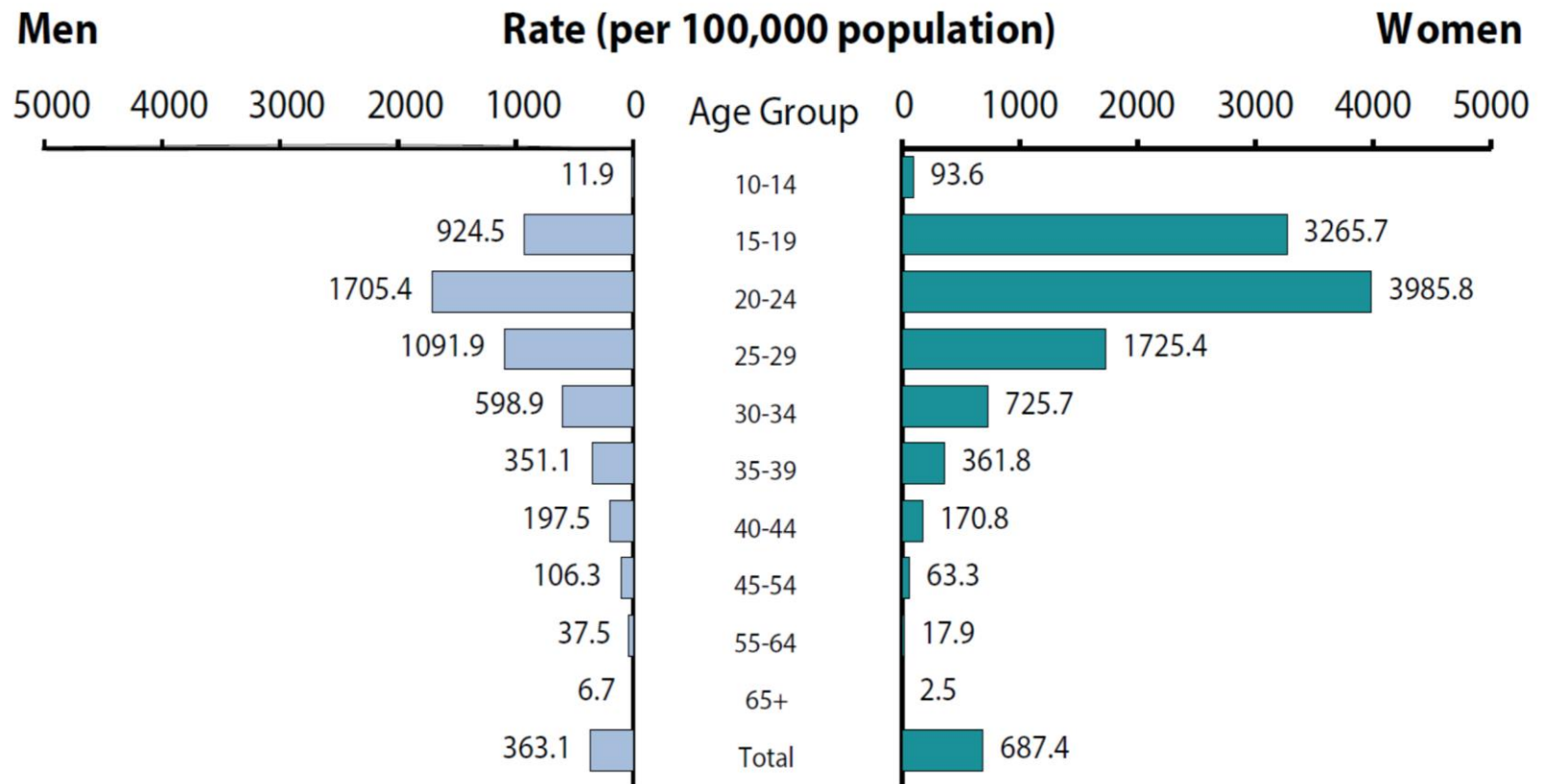
- Treatment of partners with BV is not routinely recommended
  - Female's response to therapy and likelihood of relapse or recurrence are not affected by treatment of her sex partner(s)
- Sex partners of patients with *T. vaginalis* should be treated
- Treatment of sex partners who have Candida is not recommended (unless recurrent or symptomatic)

# Additional Concerns

- Because she is a sexually active 16-year-old, she is also at risk for cervicitis.
- What are the most common identifiable causes of cervicitis?
  - Chlamydia
  - Gonorrhea

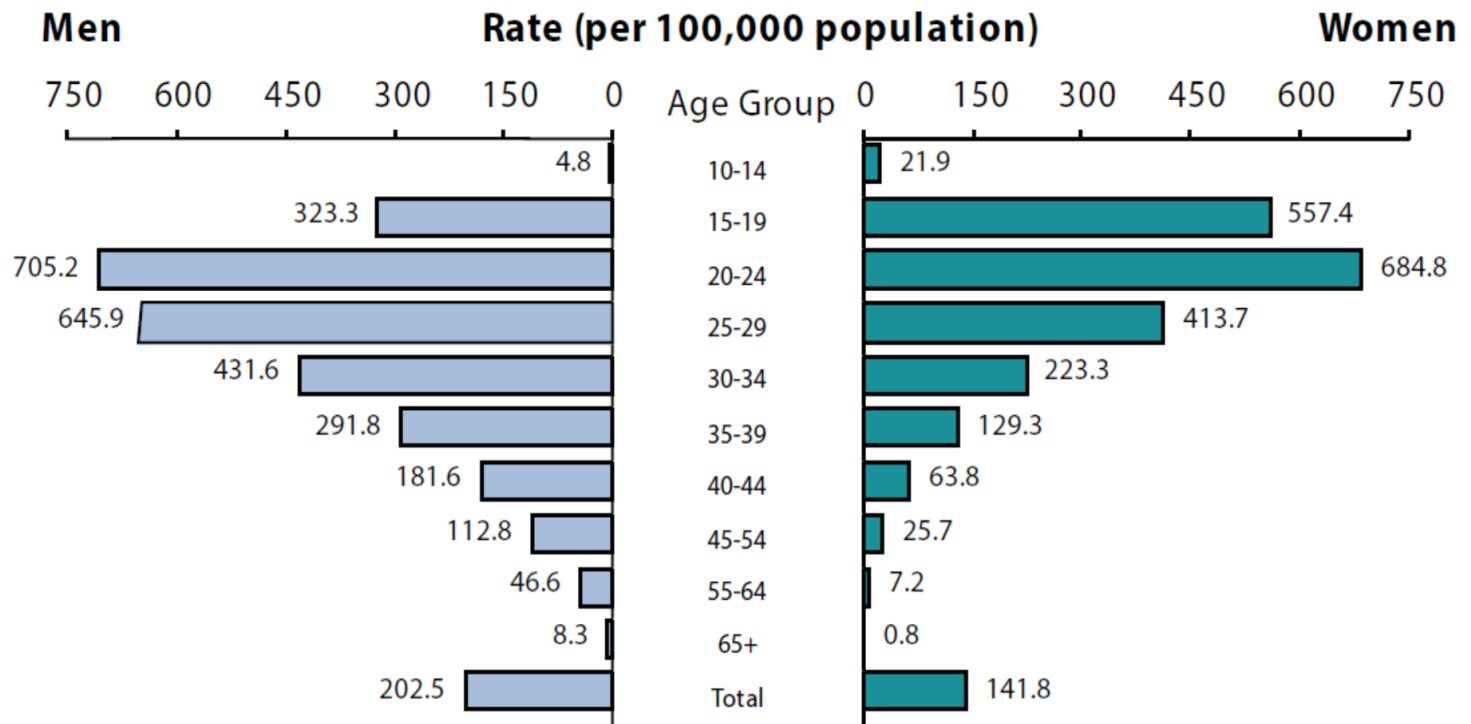


# Chlamydia — Rates of Reported Cases by Age Group and Sex, U.S., 2017



Source: <https://www.cdc.gov/std/stats17/adolescents.htm>

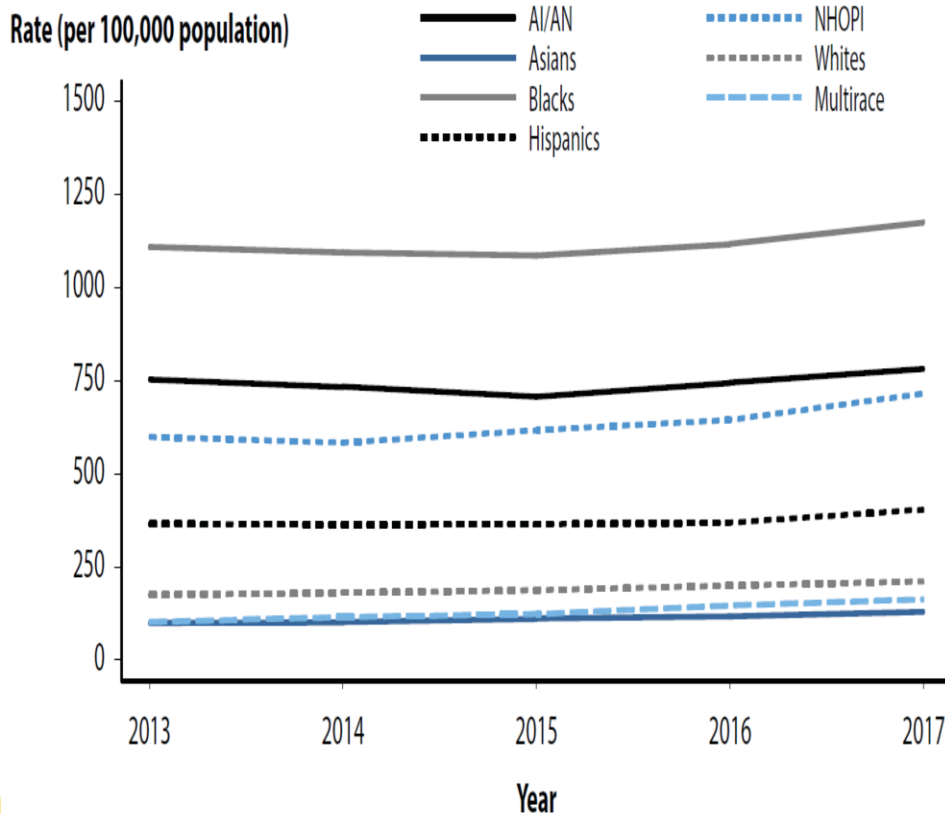
# Gonorrhea — Rates of Reported Cases by Age Group and Sex, U.S., 2017



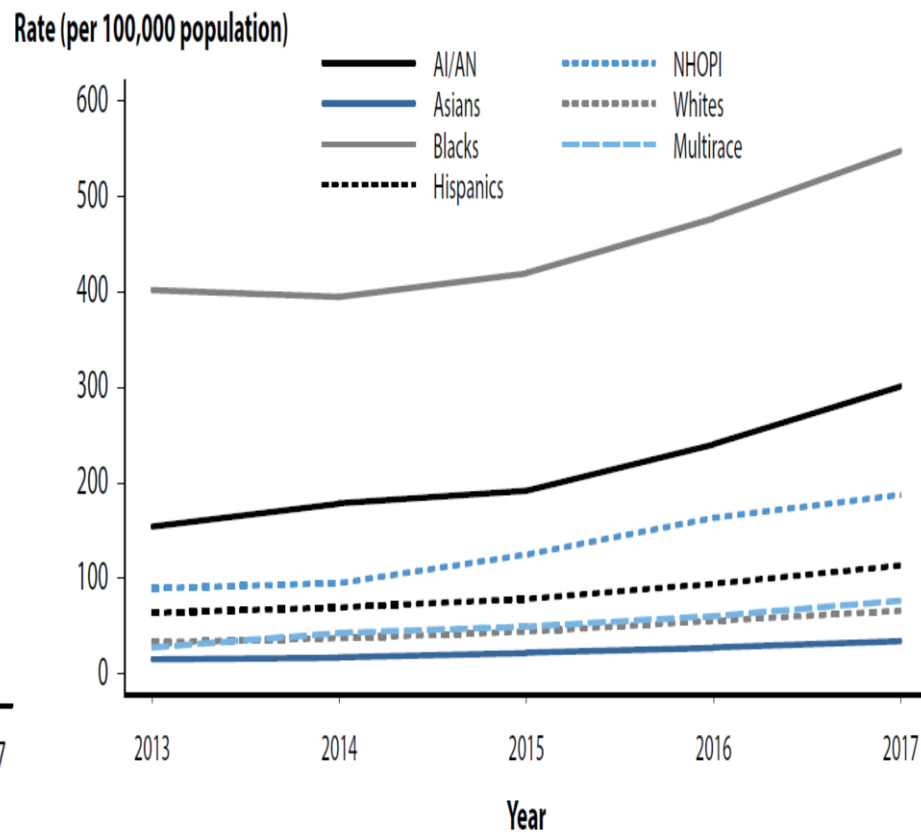
Source: <https://www.cdc.gov/std/stats17/adolescents.htm>

# Chlamydia & Gonorrhea — Rates by Race and Hispanic Ethnicity, United States, 2013–2017

## Chlamydia rates by race/ethnicity

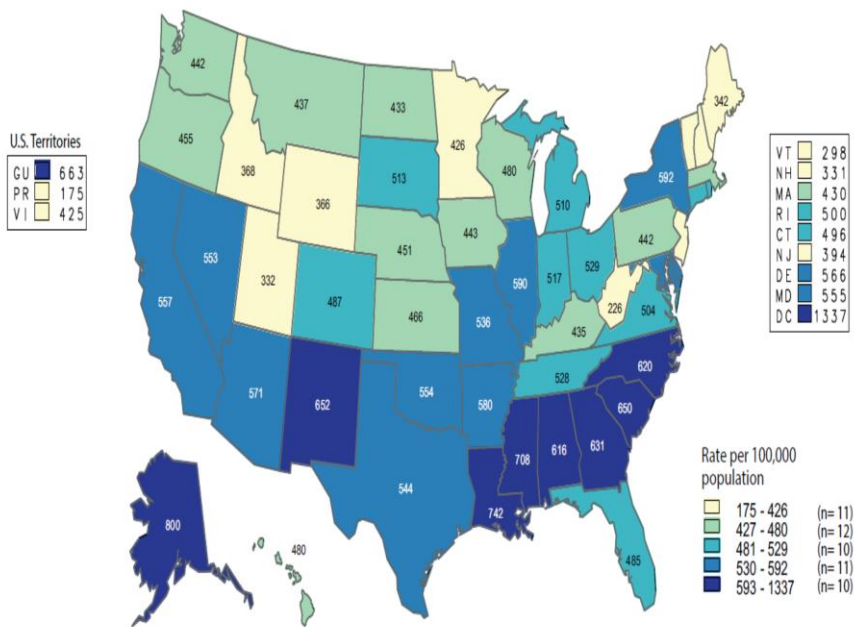


## Gonorrhea rates by race/ethnicity

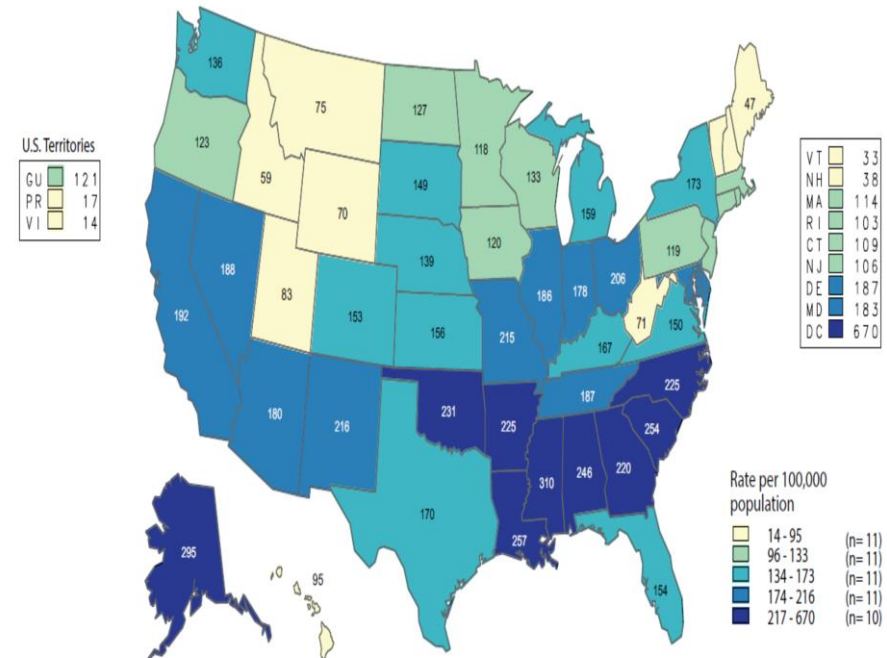


# Southern States with the highest rates in 2017

## Chlamydia Rates







## Gonorrhea Rates





# Chlamydia and Gonorrhea Diagnosis

Diagnosis	Chlamydia	Gonorrhea
Examination	<p><b>Women</b> Heavy or prolonged menses, spotting, dysmenorrhea, discharge, dyspareunia</p>  <p><b>Men</b> Penile discharge, dysuria</p> 	<p><b>Women</b> Yellow or bloody vaginal discharge, burning/painful urination, bleeding with vaginal Intercourse</p>  <p><b>Men</b> White, yellow/green pus from the penis with pain, burning during urination, swollen/painful testicles</p> 
Diagnosis	<p><b>Preferred diagnostic test: Nucleic Acid Amplified Tests (NAAT)</b>            Women – vaginal swab preferred            Men – urine acceptable</p> <p><b>**NAAT &gt; DNA Probe &gt; Culture**</b></p>	
Sequelae	<p><b>Women</b> - Symptomatic PID occurs in 10-15% of women with untreated Chlamydia - Increased risk of HIV transmission</p> <p><b>Men</b> Epididymitis, reactive arthritis, HIV transmission, proctitis</p>	<p><b>Women</b> - Cramps and pain, vomiting, fever → PID, infertility, Ectopic pregnancy . HIV</p> <p><b>Men</b> - Rare → Prostate complications, epididymis, HIV</p>

# Chlamydia Treatment

- Rx not changed
- Effectiveness: azithromycin < doxycycline
  - Data from meta-analysis of 12 randomized clinical trial
    - Urogenital chlamydial infection demonstrated that the treatments were equally efficacious, with microbial cure rates of 97% and 98%, respectively
    - Conclusion: doxy marginally superior to azithro
- Doxycycline delayed release 200 mg tabs (Doryx)
  - ↓ GI upset
  - Qday x 7 days
  - ↑\$

# Gonorrhea Dual Therapy: Uncomplicated Genital, Rectal, or Pharyngeal Infections

Ceftriaxone 250 mg IM  
in a single dose

**PLUS**

Azithromycin  
1 g orally

- Doxy no longer recommended as 2<sup>nd</sup> antimicrobial for GC Rx
  - Substantially ↑↑ prevalence of GC resistance to tetracycline vs azithromycin

# What Does Dual Therapy Mean?

- Ceftriaxone and azithromycin administered on same day
  - Preferably simultaneously and under direct observation
  - Challenge if ceftriaxone IM in office and Rx for azithromycin to fill in pharmacy
    - Must be given within 24 hr time period for adequate treatment



# Gonorrhea Treatment Alternatives 2015: Anogenital Infections

## *ALTERNATIVE CEPHALOSPORINS:*

- ❖ Cefixime 400 mg orally once

***PLUS***

- ❖ Dual treatment with azithromycin 1 g

OR

- ❖ doxycycline 100 mg BID x 7 days

➤ ***Doxy only allowed for allergy***

# Gonorrhea Treatment Alternatives Anogenital Infections

## ***IN CASE OF SEVERE ALLERGY:***

- ❖ ~~Azithromycin 2 g orally once~~  
*(Caution: GI intolerance, emerging resistance)*

Gentamicin 240 mg IM + azithromycin 2 g PO

OR

Gemifloxacin 320 mg orally + azithromycin 2 g PO

# Alternative Urogenital GC Regimens

- ❖ Non-comparative randomized trial in adults with urethral or cervical gonorrhea
  1. Gentamicin 240 mg IM + azithromycin 2 g PO, or
  2. Gemifloxacin 320 mg PO + azithromycin 2 g PO
- ❖ Rationale for regimens
  - Additive effect between gentamicin and azithromycin (*in vitro*)
  - Gemifloxacin more active against GC with known ciprofloxacin resistance

	<u>Gentamicin / Azithromycin</u>		<u>Gemifloxacin / Azithromycin</u>	
	n/N	% (L 95% CI)	n/N	% (L 95% CI)
<b>Urethra/Cervix</b>	202/202	100% (98.5%)	198/199	99.5% (97.6%)
<b>Pharynx</b>	10/10	100%	15/15	100%
<b>Rectum</b>	1/1	100%	5/5	100%

# GC Test of Cure

- Patients with **pharyngeal GC** treated with an **alternative** regimen
  - Obtain test of cure 14 days after treatment, using either culture or NAAT
- Cases of suspected treatment failure
  - Culture and simultaneous NAAT
  - Call your local health department



# Cephalosporin Treatment Failures

- Oral cephalosporin treatment failures reported worldwide
  - Japan, Hong Kong, England, Austria, Norway, France, South Africa, and Canada
- Ceftriaxone treatment failures in pharyngeal gonorrhoea and a few isolates with high-level ceftriaxone resistance reported

Unemo Eurosurveillance 2011 | Tapsall J Med Microbiol 2009 |  
Ohnishi EID 2011 | Allen JAMA 2012

**HEALTH ALERT**  
**BEWARE OF**  
**GONORRHEA**  
**SUPERBUG**



# Suspected GC Treatment Failure After Recommended Dual Therapy: What do I do?

**REPORT:** ECDOH STD program ASAP (within 24 hours)

**CULTURE:** if GC culture not available, call ECDOH

**REPEAT TREATMENT:** Gemifloxacin 320 mg + AZ 2g OR gentamicin 240 mg IM + AZ 2g

**TREAT PARTNERS:** Within 60 days with same regimen as patient receives

**TEST OF CURE (TOC):** Patient returns in 7-14 days for TOC culture and NAAT

- **If reinfection suspected instead of treatment failure, repeat Tx with CTX 250mg + AZ 1g**

# Recommendations for Screening

- CDC, AAP, USPSTF, ACOG, AAFP recommend:
  - Annual screening for CT/NG for ♀ ages 15-24 years

Source: <http://www.cdc.gov/std/tg2015/screening-recommendations.htm>

# CDC Recommendations for Screening and Prevention in Males

- Consider screening young men for CT in high prevalence clinical settings or in populations with high burden of infection (e.g. MSM)
- MSM should be screened at least annually for sexually active MSM at sites of contact (urethra, rectum, oral) regardless of condom use
- MSM should be screened annually for syphilis

# Potential High-Prevalent Settings

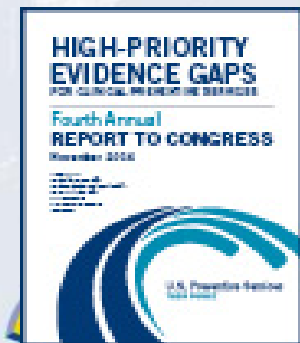
- Incarcerated populations, military recruits, and patients receiving care at public STI clinics
- Communities that experience racial segregation, in adequate access, high rates within sexual networks that contributes to racial/ethnic disparities

# USPSTF Risk-based Screening

- New sex partner
- >1 sex partner
- H/o or coexisting STIs or sex partner w/ STI infection
- Inconsistent condom use;
- H/o exchanging sex for money or drugs

# U.S. Preventive Services Task Force: High Priority Evidence Gaps

- USPSTF 4th Annual Report identified:
  - Effectiveness of screening strategies to identify high-risk adolescents
  - Long-term harms of HIV antiretroviral therapy
  - Interventions to prevent STIs in low-risk adolescents and high-risk adolescents



# Dr. Sanders Recommendations

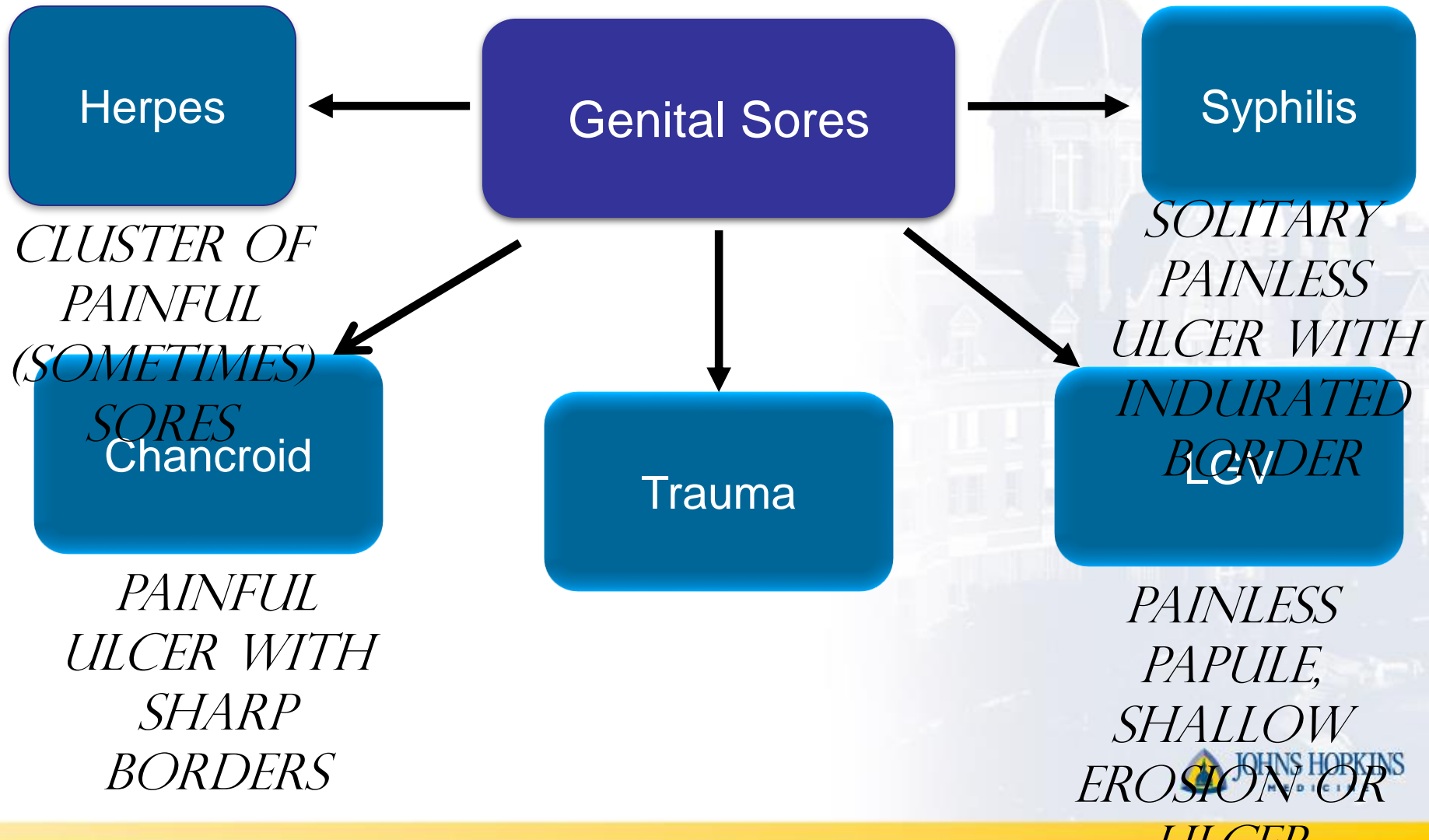
- Base decisions about STI screening on sexual behaviors, and the anatomy/body parts used for sex as identified through the sexual history
- Base frequency on new sexual partners & history of a prior sexually transmitted infection
- Encourage barrier methods including:
  - Condoms for sex involving penetration with penis or sex toys
  - Condoms or dental dams for oral/vaginal or oral/anal contact



# Case



- 18 year old male presents with non-healing ulcer & a new onset rash on trunk



# Herpes and Syphilis

Diagnosis	Herpes Simplex Virus (HSV)	Syphilis
Examination	<p><b>Types:</b> First clinical episode (primary/non-primary), recurrent symptomatic infection, asymptomatic infection</p> <ul style="list-style-type: none"> <li>- Mostly asymptomatic (90%)</li> <li>- Painful blisters/open sores (can be preceded by tingling/burning)</li> <li>- Sores typically disappear in 2-3 weeks (virus lies latent leading to future outbreaks)</li> </ul>	<p><b>3 Stages:</b></p> <ul style="list-style-type: none"> <li>- Primary (9-90days): One or more skin lesions called chancres</li> <li>- Secondary (6weeks-6months): Skin rash and mucous membrane lesions, flu-like symptoms</li> <li>- Late/latent: symptoms disappear, internal damage ensues</li> </ul>
Laboratory findings	Tzanck smear: multinucleated giant cells (insensitive)	<p>Large numbers of organisms present in exudates of lesion and in lymph nodes and</p> <p>Highly infectious; diagnosis by dark field microscopy</p>
Sequelae	<ul style="list-style-type: none"> <li>- Aseptic meningitis More common in primary infection Generally no neurological sequelae</li> <li>- Rare complications include: Stomatitis and pharyngitis Radicular pain, sacral paresthesias Transverse myelitis Autonomic dysfunction</li> <li>- Psychological distress</li> </ul>	two- to five-fold increased risk of acquiring HIV infection when syphilis is present

# Herpes and Syphilis

Diagnosis	Herpes Simplex Virus (HSV)	Syphilis
Screening	<p>Current CDC guidelines do not recommend universal screening with serology</p> <p>Consider testing if:</p> <ul style="list-style-type: none"> <li>- Past inconclusive work up for genital lesions—negative herpes culture or NAAT</li> <li>-- Have a partner with genital HSV</li> <li>-- MSM</li> <li>-- Are HIV infected</li> </ul>	<p>NOT recommended</p> <p>Screening in correctional facilities based local and institutional prevalence; MSM. Screen Q3-6 mo if hi risk w/ multiple partners or HIV+</p>
Diagnosis	<p><b>Culture:</b> Specificity &gt; sensitivity •requires a new lesion and high viral load</p> <p><b>Type-specific serology:</b> Most HSV-1 is not sexually transmitted</p> <p><b>PCR:</b> Sensitivity decreases as lesion heals</p>	<p><b>Classically:</b></p> <ol style="list-style-type: none"> <li>1.) Non-treponemal (RPR/VDRL)</li> </ol> <p><b>THEN</b></p> <ol style="list-style-type: none"> <li>2.) Treponemal (TPPA/FTA)</li> </ol> <p><b>New:</b></p> <ol style="list-style-type: none"> <li>1.) Treponemal (TPPA,FTA, EIA)</li> </ol> <p><b>THEN</b></p> <ol style="list-style-type: none"> <li>2.) Non-treponemal (RPR/VDRL)</li> </ol>

# Herpes and Syphilis

Diagnosis	Herpes Simplex Virus (HSV)	Syphilis
Treatment	<p><b>Acute therapy:</b></p> <ul style="list-style-type: none"><li>- Acyclovir 400 mg PO TID x 7-10 days</li><li>- Acyclovir 200 mg PO 5x/day x7-10 days</li><li>- Famciclovir 250 mg PO TID 7-10 days</li><li>- Valacyclovir 1 g PO BID x 7-10 days</li></ul> <p><b>Suppressive Therapy:</b></p> <ul style="list-style-type: none"><li>- Acyclovir 400 mg PO BID</li><li>- Famciclovir 250 mg PO BID</li><li>- Valacyclovir 500 mg PO daily</li><li>- Valacyclovir 1.0 g PO daily</li></ul> <p>**Treatment can be extended if healing is incomplete after 10 days of therapy.</p>	<p><b>Primary, Secondary, and Early Latent:</b> Benzathine Penicillin G—2.4 million units IM x 1 dose</p> <p><b>Late Latent:</b> Benzathine Penicillin G—2.4 million units IM x 3 doses</p> <p><b>Alternative treatment:</b> Doxycycline 100 mg PO BID x 14 days</p> <p><b>OR</b> Tetracycline 500 mg PO QID x 14 days</p>

# Case



- 18 year old male reports anal sex without a condom occurred 14 days ago
- Last HIV test (oral rapid test) was 8 weeks ago.

# Which test do you order?

1. Determine HIV-1/2 Ag/Ab Combo
2. INSTI HIV-1/HIV-2 Antibody Test
3. HIV-1 RNA Qualitative Assay

# HIV test technologies



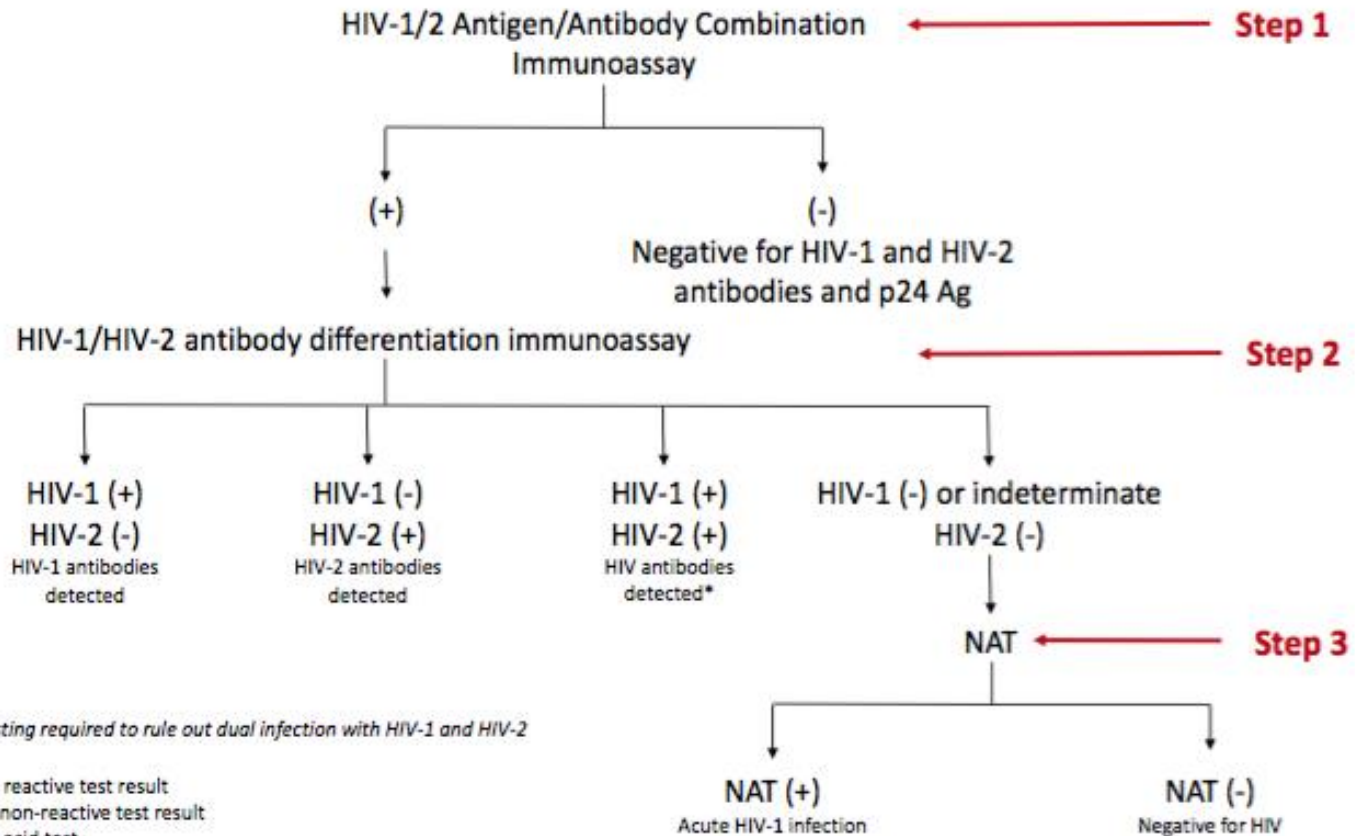
HIV test	Method	Window
1 <sup>st</sup> gen EIA (Ab)	viral lysate	~ 4-6 wks
2 <sup>nd</sup> gen EIA (Ab)	purified HIV-1/2 Ag or recombinant	~ 3-4 wks
3 <sup>rd</sup> gen EIA (Ab)	synthetic peptide, “antigen sandwich” detects IgM	~ 2-3 wks
4 <sup>th</sup> gen assay (Ab plus p24 Ag)	detects either antibody or p24 Ag	~ 2 wks
Pooled HIV RNA (HIV NAAT)		<1-2 wks

Adapted from Stekler CID 2007



# HIV Testing Diagnostic Algorithm

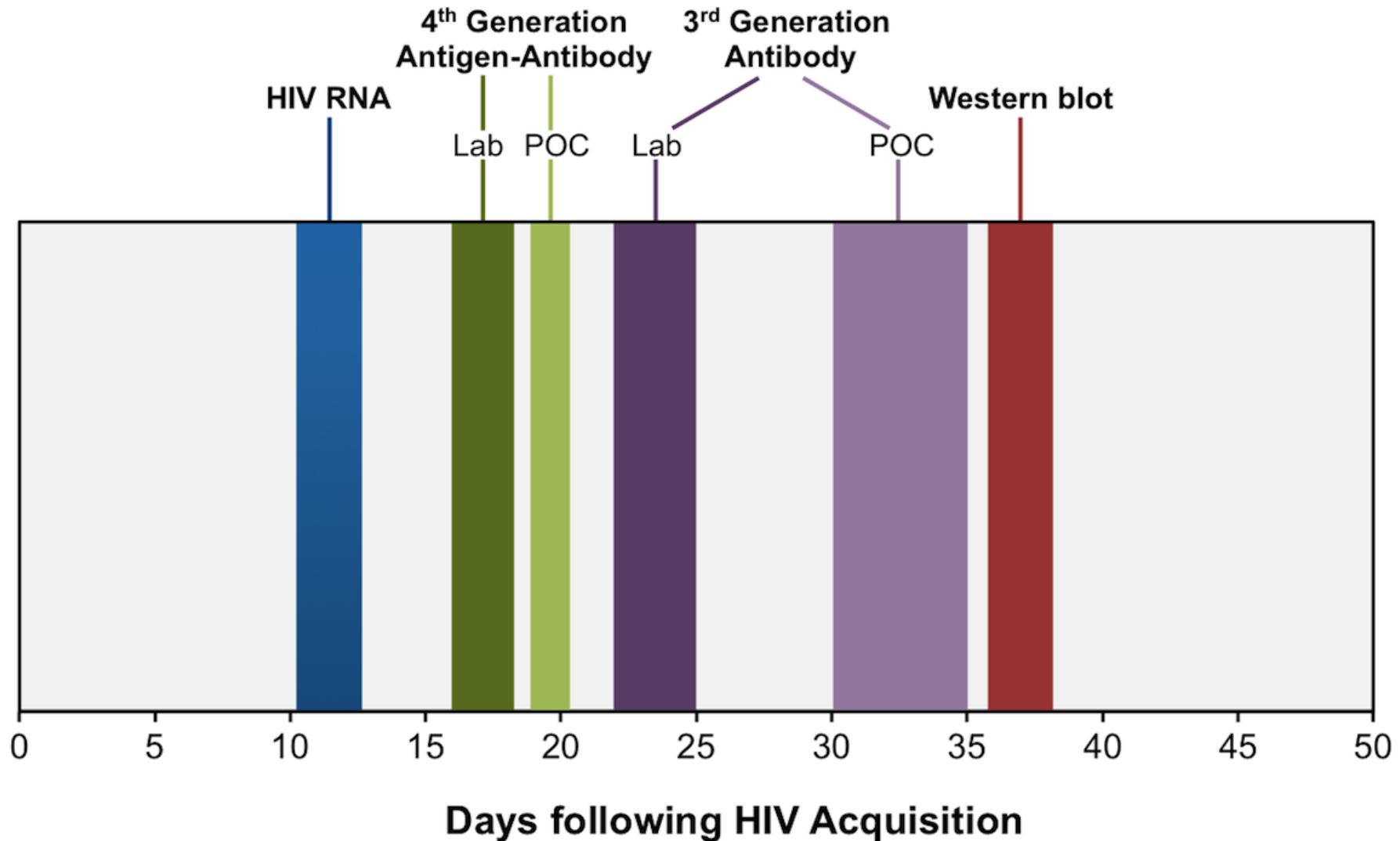
**Figure 1: HIV Laboratory Diagnostic Testing Algorithm (adapted from CDC and APHL- Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. 2014<sup>1</sup>)**



\*Additional testing required to rule out dual infection with HIV-1 and HIV-2

(+) indicates reactive test result  
 (-) indicates non-reactive test result  
 NAT: nucleic acid test

# Timing of Positivity for HIV tests



# CDC HIV Testing Recommendations: Revised 2006



**HAVE BALLS. GET TESTED.**

Getting yourself tested for HIV is the first step in taking responsibility for your sexual health and the health of your partners. [BaltimoreStatusUpdate.com](http://BaltimoreStatusUpdate.com)

An initiative of the Baltimore City Health Department.

STATUS  
UPDATE

Tobias Steinke, House of Representatives

- Screening performed routinely for all patients aged 13-64 years using an “OPT OUT” strategy
  - Based on state HIV testing laws
- Pre-/post test counseling not required
- All patients seeking treatment for STI
- Repeat screening at least yearly for those at high risk
- Repeat testing when initiating a new sexual relationship
- Consider the benefits of offering more frequent screening (e.g., once every 3 or 6 months) to youth at increased risk for acquiring HIV infection (e.g., young MSM)

Source: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>  
<https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a3.htm>

# Pre-exposure Prophylaxis



- PrEP is a prevention method for adolescents and adults who are HIV negative and at-risk for HIV to reduce their risk of becoming infected with HIV
- Co-formulated tablet with Emtricitabine (FTC)/ tenofovir disoproxil fumarate (TDF)

# PrEP Recommendations & approvals

2012



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

2012



U.S. FOOD & DRUG  
ADMINISTRATION

FDA & EC approved in persons  $\geq 35$  kg in 2018

2015



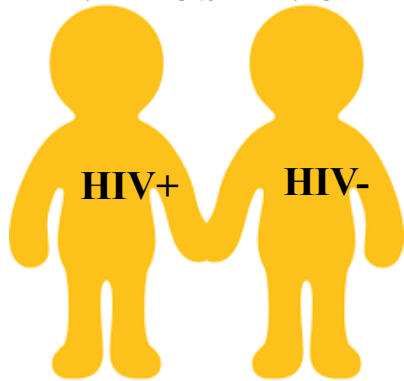
2016



EUROPEAN  
COMMISSION

# Who should take PrEP?

**HIV Positive Partner**



**No Condom Use**



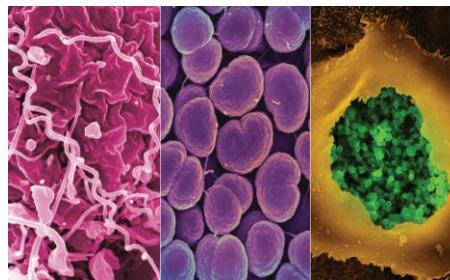
**Multiple Sex Partners**



**Engage in Sex Work**



**Bacterial STIs**



**Injection  
Drug Use**



# What is the evidence behind PrEP?

- Risk for HIV is reduced by up to 97% when PrEP is taken regularly
- Well tolerated with few side effects



<https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html>



# PrEP Randomized Control Trials among Adults

Study (population)	Regimen	Relative Risk Reduction (95% CI)	
		All Subjects	Adherent Subjects
Partners (discordant male/fem)*	TDF oral once a day	0.67 (0.44 – 0.81)	0.86 (0.57–0.95)
	TDF/FTC oral once a day	0.75 (0.55 – 0.87)	0.90 (0.56–0.98)
CDC TDF2 (hetero men/women)*	TDF/FTC oral once a day	0.62 (0.22 – 0.83)	
iPrEX (MSM, TGW)* ‡		<b>&gt;92% effective &amp; more effective with adherence</b>	
FEM-PrEP (young African women)	TDF/FTC oral once a day	0.06 (-0.41 – 0.52)	Adherence too low to assess efficacy. Trial stopped early
VOICE (women)*	TDF oral once a day	-0.49 (-1.30 – 0.04)	No difference
	TDF/FTC oral once a day	-0.04 (-0.50 – 0.30)	
CAPRISA 004 (women)*	Tenofovir (TFV) gel BAT24	0.39 (0.04 – 0.60)	>1,000 CVF increased RRR
VOICE (women)*	TFV gel once a day	0.15 (-0.20 – 0.40)	0.34 (0.13-0.87)
Bangkok (PWID)*	TDF once a day	0.49 (0.10 – 0.72)	0.70 (0.02–0.91)

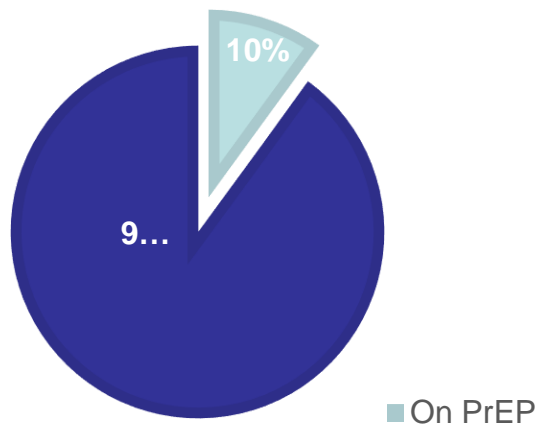
\*Adherent subjects defined by plasma/ peripheral blood mononuclear cell (PBMC)/ cervico-vaginal fluid (CVF) concentration) have greater relative risk reduction.

‡ Small numbers of transgender women (TW) were included in this study.

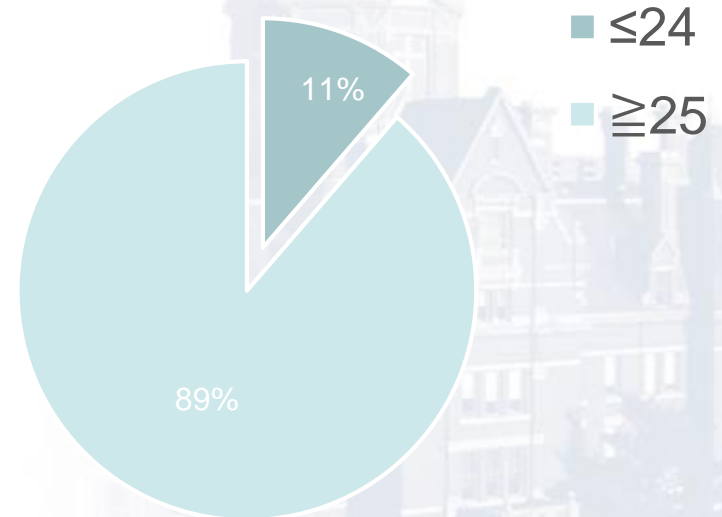
TDF/FTC is effective in TW who had detectable blood levels, however, questions still exist about the interaction of TDF/FTC with hormones (Deutsch MB, Lancet, 2015).

# Rates of PrEP use

**1 MILLION AMERICANS  
AT SUBSTANTIAL RISK  
FOR HIV**

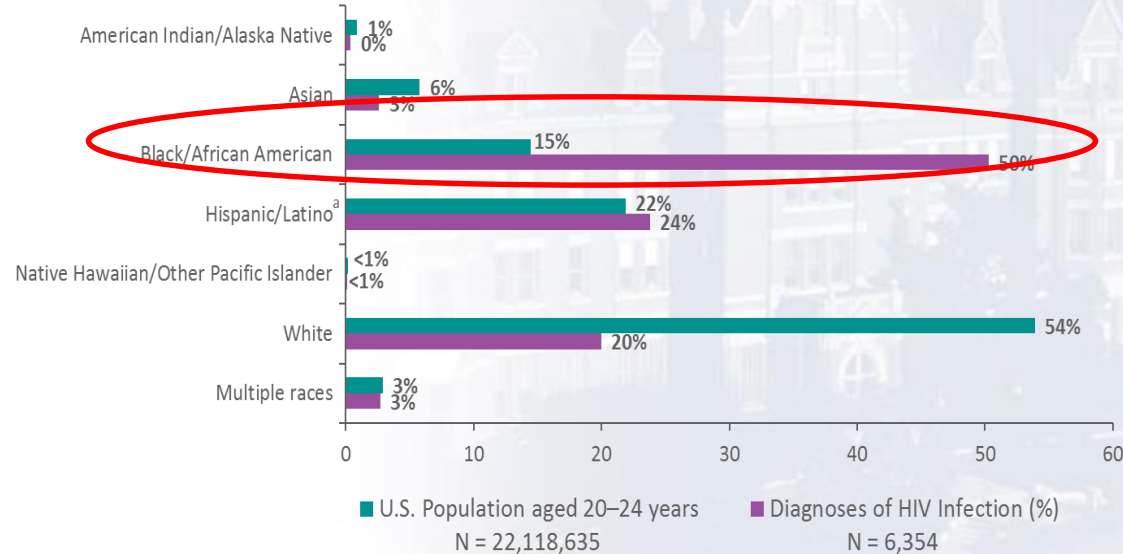
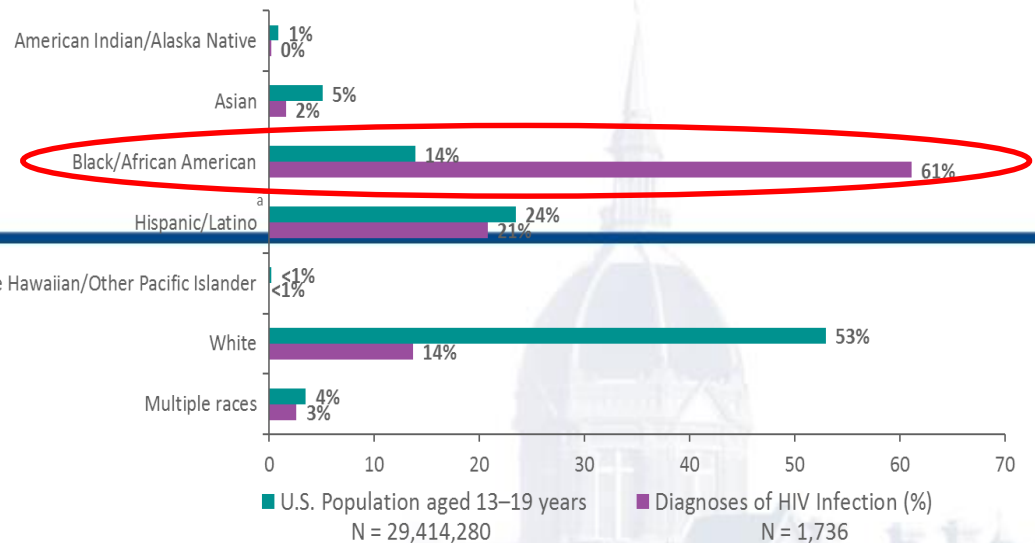


## U.S. PrEP DATA BY AGE



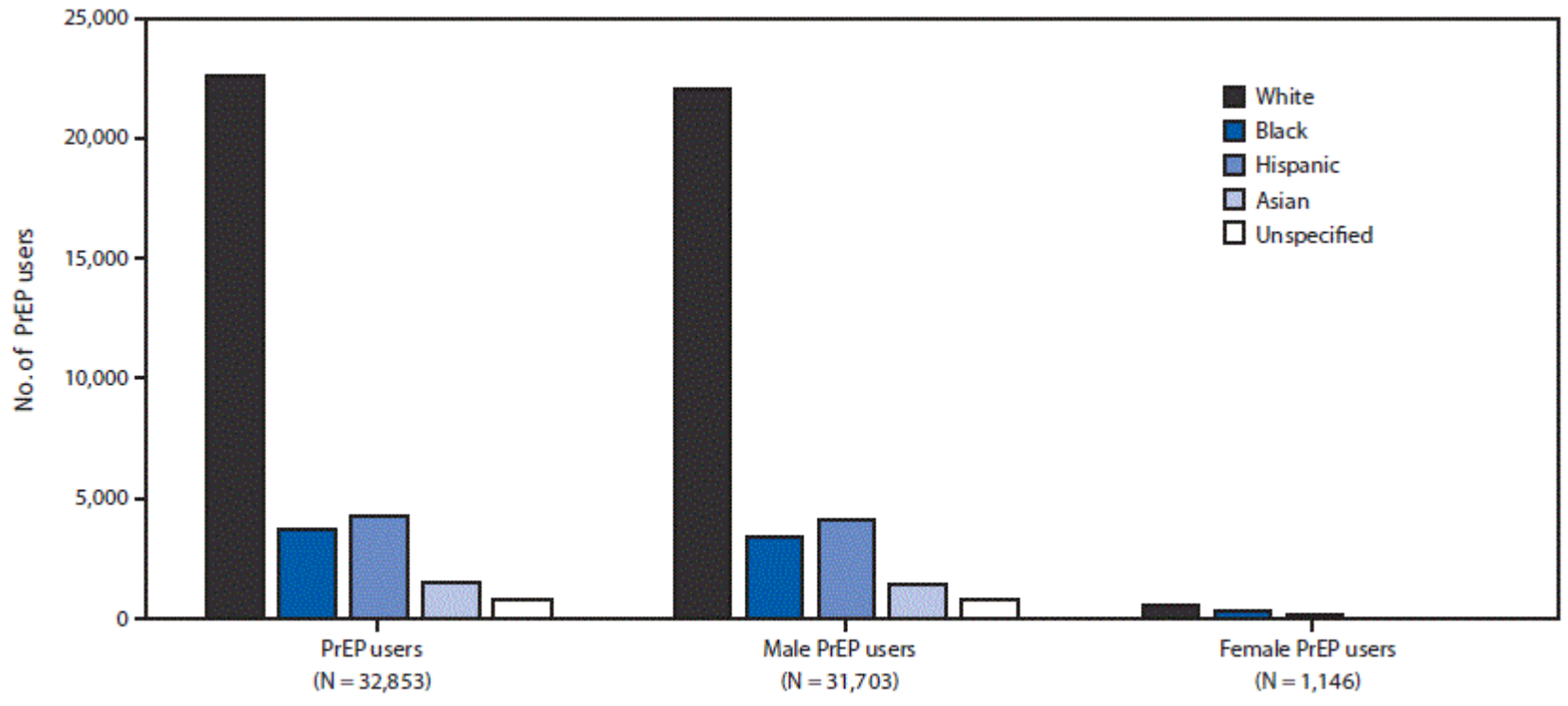
Siegler et al. Annals of Epidemiology, 2018

# HIV Rates Disproportionate Among Young Black Same Gender Loving Men

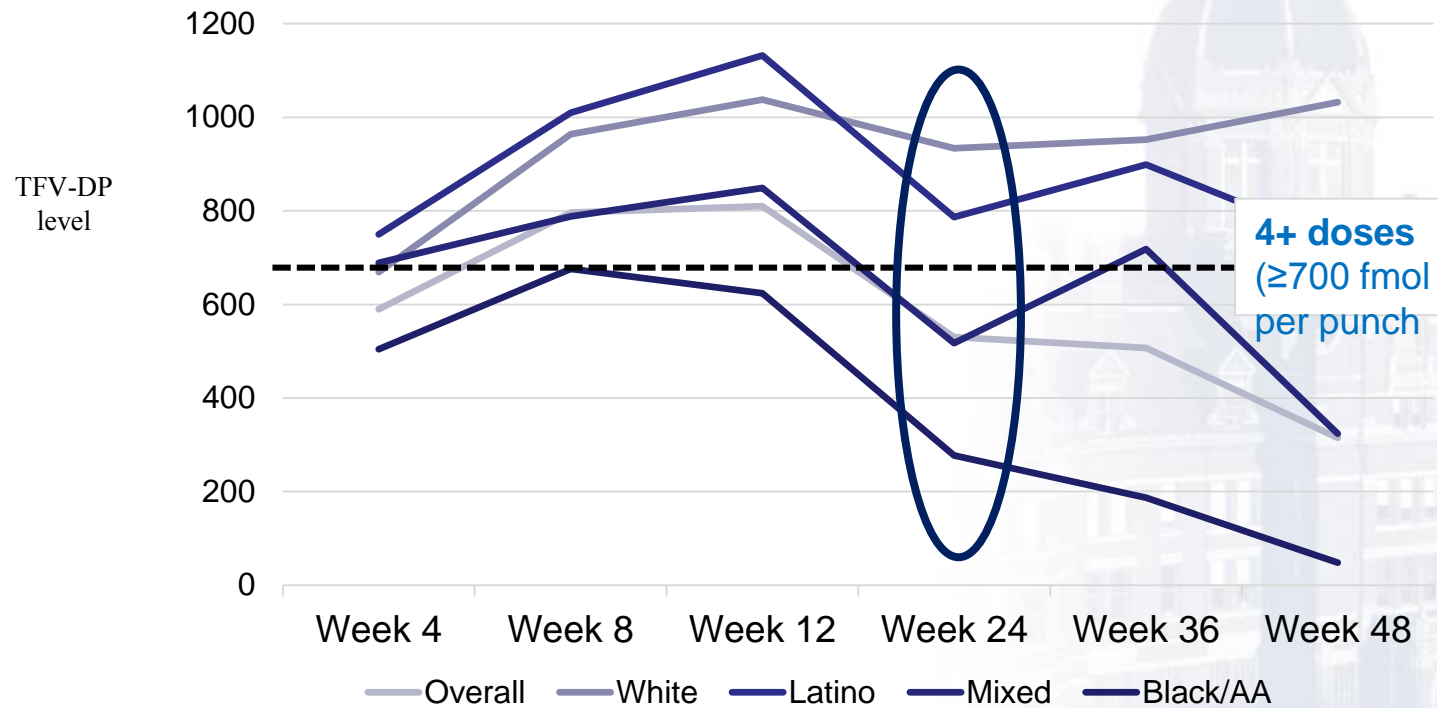


Source: CDC; HIV Surveillance Data, 2017

# Number of PrEP users by sex and race/ethnicity in U.S. 2014 - 2016



# Adherence by Race/Ethnicity



Slide Courtesy of Sybil Hosek

# Factors associated with sub-protective levels

BRIEF REPORT: PREVENTION RESEARCH

Role of Sociobehavioral Factors in Subprotective TFV-DP Levels Among YMSM Enrolled in 2 PrEP Trials

*Renata Arrington-Sanders, MD, MPH, ScM,\* Craig M. Wilson, MD,† Suzanne E. Perumean-Chaney, PhD,‡ Amit Patki, MSc,§ and Sybil Hosek, PhD||*

- Black race
- Kicked out of home due to sexual orientation
- Depressive symptoms
- Low perceived risk
- Mistrust of medications
- Fear others might see medications

Arrington-Sanders JAIDS, 2019

# How to start someone on PrEP

- Assess knowledge of and attitudes toward PrEP
- Discuss perception of risk (how risky do they feel that they are at risk for HIV)
- Identify behaviors that may be putting the participant at risk for HIV
- Discuss barriers around PrEP

# PrEP Barriers

- Insurance
- Access (don't know how to get a prescription)
- Mistrust
- Negative views towards PrEP (“Truvada Whore,” ads about side effects with PrEP)
- Parental consent
- Concerns about confidentiality



# PrEP is for YOUth Program



@The Harriet Lane Clinic

1. More than once daily pill

BUT...PrEP Involves More Than Just A Pill...  
**Approach to keep at-risk HIV negative  
individuals healthy**

2. Multidisciplinary team (Psychiatrist, SW, Navigators)

a. Counseling about condom use

b. Education about harm reduction

c. Counseling to promote adherence to PrEP

d. Assessing other needs

a. Substance use, housing, employment and  
mental health

# Labs

- Labs:
  - HIV test (4<sup>th</sup> generation Ab/Ag test)
  - Creatinine
  - Hepatitis A, B, C serology
  - Gonorrhea/Chlamydia (oral, rectal, urine)
  - Syphilis RPR
  - Urine HCG (for biologic females)
- Follow up:
  - 1 month and 3 months after PrEP start, then at least every 3 months
  - Only 90 day supply of medication prescribed

# Follow up

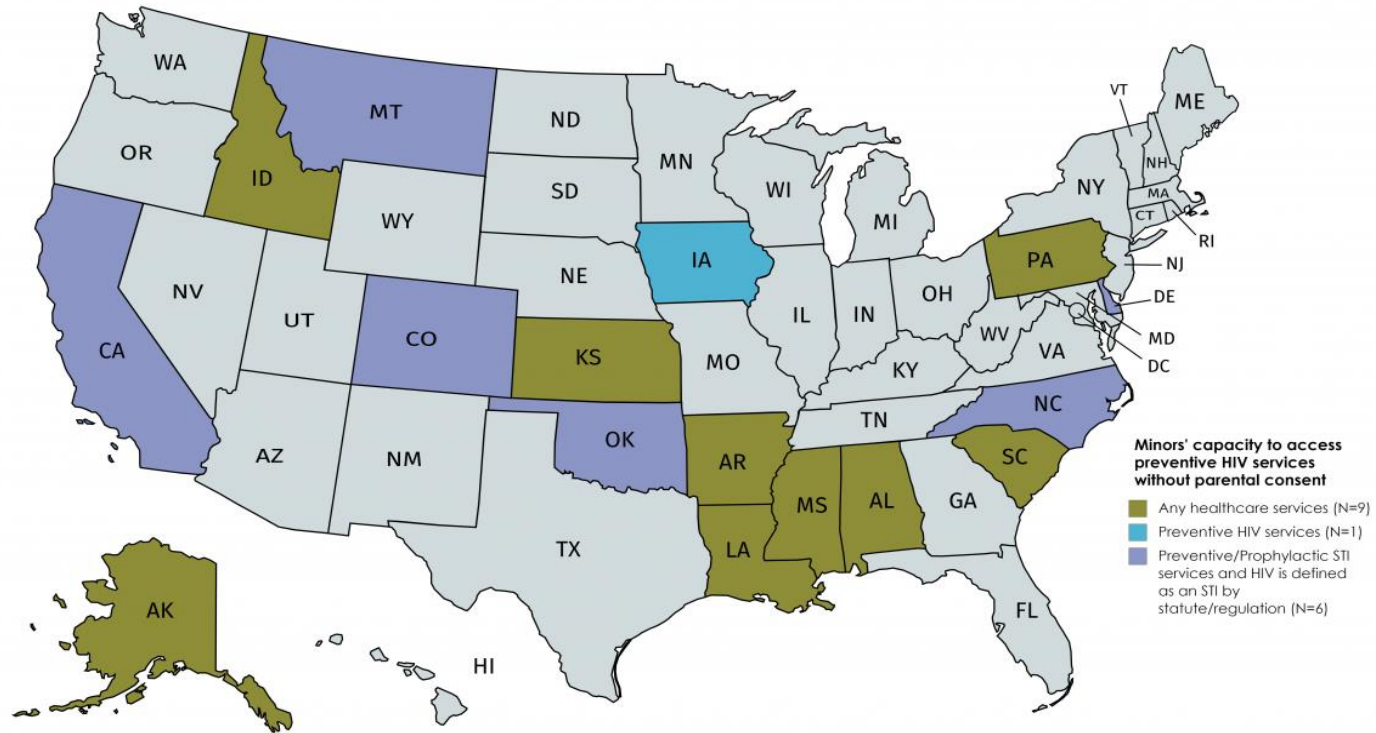
- **At each appointment**
  - Screen for difficulties with daily adherence
  - Screen for adverse effects
  - Screen for STI symptoms
  - Discuss risk reduction and provide condoms
- **Recommended testing every 3 months**
  - HIV test and pregnancy test
- **Recommended testing every 6 months**
  - Serum creatinine and STI tests
- **Recommend annually - Hepatitis C**
- **Adolescents benefit from more frequent appointments**

# Addressing PrEP Barriers

# Side Effects

- Mild symptoms
  - GI: nausea, diarrhea, indigestion
  - Occasional Headache or dizziness
    - Symptoms resolve 1-2 months
- Renal toxicity (<4%)\*
- Slight decreased bone mineral density\*
  - Mild non-progressive decrease in CrCl and bone mineral density that was reversible if medication stopped

# Minor Consent



Created with mapchart.net ©

- No state expressly prohibits minors' access to PrEP or other HIV prevention methods
- When counseling around PrEP make it apart of routine HIV testing and prevention counseling

# Access

HEALTH AND SCIENCE

## Free daily HIV prevention pills will soon be available to private insurance holders

PUBLISHED TUE, JUN 11 2019 1:50 PM EDT | UPDATED TUE, JUN 11 2019 4:19 PM EDT



Berkeley Lovelace Jr.

@BERKELEYJR

@/IN/BERKELEYLOVELACE

SHARE

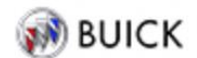


### KEY POINTS

- Patients with private health insurance will soon be able to get HIV prevention medication at no cost.
- The U.S. Preventive Services Task Force gave PrEP a grade A recommendation, meaning insurers will now be obligated to cover the medication at no cost to their policyholders.

### Find a PrEP provider

- <https://www.truvadahcp.com/prep-locator-widget>
- <https://preplocator.org/>

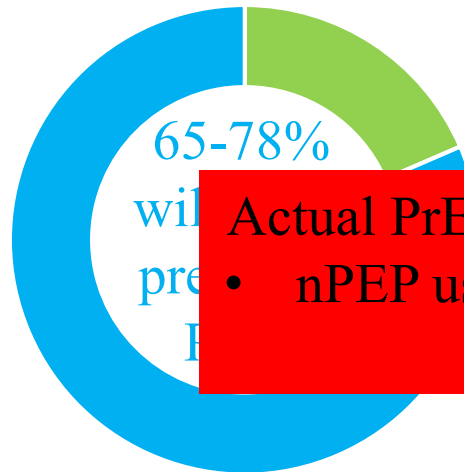


2019 ENCO



# Provider Barriers

- In a study of 162 of adolescent medicine providers in SAHM



Actual PrEP Rx in adolescents associated with:

- nPEP use & perceived adolescent adherence
- HIV positive patients



- Providers unaware that PrEP exists
  - 34% primary care docs and nurses haven't heard of HIV PrEP
- Discomfort performing sexual history
- Discomfort caring for sexual and gender minority groups
- Discomfort prescribing HIV medication
- Concern that patients on PrEP may engage in riskier behaviors

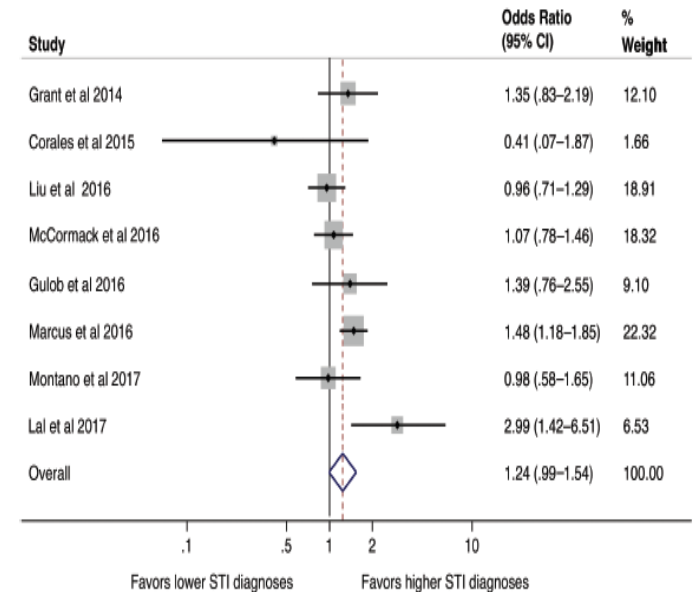


# STI rates

## Effects of Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis

Michael W. Traeger,<sup>1,2</sup> Sophia E. Schroeder,<sup>1,3</sup> Edwina J. Wright,<sup>1,4,5,6</sup> Margaret E. Hellard,<sup>1,4,5</sup> Vincent J. Cornelisse,<sup>5,7,8</sup> Joseph S. Doyle,<sup>1,5,8</sup> and Mark A. Stoové<sup>1,4,9</sup>

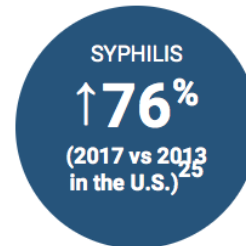
- Meta-analysis of PrEP on sexual risk behavior in MSM
  - Pooled OR was 1.24 (0.99-1.54), p value 0.059
  - Increased any rectal STI - 1.39 (1.03-1.87) & rectal CT 1.59 (1.19-2.13)
  - **Nonsignificant increase** in syphilis (OR, 1.12; 95% CI, .86–1.47; P = .41), CT (OR, 1.23; 95% CI, 1.00–1.51; P = .051), and GC (OR, 1.13; 95% CI, .78–1.64; P = .515) infection from any anatomical site



**Figure 2.** Random effects meta-analysis of effects of pre-exposure prophylaxis on sexually transmitted infection diagnosis. Abbreviations: CI, confidence interval; STI, sexually transmitted infection.

A record high of 2.3 million new cases of syphilis, gonorrhea, and chlamydia combined were diagnosed and reported in 2017<sup>24</sup>

# Those at greatest risk also have the greatest need!



Genital ulcers are associated with

**5x**

increased risk of becoming HIV+<sup>26</sup>

Among women, syphilis is associated with

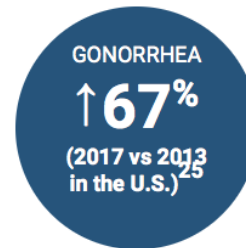
**20x**

increased risk of becoming HIV+<sup>27</sup>

Among men with syphilis

**~20%**

became HIV+ within 10 years<sup>28</sup>



A history of 2 prior rectal gonorrhea infections is associated with

**8x**

increased risk of becoming HIV+<sup>29</sup>

Among MSM with a history of rectal gonorrhea or chlamydia

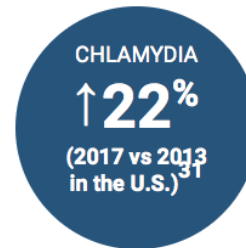
**1 in 15**

become HIV+ within 1 year<sup>30</sup>

Among women with a history of gonorrhea, there was

**6x**

increased risk of HIV diagnoses<sup>27</sup>



A history of 2 prior rectal chlamydia infections is associated with

**8x**

increased risk of becoming HIV+<sup>29</sup>

Among women, chlamydia is associated with

**2x**

increased risk of becoming HIV+<sup>27</sup>

Among MSM with a history of rectal gonorrhea or chlamydia

**1 in 15**

become HIV+ within 1 year<sup>30</sup>

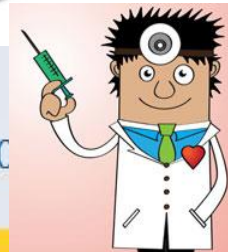
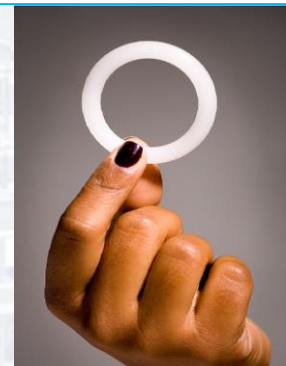
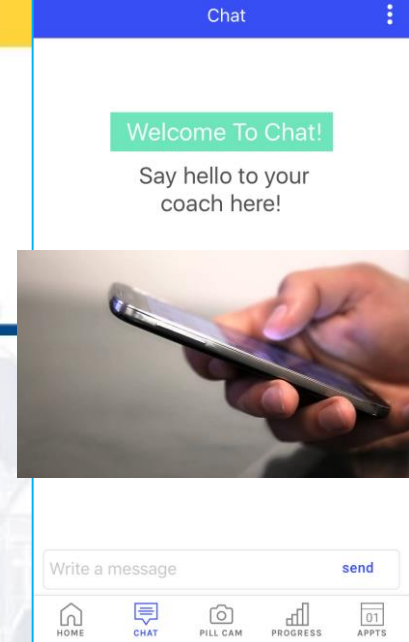
Many STIs are **asymptomatic**. Comprehensive STI screening is recommended, including at all sites of exposure.<sup>32,33</sup>

- It is estimated that **95%** of gonorrhea infections among MSM would be missed by screening the urethra only<sup>32</sup>
- **86%** of rectal chlamydia and **84%** of rectal gonorrhea infections are asymptomatic<sup>34</sup>

**51% of people newly diagnosed with HIV had an STI history that included chlamydia, gonorrhea, or syphilis in a real-world study (n=214)**<sup>35</sup>

# Difficult adherence

- Pill boxes and alarms
- Mobile applications
- Other formulations
- Efficacy of PrEP improves with better adherence
  - Females – 20 days for protection
  - In males:
    - ~99% decreased risk with 7 doses/week
    - ~96% decreased risk with 4 doses/week
    - ~76% decreased risk with 2 doses/week



# Post-exposure Prophylaxis

## PEP 101

If you may have been exposed to HIV\* in the last 72 hours, talk to your health care provider, an emergency room doctor, or your local health department about PEP right away. PEP can reduce your chance of becoming HIV-positive.



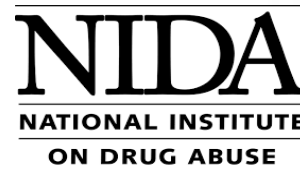
- Taking medications after possible exposure to HIV
- Must be started within 72 hours of exposure
- Eligibility for PEP:
  - Sexual assault
  - Unprotected anal or vaginal sex
  - Needle sharing (drug use, hormones)
- 28-day regimens
  - **Preferred:** TDF/FTC *plus* raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily
  - **Alternative:** TDF/FTC *plus* DRV + RTV

# PrEP in Adolescents

- Providers should routinely prescribe PrEP despite barriers
  - Those youth are at greatest risk have the biggest need
- Requires multi-disciplinary teams that are willing to routinely provide information about PrEP, help youth to prioritize their health and understand their risk, and address psychosocial factors that impact risk for HIV including:
  - Unemployment, inadequate housing, structural racism, and comprehensive sex education

# Acknowledgements

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- Sybil Hosek, PhD
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- PrEP team at Johns Hopkins
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  - Arik V. Marcell, MD, MPH
  - Christopher Reed
  - Miles Oliva
  - James Conley
  - Noah Wheeler, MPH



# Resources

- Primary Care Development Corporation (PCDC) Provides High Impact Prevention (HIP) Email: [hip@pcdc.org](mailto:hip@pcdc.org) Website: [www.pcdc.org/hip](http://www.pcdc.org/hip)
- <https://www.truvadahcp.com>
- Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at <http://stacks.cdc.gov/view/cdc/23447>. Published June 27, 2014. Accessed September 30, 2019.
- Centers for Disease Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline U.S. Department of Health and Human Services; 2015
- <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/prep-pep-pocket-guide.pdf>