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.
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
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 services
  - HIV/STD prevention, education, and outreach services
  - Policy and advocacy services
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
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
HIV and HIV Prevention among U.S. Women: A Role for PrEP

Charlene A. Flash MD MPH
Baylor College of Medicine
May 10, 2016
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
U.S. Epidemiology of HIV among Women
Estimated HIV Incidence among Adults and Adolescents in the United States, 2007–2010


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

- American Indian/Alaska Native: 2%
- Asian: 1%
- Black/African American: <1%
- Hispanic/Latino*: 16%
- Multiple races: 18%
- White: 62%

Female Population, United States
N = 136,147,401

- Hispanic/Latino*: 2%
- Native Hawaiian/other Pacific Islander: 1%
- Black/African American: <1%
- American Indian/Alaska Native: 6%
- Asian: 13%
- White: 64%

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.

* 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. Hispanics/Latinos can be of any race.

[Graph showing HIV diagnoses by race/ethnicity from 2010 to 2014]
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.

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

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>No.</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>18</td>
<td>1.8</td>
</tr>
<tr>
<td>Asian</td>
<td>12</td>
<td>0.2</td>
</tr>
<tr>
<td>Black/African American</td>
<td>2,527</td>
<td>15.0</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>570</td>
<td>2.8</td>
</tr>
<tr>
<td>Native Hawaiian/other Pacific Islander</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>White</td>
<td>743</td>
<td>0.9</td>
</tr>
<tr>
<td>Multiple races</td>
<td>239</td>
<td>11.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4,110</td>
<td><strong>3.0</strong></td>
</tr>
</tbody>
</table>

**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.

\(^{b}\) Hispanic/Latino 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
- Injection drug use: <1%
- Heterosexual contact: 91%
- Other: 9%

Hispanic/Latino\(^a\)
N=1,490
- Injection drug use: 13%
- Heterosexual contact: 86%
- Other: 1%

White
N=1,483
- Injection drug use: 1%
- Heterosexual contact: 75%
- Other: 24%

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.
• 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

Aral SO, Lancet 2008
Risk Factors

- 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

Aral SO, Lancet 2008
Risk Factors

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

Aral SO, Lancet 2008
Risk Factors

• Structural factors
  – Poor access to health care
  – Lack of stable housing
  – Limited HIV prevention education

• Increased prevalence of other STIs

Aral SO, Lancet 2008

www.thewellproject.org
HIV Risk Among Women

- HIV risk during vaginal sex without a condom/other protection (i.e., PrEP) higher for women than 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.

Copen CE. National Health Statistics Reports No.88, 2016

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


www.thewellproject.org
A Role for PrEP among Women
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
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

Oral PrEP
Partners PrEP

• 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

• TDF $\rightarrow$ 62% fewer infections
• FTC-TDF $\rightarrow$ 73% fewer infections

Table 1: Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Men Who Have Sex with Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
</table>
| Detecting substantial risk of acquiring HIV infection | HIV-positive sexual partner  
Recent bacterial STI  
High number of sex partners  
History of inconsistent or no condom use  
Commercial sex work | HIV-positive sexual partner  
Recent bacterial STI  
High number of sex partners  
History of inconsistent or no condom use  
Commercial sex work | HIV-positive injecting partner  
Sharing injection equipment  
Recent drug treatment (but currently injecting) |
| Clinically eligible | 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 | 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 | Assess pregnancy intent  
Pregnancy test every 3 months  
Access to clean needles/syringes and drug treatment services |

STI: sexually transmitted infection
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
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

www.thewellproject.org
Unique Considerations for Women
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

www.thewellproject.org
Importance of Adherence and Acceptance

• Nonjudgmental
  — Adherence assessment
  — Adherence support

• Acceptability

• Many at-risk people may not be engaged in care
  — Prescriber
    o “PrEP will empower women” → willing to prescribe
  — Monitoring

www.thewellproject.org
Oral PrEP: Importance of Adherence
Fem-PrEP and VOICE

• Fem-PrEP
  – RCT ~2000 high-risk women
    o Kenya, South Africa, Tanzania
    o > 1 partner in past month
    o ≥ 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.

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
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

CDC Guidelines

www.thewellproject.org
 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*
Future PrEP formulations
Selected References


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
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
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.
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**

**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)
PrEP Focus Group Studies: Pre-FDA Approval


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

www.thewellproject.org
**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

**IX International AIDS Conference**
July 21, 2012
Washington, DC, USA
(Abstract: PRIB004)

---

"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), Susan Brown (San Francisco Women’s Network, UCSF), Carolyn Chiles (AIDS United)

**Background**

Oral tenofovir was approved for HIV pre-exposure prophylaxis (PrEP) in late 2012 and CDC issued guidelines in May 2013. The core of the emptied clinical trial showing PrEP efficacy included U.S. women, who comprised 20% of the participants. Those women indicated a strong interest in PrEP, and HIV prevention among at-risk American women is unmet.

**Methods**

We conducted 11 focus groups (35 participants) with 154 at-risk women in cities throughout the U.S. in 2012 and 2013. Participants were African American and non-African American women ages 18-45 years.

**Results**

Once informed about PrEP, most found it an important option and more report that they had not yet heard about it.

"I heard about PrEP, it is not a drug... I think it is a pill. It is an option. I would definitely use it if it was available." - Participant

**Conclusions**

Despite awareness, women use condom and vaginal barrier methods as effective, but once less reduction in risk perception.

---

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

Judith D. Auerbach, PhD; Suzanne Koslow, MPH; Gine Brown, MSW; and Vignette Charles, PhD

**Abstract**

Although the Food and Drug Administration (FDA) approved oral tenofovir for pre-exposure prophylaxis (PrEP) for women at risk of HIV infection in the U.S. in July 2012, and the Centers for Disease Control and Prevention (CDC) issued guidelines for clinicians to provide PrEP to women “at substantial risk of HIV acquisition” in May 2014, there remains no clinical trial data on efficacy among U.S. 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 study (FGS) with 114 at-risk women in 7 cities between July and September 2013, including locations in the US where HIV infections among women are most prevalent. FGs elicited awareness of PrEP, attitudes toward administration and barriers to and facilitators of use. Women expressed an interest in the fact that they had not heard of PrEP prior to the study, but once informed most found it attractive. PrEP was seen as an additional, not substitutive, prevention strategy, and participants discussed several dissemination strategies to meet 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**

A RECORD NUMBER of all people living with HIV in the US are women, and women account for 20% of new HIV infections and 25% of new AIDS diagnoses in 2013. The vast majority (84%) of HIV infections among women are attributed to heterosexual sex. Although the overall rate of new infections among women in the US has declined, 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. In 2013, the rate of new infections among Black/African American women in the US was 2.7 times that of white women. Hispanic/Latina women were 2.4 times that of white women. Young women, including those older than 25 years and significantly affected nearly one-third of new infections (39%) among women aged 13-24, and 21% among women aged 25-44.

PrEP has demonstrated efficacy in three randomized clinical trials conducted mostly outside the US involving gay men, men who have sex with men, and heterosexual men and women. The two studies involving only women were not able to demonstrate efficacy. Although the Food and Drug Administration (FDA) approved oral PrEP for females in 2012, there has been no clinical trial data on efficacy among U.S. women. In light of knowledge, attitudes, and likelihood of use of PrEP 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, men who have sex with men, and heterosexual men and women.

**Table:**

<table>
<thead>
<tr>
<th>PrEP Experience</th>
<th>Challenges</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical phase</td>
<td>90% efficacy</td>
<td>Easy access, lower cost</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>100% efficacy</td>
<td>Proven efficacy, widespread use</td>
</tr>
</tbody>
</table>

**Implications**

Women at risk for HIV in the US are better to use PrEP if it is carried out and it is more effective, affordable, lacking significant side effects, and provided by trusted sources.

Contact: Judith D. Auerbach, PhD, Email: judith@awprf.org

---

**University of California San Francisco**

**AIDS Research Institute**

---

**PrEP Focus Group Studies**

**Pre- and Post-FDA Approval**

---

"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; Suzanne Koslow, MPH; Gine Brown, MSW; and Vignette Charles, PhD

**Abstract**

Although the Food and Drug Administration (FDA) approved oral tenofovir for pre-exposure prophylaxis (PrEP) for women at risk of HIV infection in the U.S. in July 2012, and the Centers for Disease Control and Prevention (CDC) issued guidelines for clinicians to provide PrEP to women “at substantial risk of HIV acquisition” in May 2014, there remains no clinical trial data on efficacy among U.S. 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 study (FGS) with 114 at-risk women in 7 cities between July and September 2013, including locations in the US where HIV infections among women are most prevalent. FGs elicited awareness of PrEP, attitudes toward administration and barriers to and facilitators of use. Women expressed an interest in the fact that they had not heard of PrEP prior to the study, but once informed most found it attractive. PrEP was seen as an additional, not substitutive, prevention strategy, and participants discussed several dissemination strategies to meet 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**

A substantial number of all people living with HIV in the U.S. are women, and women account for 20% of new HIV infections and 25% of new AIDS diagnoses in 2013. The vast majority (84%) of HIV infections among women are attributed to heterosexual sex. Although the overall rate of new infections among women in the US has declined, 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. In 2013, the rate of new infections among Black/African American women in the US was 2.7 times that of white women. Hispanic/Latina women were 2.4 times that of white women. Young women, including those older than 25 years and significantly affected nearly one-third of new infections (39%) among women aged 13-24, and 21% among women aged 25-44.

PrEP has demonstrated efficacy in three randomized clinical trials conducted mostly outside the US involving gay men, men who have sex with men, and heterosexual men and women. The two studies involving only women were not able to demonstrate efficacy. Although the Food and Drug Administration (FDA) approved oral PrEP for females in 2012, there has been no clinical trial data on efficacy among U.S. women. In light of knowledge, attitudes, and likelihood of use of PrEP 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, men who have sex with men, and heterosexual men and women.

**Table:**

<table>
<thead>
<tr>
<th>PrEP Experience</th>
<th>Challenges</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical phase</td>
<td>90% efficacy</td>
<td>Easy access, lower cost</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>100% efficacy</td>
<td>Proven efficacy, widespread use</td>
</tr>
</tbody>
</table>

**Implications**

Women at risk for HIV in the US are better to use PrEP if it is carried out and it is more effective, affordable, lacking significant side effects, and provided by trusted sources.

Contact: Judith D. Auerbach, PhD, Email: judith@awprf.org

---

**University of California San Francisco**

**AIDS Research Institute**

---


Sample:

- 2 Rounds; Total N=236 women
  - 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
<table>
<thead>
<tr>
<th></th>
<th>Round 1 (N=92)</th>
<th>Round 2 (N = 144)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>69%</td>
<td>92%</td>
</tr>
<tr>
<td>Latina/Hispanic</td>
<td>19%</td>
<td>7%</td>
</tr>
<tr>
<td>White/Other/Missing</td>
<td>7%</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-30</td>
<td>24%</td>
<td>29%</td>
</tr>
<tr>
<td>31-50</td>
<td>55%</td>
<td>50%</td>
</tr>
<tr>
<td>51-60</td>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td><strong>Employed</strong></td>
<td>50%</td>
<td>53%</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least some college</td>
<td>59%</td>
<td>30%</td>
</tr>
<tr>
<td>High School or GED</td>
<td>29%</td>
<td>52%</td>
</tr>
<tr>
<td>Income: Less than $20K per year</td>
<td>69%</td>
<td>57%</td>
</tr>
</tbody>
</table>
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
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
• “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)
"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)
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)
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)
“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).
PrEP Focus Group Studies: Post-FDA Approval


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
PrEP Focus Group Studies: Post-FDA Approval


**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

www.thewellproject.org

**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

www.thewellproject.org

**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

**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
CRUSH PrEP for Women: Reaching Women in Primary Care

**PrEP REFERRAL PARTNER & CLINICAL CONSULTATION**
EAST BAY AIDS CENTER/DOWNTOWN YOUTH CLINIC (CRUSH)
Consultative support for outreach, referrals and clinical supervision of PrEP

**PrEP EXPERTISE**
GLADSTONE INSTITUTE OF VIROLOGY & IMMUNOLOGY
Provide technical assistance with provision and management of PrEP

**PRIMARY CARE AND PROVISION OF PrEP**
LIFELONG PRIMARY CARE BERKLEY & EAST OAKLAND
In-reach, outreach and enhanced primary care (PrEP Provision)

**RESEARCH & EVALUATION**
UNIVERSITY OF SAN FRANCISCO CENTER FOR AIDS PREVENTION STUDIES
Consultative support for outreach, recruitment and enrollment

**COMMUNITY PARTNERSHIP & ADVISORY EXPERTISE**
PANGAEA GLOBAL AIDS FOUNDATION
Provide technical assistance with outreach, recruitment and community partnerships
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
**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
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
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

www.thewellproject.org
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
Culturally Competent PrEP Education for Women of Color

Martha Cameron, MPH
The Women’s Collective
May 10, 2016
Why PrEP and Women Education?

- Background to HAHSTA (HIV/AID, 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

www.thewellproject.org
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*

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

www.thewellproject.org
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
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
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!

www.thewellproject.org
Marketing Materials
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

www.thewellproject.org
The Well Project 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
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
Now open! Please provide your input and help us improve our programs and better serve the needs of women and girls living with HIV!

Thank You!

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