Follow-up questions to 10/28 PrEP-ception webinar
US Women & PrEP Working Group

On October 28, 2013, the US Women and PrEP Working Group held a webinar, *PrEP-ception: Sero-discordant couples using PrEP to reduce HIV transmission risk while achieving pregnancy*. More questions were received than could be answered in the allotted time, so the Working Group has responded below to the ones that were not addressed during the webinar. For more information, slides and recordings from this and other webinars organized by the US Women and PrEP Working Group, please visit [www.prepwatch.org/uswomenwebinars](http://www.prepwatch.org/uswomenwebinars).

How soon after conception do you stop taking Truvada? Is there any research on possible negative effects on the zygote from taking an ARV while trying to get pregnant?

The decision to stop taking PrEP is made in relation to the patient and providers assessment of the patient’s overall risk factors for acquiring HIV. In the scenario where a couple consistently uses condoms except for unprotected sex during timed intercourse for conception, and the partner is on an effective suppressive ARV regimen with reliable adherence, the woman has the option to continue or stop PrEP after her last exposure. In the scenario where an HIV-affected couple has ongoing unprotected sex, the HIV-negative female partner may choose to continue taking PrEP for HIV prevention during her pregnancy and breastfeeding given the higher rates of HIV transmission to the fetus/infant during acute infection. Additionally, there are higher rates of HIV transmission and acquisition during pregnancy, which should be considered as well.

The data from the ARV pregnancy registry with regards to viread and emtricitabine (Truvada) use during pregnancy is reassuring with regards to side effects for the women and long term toxicity for the infant. There is no evidence of human teratogenicity of either drugs, a 2-fold increase in overall birth defects has been ruled out. (Refer to Table 5 in the Perinatal Guideline: [http://aidsinfo.nih.gov/guidelines](http://aidsinfo.nih.gov/guidelines))

What different considerations need to be taken for an HIV- male and a HIV+ female wanting to get pregnant?

In this scenario, we still focus on the HIV-infected person having an undetectable viral load and maximizing the health of the female (stop smoking, take folic acid, etc.) For conception, it is possible for the HIV-male/HIV-positive female couple to use timed home insemination to conceive with absolutely zero risk to the HIV-negative male if they consistently use condoms. Please see the home insemination hand out and video on the BAPAC website: [http://hiv.ucsf.edu/care/perinatal/resources.html](http://hiv.ucsf.edu/care/perinatal/resources.html); [http://hiv.ucsf.edu/care/perinatal/videores.html](http://hiv.ucsf.edu/care/perinatal/videores.html)

Did baby have to take ARVs for first 6 months of life? Does mom continue to take Truvada?

HIV-exposed infants (infants born to an HIV infected mom) are prescribed 6 weeks of ARVs for prevention of HIV. If you are referring to Poppy’s baby, no ARVs were required as Poppy remained HIV-negative through her pregnancy. A fetus is only exposed to HIV through the mom. While our goal is always to prevent HIV transmission to the partner, it is particularly important during pregnancy and breastfeeding to avoid exposing the fetus or infant to HIV.

An HIV-negative women with an HIV-positive male partner has the option of continuing Truvada for prevention of HIV acquisition during pregnancy and particularly during breastfeeding where the risk of transmission is high if the mother acquires HIV during breastfeeding.
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I think I've heard of positive women with undetectable viral loads having negative babies... this has happened, right?

In the United States, if a woman is identified as HIV positive and is in care with an undetectable viral load, there is a less than 1% perinatal HIV transmission rate. You can find many resources and a video for HIV+ women who wish to conceive on the BAPAC website: [http://hiv.ucsf.edu/care/perinatal.html](http://hiv.ucsf.edu/care/perinatal.html) and in the Perinatal Guidelines: [http://aidsinfo.nih.gov/guidelines](http://aidsinfo.nih.gov/guidelines)

Here in LA we have a few locations that provide Prep for people that feel that they might have had sex with someone that is positive. Is there a limit on how many times one can get the medication? Or will the government continue to provide the medication even if they come in monthly to get the medication?

Accessing PEP and PrEP may be handled differently according the clinic and the insurance coverage. As for PrEP access, we have not heard of insurance denying coverage following appeal. Also, Gilead offers a Medication Assistance Program which will cover HIV testing and Truvada for any patient who qualifies (does not have other coverage and meets an income requirement). Most providers are prescribing PrEP for a three month period and then a follow up appointment for testing, labs, adherence counseling, etc.

For those persons who have had an exposure and would like to take ARVs to prevent acquisition of HIV there are guidelines for Post Exposure Prophylaxis: [http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf](http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf)

Did insurance pay for PrEP for Poppy or her husband's monthly blood draws?

Poppy and her husband’s insurance covered the PrEP, HIV testing, and monthly viral loads as part of their routine primary and prenatal care.

How does the PrEP Registry maintain privacy?

The ARV Pregnancy Registry is not name based, all information is de-identified. All pregnant women who are prescribed ARVs, whether the women are HIV-positive or HIV-negative, should be included in the ARV Pregnancy Registry. Gathering this data will help inform future research and clinical practice for pregnant and breastfeeding women who need ARVs for treatment or prevention. The Gilead Medical Assistance Program requires a short two page document, which does include demographic information for prescription purposes.

What do you think the role of adjunctive semen processing/washing is?

Sperm washing and IUI or IVF/ICSI is a safe option for couples where the male is HIV positive and the female is HIV negative. However, there is limited access to sperm washing because of geography and/or finances; most insurance carriers do not cover the costs. PrEP is an additional option to offer couples. All the safer conception options for HIV+ male/HIV-negative female couples are covered in this handout: [http://hiv.ucsf.edu/care/perinatal/pro_men/safer_conception_hiv-pos_male_hiv-neg_female.pdf](http://hiv.ucsf.edu/care/perinatal/pro_men/safer_conception_hiv-pos_male_hiv-neg_female.pdf)

Additionally, Interim Guidance for PrEP in Heterosexual couples can be found on the CDC website: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm)
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I am currently working with a sero-different couple and although they have decided at this point to try sperm washing, the cost is so high. Are there financial resources that can provide assistance? They had tried Truvada for several months but the wife decided against using it any further out of fear of side-effects.

Some insurance companies cover assisted reproduction for couples. It is worth the time to explore the various fertility coverage options amongst your insurance choices. I know couples who have switched insurance providers during their open enrollment to maximize their fertility coverage during a year they planned to conceive. HIV is, however, not a fertility factor so women and men need to work with their providers to find the best methods for utilizing their insurance benefits. You are right that many, if not most, people do not have insurance to cover assisted reproduction. In the case the couple opts for PrEP and timed intercourse, PrEP can be covered through insurance or the Gilead Medical Assistance Program. You can reassure the couple that few side-effects on the mother and the infant have been found.

Perinatal HIV Guidelines http://aidsinfo.nih.gov/guidelines

Should the male and female partner be screened for their ability to conceive before attempting conception (i.e., semen analysis for the male and ovulation/tubal patency for the female partner)?

Great question and yes! Often the semen analysis is covered by insurance. In the case it is not covered, it can often be done for a few hundred dollars and many couples find this well worth the effort and money to learn if there are viable sperm. 50% of the time when there is a fertility issue (unrelated to HIV) it is male factor. Ruling in viable sperm is a good idea.

Since most STIs are asymptomatic, what kind of STD testing is being done if no symptoms are present?

Great question and point! All the data related to the massive reduction in HIV transmission with an undetectable viral load is based on couples who were also screened and treated for STIs. Screening and treating STIs should be a routine component of a preconception visit since STIs increase the risk of HIV transmission and acquisition. The CDC Interim Guidance for PrEP recommend screening for STDs prior to initiating PrEP, every 6 months thereafter, and more often if symptomatic or exposure to an STD is reported.

Can you expand on breastfeeding guidelines on PrEP? Where can these be found?

There are no PrEP and breastfeeding guidelines. In the scenario an HIV-negative woman with an HIV-positive male partner who chooses to breastfeed PrEP is a viable option. ARVs have been identified in breast milk and there have been no studies to date on the effects on the infant. One must weigh the risks and benefits of using PrEP during breastfeeding: there is reassuring data on Truvada during pregnancy which may be analogous to effects on the infant during breastfeeding; as compared to the high risk of transmission to the infant through breast feeding in the face of acute retroviral syndrome. PrEP is a viable option for protection of the infant during breastfeeding and for protection of the woman. I would advise calling the National Perinatal HIV Hotline (for a consultation on the regimen, testing, follow up).

I believe that Gilead originally and purposefully decided not to have a national PR or marketing campaign around the use of Truvada for PrEP. Do you know if they are modifying this stance?

I believe this remains the same.

Is anyone tracking the number of infections averted due to the use of PrEP in "sero-different couples"?

At this time, there is not a registry or ongoing study tracking PrEPception cases.
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For those who do not have insurance, it is only for heterosexual couples, not same sex sero-different status who can gain assistance?

*Any person, regardless of sexuality or HIV risk category can access Gilead’s Medical Assistance Program for the provision of HIV testing and Truvada as HIV prevention.*

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**The U.S. Women and PrEP Working Group** is coalition 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.