HIV PREVENTION FOR WOMEN IN THE US

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Learning Objectives

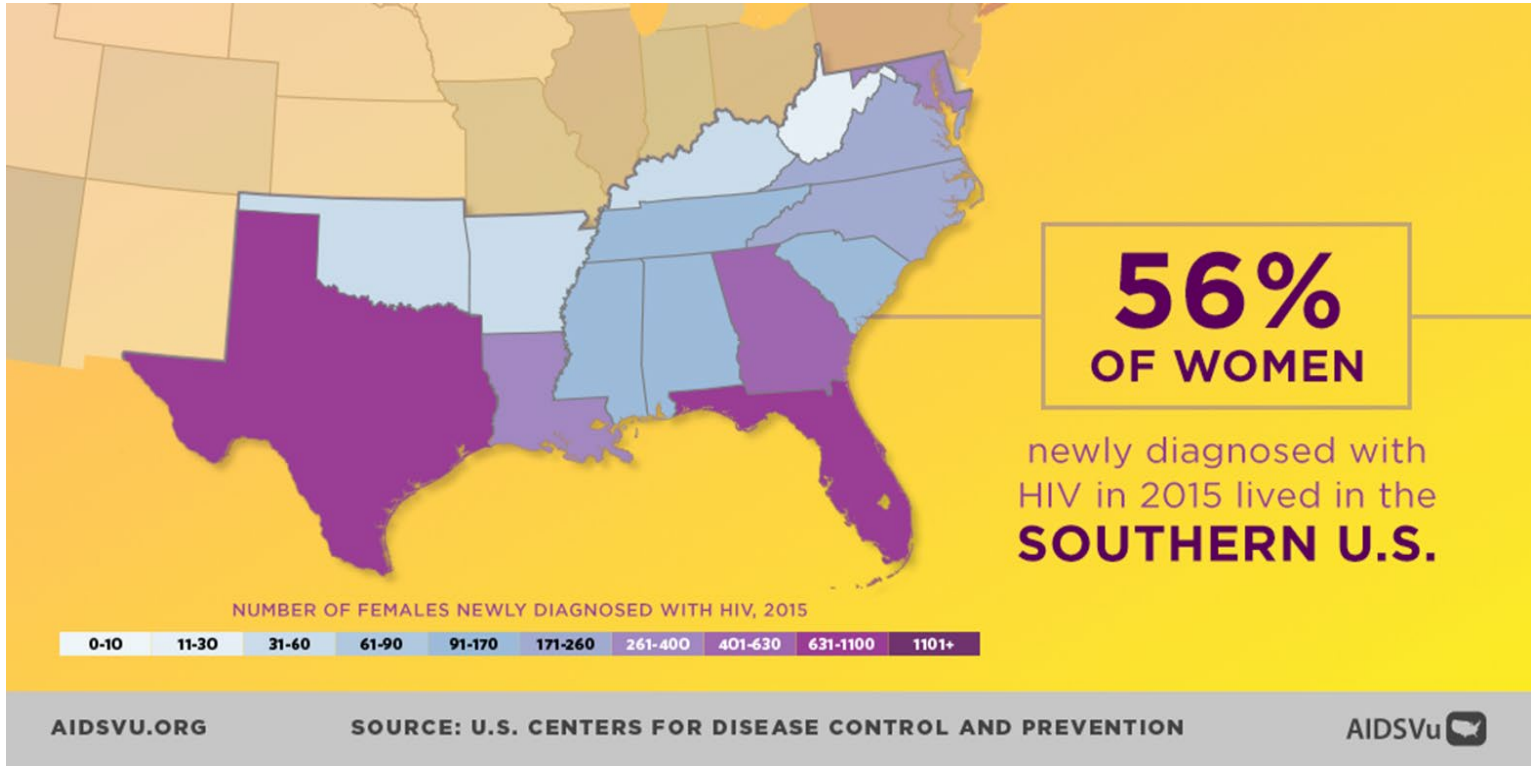
Upon completion of the activity, the participants should be able to:

1. **Understand disparities and barriers to PrEP use among women in the US**

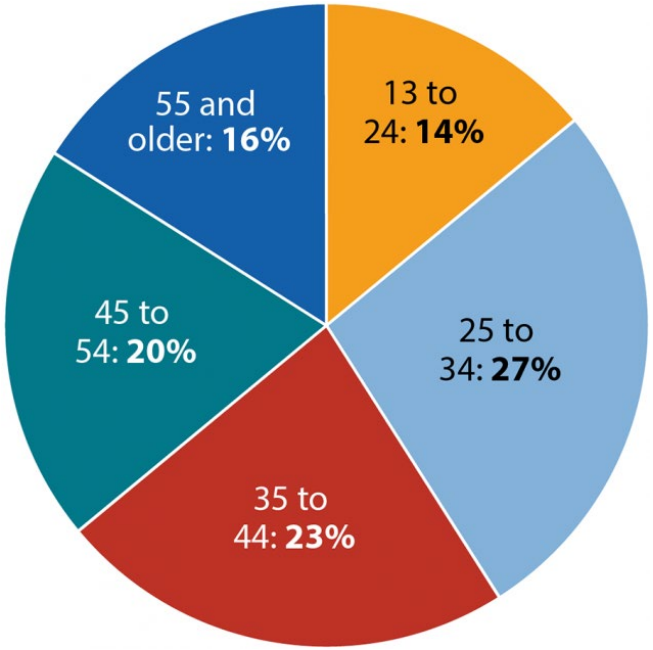
2. **Apply best practices in implementing PrEP for women, incorporating patient and healthcare provider perspectives and using 2021 CDC guidelines**

3. **Describe novel PrEP drugs and delivery approaches**

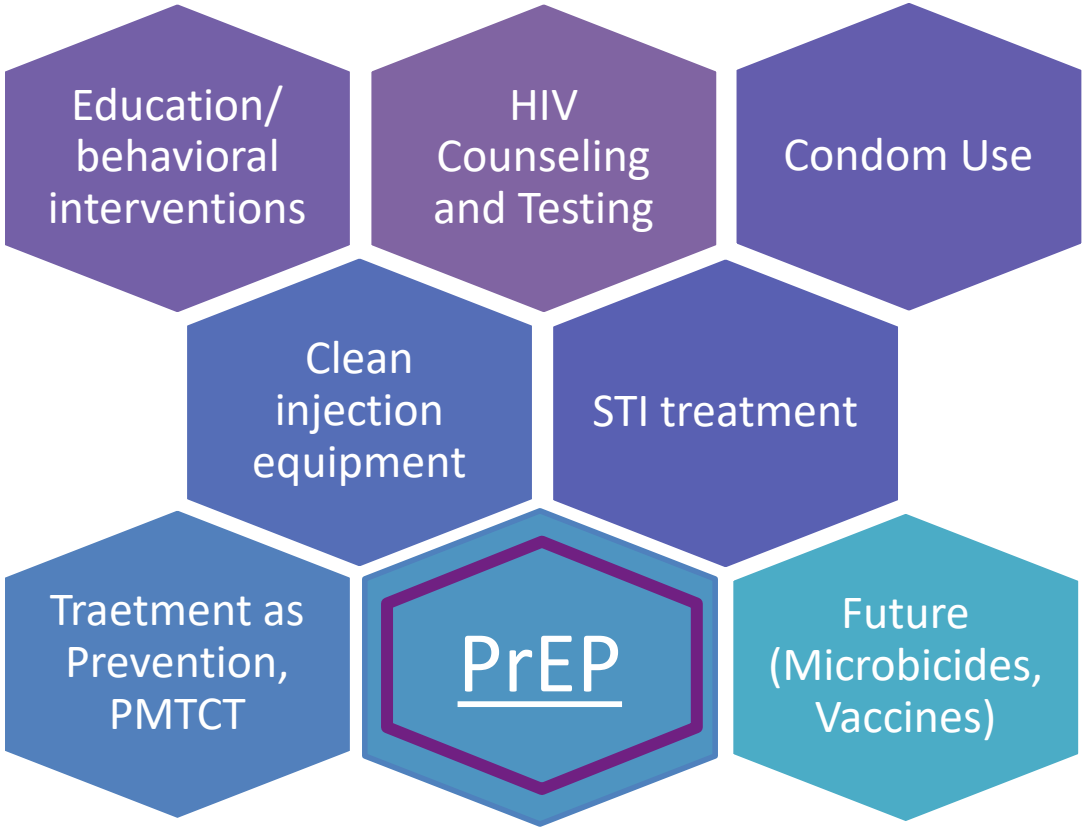
Women and HIV in the U.S. South



New HIV Diagnoses among US Women by Age, 2017



Growing HIV Prevention Toolkit



Condoms are not enough!

- **Not user-controlled**
- **May be inconsistently and/or incorrectly used**
- **Imperfect efficacy even with consistent use (70-80% for anal/vaginal sex)**
- ***New HIV infections continue despite decades of condom promotion***

HIV Pre-exposure Prophylaxis (PrEP)

Medicines used before potential exposure to prevent getting HIV

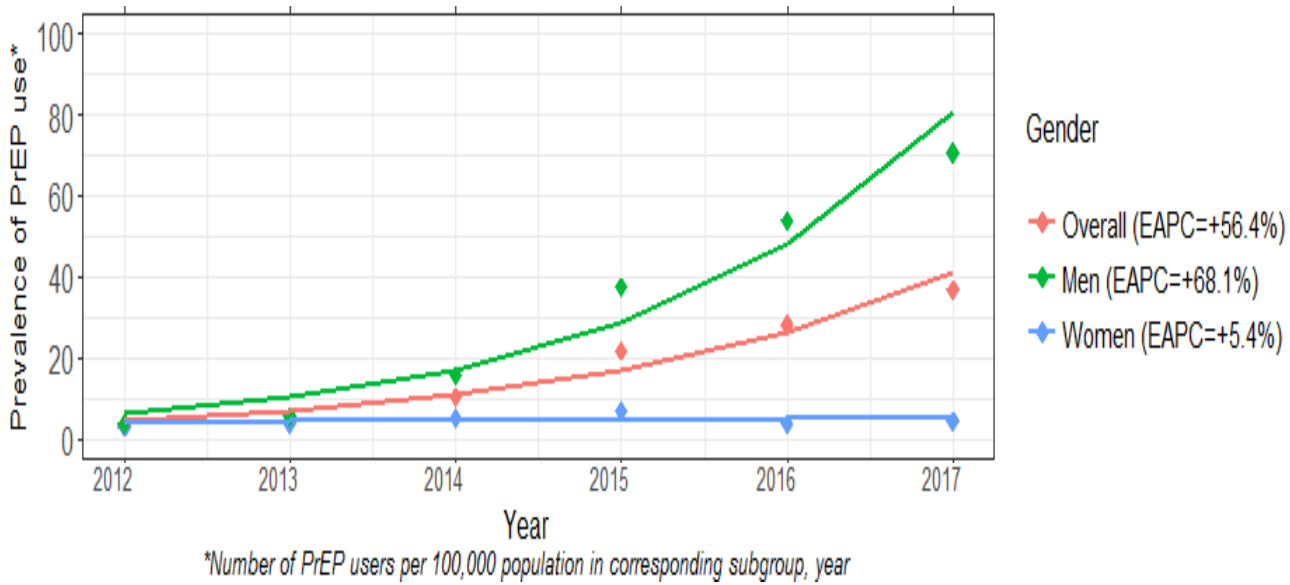
tenofovir disoproxyl fumarate (TDF) + emtricitabine (FTC) **[Truvada®, F/TDF]** • FDA approved for HIV prevention in 2012
tenofovir alafenamide (TAF) + emtricitabine (FTC) **[Descovy®, F/TAF]** • FDA approved for HIV prevention in 2019, but not for vaginal sex
cabotegravir injectable suspension every 2 months **[Apretude®, CAB]** • FDA approved for HIV prevention in 2021 (not widely available yet)

PrEP is an effective HIV prevention strategy, *including for women*

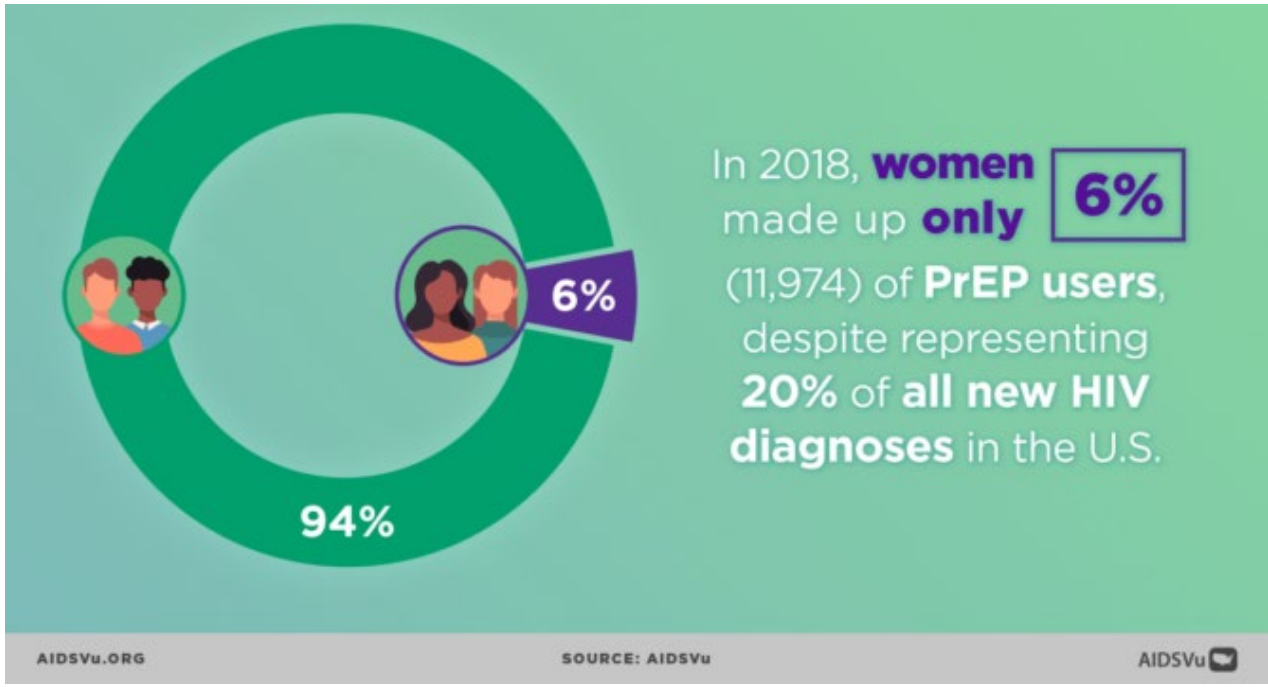
Recommended by CDC (2014), WHO (2015), and USPSTF (Grade A, 2019)

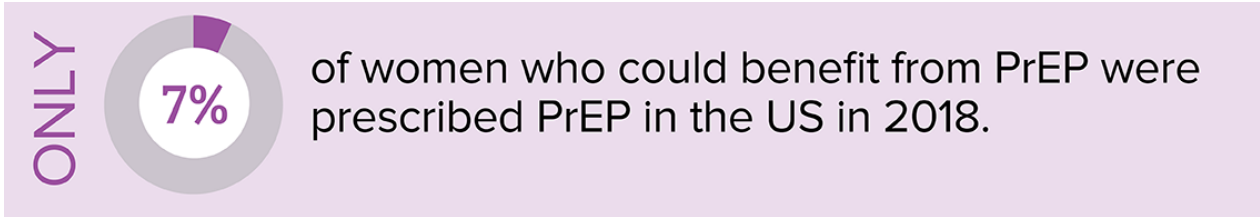
PrEP Use in Women is Especially Low

PrEP Use by Gender, US, 2012-2017



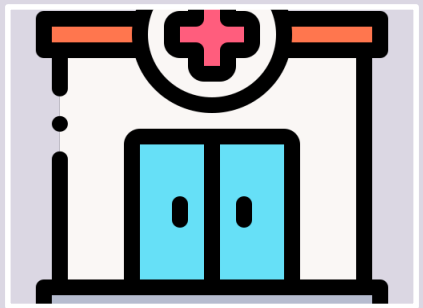
*Number of PrEP users per 100,000 population in corresponding subgroup, year

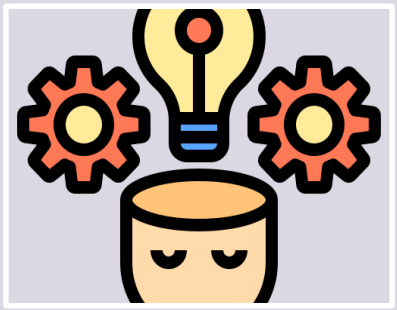




Sullivan P, et al, Ann Epidemiol 2019

Supply and Demand Constraints Affect HIV Prevention Services for US Women





Women's healthcare providers aren't providing PrEP

Women still don't know about PrEP

How to Identify Individuals Who May Benefit from PrEP

	Summary of Guidance for PrEP Use
Sexually active adults & adolescents	Sexual partner with HIV (esp if high/unknown VL)
	Recent bacterial STI
	Inconsistent or no condom use
Persons who inject drugs	Injecting partner with HIV
	Sharing injection equipment

CASE

- 29yo cisgender woman
- Presented to ED with symptomatic acute HIV infection
- HIV Ag/Ab+, HIV 1/2 neg, HIV-1 RNA >10 million *(consistent with acute HIV infection)*
  - 2 sex partners in 6 months, usually uses condoms
  - No partner risk behaviors
  - Negative HIV and STI testing 18 months earlier
  - GC and RPR neg, CT pos at time of HIV diagnosis

→ *Not considered to have an indication for PrEP by CDC guidelines*

Re-thinking How to Identify Women who May Benefit from PrEP

- **PrEP guidelines rely on patient *disclosure* of risk behaviors, patient knowledge of *partner's* behaviors, and providers *judgement* of risk**

- **These guideline criteria provide a *platform* to start PrEP conversations, but may *miss women who may benefit from and want PrEP***

- **Recommend: standardized tools to capture sexual health indicators, routine PrEP education irrespective of risk, and offer PrEP to anyone who wants it**

Calabrese S et al, JAIDS 2019; Calabrese S et al, Clin Infect Dis 2019

How to Identify Individuals Who May Benefit from PrEP: Revised CDC Clinical Practice Guidelines (2021)

	Summary of Guidance for PrEP Use
Sexually active adults & adolescents	Sexual partner with HIV (esp if high/unknown VL)
	Recent bacterial STI
	Inconsistent or no condom use
Persons who inject drugs	Injecting partner with HIV
	Sharing injection equipment

- ***Discuss*** **PrEP with all sexually active patients**
- ***Prescribe*** **PrEP if requested**

How to Identify Individuals Who May Benefit from PrEP: CDC Clinical Practice Guidelines (2021)

- ***In addition to the guidelines, discuss:***
  - **Self or partner incarceration**
  - **Repeated unintended pregnancies**
  - **Substance use (including non-injection)**
  - **Sexual, physical, or emotional violence**
  - **Do you think you are at risk for HIV?**
  - ***Are you interested in learning more about PrEP?***

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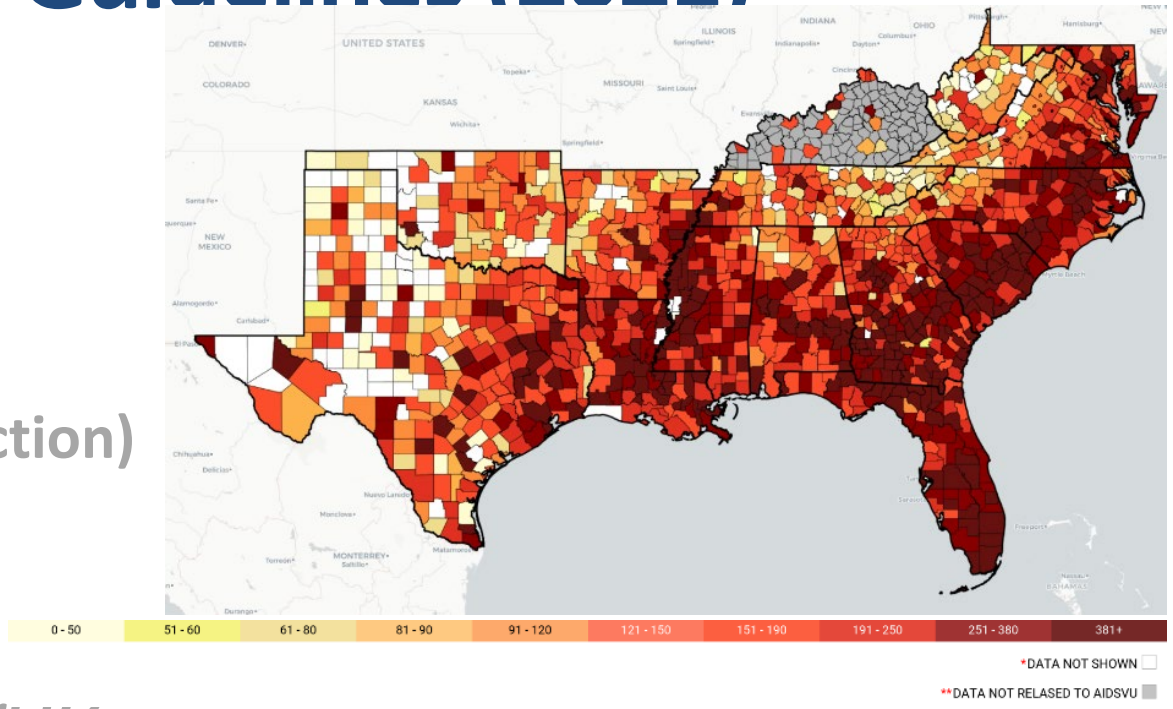


- **Be familiar with HIV statistics in your area (aidsvu.org)**
  - **Sexual activity in a high HIV prevalence community increases HIV exposure risk**

Using a Sexual History for PrEP Conversations

- **Best practices for taking a sexual history**
  - Explain that you ask these questions of everyone as an important part of overall health
  - Ensure privacy - ask others to step out of the room
  - Be open-minded, non-judgmental, be mindful of body language
  - Start with open-ended questions, followed by closed- ended questions for specific information
  - Questions to cover 5P's (Partners, Practices, Past STI, Protection, Pregnancy plans + Pleasure)

- **Use standardized assessment tools for all adult and adolescent patients**
  - Reduces stigma, normalizes sexual health conversations
  - Use information from assessment as a platform for conversations about HIV prevention & PrEP

https://www.cdc.gov/hiv/clinicians/screening/discussing-sexual-health.html

Women Patient's Feedback on Using a Standardized Tool to Start PrEP Conversations

Patient Feedback

- Desire conversations about HIV & PrEP with healthcare provider
- Routine use of sexual health assessment was acceptable
- All women should know about PrEP
- Need community outreach & education about PrEP

Sales JM et al, JAIDS 2019; Sales JM et al, Contraception 2019

PrEP Care Steps (2021 CDC Guidelines)

Step 1: PrEP Education/Counseling

- Take a sexual health history
- Discuss PrEP with all sexually active patients
- Assess PrEP interest & readiness
- Counsel about PrEP

Step 2: Visit & Lab Testing

- Assess for acute HIV
- Lab tests for eligibility
  - HIV test (Ag/Ab preferred)
  - Creatinine
- HBV tests/ vaccine
- Test for STIs & treat

Step 3: Prescribe and Monitor

- Support med access & adherence
- ≤ 90d supply at a time
- Harm reduction
- Lab monitoring
  - HIV test q3mo & assess for acute HIV
  - STI tests q3-6mo
  - Cr q6mo (≥50yo) or q12mo (<50yo)
  - Lipid profile (TAF/FTC only)

PrEP Counseling

PrEP is highly effective (90-99%)

Favorable safety profile (comparable to aspirin)

- **Common side effects: nausea, bloating, fatigue (“start-up syndrome”)**
- **Uncommon side effects (<1%, reversible): renal and bone**

Medication coverage available

- **Insurance, co-pay assistance, medication assistance program, generic med option**

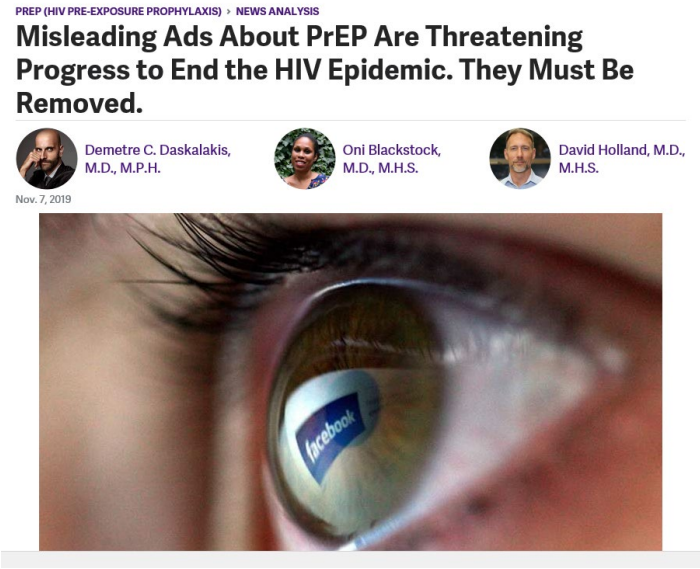
Can be used during pregnancy/lactation & with any birth control method

Adherence to daily dosing is especially important for women

PrEP puts you in control of your sexual health

Discuss PrEP with Sex Positive Messages

Acknowledge Mistrust, Tackle Misinformation



Clinic-based Approach to Expand PrEP Access for Women

Access to PrEP Clinics is Low in the South (low density, long distances)

Women *more likely* to have a healthcare visit before HIV diagnosis

- **Missed opportunity for PrEP**

Women want to hear about PrEP from their *healthcare providers*

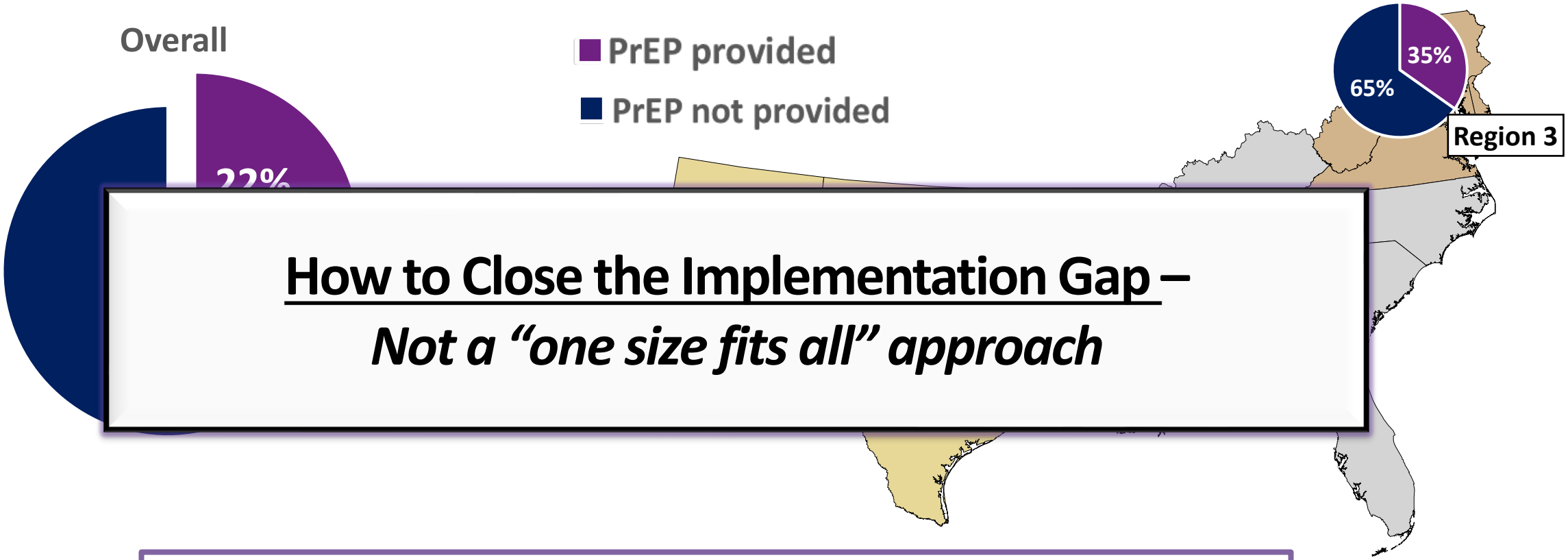
Most women use *family planning clinics* for sexual health services

- **Often their only source of care**

Non-clinic PrEP models (pharmacy, mobile, telemedicine) *not studied in women*

Seigler AJ et al, Ann Epidemiol 2018; Seigler AJ et al, Am J Public Health 2019; Auerbach et al, AIDS Patient Care STDs 2015; Flash C et al, Adherence 2017 #406; Smith DK et al, Clin Infect Dis 2019; Stormo et al, JAMA Int Med 2014

Low PrEP Provision in Publicly-Funded Family Planning Clinics in the South (Feb-June 2018, N=286)



How to Close the Implementation Gap –

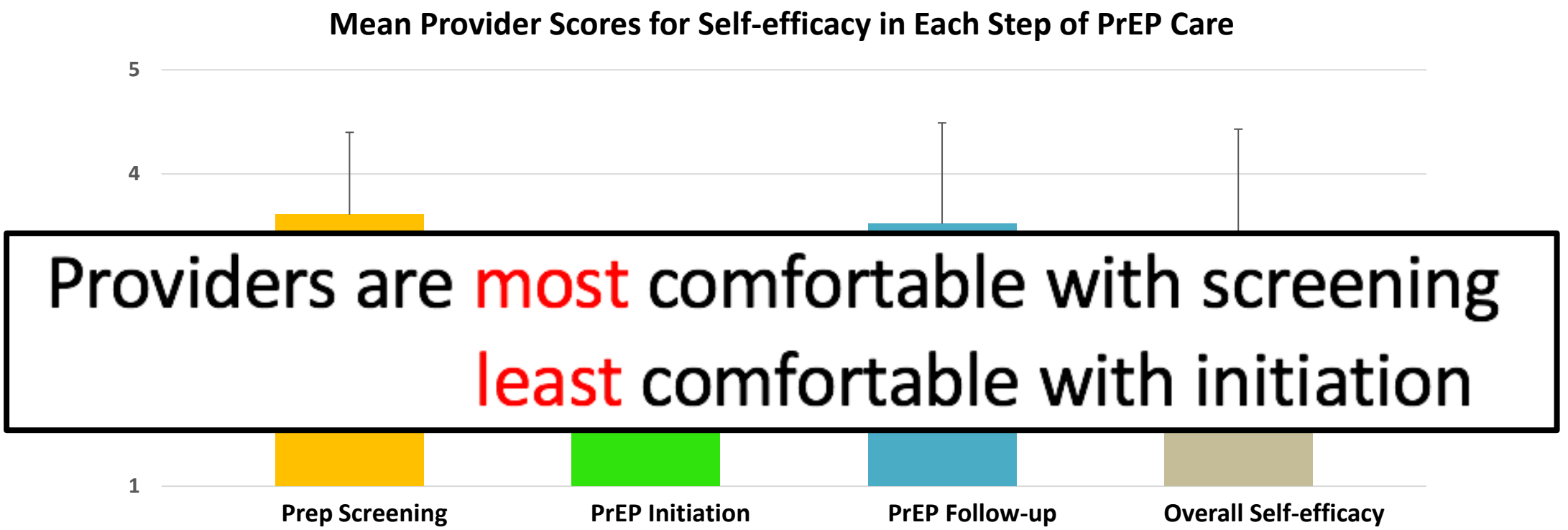
Not a "one size fits all" approach

Half use referral services for most steps of PrEP care

Sales JM and Sheth AN, *AIDS and Behavior* 2021; Piper K et al, *J Adolesc Health* 2020; Piper K et al, *Implement Sci Commun* 2021

ATN ADOLESCENT MEDICINE TRIALS NETWORK FOR HIV/AIDS INTERVENTIONS

Providers are least comfortable with PrEP initiation



Providers are most comfortable with screening

least comfortable with initiation

Step 1: Screening

- Engagement
- Clinical Evaluation

Step 2: Initiation

- Insurance
- Prescription

Step 3: Follow-up

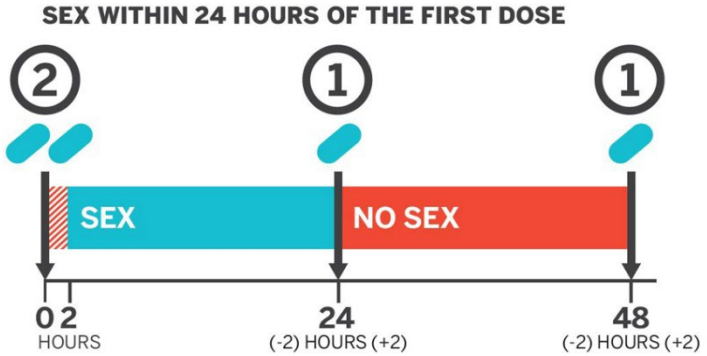
- Lab monitoring
- Assessment

Ramakrishnan A et al, IDWeek 2021

Alternative PrEP Strategies

Same-day PrEP start

Telehealth PrEP



On-demand PrEP

- **Off-label F/TDF dosing schedule for adult MSM**

Beyond a Daily Pill… Updates on Long-Acting PrEP

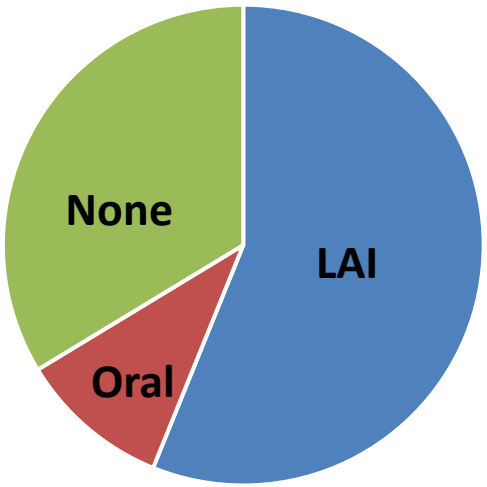
Injectable cabotegravir FDA approved for HIV prevention – December 2021

- **Approved as every 2 months gluteal injection (including for cisgender women)**
- **Included in 2021 CDC Guidelines**
- **Scale-up expected soon**

- **3000 sexually active cisgender women ages 18-45 enrolled in 7 countries in sub-Saharan Africa**
- **CAB LAI superior to daily oral TDF/FTC at preventing HIV acquisition in cisgender women (89% lower risk than TDF/FTC)**
- **Updated analysis with 92% lower risk than TDF/FTC**
- **Highest efficacy ever seen in a trial of PrEP for women**

LAI PrEP Interest and Preferences among US Women

Which would you prefer?



- **30 interviews with cisgender women without HIV**
  - **Women's Interagency HIV Study (NYC, Chi, SF, Atl, DC, Chapel Hill)**
  - **Median age 51 years**
  - **57% ever heard of PrEP**

LAI PrEP Barriers	LAI PrEP Facilitators
• Low perceived benefit • Medical mistrust • Injection concerns • More frequent visits	• Beliefs that shots were more effective than pills • Convenience/ease • Confidentiality

Philbin MM et al, *AIDS Behav* 2022

Take Home Points

- **HIV is still a public health problem in the US; women are uniquely affected**
  - ***Women must be considered in EHE initiatives***
- **PrEP is underutilized by women**
  - ***Increase awareness & access, end HIV stigma, address social determinants, including structural racism***
- **Women want to learn about PrEP, including from their healthcare providers**
  - ***Address healthcare provider knowledge, attitudes, confidence with PrEP care steps***
  - ***Support a robust, diverse HIV prevention and women's health workforce***
- **Discuss HIV prevention & PrEP, including with women, regardless of reported sexual behaviors**

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Where Were the Women? Gender Parity in Clinical Trials

Robert H. Goldstein, M.D., Ph.D., and Rochelle P. Walensky, M.D., M.P.H.

In 2017, a total of 19% of all new HIV infections in the United States and nearly half of infections more than 5000 men who have sex with men and 74 transgender

The New York Times

Half of H.I.V. Patients Are Women. Most Research Subjects Are Men.

Trials of vaccines and treatments have not included enough female participants. Now that scientists are exploring possible cures, the need to enroll women is greater than ever.

Reproductive age women affected by HIV have unique experiences

Research representation is critical

Are you interested in sharing your thoughts/ experiences?

SisterLove

EMORY

The IT-PHITS Project

Live/work in Metro Atlanta and want to share perspectives to shape the future of women's sexual health?

ITPHITSinfo@gmail.com

STAR

Study of Treatment and Reproductive Outcomes

Women ages 18-45 with or without HIV who are near Atlanta, Birmingham, Chapel Hill, DC, Jackson, & Miami

stardata@jhu.edu; STAR@emory.edu

Structural and Individual Level Barriers

- **Barriers:**
  - Low awareness
  - 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

- Koechlin et al. Values and Preferences of the Use of Oral PrEP for HIV Prevention among Multiple Populations: A systematic Review. AIDS and Behavior 2017
- Auerbach et al. Knowledge, Attitudes and Likelihood Of PrEP Use Among US Women at Risk of Acquiring HIV. AIDS Patient Care and STDs. 2015

Harold Amos Focus Groups: Methodology

- **Interviewers: 2 Black women**
- **Two independent coders –**
  - **Deductive thematic coding linked to constructs**
  - **Inductive phenomenological coding**
  - **Attributes for PrEP service delivery**
- **Coding: Code book developed in tandem after viewing 2 urban and 2 rural transcripts, iterative process**

Urban Counties

Focus Groups – Rural Counties

Participant Demographics

Characteristics	Urban (n = 22)	Rural (n = 44)
Median Age	35 (min 23 – max 54)	49 (min 20 – max 65)
Relationship Status		
Single/dating/divorced	11 (50%)	30 (68%)
Monogamous	11 (50%)	11 (32%)
Education		
High School	3 (14%)	17 (39%)
Some College	14 (64%)	17 (39%)
Bachelors or higher	5 (23%)	10 (23%)
Household Income		
< $30,000	6 (27%)	22 (50%)
$30,000 - $39,999	5 (23%)	6 (14%)
> $40,000	11 (50%)	13 (30%)
Insurance type		
None	1 (5%)	6 (14%)
Medicaid	3 (14%)	8 (18%)
Private	18 (82%)	30 (68%)

Major Themes: Focus Groups

Both	Urban (n = 22)	Rural (n = 44)
• Lack of HIV knowledge • Low perceived need for PrEP • Lack of education on PrEP targeted for Black women • Multiple structural barriers to accessing PrEP	• HIV stigma will keep Black women from accessing PrEP	• Distrust in medical institutions and doctors • Fear of accessing PrEP because of un- or intentional disclosure • Healthcare is not prioritized

Prioritized Attributes:

- Provider type
- Healthcare facility
- Where you receive medication
- Frequency of visits

DCA Demonstration

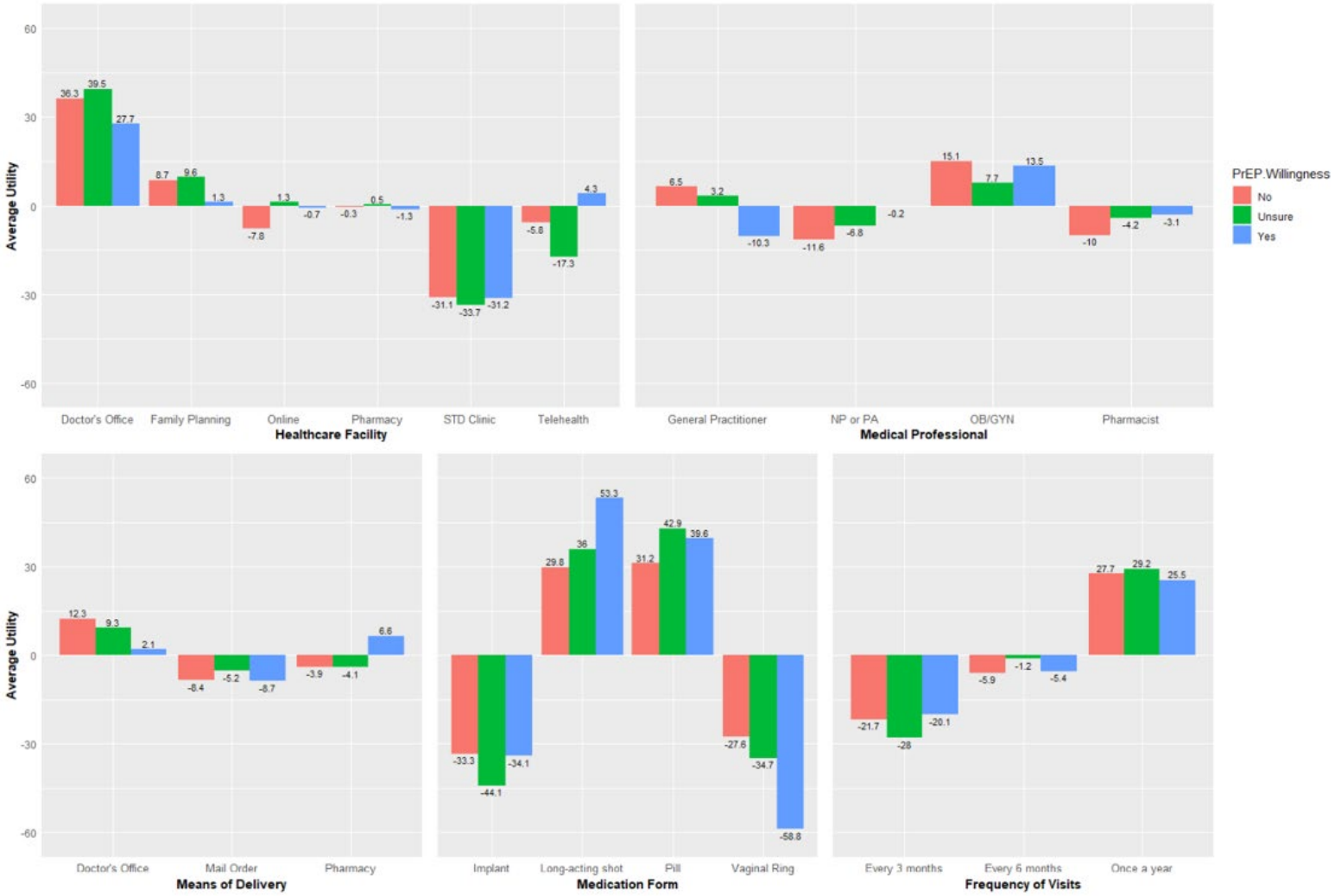
PrEP is a medication that is taken to prevent you from getting HIV. Assuming you agree to consider taking PrEP and these options were your only options to PrEP services, which would you choose?

(2 of 12)

Healthcare Facility	Telehealth **i**	STD Clinic **i**	Family Planning Clinic **i**
Medical Professional	General or Family Practitioner	OB/GYN	Pharmacist
Where you receive medication	Mail Order **i**	Doctor's Office	Pharmacy
PrEP Medication Form	Pill	Long-acting shot	Implant
Frequency of visits	Every 6 months	Once a year	Every 3 months
	✓	Select	Select

Characteristics (N = 795)	I Don't Know n = 277 n (%)	No n = 283 n (%)	Yes n = 235 n (%)
Urban	166 (60)	174 (62)	151 (64)
Rural	111 (40)	109 (38)	84 (34)
Age, mean(SD)	**37.9 (11.95)****	**37.9 (12.39)****	**33.9 (10.74)****
Education			
High School or Less	62 (22)	75 (27)	46 (20)
Some College or Associates	100 (36)	103 (36)	97 (41)
Bachelor's Degree or Higher	115 (42)	105 (37)	92 (39)
Income > $25,000	190 (69)	199 (70)	161 (69)
Insurance Status			
Uninsured	35 (13)	19 (7)	23 (10)
Medicaid	32 (11)	36 (13)	28 (12)
Private/Medicare	210 (76)	228 (80)	184 (78)
Personal Automobile	255 (92)	258 (91)	212 (90)
Regular Doctor	218 (79)	229 (81)	192 (82)
HITS, mean(SD)	4.87 (1.7)	4.80 (2.0)	4.71 (1.4)
DUREL, Total Religiosity, mean(SD)	18.56 (4.30)	18.62 (4.41)	18.18 (4.26)
Non-organized Religiosity	3.33 (1.05)	3.36 (1.06)	3.17 (1.06)
Intrinsic Religiosity	**2.76 (1.71)***	**2.69 (1.65)***	**2.42 (1.47)***
Organized Religiosity	12.48 (2.82)	12.58 (2.89)	12.60 (2.75)
Perceived Social Support (PSS), Total. mean(SD)	5.38 (1.44)	5.63 (1.48)	5.56 (1.41)
PSS from Significant Others	**5.42 (1.59)***	**5.78 (1.59)***	**5.73 (1.52)***
PSS from Family	5.30 (1.64)	5.56 (1.68)	5.40 (1.68)
PSS from Friends	5.42 (1.54)	5.55 (1.63)	5.56 (1.58)
Experiences of Discrimination, mean(SD)	**39.18 (7.75)****	**40.65 (7.89)****	**38.44 (9.17)****
HIV Knowledge, mean(SD)	**12.12 (4.65)****	**12.04 (4.61)****	**13.32 (3.49)****
Reported Need for PrEP (Yes vs. No)	**11 (4)****	**8 (3)****	**43 (18)****
Number of Sex Partners, past 6 months, mean(SD)	**1.09 (0.9)***	**1.10 (1.5)***	**1.32 (1.0)***
HIV Stigma Score, mean(SD)	23.05 (4.72)	22.48 (5.12)	22.22 (5.56)
No PrEP Indication	**199 (72)****	**219 (77)****	**154 (65)****

Figure 1. Hierarchical Bayes Analysis of PrEP Service Delivery Preferences, Black Cis-gender Participants

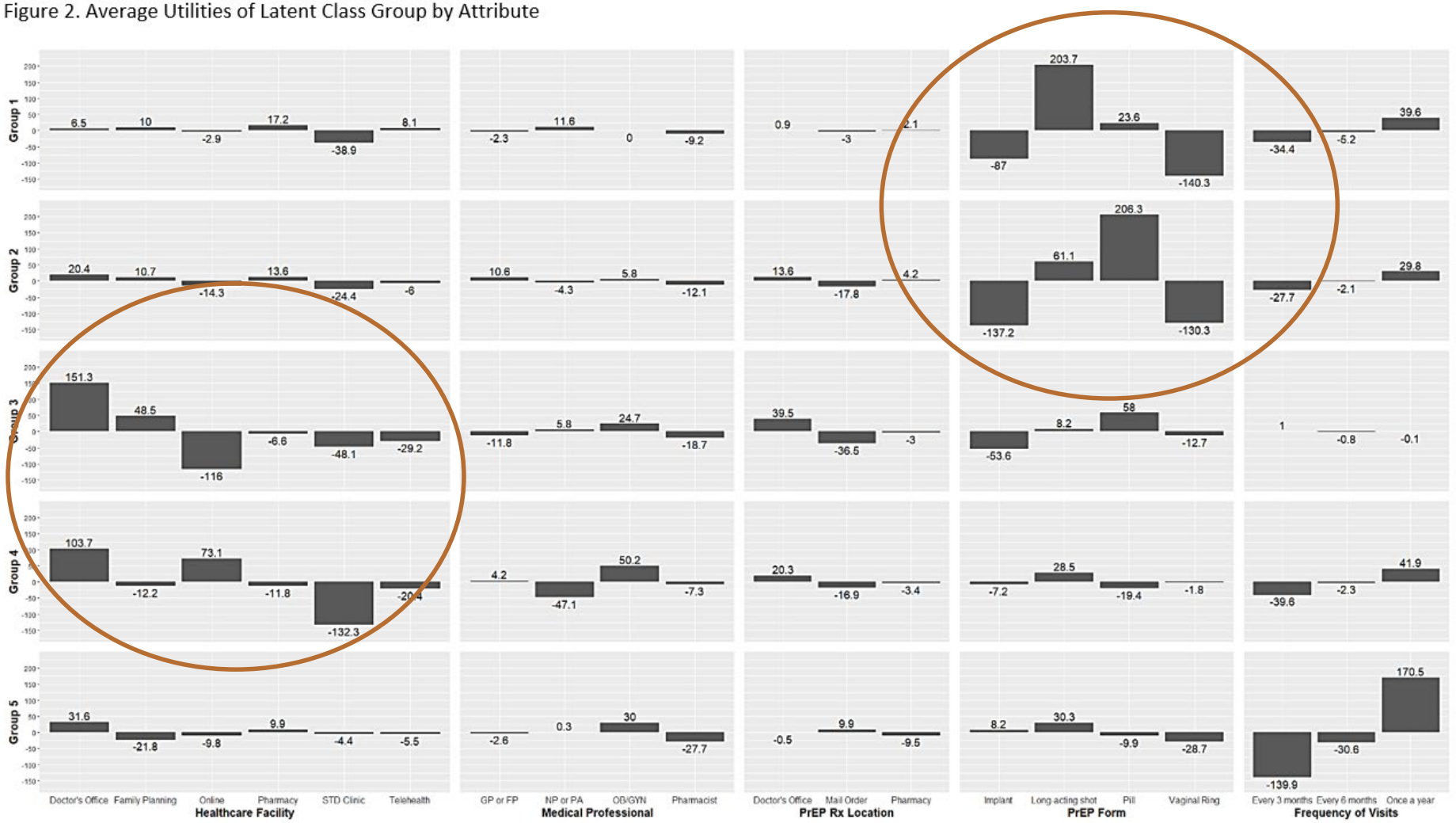


Characteristics of Participants in Latent Class Groups (N = 769)

Characteristics	Group 1 (n = 93) n(%)	Group 2 (n = 136) n(%)	Group 3 (n = 65) n(%)	Group 4 (n = 436) n(%)	Group 5 (n = 65) n(%)
Urban**	**64 (69)**	**91(67)**	**50(77)**	**239(55)**	**47(72)**
Education**					
High School or Less	**15 (16.1)**	**17 (12.5)**	**14 (21.5)**	**128 (29.4)**	**9 (13.8)**
Some College or Associates	**38 (40.9)**	**58 (42.6)**	**29 (44.6)**	**150 (34.4)**	**25 (38.5)**
Bachelor's Degree or Higher	**40 (43.0)**	**61 (44.9)**	**22 (33.8)**	**158 (36.2)**	**31 (47.7)**
PSS Total, mean(SD)*	**5.50 (1.23)**	**5.79 (1.17)**	**5.87 (1.30)**	**5.40 (1.54)**	**5.49 (1.67)**
PSS from Significant Others	5.72 (1.45)	5.79 (1.40)	6.01 (1.43)	5.52 (1.64)	5.63 (1.74)
PSS from Family**	**5.46 (1.54)**	**5.75 (1.45)**	**5.83 (1.67)**	**5.26 (1.71)**	**5.43 (1.83)**
PSS from Friends*	**5.30 (1.58)**	**5.83 (1.27)**	**5.77 (1.44)**	**5.43 (1.66)**	**5.40 (1.74)**
Experiences of Discrimination, mean(SD)*	**36.99(8.54)**	**39.82(7.07)**	**40.69(8.00)**	**39.77(8.59)**	**39.22(7.98)**
HIV Knowledge, mean(SD)**	**13.47(3.94)**	**13.50(3.33)**	**11.86(4.41)**	**11.89(4.63)**	**13.09(4.24)**
Willing to use PrEP (Yes)**	**45 (45.2)**	**46 (33.8)**	**9 (13.8)**	**118 (27.1)**	**20 (30.8)**

* indicates a p-value <0.05 and ** indicates p-value < 0.01

Figure 2. Average Utilities of Latent Class Group by Attribute

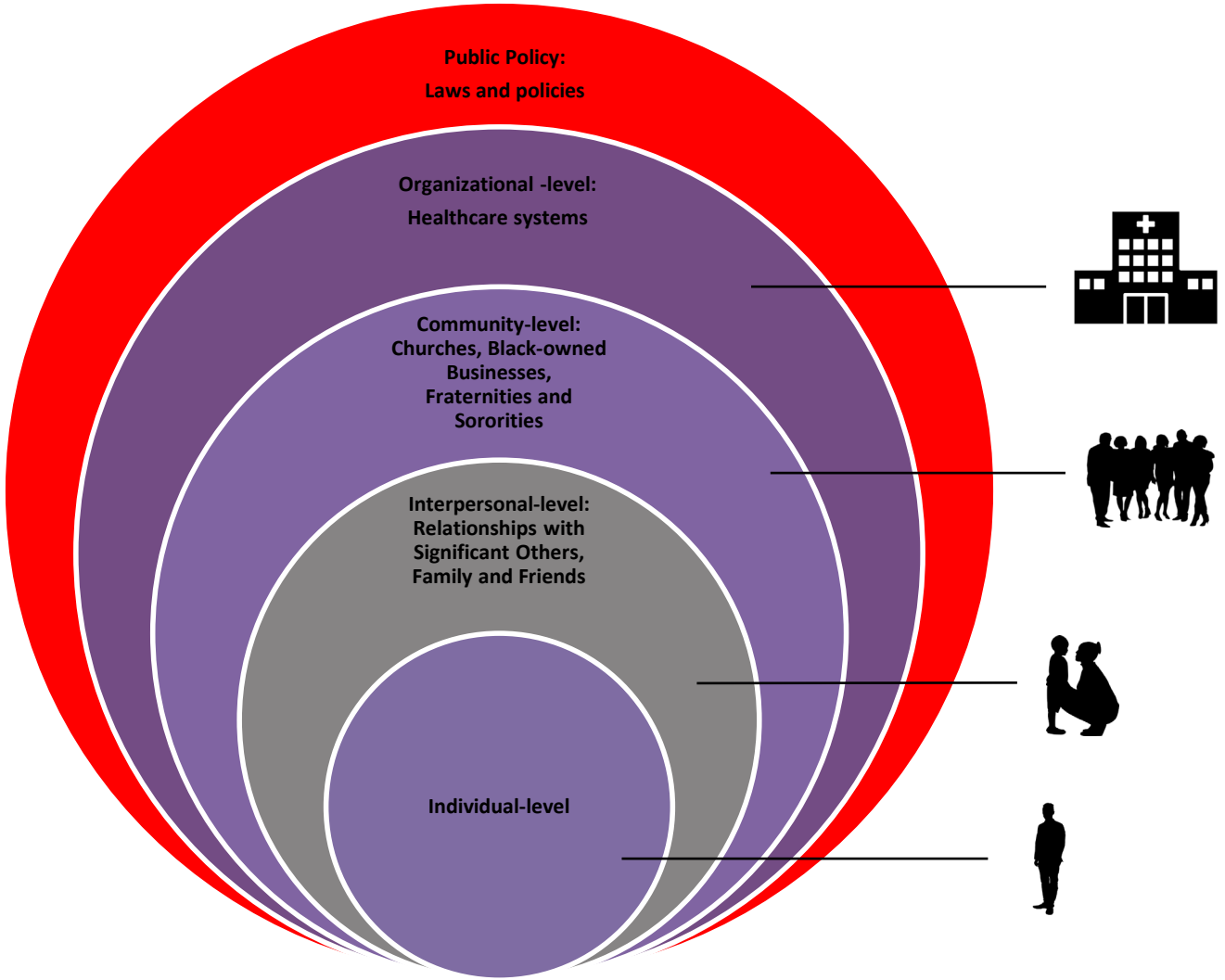


PrEP4Her – Integrating PrEP in GYN care

Improve engagement in PrEP care among Black cis-gender women in the South, by developing and piloting PrEP service delivery at gynecology clinics as part of routine reproductive and sexual health care visits.

- **Evaluate contextual barriers to PrEP implementation in GYN clinics**
- **Develop and refine a multi-component implementation strategy**
- **Pilot PrEP4Her**

Multi-level Interventions



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

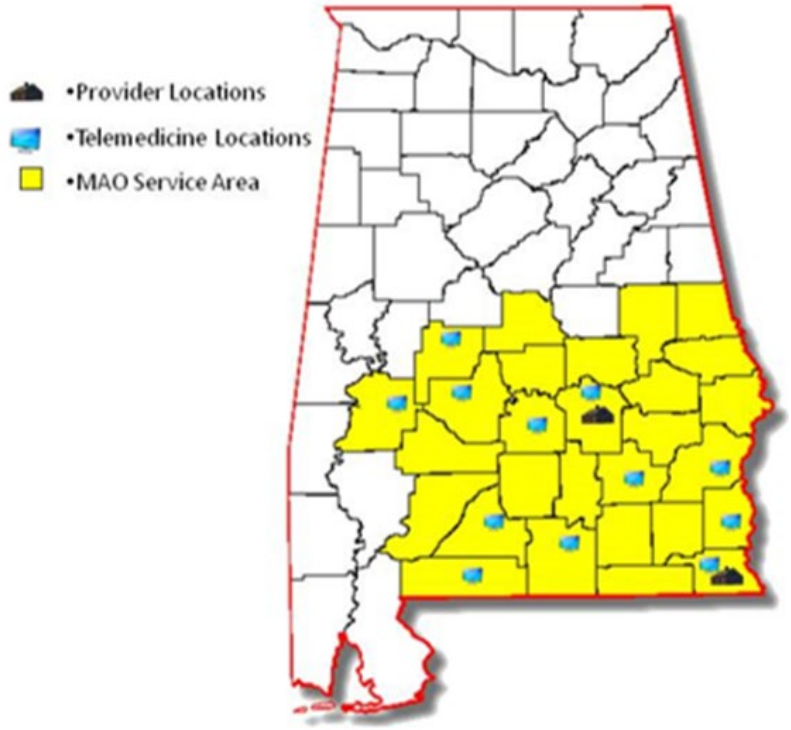
- Effective messaging to increase awareness
  - One study suggests action messaging that is brief, referred to PrEP as a pill and not mentioning condoms or STI testing as appealing

- Effectively implementing PrEP in Southern and Rural communities
  - Family Planning and Title X Clinics
  - OB/GYN Partnerships

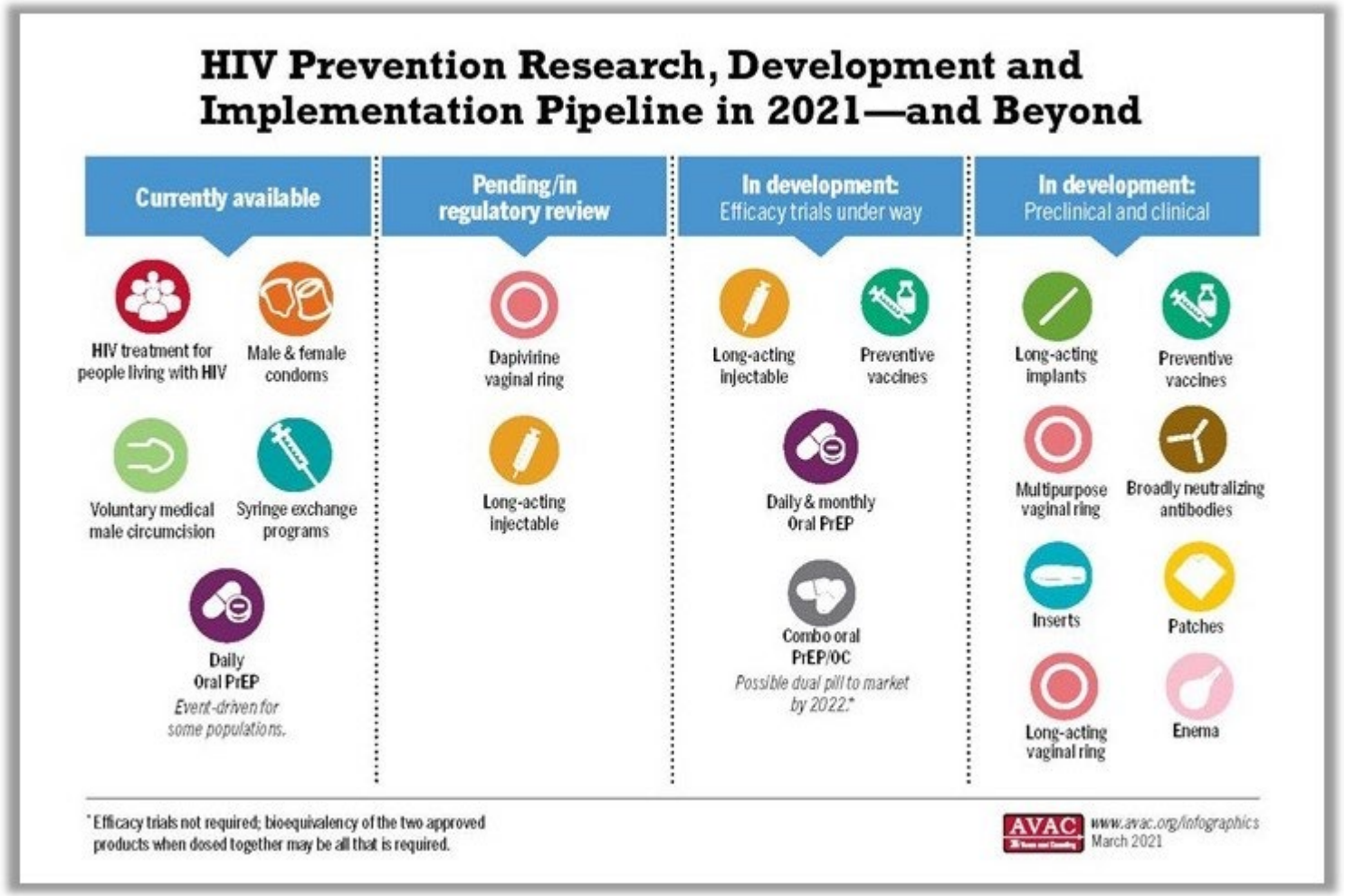
- Willie et al. IPV and PrEP Acceptability among Low Income, Young Black Women. AIDS Behavior. 2017
- Collier. Raising Awareness of PrEP among Women in New York City. J Healht Communication. 2017

Potential Service Delivery Models

- 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
    - 30 people on PrEP
    - All insured or self-pay

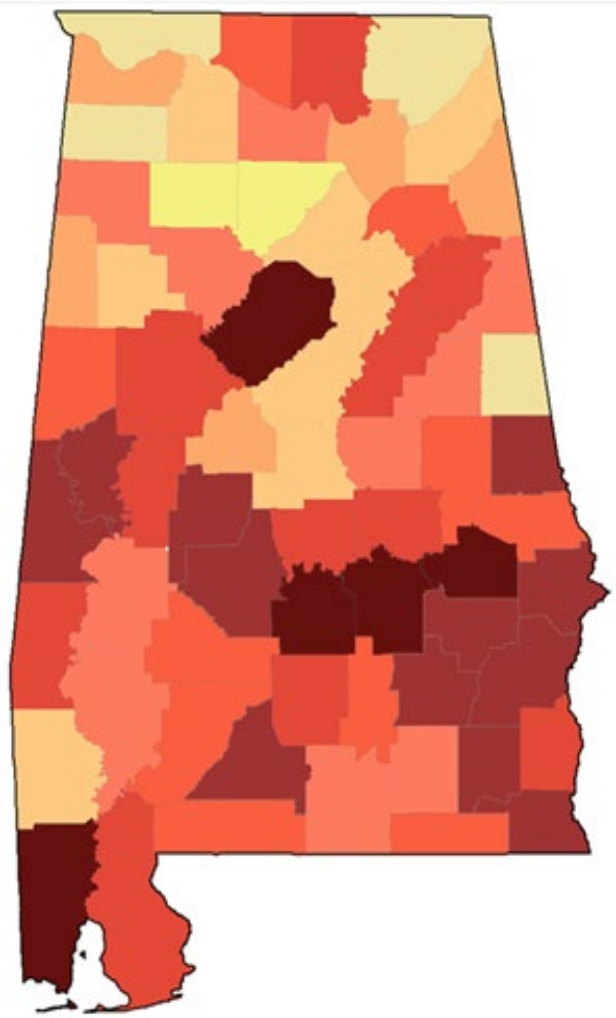


Other Options for PrEP Delivery



HIV in Alabama

- **Poverty in Alabama**
  - 18% of population live below the poverty line (AL 9th most impoverished state in the U.S.)
  - Non-Medicaid expansion state
    - Parents of dependent children only receive coverage if they have an income < $302/month for a family of 3 (cannot exceed 18% of federal poverty line)
    - Single adults and childless adults cannot receive coverage
    - Plan 1st Medicaid – Female ages 19-55 (family planning) and males > 21 (vasectomies only)
- **HIV in AL**
  - Jefferson County has the highest number of HIV cases each year
    - Highest rate of new infections per 100,000 residents occurs in rural counties
  - Black women are 10 x more likely to acquire HIV than other women
    - Most affected age group is from 15-29
    - Most common risk factor is heterosexual sex



https://www.cdc.gov/hiv/pdf/statistics/cdc-hiv-geographic-distribution.pdf http://www.al.com/opinion/index.ssf/2016/03/the_case_for_medicaid_expansio.html

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