



**Increasing Uptake of PrEP among
Urban and Rural Southern
Black Women**

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Disclosures

Federal Grants/Funding

- NIH/NIMH 1K23MH112417-01 (Elopre PI)
- Robert Wood Johnson Foundation, Harold Amos Scholar (Elpore PI)
- Gilead

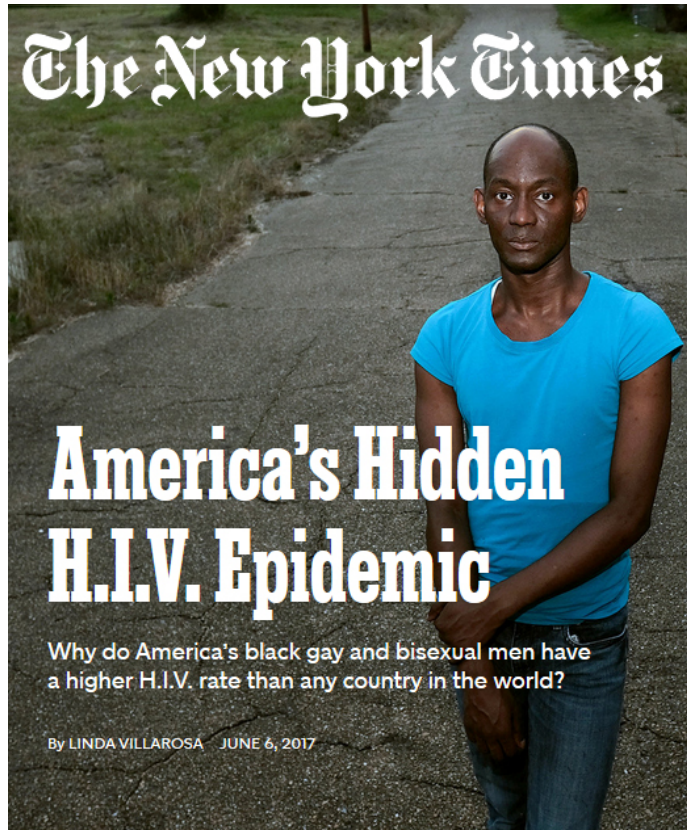
Contracts/Consultation

- MediQ

Objectives

- Understand the indications for PrEP for heterosexual women
- Evaluate the disparate uptake of PrEP based on race/ethnicity and potential for augmented HIV health disparities
- Review the literature to understand barriers for uptake of PrEP among black women in urban and rural areas

Domestic HIV Epicenter: US Deep South



National HIV/AIDS
Strategy: (Right: People,
Places, Practices)

- **Black women**
- **Deep South**
- **Biomedical prevention**

Domestic HIV Epicenter: US Deep South

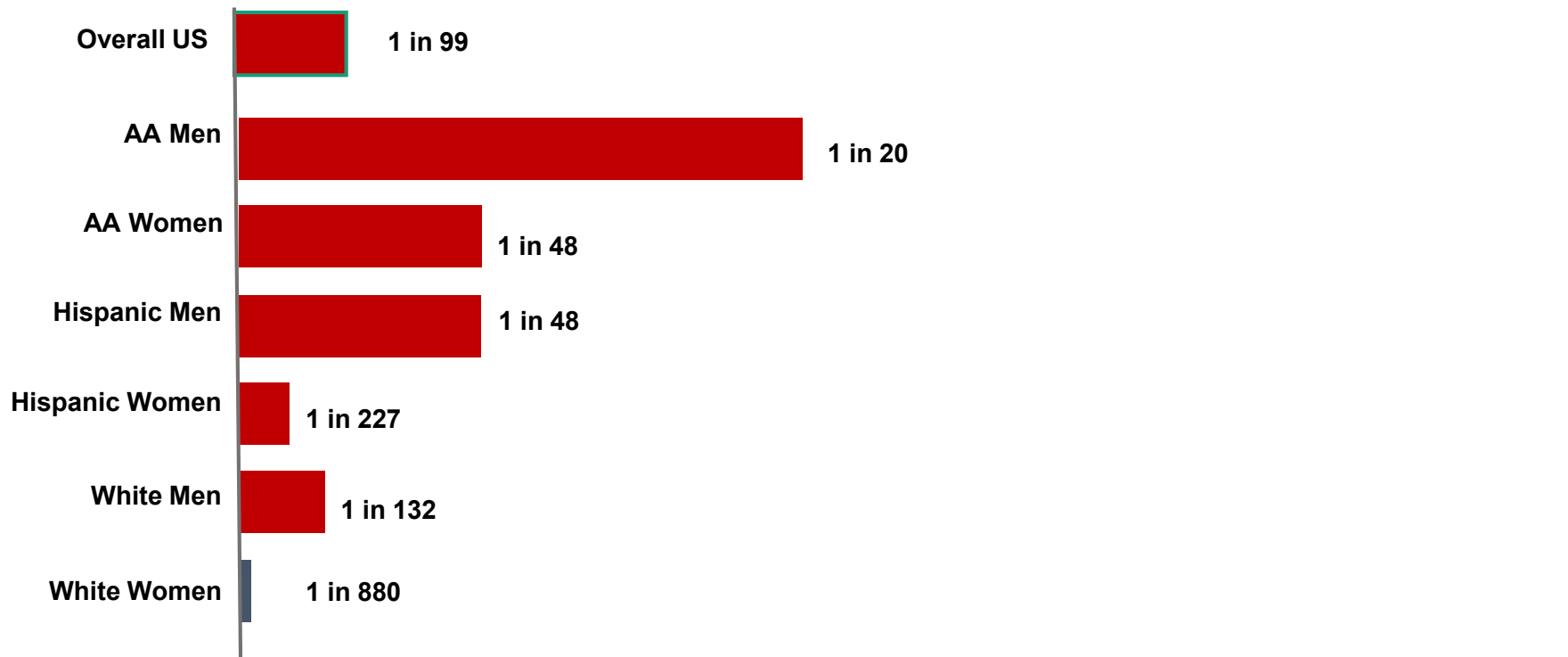


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African-Americans Have the Highest Lifetime Risk of HIV Diagnosis

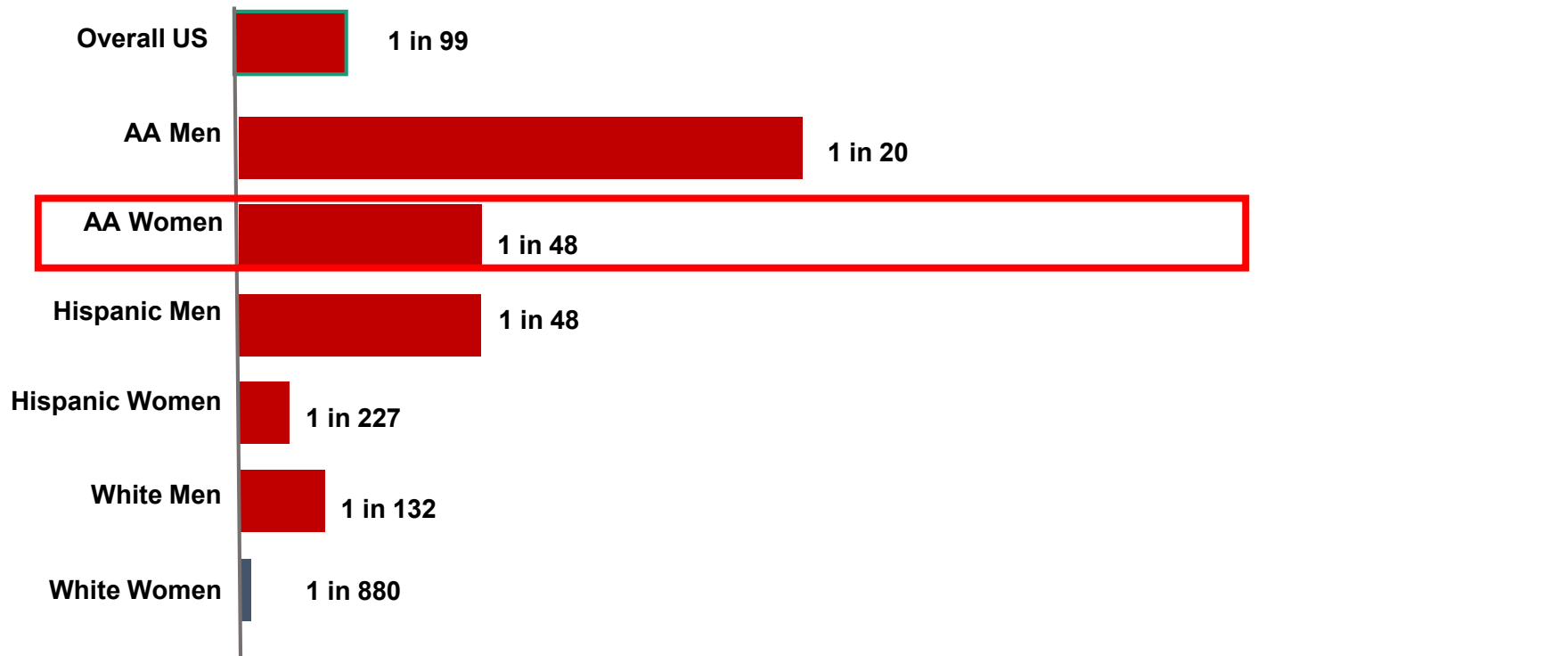
Lifetime Risk of HIV Diagnosis by Race/Ethnicity



Availability of FTC/TDF for PrEP and other prevention methods are urgently needed to reduce new HIV infections

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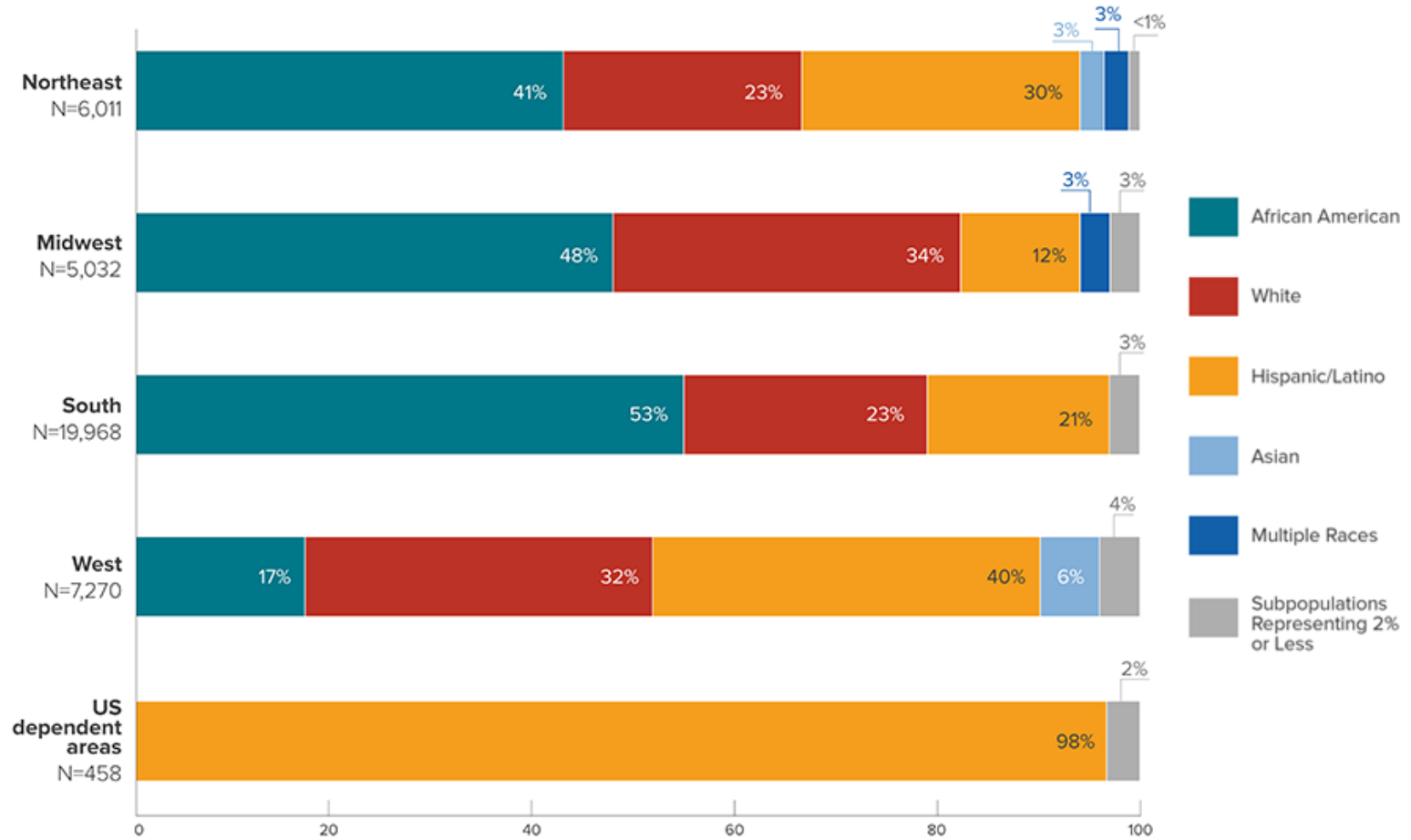
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HIV in the Southern U.S.

New Diagnoses in the US by Race/Ethnicity and Region of Residence, 2017



HIV Pre-Exposure Prophylaxis (PrEP)

- Approved July 2012 by FDA
- Tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)
- 92% efficacy with consistent use

PrEP:
*HIV PREVENTION
WITH JUST
1 PILL A DAY*



Estimated Number of Adults Who Could Benefit from PrEP, 2015

	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
Total who could potentially benefit from PrEP	813,970	258,080	72,510	1,144,550

Notes: PrEP=pre-exposure prophylaxis; data for "other race/ethnicity" are not shown



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

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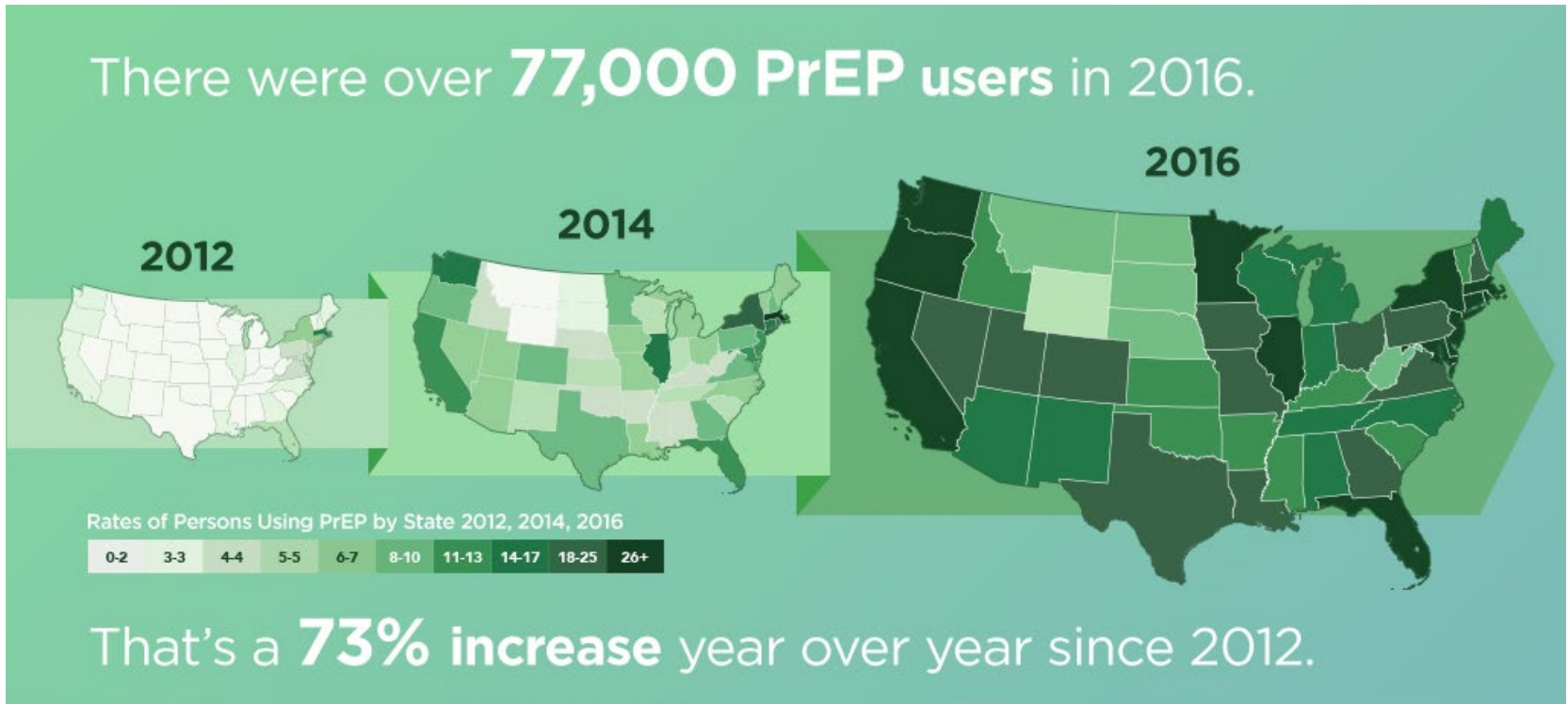
Increase in PrEP Prescriptions in the U.S.

There were over **77,000 PrEP users** in 2016.

2016

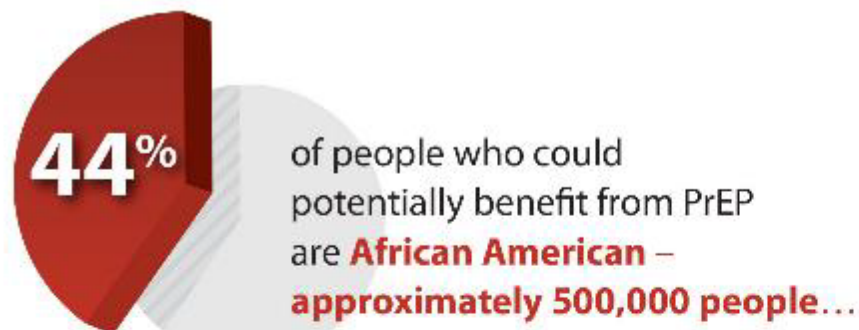
2012

2014



That's a **73% increase** year over year since 2012.

Disparate Utilization and Prescription of PrEP



...but only **1%** of those – **7,000 African Americans** – were prescribed PrEP*

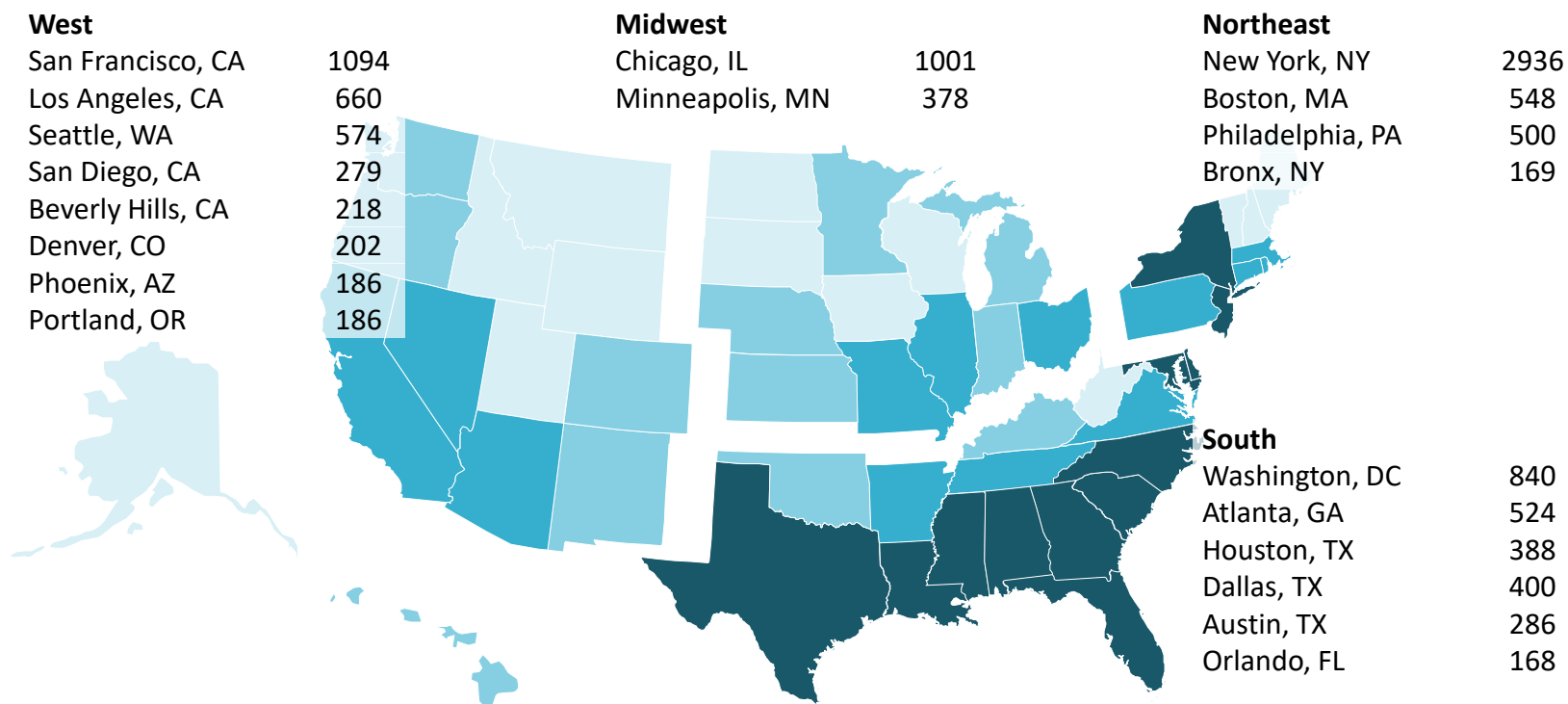


...but only **3%** of those – **7,600 Latinos** – were prescribed PrEP*



Top 20 US Cities with PrEP Use (2015)

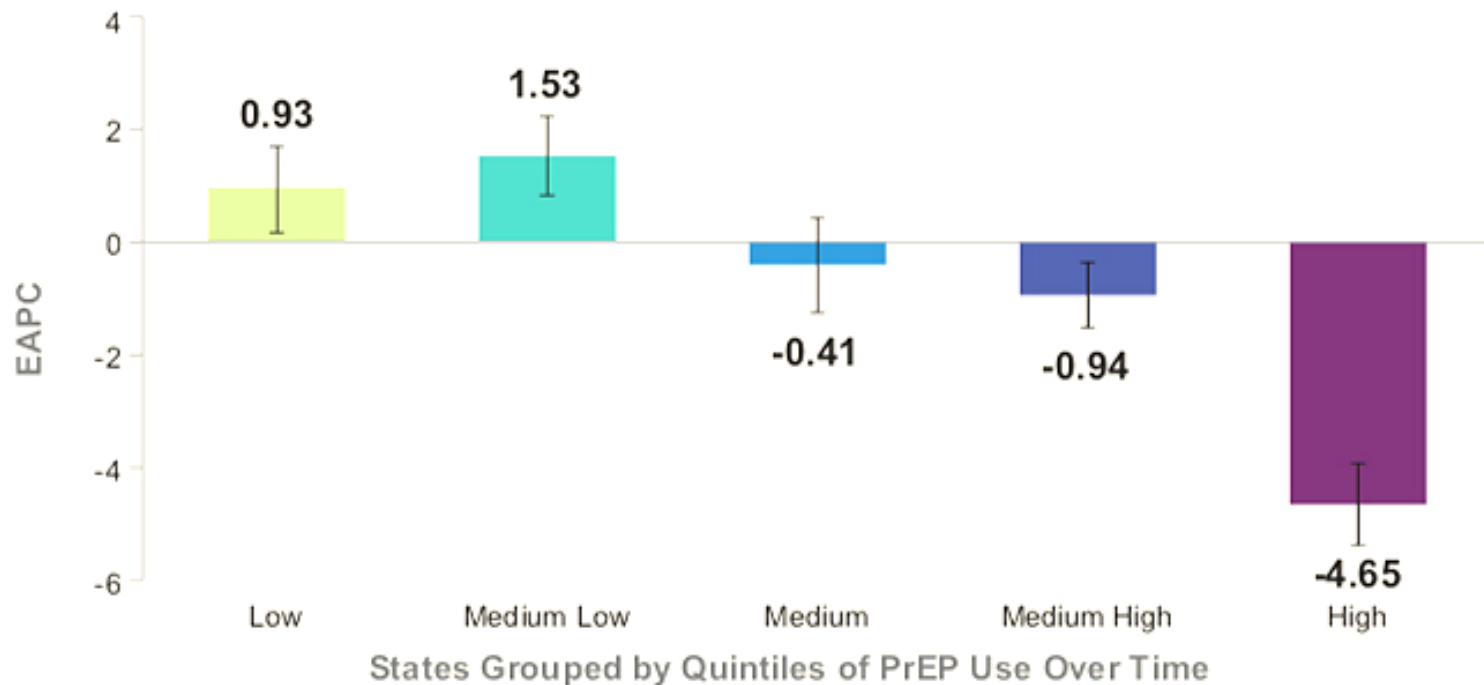
Total Number of Individuals Prescribed FTC/TDF for PrEP in 2015



2015 accounts for 39-55% of starts in each city



Decreased HIV Rates with High PrEP Use



	Low PrEP Use Quintile	High PrEP Use Quintile
Unadjusted EAPC in HIV diagnosis (95% CI)	+0.9 (+0.2, +1.7%)	-4.7 (-5.4, -3.9)
Mean prevalence of FTC/TDF PrEP use in 2016, n/N (%)	33/1000 (3.3)	110/1000 (11)

Adherence Variable among Women

Study Name	Population	N	Results	Efficacy by Blood Detection of TFV, %
FEM-PrEP Kenya, S Africa, Tanzania	Heterosexual Women	2120	FTC/TDF: futility	TFV levels: 35-37% un-infected TDF/FTC
VOICE South Africa, Uganda, Zimbabwe	Heterosexual Women	5029	TDF: futility Vaginal TFV gel: futility FTC/TDF: futility	TFV levels: 25-30% non-placebo group
FACTS South Africa	Heterosexual Women	3844	Vaginal TFV gel: futility	20% participants reported high adherence
Partners PrEP Kenya, Uganda	Heterosexual discordant couples	4758	TDF: 67% efficacy FTC/TDF: 75% efficacy	86 (TDF) 90 (TDF/FTC)
HPTN 067 ADAPT South Africa	Heterosexual Women	179	FTC/TDF Open Label Study – 75% daily, 63% time driven and 53% even driven	

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Grant RM, et al. Lancet Infect Dis. 2014; 14:820-829. 3. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 4. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 5. Choopanya K, et al. Lancet. 2013;381:2083-2090. 6. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 7. Marrazzo J, et al. CROI 2013. Abstract 26LB.



Why was Adherence so Variable?

- Delivery modality for PrEP
 - Gel vs. oral (consistency of gel)
- Contextual Factors : gender roles, HIV stigma (ARV associated with illness) and social acceptance of product use
- Partner awareness and support to adhere to regimen
- Placebo-controlled trial vs. Open label
 - Unknown efficacy of products and medical distrust

Corneli et al. PLOS One. 2015

Van der Straten PLOS One 2014.

Amico et al. AIDS and Behavior 2017



Adherence Impacts Efficacy

- Sex hormones in the female genital tract leading to variable drug concentrations
- 6 doses per week are required to block HIV transmission in vaginal tissue
 - 2-3 doses per week in colorectal tissue
- Robust adherence support is necessary for women to effectively use PrEP

Indications for PrEP Use for Women

Indications for Heterosexual Women

Any sex with an opposite sex partner in the last 6 months

Not in a monogamous relationship with a recently tested HIV-negative partner

AND at least 1 of the following:

inconsistent condom use with partner(s)

STI in the pat 6 months

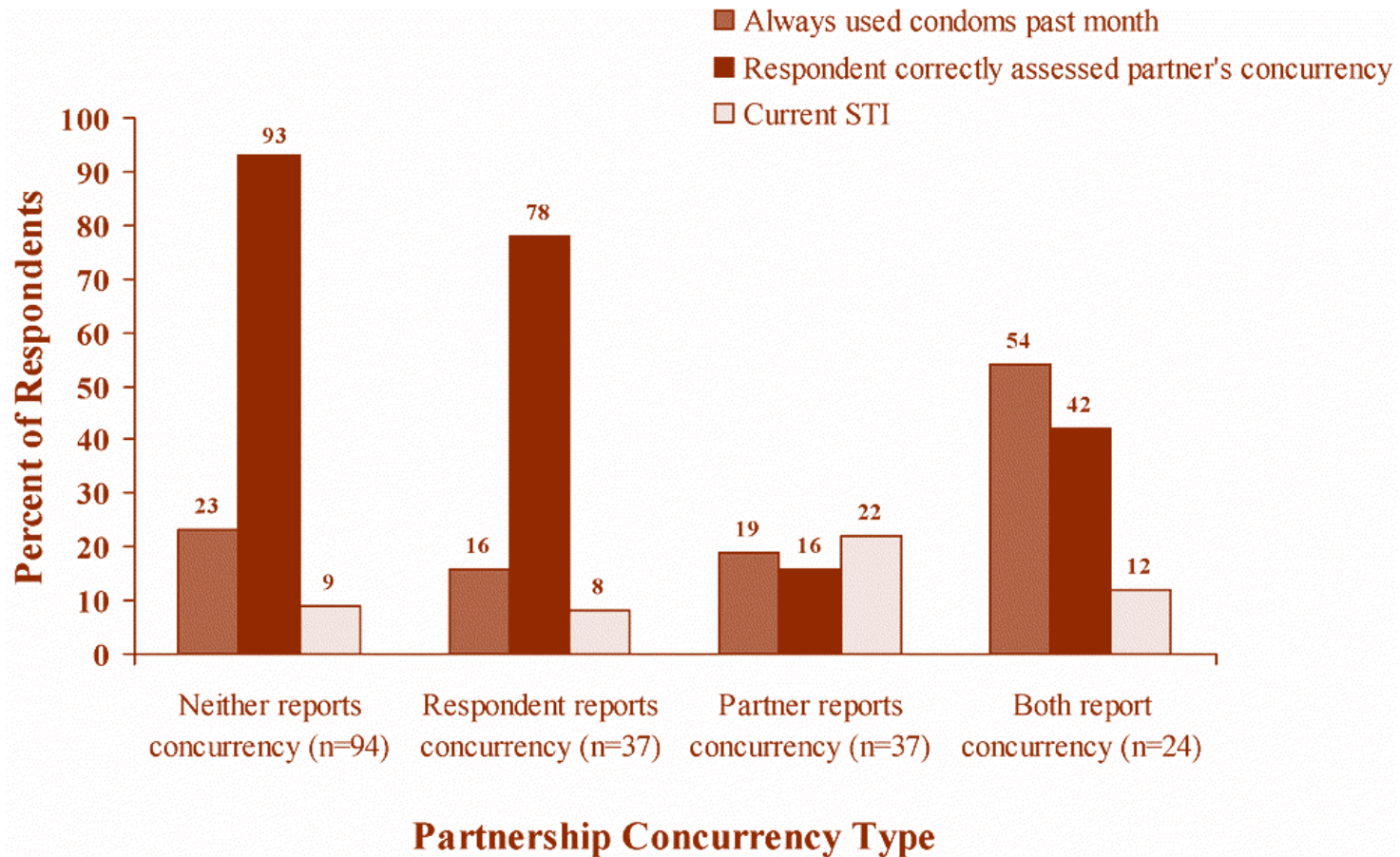
Serodiscordant relationship male partner



PrEP: Contraception and Pregnancy

- PrEP does not reduce contraceptive efficacy
- Peri-conception PrEP experience growing and appears safe
- Data indicates that PrEP is safe during pregnancy
 - Potential risks and benefits of PrEP medication use during pregnancy should be discussed

Do People really Know Their Sex Partners?





High-Risk Sexual Behavior among Urban Black Women

Individual-Level Barriers:

- Protective Factors – Ethnic identity; high self-esteem in relation to condom negotiation, self-efficacy and partner communication

Partnership-Level Barriers:

- Economic inequalities, various social norms about gender and relationships that may discourage condom use, and heterosexual partnerships defined by gendered power differences



Negotiating Condom-Use

- Main partners, condomless vaginal sex
 - Predictors: IPV
 - Protectors: Positive condom attitudes and partners not resisting condom use
- Non-main partners, condomless vaginal sex
 - Predictors: IPV
 - Protectors: Greater decision-making power, partners not resisting condom use and positive condom attitudes



What Factors Contribute to Risk in Rural Areas?

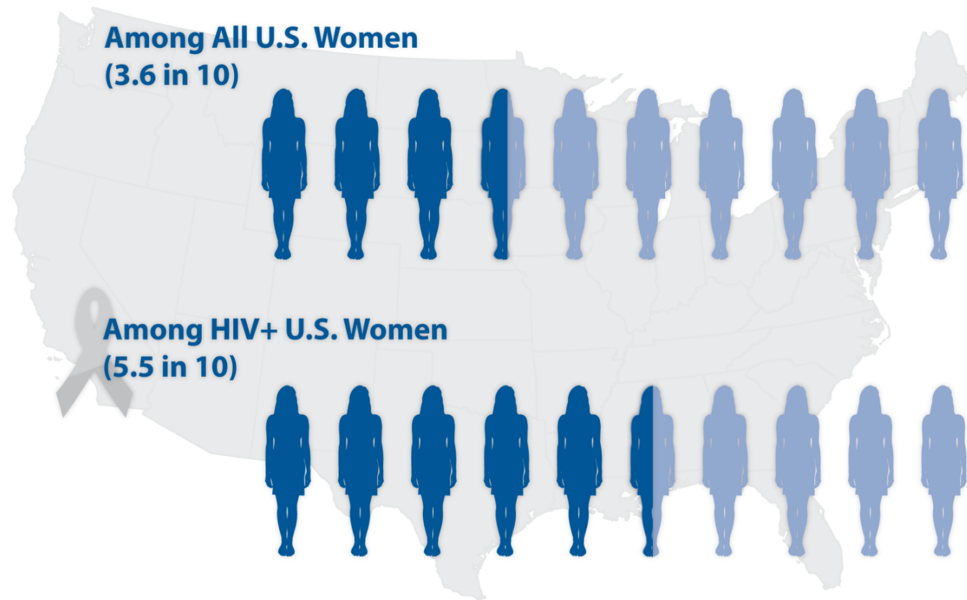
- **Individual factors** – High sexual coercion, exchange of sex for drugs/money, inability to negotiate condom use and substance abuse
- **Contextual factors** – Pervasive economic and racial oppression; lack of community recreation and boredom with resultant high substance abuse; high incarceration rates of black men leading to a male shortage with resultant concurrent sexual partnerships

IPV and HIV-Risk

Figure 1

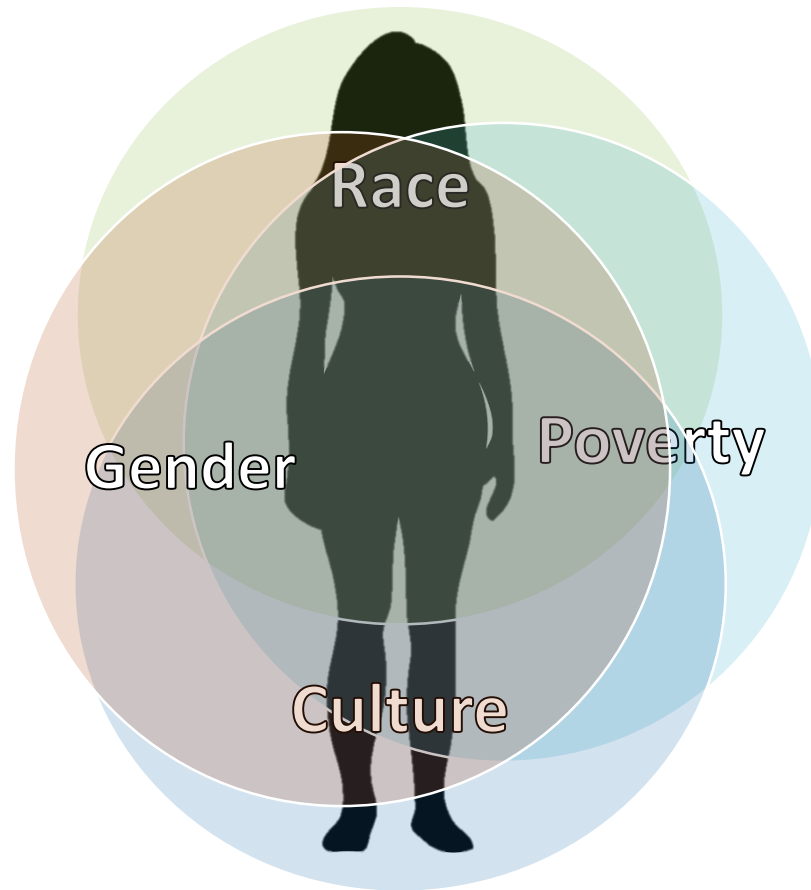
Experience of Intimate Partner Violence and Women, Overall and with HIV

Lifetime Experience of Intimate Partner Violence (IPV)



Source: Matthew J. Breiding, Jieru Chen, and Michele C. Black. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. The National Intimate Partner and Sexual Violence Survey: Intimate Partner Violence in the United States — 2010. Atlanta, GA, 2014.; Machtiger, E.L., et al. (2012) Psychological Trauma and PTSD in HIV-Positive Women: A Meta-Analysis. *AIDS and Behavior*. 16(8): 2091-2100.

Intersecting Disparities



Intersecting Disparities



Provider PrEP Knowledge and Attitudes

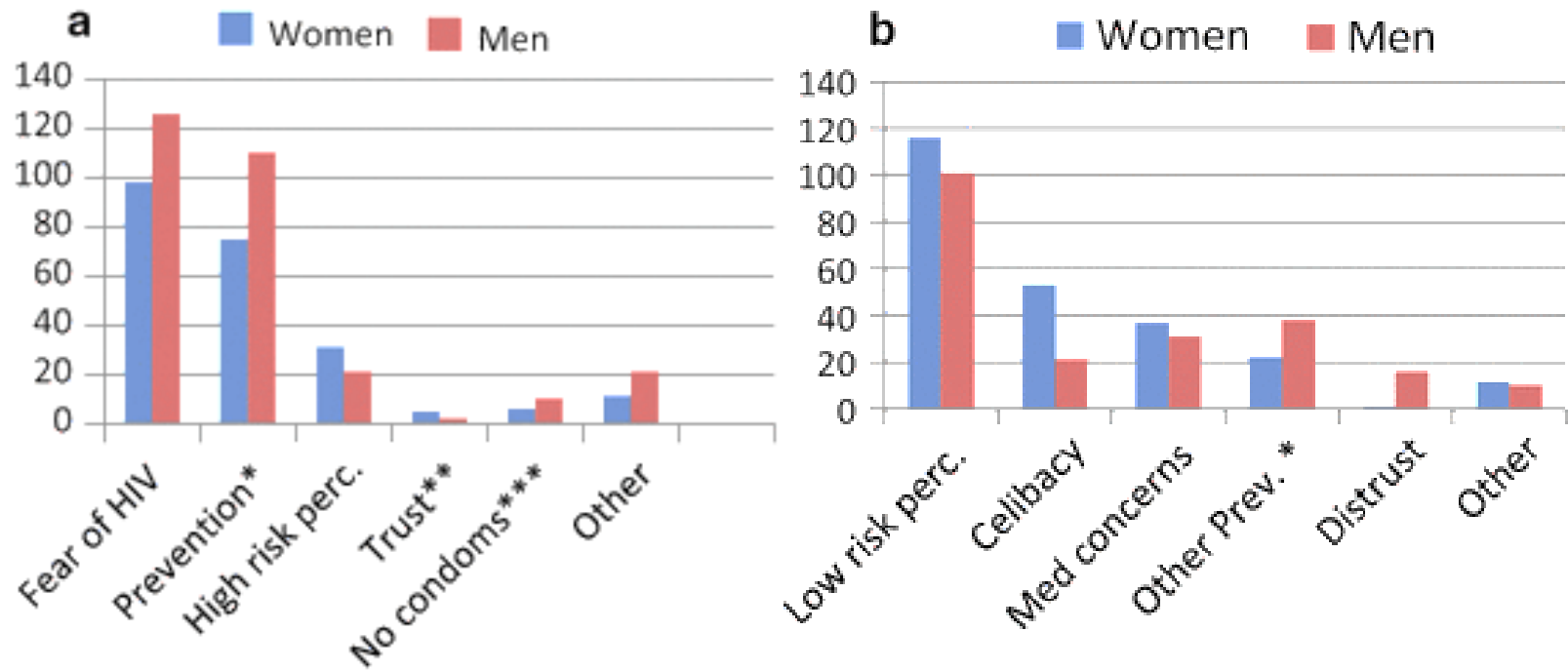
- Natural Fit – Women’s Healthcare Providers screen, counsel and offer PrEP to women at risk
- Knowledge among Family Planning Clinic Providers low
 - Only 1/3 correctly defined PrEP and knew its efficacy
 - Of those who were knowledgeable of PrEP, the majority were in the Northeast or Western U.S.
 - **Main Barrier to PrEP implementation: Lack of Training**



PrEP use in Cis-Gender Women

- In one study at a large comprehensive sexual health clinic (Dec 2014 – Aug 2016), 21/554 women receiving care were prescribed PrEP
- Majority (86%) of women were in serodiscordant relationships
 - Trying to conceive
 - Partners are on ART (two thirds virally suppressed)
- Low persistence in care
 - At 3 months, 61% in care
 - At 6 months, 38% in care

Attitudes toward PrEP at an Urban Clinic



Structural and Individual Level Barriers 38

- Barriers:
 - Medical Distrust
 - Cost
 - Safety and Side Effects
 - Low perceived personal risk of HIV (despite actual risk) and partner risk of HIV
 - HIV Stigma
 - Difficulty negotiating PrEP use with partners
- Facilitators
 - Partner and peer support
 - **Private** prevention control, esp. when perceived low condom use negotiation



Story of STI Screening

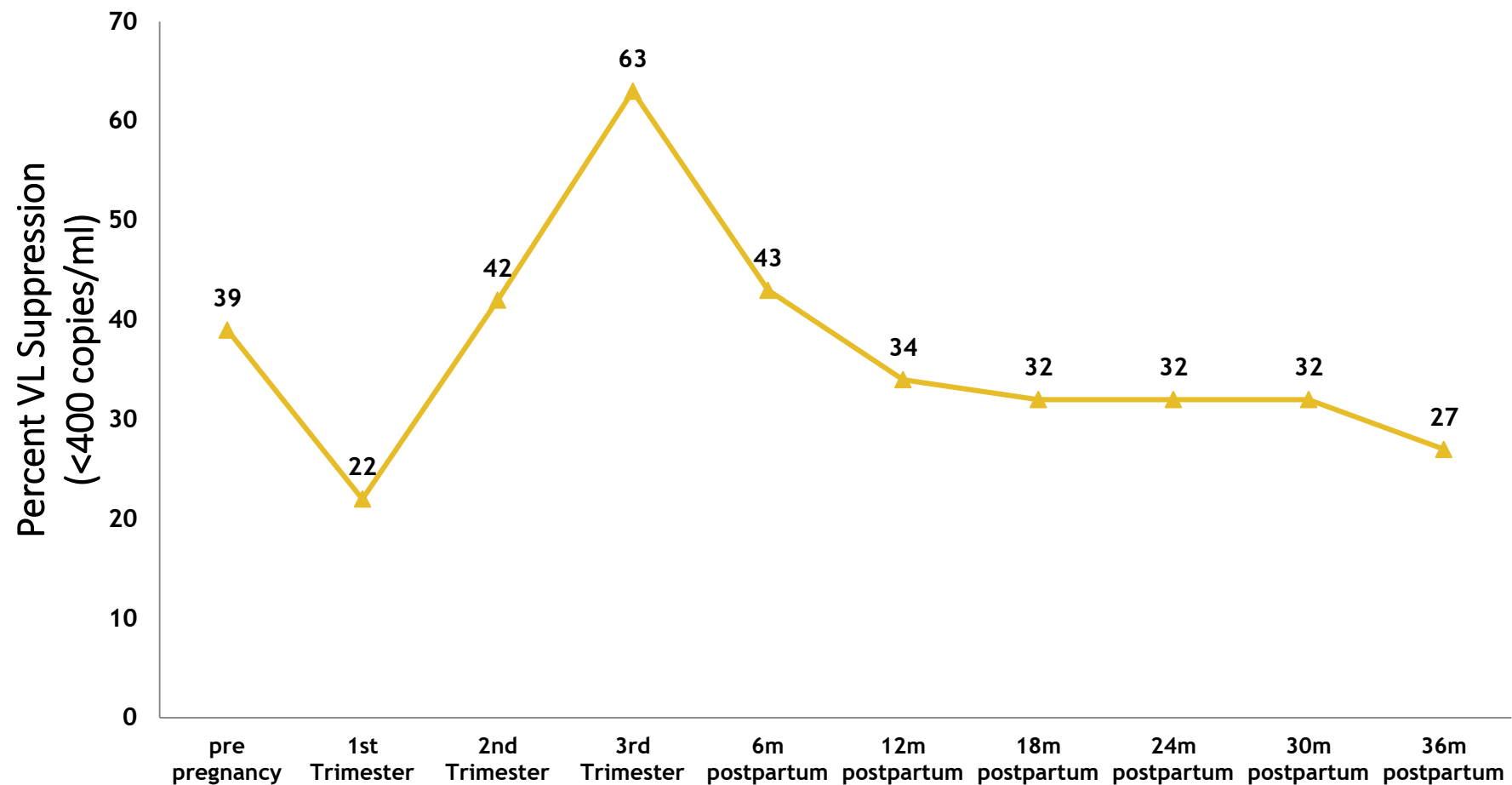
- Annual chlamydia testing is recommended by ACOG and USPSTF for women ≤ 25 years of age annually, pregnant women and women > 25 at risk:
 - Chlamydia testing patterns in Title X Clinics – 55% of women < 25 years were tested and 42% aged ≥ 25 were tested
 - Chlamydia testing patterns, insured women – young women are under tested (34%) and older women are over tested (18%)
- Prenatal screening visits
 - Chlamydia screening – 83% of Medicaid patients and 70% commercially insured
 - Gonorrhea screening – 75% of Medicaid patients and 69% of commercially insured
- Community Health Clinic Providers in Indiana
 - Chlamydia and GC screening provided primarily at patient request despite CDC screening guidelines

Tao et al. Chlamydia Testing Patterns for Commercially Insured Women, 2008. American Journal of Preventive Medicine 2012.

Ross et al. Screening for HIV and other STI among U.S. women with prenatal care. Obstet and Gynecol. 2015



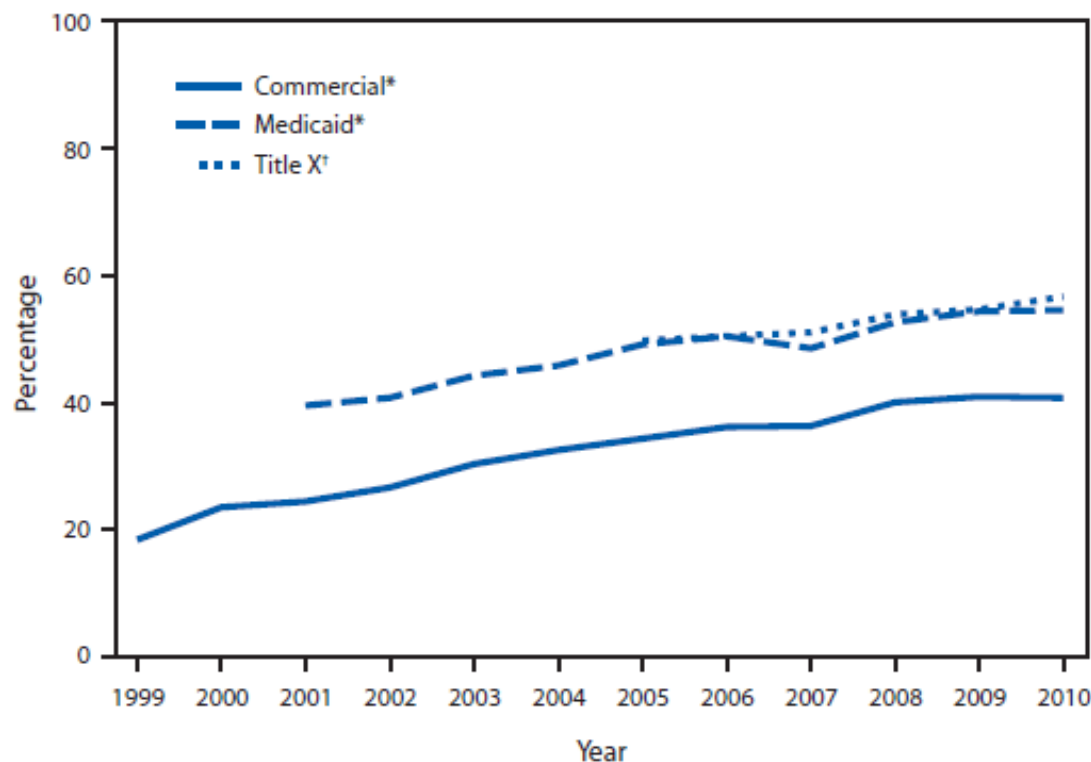
Percent Viral Load Suppression Pregnancy and Postpartum



Prenatal and Postpartum Care Visits

Successes with STI Screening

Percentage of Females Tested for Chlamydia – United States, 1999 – 2010



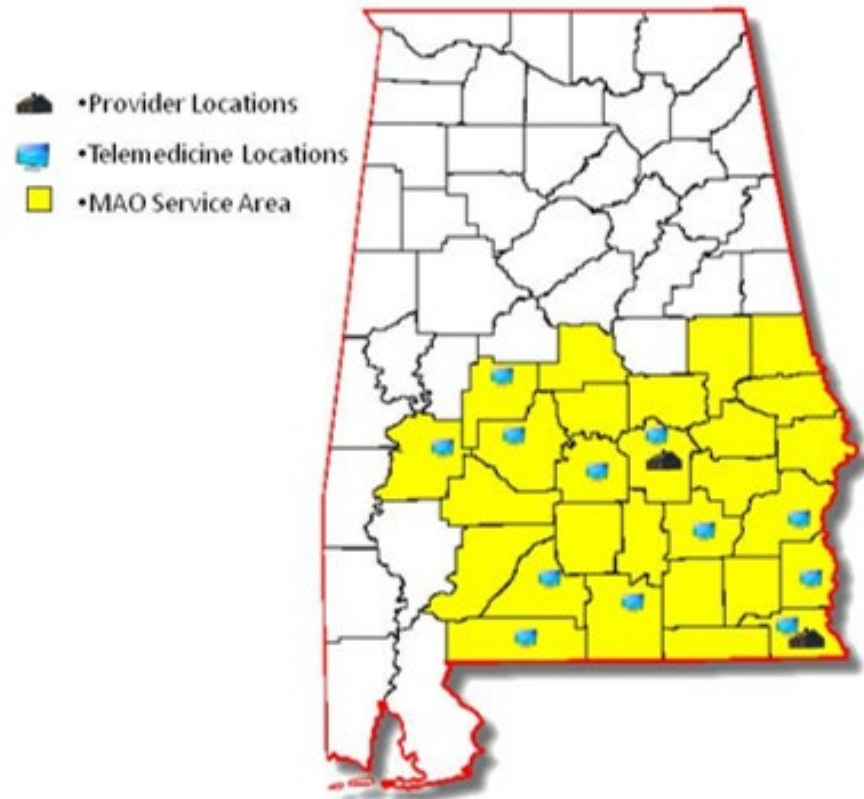
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Possible Implementation Strategies

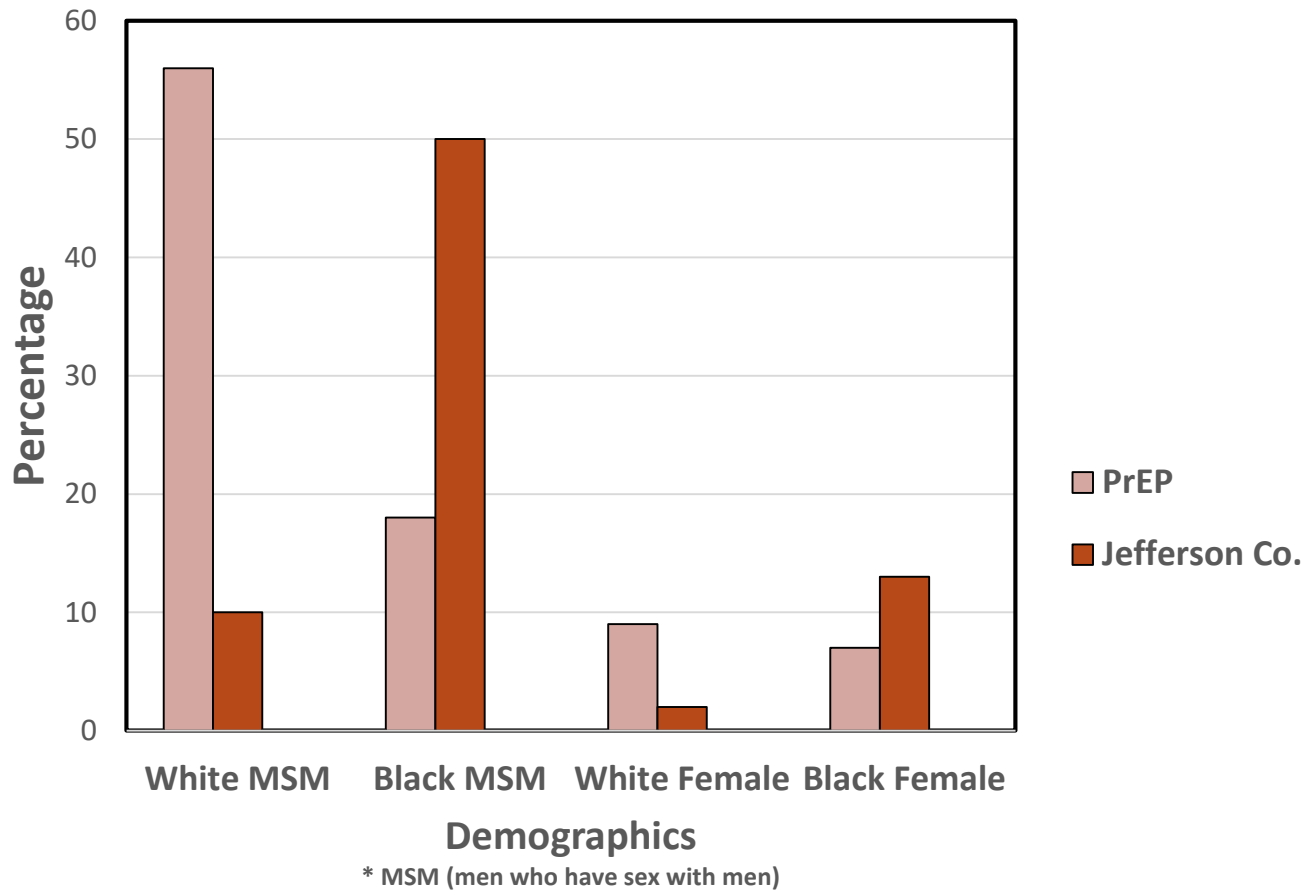
- Successful Implementation of PrEP beyond peri-conception and serodiscordant partnership as a part of global women's healthcare
 - STD Clinic referrals at Jefferson County Department of Health
 - Adolescent Health Clinics
- Effective messaging to increase awareness
 - One study suggests action messaging that is brief, referred to PrEP as a pill and not mentioning condoms or STI testing as appealing
- Effectively implementing PrEP in Southern and Rural communities
 - Family Planning and Title X Clinics
 - OB/GYN Partnerships

Potential Service Delivery Models for Rural South

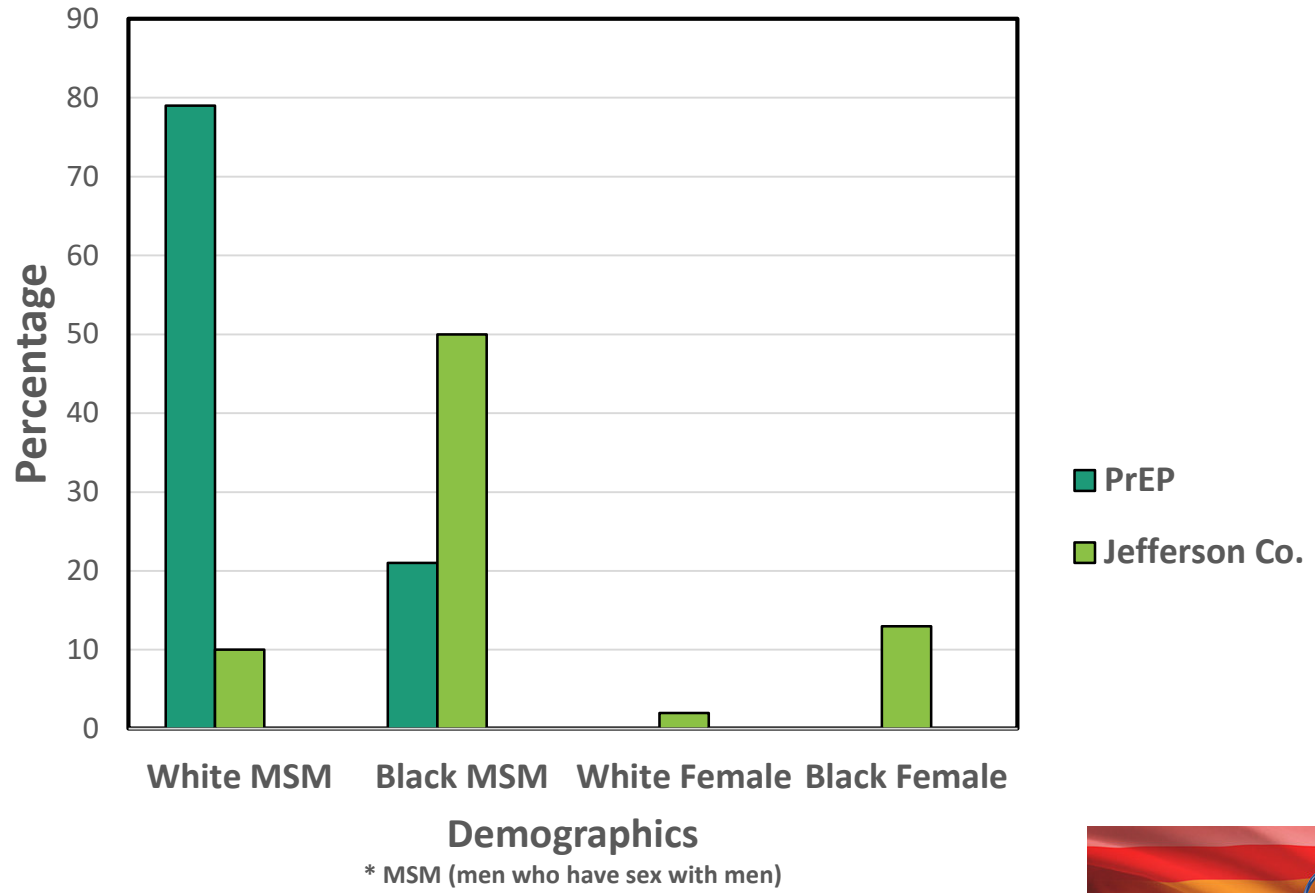
- Telemedicine
 - Structural Barriers – transportation
 - Individual Barriers – stigma
- MAO (Medical Advocacy and Outreach)
 - Ryan White Clinic
 - 10 telemedicine satellite rural clinics
 - PrEP services started Jan. 2016 (not yet through teled)
 - 30 people on PrEP, 6 are women in sero-discordant relationships
 - All insured or self-pay



PrEP Clinic Demographics – 1917 Clinic

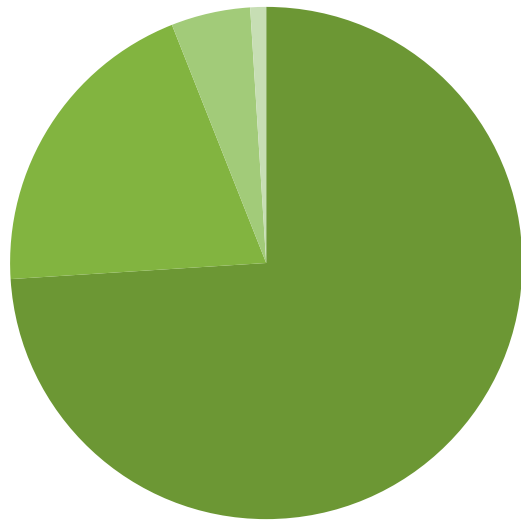


PrEP Clinic Demographics – MGWC Clinic

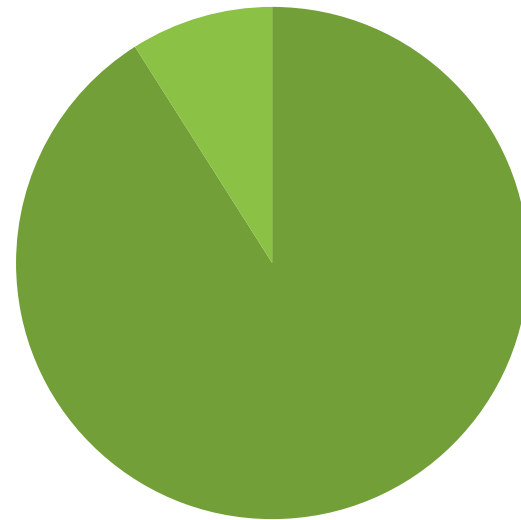




PrEP Clinic Demographics – THRIVE Clinic



- White
- Black
- Hispanic
- Pacific Islander



- Male
- Female
- Transgender

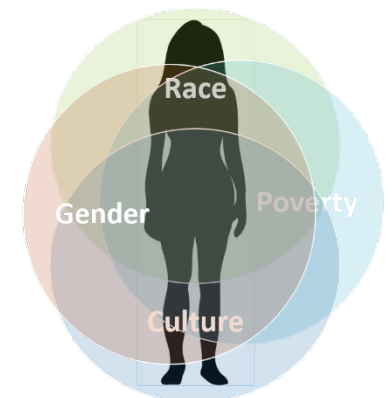


Proposal Objective

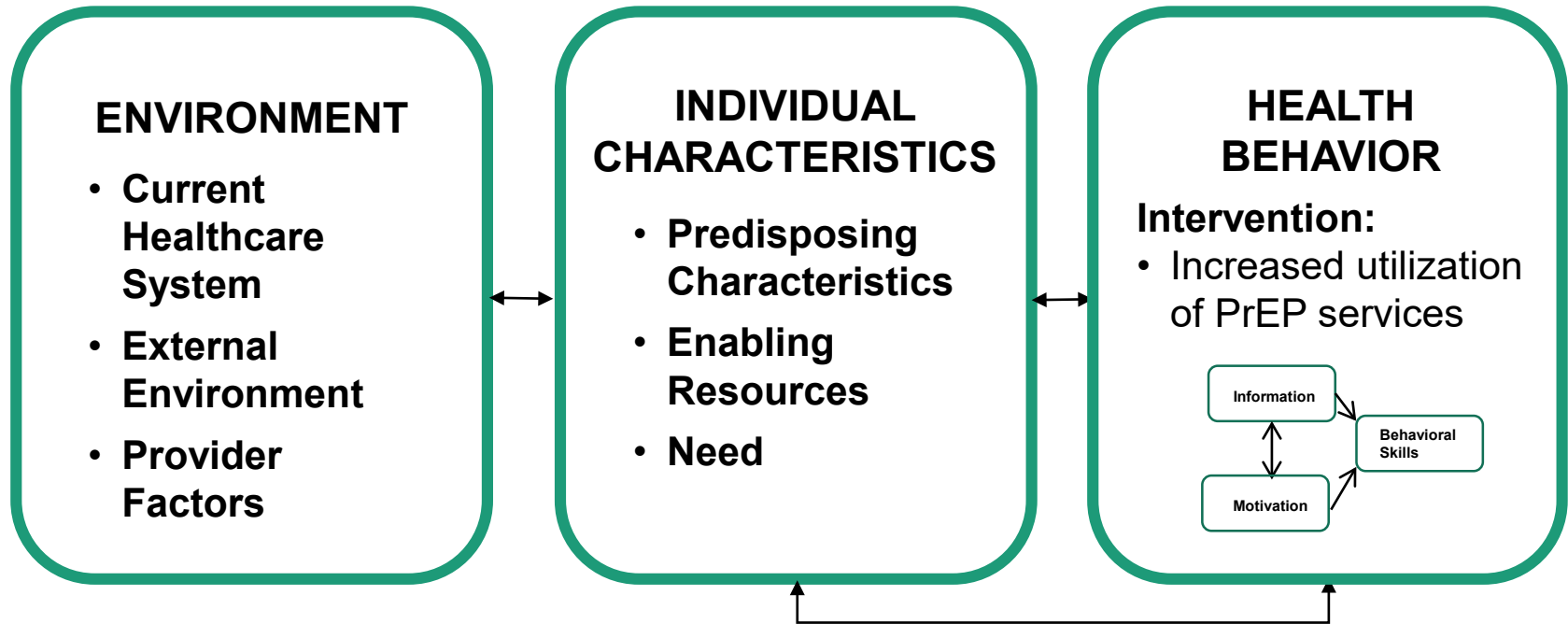


Understand PrEP awareness, barriers and delivery preferences among Black women in rural and urban areas in the Deep South

WHY? To overcome disparities in HIV infection rates among Southern Black women



Conceptual Model: ABM with sIMB Constructs

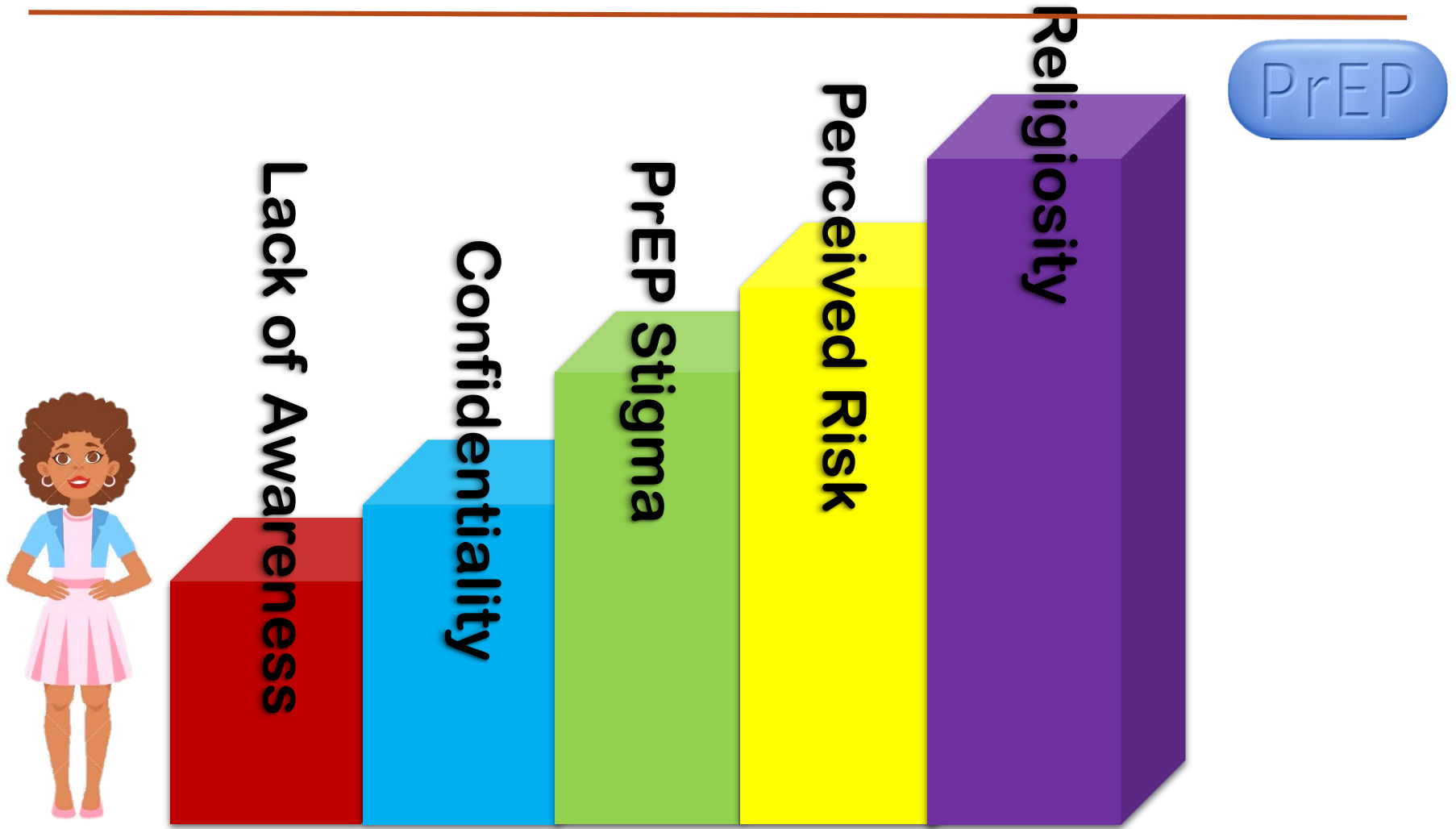


Adapted from Anderson Behavioral Model (ABM) and situated Information, Motivation and Behavioral Skills (sIMB).

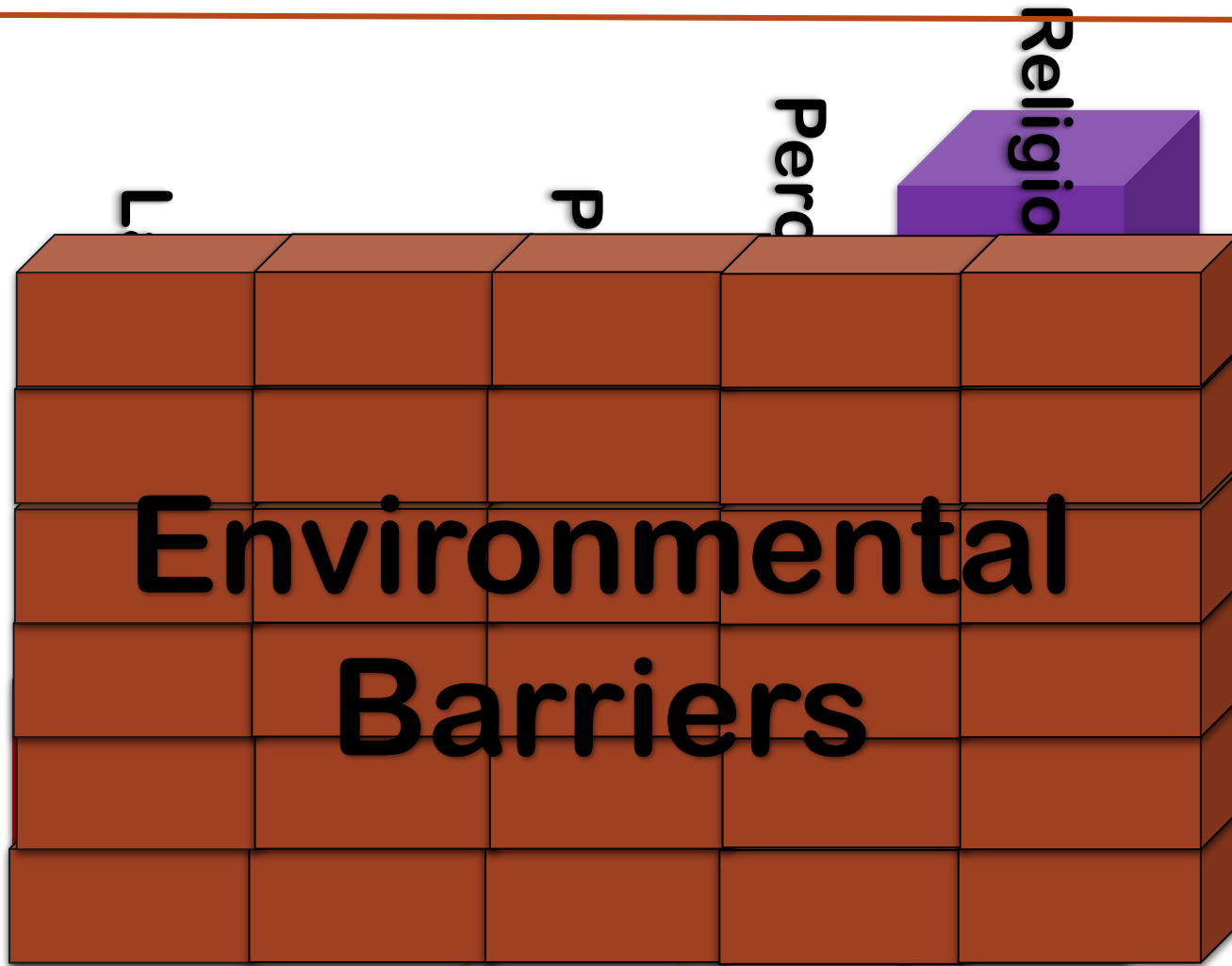
Characteristics of Black Women Aged 16-65 Participating in Focus Groups

Characteristics	Rural Counties (N = 25)	Urban Counties (N = 22)
Median Age, years (range)	44, 20-65	35, 23-54
Relationship Status		
Married/Domestic Partnership	4 (16%)	7 (31.8%)
Monogamous Relationship/not married	3 (12%)	4 (18.2%)
Single, Divorced, Dating	18 (72%)	11 (50%)
Education Level		
Grade 12 or GED	7 (28%)	2 (9.0%)
Some College, Associates or Technical	9 (36%)	8 (36.3%)
Bachelor's Degree	7 (28%)	5 (22.7%)
Insurance Status		
Insured	21 (84%)	20 (90.9%)
Household Annual Income ^a		
\$0-10,000	3 (12%)	1 (5%)
\$10,000-24,999	9 (36%)	2 (9%)
\$25,000-49,999	7 (28%)	13 (59%)
\$50,000-or more	3 (12%)	4 (18%)
Employment Status		
Full-time	12 (48%)	14 (63.6%)
Part-time	2 (8%)	3 (13.6%)
Unemployed	5 (20%)	4 (18.1%)

Major Themes



Major Themes



Who is PrEP For?

- *“Over sexually active people, promiscuous people”*
- *“Prostitutes.”*
- *“If you’re single and sexually active, I think you need it because you’re at risk. You’re at risk”*

Confidentiality

- *“If you live in a real small town, everybody in the pharmacy know you. Everybody knows everybody”. (Dallas)*
- *“They probably—another thing to that is that too often, some of these doctor’s offices and these pharma, these people talk, for real. Folks tell you, really.”*

Religiosity

“People talk about praying all the time, they’re really religious. They’re gonna pray it away, but I think there’s a balance between—there has to be a balance between praying and actually going to get medications that could help prevent or cure whatever the disease is that you may have.”

Case # 1

- Ashley is a 26 year old female who is a patient returning for a routine f/u visit with her Primary Care Office. She is HIV negative. When taking a sexual history, you learn that she has had 2 sexual partners in the past 6 months, but reports her relationships were not concurrent. She has engaged in vaginal sex and reports giving oral sex. She uses condoms occasionally and does not inquire about her partners HIV status.

How would you discuss PrEP and sexual health with this patient?



Case #2

- Tiffany is a 20yo F presenting to her PCP c/o yellow vaginal discharge. She denies having any other systemic symptoms. On sexual history she reports 1 sex partner in the past 12 months. They no longer use condoms and engage in vaginal and oral sex.
- Tiffany has STI screening and is positive for gonorrhea. She is treated with Ceftriaxone IM and Azithromycin and expresses she is concerned about how she got this STI.

How would you address her HIV prevention needs?



Funding and Acknowledgements

Special Thanks

- RISC
- Eddie Jackson and Tammy Thomas for conducting interviews
- AIDS Alabama and Birmingham AIDS Outreach
- **Co-Mentors** CFAR Pilot – Drs. Michael Mugavero and Janet Turan
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 - UAB CFAR Development Core – Drs. Donna Porter, Paul Goepfert, Michael Mugavero, Laura Timares and Michael Saag

A close-up photograph of two dark-skinned hands cupped together, holding a red awareness ribbon. The background is a soft, out-of-focus white. The text 'Thank You!' is centered over the hands.

Thank You!

Questions?