

Overcoming the Barriers to PrEP

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Disclosures and Objectives

- ▣ No disclosures

- ▣ Objectives
 1. Overcoming Barriers to PrEP
 2. Transitioning from TDF to TAF
 3. Maneuvering Payment

PrEP Option #1

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR
THE PREVENTION OF HIV
INFECTION IN THE UNITED STATES
– 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE



- HIV PrEP
 - Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg has been shown to be **safe and effective** in reducing the risk of HIV acquisition in at risk adults(AI)¹
 - Truvada® (FDA approved) for patients with eCrCl of ≥ 60 ml/min
 - FDA approved for adolescents over 35 kgs(2018)



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 595 • May 2014
(Reaffirmed 2017)

Committee on Gynecologic Practice

This Committee Opinion was developed with the assistance of the HIV Expert Work Group. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus



U.S. Preventive Services
TASK FORCE

Release Date: June 2019

Recommendation Summary

Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A

1. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

2. Centers for Disease Control and Prevention. *HIV surveillance Report, 2016*; vol 28. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf>

PrEP: An Alternative to TDF/FTC



Tenofovir disoproxil fumarate (TDF) on



- Considered an alternative in certain populations
 - People who inject drugs
 - Heterosexually active men and women
- Lack of data: MSM, transgender

US Public Health Service

**PREEXPOSURE PROPHYLAXIS FOR
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PrEP: An Alternative to daily TDF/FTC

On-Demand or Event-Driven PrEP

(“2-1-1”) Peri-coital TDF/FTC

■ MSM with infrequent sexual exposures (IPERGA)

- 2 doses with food 2-24hrs before sex
- 1 dose 24 hours after the first (double) dose
- 1 dose 24 hours later

■ Detectable levels in colorectal tissue in 81% and 98% of the population when administered 2 and 24 hours prior³

- For consecutive sexual contacts,
 - Initiate double dose, then 1 pill/day until 2 days after the last encounter

■ Not if Hep B+

International Antiviral Society–USA Panel
Saag et al JAMA 2018

Approved in France

Lack of data:
transgender,
heterosexuals
and IVDU

1. Molina *N Engl J Med.* 2015; 2 Molina 9th International AIDS Society Conference 2017; 3 Cottrell *J Infect Dis.* 2016

PrEP: Option #2

1. TAF/FTC –FDA approved for MSM and transgender women (October 2019)
 - Not yet incorporated into guidelines
 - eCrCl > 30 mL/min



Not an option
for
Cis Women

PrEP: Who Needs It?

MSM	Heterosexual Men and Women	Injection Drug Users
<ul style="list-style-type: none"> Commercial sex workers HIV+ partner Recent STI Multiple partners Inconsistent/No condoms 	<ul style="list-style-type: none"> Commercial sex workers HIV+ partner Recent STI Multiple partners Inconsistent/No condom use High prevalence area 	<ul style="list-style-type: none"> HIV positive injecting partner Sharing needles/injection equipment

Transgender People

Trans women of color²
(National HIV/AIDS Strategy 2010, 2015)

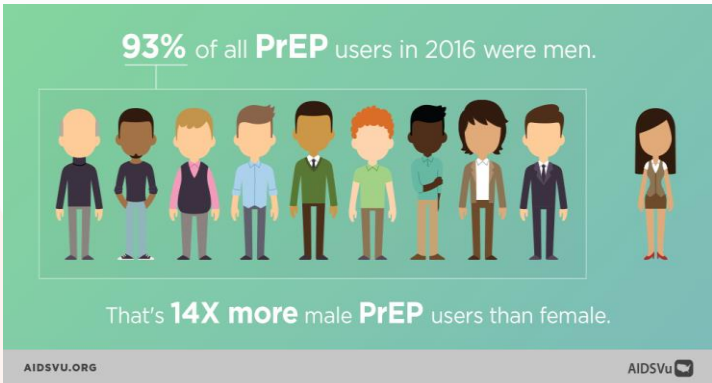
GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV: Recommendations for use in the context of demonstration projects
July 2012



US Public Health Service
PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE
A CLINICAL PRACTICE GUIDELINE

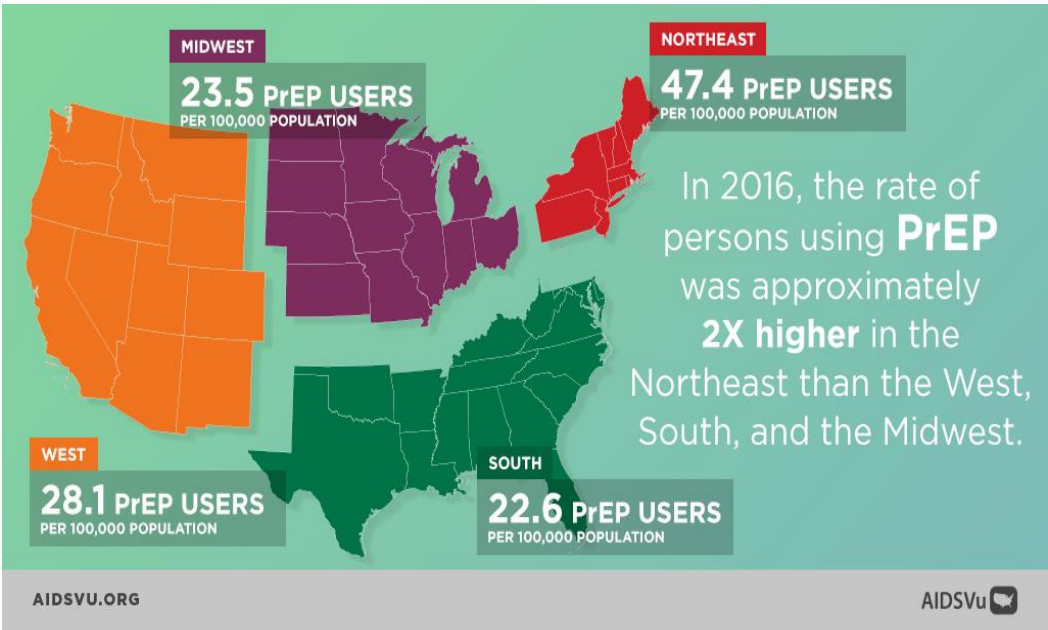
- <https://www.cdc.gov/hiv/risk/prep/index.html> (2017 guidelines)
- Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in US. AIDS Behav 2008
- https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s_cid=mm6827a1_

PrEP Uptake



The CDC estimates **468,000 U.S. WOMEN** are eligible for PrEP

Women's health care providers are uniquely positioned to screen, counsel about, and offer PrEP



220,000-225,000
Estimated Number of Current PrEP Users i

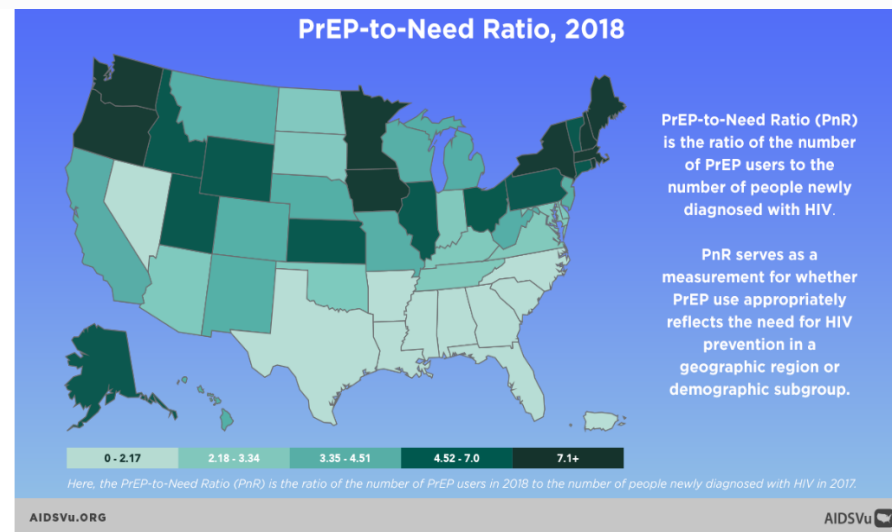
Data Updated: August 13, 2018

- <https://hiveonline.org/prep4women-disparities/-UCSF>
- DC'S PrEP AWARENESS CAMPAIGN

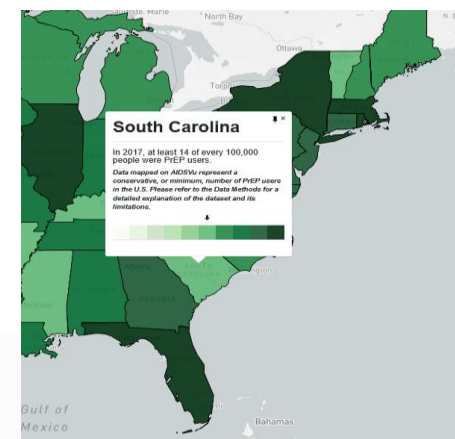
AVAC

PrEP Uptake

- From 2014 to 2017
 - PrEP awareness among MSM increased from 60% to 90%
 - Use of PrEP increased overall from 6% to 35%¹



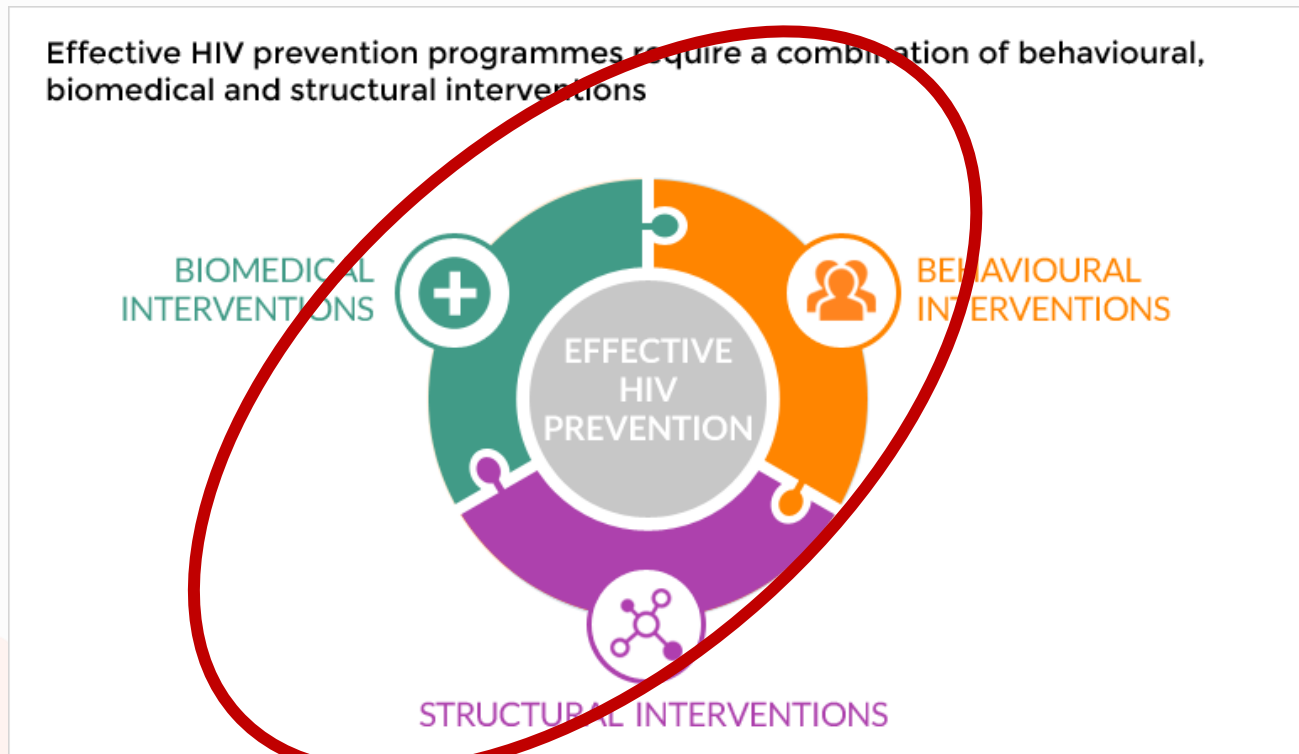
- Overall, the annual PnR increased from 0.2 in 2012 to 3.4 in 2018. In other words, in 2018, for every one person newly diagnosed with HIV, there were 3.4 HIV-negative persons using PrEP.
- In 2018, the PnR for women (1.2) was less than a third of the PnR for men (4.0), indicating an inequity in PrEP use for women relative to their need.
- The Southern U.S. represented half of new HIV diagnoses in 2017 (52%) but had the lowest PnR (2.1) in 2018 among all regions. In contrast, the Northeast region had the highest PnR (6.4) in 2018.
- While the annual PnR increased for all age groups from 2012 to 2017, those aged 24 years and younger had the lowest PnR (2.1) and those aged 35 to 44 years had the highest PnR (4.2).



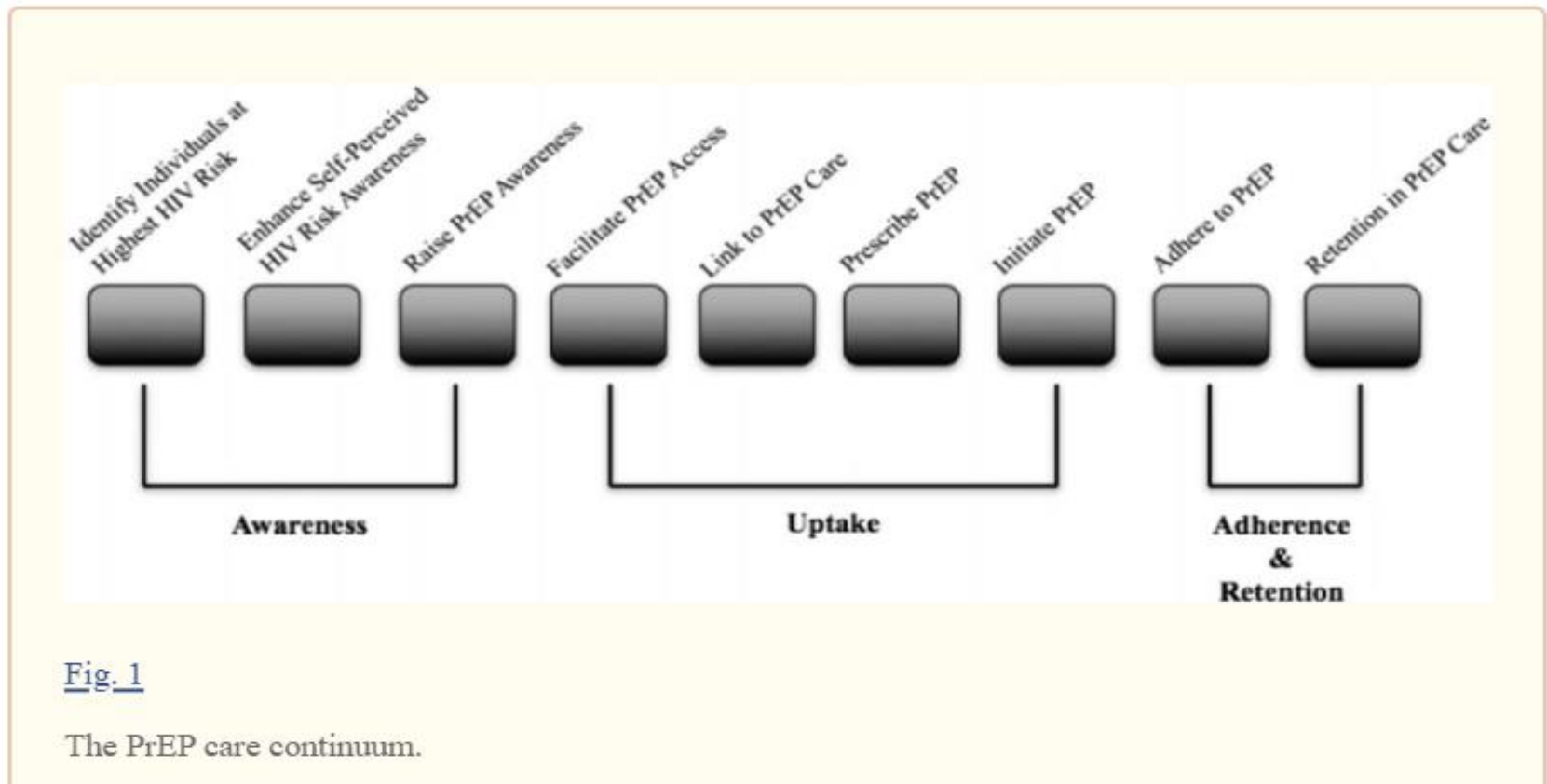
1. https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s_cid=mm6827a1_w
2. AVAC

Overcoming the Barriers

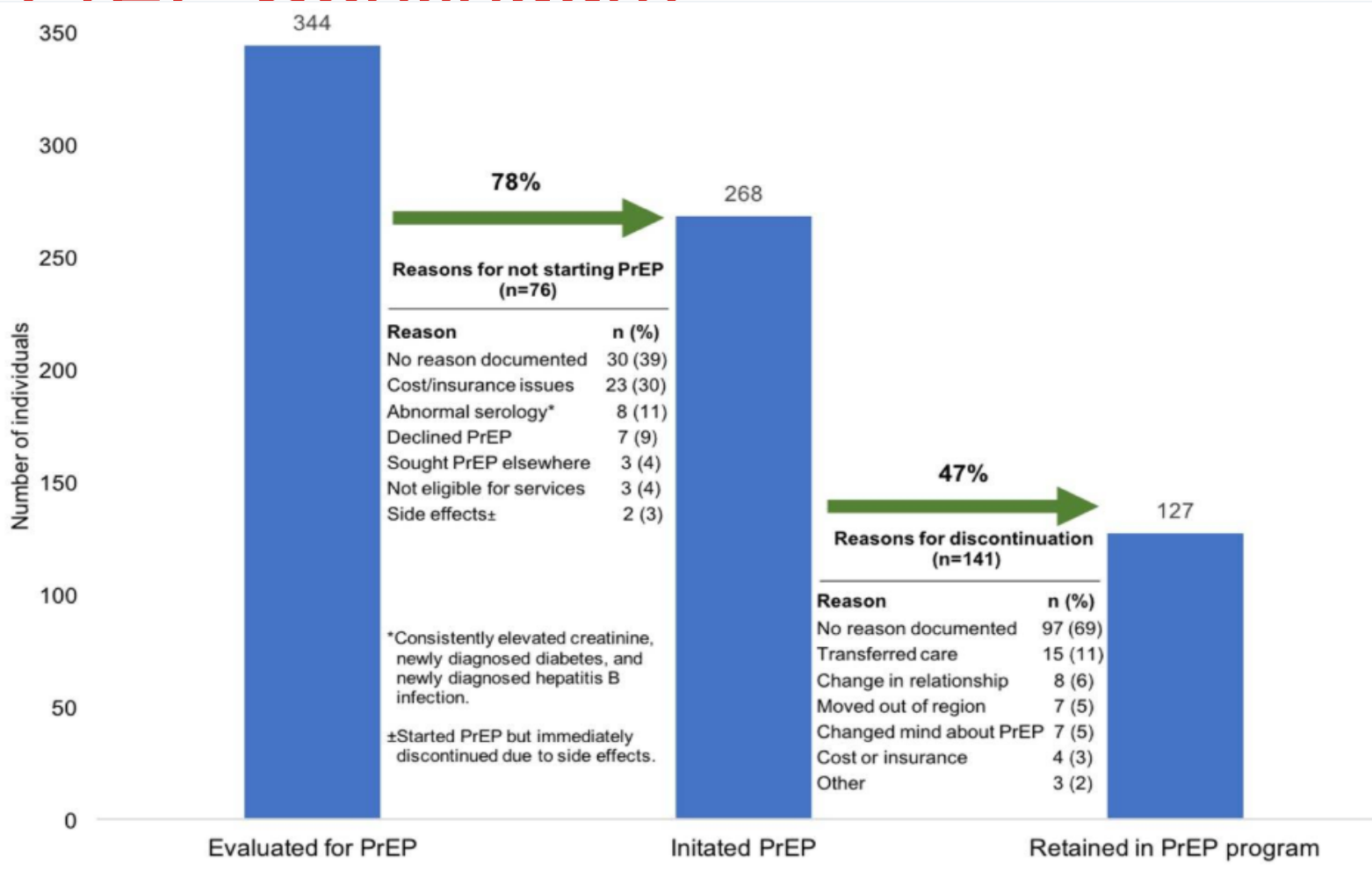
- How to increase our PrEP efforts?



PrEP Continuum: How is it affected by barriers



PrEP Continuum



Hojilla – AIDS behav. 2018

Barriers to PrEP

Potential Barriers Solutions

Access²

Training providers

Cost²

Medication assistance programs

Adherence

Counseling/Reminders/Behavioral / Intervention

Resistance¹

HIV testing while on PrEP

Side effects
PrEP q12 months

OTC meds, Revisit need for

Risk compensation²

Emphasize condom use and
screen for STIs frequently

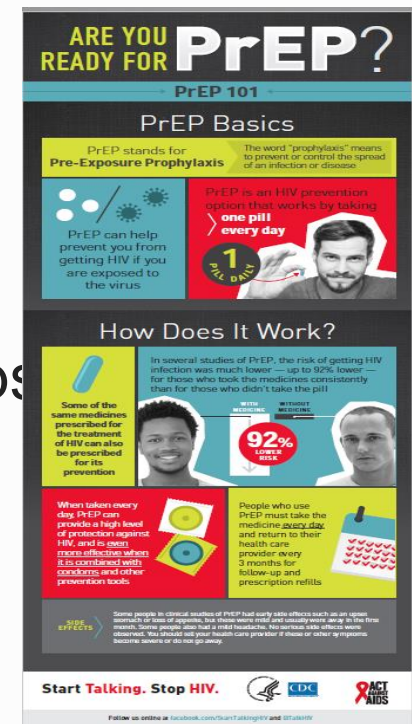
Heterosexism³
health burden, checking biases

Training, Education on HIV public

Barrier : Access

Providers Comfort

- Sexual history usually deferred by various groups
 - Primary care¹
 - STI care²
 - HIV care³⁻⁵
- Persons with greater heterosexism, more strongly anticipated increased risk behavior and adherence problems → lower prescribing intention⁶



1 Wimberly YH et al . Sexual history-taking among primary care physicians. *J Natl Med Assoc.* 2006

2. Kurth AE. A national survey of clinic sexual histories for sexually transmitted infection and HIV screening. *STD 2005*

3. Laws MB, Discussion of sexual risk behavior in HIV care is infrequent and appears ineffectual: *AIDS Behav.* 2011

4. Metsch LR., Delivery of HIV prevention counseling by physicians at HIV medical care settings in 4 US cities. *Am J Public Health.* 2004

5. Duffus WA, Effect of physician specialty on counseling practices /referral patterns among physicians caring for disadvantaged HIV populations. *CID 2003*

6. Sarah K. Calabrese **A Closer Look at Racism and Heterosexism in Medical Students' Clinical Decision-Making Related to HIV Pre-Exposure Prophylaxis (PrEP): Implications for PrEP Education** *AIDS 2018*

Barrier: Access

- Providers comfort with sexual health

Approach: In the past 6 mos: (Heterosexual men and women)

- Have you had sex with men, women, or both? (if opposite sex or both sexes) How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?
(if any positive) With these HIV +partners, how many times did you have vaginal or anal sex without a condom?

The five “P”s stand for:

- **Partners**
- **Practices**
- **Protection from STDs**
- **Past history of STDs**
- **Prevention of pregnancy**

CDC. PrEP Guidelines. 2017.

Barrier : Access

Patient Experience

Negative Exp.
= Lack of
Engagement /retention

- Gay and bisexual men get less routine health care than other men²
 - Low insurance rate- no insurance for unmarried partners
 - Fear of discrimination = no disclosure
 - Negative experience with HCP
- Transgender people (n=27,715)¹
 - 33% had at least 1 negative experience in a health care setting
 - Had to teach the provider about trans people(24%)
 - Asked unnecessary or invasive questions about trans(15%)
 - Refuse to give them transition related care (8%)

50% among
Native Indian

1. 2015 Transgender Survey

2. Quinn Cancer and LGBTQ Populations. *CA Cancer J Clin.* 2015

Barrier : Access

Patient Exp. A Welcoming Environment*

1. No assumptions RE gender identity, sexual orientation, or behavior
 - HCP should be non judgmental
2. Inclusive language
 - Appropriate pronouns/preferred name
 - Adding 'Transgender' or 'Other' option
3. Assurance of confidentiality
4. Training staff to increase their knowledge and sensitivity
 - Including front desk, phlebotomist, pharmD etc
5. The adoption and posting of a nondiscrimination policy (organizational support)



Gay and Lesbian Medical Association. Guidelines for care of lesbian, gay, bisexual, and transgender patients. Washington, DC: GLMA; 2006.

*http://www.glma.org/_data/n_0001/resources/live/GLMA%20guidelines%202006%20FINAL.pdf

What to expect

- Symptoms
 - Flatulence, nausea / GI upset
 - Headache and rash
 - Arthralgia
- This start up syndrome resolves within first 4-6 wks , for most
 - Use OTC medications
- Uncommon – drop in bone density, renal dysfunction (subclinical)

lactic acidosis, transaminitis

- 1.US Public Health Service. PrEP Guideline – 2017
- 2 Martin et al. Renal function of participants in the Bangkok tenofovir - Thailand, 2005–2012. CID 2017
- 3 Solomon et al. Changes in renal functionPrEP. AIDS. 2017
- 4 Liu et al. Bone mineral density in .. PrEP ... in San Francisco. PLoS One. 2011
- 5 PROUD: McCormack S, et al. Lancet 2015

The screenshot shows the dhcc website with a navigation bar at the top containing links for 'About Us', 'Health', 'Environment', 'For Business', 'Food Safety', and 'Vital Records'. The main content area is titled 'Pre-Exposure Prophylaxis (PrEP)' and includes a dhcc logo and a paragraph explaining that PrEP is a pill (Truvada) that can reduce the risk of getting HIV by more than 90% if taken as directed. Below this, a warning states: 'PrEP WILL NOT protect you from STIs, like syphilis, gonorrhea, or chlamydia, so using condom while on PrEP is'. To the right, a sidebar menu titled 'PrEP' contains several links: 'PrEP Provider Locator', 'PrEP 101 (pdf)' (which is circled in red), 'PrEP FAQs (pdf)', and 'PrEP Patient Assistance'. The 'PrEPMeSC' logo is also visible at the bottom left of the main content area.

Barrier: SE

Bone Health



- Small (~1%) decline in BMD occurred in first few months → either stabilized or returned to normal ^{1,2}
 - iPrEx trial (TDF/FTC) & CDC PrEP safety trial in MSM (TDF)
 - No increase in fragility (atraumatic) fractures over the 1-2 years
- DEXA scans or other assessments are NOT recommended

1 Grant. lancet 2014
2 Mulligan CROI 2011

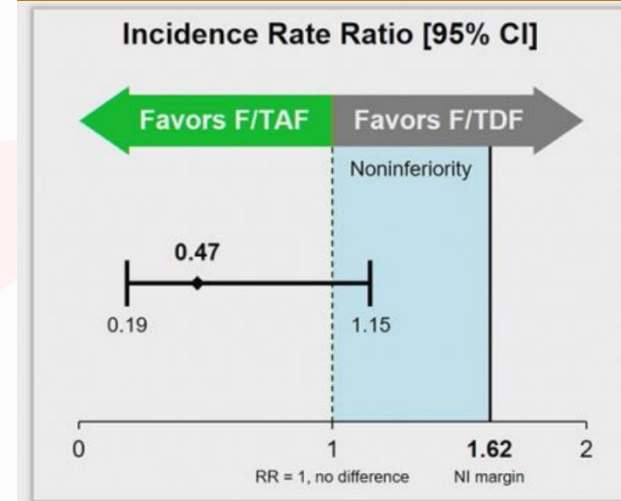
Bone and Renal Health

TAF data – When to transition and who gets transitioned

- Truvada (FTC /TDF) only fully FDA approved drug for PrEP
- In treatment trials TAF less renal toxicity and bone toxicity than TDF
- Can FTC/TAF (Descovy®) be used for PrEP?

- RCT of Truvada® versus Descovy® for PrEP
 - MSM and TGW
 - Enrolled ~6000
 - **74 TGW**
 - Followed- 96 wks
 - 9% black
 - High rates STI and chem-sex

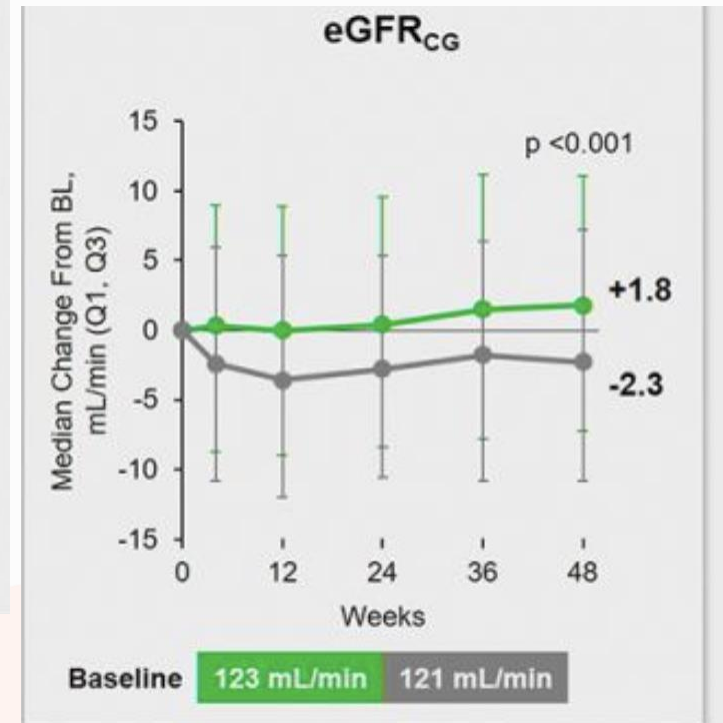
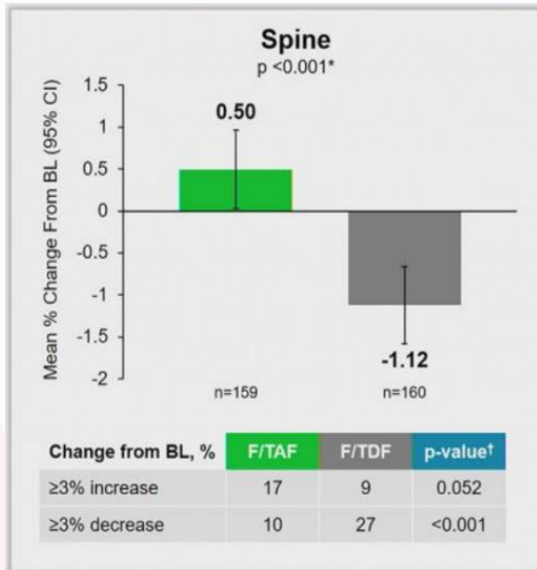
- 22 HIV transmission
- 7 TAF and 15 TDF



CROI 2019-Discover: Phase III RCT of F-TAF vs. F-TDF for PrEP

Bone and Renal Health

TAF data – When to transition and who gets transitioned



*p-values from analysis of variance model with baseline F/TDF for PrEP and treatment as fixed effects; †p-value was based on a dichotomized response (ie, ≥3% vs <3%) from Cochran-Mantel-Haenszel test for nominal data (general association statistic) adjusting for baseline F/TDF for PrEP. BL, baseline.

TAF safer for bone and kidney health

CROI 2019-Discover: Phase III RCT of F-TAF vs. F-TDF for PrEP

Barrier : Cost

PrEP: Cost Benefit Analysis

- Lifetime HIV treatment cost in SC is ~ \$367,000 per person¹
- Several studies with PrEP cost effectiveness in high risk MSM^{3,2,4}
- Annual cost of PrEP without meds \$1,900- \$2, 500
 - Medication \$19,000 (1,585/month) - free
 - Cr /HIV/provider - \$545 – \$1,345
 - STI (triple site and syphilis* 4) - \$ 920
 - Hepatitis Bs Ab and Ag /Hep C/ Pregnancy*1- \$149

CHC
MHC
FQHC
University

HRSA
grants

1 Centers for Disease Control and Prevention: HIV Cost-effectiveness. <https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html> . Assessed May 4, 2018.

2. Drabo A cost-effectiveness analysis of PrEP for the prevention of HIV. Clin Infect Dis. 2016

3. Ross EL, cost-effective, HIV preexposure prophylaxis to high-risk MS . J Acquir Immune Defic Syndr. 2016

4. Shen, cost-effectiveness of oral HIV PrEP and early ART BMC Medicine. 2018

Barrier : Cost

PrEP: High Impact Prevention Measure

NNT to prevent 1 HIV infection = 25¹ (13 – 48)^{1,2,3}

Outcome to Prevent	Intervention	Number needed to treat (NNT) to prevent one case
Death from colorectal Ca	Annual fecal occult blood testing colorectal screen ^a	4551
MI in individuals with HTN and average cholesterol	Atorvastatin 10 mg daily ^{b,c}	100
HIV infection in MSM	TDF/FTC 1 pill daily ^d	13

Compliments of
James J Gibson MD, MPH
and CDC/DHAP team-Dawn Smith MD and Mary Tanner MD

1. Jenness JID 2016
2. McCormack S, et al. CROI 2015 (PROUD- NNT = 13)
3. Molina JM, et al. CROI 2015 (IPERGAY – NNT 18)
4. Mascolini 2017

^aMandel JS, et al. *N Engl J Med*. 1993

^bBerger JS, et al. *JAMA*. 2006; ^cSever PS, et al. *Lancet*. 2003

^dMcCormack S, et al. CROI 2015. Abstract 22LB (PROUD)

Overcoming PrEP Cost

Insured

- Check coverage, prior authorization
 - Clinic staff- COMVERMYMED
 - Specialty pharmacy partner
- Copay cards available
 - <https://www.gileadadvancingaccess.com/copay-coupon-card>
 - Covers up to \$7,200
 - Not eligible - government healthcare programs (Medicare Part D, Medicaid, TRICARE, or VA)
 - SC Medicaid covers TAF/FTC and TDF/FTC

DHEC > Health... > Diseases A... > Infectious... > HIV, AIDS... > PrEP

Pre-Exposure Prophylaxis (PrEP)



PrEPMeSC

PrEP is a pill (Truvada) that can be taken once a day to greatly reduce your chances of getting HIV, if exposed to the virus. If taken as directed, PrEP can reduce your risk of getting HIV by more than 90%.

PrEP WILL NOT protect you from STIs, like syphilis, gonorrhea, or chlamydia, so using condom while on PrEP is

PrEP

PrEP Provider Locator

PrEP 101 (pdf)

PrEP FAQs (pdf)

PrEP Patient Assistance

Copay Cards transfer from TDF--> TAF

For switch TDF→TAF PA needed - United HC; cig; Anthen

Some info complements of Michael DeMarco
Gilead Sciences, Inc.

Gilead's Advancing Access program is committed to helping you afford your medication no matter your situation. Whether you have insurance or not, we can explore potential coverage options that might be right for you.

Our dedicated program specialists are here to help you. Talk to someone right away by calling 1-800-226-2056. Advancing Access phone lines are open M - F 9am - 5pm ET. If you reach us after hours, leave a message, and we will call you back during the next business day.

The Advancing Access CO-PAY COUPON PROGRAM



See if you're eligible to save on your Gilead prescription with our co-pay coupon card.

[Get Started](#)

The Advancing Access PATIENT SUPPORT PROGRAM



Enroll today and get access to the live support you need for your Gilead medication.

- Uninsured 24/7 support >
- Get started easily and enroll online >
- Download the enrollment form >

Overcoming PrEP Cost - Uninsured

Covering the Cost of PrEP Care

Insured

Medication	Lab Test	Clinic Visits
Bill insurance Apply for copay assistance from Gilead or PAF	• Bill insurance	• Bill insurance

Not insured But may be eligible for Medicaid or ACA Plans

Apply

Not eligible for Medicaid or ACA plans OR Insurance denies claim

PrEP Medication Assistance Program

Family Size	500% Federal Poverty Level Household Annual Income must be less than:
1	\$58,850
2	\$79,650
3	\$100,450
4	\$121,250
5	\$142,050
6	\$162,850

Medication	Lab Test	Clinic Visits
• Gilead Medication Assistance Plan • WA State Medication Assistance	• Care at CHC • Care scale • NY State PrEP Assistance Plan	• Care at CHC • Care at CHC • NY State PrEP Assistance Plan

Medication	Lab Test	Clinic Visits
• Bill insurance • Apply for copay assistance from Gilead or PAF	• Bill insurance	• Bill insurance

ABBREVIATIONS:
ACA - Affordable Care Act
FPL - Federal Poverty Level
CHC - Community Health Center
PAF - Patient Advocate Foundation

DEFINITIONS:
PrEP: Daily pill to prevent HIV infection (pre-exposure prophylaxis)
Co-pay: Fixed amount to be paid by insured person per prescription
Co-insurance: Fixed percentage of prescription cost to be paid by insured person
Deductible: Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

PrEP MEDICATION ASSISTANCE PROGRAM:
(Gilead Sciences)
People eligible for this program must:




- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income ≤ 500% of the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient's home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months by the provider

RESOURCES:

To apply for health insurance on the federal exchange: www.healthcare.gov
 Community Health Center Locator: findahealthcenter.hrsa.gov
 NASTAD on-line tool to assist with paying for PrEP at PrEPCost.org
 Gilead Sciences: Medication Assistance Program and Co-Pay Assistance - www.truvada.com/how-to-get-truvada-for-prep/truvada-cost
 Patient Advocate (PAF) Foundation: Co-Pay Relief Program - www.copays.org/diseases/hiv-aids-and-prevention

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-PayingforPrEP-flyer.pdf>

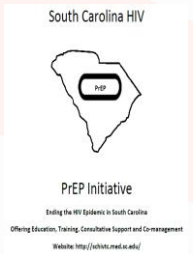
Barrier – Time

Barrier: Human Resources

Solution – PrEP champion

Identifying the PrEP champions

- Medical assistant/RN
- Pharm D
- Counsellor
- Training goals
 - Get comfortable with sexual and substance abuse history
 - Trainings or modules available
 - PrEP Telehealth/ preceptorship/ technical support
 - CDC
 - WHO
 - HRSA



Assess Patients' Risk Behavior

Brochures
With MH/Drug screen
Have nurse ask
Part of H&P

- In the past 6 mos: (MSM)
 - Have you had sex with men, women, or both?
 - *If men or both:* How many men have you had sex with?
 - How many times did you have receptive anal sex (were the bottom) with a man who was not wearing a condom?
 - How many of your male sex partners were HIV positive?
 - *If any positive:* With these HIV-positive male partners, how many times did you have insertive anal sex (ie, the top) without you wearing a condom?
 - Have you used methamphetamines (crystal or speed)?

CDC. PrEP Guidelines. 2017.

PrEP Workflow



Palmetto Health USC
MEDICAL GROUP

Time management

HIV PrEP Implementation Toolkit

Bolded items mandatory

1 vs 2 visits

PrEP Orientation Visit:

- Discuss PrEP use
- Review insurance coverage/med. assistance
- Perform baseline laboratory tests:
 - **HIV Ab/Ag screen^ (4th generation)**
 - **Cr**
 - **Hepatitis Bs Ag/Ab** and cAb
 - Hepatitis C Antibody
 - RPR/Trep Ab
 - Triple site GC/CH testing- Urine, Rectal, Oral (based on exposure)
 - **Pregnancy test** (if female)

Initial Provider Visit:

- Discuss PrEP use (7 day interval before adequate levels in rectal tissue and 20 days for vaginal tissue/blood; compliance; SE)
- Risk reduction counselling, condoms
- PrEP Clinic Questionnaire(initial)
- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (**start within 7 days of HIV screen**)



PrEP Workflow

Every visit(Q 3mths)

- Provide condoms
- HIV Ag/Ab → refills
- Assess adherence
- Risk reduction counseling

Decide who sees the person

PrEP Orientation Visit:

- Discuss PrEP use
- Review insurance coverage/med. assistance
- Perform baseline laboratory tests:
 - HIV Ab/Ag screen^ (4th generation)
 - Cr
 - Hepatitis Bs Ag/Ab and cAb
 - Hepatitis C Antibody
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Initial Provider Visit:

- Discuss PrEP use (7 day interval before adequate levels in rectal tissue/blood; compliance; SE)
- Risk reduction counselling, condoms
- PrEP Clinic Questionnaire(initial)
- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (**start within 7 days of HIV screen**)

30-day visit:

- Adherence review with nurse/ PharmD, risk reduction counselling, assess side effects
- Cr

60-day supply of PrEP

3-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag Test, Pregnancy test, STI screen in MSM^ (RPR/Trep Ab, GC/CH(triple site))**

90-day supply of PrEP

6-month visit/ 12 month visit:

- PrEP Clinic Questionnaire (long)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag , Pregnancy test, Cr, RPR/Trep Ab, GC/CH(triple site), Hep C ab annually**

90-day supply of PrEP

9-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit , risk reduction counselling, condoms
- **HIV Ab/Ag, STI screen in MSM(RPR/Trep Ab, GC/CH(triple site))**

90-day supply of PrEP

After the 12 month visit: (re-evaluation of need for continuing PrEP)

Q 3 monthly visit with Adherence nurse/ Pharm D, risk reduction counselling, , condoms.

- PrEP Clinic Questionnaire (short)
- **HIV ab/ab q 3 monthly** and STI screen q 3 monthly in MSM
- 90 day supply of PrEP

Q 6 monthly visit with Provider

- Pregnancy test, Cr, RPR/Trep Ab, GC/CH(triple site) ,Hep C
- 90-day supply of PrEP, condoms





Barrier: Adherence

Adherence
=
Efficacy



<https://www.caringvillage.com/2018/02/09/the-top-five-medication-management-apps/>
<https://www.ripplephx.org/?p=5234>



TAF/FTC – 30
day Blister pack

Barriers: Adherence

Interdisciplinary
support

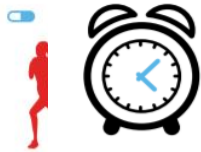
- Retention/adherence rates varies – higher in multidisciplinary scenarios 75%- 90%^{1,3}
 - **Pharmacist**¹ and **nurse models**⁴
- **Text messaging**² service or PrEPmate(**app**)⁵
 - Those who opted for text; more likely to remain in clinic (76% vs. 53%)²
 - App had better adherence to visits/ therapeutic levels (56 vs 40% @ 36 wks)
- Brief **behavioral intervention** (sexual health or adherence) → less missed pills/higher drug levels (96.6%vs 84%; p = 0.02)- NYC³

1. CROI 2017 Tung et al FEASIBILITY OF A PHARMACIST-RUN HIV PREP IN A COMMUNITY PHARMACY
2. CROI 2017 (Abstract 964)- Khosropour et al
3. CROI 2017 (Abstract 965) – Sarit
4. Gibson, S. et al. AIDS 2016 (Strut)
5. *Clinical Infectious Diseases*, ciy810, <https://doi.org/10.1093/cid/ciy810>

Overcoming Adherence Barrier



What should I do if I forget a dose?



- Take the missed dose as soon as you remember it.
However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.
- An occasional missed dose will not greatly impact overall effectiveness, but it is important to take the medicine every day. If you miss doses frequently, talk to your doctor.

What side effects can this medication cause?

- Most people do not have side effects while taking PrEP. However, you might experience some of the following when you begin taking the medication:
 - upset stomach
 - headache
 - vomiting
 - loss of appetite
- These side effects usually fade during the first month of taking PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

What other information should I know?

Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- fever or chills especially with sore throat, cough, rash or other signs of infection

What other information should I know?

- Do not let anyone else take your medication.
- Store your medicine in the container it came in, tightly closed, and out of reach of children.

Culturally Competent Care

Información básica sobre la PrEP

¿Es usted VIH negativo, pero tiene un alto riesgo de contraer el VIH? Si toma los medicamentos de la PrEP todos los días, estos pueden mantenerlo libre de la infección por el VIH.

¿Qué es la PrEP?

- La PrEP, o profilaxis preexposición, son medicamentos diarios que pueden reducir las probabilidades de contraer el VIH.
- La PrEP puede impedir que el VIH se establezca y se propague en el cuerpo.
- La PrEP es altamente efectiva cuando se toma diariamente según lo prescrito. La PrEP es mucho menos efectiva si no se toma consistentemente.
- Solo los condones protegen contra otras ETS, como la sífilis y la gonorrea.



¿Es la PrEP lo adecuado para usted?

La PrEP puede ser de beneficio si usted es VIH negativo y si **CUALQUIERA** de las siguientes condiciones aplican a usted:

Usted es un hombre gay o bisexual y

- tiene una pareja VIH positiva;
- tiene múltiples parejas sexuales, su pareja tiene múltiples parejas o si usted no sabe si su pareja tiene el VIH; y también
 - tiene relaciones sexuales anales sin condón, o
 - tuvo hace poco una enfermedad de transmisión sexual (ETS).

Usted es heterosexual y

- tiene una pareja VIH positiva;
- tiene múltiples parejas sexuales, su pareja tiene múltiples parejas o si usted no sabe si su pareja tiene el VIH; y
 - no siempre usa condones cuando tiene relaciones sexuales con personas que se inyectan drogas, o
 - no siempre usa condones cuando tiene relaciones sexuales con hombres bisexuales.

Usted se inyecta drogas y

- comparte las agujas, jeringas, u otros equipos para inyectarse drogas;
- está en riesgo de contraer el VIH a través de las relaciones sexuales.



Visite a su proveedor de atención médica

- Para averiguar si la PrEP es lo adecuado para usted.
- Cada 3 meses si está tomando los medicamentos de la PrEP, para repetir las pruebas de detección del VIH, surtir sus medicamentos y hacer seguimiento.
- Si mientras está tomando los medicamentos de la PrEP tiene algún síntoma que se ha vuelto intenso o no desaparece.
- Si no tiene un proveedor, visite www.preplocator.org para localizar uno.



¿Cómo puede obtener ayuda para pagar la PrEP?

- La mayoría de los planes privados y los planes estatales de Medicaid cubren la PrEP. Si tiene la cobertura de Medicaid, hable con su asesor de beneficios.
- Si tiene seguro médico, puede recibir asistencia del fabricante del medicamento o de una fundación de defensa del paciente para cubrir el copago.
- Si no tiene seguro médico, piense en inscribirse en uno de los planes del mercado de seguros, en el programa de asistencia del fabricante o en el plan de Medicaid de su estado si cumple los requisitos.
- Obtenga más información sobre cómo pagar la PrEP en www.PrEPcost.org.

Para obtener más información visite la página www.cdc.gov/hiv/spanish

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention



MS-200328_7

<https://www.cdc.gov/stophivtogether/library/prescribe-hiv-prevention/brochures/cdc-lsht-php-brochure-taking-prep.pdf>

<https://www.cdc.gov/hiv/pdf/library/factsheets/prep101-consumer-info.pdf>

Barriers to Retention

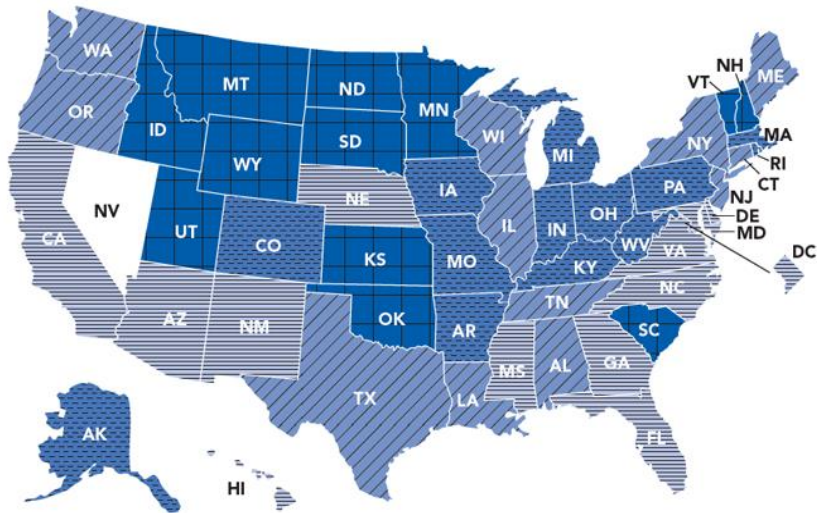
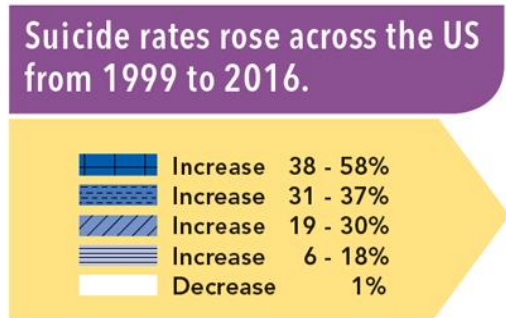
- Other Issues that affect retention

Barriers to Retention

Mental Health

Suicide rising across the US

More than a mental health concern



SOURCE: CDC's National Vital Statistics System; CDC Vital Signs, June 2018.

Suicide rates rose across the US from 1999 to 2016.

State	Increase/Decrease	Overall Percent Change
US (national)	Increase	25.4
SC	Increase	38.3

Barriers to Retention

- Mental Health in LGBTQIA+

- LGBTQ+ adults >twice as likely as heterosexuals to have MH condition¹
 - Includes suicidal thoughts/attempts ; more serious symptoms ³
- LGB high schoolers >4X more likely to attempt suicide vs

- Trans adults in states with more LGBTQ-affirming environments are < likely to have attempted suicide⁷

¹ https://suicidepreventionlifeline.org/wp-content/uploads/2017/07/LGBTQ_MentalHealth_OnePager.pdf

² Kann, *Sexual Identity, Sex of Sexual Contacts, and Health-Related Behaviors Among Students in Grades 9–12, 2016*

³ Medley, *National Survey on Drug Use and Health*. <https://www.samhsa.gov/data/sites/default/files/NSDUH-Sex>

⁴ 2015 The National Gay and Lesbian Task Force and the National Center for Transgender Equality

⁵ Chung, et al. Positively Trans: Initial report of a national needs assessment ... Oakland, California: Transgender Law Center

⁶ Marshal, *J Adolesc Health*, 2011; ⁷ Perez-Brumer 2015

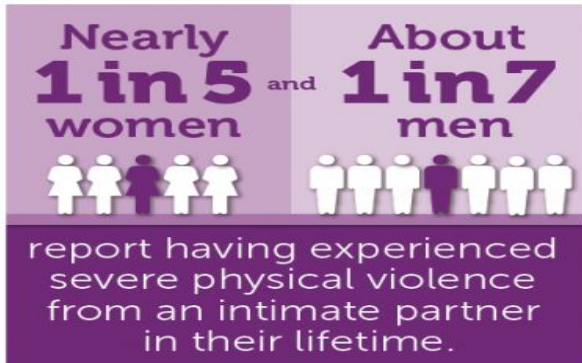
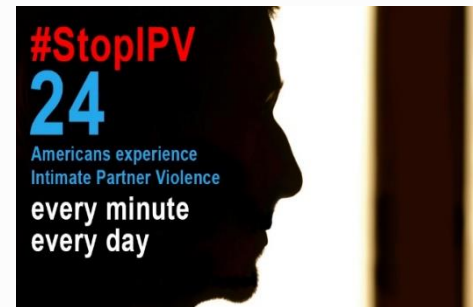


In state legislatures across the country, extreme lawmakers are filing legislation to prohibit medical professionals from providing medically necessary gender-affirming care to transgender patients. These bills run counter to the best medical practices that are supported by major medical associations, including the American Medical Association, the American Academy of Pediatrics, and the American Academy of Family Medicine. It's more vital than ever that medical professionals – especially those in Southern states who serve transgender young people or any transgender people – speak out against these attacks. If you are a physician, nurse, physician assistant, or psychiatrist, please add your name to this sign-on letter, which appears below the sign-up form.

[JUMP TO SIGN-UP FORM](#)

Barriers to Retention

- Intimate Partner Violence



Intimate Partner Violence (IPV) and PrEP^{3,4,5}

- Recent IPV (3 mths) associated with a lower adherence
- Women reported taking pills and pill counts (unused) pills suggested they took their PrEP (VOICES trial)
 - BUT serum drug levels undetectable
- Themes of stigma, fear, relationship conflict and lack of understanding

³Roberts ST, et al. CROI 2015. Abstract 980; ⁴Saag MS. N Engl J Med. 2015; 372:564

⁵van de Straten A, et al. JIAS. 2014;17 (supple):19146

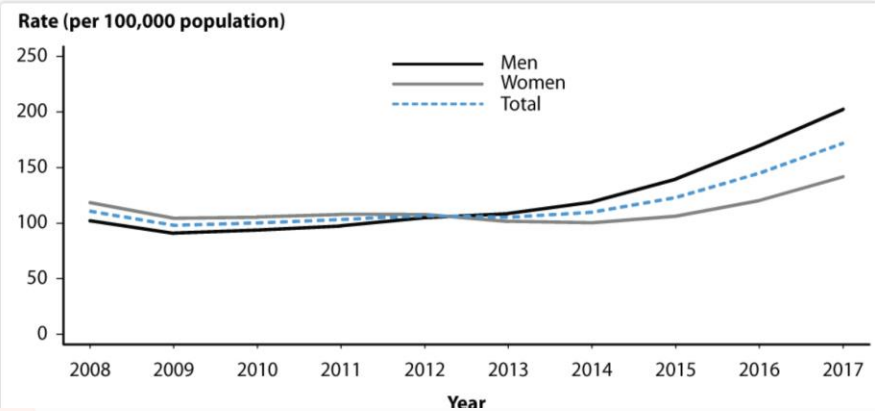
Barriers: Risk Compensation

- What is risk compensation
 - Introduction of an intervention that reduces the perceived risk of the behavior → increase risky behavior
- Older studies have found this not to be true
 - i-PrEx trial, there was no change in reported sexual practices from baseline through follow-up and no difference in overall syphilis incidence in the perceived treatment group
 - BUT these studies emphasized condom use

Grant NEJM 2010

STI Rates – Gonorrhea/Chlamydia 2017

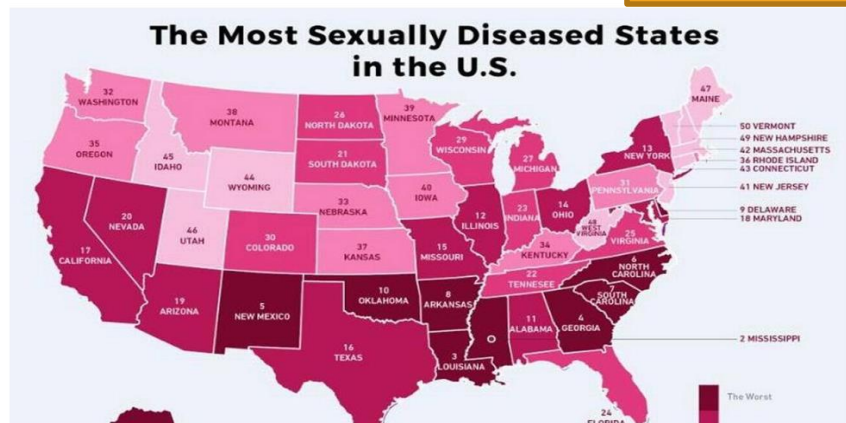
Figure 18. Gonorrhea — Rates of Reported Cases by Sex, United States, 2008–2017



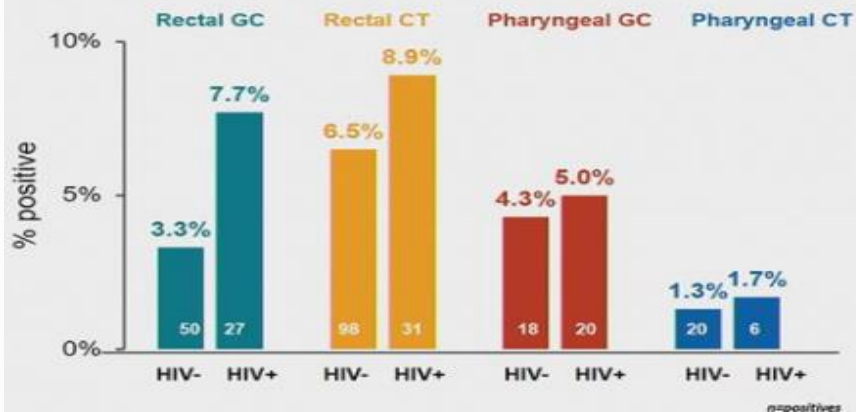
South Carolina is the 7th most 'sexually diseased' state in the nation

BY MICHAELA BROYLES
OCTOBER 26, 2017 11:56 AM, UPDATED OCTOBER 26, 2017 12:07 PM

Based on
GC/CT #



Extragenital Gonorrhea & Chlamydia, MSM, NHBS 2017



STI in 2017	Rank	State	Cases per 100,000	National average per 100,000
GC	4	SC	254	172
CT	5	SC	650	529

<https://www.cdc.gov/std/stats17/figures/18.htm>

Identifying Candidates for PrEP

- Based on STDs: Syphilis Rates Nationally

Primary and Secondary Syphilis — Rates of Reported Cases by Region, United States, 2008–2017

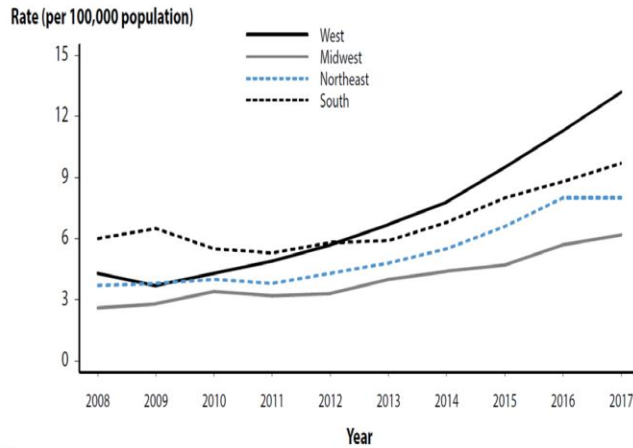
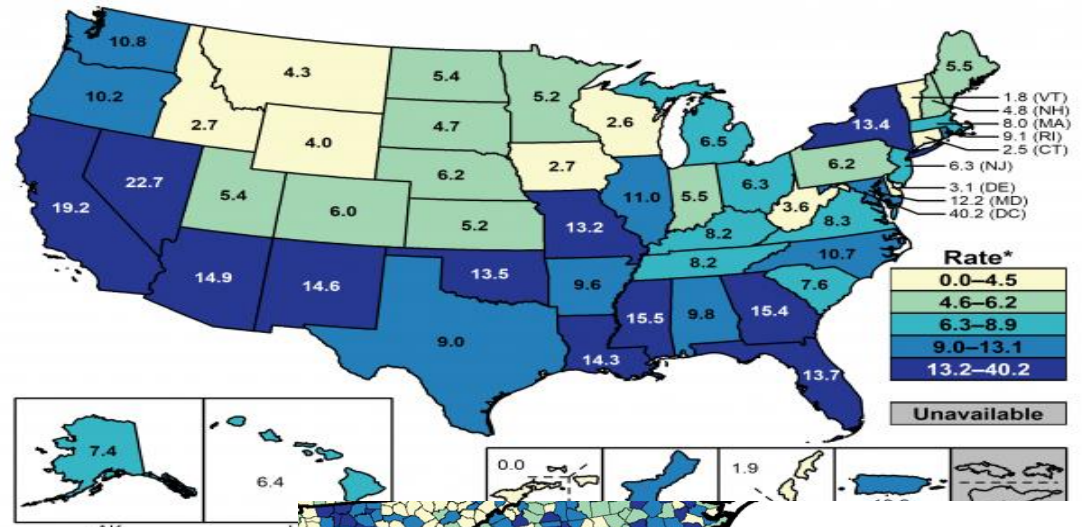
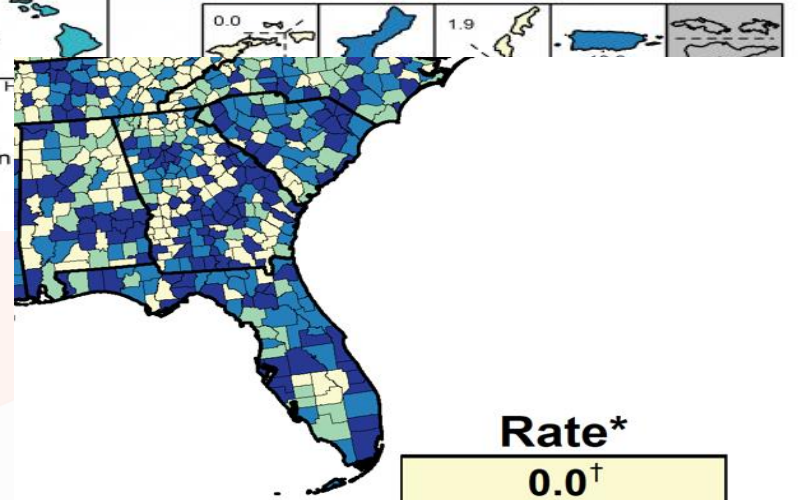


Figure 37. Primary and Secondary Syphilis — Rates of Reported Cases by State and Territory, United States, 2018



* Per 100,000.
NOTE: Section A1.11 in US territories.



Rank	State	Cases	Rate per 100,000 population
22→25	SC	361	7.3→7.6



Barriers: Risk Compensation

- Can we blame PrEP

■ Baseline STI rates

- 60% with STI in 12 mths prior (PROUD)
- 38% of trans had STI in prior 6 mths (iPrEX Trans³)
- 27 % had STI at beginning of study (IPERGAY)

□ During studies

- Risk compensation⁴
 - 30% had more condomless sex @4 mths
 - STI overall increased
- 30-35% had STI^{1,2}
 - Rectal chla & urethral GC

□ PrEP independently asso. with new STI⁵

- Rate of 24.6 per 100 person years, vs 10.4 per 100 person-years among non PrEP users

1 Volk JE, Marcus JL. Nonnew HIV infections with increasing use of HIV PrEP. CID .2015

2. Volk, J et al. JAIDS 2016;73(5):540-46 (Kaiser:)

3 Deutsch HIV PrEP in transgender women: iPrEx trial. Lancet HIV. 2015

4. STRUT Gibson, S. et al. AIDS 2016

5 Mayer STI in MSM Boston community healthcenter (2005-2015). Open Forum Infect Dis. 2017

Screen more

!!!!!!



PrEP in Special Populations

- Additional Barriers to overcome

1. Women
2. Adolescents
3. Transgender

Barriers to PrEP in Cis-Women



- Why are women at risk for HIV
 - **Unaware of their male partner's risks** (IVDU or having sex with men) → No condoms (93% of HIV-negative high-risk women had vaginal sex without a condom; 26% had anal sex without condom²)
 - **At higher risk for getting HIV during vaginal/anal sex** with their sex partners
 - HIV **testing rates lower** among women (20% who had anal sex had HIV test³)
 - **STI** (gonorrhea, syphilis) greatly increase the likelihood of HIV transmission
 - Women s/p sexual abuse more likely to **engage in sexual risk behaviors** - sex for drugs, multiple sex partners, or having sex without a condom

“Southern women are sometimes too polite to ask” -TC

1 <https://www.cdc.gov/hiv/group/gender/women/index.html>

2. behavioral survey (<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-number-19.pdf>)

3. Evans et al Am J Obstet Gynecol, 2018- Low HIV testing rates among US women who report anal sex and other HIV sexual risk, 2011-2015

PrEP for Women



The CDC estimates **468,000 U.S. WOMEN** are eligible for PrEP

Women's health care providers are uniquely positioned to screen, counsel about, and offer PrEP




#PrEPForHer
DOMINATE
your sex life

PrEP is a safe, daily pill that helps prevent HIV.

NCHRPSTP - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention

Women account for **1 in 5** new HIV diagnoses.¹



African American/black women have a disproportionately higher lifetime risk of infection (1 in 54 black women compared to 1 in 256 Hispanic/Latina women and 1 in 941 white women).² Although PrEP is a highly effective, woman-controlled prevention option for HIV-negative women, PrEP use among women has been very low (especially among black women).³

CDC invited subject matter experts involved in HIV prevention efforts for women to participate in a web-based series to discuss barriers to PrEP implementation.

Summary of Key Findings*

Barriers	Suggested Activities
<ul style="list-style-type: none"> Women's lack of knowledge about PrEP, HIV-related health literacy, and HIV risk perception Challenges identifying women who might benefit from HIV prevention with PrEP and assessing women's risk of acquiring HIV Healthcare provider bias based on a woman's race, social class, or sexual behavior that might hinder effective communication about HIV risk and PrEP High costs associated with PrEP Lack of resources and infrastructure to provide PrEP for women in settings and venues they frequently use for healthcare 	<ul style="list-style-type: none"> Develop and disseminate gender and culturally appropriate materials for women and clinicians to: <ul style="list-style-type: none"> Increase women's knowledge/awareness of PrEP and HIV risk Increase clinicians' PrEP knowledge and clinical skills, including providing PrEP care and effectively assessing HIV risk Equip clinicians with the skills to cultivate respectful patient-provider interactions that enable shared decision making Conduct research to identify: <ul style="list-style-type: none"> Best practices for identifying women who might benefit from PrEP Effective PrEP implementation models

Disclaimer: This is a summary of the discussion series held November 2016 through May 2017. It reflects ideas and thoughts shared by individual participants, and is not intended to represent the collective view of participants.

Conclusions

Increasing PrEP uptake will require careful attention to personal, social, and structural barriers to PrEP awareness, access, and utilization. Potential actions to address barriers:

- Creating/revising PrEP materials to be overtly inclusive of women (e.g., language, images).
- Conducting or supporting health services research to address barriers.
- Developing or strengthening existing partnerships to promote PrEP implementation for women.

References

1. CDC 2017. HIV surveillance report, 2016. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>; Hays et al. 2017. <https://doi.org/10.1016/j.amepre.2017.02.003>.
2. Bush et al. 2016. https://www.aidshealth.org/wp-content/uploads/2016/07/GLD_Bush-PrEP-Place-Utilization-est-June-2016.pdf



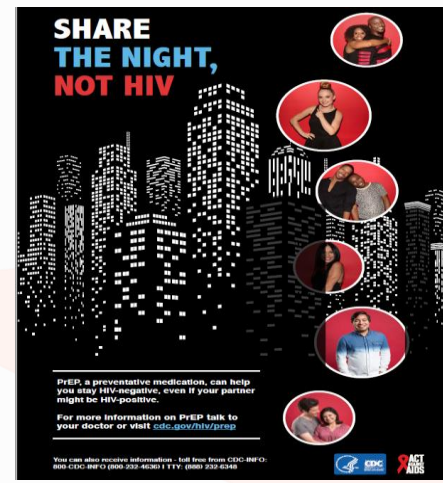

"I've lost too many people to AIDS because of ignorance. Not knowing your status will hold you back from staying healthy and strong. Get tested today."

— Anna Marie Horsford, Actress

I'M DOING IT
Testing for HIV

#DoingIt

Testing is Fast, Free, and Confidential | cdc.gov/DoingIt



SHARE THE NIGHT, NOT HIV

PrEP, a preventative medication, can help you stay HIV-negative, even if your partner might be HIV-positive.

For more information on PrEP talk to your doctor or visit cdc.gov/hiv/prep

You can also receive information - call free from CDC-PrEP: 800-CDC-PrEP (686-724-6341) | TTY: (800) 232-6348

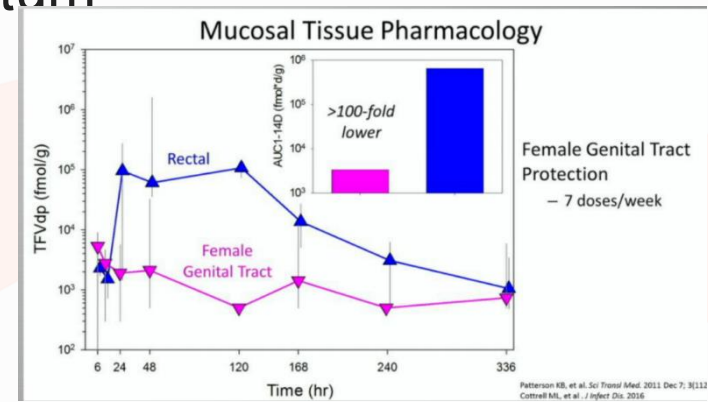
1. <https://hiveonline.org/prep4women-disparities/-UCSF>
2. DC'S PrEP AWARENESS CAMPAIGN <https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women-and-PrEP-discussion-series.pdf>

PrEP in Women: Why didn't it work?

- 2 large studies (FEM-PrEP and VOICE trials), PrEP was not effective in preventing HIV^{1,2}
 - Non-adherence was a major factor in study failure
 - Overall adherence <30%
 - More common in young women <25 yo
 - Differences in vaginal concentrations of drug plausible role in lack of efficacy- > 100 fold lower than rectum

- Women have to work harder
- Need to focus counselling efforts on cultural/social barriers

1 Van Damme L, et al. N Engl J Med. 2012;367:411-422
2 Murrain JN, et al. N Engl J Med. 2015;371:509-518
3 Patterson STM 2011 and Cottrell JID 2016

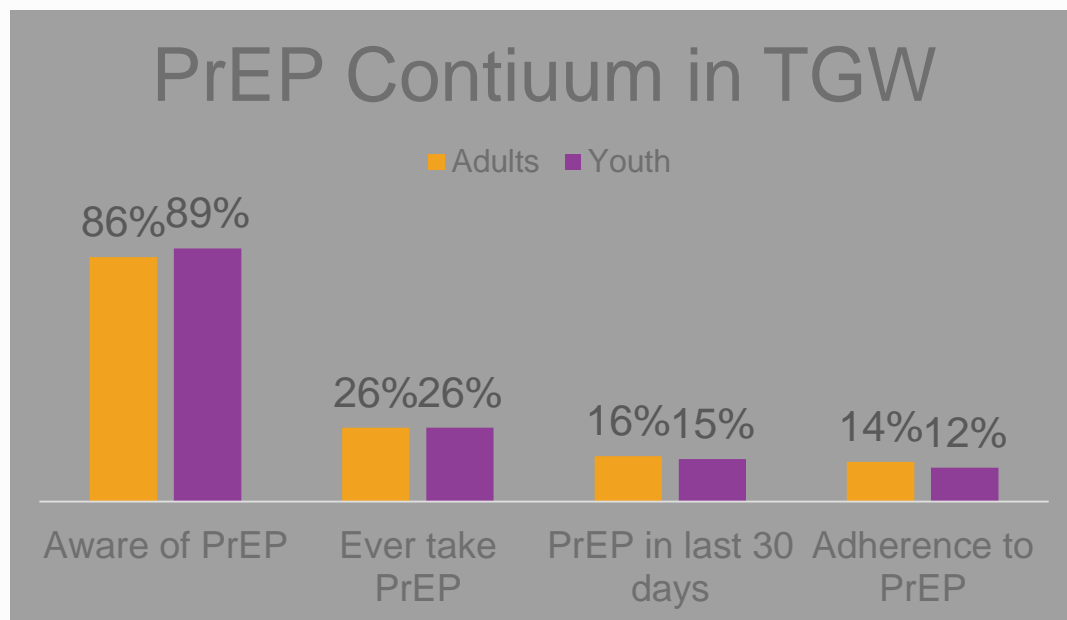


PrEP continuum

The Reality for Transgender

■ The LITE Study

- HIV uninfected TGW in 6 cities (including Southern U.S.)
- 3 months visits with testing and survey
- App-based GPS data collection



Adherence
counselling
crucial

<http://www.croiwebcasts.org/console/player/41371?mediaType=audio&>

PrEP fears to be addressed

The Reality for Transgender

iPrEx Trial had 339 MtF (no trans men)³

- PrEP did not affect risk behavior
- Overall adherence poor, less for MtF compared to MSM
- if > 4 tablets/week, rate of infection per 100,000 pt/yr = 0
- Does PrEP interfere with gender affirming hormones? No
 - PrEP does not affect the efficacy of sex hormones and PrEP^{1,2}
 - But hormones can drop PrEP levels → Ensure Compliance
 - When not addressed with patients, adherence with PrEP declined due to fear of drug-drug interaction with hormones³

Similar barriers to adherence as women

¹ WHO endorsed

² Kearney Lack of effect of TDF on pharmacokinetics of hormonal

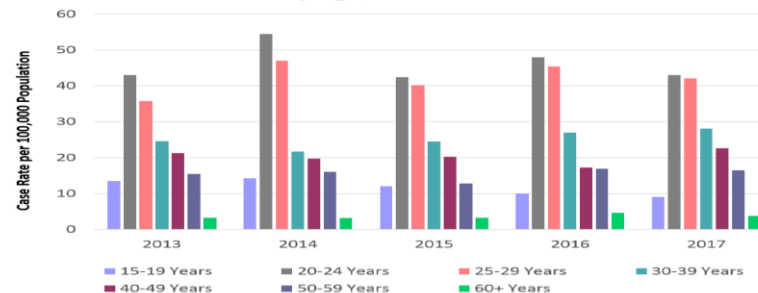
³ Deutsch HIV PrEP in transgender women: iPrEx trial. Lancet HIV. 2015

contraceptives. *Pharmacotherapy*. 2009

PrEP and Adolescents

- PrEP Adherence is poor in this group
 - Chicago MSM ages 18-22 yrs(n=68)- adherence declined to 20% by week 24(ATN 082)²
 - No seroconversions
- Also consider local laws and regulations on autonomy²
 - Age of majority in SC in 18 years²
 - Age of consent for HIV is 16 years^{3,4}
 - Appears on insurance

Figure 2.08: S.C. HIV/AIDS Incidence case rate by age, 2013-2017



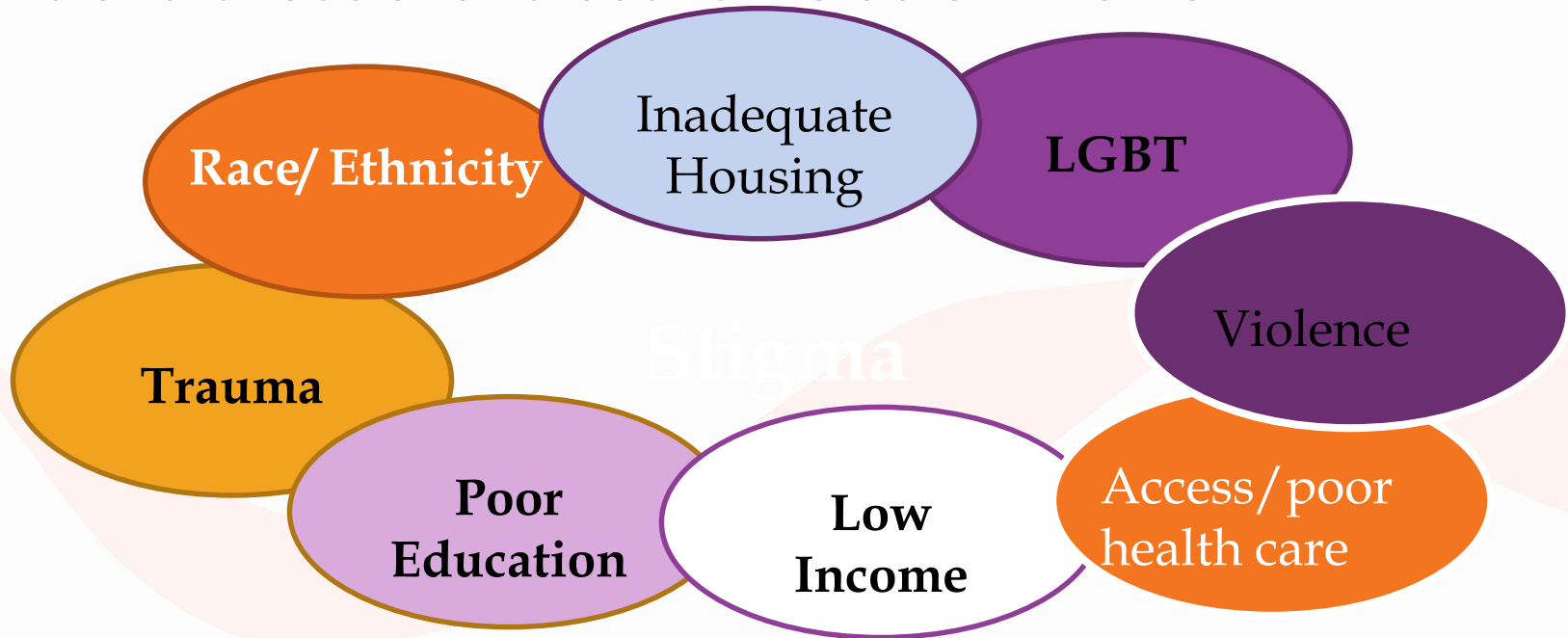
- Discuss risk and benefits
- Adherence counselling crucial

1. http://www.scdhec.gov/Health/docs/stdhiv/pp_CH1-EpiProfile.pdf
2. Hosek et al. The acceptability and feasibility of an HIV PrEP trial with young MSM. *J Acquir Immune Defic Syndr*. 2013
3. http://www.scdhec.gov/Health/docs/stdhiv/pp_CH1-EpiProfile.pdf
4. Culp L, State adolescent consent laws and implications for HIV pre-exposure prophylaxis. *Am J Prev Med*. 2013
5. <https://www.hivlawandpolicy.org/states/south-carolina>
6. Code of Laws Title 63 South Carolina Children's CodeSECTION 63-5-340. Minor's consent to health service

Social Determinants of Health

Additional Hurdles to jump

- **Social Determinants of Health** = integrated and overlapping social structures and economic systems that impact population health
- Health disparities inextricably linked to a complex blend of social and economic determinants



Challenges: People of Color Engagement

A Welcoming Environment

- Non judgmental
- Understand Stigma or fear of health care system
- Engage patients /language
 - Staff
 - Posters



TREATMENT AND PREVENTION

Antiretroviral Therapy
The use of medications to treat HIV is called Antiretroviral Therapy (ART). ART decreases the amount of HIV in the body. ART also stops HIV from multiplying. Though ART does not cure HIV, it can help people to live with HIV continue to lead healthy lives, and also reduce the likelihood of transmitting HIV. This is called having an undetectable viral load, or U=U (undetectable=untransmittable).

Condom Use
HIV is spread through contact with blood or bodily fluids, so the way to reduce the chance of HIV can be prevented by using condoms with these fluids. Condom use during vaginal or anal sex is a very effective way of preventing HIV.

PrEP
There is also a daily pill called PrEP (Pre-Exposure Prophylaxis) that can prevent HIV by 92% in women. If you are HIV positive, treatment can lower your viral load, for people where the virus is undetectable and therefore untransmittable. If your partner is HIV negative, PrEP can help in decreasing the chance of your partner acquiring HIV. Also, there is a series of pills called PrEP which can be taken if you believe you have had sex contact with the HIV virus.

Regular Testing
Getting tested for other STIs regularly is also an important tool in preventing the spread of HIV, as HIV is more transmittable when in the company of other STIs.

Payment Assistance
Since the passage of the Affordable Care Act, most jobs

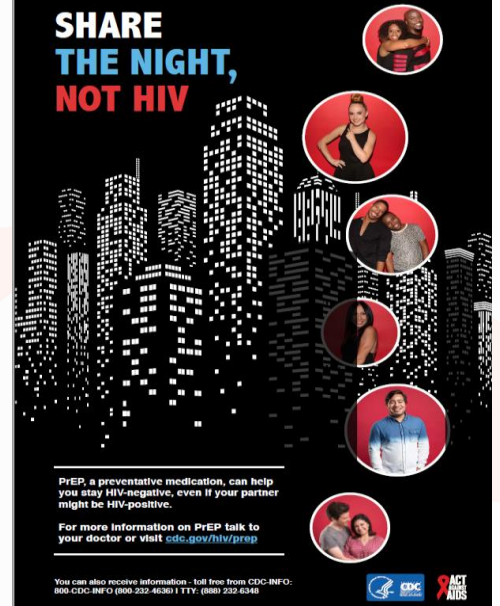
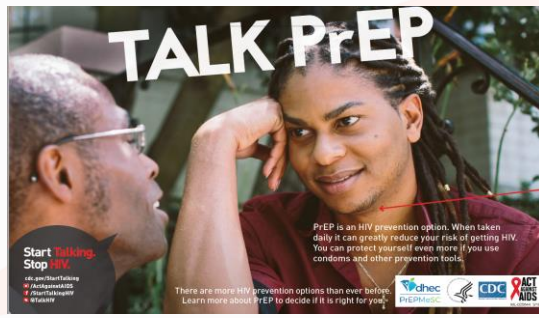
ADDITIONAL RESOURCES

General Information
www.blackaids.org
www.gettingstarted.org/blackaidsforafricanamerican
www.hivonline.org
www.cdc.gov/hiv/about/index.html
www.cdc.gov/hiv/prep/asktheexpertseries/asktheexpertseries.html
www.gettingstarted.org
www.gettingstarted.org

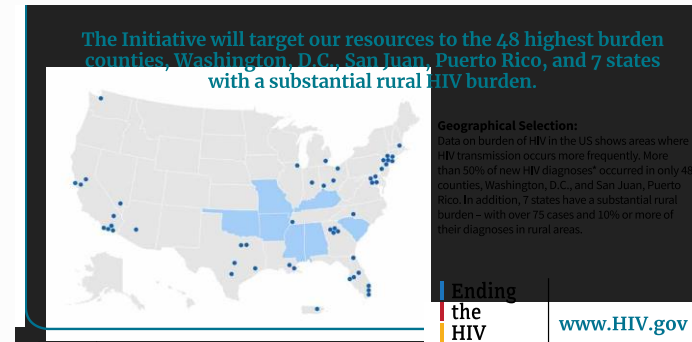
General Information on PrEP
www.blackaids.org/news-and-events/black-women-prep
www.blackaids.org/prep
www.hivonline.org/prep/basics
www.gettingstarted.org/prep/basics
www.gettingstarted.org/prep/basics

Payment Assistance Programs
www.gettingstarted.org/prep
www.gettingstarted.org/prep
www.gettingstarted.org/prep
www.gettingstarted.org/prep

Your Rights and HIV
www.gettingstarted.org/prep
Guidelines for People Living with HIV who are Transmitted with or Are Taking, Considered Protection for HIV Medication or Exposure: The Center for HIV Law & Policy: www.hivlawandpolicy.org
www.gettingstarted.org/prep



Challenges: Rural US



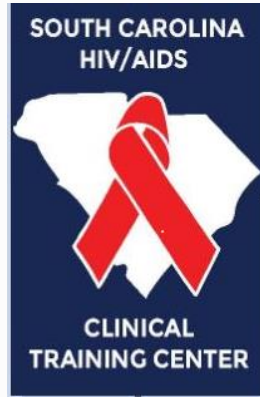
- Rural residence -risk factor for late HIV diagnosis
 - Less likely to **obtain HIV testing** and Rx
- Challenges of rural pts with HIV (Can extrapolate to PrEP care):
 - Stigma and social isolation
 - Long travel distances to care
 - Lack of transportation
 - Lack of providers with “HIV” expertise
 - 95% of rural counties lack “HIV” providers compared to 69% of urban counties



Vyavaharkar, M. (2013). HIV in Rural America. A technical report by the SCRural Health Research Center.
Ohl ME, et al. BMC Public Health. 2011; 11:681.; Weis KE, et al. J Rural Health. 2010; 26(2):105-12.;



SOUTH CAROLINA HIV PrEP INITIATIVE



Overcoming Barriers to PrEP



HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
EDUCATION TRAINING CONSULTATIVE SUPPORT CO-MANAGEMENT

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