

Five HPTN abstracts have been accepted so far for the 8th IAS Conference on HIV Pathogenesis, Treatment & Prevention in Vancouver, Canada, July 19-22:

Identification of factors associated with viral suppression and treatment failure when antiretroviral therapy is used for HIV prevention: Results from the HIV Prevention Trials Network (HPTN) 052 Trial

Analysis of HIV drug resistance in adults receiving early antiretroviral treatment for HIV prevention: Results from the HIV Prevention Trials Network (HPTN) 052 Trial

Perceived cultural beliefs and disclosure to primary sexual partners among women living with HIV in Brazil, Thailand and Zambia: Results from HPTN 063

HPTN 067 ADAPT: 'PrEP Ubuntu' and experiences with open-label PrEP among African women

Household socioeconomic status, sexual behavior, and prevalence of HIV and HSV-2 among sexually experienced South African school girls: HPTN 068

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## A Closer Look

### Network Profile Spotlights Brett Hanscom



Brett Hanscom

Brett joined the HPTN as Staff Scientist at SCHARP in October 2014 after receiving a PhD in biostatistics at the University of Washington at Seattle. His dissertation on how to obtain better estimates of HIV infectivity rates is based on large discordant partner studies much like HPTN 052, so the job seemed a natural fit. Brett is working on trial design and protocol development for HPTN 083 (see page 2), as well as monitoring the HPTN 074 study and analyzing data from HPTN 065. It is work he enjoys, for a number of reasons. "I love the collaboration with not only the statisticians, but the whole team across the Network," he explains. "It's a very talented group of people who are here because they want to do this work, and some of the studies we're working on have the potential to have a huge impact on public health." Brett is also glad that he found a job in Seattle, where he enjoys hiking, cycling, and playing sports with his wife, Rachel, and three children.

## HIV in the News

### Global Study Shows Early ART is Effective

People who start taking antiretroviral drugs early after an HIV diagnosis, before their immune systems show signs of weakening, are considerably less likely to develop AIDS or other serious illnesses, a major international study has found.

The interim results from this randomized clinical trial were so compelling that its Data and Safety Monitoring Board recommended releasing them more than a year early and offering all study participants antiretroviral treatment (ART).

Conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) at 215 sites in 35 countries, the Strategic Timing of Anti-Retroviral Treatment (START) study enrolled 4,685 men and women with HIV who had never received ART and had CD4 cell counts above 500 cells per cubic millimeter (cells/mm<sup>3</sup>).

Study participants were randomly assigned to receive ART immediately or after their CD4 cell counts dropped below 350 cells/mm<sup>3</sup>. The study measured any serious AIDS events (such as AIDS-related cancer), serious non-AIDS events (major cardiovascular, liver, and renal disease and cancer), and deaths that occurred in each group.

Over an average follow-up period of three years, the risk of developing serious illness

or death was reduced by 53 percent among participants who began ART early compared to those in the delayed treatment group.

A press release from the study's primary funder, the US National Institute of Allergy and Infectious Diseases (NIAID), concludes that "together with data from previous studies showing that antiretroviral treatment reduced the risk of HIV transmission to uninfected sexual partners, these findings support offering treatment to everyone with HIV."

The current World Health Organization guidelines for HIV treatment call for initiation of ART at CD4 counts below 500 cell/mm<sup>3</sup>. Mounting evidence may lead to a new recommendation of universal treatment regardless of CD4 count, as is recommended in the United States and several other countries. However, regardless of WHO or national guidelines, many people living with HIV remain undiagnosed or initiate treatment at advanced stages of HIV disease.

HPTN Principal Investigator Dr. Wafaa El-Sadr says the START results have important implications for HPTN's work. "This study provides further evidence that early initiation of ART can save lives and adds urgency to our search for better ways to reach people at risk of HIV, engage them in HIV testing and care, and support sustained adherence to treatment," she says.



## What's New in the HPTN?

### Prevention for Key Populations

Despite tremendous advances in prevention and treatment, the global HIV epidemic persists, with a disproportionate effect on some of society's most vulnerable populations. Young women ages 15 to 24, for example, account for 22 percent of all new HIV infections, and men who have sex with men (MSM) and transgender people are far more likely to acquire HIV compared to other adults.

Four HPTN studies in development will assess innovative approaches to preventing HIV among these at-risk populations. "The new studies will help us find better ways of reaching key populations with a wider range of HIV prevention options," says Dr. Nirupama Sista, HPTN LOC Director.



### HPTN 078

Viral suppression through early initiation of antiretroviral therapy (ART) has been proven to reduce HIV transmission, but many people living with HIV do not achieve this goal because they do not know they are infected, do not receive care, or have difficulty adhering to treatment. In the US, participation in HIV testing and care is particularly challenging in minority communities and is lowest among young black MSM, who also have the highest rates of HIV prevalence.

HPTN 078 is designed to assess the efficacy of an integrated strategy to identify, recruit, link to care, retain in care, and maintain

viral suppression among HIV-infected MSM in four US cities: Baltimore, Birmingham, Boston, and New York City.

The study will assess the ability of Deep-Chain Respondent Driven Sampling (DC-RDS) to recruit MSM living with HIV who are not virally suppressed. DC-RDS is a method of identifying and recruiting study participants that has the potential to reach the most marginalized subsets of a population.

Approximately 2,700 MSM will be recruited for HIV testing to identify 356 HIV-positive MSM who are not virally suppressed. These men will be randomly assigned to receive either standard HIV care or the study intervention, which consists of tailored support from a trained case manager. The effectiveness of this strategy will be assessed by comparing viral suppression at 24 months between the two study arms.

### HPTN 081/HVTN 703

The HPTN is collaborating with the HIV Vaccine Trials Network to assess a novel approach known as antibody-mediated protection (AMP) among at-risk populations (see page 3).

### HPTN 082

Daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) is approved by the US FDA for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV in adults at high risk. However, after the FEM-PrEP and VOICE studies were unable to demonstrate efficacy because participants did not take their pills as directed, many concluded that daily oral PrEP was not a viable prevention strategy for most African women.

Recent results from the Partners PrEP Demonstration Project and women assigned to daily oral PrEP in the HPTN 067 study

## Coming Soon

### 8th International AIDS Society Conference on HIV Pathogenesis, Treatment & Prevention

July 19-22, 2015



For a list of the HPTN abstracts accepted for the conference, see page 4.

### 19th Annual United States Conference on AIDS Washington, DC

September 10-13, 2015



suggest that may not be the case. Did women adhere to daily oral PrEP regimens in these open-label studies because they knew they were taking an effective drug and not an experimental drug or placebo, or were other factors at play? Do some characteristics of adherence support or women's experiences make it easier—or harder—for them to take a daily pill for HIV prevention?

These are some of the questions the HPTN 082 study is designed to answer as it evaluates daily oral FTC/TDF as a primary prevention method for young women. This prospective observational study will assess PrEP initiation, adherence, acceptability, and continuation among a cohort of 400 HIV-negative women ages 16 to 25 at three sites in southern Africa.

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## Prevention for Key Populations Continued from page 1

All participants will be offered a daily dose of FTC/TDF, along with adherence counseling sessions, two-way text-message communication, adherence support clubs, and standard HIV prevention services, and a subset of participants will be interviewed about facilitators and barriers to taking PrEP.

### HPTN 083

While some HPTN studies seek more effective ways of delivering proven interventions to key populations, others aim to expand options for HIV prevention. One option under study—a long-acting (LA) injectable form of an antiretroviral (ARV) drug called cabotegravir—offers the promise of a PrEP method that does not require adherence to a daily drug regimen.

HPTN 083 is a Phase 2B/3 double-blind randomized study that will assess the efficacy of quarterly injections of cabotegravir (CAB LA) for PrEP among 4,500 HIV-uninfected MSM and transgender women who have sex with men by comparing it with daily oral PrEP (FTC-TDF).

The study is expected to begin in 2016 at research sites located in the Americas and Asia. At each of these sites, the teams will forge partnerships with leaders of MSM and transgender communities, as well as advocacy and support groups. Participants at the highest risk of acquiring HIV, including young black MSM and transgender women, are the affected populations of greatest interest for this study.

One of two injectables being evaluated by the HPTN, CAB LA is the first ARV to be assessed for HIV prevention before receiving regulatory approval as an HIV treatment. Trials of the drug for treatment and prevention of HIV are running in parallel.

The drug's manufacturer, ViiV Healthcare, is conducting studies of CAB LA for treatment that have yielded promising safety and efficacy data so far. Early-phase studies of CAB LA for prevention, including HPTN 077 and ViiV Healthcare's ÉCLAIR study, will gather additional safety data among people at lower risk of acquiring HIV infection.

## HPTN Welcomes 2015-16 Scholars

The HIV Prevention Trials Network is pleased to announce the new group of HPTN Scholars. During the next 18 months, these five scholars will conduct secondary analyses of HPTN study data, working alongside leading HIV prevention researchers affiliated with the Network.



Brandon Brown

**Brandon Brown** of the University of California's Riverside Center for Healthy Communities will work with mentor Dr. Tom Coates of the University of California at Los Angeles. Dr. Brown will identify variables associated with self-reported HIV testing in the past 12 months among participants in the HPTN 043 study of mobile HIV testing and post-test support. He will investigate characteristics such as experience of negative life events and higher number of unprotected sexual acts.



Dustin Duncan

**Dustin Duncan** of the Department of Population Health at New York University School of Medicine will work with mentors Dr. Steven Safren and Dr. Ken Mayer, both of The Fenway Institute and Harvard Medical School. Dr. Duncan's study of community-level norms, sexual beliefs and behaviors, and sexually transmitted infections among HIV-infected men enrolled in the HPTN 063 positive prevention study will include comparisons between heterosexual men and MSM.



Mandy Hill

**Mandy Hill** of the University of Texas Medical School at Houston will work with mentor Dr. Carl Latkin of the Johns Hopkins University (JHU) Bloomberg School of Public Health. Analyzing data from the HPTN 037 trial of a network-oriented peer educator intervention, Dr. Hill will identify mediating and moderating factors contributing to sexual risk among a social network of people who inject drugs in Philadelphia.



Florence Momplaisir

**Florence Momplaisir** of the Drexel University College of Medicine will work with mentors David Metzger of the University of Pennsylvania School of Medicine and Dr. Carl Latkin of JHU's Bloomberg School of Public Health. She will also analyze HPTN 037 data, examining racial disparities in network mixing patterns and preventive behaviors among people who inject drugs in Philadelphia. Dr. Momplaisir will develop an innovative network risk score and will use geographic information system technologies to identify the contexts in which such networks evolve.



Tonia Poteat

**Tonia Poteat** of the JHU Bloomberg School of Public Health (SPH) will work with Dr. David Celentano, also of JHU SPH. Dr. Poteat's research will focus on MSM living with HIV who were enrolled in HPTN 063, asking both quantitative and qualitative questions about social support, mental health factors, risk perception, and the factors influencing sexual practices following an HIV diagnosis.

Supported by the US National Institute of Allergy and Infectious Diseases (NIAID), the HPTN Scholars Program is designed to increase opportunities for scientists traditionally underrepresented in HIV prevention research. This career development program has been so beneficial to both participants and the Network that the HPTN plans to begin an International Scholars Program in 2016.

## HPTN Collaborates with HVTN to Test Novel Approach

The HPTN is collaborating with the HIV Vaccine Trials Network (HVTN) to assess a promising new approach to HIV prevention, using broadly neutralizing antibodies (bNAbs) that have been shown to block many different strains of HIV from infecting human cells.

The approach is known as antibody-mediated prevention (AMP). It involves the use of intravenous infusion to administer bNAbs that have been engineered in a laboratory, based on an antibody isolated from a single cell from a person with HIV. Ultimately, scientists seek to develop vaccines that prompt the immune system to generate bNAbs.

The two networks are joining forces to conduct a safety and efficacy study of AMP with VRC01, a monoclonal antibody that has shown promise in laboratory and animal studies and in small safety studies in humans. The HPTN081/HVTN 703 trial will be the first large-scale phase 2B study of intravenous administration of a bNAb to prevent acquisition of HIV through sexual intercourse.

Dr. Myron Cohen, HPTN Principal Investigator (PI), and Dr. Lawrence Corey, HVTN PI, chair the protocol team. Dr. Cohen notes HPTN081/HVTN 703 is an ideal choice for the first major

collaboration between the two networks because it will inform both HIV prevention and vaccine development. "This approach brings a natural alliance," Dr. Cohen says. "It is an exciting collaboration that will synergize efforts from both networks to determine if the VRC01 antibody offers protection from HIV."

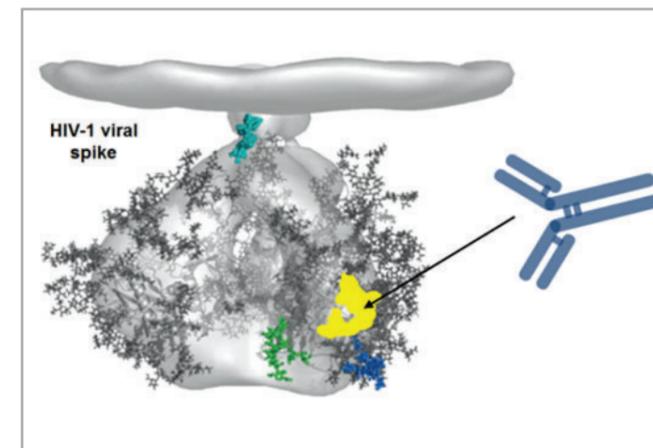
The study plans to enroll 3,900 participants in the trial. There will be two cohorts: 2,400 men who have sex with men and transgender people in the United States and South America and 1,500 sexually active women in sub-Saharan African.

In each cohort, participants will be randomly assigned to receive one of two different doses (10 mg/kg and 30 mg/kg) of VRC01 or a saline solution that will serve as the control. Each participant will receive an intravenous infusion every eight weeks for a total of 10 infusions over 72 weeks, followed by 20 weeks of follow-up without infusions. HIV testing will occur at least every four weeks, and participants will also be tested after reporting any possible exposure to HIV.

In addition to assessing the effectiveness of VRC01 for HIV prevention, the study will address questions critical to vaccine development. These questions include determination of the concentration of

VRC01 required to prevent infection and examination of all the ways in which VRC01 might prevent HIV infection.

Site selection is under way, and the protocol team hopes to have the study protocol ready for review by the relevant institutional review boards by the end of the summer.



The Y-shaped monoclonal antibody VRC01 neutralizes HIV by binding to a specific part of HIV's surface (the CD4-binding site).

## Hot Off the Press

Montgomery BE, Rompalo A, Hughes J, et al. "Violence against women in selected areas of the United States." *American Journal of Public Health*. 2015:e1-e11.

Pettifor A, Corneli A, Kamanga G, et al. "HPTN 062: A pilot randomized controlled trial exploring the effect of a motivational-interviewing intervention on sexual behavior among individuals with acute HIV infection in Lilongwe, Malawi." *PLoS One*. 2015;10(5):e0124452.

Rosenberg M, Pettifor A, Lippman SA, et al. "Relationship between community-level alcohol outlet accessibility and individual-level herpes simplex virus type 2 infection among young women in South Africa." *Sexually Transmitted Diseases*. 2015;42(5):259-65.

Rosenberg M, Pettifor A, Van Rie A, et al. "The relationship between alcohol outlets, HIV risk behavior, and HSV-2 infection among South African young women: A cross-sectional study." *PLoS One*. 2015;10(5):e0125510.

Safren SA, Mayer KH, Ou SS, et al. "Adherence to early antiretroviral therapy: Results from HPTN 052, a phase III, multinational randomized trial of ART to prevent HIV-1 sexual transmission in serodiscordant couples." *Journal of Acquired Immune Deficiency Syndromes*. 2015;69(2):234-40.