

Counseling Framework for HIV-serodiscordant Couples on the Integrated Use of Antiretroviral Therapy and Pre-Exposure Prophylaxis for HIV Prevention

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PARTNERS DEMONSTRATION PROJECT



BILL & MELINDA
GATES *foundation*



Background – HIV prevention

- ART and PrEP substantially reduce HIV risk, by more than 90% when used with high adherence (Cohen et al. NEJM 2011, Baeten et al. NEJM 2012)
- For HIV serodiscordant couples, both ART and PrEP are recommended prevention tools (WHO 2014/2015)
- Prevention benefits are only realized when adherence is high (Grant et al. Lancet 2014, Cottrell J Infect Dis 2016)
- Counseling sessions offer opportunities to identify and problem-solve barriers to adherence (Ngure et al AIDS Patient Care STDs 2016, Coates JAIDS 2013)



Background – work with HIV discordant couples

- Since 2004, we have been conducting HIV prevention research with discordant couples in East and south Africa

Study name	Couples enrolled
Partners in Prevention HSV/HIV Transmission Study, 2004-2008	3408
Couples Observational Study, 2008-2010	495
Partners PrEP Study, 2007-2012	4758
Partners Demonstration Project, 2013-2016	1013
Total couples	9674

- Always done under the premise of comprehensive HIV prevention counseling for discordant couples



Partners Demonstration Project

- The Partners Demonstration Project was an open-label, prospective interventional study of integrated ART and PrEP delivery for HIV prevention among heterosexual HIV serodiscordant couples
- The project was conducted at 4 clinical sites:
 - Kisumu & Thika in Kenya and Kabwohe & Kampala in Uganda
- The overall goal was to evaluate, using implementation science methods, a scalable delivery system for PrEP and ART for HIV prevention in couples
 - With counseling, adherence promotion, and follow-up designed to reflect approaches suitable for public health clinic settings
 - **Initiated November 2012 & concluded follow-up June 2016**
- The project demonstrated a 96% reduction in HIV transmission (Baeten et al. Plos Medicine 2016)



Design

- Population:
 - Heterosexual HIV serodiscordant couples, not using ART or PrEP and ***with characteristics defining higher risk for HIV transmission***
 - *None participated in the Partners PrEP Study clinical trial of PrEP*
- Intervention:
 - ART offered per Kenya/Uganda guidelines, which recommend ART for all infected partners in serodiscordant couples, regardless of CD4 count
 - PrEP (daily oral FTC/TDF) offered to the uninfected partner until the infected partner has been on ART for 6 months, permitting time to achieve viral suppression (***=PrEP as a bridge to ART***)
- Follow-up:
 - Month 1 and then quarterly thereafter, for 24 months



Counseling Sessions

- Intervention was delivered in the context of HIV serodiscordant couples counseling
 - Couples encouraged to attend together
 - All participants also had an individual counseling session
 - Sessions used an adaptable, client-centered approach
 - Sessions ~30-45 minutes
- Sessions conducted by nurse counselors or HIV prevention counselors
 - Pharmacists and clinicians also delivered messages when appropriate



Goal of this manuscript

Our goal was to use an iterative process to describe the counseling process for HIV discordant couples participating in the Partners Demonstration Project and key messages about the integrated PrEP and ART strategy that was delivered



Development of counseling messages

- **Phase I: Message Development**
 - To accompany the integrated delivery of PrEP and ART, we used lessons learned from prior work to developed more than 80 counseling messages
 - 30 CHCT-experienced study counselors were trained to develop the messages
- **Phase II: Message Refinement**
 - Iterative process with study counseling staff to identify and refine key simple and accurate messages
 - Four iterations of refinement
- **Phase III: Message Validation**
 - Refined messages were tested with participants
 - Consulted qualitative work to ensure counselor experiences matched participant experiences



Framework for counseling HIV discordant couples about an integrated PrEP and ART strategy

Counseling about HIV discordance and HIV testing

Counseling on all prevention options including ART and PrEP used in an integrated way

Counsel the HIV positive partner about the importance of ART

Counsel the HIV negative partner about PrEP and its role as a time-limited strategy

Encourage the negative partner to discontinue PrEP once ART use is sustained (at least 6 months after ART initiation)

PrEP can be re-started if HIV risk changes because of fertility intentions, new partners, problems with ART adherence or other factors



ART Messages



ART as HIV treatment. ART use treats HIV infection and improves health; starting as soon as possible after diagnosis and continuing for life is the best strategy.



ART as HIV prevention. ART is also an HIV prevention strategy. ART reduces the amount of HIV in the body. Because of this, it makes someone less likely to pass their infection to other people.



Adherence. In order for ART to work as treatment and prevention, it must be taken daily without interruptions. It is important to plan ahead to make sure ART does not run out.



Viral suppression. It takes 3-6 months of ART used daily for someone to decrease the amount of HIV in their body to a level where they will not pass on their infection.



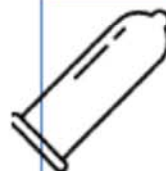
Resistance. If there are inconsistencies in ART use, one problem may be the development of resistance and the need to change ART medications. There are a limited number of ART medications.



Pregnancy. ART is safe to use for people who are planning to get a baby, pregnant and breastfeeding. It is important to use ART to prevent HIV infection from passing to the baby.



Side effects. All medications have side effects. Side effects from ART may affect each person differently. Most side effects will lessen after the first 1-2 months of regular use, once the body gets used to the medications.



Condoms. When ART is used, condoms have a role to prevent other sexually transmitted infections and pregnancy as well as being another HIV prevention method.



PrEP Messages



PrEP for HIV prevention. PrEP prevents HIV infection in men and women.



HIV testing. Individuals who are taking PrEP need to have regular HIV testing.



PrEP discontinuation. PrEP should be used when someone has a risk of getting HIV. When this risk is no longer there, PrEP can be stopped.



Side effects. Side effects from PrEP affect each person differently. Most side effects will lessen after the first 1-2 months of regular use, once the body gets used to the medications.



Daily use. PrEP must be taken every day to prevent HIV infection.



Pregnancy. PrEP is safe to use when trying to become pregnant.



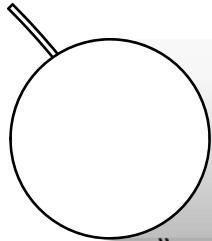
Adherence. Counselors can talk about the best strategies to help people take their daily pills. They help people find ways to take their pills during difficult times such as travel, in the face of stigma, or when there are new partners.



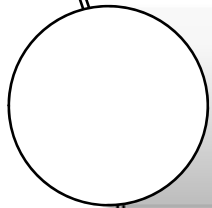
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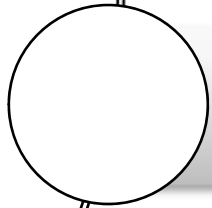
Messages about the integration of PrEP and ART



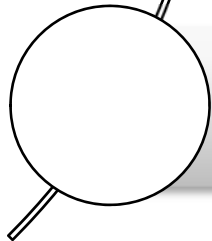
At the outset, both partners use medications and both partners have role in supporting each other's medication use and adherence.



PrEP has a short term role to protect the negative partner during the time before the positive partner starts ART and while the positive partner is getting used to taking ART and reducing the amount of HIV in their blood (about 6 months).



When couples attend HIV counseling together, they have the opportunity to talk with a counselor about prevention strategies and strengthen their relationship.



When it is time for PrEP use to stop, ART use by the positive partner and the support for ART use provided by the negative partner are habits and are likely to continue.



Summary

- The counseling framework was designed to accompany the delivery of integrated PrEP and ART in an open-label demonstration project
- The messages were developed to help couples understanding confusing concepts such as HIV discordance, how antiretroviral-based HIV prevention works
- The counseling framework and accompanying messages can be adopted for programmatic scale up of integrated PrEP and ART delivery for HIV serodiscordant couples



Partners Demonstration Project Team

Investigators

- University of Washington Coordinating Center: Jared Baeten (protocol chair), Connie Celum (protocol co-chair), Renee Heffron (project director), Deborah Donnell (protocol statistician), Ruanne Barnabas, ICRC Operations, Data and Administration teams
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- MGH/Harvard: Jessica Haberer, Norma Ware
- Johns Hopkins: Craig Hendrix, Mark Marzinke
- DF/Net Research (data management)

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Research participants



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