the site's CAB liaison staff person to join the call. Core often asks GCAB representatives to work from their local CAB to allow them to be part of these communications and meet stated deadlines. GCAB representatives as well as with the staff of the CAB will try to establish this while meeting the expectations of the CAB local liaison person to join the call. Core expects GCAB representatives to participate in the Global CAB due to language barriers.

- GCAB representatives should always feel comfortable to directly contact either the GCAB officer or their site liaison if they have a question, whether it is something that is immediately logistical.

The HVTN could not do its work without the dedication and commitment of community members around the globe. CAB members are also those who serve on Network committees, play a crucial role in ensuring that the concerns of their communities are being addressed by the Network. GCAB representatives are an essential link in the communication between CAB, their site and the HVTN. We hope that the expectations outlined above can keep communication between CAB members and the Network both fruitful and robust.

- The list of expectations above has been adapted from the HVTN Manual of Operations (MOP). The MOP also lists three additional aspects of CAB involvement and HVTN Core procedures in general. To view the complete document, please visit CAB liaison person to help you access it through the HVTN website or the Atlas portal.

About CABs

The Global Community Advisory Board (GCAB) is open to any and all CAB members. The GCAB represents the perspective of community members to the HVTN. To be a part of the GCAB, CAB members are encouraged to select an alternate representative and help their local CAB to be part of the GCAB. Core expects GCAB representatives to participate in the Global CAB due to language barriers.

- GCAB members are representatives of the CAB from local clinical research sites, scientists, and nodes who have relevant experience in the area of sexually transmitted infections and HIV/AIDS prevention trials, this means whether the product can prevent new HIV infections, or lower viral load in those who are already infected. Prevention trials, this means whether the product can prevent new HIV infections, or lower viral load in those who are already infected.

- One of the primary roles of GCAB representa- tives is to communicate between CAB members and the Network both fruitful and robust.

- The list of expectations above has been adapted from the HVTN Manual of Operations (MOP). The MOP also lists three additional aspects of CAB involvement and HVTN Core procedures in general. To view the complete document, please visit CAB liaison person to help you access it through the HVTN website or the Atlas portal.

- The HVTN could not do its work without the dedication and commitment of community members around the globe. CAB members are also those who serve on Network committees, play a crucial role in ensuring that the concerns of their communities are being addressed by the Network. GCAB representatives are an essential link in the communication between CAB, their site and the HVTN. We hope that the expectations outlined above can keep communication between CAB members and the Network both fruitful and robust.

- The list of expectations above has been adapted from the HVTN Manual of Operations (MOP). The MOP also lists three additional aspects of CAB involvement and HVTN Core procedures in general. To view the complete document, please visit CAB liaison person to help you access it through the HVTN website or the Atlas portal.
In the past few years, the idea of PrEP has taken the HIV biomedical prevention field by storm. With PrEP, which stands for Pre-Exposure Prophylaxis, drugs originally designed to treat HIV infections are used for prevention. For more information on what PrEP effectiveness may mean for future HIV studies, see “Planning for PrEP,” in the December 2010 CAB Bulletin, hvtn.org/community/bulletins/HVTN/CABBulletin_D2010.pdf.

CAB203 extended safety study
Once daily Tenofovir (Viread) as PrEP (compared to placebo)
N=400
HIV negative
San Francisco, Atlanta, Boston
Amended July 2010: no significant differences in HIV risk behaviors between study arms; no serious adverse events, *not designed to evaluate efficacy.*

iPrEx Phase 3 efficacy study
Once daily tenofovir-FTC (Truvada) as PrEP (compared to placebo)
Men and transgender women who have sex with men
N=2689
HIV negative
Brazil, Ecuador, Peru, South Africa, Thailand, US
Amended November 2010: reduced the risk of HIV infection by an average of 38%. Patients also received intensive counseling about safer sex, HIV testing, condoms, treatment for STIs and other prevention services monthly; early analysis indicates that adherence to a factor which significantly impacts efficacy.*

FEM-PrEP Phase 1 efficacy study
Once daily tenofovir-FTC (Truvada) as PrEP (compared to placebo)
N=80
Women whose primary risk factor is vaginal sex
HIV negative
Kenya, Tanzania, South Africa
Amended April 2011: at a scheduled interim review by the DSMB, it was determined that the trial would not be able to answer the question of whether the study drug decreased risk of HIV infection among HIV-negative women at risk via sexual transmission; study discontinued.

HPTN 052 Phase 3 efficacy study
Does early initiation of ART* upon study entry (in the involved partner) reduce the risk of HIV transmission in serodiscordant couples* who were assigned to the CD4 count below 350/mL or who have an AIDS-related illness?
Serodiscordant couples: Infected partner has not started ART and has a CD4 count of 200-500 cells/mm3 at enrollment
N=7782 couples
HIV-infected individuals and their uninfected partners (56% same heterosexual)
Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, Zimbabwe
Amended May 2011: at a scheduled review by the DBSR, it was determined that early initiation of ARV resulted in a 96% reduction in HIV transmission to the uninfected partner. The DSMB recommended stopping randomization and making treatment immediately available to those in the delayed-initiation group. The study is ongoing, but the placebo group is now being offered PrEP. This reduction of risk was achieved in both men and women enrolled in the study.

Partners PrEP Phase 3 efficacy study
Comparison of once daily tenofovir (Viread) or tenofovir-FTC (Truvada) as PrEP (compared to placebo)
N=4578 couples
HIV-infected individuals and their uninfected partners (heterosexual)
Kenya, Uganda
Amended July 2011: at a scheduled review by the DSMB, it was determined that the tenofovir arm had an average of 4% fewer infections and the Truvada arm had 75% fewer infections than the placebo group. The study is ongoing, but the placebo group is now being offered PrEP. This reduction of risk was seen in men and women. Adherence was very high, with 86% of dispensed doses taken.

SOP2 extended safety study
Once daily tenofovir +FTC (Truvada) as PrEP (compared to placebo)
Heterosexually active, young adults
HIV negative
Botswana
Amended July 2011: PrEP is safe when taken daily, and though the study was not designed to show efficacy, the data did show a 56% reduction in the risk of acquiring HIV infection. A separate analysis was done to better understand the level of effectiveness among trial participants believed to be taking study medications. It showed any HIV infections that occurred more than 30 days after a participant’s last reported drug pill, because these individuals could not have been taking study pills at the time of infection. These results indicate that Truvada reduced the risk of HIV infection by 76%.

Other questions:
- How should such care be implemented?
- Is there similar efficacy in other populations?
- Is this efficacy to be replicated in this population, and is such replication necessary?

Getting PrEPared: Results and Remaining Questions from Recent Biomedical HIV Prevention Trials

**STUDY**

**STUDY DRUGS/INTERVENTION**

**STUDY POPULATION & SIZE**

**PARTICIPANT HIV STATUS**

**LOCATION**

**STUDY RESULTS**

**DOE REMAINING QUESTIONS**

**IMPACT FOR PREVENTIVE VACCINE TRIALS**

- Additional safety info needed regarding age, gender, HIV risk, and use in combination with other medicines.
- What is the safest dose?
- Can PrEP with Truvada be equally effective when used independently of the other prevention services?
- Can PrEP with Truvada be effective when used intermittently rather than daily?
- Are there ways to improve adherence to the dosing regimen?
- Is there similar efficacy in other populations?
- Can this efficacy be replicated in this population, and is such replication necessary?
- We will be studying the impact of PrEP on immune system responses to vaccines.
- There is no need to advise PrEP use with Viread on the basis of any safety concerns.
- Contributed to the reduction of HIV in the US by 30%, with less restrictive inclusion criteria for PrEP use, educating participants about PrEP, additional counseling messages, and additional exploratory objectives to look at PrEP/vaccine interactions.
- The CDC issued preliminary guidelines for use of PrEP in some MSM groups. Consultations continue as analysis from several studies continue, and will provide further guidance on use and any study-specific indications and contra-indications.
- It will change the standard of HIV prevention used in clinical trials.
- None at this time.
- It will change the standard of prevention should it change, or if any change should apply only to specific populations, since the trial had no significant negative results, whereas iPrEx and TDF had favorable results.
- If this use of treatment as prevention is implemented, it could change the size of trials in which participants are to be randomized to placebo. This will thereby change the way preventive vaccine studies are designed and statistically evaluated.
- There is no need to advise against PrEP use with Viread on the basis of any safety concerns.
- We will be studying the impact of PrEP on immune system responses to vaccines.
- There is no need to advise PrEP use with Viread on the basis of any safety concerns.
- Contributed to the reduction of HIV in the US by 30%, with less restrictive inclusion criteria for PrEP use, educating participants about PrEP, additional counseling messages, and additional exploratory objectives to look at PrEP/vaccine interactions.
- The CDC issued preliminary guidelines for use of PrEP in some MSM groups. Consultations continue as analysis from several studies continue, and will provide further guidance on use and any study-specific indications and contra-indications.
- It will change the standard of HIV prevention used in clinical trials.
- None at this time.
- It will change the standard of prevention should it change, or if any change should apply only to specific populations, since the trial had no significant negative results, whereas iPrEx and TDF had favorable results.
- If this use of treatment as prevention is implemented, it could change the size of trials in which participants are to be randomized to placebo. This will thereby change the way preventive vaccine studies are designed and statistically evaluated.
- There is no need to advise against PrEP use with Viread on the basis of any safety concerns.
- We will be studying the impact of PrEP on immune system responses to vaccines.
- There is no need to advise PrEP use with Viread on the basis of any safety concerns.
- Contributed to the reduction of HIV in the US by 30%, with less restrictive inclusion criteria for PrEP use, educating participants about PrEP, additional counseling messages, and additional exploratory objectives to look at PrEP/vaccine interactions.
- The CDC issued preliminary guidelines for use of PrEP in some MSM groups. Consultations continue as analysis from several studies continue, and will provide further guidance on use and any study-specific indications and contra-indications.