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## What's New in the HPTN?

### New Combination HIV Prevention Strategy Study

HPTN's newest study, PopART, (HPTN 071), will examine the impact of a combination prevention strategy, including early antiretroviral therapy (ART), on population level HIV incidence in Zambia and South Africa. Partners for this study include the London School of Hygiene and Tropical Medicine, Imperial College, London, the Zambia AIDS Related Tuberculosis Project (ZAMBART), and the Desmond Tutu TB Centre (DTTC).

HPTN 071 is a natural extension of HPTN's robust HIV prevention research and will build upon the network's groundbreaking studies. The primary objective of HPTN 071 is to evaluate a prevention package utilizing a combination of interventions including voluntary testing, counseling and antiretroviral therapy (ART). The study is in line with the goals of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) which aims to "expand its emphasis on HIV prevention, and matching interventions and investments with epidemiological trends and needs in order to improve impact."

Data from recent clinical trials have been helpful in determining the impact of HIV prevention strategies at the individual level (e.g., use of antiretroviral drugs (ARVs) for prevention of infection in men and women, use of topical ARVs for prevention of HIV infection in women, male circumcision). Earlier this year two large scale HPTN studies showed impressive results which have helped to propel HIV prevention research. Project Accept (HPTN 043) was a randomized study that found that adding community mobilization and support services to a mobile HIV counseling and testing program can improve rates of testing in rural communities. HPTN 052 was the first randomized trial to show that treating an HIV-infected individual with ART can reduce the risk of sexual transmission of HIV to an uninfected partner. After evaluating the components of testing and treatment separately, HPTN 065 is designed to evaluate a combination of prevention strategies. Known as TLC-Plus (Test, Link to Care, Plus Treatment), this study will evaluate the impact of expanded HIV testing, linkage to care, viral suppression through adherence to ART, prevention for positives through risk-reduction counseling, and patient and provider surveys.

Starting in 2012, HPTN 071 will be carried out in 24 communities in Zambia and South Africa. Eight communities will receive the full PopART intervention, while eight communities will receive current standard of care. The remaining eight communities will receive an intermediate intervention

## Did You Miss the Annual Meeting?

In June, approximately 450 people from more than 10 countries attended the HPTN annual meeting in Washington, DC. Highlights included three plenary sessions, recognition of the HPTN 052 and HPTN 065 study teams for their achievements, and presentations by the HPTN scholars who contributed to the network's domestic research agenda over the past year. A heartfelt thank you goes out to everyone who made the meeting a successful one. And for those who weren't able to attend, many of the plenary presentations are still available online, including those from the joint HPTN/IMPAACT session. You can access the presentations [here](#).

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## Best Practices in Community Involvement: A Community Forum of the Six DAIDS-funded Networks

At the HPTN annual meeting a forum was held to highlight the successful implementation of the *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS Clinical Trials Research*. The "Recommendations"

which includes all the components of PopART but adheres to current ART national guidelines. A total of 60,000 adults will be followed for two years to measure the impact of these interventions on the rate of new HIV infections.

HPTN 071 will evaluate the impact of HIV prevention combinations at the population level. This study will provide important data on how best to combine interventions for HIV prevention in different populations and settings to optimize the reduction in HIV incidence. The study will also provide evidence as to which combinations of interventions, doses and levels of coverage are optimal for decreasing HIV transmission, including data on cost-effectiveness.

The HPTN is excited to add the 071 study to its scientific portfolio. It represents another important step in developing and implementing combination prevention strategies that demonstrate a significant and measurable reduction in HIV incidence in populations that bear a disproportionate burden of HIV infection.

The HPTN 071 study was selected after two sequential and systematic peer reviews of proposals. The solicitation, *Evaluation of the effectiveness of combination HIV prevention interventions for generalized HIV epidemics in countries receiving PEPFAR support*, was made available under Cooperative Agreement UM1 AI068619, funded by the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Mental Health, (NIMH). This specific award was underwritten by the Office of the United States Global AIDS Coordinator (OGAC) with substantial additional support from that National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation (BMGF).

### HPTN 058 Study Closes

The HPTN 058 HIV prevention study is being closed to new enrollment, and a phase-out of the study will be initiated. The study was designed to evaluate the efficacy of treatment for opiate dependence as an intervention to prevent HIV infection and death among injection drug users.

An independent Data Safety and Monitoring Board (DSMB) met on September 27, 2011 and determined there was insufficient evidence to adequately answer the primary objectives of the study. As a result, HPTN 058 ended enrollment of new participants. Because the DSMB identified no safety concerns, current participants will be gradually rolled off the study in an orderly and safe fashion.



Chief counselor meeting with HPTN 058 participant in Xinjiang, China

buprenorphine/naloxone and a behavioral intervention for opiate-dependent participants would achieve a long term reduction (that is, when evaluated at 104 Weeks after enrollment) in cumulative HIV incidence and death compared to Short-Term (~ 3 weeks) Medication-Assisted Treatment with buprenorphine/naloxone and the same behavioral intervention. Approximately

document describes the history, progress, problems, and innovative solutions of community involvement, and delineates specific roles and responsibilities of the key individuals who directly impact community involvement in the research process. Since there were no formal guidelines for community involvement among the many policies and procedures governing most aspect of clinical trials research, Community Partners felt recommendations were needed to help define and streamline the role of the community in the research process and to assist researchers as they seek community input and engagement.

## Making Progress

### HPTN 067 Begins Enrollment in Cape Town

Congratulations to the HPTN 067 study team for activating its site in Cape Town, South Africa. As of October 17, 23 participants have been enrolled. HPTN 067 is a Phase II study to determine the feasibility of intermittent dosing of Truvada as pre-exposure prophylaxis (PrEP) to prevent HIV in heterosexual women and in men who have sex with men. In the first part of the study, pill-taking will be directly observed to determine an objective measure of drug exposure for each participant. Participants will then be randomized to receive daily dosing, time-driven dosing, or event-driven dosing. They will also be called every week so that they can report their pill-taking and sexual behaviors. Results will help identify the optimal regimens for facilitating adherence and encouraging healthy sexual practices. This is the first HPTN study to use [Wisepill Technologies](#) to help determine when participants take their pills. A second study site is expected to open in Bangkok, Thailand, in early 2012.

### Enrollment Going Well for HPTN 068

Over the past seven months, the [HPTN 068](#) study site in Agincourt, South Africa, has reached more than 60% of its target enrollment. More than 1,780 young women ages

1,250 participants were enrolled at sites in Thailand and China. After analyzing the data currently available, the DSMB determined that the study would not be able to demonstrate a difference between the two treatment groups. However, the study will be able to address a number of important secondary objectives. Analysis of data from HPTN 058 will provide much needed new information on promising approaches for HIV prevention among injection drug users.

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## What's New in Prevention?

### Let's Talk about PrEP

It has been an interesting year on the HIV prevention front for pre-exposure prophylaxis, (PrEP). Several studies have shown great promise for PrEP in reducing the risks of HIV infection while others have not been able to demonstrate efficacy because of futility.

In September, the [Microbicides Trial Network \(MTN\)](#) announced that its HIV-prevention study, [VOICE](#), (Vaginal and Oral Interventions to Control the Epidemic), would be modified and the daily oral dose of Tenofovir disoproxil fumarate (TDF) in one arm would be discontinued. This decision followed an independent Data



Women in Africa attending an AIDS prevention counseling session. Photo Credit: S.J. Staniski

Safety and Monitoring Board (DSMB) review which determined that the trial would not be able to demonstrate that tenofovir tablets (TDF) used orally are effective in preventing HIV in the women enrolled in the trial. The arms of the study that are testing Truvada® and the vaginal gel form of tenofovir are continuing.

The VOICE study modification comes on the heels of two studies with promising PrEP results. In July, the TDF2 study sponsored by the United States Centers for Disease Control and Prevention (CDC), provided evidence that HIV infection among heterosexuals can be prevented by taking a daily oral dose of Truvada®, a formulation that is a combination of tenofovir and emtricitabine (TDF/FTC). In TDF2, study participants in Botswana were given either a placebo or a daily, oral dose of Truvada. Using an intent-to-treat analysis the study found Truvada reduced HIV acquisition by 63%.

A second study, Partners PrEP, sponsored by the Bill and Melinda Gates Foundation, and conducted in Kenya and Uganda, was a three arm trial evaluating a daily oral dose of tenofovir (TDF), or a daily oral dose of Truvada® against a placebo. The study found that both regimens were effective in reducing HIV acquisition for men and women: 62% efficacy for tenofovir (TDF) and 73% efficacy for Truvada (TDF/FTC).

“Given the positive results from the Partners PrEP study that compared daily oral tenofovir to Truvada® in discordant couples and established safety and efficacy with both products, the rationale for the DSMB recommendation to stop the tenofovir arm of the VOICE study for futility awaits further analysis from this arm of the VOICE study,” says Quarraisha Abdool Karim, co-principal investigator of the HPTN, and lead author of the CAPRISA 004

13–20 years are enrolled so far in the large Phase III study, which will evaluate whether conditional cash transfers can reduce the young women's risk of being infected with HIV. Research has shown that not completing high school, which is common in many resource-poor settings, can increase a young woman's risk of acquiring HIV. Thus, in this study, cash will be transferred to the young women and their households only if the women continue to attend school regularly. However, because the study is a randomized controlled trial, only half of the enrolled women will be in the intervention group. The other half will be in a control group that will not be eligible for the cash transfers. The study is expected to last about four years.

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## Coming Soon

### HPTN Prevention Management Group Meeting

October 18–19, 2011  
Arlington, VA

### [12th International Union against Sexually Transmitted Infections \(IUSTI\) World Congress](#)

November 2–5, 2011  
New Delhi, India

### [World AIDS Day](#)

December 1, 2011

### [16th International Conference on AIDS and STIs in Africa \(ICASA\)](#)

December 4–8, 2011  
Addis Ababa, Ethiopia

### [2nd International Workshop on HIV & Women](#)

January 9–10, 2012  
Bethesda, MD

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## Topics For Discussion

### Time to Curb Our Enthusiasm?

An editorial in the September issue of [The Lancet Infectious Diseases](#) cautions that the enthusiasm building around the use of antiretroviral drugs for HIV prevention may need to be tempered. The drugs will likely offer only partial protection against HIV,

tenofovir microbicide trial. "We need to further analyze and compare data from completed trials with oral and topical formulations of anti-retrovirals to better understand why we have observed efficacy in some instances and not in others."

VOICE is the second PrEP study to be modified this year. In April, FEM-PrEP stopped its Phase III, randomized, placebo-controlled clinical trial of a daily oral dose of Truvada® for HIV prevention among women in sub-Saharan Africa, following the trial's Independent Data Monitoring Committee's determination that it would be unlikely to demonstrate Truvada's effectiveness in preventing HIV infection in the study population.

Dr. Sten Vermund, principal investigator of the HIV Prevention Trials Network, and Amos Christie Chair of Global Health at Vanderbilt University School of Medicine says, "In light of the Partners PrEP and CDC TDF2 HIV prevention studies which have shown strong evidence that PrEP can provide protection against HIV acquisition in women, it is disappointing that oral tenofovir did not reduce HIV infection in VOICE study participants. We need to be resolute in our scientific endeavors to understand these disparate results and look closely at the issue of adherence to prophylactic medications."

### HPTN 052 Highlighted at IAS Conference in Rome, Italy

HPTN 052 lead investigator Dr. Myron Cohen received a standing ovation at the [6th IAS Conference on HIV Pathogenesis, Treatment, and Prevention](#), after presenting expanded analyses of 052 data. The results were simultaneously published in the July 18, 2011 on-line edition of the New England Journal of Medicine: [Prevention of HIV-1 Infection with Early Antiretroviral Therapy](#). The print edition became available August 11, 2011. (Cohen, M. S., Y. Q. Chen, et al. "Prevention of HIV-1 infection with early antiretroviral therapy." N Engl J Med 2011; 365:493-505).



Dr. Myron Cohen, HPTN 052 Protocol Chair

represented at IAS with six oral presentations and three exhibit posters. A summary report of [HPTN at IAS](#) includes links to oral presentations at the conference, 052 video press conference excerpts, as well as links to various documents highlighting HPTN's research.

The study found that in HIV serodiscordant couples, in which one person is infected with HIV and the other is not, providing early antiretroviral therapy to the HIV infected person reduced sexual transmission of HIV to the uninfected partner by 96%.

Along with the special symposium for 052, the HPTN was well

and their expanded use could increase drug resistance. A dilemma also remains about whether it is ethical to provide antiretroviral drugs to HIV-negative individuals when so many HIV-positive individuals still can't access the drugs for treatment. Do you think we're getting ahead of ourselves? Send your comments to [news@hptn.org](mailto:news@hptn.org) (including your name and affiliation), and we will print some of them in a future issue of the newsletter.

### Engaging Social Science in HIV Research

In September, the *Journal of the International AIDS Society* released a supplemental issue on balancing social and biomedical perspectives in HIV research. Although written primarily by social scientists, the articles in the issue cover concerns that are also widely recognized by biomedical and public health researchers, such as understanding how new medical technologies affect relationships and social networks. The fact that the HPTN already integrates social and behavioral perspectives into its biomedical research makes our voice an important one in this conversation. The supplemental issue of the journal, which is available free [online](#), includes comment boxes at the end of each article. Feel free to leave a comment and make sure our voice is heard!

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### Want to Read More?

HIV Prevention Trials Network  
<http://www.hptn.org/index.htm>

HPTN Annual Meeting Presentations  
[http://www.hptn.org/network\\_information/2011AnnualMtgPrsntns.htm](http://www.hptn.org/network_information/2011AnnualMtgPrsntns.htm)

HPTN at IAS  
[http://www.hptn.org/web%20documents/IAS/HPTN\\_IAS\\_report24Aug2011.pdf](http://www.hptn.org/web%20documents/IAS/HPTN_IAS_report24Aug2011.pdf)

HPTN 061  
[http://www.hptn.org/research\\_studies/](http://www.hptn.org/research_studies/)

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## In the Community

### New Community Working Group Co-Chair

Melissa Turner was appointed the new U.S. domestic HPTN CWG Co-Chair. Since 1992, Melissa has been the Social Worker Coordinator for National Programs in HIV Clinical Research at the Washington Veterans Affairs Medical Center, Research Service/Infectious Disease Section. She

has worked as a clinical social worker and community organizer in HIV care and service in Washington D.C. and worked as a member of the HIV clinical trial leadership teams providing administrative oversight and management of national and international clinical trial projects.

"We are delighted to have Melissa in this leadership role," says Janet Frohlich, Chair of the HPTN Community Working Group. "She has established working relationships with key stakeholders and brings a wealth of understanding to HIV prevention science as well as insight and experience in providing direct care to at-risk populations."

Melissa began working with the HPTN in 2007 and has been actively involved in HPTN 061, HPTN 064, and serves on the protocol team for HPTN 065. "I am excited to take on the challenges of this position," says Turner. "I am especially committed to identifying creative and effective solutions to bridge the divide that exists between HIV science and the community at-large."



Melissa Turner, MSW, MPA U.S. domestic HPTN CWG Co-Chair

### Deciding Moments Campaign

At the HPTN 2011 annual meeting in June, HPTN welcomed the [Black AIDS Institute](#) (BAI) as they hosted the [Greater than AIDS](#)/Deciding Moments Campaign. The campaign aims to increase knowledge and understanding about HIV/AIDS and confront the stigma surrounding the disease.



Members of the HPTN Executive Committee: Wafaa El-Sadr, Sten Vermund, Kathy Hinson

together, they can achieve a greater goal and collectively change the course of the epidemic.

Deciding moments are opportunities to take a stand against HIV and be "greater than" the disease. The campaign encourages people to be agents for change; to make a commitment to get tested, correct misinformation about HIV/AIDS, and keep up with medications. The central idea behind Greater than AIDS is that through the power of individuals acting



A series of [public service ads](#) was inspired by Greater than AIDS. It features true stories from people across the United States, including those living with HIV, who share their own deciding moments in the hope of inspiring others to join the effort to take a stand against HIV and help stop the spread of the disease.

[hptn061.asp](#)

HPTN 067

[http://www.hptn.org/research\\_studies/hptn067.asp](http://www.hptn.org/research_studies/hptn067.asp)

HPTN 068

[http://www.hptn.org/research\\_studies/hptn068.asp](http://www.hptn.org/research_studies/hptn068.asp)

HPTN 071

[http://www.hptn.org/research\\_studies/hptn071.asp](http://www.hptn.org/research_studies/hptn071.asp)

HIV/AIDS Network Coordination

<http://www.hanc.info/Pages/default.aspx>

## Hot Off the Press

Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, Hakim JG, Kumwenda J, Grinsztejn B, Pilotto JH, Godbole SV, Mehendale S, Chariyalertsak S, Santos BR, Mayer KH, Hoffman IF, Eshleman SH, Piwowar-Manning E, Wang L, Makhema J, Mills LA, de Bruyn G, Sanne I, Eron J, Gallant J, Havlir D, Swindells S, Ribaudo H, Elharrar V, Burns D, Taha TE, Nielsen-Saines K, Celentano D, Essex M, Fleming TR, HPTN Study Team. [Prevention of HIV-1 infection with early antiretroviral therapy](#). *N Engl J Med* 2011;365(6):493-505. PMID: 21767103.

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## A Closer Look

### Project SOS (Saving OurSelves)

It wasn't long after losing his childhood best friend to AIDS in 1991 that Benjamin Perkins decided to devote his life to HIV prevention work. "Back then there was so much stigma associated with the disease," says Perkins. "My friend never told me he was sick." Perkins is the SOS Project Director at the [Fenway Institute](#) in Boston, Massachusetts, one of six study sites for the [HPTN 061](#) BROTHERS study (Broadening the Reach of Testing, Health Education, Resources and Services for Black Men Who Have Sex with Men). The other sites include, Atlanta, GA, New York, NY, Los Angeles, CA, San Francisco, CA and Washington, DC.

Even though Black men who have sex with men (Black MSM) make up less than half of one percent of the U.S. population, CDC data show that in 2009 they accounted for more than 20% of new HIV infections. "These rates of infection are astounding," says Perkins. "A lot of attention has been paid internationally to high levels of HIV in areas like sub-Saharan Africa, but this allows us to take a closer look at the problem in our own backyard."



Project SOS Team: (front row left to right) Fred Mazyck, Kenneth Mayer, and Blake Rowley, (second row) Benjamin Perkins, Greg-Eugene Sullivan, and Kelvin Powell, (back row) William H. Alexander, Alton Crocker

HPTN 061 hopes to gain a better understanding of Black MSM and their lives, risks, attitudes and how the men might be affected by their religious experiences, or perceptions of racism and experience of homophobia, or sexual abuse while a child.

The [Project SOS](#) study is designed to evaluate new approaches to reduce HIV risk in Black MSM through a multi-pronged approach:

- Asking participants to describe their sexual and social networks
- Providing Black MSM with a peer counselor, someone who is specially trained to help Black MSM get the healthcare services and treatment they need in the community
- Providing culturally sensitive testing and counseling for HIV
- Providing testing, counseling and treatment for Sexually Transmitted Infections (STIs)
- Encouraging Black MSM to refer their sexual partners to participate in the study

Perkins believes HIV prevention work is about social justice, equal access to care and treating people with dignity and respect. He says Project SOS is a great example of the importance of community buy-in and assembling a strong study team. He jokingly refers to his team as the "SOS

[Project Accept \(HPTN043\)](#). *AIDS Behav* 2011; Aug 6. [Epub ahead of print]

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[Nelfinavir and lamivudine pharmacokinetics during the first two weeks of life](#). *Pediatr Infect Dis J* 2011;30(9):769–772.

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Mayer KH. [Antiretrovirals for HIV prevention: translating promise into praxis](#). *Lancet* 2011;378(9787):206–208.

Abdool Karim SS, Kashuba AD, Werner L, Abdool Karim Q. [Drug concentrations after topical and oral antiretroviral pre-exposure prophylaxis: implications for HIV prevention in women](#). *Lancet* 2011;378(9787):279–281.

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Padian NS, McCoy SI, Abdool Karim SS, Hasen N, Kim J, Bartos M, Katabira E, Bertozzi SM, Schwartländer B, Cohen MS. [HIV prevention transformed: the new prevention research agenda](#). *Lancet* 2011;378(9787):269–278.

## Contact Us



Band". "This is an amazing group of guys who are passionate about the community and really believe in this work. I am extremely proud of all of them."

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