Webinar Series No. 2: PrEP–Ception
October 28, 2013
Webinar Participation

There will be a Q & A after all speakers have presented. To ask a question:

- Enter it into the chat box in ReadyTalk
- Email your question to avac@avac.org
- Tweet @hivpxresearch

For more information: www.prepwatch.org

Webinar recording will be available at www.avac.org/meetingreports

To dial-in by phone: (800) 754-1336
The Agenda


- Defining the Need for Safer Conception Options: The Role of “PrEP-ception” – Shannon Weber, MSW, Director, Perinatal HIV Hotline, Bay Area Perinatal AIDS Center

- One Mom’s Story – Poppy

- A Framework for the Integration of PrEP – Erika Arron, CRN, Drexel University College of Medicine, Division of Infectious Diseases and HIV Medicine

- Questions/Discussion
  Dázon Dixon Diallo, Moderator
The Group

- Leadership Team (3) and Group Members (25+)
- Face-to-Face & teleconference meetings
- More than 50 signers and supporters
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
PrEP Today

- Gilead achieves approval of Truvada for PrEP
- National & International Debate
- Ongoing research of current PrEP and other PrEP strategies and ARVs/drugs
The Purpose of the Working Group

- First National Response 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 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 2013

INTRODUCTION

We are a group of U.S.-based women’s health advocates and other interested parties who have been meeting since March 2012 to build a common understanding of what pre-exposure prophylaxis (PrEP) as a new HIV prevention tool could mean for women in the United States.

In July 2012, the US Food and Drug Administration (FDA) approved the use of daily oral Truvada® (Emtricitabine/Tenofovir Disoproxil Fumarate), a combination antiretroviral drug already used to treat HIV infection for HIV prevention as PrEP in HIV-negative adult men and women at risk for HIV infection. The FDA approval was based on data from clinical trials that have demonstrated the efficacy of Truvada in preventing HIV acquisition in populations of gay and other men who have sex with men (MSM), transwomen, and heterosexual women and men in a number of studies around the world.

However, none of these trials included U.S. women, leaving critical questions unanswered:
• How will PrEP be used for HIV prevention by women in the United States?
• What data are needed regarding PrEP’s acceptability and effectiveness among these women?
• How will PrEP be promoted, made accessible and affordable for use by U.S. women?

This Statement summarizes the recommendations of our Working Group for ways to respond to these critical questions: fill the corresponding gaps in research, public and provider education, social marketing and public policies, and define the next steps required for “real-world use” of PrEP among women in the United States.

Our recommendations address three “key areas” in order to achieve discussion of:
• The rollout of PrEP for use by U.S. women;
• How to pinpoint and address the gaps in research regarding PrEP implementation among U.S. women and how and by whom federal agencies and other stakeholders need to collaborate on joint collection of the data needed to answer these questions.

THREE KEY POINTS

1. Daily oral Truvada has the potential to be a prevention tool that women, including transwomen, can use to reduce their risk of HIV infection.

2. A consistent and comprehensive vision of how implementation of PrEP use among U.S. women will occur has yet to be well articulated. Further has there been a consensus for women on the subject of PrEP implementation that is proportionate to women’s presence in the U.S. workforce. Establishing better communication and collaboration among thought leaders and public health agencies is imperative.

3. Available clinical trial data justify exploring daily oral PrEP at a rate, but many unanswered questions remain about how to offer this intervention to women. These include questions about the female target populations for PrEP, strategies for training health care providers, the role of social marketing directed to women in this method, and the safety, efficacy, options, and adherence to PrEP use over the long term – in both women and men.
Key Points – Expectations

- Articulated pathway to responding to questions posed in Statement
- Civil Society engagement in process of planning and rolling out PrEP
- 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?
The Meeting – Highlights

- Defining high risk in US Women
- Community engagement is vital
- Education & Social Marketing
- Interagency Coordination
- Committed to respond within a few weeks
PrEP Advocacy Partnerships

- AVAC PxROAR
- 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)
- Network of PrEP projects funded by Gilead Sciences
What’s Next?

- Follow Up with Federal Partners
  - Demo Projects & Implementation Pilots
  - Response to Inquiries & Recommendations

- National Webinars on US Women & PrEP

- Next USW&P WG Face-to-Face

- National & International Engagement (USCA, CROI, AIDS2014, IAPAC, etc.)

- SisterLove implements STARSHIPPP
TLC is for EveryOne!

HIV –

HIGH RISK?

High Impact Prevention?

MOD/LOW RISK?

Behavioral Interventions?

HIV +

Care Cascade
TOWARD ELIMINATION OF SEXUAL HIV TRANSMISSION:
THE CASE FOR EXPANDING REPRODUCTIVE HEALTH OPTIONS

Shannon Weber, MSW
Director, National Perinatal HIV Hotline
Coordinator, Bay Area Perinatal AIDS Center
Shannon.weber@ucsf.edu
February 2010: CROI discussion

- Hosted by the National Perinatal HIV Hotline, moderated by Dr. Cohan
- 26 participants
- PrEPception vs. Con-PrEP-tion coined

- *This document does not necessarily reflect the beliefs of all participants at the discussion but, instead, is intended to summarize some of the points raised by the clinicians, policy-makers and researchers who attended. All participants acknowledged that this is currently a “data-free” zone, but that discordant couples have begun requesting PrEP for the purposes of conception.*
What are reproductive rights?

• The basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health.

World Health Organization
Few Americans believe that HIV+ women should have children.
HIV+ women internalize stigma around conception

Women Living Positive Survey
• n=700 HIV+ women on ARVs for 3+ yrs
• 59-61% believed could have children if appropriate care
• 59% believed society strongly urges not to have children

Squires et al. AIDS PATIENT CARE and STDs 2011
WE ARE EMPOWERED. Grammy Award-winning artist and HIV advocate Alicia Keys teamed up with Greater Than AIDS to reach women about HIV/AIDS. One in four people living with HIV in the U.S. today is a woman. As mothers, daughters, sisters, friends, partners and people living with HIV, we have the power to change the course of this disease through our actions.
March 2013
Washington DC
bus shelter
Unintended pregnancy

<table>
<thead>
<tr>
<th>US general population</th>
<th>49% pregnancies unintended</th>
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<tr>
<td>US, WIHS</td>
<td>232</td>
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<tr>
<td>US</td>
<td>1090 adolescents</td>
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<tr>
<td>Italy</td>
<td>334</td>
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<td>US, MMP</td>
<td>1407</td>
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Finer/Henshaw Perspec Sex Repro Health 2006; Massad AIDS 2004; Koenig AJOG 2007; Floridia Antivir Ther 2006; Sutton CROI 2012 abstract 1044
<table>
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<tr>
<th>US reproductive-aged women</th>
<th>35%</th>
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<tr>
<td></td>
<td>4% tubal regret</td>
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<tr>
<td>Cross-sectional, n=118</td>
<td>Rochester</td>
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<td></td>
<td>20% yes, 15% unsure</td>
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<td>12% tubal regret</td>
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<td>Cross-sectional, n=182</td>
<td>British Columbia</td>
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<td>25.8%</td>
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<td>Cross-sectional, n=181</td>
<td>Baltimore</td>
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<td></td>
<td>59%</td>
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<tr>
<td>Cross-sectional, n=127</td>
<td>Atlanta</td>
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<td></td>
<td>29.4%</td>
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<td>36.4% tubal regret</td>
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<td>HCSUS probability sample, n=1421</td>
<td>US, HCSUS</td>
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<tr>
<td></td>
<td>29% women</td>
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<td>28% men</td>
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Disco Survey: HIV- ♀ in a relationship with an HIV+ ♂ & desire children

- IRB approval to recruit from other sites; study is ongoing
- 100 started, 64 completed
- 88% want children with their HIV+ male partner
- 25% have tried to get pregnant with their HIV+ male partner
- 66% had vaginal sex without condom with HIV pos partner
- 53% are willing to use PrEP
- 27% would pay $100-499 to get pregnant, 8% $1000-5000, 3% $500-999, 3% 5000-15,000, 3% >15,000
- 33% used condom always, 44% used condom half time, 22% never used condom
- 52% have seen a provider to discuss ways to get pregnant
  46% same PMD, 83% saw an HIV specialist, 37% OBGYN, 34% REI

http://hiv.ucsf.edu/care/perinatal/pro_men.html
“All the men know how to get babies. And people with HIV know how to abstain from having sex. But if you have sex with a woman who doesn’t have HIV and try to have a baby? We want information on what to do and how to do it. Because I still don’t know how to do it. “

PRO Men focus group participant, July 2012
U.S. HIV heterosexual serodifferent couples

Estimated to be 140,000 U.S. serodifferent couples

• About half desire children

• Increasing call volume to the National Perinatal HIV Hotline (888-448-8765) from clinicians and patients seeking safer conception options.
Epidemiology of US HIV Heterosexual Serodifference

- HIV Cost and Services Utilization Study (1996)
- Probability sample, n=1421 (34,833 ♀, 53,177 ♂)
  - Currently married or with heterosexual partner

Chen et al. Family Planning Perspectives, 2001
hello, OPPORTUNITY!
New HIV Prevention Strategies

Antiretroviral treatment ("Treatment as Prevention")
- HPTN 052 96% reduction in sexual transmission with undetectable viral load

Pre-exposure prophylaxis or PrEP
- Several PrEP studies indicate a dramatic reduction in HIV acquisition with adherence

more options = POSSIBILITY
If we succeed at integrating reproductive & sexual health care into primary care:

- Every HIV-exposed pregnancy will be planned and well-timed
- There will be no HIV transmission to infants or to uninfected partners
- The health of all HIV-affected parents and infants will be optimized
Poppy: One mom’s story
INTEGRATION OF PREP INTO THE CLINICAL SETTING

ERIKA AARON, MSN CRNP
DREXEL COLLEGE OF MEDICINE
WHAT WE KNOW ABOUT PREP AND WOMEN

- **Effective** in Partners PrEP
  - Women were older (mean age 36)
  - All in committed relationship with a partner they knew was HIV-positive; both partners aware of HIV risk
  - Among higher-risk subgroups of women PrEP had consistently high efficacy for HIV-1 protection (AIDS 2013)

- **VOICE**
  - Daily approach – gel or tablet – was not right for the population of women in VOICE
  - Younger (under 25), unmarried women were least likely to use the products and the most likely to acquire HIV

- **PrEP, when used with high adherence, is a highly effective prevention strategy for women.**
LESSONS FROM VOICE

- The women who need safe and effective HIV prevention methods must also be willing and able to use them – and they must actually use them.
- Is there stigma with using an ARV product for prevention?
- Is daily use asking too much?
**BENEFITS OF PREP AS AN ADJUNCTIVE METHOD DURING ATTEMPTED CONCEPTION BETWEEN HIV- WOMEN AND HIV+ MALE PARTNERS: A MODELING APPROACH**

**HOFFMAN IAS 2013**

- **AIM:** evaluate the additive benefit of PrEP for conception, without HIV transmission, with an HIV+ male and HIV- female

- **PrEP provided little added benefit when all are true:**
  - The HIV+ male partner is on ART
  - Unprotected intercourse is limited to the period of ovulation
  - STIs are diagnosed and treated in both partners

- **ART treatment of the HIV+ male partner** drives the differences between strategies

- **Younger age** is associated with the desired outcome

- These data are reassuring that patients can have desired results without the addition of PrEP if they are motivated to optimize other modifiable risk factors (provided ART is available)
NOT ALL PERSONS WITH HIV ARE READY TO START ART

- Kenya 772 serodiscordant couples in Partners PrEP study
- Would you be willing to start ART if it would lower your chance of giving HIV to your partner:
  - HIV+Men: 58% - Yes  42% - No
  - HIV+ Women: 70% Yes  30% No
- Concerns: Side effects, stigma, pill burden potential for ART resistance
  
  Heffron JAIDS 2012

- PrEP could be used as a bridge to ART as a public health strategy
PREP DURING PREGNANCY

- From studies of HIV+ women using tenofovir for treatment
  - No association with any adverse outcomes at birth
  - No association with preterm, SGA or adverse birth outcome
  - No association of TDF with teratogenicity
  - Minimal (0.4 cm) reduced mean length at month 12; significance uncertain
  
- From studies of HIV-uninfected women using tenofovir as PrEP
  - Limited data from first trimester suggest no increased risk for poor birth outcomes and no delays in infant growth

Siberry AIDS 2012
Mugo CROI 2012
PREP IN COUPLES
PLANNING PREGNANCY

- The male HIV-infected partners were receiving ART and had undetectable plasma HIV RNA levels.
- One dose of oral tenofovir was taken by the women at luteinizing hormone peak and a second oral dose was taken 24 hours later.
- None of the women became HIV infected and pregnancy rates were high, reaching a plateau of 75% after 12 attempts.

Vernazza, Graf et al 2011
TENOFOVIR & BREASTFEEDING

- No data infant safety with exposure through breastfeeding
- Experience with TDF and pregnancy outside of clinical trials has been among HIV-1 infected women for PMTCT & maternal health
- In the USA: PMTCT guidelines recommend against breastfeeding
- Tenofovir crosses through to breast mild in small quantities
- The Gilead manufacturing insert for Truvada states:
  - Do not breastfeed if you have HIV because of risk of passing HIV to your baby.
  - Truvada can pass to your baby in your breastmilk. It is not known if this will harm your baby
US WOMEN ARE BEING PRESCRIBED PREP

- Total of 1,774 subjects were identified as starting TVD for PrEP.
  - 47.7% were women

Mera RM et al. ICAAC 2013
KNOWLEDGE AND ACCEPTABILITY OF PREP AMONG HIV+ INDIVIDUALS (DREXEL UNIVERSITY COLLEGE OF MEDICINE)

Cross sectional survey between 1/2013 and 6/2013 of HIV+ persons
  • 206 subjects included

Survey was based on a CDC validated survey which examined knowledge, attitudes and acceptability of PrEP

Results:
  • Only 15% were aware of PrEP
  • MSM (p=0.014) and males (p=0.013) were more likely to be aware of PrEP
  • Once educated about PrEP 89% said that would be extremely likely/likely to recommend PrEP to a negative partner
  • Of those subjects who had HIV negative partners and who had not missed a dose of their ART in the last 7 days (p=.05), were more likely to have heard of Prep (p=.05) and were more likely to recommend this for their partner (p=.049).
PREP AT DREXEL COLLEGE OF MEDICINE HIV CLINIC, PHILA

- Majority of persons who have expressed interest are pregnant women with HIV+ partners, and HIV- partners of HIV+ pregnant women
  - 10 HIV- pregnant women of HIV+ partner
  - 8 HIV – male partners of HIV+ pregnant women
  - 5 HIV- women who are attempting conception
- Excellent adherence to meds and apts
  - 85% reported no missed meds in last 7 days.
  - No transmissions
- 8 of the women received PrEP in the OB/GYN clinic associated with the HIV clinic.
INTERIM PREP FOR THE PREVENTION OF HIV INFECTION IN HETEROSEXUALLY ACTIVE ADULTS

Before initiating PrEP Determine eligibility

- Document negative HIV antibody test immediately before starting PrEP medication.
- Test for acute HIV infection (Viral Load) if person has symptoms consistent with acute HIV infection or reports unprotected sex or sharing IDU equipment with an HIV-positive person in the preceding month.
- Determine if women are planning to become pregnant, is currently pregnant, or plans to breastfeed:
  - Discuss safety profile for infants exposed during pregnancy through the antiretroviral pregnancy registry - the risk of teratogenicity is <2%.
  - Discuss to women that safety for infants exposed during breastfeeding is not fully assessed but no harm has been reported.
- May consider using PrEP as harm reduction for a female who is breastfeeding and continues to have unprotected sex with a partner with HIV or a high risk partner.
DETERMINE ELIGIBILITY, CONT’D

- If sexual partner is known to be HIV-infected, determine whether receiving ART; assist with linkage to care if not in care or not receiving ART.
- Confirm that calculated creatinine clearance is ≥60 mL per minute (Cockcroft-Gault formula†).
- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision regarding prescribing PrEP.
- Screen and treat as needed for sexually transmitted infections (STIs).
BEGINNING PREP

- Prescribe tenofovir disoproxil fumarate (TDF) 300 mg plus emtricitabine (FTC) 200 mg (i.e., one Truvada [Gilead Sciences] tablet) daily.
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected.
- At each follow-up visit for women, conduct a pregnancy test and document results; if pregnant, discuss continued use of PrEP with patient and prenatal-care provider.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC, which may serve as both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and condoms.
- Evaluate and support PrEP medication adherence.
- Assess STI symptoms and, if present, test and treat for STIs as needed.
- Three months after initiation, then every 6 months while on PrEP medication, check serum creatinine and calculate creatinine clearance.
DISCONTINUING PREP (AT PATIENT REQUEST, FOR SAFETY CONCERNS, OR IF HIV INFECTION IS ACQUIRED)

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV-positive, order and document results of resistance testing, establish linkage to HIV care.
- If HIV-negative, establish linkage to risk reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B infection.
- If pregnant, inform prenatal-care provider of TDF/FTC use in early pregnancy and coordinate care to maintain HIV prevention during pregnancy and breastfeeding.
ATTEMPTING PREGNANCY OR PREGNANT WOMEN ON PREP

- Consider more frequent visits, possibly monthly. For HIV testing and close monitoring for adherence.
- Woman trying to get pregnant should come in for an unscheduled visit if missed menses.
- If pregnant, report to Antiretroviral Pregnancy Registry
  - http://apregistry.com/
  - Phone: 800-258-4263
  - Fax: 800-800-1052
- Post-Partum options
  - Discuss risks/benefits of breastfeeding on PrEP
  - Strict condom use
  - HIV+ partner’s viral load undetectable
  - Formula feeding and continuing PrEP for own health postpartum.
PROTOCOL FOR PREP IN AN HIV CLINIC

- Patient appointments made on the provider template by the front desk staff.
  - A separate visit code will be assigned
  - A notation will be put into the provider schedule to alert for reason of visit
- Patients who require a referral should be for an infectious disease consult.
- If patient has no insurance:
  - Can be seen as a Family Planning patient if clinic has Title X funding
  - **Gilead patient assistance program pays for HIV test and HBV**
- Billing code for PrEP:
  - **V01.7**: contact with or exposure to viral disease including 042 (HIV)
  - Or **V01.79**: Exposure to HIV.
# PREP PATIENT ASSISTANCE PROGRAM

![Application Form](image)

## Social Security Information
- **Social Security #:** [Enter Social Security Number]
- **Date of Birth:** [Enter Date of Birth]
- **Gender:** [Male/Female/Other]
- **Resides in U.S./U.S. Territories:** [Yes/No]

## General Information
- **Primary Contact:** [Enter Name]
- **Relationship:** [Enter Relationship]
- **Phone Number:** [Enter Phone Number]

## Applicant Financial Information
- **Current Annual Household Income:** [Enter Income Amount]
- **Number in Household:** [Enter Number of People]
- **Please include current documentation for all sources of income (e.g., tax return, W2, last 2 pay stubs, etc.).**

## Applicant Insurance Information
- **Applicant is insured:** [Choose Yes/No]
- **Applicant is uninsured:** [Choose Yes/No]

## Statement of Medical Necessity

**Statement of Medical Necessity for Financially Needy Applicants.** To the best of my knowledge, this applicant has no coverage (including Medicaid or other public programs) for TRUVADA. I certify that the medication(s) listed above are medically indicated for this applicant and that I will be supervising the applicant's treatment. I certify that I am prescribing TRUVADA for PrEP as part of a risk reduction strategy for HIV prevention for this applicant. I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

**Sign Here**
- **Prescriber Signature:** [Sign Here]
- **Date:** [Enter Date]

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**Applications are considered complete only if they include all of the following:**
- Front and Back Pages of Enrollment Form
- Applicant as well as Prescriber Signatures and Dates
- Documentation of Income Sources and Residency
- Copy of Prescription

**Gilead Sciences, Inc.**
- **Medication Assistance Program**
- **P.O. Box 13185**
- **La Jolla, CA 92039-3185**

**When complete, FAX application and documentation to:** 1-855-330-5478
FAMILY PLANNING MODEL

Family planning services is prevention:

- Prevention of unwanted pregnancy
  - Birth Control provided on site
  - Preconception counseling provided for those interested in conception
- Prevention of STDs
  - STD treatment provided on site for patients and their partners
- Prevention of HIV
  - HIV testing and counseling
  - Condom supply
  - **PrEP counseling**
STEPS FOR A NATIONAL AGENDA FOR PREP IMPLEMENTATION

- Educational campaign to increase awareness for persons who might benefit from PrEP use
- Educational campaign to train providers interested in offering PrEP to their patients
  - Systematic training in medical, family planning, HIV, and OB/GYN clinics
- Monitor PrEP use and its health impact
- Disburse information on models of implementation
- Disburse information on clinical research
- Ensure insurance policies reimburse billing codes
- Coverage for uninsured needs to be worked out: lab costs, coverage for visit etc.
PATIENT INFORMATION SITES

Project Prepare Website:  [www.projectprepare.net](http://www.projectprepare.net)
http://www.prepwatch.org/#women


San Francisco Department of Public Health: [www.prepfacts.org](http://www.prepfacts.org)


Bay Area Perinatal AIDS Center: Positive Reporductive Outcomes for Men: [hiv.ucsf.edu/care/perinatal/pro_men.html](http://hiv.ucsf.edu/care/perinatal/pro_men.html)
National HIV/AIDS Clinicians’ Consultation Center
UCSF – San Francisco General Hospital

Perinatal HIV Hotline  (888) 448 - 8765
National Perinatal HIV Consultation & Referral Service
Advice on testing and care of HIV-infected pregnant women and their infants
Referral to HIV specialists and regional resources

Warmline  (800) 933 - 3413
National HIV Telephone Consultation Service
Consultation on all aspects of HIV testing and clinical care

PEPline  (888) 448 - 4911
National Clinicians’ Post-Exposure Prophylaxis Hotline
Recommendations on managing occupational exposures to HIV and hepatitis B & C

HRSA AIDS ETC Program & Community Based Programs, HIV/AIDS Bureau & Centers for Disease Control and Prevention (CDC)

www.nccc.ucsf.edu
HIV risk perception: How do we define high risk among women? Who thinks they are at risk? Who doesn’t? What affects those perceptions?

Monday, December 9, 2013

Speakers: Rivet Amico, PhD, Judy Auerbach, PhD Celeste Watkins-Hayes, Ph.D, JoAnne Keatley, Ph.D. (invited)

Moderator: Vignetta Charles, AIDS United

Co-sponsors: AVAC, NWHN, HIV PJA and The Well Project
Q & A

To ask a question:
- Enter it into the chat box in ReadyTalk
- Email your question to avac@avac.org
- Tweet @hivpxxresearch

For more information: www.prepwatch.org

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