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PrEP in Practice: Considerations for HIV Prevention Among Women of Color

Tuesday, May 10, 2016

12:00 PM - 1:30 PM

Together, we can change the course of the HIV epidemic...one woman at a time.



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About The Well Project

- Non-profit organization with a mission to change the course of the HIV/AIDS pandemic through a unique and comprehensive focus on women and girls
- Leverages technology to improve health outcomes and increase quality of life for women and girls living with HIV
- Focus is to provide accessible and comprehensive #information, #community support, and #advocacy building
- Access our resources and join our community at www.thewellproject.org



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About The Women's Collective

- Founded in 1990 by Patricia Nalls as a private phone line
- In 1992, phone line transformed into support group called “Coffee House”
- In 1995, incorporated as a non-profit organization
- Secured first two grants in 1996/opened first office in 1997
- We are still ONLY girl and woman focused community health and human service agency in D.C. that provides:
 - HIV/AIDS care & support services
 - HIV/STD prevention, education, and outreach services
 - Policy and advocacy services



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Webinar Agenda



HIV and HIV Prevention Among US Women: A Role for PrEP,
Charlene Flash, MD, MPH, Baylor College of Medicine



**Knowledge, Attitudes, and Likelihood of PrEP Use Among
Women of Color in the U.S.,** Judith Auerbach, PhD, University of
California, San Francisco, and The Well Project



Culturally Competent PrEP Education for Women of Color,
Martha Cameron, MPH, The Women's Collective



Co-Moderator, Krista Martel, Executive Director, The Well Project



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Webinar Details

- Webinar will last approximately 90 minutes with Q&A at end
- Use live chat box on left side to enter questions while someone is talking; questions will be put in queue
- If you are listening to webinar via your phone, please enter second audio pin to connect your phone to computer * (3-digit number)#
- Participants' lines will be muted



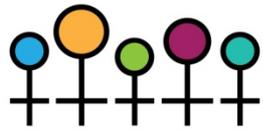
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HIV and HIV Prevention among U.S. Women: A Role for PrEP

Charlene A. Flash MD MPH
Baylor College of Medicine
May 10, 2016

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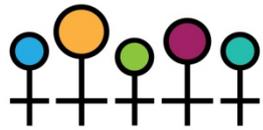
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Objectives

- Participants will learn about the epidemiology of HIV in the U.S. among women
- Participants will learn the potential role for PrEP among U.S. women
- Participants will be introduced to unique considerations of prescribing to women

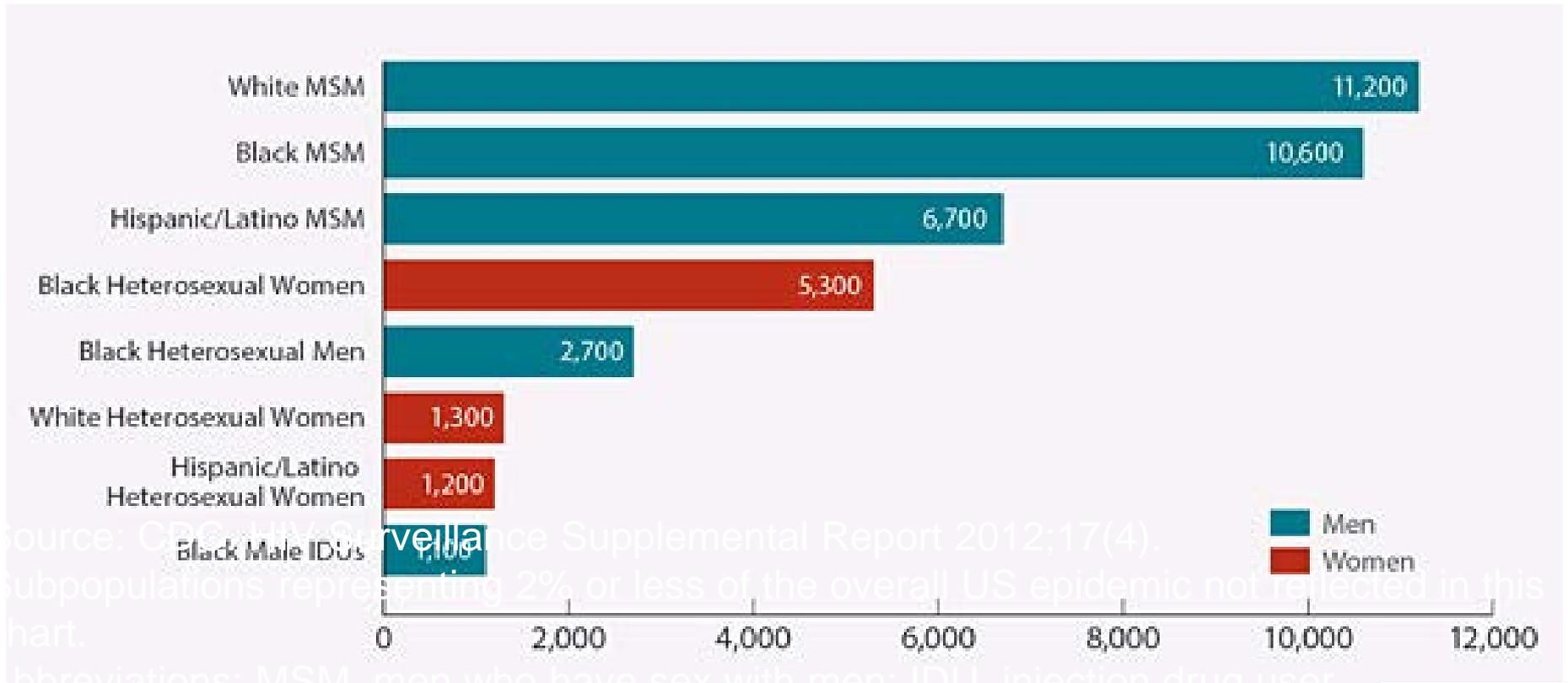


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U.S. Epidemiology of HIV among Women

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Estimated HIV Incidence among Adults and Adolescents in the United States, 2007–2010



Source: CDC. HIV Surveillance Supplemental Report 2012;17(4).

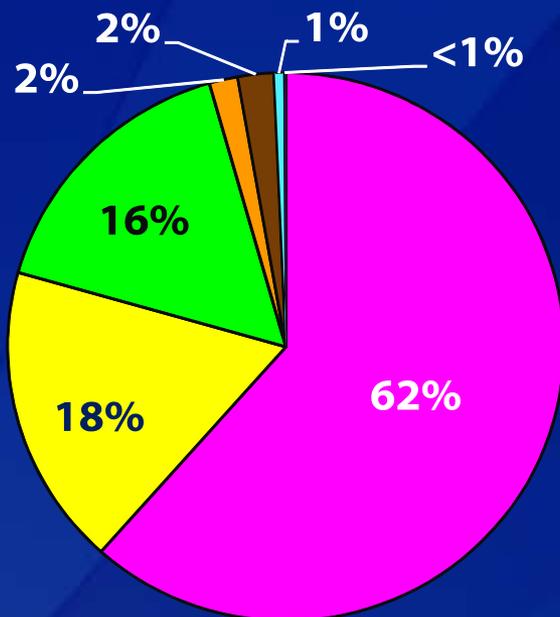
Subpopulations representing 2% or less of the overall US epidemic not reflected in this chart.

Abbreviations: MSM, men who have sex with men; IDU, injection drug user.

Diagnoses of HIV Infection and Population among Adult and Adolescent Females, by Race/Ethnicity 2014—United States

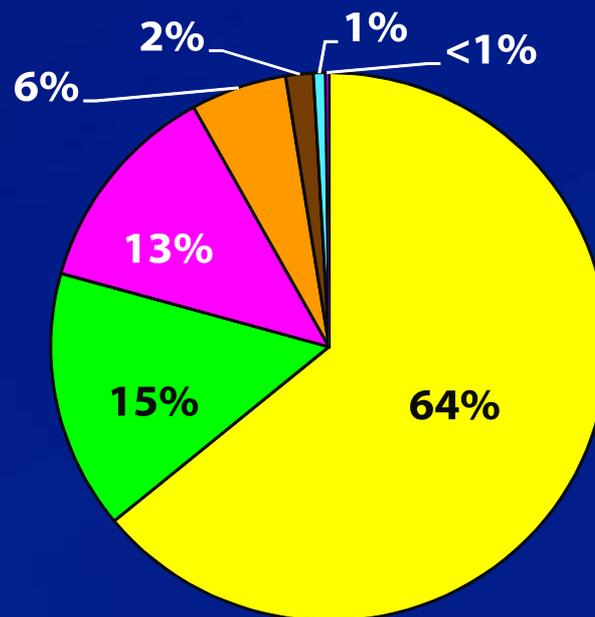
Diagnoses of HIV Infection

N = 8,328



Female Population, United States

N = 136,147,401



 American Indian/Alaska Native

 Asian

 Black/African American

 Multiple races

 Hispanic/Latino^a

 Native Hawaiian/other Pacific Islander

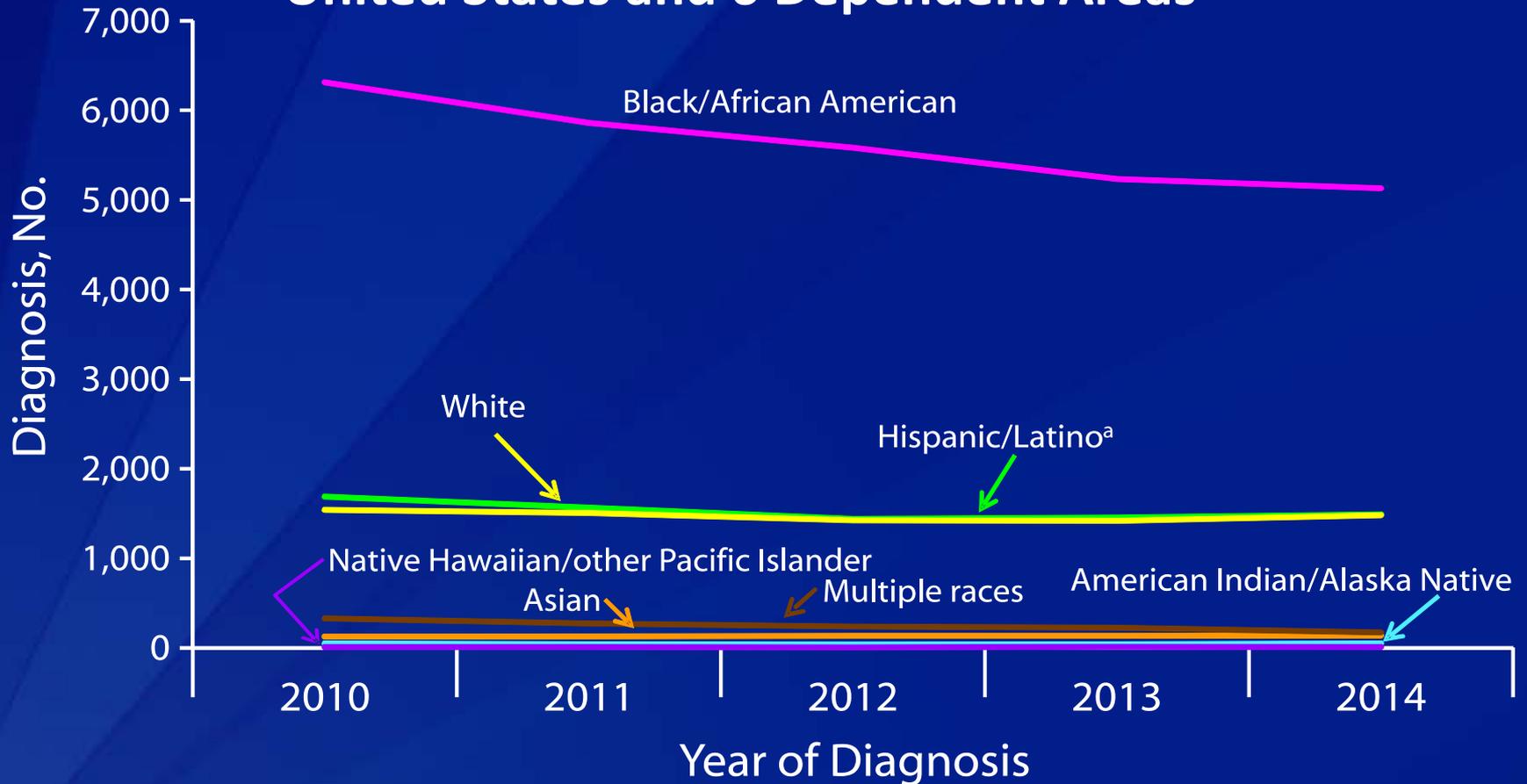
 White

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

^a Hispanics/Latinos can be of any race.



Diagnoses of HIV Infection among Adult and Adolescent Females, by Race/Ethnicity, 2010–2014 United States and 6 Dependent Areas

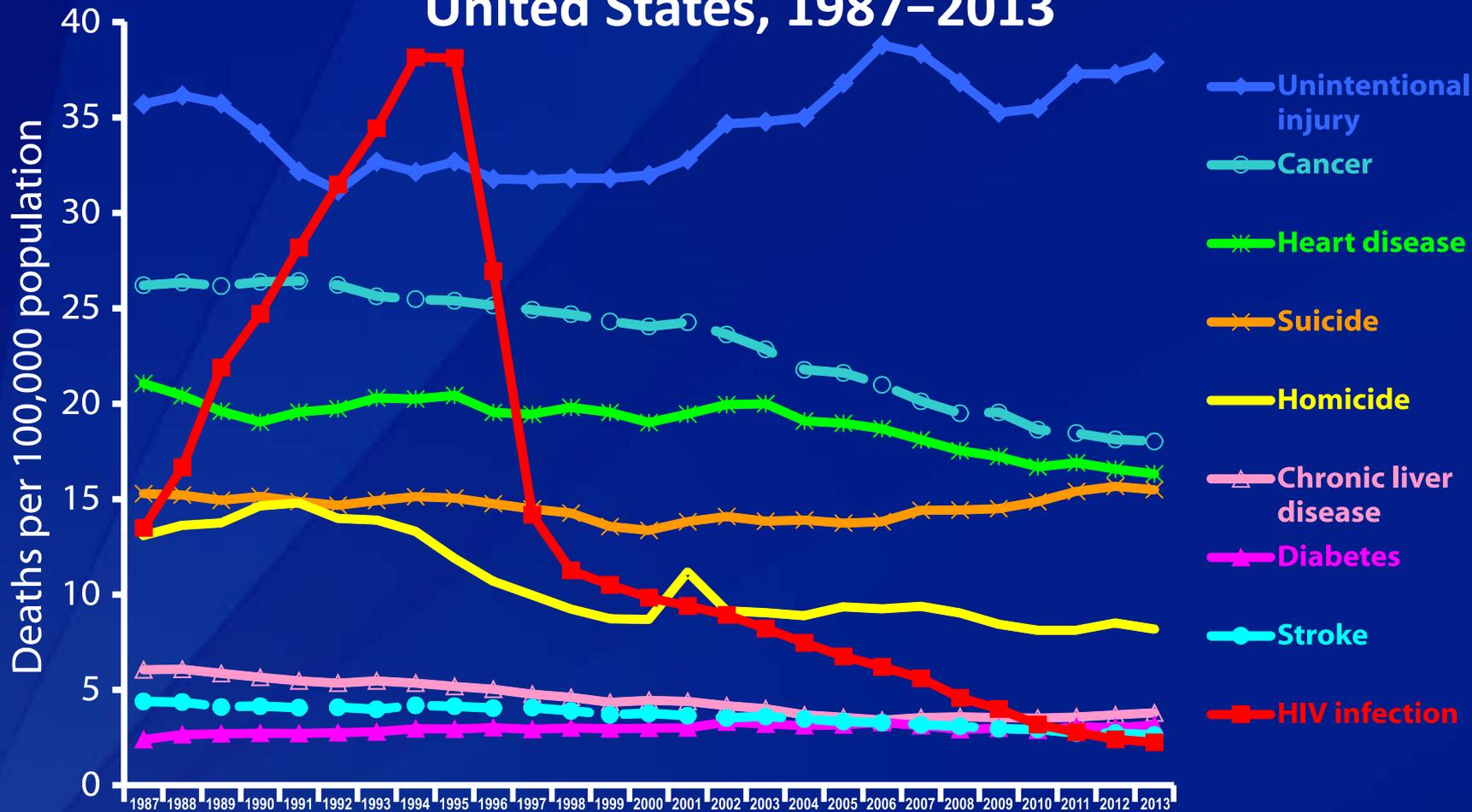


Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

^a Hispanics/Latinos can be of any race.



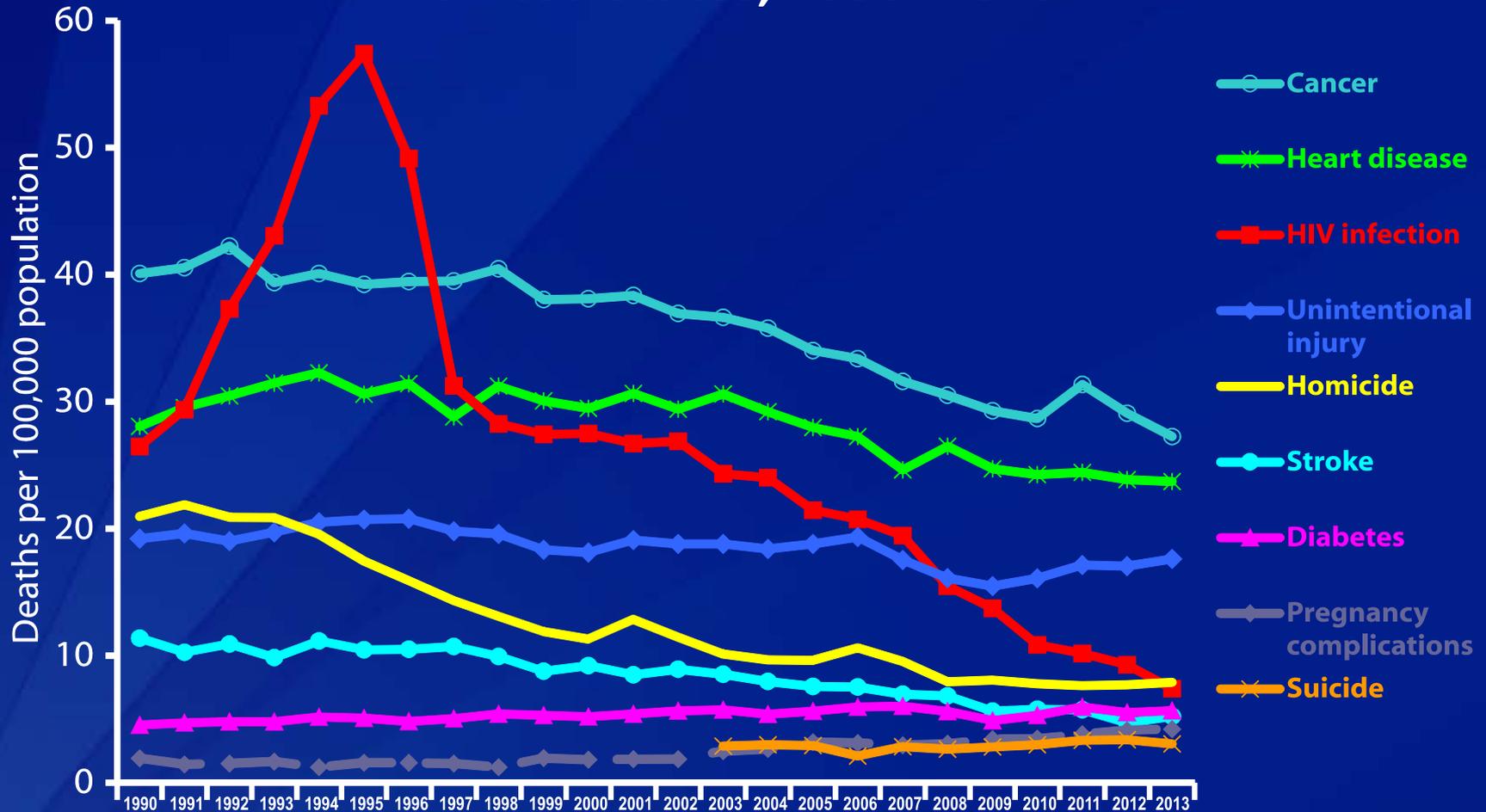
Trends in Annual Rates of Death due to the 9 Leading Causes among Persons 25–44 Years Old, United States, 1987–2013



Note: For comparison with data for 1999 and later years, data for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.



Trends in Annual Rates of Death due to the 9 Leading Causes among Black/African American* Women 25–44 Years Old, United States, 1990–2013



Note: For comparison with data for 1999 and later years, data for 1990–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.

*Does not include persons of Hispanic/Latino ethnicity



Deaths of Adult and Adolescent Females with Diagnosed HIV Infection, by Race/Ethnicity 2013—United States

Race/ethnicity	No.	Rate
American Indian/Alaska Native	18	1.8
Asian ^a	12	0.2
Black/African American	2,527	15.0
Hispanic/Latino ^b	570	2.8
Native Hawaiian/other Pacific Islander	2	1.0
White	743	0.9
Multiple races	239	11.6
Total^c	4,110	3.0

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Deaths of persons with diagnosed HIV infection may be due to any cause. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Rates are per 100,000 population.

^a Includes Asian/Pacific Islander legacy cases.

^b Hispanics/Latinos can be of any race.

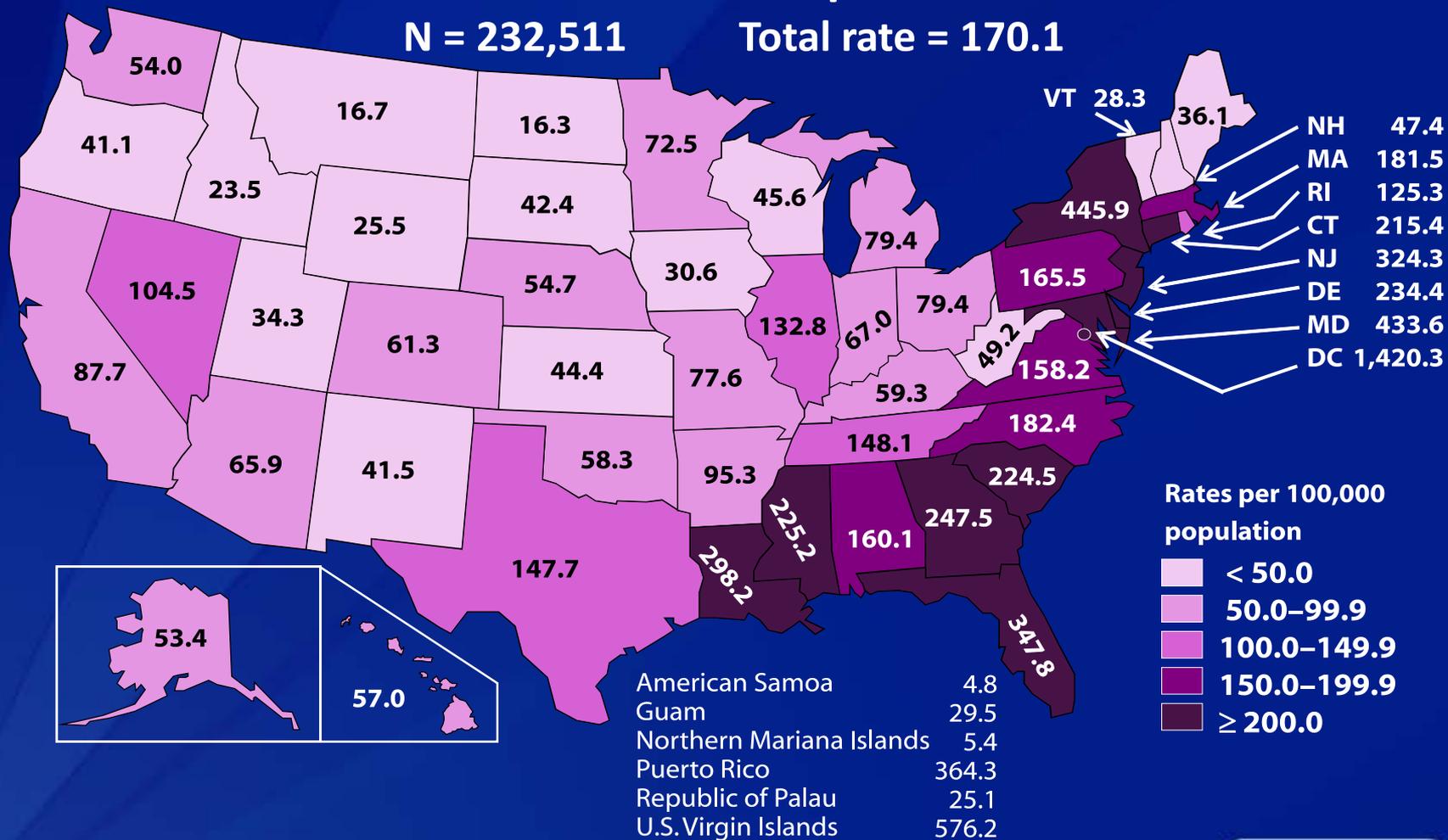
^c Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total.



Rates of Adult and Adolescent Females Living with Diagnosed HIV Infection, Year-end 2013— United States and 6 Dependent Areas

N = 232,511

Total rate = 170.1



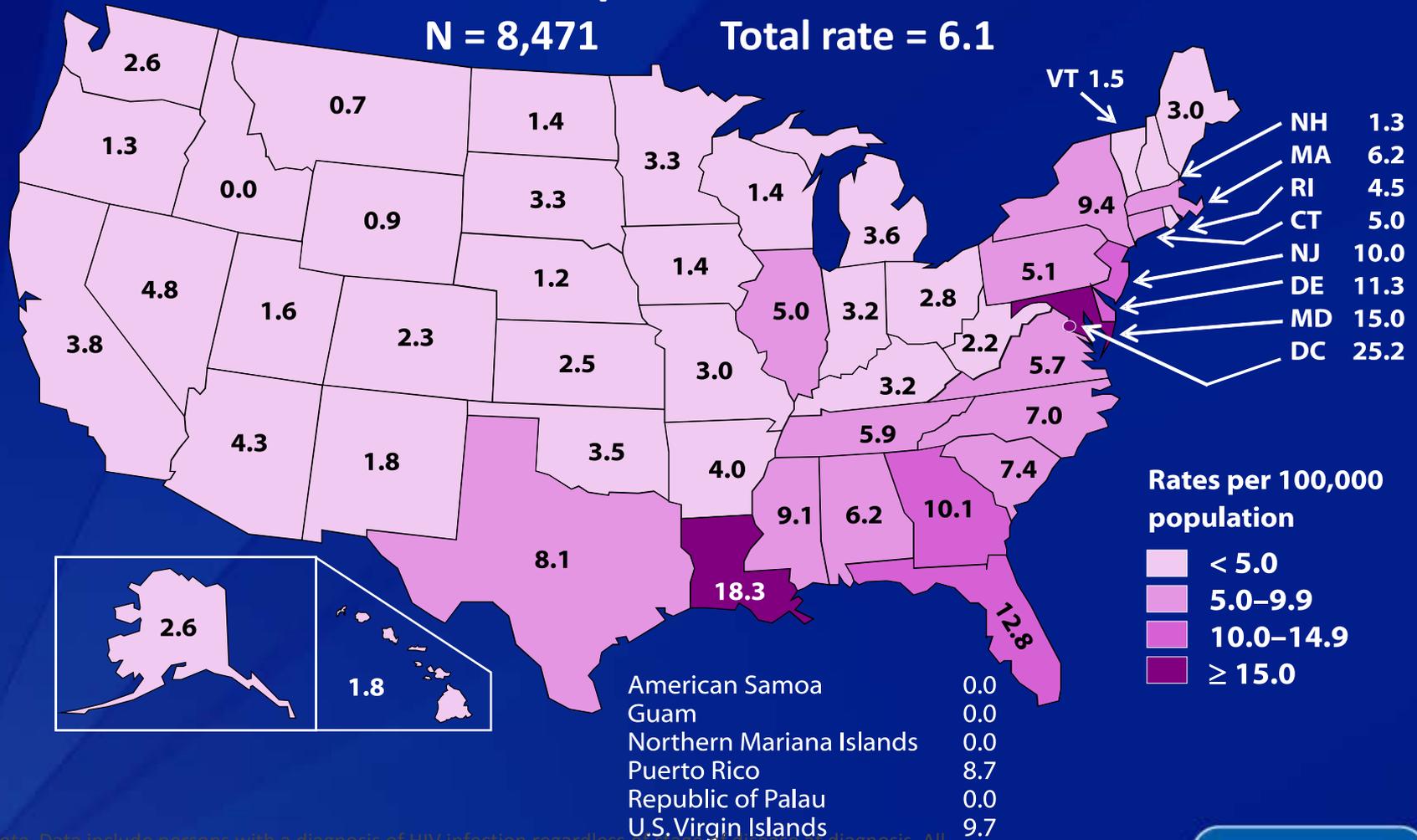
Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.



Rates of Diagnoses of HIV Infection among Adult and Adolescent Females, 2014—United States and 6 Dependent Areas

N = 8,471

Total rate = 6.1

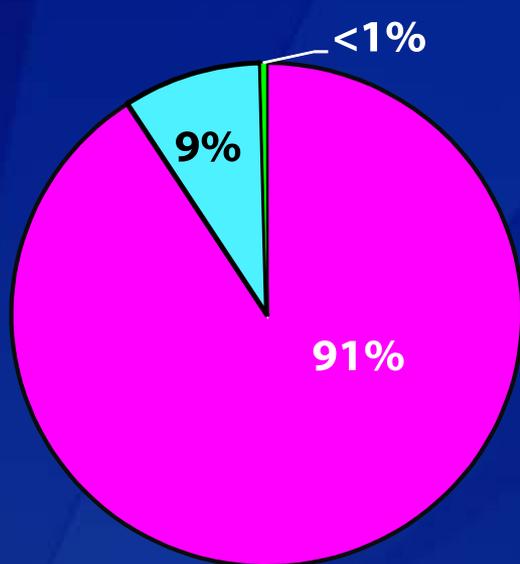


Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

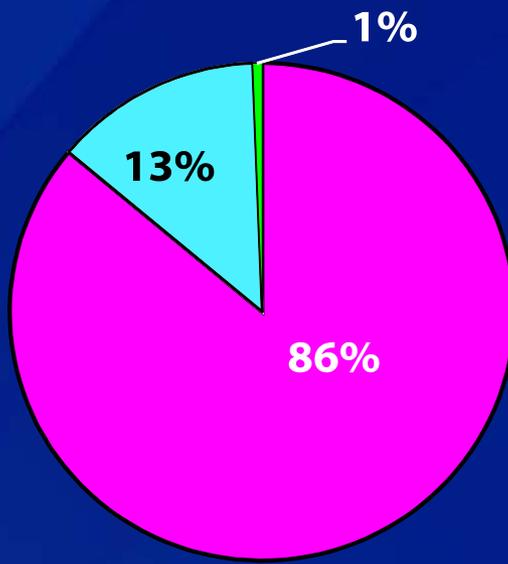


Diagnoses of HIV Infection among Adult and Adolescent Females, by Race/Ethnicity and Transmission Category 2014—United States and 6 Dependent Areas

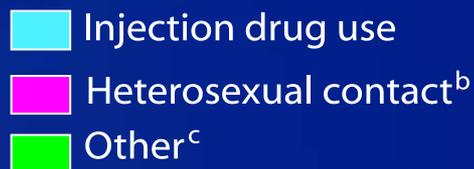
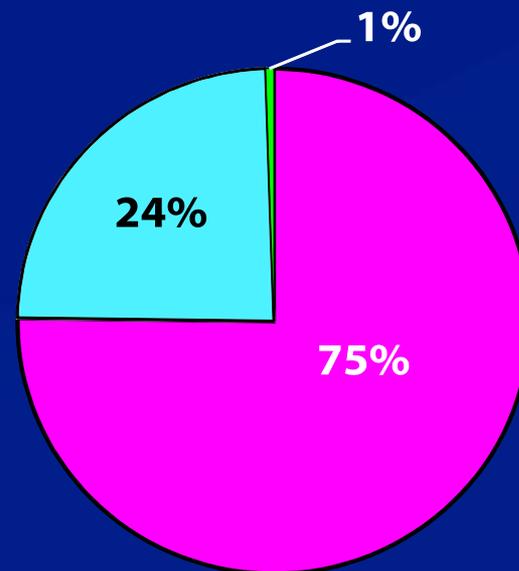
Black/African American
N=5,131



Hispanic/Latino^a
N=1,490



White
N=1,483



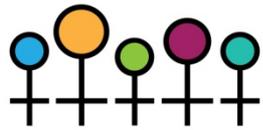
Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

^a Hispanics/Latinos can be of any race.

^b Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

^c Includes blood transfusion, perinatal exposure, and risk factor not reported or not identified.





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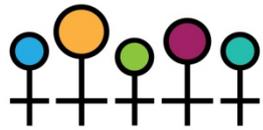
Risk Factors

- Majority of transmission among U.S. women via intercourse
- High prevalence of HIV among U.S. Black women is disproportionate to their engagement in traditional risk behaviors
 - Number of partners
 - Non-condom use

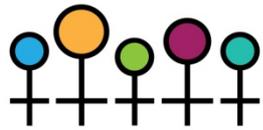
Wingood GM, Health Educ Behav, 2000.
Aral SO, Lancet 2008

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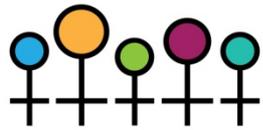


- Sexual mixing patterns
 - High HIV prevalence in African-American and Hispanic/Latino communities
 - Many people tend to have sex with partners of the same race/ethnicity
 - Women from these communities face greater risk of HIV infection with each new sexual encounter



Risk Factors

- Injection drug and other substance use
 - Directly
 - Sharing drug injection equipment contaminated with HIV
 - Indirectly
 - Engaging in high-risk behaviors while under the influence of drugs or alcohol



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Risk Factors

- Structural factors
 - Poor access to health care
 - Lack of stable housing
 - Limited HIV prevention education
- Increased prevalence of other STIs

Wingood GM, Health Educ Behav, 2000.
Aral SO, Lancet 2008

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HIV Risk Among Women

- HIV risk during vaginal sex without a condom/other protection (i.e., PrEP) higher for women for men
- Anal sex without a condom/PrEP riskier for women than vaginal sex
 - More than 20% of women 20 - 39 who responded to a national survey reported anal sex in the past year
- Some women afraid partner will leave or physically abuse them if they try to talk about condom use

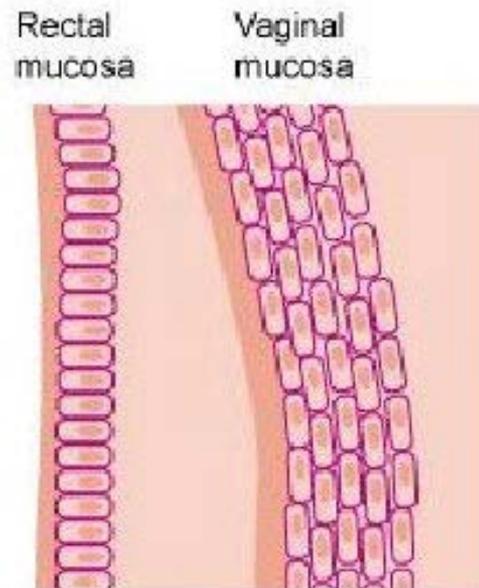
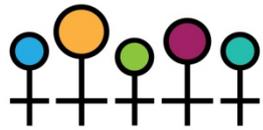


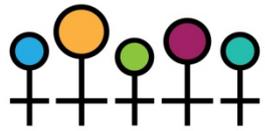
Image from Microbicide Trial Network.
<http://www.mtnstopshiv.org/node/2864>



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Barriers to Condom Use

- Personal perception of being low-risk
- Educational status
- Low socio-economic status
- Desire to conceive
- High partner-related barriers to condom use
 - Fear of perceptions of unfaithfulness
 - Intimate partner violence
 - Sexually abused women may be more likely to exchange sex for drugs, have multiple partners, or have sex with a partner who is physically abusive when asked to use a condom



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A Role for PrEP among Women

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Pre-exposure Prophylaxis (PrEP)

- Vulnerable people take a pill on a daily basis to prevent HIV
- Only one FDA approved drug
 - Once-daily tablet
 - Co-formulated tenofovir disoproxil fumarate 300 mg (TDF) and emtricitabine (FTC) 200 mg
- 44 to 67% effective in clinical trials

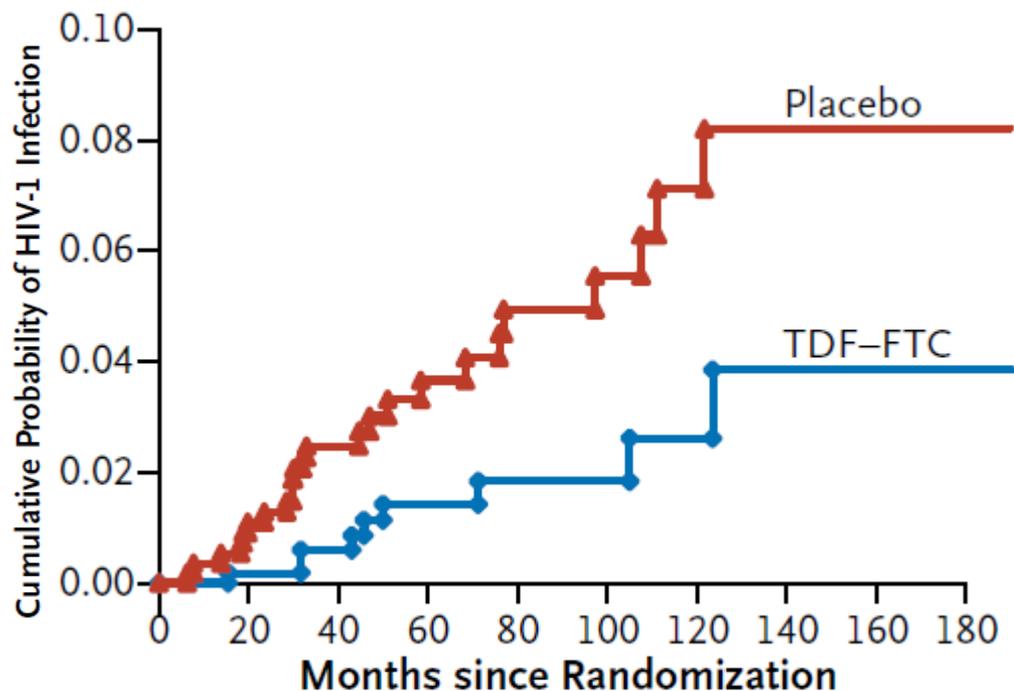


....If taken perfectly 92% effective in clinical trials and 100% effective in published data on real world implementation



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Oral PrEP TDF2-CDC



- Randomized Control Trial
- 1200 men and women
 - Botswana
 - Daily oral
 - FTC-TDF vs. placebo

- 63% reduction in the risk of HIV acquisition

Thigpen, M.C., N Engl J Med, 2012.

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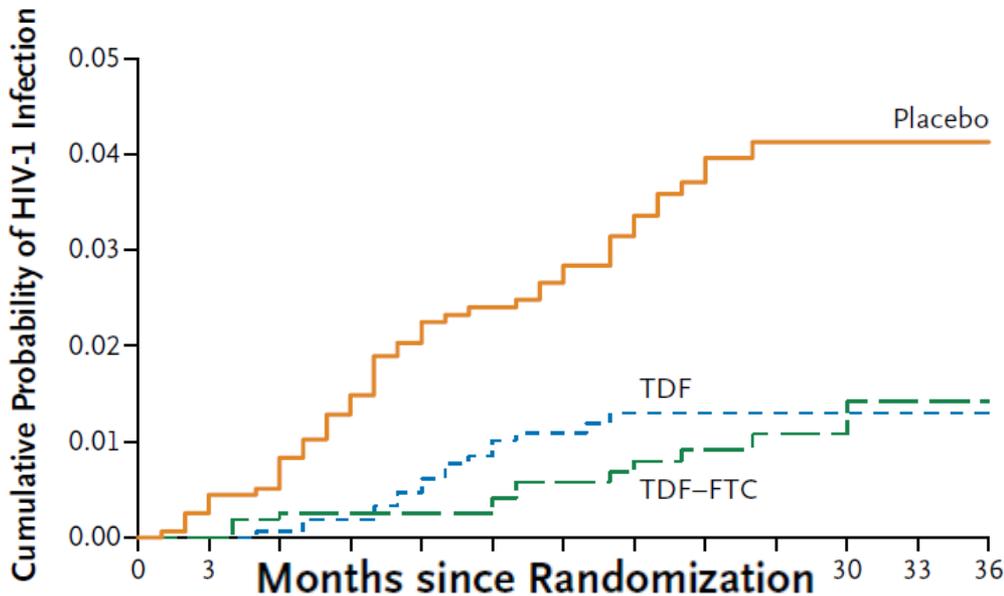
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Oral PrEP

Partners PrEP



- TDF → 62% fewer infections
- FTC-TDF → 73% fewer infections

Baeten, J.M. N Engl J Med, 2012.

- 4758 HIV sero-discordant heterosexual couples
 - Kenya & Uganda
 - TDF vs. FTC-TDF vs. placebo
 - Pregnancy rate was high (10.3 per 100 person-years) with no diff between groups



Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	<ul style="list-style-type: none"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	<ul style="list-style-type: none"> Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs 		
	Do oral/rectal STI testing	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	Access to clean needles/syringes and drug treatment services

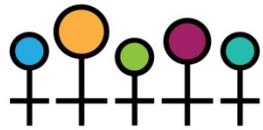
STI: sexually transmitted infection



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Potential PrEP Users

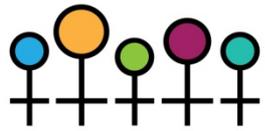
- Known partner who has HIV
 - Indicate that they do not always use condoms
 - HIV + partner's viral load not consistently undetectable
- Recent history of transactional sex
- Bacterial sexually transmitted infection
- Inconsistent or non-condom use
- Injection drug use, alcohol dependence
- Incarceration
- High risk partner



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PrEP Empowers Women!

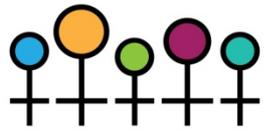
- Women
 - Can control her risk of getting infected with HIV
 - Without relying on HIV+ partner ART adherence
 - Without relying on ability to navigate condom use
 - Privately and safely



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Unique Considerations for Women

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How Long Until it Takes Effect?

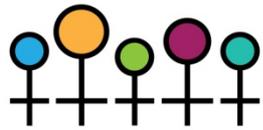
- For oral PrEP
 - Maximum intracellular concentrations
- Cervicovaginal tissue – 20 days
- Blood – 20 days
- Rectal tissue - 7 days
 - 5 to 20% of at-risk women in the U.S. and Africa engage in anal intercourse



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Importance of Adherence and Acceptance

- Nonjudgmental
 - Adherence assessment
 - Adherence support
- Acceptability
- Many at-risk people may not be engaged in care
 - Prescriber
 - “PrEP will empower women” → willing to prescribe
 - Monitoring



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Oral PrEP: *Importance of Adherence*

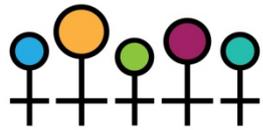
Fem-PrEP and VOICE

- Fem-PrEP
 - RCT ~2000 high-risk women
 - Kenya, South Africa, Tanzania
 - > 1 partner in past month
 - ≥ 1 intercourse in past week
 - Daily oral FTC-TDF vs. placebo
- Interim data **no difference** in rate of new HIV infections
- Adherence < 40%
 - Only 30% felt themselves to be at risk.

Van Damme, L., N Engl J Med, 2012.

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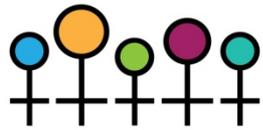
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Efficacy and Safety

- Real-world efficacy
- Long-term drug safety considerations
 - Nausea and mild inadvertent weight loss
 - in about 1-2% of the study participants
 - 1% BMD loss at the total hip and femoral neck
 - rate of bone fractures was no different



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PrEPception

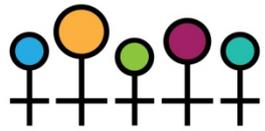
- PrEP should be discussed with heterosexually active women and men whose partners are known to have HIV infection
- One of several options (IIB)
- Begin **one month before** conception
- Continue **one month after** conception



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Breastfeeding and PrEP

- Details of PrEP safety for infants exposed during lactation could benefit from further study.
- *Infants born to HIV-infected mothers and exposed to TDF or FTC through breast milk suggest limited drug exposure.*
- *World Health Organization recommends TDF/FTC or 3TC/efavirenz for all pregnant and breastfeeding women to prevent perinatal and postpartum mother-to-child transmission of HIV*



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Future PrEP formulations



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Selected References

1. Baeten, J.M., et al., *Antiretroviral prophylaxis for HIV prevention in heterosexual men and women*. N Engl J Med, 2012. 367(5): p. 399-410.
2. Cohen, M.S., et al., *Prevention of HIV-1 infection with early antiretroviral therapy*. N Engl J Med, 2011. 365(6): p. 493-505.
3. Thigpen, M.C., et al., *Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana*. N Engl J Med, 2012. 367(5): p. 423-34.
4. Flash C, Krakower D, Mayer K: The Promise of Antiretrovirals for HIV Prevention. Curr Infect Dis Reports 2012.
5. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, et al: Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med, 363(27):2587-2599.
6. Hallfors DD, Iritani BJ, Miller WC, Bauer DJ. *Sexual and drug behavior patterns and HIV and STD racial disparities: the need for new directions*. Am J Public Health 2007 Jan;97(1):125-32.
7. Marks G, Crepaz N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. AIDS. 2006;20(10):1447–50.
8. US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection In The United States – 2014: A Clinical Practice Guideline. <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>



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Thomas Street Health Center

2015 Thomas Street, Houston TX

Prevention Program

Walk-up testing, 1st floor

phone: 713.873.4157

flash@bcm.edu

For more information:

www.PrEPHouston.org



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Knowledge, Attitudes, and Likelihood of PrEP Use Among Women of Color in the U.S.

Judith D. Auerbach, PhD
University of California, San Francisco and
The Well Project
May 10, 2016

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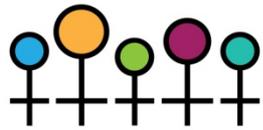




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Introduction

- None of the completed, large-scale clinical trials of PrEP efficacy has included U.S. women
- Notwithstanding this, the FDA approved the use of oral Truvada for PrEP among U.S. women in 2012, even though little, if anything was known about knowledge, attitudes, and likelihood of using PrEP among them
- In the past few years, a number of studies have been conducted to ascertain what women at risk for HIV infection know and think about PrEP
- Findings from these studies should help inform PrEP implementation programs and clinical practice



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Overview

- Focus Group Studies
 - Pre- and Post-FDA Approval
- Surveys
 - Nationally representative household survey-adult women
 - Behavioral risk survey w/transwomen in SF
 - Cross-sectional survey HIV+ men/women urban clinic Philadelphia
- Common Findings & Themes



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PrEP Focus Group Studies

Pre-FDA Approval

Smith DK, Toledo L, Smith DJ, Adams MA, and Rothenberg R. 2012. Attitudes and program preferences of African-American urban young adults about pre-exposure prophylaxis (PrEP). *AIDS Education and Prevention*, 24(15):408-421.

Sample:

- African-American young men and women, ages 18-24 year, at risk for HIV acquisition
- 8 mixed gender and 2 MSM-only focus groups in Atlanta, June-August, 2009
- In the mixed gender groups, young women were 60.3% of participants (N=35)

Key Findings:

- Participants reported substantial interest in PrEP
- Core issues: cost, effectiveness, and ease of accessing services and medications
- Barriers: low perceived susceptibility to contracting HIV; ability to take a pill every day; concern about others' perceptions about someone taking medication
- Majority of participants thought PrEP wouldn't alter condom use practices (continued concern about other STIs)



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PrEP Focus Group Studies: Pre-FDA Approval

Flash CA, Stone VE, Mitty JA, Mimiaga MJ, Hall KT, Krakower D, Mayer KH. 2014. Perspectives on HIV prevention among urban black women: a potential role for HIV pre-exposure prophylaxis. *AIDS Patient Care and STDs*, 28(12):635-642.

Sample:

- 5 focus groups with 26 black women, ages 18-50 (mean age 40), recruited from a primary care facility and its affiliated HIV testing sites in Boston; Jan-March 2012

Key Findings:

- A majority of women expressed interest in PrEP; Most preferred pills to gel
- Concerned about cost
- Women under 30 more open to consider using combination approaches, e.g., pill and condoms, and would be interested in trying either pill, gel, or both
- Some were not interested in using PrEP at all, due to mistrust of pharma (just want to make money) and worry about being “guinea pigs”
- Participants preferred daily dosing (to intermittent), believing it would enhance adherence



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PrEP Focus Group Studies Pre- and Post-FDA Approval



Will and Should Women in the U.S. Use PrEP? Findings from a Focus Group Study of At-risk HIV-negative Women in Oakland, Memphis, San Diego, and Washington, DC

Judith D. Auerbach, Research Consultant to AIDS United & San Francisco AIDS Foundation, San Francisco, CA
Alyx Banyan, Project Consultant to AIDS United, Oakland, CA
Maura Riordan, AIDS United, Washington, DC

XIX International AIDS Conference
July 27, 2012
Washington, DC, USA
(Abstract FRLBD04)



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Knowledge, Attitudes, and Likelihood of Pre-Exposure Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV

Judith D. Auerbach, PhD¹, Suzanne Kinsky, MPH², Gina Brown, MSW², and Vignetta Charles, PhD⁴

Abstract

Although the Food and Drug Administration (FDA) approved oral Truvada for pre-exposure prophylaxis (PrEP) for women at risk of HIV infection in the US in July 2012, and the Centers for Disease Control and Prevention (CDC) issued guidance for clinicians to provide PrEP to women "at substantial risk of HIV acquisition" in May 2014, there remain no clinical trial data on efficacy among US women, and there is a dearth of research on knowledge, attitudes, and likelihood of use of PrEP among them. We conducted a qualitative focus group (FG) study with 144 at-risk women in six US cities between July and September 2013, including locations in the Southern US, where HIV infections among women are most prevalent. FG questions elicited awareness of PrEP, attitudes about administration and uptake, and barriers to and facilitators of use. Women expressed anger at the fact that they had not heard of PrEP prior to the study, but once informed most found it attractive. PrEP was seen as additional, not substitute, protection to condoms, and participants suggested several dissemination strategies to meet the diverse needs of women. Key barriers to PrEP uptake included distrust of the medical system, stigma, and cost. Findings suggest that US women view PrEP as an important prevention option, assuming side effects and the cost to the consumer are minimal, the efficacy of the drug is reasonable, and PrEP is delivered by trusted providers in trusted venues.

Introduction

APPROXIMATELY ONE-QUARTER of all people living with HIV in the US are women,^{1,2} and women accounted for 20% of new HIV infections³ and 25% of new AIDS diagnoses in 2011.³ The vast majority (84%) of HIV infections among women are attributed to heterosexual sex.⁴ Although the overall rate of new infections among women in the US has declined,⁵ there exist significant racial and ethnic disparities. Black women account for nearly two-thirds (64%) of new infections among women, though they represent only 13% of the American population.⁶ In 2010, the rate of new infections among black/African American women was 20 times that of white women and the rate among Hispanic/Latina women was 4 times that of white women.⁷ Young women, including those of reproductive age, are significantly affected: nearly one-third of new infections (29%) among women occur among those aged 25–44, and 22% among women aged 13–24.⁸

As HIV transmission continues to occur among women, it is imperative to make effective HIV prevention strategies available to them—particularly those that women can control (unlike the use of male condoms, for example). One such strategy that has received increased attention in recent years is oral pre-exposure prophylaxis (PrEP) with antiretroviral drugs. PrEP has demonstrated efficacy in three randomized clinical trials conducted mostly outside the US involving gay men, serodiscordant couples, and heterosexual men and women,^{9–11} but two studies involving only women were not able to demonstrate efficacy.^{9,10} Although the Food and Drug Administration (FDA) approved oral Truvada (emtricitabine/tenofovir disoproxil fumarate) for PrEP for at-risk women in the US in July 2012,¹¹ and the Centers for Disease Control and Prevention (CDC) issued guidance for clinicians to provide PrEP to women "at substantial risk of HIV acquisition" in May 2014,¹² there remain no clinical trial data on efficacy among US women. There is a dearth of research on knowledge, attitudes, and likelihood of use of PrEP among

"Why Haven't We Heard About This?" Knowledge, Attitudes and Likelihood of Use of PrEP among At-risk Women in the U.S.

Judith D. Auerbach, PhD (University of California, San Francisco), Gina Brown (Positive Women's Network-USA), Vignetta Charles, PhD (AIDS United)

Background

Oral Truvada was approved for HIV pre-exposure prophylaxis (PrEP) in July 2012 and CDC issued guidelines in May 2014. But none of the completed clinical trials evaluating PrEP efficacy has included U.S. women, who comprise 20% of HIV infections in the country. Thus PrEP's potential as an HIV prevention strategy for at-risk American women is unknown.

Methods

We conducted 12 focus groups (FG) with 144 at-risk women in six cities between July and September 2013. 91% were Black/African American and 60% were aged 18–40.

Focus Group Sites

ATLANTA: SistaLove
CHICAGO: AIDS Foundation of Chicago
DALLAS: Alys Center
NEWARK: EHealth
NEW ORLEANS: Women With a Voice
NEW YORK: Ito House

Results

Once informed about PrEP, nearly all found it an important option and were upset that they had not yet heard about it.

"I feel like HIV is killing a lot of black people and they don't mind it happening. They're not going to tell us stuff that there are other things to prevent it. They are just not telling us about it. I will help campaign." (Atlanta)

PrEP was seen as additional, not substitute, protection to condoms.

"I would advise...if I had a man and I'm on PrEP - to use a condom because PrEP is just for HIV. We got all our STI and we got to protect ourselves anyway. So you're not just using the condom for HIV. You're having a condom to protect your body from getting anything." (New York)

Overwhelmingly, women saw oral and injectable formulations as desirable, but were less enthusiastic about vaginal rings.

"So I think that different strokes for different folks, but I think the pill will be something good. The secretive people would want the shot... But if we want to start opening up that conversation and opening up people's minds to PrEP, then it shouldn't even matter what the [formulation is]." (Dallas)

Table 1: Additional Facilitators and Barriers to PrEP Uptake Identified by FG Participants

Facilitator	Barrier
Primary Care Physician, OB-GYN	Lack of Communication Among Community Members
CBOs, Family Planning Clinics, and Community Health Centers	Mistrust of the Medical System
Media	Cost
Schools	Side Effects
Peer-to-peer, friend-to-friend, outreach	Stigma
	Nervousness
	Timing

Implications

Women at risk for HIV in the U.S. are likely to use PrEP if they learn about it and know it to be highly effective, affordable, lacking significant side effects, and promoted by trusted sources.

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AU PrEP Focus Group Studies Pre- and Post-FDA Approval

Auerbach JD, Banyan A, Riordan M. 2012. Will and Should Women in the U.S. Use PrEP? Findings from a Focus Group Study of At-risk HIV-negative Women in Oakland, Memphis, San Diego, and Washington DC. Oral Late-Breaker Presentation (Abstract FRLBD04). XIX International AIDS Conference, July 27, 2012, Washington, DC.

Auerbach JD, Kinsky S, Brown G, and Charles V. 2015. Knowledge, attitudes, and likelihood of pre-exposure prophylaxis (PrEP) use among US women at risk of acquiring HIV. *AIDS Patient Care and STDs*, 29(2):102-110.

Sample:

- 2 Rounds; Total N=236 women
 - Round 1 = before PrEP approved by FDA: 92 HIV-negative women in 4 cities: Oakland, Memphis, San Diego, Washington, DC, March-April 2012
 - Round 2 = After PrEP approved by FDA: 144 HIV-negative women in 6 cities: Atlanta, Chicago, Dallas, New Orleans, New York, Newark, July-September 2013
- Recruitment by local women-serving CBOs; FG led by trained, local facilitators



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AU FG Studies: Demographic Characteristics

	Round 1 (N=92)	Round 2 (N = 144)
Race/Ethnicity		
Black/African American	69%	92%
Latina/Hispanic	19%	7%
White/Other/Missing	7%	1%
Age		
18-30	24%	29%
31-50	55%	50%
51-60	21%	21%
Employed	50%	53%
Education		
At least some college	59%	30%
High School or GED	29%	52%
Income: Less than \$20K per year	69%	57%

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AU Focus Group Questions & Discussion Topics

- Basic concepts: HIV transmission and PrEP
- Ever heard of PrEP?
- For which women might PrEP be most helpful?
- Perceived barriers to uptake among women
- Best sources of information about PrEP
- Will PrEP encourage more women to get HIV test?
- Comfort with asking medical provider for PrEP
- Potential impact of PrEP on woman's sex life, including use of condoms
- Desired level of efficacy of PrEP
- Key considerations for women re: taking PrEP
- Adherence Issues
- Formulations

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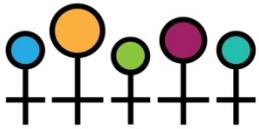


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AU PrEP Focus Group Studies Pre- and Post-FDA Approval

Key findings

- Women were dismayed –angry—that they had not heard about PrEP before the FGs
- Had mostly good relationships with their primary care doctors and OB-GYNs, and expressed willingness to turn to them for PrEP information and services;
- Did not trust men
- Had distinct ideas about how PrEP might affect their sex lives, including condom use
- Supported a range of PrEP delivery options, including pills, gels, injectables, and vaginal rings
- Key barriers to PrEP uptake were lack of information, cost, side effects, mistrust of medical system & government



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Anger--Lack of Information

- *“I didn’t know it was on the market for women. I knew it was for men, men who have sex with men. I’ve heard this about it, but I just didn’t know that it had become something for women. I heard about it was for the guys.” (Atlanta)*
- *“Let me just say something first, because of the spread of AIDS, we knew it so fast. I never heard of that before. I’ve never heard of this. **And if people are using it already, why is it not spreading? Why is not being sold to people? Why are they not getting the knowledge that they need to --?**” (New York)*
- *“I mean she basically took it out of my mouth because I’ve been to several HIV orientations because my best friend’s mom, she has HIV, so every now and then I do go to orientations with her. **But basically the orientation just basically teaches me what HIV is, where it comes from, but they never mention anything about PrEP.**” (Dallas)*

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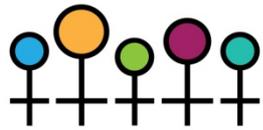
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Distrust of Men

- *“I just turned 21 and I know a lot people that’s pretty much my age or younger that’s pretty out here and . . .it could benefit everybody, like pretty much everybody, **‘cause like my mother said you pretty much don’t know whose doin’ what. . . .you don’t know if your partner is faithful to you, and . . . I think everybody could benefit from it, just like anybody can catch a disease, I think everybody could benefit.**” (Washington, DC)*
- *“I say any woman because, like, **if you meet someone you don’t know their background you don’t know if they gonna tell you the truth or not. . . .**”*
- *“And they might not know either.”*
- *“I would go with any woman, too because even if. . . you’ve heard **married too, ‘cause you never know what their husband’s doing. . . .**” (Oakland)*



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Impact of PrEP on Sex Life

- *“It would be good, to be able to have sex with more confidence and safety.”*
- *“You wouldn’t be with the fear of being infected.”*
- *“To enjoy sex without thinking about blame, to be able to enjoy sex in a simple way without worrying ‘I’m going to get infected.’”*
- *“Less stress.”*

F: “So no one thinks that there might be a negative impact?”

- *“As long as there are no side effects, which none of us want, then no!” (San Diego)*

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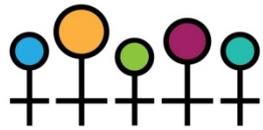


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Doctor/Medical Provider (1)

F: *“Would you feel comfortable asking your current doctor or medical provider for PrEP? Why? Whenever you’re going to the doctor now, would you be comfortable having this conversation with him?”*

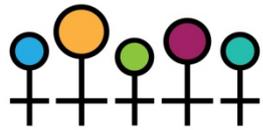
- *“Yeah. I would ask him some questions as to if that provider really knew [cross-talking] anything about it to tell me how -- to really know about it. **Are they informed?**”*
- *“I just wouldn’t feel comfortable just going to any provider thinking that they’re going to give me the correct information that I need.”*
- *“Well, I will first have the open discussion if they even knew about it and what could they tell me . . . **I will bring it to him because you are my provider and I would expect you to give me some type of good information about it, but we can learn together.** You know what I’m saying? So you go and do some research or **you bring me some research, I can bring you some research.** But I feel I’m comfortable with my provider. So even if you don’t know, inform me, inform yourself, and inform somebody else. **So I’m just saying I’m comfortable with my provider, but I can say that the white coat thing, I’m not going to go in there like I believe everything you say.**” (Dallas)*



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Doctor/Medical Provider (2)

- *“I agree with that, but I think also, for me, going to my gynecologist and asking for it would also be like so you're having sex with your husband and you don't trust him. That will be a little bit uncomfortable for me because then even though she and I were good and I talk to her about everything - I have the itch, I have something - I would talk about it. She might ask me, “Well, then why do you need it?” And then I would have to say, “Well, to protect myself.” Then it's like, “Protect yourself from what? Is your husband -- are you sleeping with someone else?” **I think that will kind of bring shame and embarrassment for me so I'm not really sure if I would necessarily ask. I would be a little bit hesitant to ask.**” (Newark).*



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PrEP Focus Group Studies: Post-FDA Approval

Goparaju L, Experton LS, Praschan NC, Warren-Jeanpiere L, Young MA, and Kassaye S. 2015. Women want pre-exposure prophylaxis but are advised against it by their HIV positive counterparts. *Journal of AIDS & Clinical Research* 6: 521.

Sample:

- Eight focus groups segregated by HIV serostatus, February-May 2014
- N=39 (19 HIV+ and 20 at risk HIV-negative women; age 31-62 (median 49); All part of WIHS cohort
- All HIV+ were African American; of the HIV-, 16 = African American, 2 = Latina, 2 = other
- All but one HIV+ women had used ARVs



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PrEP Focus Group Studies: Post-FDA Approval

Goparaju L, Experton LS, Praschan NC, Warren-Jeanpiere L, Young MA, and Kassaye S. 2015. Women want pre-exposure prophylaxis but are advised against it by their HIV positive counterparts. *Journal of AIDS & Clinical Research* 6: 521.

Key Findings:

- All HIV- women had family members with HIV and perceive themselves to be at high risk
- Awareness and knowledge of PrEP was almost nonexistent among all the women (HIV+ & HIV)
- Reactions to PrEP differed according to serostatus; HIV- enthusiastic; HIV+ concerned based on experience with ARVs
- HIV-women thought combination of PrEP and condoms was best prevention approach (saw PrEP as “extra” and “back-up” protection); HIV+ women preferred condoms alone
- Women thought that sex workers and serodiscordant couples could be potential targets populations for PrEP, but PrEP may not be suitable for young adults



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PrEP Interviews/Surveys

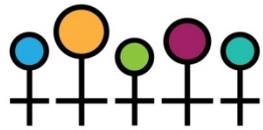
Wingood GM, Dunkle K, Camp C, et al. 2013. Racial differences and correlates of potential adoption of preexposure prophylaxis. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 63(01):S95-S101.

Sample:

- Nationally representative, random sample of unmarried African-American (N = 1042) and white women (N = 411) aged 20-44 years; random digit dial survey—interview

Key Findings:

- Women with lower educational status, greater lifetime sexual partners, provider recommendations supportive of PrEP, and peer norms supportive of PrEP use were more likely to report potential PrEP uptake
- Compared with white women, African-American women were significantly more likely to report potential use of PrEP, more likely to report use of PrEP if recommended by a health-care provider, less likely to report that they would be embarrassed to ask a health-care provider for PrEP, and more likely to report use of PrEP if their female friends also used PrEP
- The potential cost for PrEP was identified as a barrier to adoption by both African-American and white women



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PrEP Interviews/Surveys

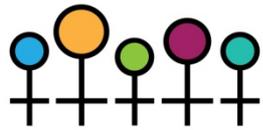
Wilson EC, Jin J, Liu A, Raymond HF. 2015. Knowledge, indications and willingness to take pre-exposure prophylaxis among transwomen in San Francisco, 2013. *PLoS ONE* 10(6):e0128971.

Sample:

- HIV behavioral risk survey conducted with 233 transwomen (HIV- and HIV+), 18 years or older, in S.F. August –Dec. 2013; mostly Latina & African American

Key Findings:

- Only 13.7% had heard of PrEP
 - More HIV+ transwomen than HIV- transwomen knew about PrEP (20% vs. 10.5%)
- Of the overall sample, 149 were HIV negative. Of these, 45 (30.2%) were deemed eligible for PrEP, based on CDC criteria (for MSM and IDU)
 - Of those who had heard of PrEP, 15.6% would be candidates. But no participants who would be candidates for PrEP said they would be willing to use it
 - Concerns include: interaction of PrEP with hormones, general lack of access to healthcare and social support services, dearth of compassionate/culturally competent health care providers, distrust of medical system



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PrEP Interviews/Surveys

Jayakumaran JS, Aaron E, Gracely EJ, Schriver E, Szep Z. 2016. Knowledge, attitudes, and acceptability of pre-exposure prophylaxis among individuals living with HIV in and urban HIV clinic. *PLoS ONE* 11(2):e0145670.doi:10.1371/journal.pone.0145670.

Sample:

- Cross-sectional survey, Jan-June 2013 among 206 HIV+ at HIV clinic in Philadelphia
- Median age 46 years; 77% AA; 6% Hispanic/Latino; 8% mixed or other; 9% Caucasian; 57.6% (118) men (45% identified MSM); 42.4% (87) women; 164 had main partner

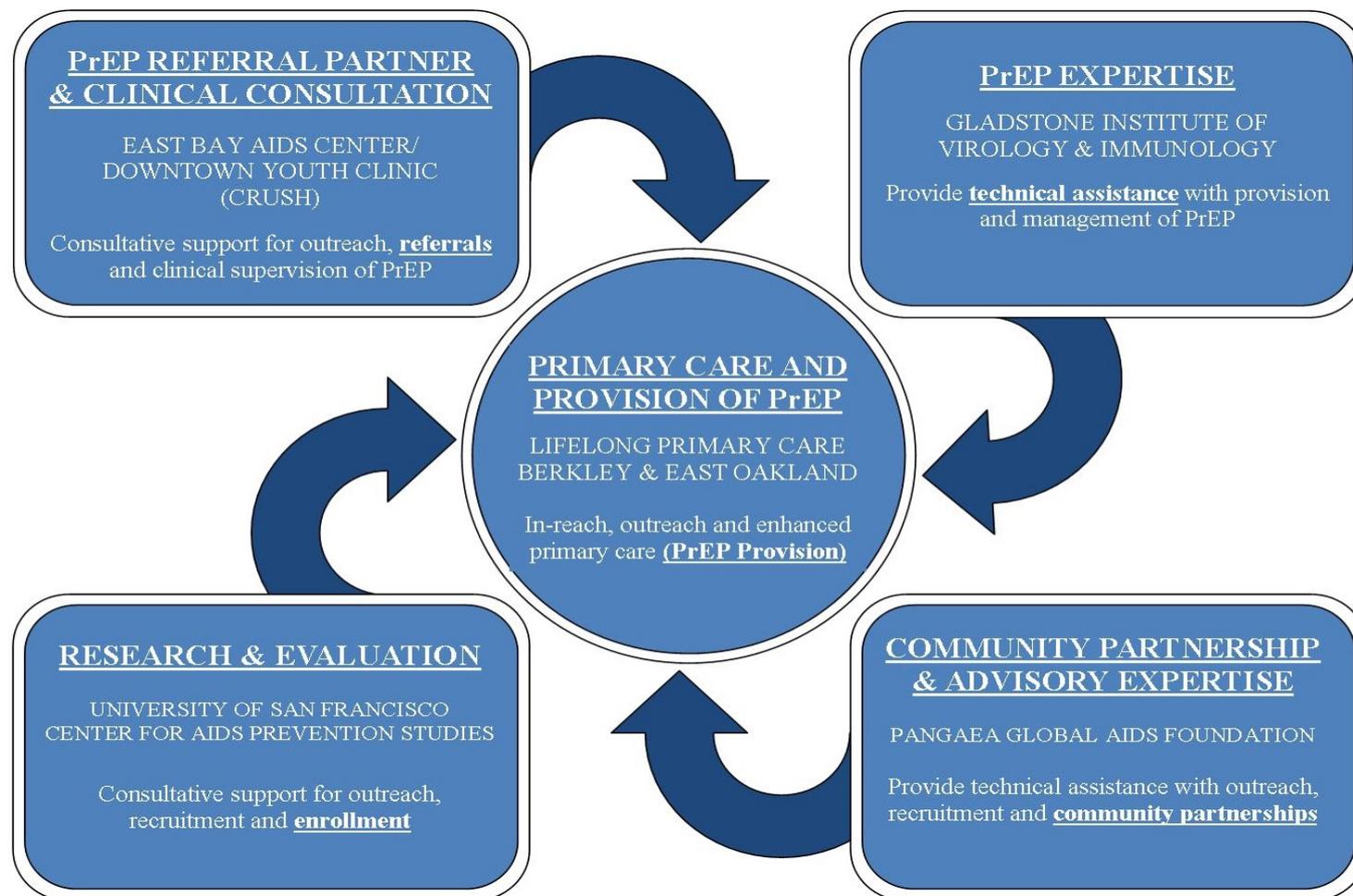
Key Findings:

- Of whole cohort, only 15.3% had previous knowledge of PrEP
- Once educated about it, 88.8% of whole cohort said they would recommend PrEP to their partners
- 84% said it would give them more hope about the future if their partner took PrEP
- 95% said PrEP should be available and free; and 92% said they would want to discuss PrEP with their providers
- 77% said they would be “extremely likely/likely” to use condoms every time they have sex if their partner was taking PrEP



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CRUSH PrEP for Women: Reaching Women in Primary Care



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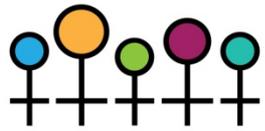
Lifelong Medical Care East Oakland



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Lifelong East Oakland

- 2,064 female patients over age of 18
- 66% African American, 15% White, 9% Latina and 10% other
- 23% tested for HIV in last year
- 1 on PrEP
- 3 newly diagnosed with HIV In last 2 months



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CRUSH-PrEP for Women

Focus Group

- **Sample:**
 - 10 cisgender women; diverse ethnicities; overall young
- **Key Findings:**
 - All but one knew about/heard of PrEP
 - General support for PrEP use
 - Participants noticed PrEP advertisements, learned from gay friends; some have friends on PrEP
 - Participants did not see women as PrEP targets
 - Strong endorsement of offering PrEP to women, education is first step
 - Key questions were about cost, side effects, impact on ability to have children, what happens with missed dose

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Key Common Themes & Findings (1)

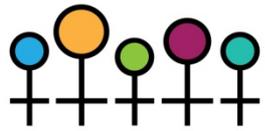
- General enthusiasm among HIV- women (less so transwomen)
 - Many see PrEP as “life-saving”
- Mixed feelings among HIV+ women
 - Experiences of ARVs are relevant
- HIV- women of color are angry about not having heard about PrEP
 - Think information is being withheld from them
- Think PrEP is good option for all women, particularly sex workers and women in sero-discordant relationships
 - Some concern about appropriateness for young women



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Key Common Themes & Findings (2)

- Concerns focused on cost, availability, side effects
 - Young women want to be able to have children
- There is significant mistrust among women of color, based on experience
 - Of men, medical system, pharma & government
- Most view PrEP as additional HIV protection, not substitute for condoms
 - Recognize other STI prevention needs
- Many HIV- and HIV+ individuals are eager to talk with their medical providers about PrEP
 - But they are not convinced providers have all the information



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Acknowledgements

- Maura Riordan, AIDS United
- Vignetta Charles, ETR (formerly AIDS United)
- Rebecca Packard, CRUSH PrEP for Women, UCSF
- Krista Martel, The Well Project
- Connie Celum, University of Washington, Seattle





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Culturally Competent PrEP Education for Women of Color

Martha Cameron, MPH
The Women's Collective
May 10, 2016



www.thewellproject.org



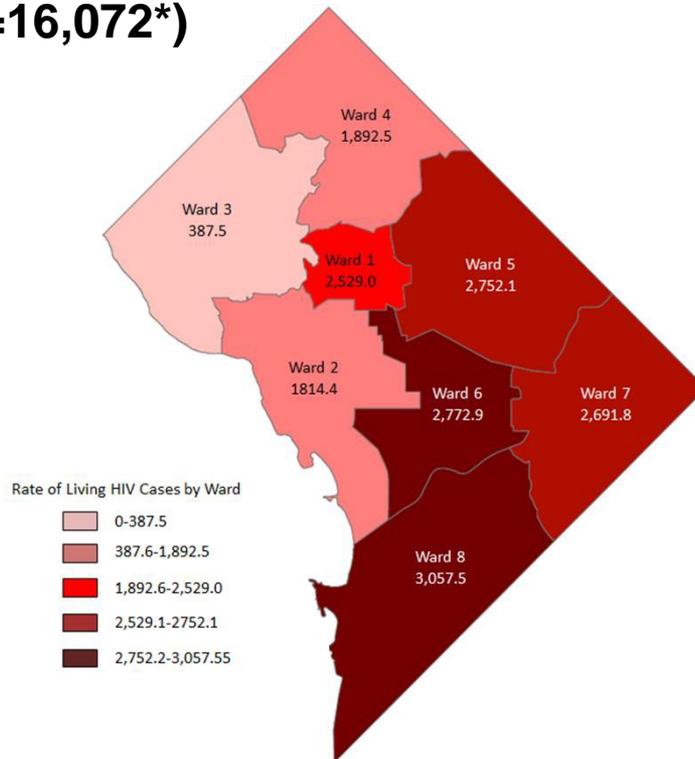
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Why PrEP and Women Education?

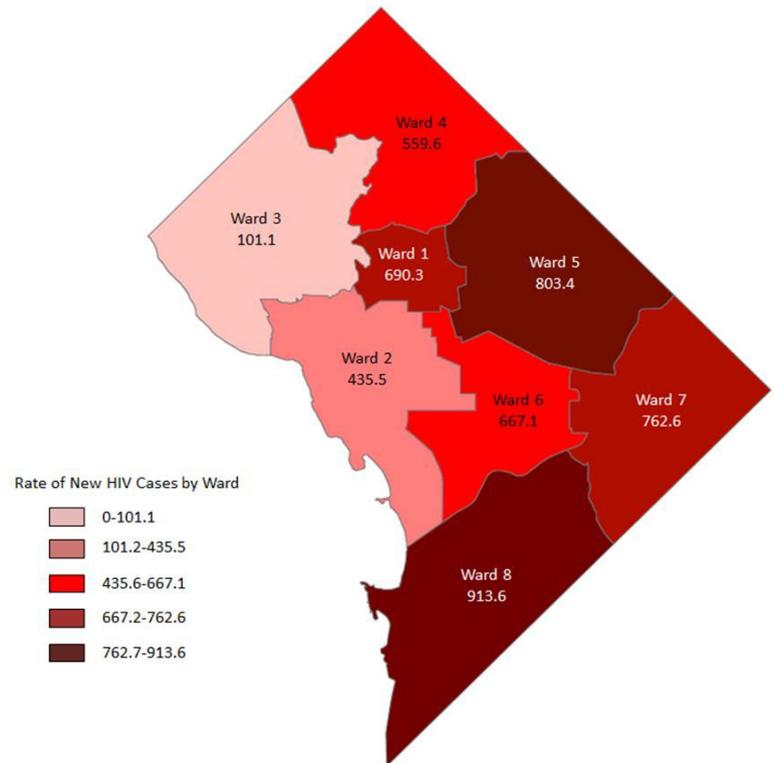
- Background to HAHSTA (HIV/AIDS, Hepatitis, STD and Tuberculosis, Administration) PrEP Education Grant
- Activities:
 1. Engaging clients to receive PrEP education
 2. Provide culturally competent support and navigation clients to access prescribing doctors or program
 3. Provide on-going case management for clients who are prescribed PrEP and who are at high risk of contracting HIV



Rate of Adults and Adolescents Diagnosed and Living with HIV by Ward, per 100,000 persons, District of Columbia, Cumulative cases through 2012 (N=16,072*)



Rate of Newly Diagnosed HIV Cases by Ward, per 100,000 persons, District of Columbia, 2008-2012, N= 4,330*



Source: HIV/AIDS, Hepatitis, STD, and TB Administration District of Columbia, Department of Health , 2014



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Focus Groups

- Goal is to provide relevant and culturally competent education and services for our target population
- Collaboration: Octane, Black Women's Health Imperative, George Washington University
- Outcomes: frame the PrEP education and messaging material
- Demonstrated a gap in the knowledge and awareness of PrEP
- Themes
 - Varied social and community attitudes, expectations. concerns and even anger
 - Suspicions of efficacy, side effects, adherence, and cost of PrEP
 - General fear of stigma and violence related disclosures
 - Supportive that PrEP is 'discreet' unlike female condoms

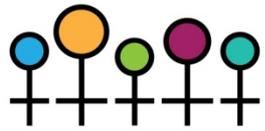




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Need for Enhanced Guidelines?

- Self perception of risk: our greatest challenge was communicating this to both client and provider to ensure unnecessary denial
- Develop enhanced eligibility criteria that includes screening for trauma, violence, and mental health
- Lack of PrEP educational (and marketing) material targeting women of color was barrier that had to be overcome immediately



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Infrastructure

- Integrated STI/HEP C/HIV testing and Counseling
- Ongoing navigation by Prevention Outreach workers and Community Health Workers
- Ongoing referral of high-risk individuals and clients prescribed PrEP to Prevention Case Management
- Ongoing monthly meetings to track progress, address operational and data collection issues

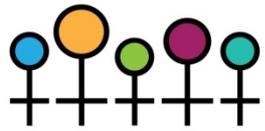


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What We Have Done so Far

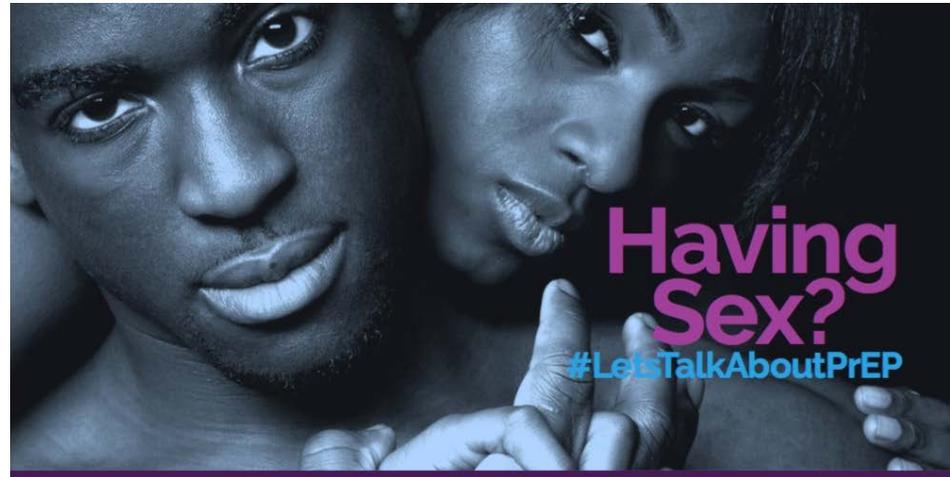
- Screening and intake forms for Prevention and Care Department include PrEP screening questions.
- Prevention Case Management Acuity Scale & Intake
- PrEP Pre & Post Education/Referral Form
- More than 350 people given PrEP education; an average of 15 people a month participating in PrEP education groups or events
- Marketing materials for women!





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Marketing Materials





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Support for Women on PrEP

HIV-negative women experience the same barriers to access to care and adherence and need:

- Prevention Case Management
- Support when prescribed PrEP
 - I. Transportation, childcare, food
 - II. Social Services/emergency financial assistance
 - III. Treatment adherence and psycho-social support

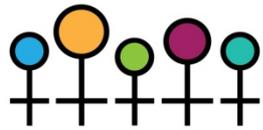


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Resources

- To learn more, and for links to articles featuring more details, please read the full fact sheets:
 - [PrEP for Women](#)
 - [Women and HIV](#)
 - [Update from CROI 2016](#)
 - [Microbicides](#)
- For more fact sheets and to connect to our community of women living with HIV, visit:
 - www.thewellproject.org
 - www.facebook.com/thewellproject
 - www.twitter.com/thewellproject



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Additional Resources

- [The Women's Collective](#)
- [Black Women's Health Imperative](#)
- [AVAC](#)
 - [AVAC's PrEP basics](#)
- [HIVE Online](#)
- www.whatisprep.org
- [PrEPWatch](#)
- [US Women and PrEP Working Group](#)
- [CDC – PrEP basics](#)



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The Well Project 2016 Survey



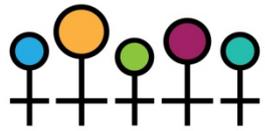
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Your Voice Counts! The Well Project 2016 User Survey

Now open! Please provide your input and help us improve our programs and better serve the needs of women and girls living with HIV!

<https://www.surveymonkey.com/r/TWPSurvey2016>





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Thank You!



Questions & Answers

The Q & A will come from the questions submitted to the presenters through the chat box during the webinar session.