Webinar Series No. 2.1: PrEP @2 Years—
and still counting women in...
June 30, 2014
Webinar Participation

- Burning questions after each presentation and discussion after all speakers

To ask a question:
- The call is in global mute
- Unmute your line by pressing *7 and ask it on the line (remute your line by pressing *6)
- Enter your question into the chat box in ReadyTalk
- Email your question to avac@avac.org
- Webinar recording will be available at www.avac.org/meetingreports

Many thanks for the support of the Working Group and Webinar series from WG members, AVAC, Sisterlove and Gilead Sciences
The Agenda


- Women & PrEP Implementation in the US – Karen Hooveer, MD MPH, Team Lead, Research for Prevention, CDC

- Knowledge, Attitudes & Likelihood of Use of PrEP by At-Risk Women in the US – Judy Auerbach, Professor, UCSF School of Medicine & Research Consultant AIDS, United


- Questions/Discussion Dázon Dixon Diallo, Moderator
The Group

- Leadership Team (3) and Group Members (80)
- Face-to-Face & teleconference meetings
- Webinars, Research, & Communications
The Advocacy

- Sexual & Reproductive Health & Rights Service Delivery & Advocacy
- Women’s Power to Prevent HIV in Women’s Hands
- Global Advocacy for Appropriate Research & Development
- Cooperation and Collaboration among domestic and international partners
The Purpose of the Working Group

- National Community representing women’s voices
- Inquiry, Advocacy & Accountability
- Ensure women’s safety, efficacy and accessibility in PrEP research & rollout
- Educate and engage community in PrEP discourse and information dissemination
- Mobilize a diversity of women’s HIV and health advocates, researchers and policy makers in PrEP and other BmPO for women
WORKING GROUP ON U.S. WOMEN AND PREP STATEMENT

4 March 2011

INTRODUCTION

We are a group of U.S. based women's health advocates and other interested parties who have been meeting since March 2010 to build a common understanding of what we consider preexposure prophylaxis (PrEP) as a new HIV prevention tool means for women in the United States.

In July 2010, the US Food and Drug Administration (FDA) approved the use of tenofovir and emtricitabine (Truvada) for HIV prevention as PrEP in HIV-negative adult men and women at risk for HIV infection. The trial approach was based on data from clinical trials that had demonstrated the efficacy of Truvada in preventing acquisition of HIV infection in heterosexual men on HAART (highly active antiretroviral therapy) and discordant couples in which men are HIV-infected and women are HIV-uninfected and in a number of other trials around the world.

However, none of these trials included U.S. women, leaving critical questions unanswered:

3. How will PrEP be used for HIV prevention by women in the United States?
4. How was PrEP to be used for HIV prevention by women in the United States?
5. What data are needed regarding PrEP's acceptability and effectiveness among these women?
6. What will be the impact of PrEP on HIV prevention in the United States?

This statement summarizes the recommendations of our Working Group for ways to respond to these critical questions. It contains recommendations for research, public and private sector education, outreach, and implementation and public policy, and defines the next steps required for “real-world use” of PrEP among women in the United States. The recommendations address these “key points” in order to advance discussion of:

4. How to interpret and address the gaps in research regarding PrEP implementation among U.S. women and the impact on high-risk populations and other stakeholders need to collaborate on joint collection of the data to answer these questions.

3. Three key points:

1. During and throughout this process, the potential for a prevention tool that women, including transwomen, can use to reduce their risk of HIV infection.
2. A comprehensive and comprehensive review of how implementation of PrEP among U.S. women will be used and how to implement this program in an environment that is supportive of women's health and rights.
3. Available clinical trials data provide preliminary evidence that Truvada as PrEP, while many questions remain, can be used to help women in the context of HIV prevention. These include questions about how to interpret and address the gaps in research regarding PrEP implementation among U.S. women and the impact on high-risk populations and other stakeholders need to collaborate on joint collection of the data to answer these questions.

4. Available data suggest that the use of PrEP among women who are at risk for HIV infection is feasible and can be integrated into existing care programs. This information will be helpful in demonstrating the feasibility of using PrEP among women in the United States.
Key Aims of the Working Group

- Articulated pathway to responding to questions posed in Statement
- Civil Society engagement in process of planning and rolling out PrEP/BmPO
- National plan for provider education and social marketing about PrEP
- Plan for incorporating PrEP education and access for women into the NHAS
- Process including milestones, feedback mechanisms, resources and accountability
Unanswered Questions

- Access & Adherence?
- Risks, Safety & Side Effects?
- Gender Specific Guidelines?
- National Coordinated Plan?

- Release of National Statement CROI2013
- High level meeting at White House
- Articles, Workshops, Roundtables, Oral & Poster Sessions
- 3 Webinars
  - Ready, Set, PrEP!!!
  - PrEP–Ception
  - Risky Women
PrEP Advocacy Partnerships

- AVAC, PxROAR and www.prepwatch.org
- Black Treatment Advocates Network
- Women’s HIV Research Collaborative
- Women’s Research Initiative (The Well Project)
- HPTN Women–At–Risk Subcommittee
- Be The Generation Bridge Initiative
- IRMA/My PrEP Experience (PrEP Stories)
- Consortium of PrEP projects funded by Gilead Sciences
What’s Next?

- Ongoing communication w/ Federal & Industry Partners
- National Webinars on US Women & PrEP & other BmPO
- WG Face2Face Meeting – Seattle, February 2015
- National & Int’l Engagement (USCA, CROI, AIDS2014, NIH Networks, IAPAC, R4P, etc.)
- Articles, Workshops, Satellites, Orals & Posters
  ◦ Early September 2014

Risky Women: Disrupting Simple Notions of Women’s HIV Risk
  ◦ Early November 2014
THANKS FOR JOINING US!

LET’S GET STARTED!
Women and PrEP implementation

Karen Hoover, MD, MPH
Health Services Research for Prevention with Negatives
Division of HIV/AIDS Prevention

June 30, 2014
New HIV infections in most affected subpopulations, United States 2010

Number of HIV infections

<table>
<thead>
<tr>
<th>Category</th>
<th>U.S. subpopulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>White MSM</td>
<td>11,200</td>
</tr>
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<tr>
<td>Black male IDU</td>
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HIV Surveillance Supplemental Report 2012
New HIV infections in most affected subpopulations, United States 2010

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Why are women at risk of HIV infection?

- Unaware of their male partner’s risk factors
- Risk of HIV acquisition is high for the female receptive partner
  - Significant risk during vaginal sex
  - Higher during anal sex
    - >20% of women aged 20-39 years reported anal sex in the past year (NSFG)
- Women are sometimes unable to negotiate safer sex practices such as condom use
- STDs often are undiagnosed, and can increase the risk of HIV transmission and acquisition
- Greater rates of PLWH in black and Hispanic communities
  - Sex with partners of the same race and ethnicity
HIV-infected persons engaged in continuum of HIV care

- HIV-infected: 1,178,350
- Diagnosed: 941,950
- Linked: 725,302
- Retained: 480,395
- ART: 426,590
- Suppressed: 328,475

Percentage Engagement in HIV care

MMWR 2011
Evidence of Behavioral Risk Increase in HIV Discordant Couples

Sex with HIV+ partner

Sex with outside partner

Mugwanya et al. 2013
The other half of the continuum of care: preventing HIV infection with PrEP among uninfected women

- HIV test
- At-risk
- PrEP
- Adherence
- Remain uninfected
The other half of the continuum of care: preventing HIV infection with PrEP among uninfected women

* Use of 4th generation HIV testing
† Patient adherence to PrEP and provider adherence to recommendations for clinical management of PrEP patients
<table>
<thead>
<tr>
<th>Trial (Sponsor)</th>
<th>Sample Size</th>
<th>Intervention vs. placebo</th>
<th>Population</th>
<th>Outcome (TDF detected in blood)</th>
</tr>
</thead>
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<tr>
<td><strong>iPrEx</strong> (NIH; Gates)</td>
<td>n=2499</td>
<td>Oral TDF/FTC</td>
<td>MSM, transgender women</td>
<td>0.92 (0.40 – 0.99)</td>
</tr>
<tr>
<td><strong>Partners PrEP</strong> (Gates)</td>
<td>n=4,747 couples</td>
<td>Oral TDF/FTC, Oral TDF</td>
<td>Heterosexual serodiscordant couples</td>
<td>0.90 (0.58 – 0.98), 0.86 (0.67 – 0.94)</td>
</tr>
<tr>
<td><strong>TDF2</strong> (CDC)</td>
<td>n=1,200</td>
<td>Oral TDF/FTC</td>
<td>Sexually active adults</td>
<td>Drug detected: 50% among HIV infected, 80% among not infected</td>
</tr>
<tr>
<td><strong>Bangkok Tenofovir</strong> (CDC)</td>
<td>n=2,413</td>
<td>Oral TDF</td>
<td>Injection drug users</td>
<td>0.74 (0.17– 0.94)</td>
</tr>
<tr>
<td><strong>FEM-PrEP</strong> (USAID, Gates, FHI 360)</td>
<td>n=1,951</td>
<td>Oral TDF/FTC</td>
<td>Heterosexual women</td>
<td>Drug detected: &lt;40% among participants</td>
</tr>
<tr>
<td><strong>VOICE</strong> (MTN-003)</td>
<td>n=5,029</td>
<td>Oral TDF/FTC, Oral TDF, 1% tenofovir gel</td>
<td>Heterosexual women</td>
<td>Drug detected: &lt;30% among participants</td>
</tr>
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</table>
Recommended indications for PrEP

- Adult heterosexually active men and women who are at substantial risk of HIV acquisition
  - History of inconsistent or no condom use
  - HIV-positive sexual partner
    - Including women who are or intend to become pregnant
  - Recent bacterial STD
  - High number sexual partners
  - Commercial sex work
  - In high prevalence area or network
Recommended care for patients receiving PrEP

- **Initiation**
  - Negative HIV test
  - No symptoms or signs of acute HIV infection
  - Normal renal function
  - No contraindicated medications
  - Hepatitis B virus infection and vaccination status

- **Follow-up visits**
  - Every 3 months
    - HIV test
    - Pregnancy test
  - At 3 months, then every 6 months
    - Renal function
  - Every 6 months
    - STD testing (syphilis, chlamydia, gonorrhea)
PrEP use in the United States is low but increasing

- Based on an analysis of prescription data by Gilead
  - 150 users in 2010
  - 1,274 Users in 2011
  - 48% women
  - 14% for persons younger than 25 years
  - Most prescriptions by family practitioners, internists, and emergency medicine physicians
Barriers to implementation

- **Patient**
  - Unaware of PrEP
  - Concern about medication side effects
  - Potential stigma about taking HIV medications
  - Co-payments

- **Primary care provider**
  - Unaware of PrEP
  - Inexperience with HIV medication
  - Concern about enabling risk behavior
  - Issues with conducting patient sexual risk history
    - Limited time during visit
    - Uncomfortable for both provider and patient
A roadmap for PrEP implementation

**Needs**
- Documented efficacy and safety
- Consensus on PH use
- Provider support
- User acceptability
- Advocates for access
- Policy/regulatory support
- Evaluation framework

**CDC sphere of control**
- Trials
- Consultations
- Targeted evaluations
- Guideline development
- Policy development
- Training materials
- Educational materials
- Tool creation
- Media campaigns

**CDC sphere of influence**
- Providers trained
- Risk ppn recruited
- Funding available
- Counseling available
- Practice-based evidence
- Best Practices

**Outputs**
- Immediate Outcomes (outreach/access)
  - Providers trained
  - Risk ppn recruited
  - Funding available
  - Counseling available
- Intermediate Outcomes (coverage/compliance)
  - Adherence high
  - Little risk compensation
- Objective
  - Reduced HIV incidence

**Identify needed improvements**

Smith et al. 2013
Implementation of PrEP for at-risk women

- Clinical venues of care for women
  - Ob/gyn clinics
  - Family planning clinics
  - FQHCs
  - Primary care clinics
  - STD clinics

- Educate women about PrEP as an HIV prevention tool

- Evaluate and disseminate best practices for PrEP delivery
Ways to engage the community and medical and non-medical providers around PrEP
engaging community and providers

- **Online sources:** information, discussion groups
- **Print materials:** brochures, booklets
- **Community advocacy:** forums, local awareness
- **Provider trainings:** San Francisco as an example
- **Social media:** #TruvadaWhore
engaging community and providers

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**COMMUNITY EDUCATIONAL RESOURCES**
- gay men
- women
- straight men
- transexual m/w
- PWIDs
Centers for Disease Control

- **Federal Clinical Practice Guidelines** (evidence, prescribing information, etc.)
- **Providers’ Supplement** (checklist, PrEP-related ICD, CPT and LOINC Codes, info sheets, assessments, etc.)

www.cdc.gov/hiv/prevention/research/prep/

*Talk to your doctor about PrEP:*
resources for providers

National Clinician Consultation Center
- Hosted by UCSF
- Provides guidance only to medical providers around PrEP
- 800-933-3413, 9a–8p PST, M–F, leave messages

http://nccc.ucsf.edu
resources for providers

BAPAC (Bay Area Perinatal AIDS Center)

- Hosted by UCSF
- Expert guidance to medical providers around PrEP and family planning
- Videos for both women and men

http://hiv.ucsf.edu/care/perinatal.html
resources for providers

Clinical Care Options

- Resource by/for medical providers
- Slide decks on best practices, search for “PrEP”
- Mostly 2012/13 dates, hopefully will see newer information

www.clinicaloptions.com
resources for providers

TRUVADA for a Pre-exposure Prophylaxis (PrEP) Indication

TRUVADA is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 in adults at high risk. TRUVADA does not cure HIV infection or AIDS.

Click one of the boxes below:

- Healthcare Providers
- Uninfected individuals
- Educators

Are you looking for the PrEP Risk Evaluation and Mitigation Strategy (REMS)?

Visit www.truvada.com/rems

Are you looking for information on another approved use of TRUVADA?

Visit www.truvada.com

Gilead Sciences

- http://start.truvada.com/#
resources for providers

Day-long provider CME training, San Francisco, March 2014

- Collaboration among PTC, PAETC and SFAF
- ~100 providers and community reps
- Presentations by researchers (BGrant, SCohen, etc.)
- Panel discussions with young and trans people on PrEP
- Small group discussions
- Likely other similar trainings are being scheduled around the US

Start the conversations locally to develop your own ANAC chapters have begun educational forums
resources for community

Project Inform

- HIV Health InfoLine (800-822-7422)
- 4 videos (all young gay men) that anyone can link to, resource list
  2 new women’s videos in 2014
- Booklets (Eng/Sp), order form, ship to providers for free
  - Is taking PrEP the right choice for you? (for MSM)
  - PrEP: A new option for safer loving (for women)
  - How to get PrEP (self-advocacy)
- Working through a difficult medical visit

www.projectinform.org/prep
resources for community

The Well Project

- Concise information on PrEP
- New outreach initiative asking community/providers to share their stories:
  kmartel@thewellproject.org

www.thewellproject.org/hiv-information/prep-women
resources for community

AIDS Foundation of Chicago

• Personal stories from PrEP users, videos, resources

• Mostly men but some women, encourages everyone to submit

• Ready. Set. PrEP. City-wide provider and community education program


http://myprepexperience.blogspot.com
resources for community

PrEP Facts Facebook forum

- 3,105 followers
- Vibrant online discussion of PrEP, facilitated by NY mental health specialist, Damon Jacobs
- Emphasis on science-based evidence, access, community awareness, strategies
- Primarily gay men, but some women follow (primarily providers)

https://www.facebook.com/groups/PrEPFacts/
resources for community

**What is PrEP?**

PrEP REP project

- Univ of CT, Stroger Hospital Cook County
- Video explaining PrEP and how it works within the body, resources
- Doesn’t target any specific demographic

www.whatisprep.org
resources for community

AIDS Vaccine Advocacy Coalition

- PrEP research, clinical data, reports, policy/advocacy work, resources, great infographics
- Useful for providers and motivated individuals
- www.prepwatch.org/local-programs/ (local PrEP services, email avac@avac.org to add known local resources to page)

www.prepwatch.org
San Francisco AIDS Foundation

- Basic info, Q&A, conduit to local demonstration project, resources
- 3 major sections: MSM, heterosexual men/women, in Spanish
- Distinctive graphics, large format, easy to read website
- Library: [http://prepfacts.org/asset-library/](http://prepfacts.org/asset-library/) (posters, postcards, brochures)
resources for community

NYC Health Department

- Basic info, local services, resources, PEP as well as PrEP
- Posters available, includes MSM, women and straights couples

resources for community

Positively Aware

- Hosted by TPAN Chicago
- Full issue dedicated to PrEP, summer 2013
- Personal stories (especially young men & women, POC), basic info, clinical data, guest columnists

resources for community

AIDS.gov

- Basic PrEP info, video, infographics, links to other federal resources

www.aids.gov
The Stigma Project

- Engaging graphics for community education

www.thestigmaproject.org
resources for community

Many community educational forums/programs taking place around the US

- NYC, Miami, Ft Lauderdale, Chicago, SFBA, Houston, Bakersfield, etc.
- Ask others in your community. Often collaborations among gay activists, LGBT centers, PFLAGs, DPHs, researchers/providers, and local demo projects
- Gilead community education recipients providing programs: SisterLove, Abounding Prosperity, Project Inform, AIDS Foundation of Chicago, others
- Non-Gilead recipients: NMAC (WDC), Philadelphia FIGHT, SHERO (Oakland), many others
- 2014 USCA PrEP exhibit booth

PrEP services

- www.prepwatch.org/local-programs/ (email avac@avac.org to update page)
• **prefacts:** Facebook forum
• **hashtags:** #PrEPnews, #PrEP4ALL, #TruvadaWhore, #LoveStigmaFree
• **tumblr:** just beginning to appear more often, search for “HIV PrEP”
• **Reddit:** quite a few threads, search for “HIV PrEP”
• **Instagram:**
social media

#TruvadaWhore

What is it about Truvada PrEP that is so upsetting to some people?

We all know change is hard... especially after you’ve been trained to have sex a certain way your entire life, after you’ve watched dozens of your friends pass away in mere months, after you’ve repressed your sexuality since childhood, all the while fearing death, disease, and social rejection. These things are hard to talk about. There is certainly a great deal of stigma surrounding HIV/AIDS, even in San Francisco. Conversations about HIV status, viral load, and PrEP aren’t happening as often as they should be.

#TruvadaWhore blog

- Example of community activism and PrEP education
- Turns negative “slut-shaming” name-calling into a community conversation starter
- Produces/sells T-shirts to raise awareness in community

http://truvadawhore.blogspot.com/
other resources

- aidsmap.com (clinical study reporting)
- aidsmeds.com (clinical study reporting)
- HIVandHepatitis.com (clinical study reporting)
- projectinform.org (clinical study reporting)
- www.imstilljosh.com/lgbtprep/ (community education)
ideas? feedback? other resources?

Alan McCord
amccord@projectinform.org