



Prevention Now!

HIV PREVENTION TRIALS NETWORK

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What's New in the HPTN?

HPTN Scholars Program Launches

As part of the 2010 HPTN Scholars Program, six young African-American professionals have been awarded funding for participation in HPTN's domestic research agenda. The new program, which is supported through a training supplement from the National Institute of Allergy and Infectious Diseases, officially launched on June 1, 2010.

"We are most gratified that so many strong candidates applied from a variety of universities and organizations across the nation," says Dr. Sten Vermund, principal investigator for the HPTN and one of three members of the selection committee. "This is a credit to our executive committee, our Black Caucus, and our site investigators for getting the word out and for conveying the sense of excitement we have about our targeted studies," he says.

For one year, each awardee will work alongside a mentor (or mentors) from HPTN 061 or HPTN 064. Also known as the BROTHERS study, HPTN 061 is evaluating prevention strategies for lowering HIV infections among African-American men in the United States who have sex with men. HPTN 064 is estimating the incidence of HIV among U.S. women who live in distinct geographic areas with high rates of HIV infection and poverty.

The scholars program was designed to support the early career development of research investigators from under-represented racial or ethnic communities. Dr. Darrell Wheeler leads the program and chaired this year's selection committee. The six new scholars will be attending the HPTN annual meeting in Washington, DC.

Meet Our Scholars

| Awardee | Primary Mentor | Trial |
|---|---------------------------|----------|
| Dr. Russell Brewer AED | Dr. Alan Greenberg GWU | HPTN 061 |
| Dr. Yvonne Carter East Carolina University | Dr. Adaora Adimora UNC | HPTN 064 |
| Dr. Risha Irvin | Dr. Susan Buchbinder | HPTN 061 |

Making Progress

HPTN 052 Completes Enrollment!

Congratulations to the [HPTN 052](#) study team for completing enrollment of 1,750 serodiscordant couples from study sites in Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, and Zimbabwe. The Phase III trial, which began in 2005, is comparing antiretroviral therapy plus HIV primary care versus HIV primary care alone for preventing sexual transmission of HIV. Follow-up will continue for five years.

Nearly Half of Participants Enrolled for HPTN 058

Enrollment is progressing for [HPTN 058](#)—a Phase III trial of two strategies for preventing HIV and death among opiate-dependent injectors in China and Thailand. So far, 694 of approximately 1,500 expected participants have been enrolled in the two countries. We are happy to announce that in mid April, a fourth study site opened to accrual (in Nanning, China). This should help accelerate the rate of enrollment.


HPTN 062 Opens for Enrollment in Malawi

Thanks to a strong collaboration between Family Health International and the University of North Carolina (UNC), [HPTN 062](#) opened to enrollment in early April. Four participants have already been enrolled at the Tidzewe Center, which is the home of the UNC Project in Lilongwe, Malawi. The study will evaluate the feasibility and acceptability of an enhanced counseling program for individuals who have recently been infected with HIV. It will also determine whether the program helps participants change the behaviors that put them and their partners at risk for sexually

| UCSF | UCSF | |
|---|---|----------|
| Dr. LaRon Nelson University of Toronto | Dr. Kenneth Mayer The Fenway Institute Boston | HPTN 061 |
| Dr. Typhanye Penniman Johns Hopkins University | Dr. Steve Shoptaw UCLA | HPTN 061 |
| Dr. Zandraetta Tims-Cook Emory University | Dr. Carlos del Rio Ponce de Leon Center Atlanta | HPTN 064 |

Abbreviations: AED = Academy for Educational Development; GWU = George Washington University; UCSF = University of California, San Francisco; UCLA = University of California, Los Angeles; UNC = University of North Carolina, Chapel Hill.

New Communications Handbook Incorporates HPTN's Work

 image of Handbook

Various HPTN site teams made important contributions to the [Communications Handbook for Clinical Trials](#), which was launched in May at the M2010 conference. This new handbook provides practical guidance to trial sites and research partners on how to anticipate and respond to the special communications challenges posed by the conduct of clinical research. An HPTN case study and contributions from several HPTN trials are included. Thanks also to the HPTN members who helped develop and review the book.

In the Community

Community Working Group to Hold Forum

The [HPTN Community Working Group](#) (CWG) will hold a "Community and Science Forum" on June 10, 2010 (the last day of the HPTN annual meeting), at the Marriott Wardman Park hotel in Washington, DC.

Community representatives from study sites in Botswana, India, Malawi, South Africa, Thailand, Zambia, Zimbabwe, and the United States will be speaking about their experiences working with the HPTN.

"This forum will put the CWG at the forefront of the international partnership between communities and science," says Dr. Janet Fröhlich, the co-chair of the CWG. "We are looking forward to interactive dialogue and the opportunity to engage with our colleagues and stakeholders at the forum. The rich exchange of experiences related to community involvement in HIV prevention research will also help inform future HPTN trials."

The CWG is a committee of site representatives and community specialists that advises and advocates for community participation at all

transmitted infections.

HPTN 063 Opens for Enrollment in Thailand

We are happy to report that the [HPTN 063](#) site in Chiang Mai, Thailand, was activated in mid March and that 35 participants have already enrolled there. Protocol-specific training has also been completed at the site in Rio de Janeiro, Brazil, which is expected to open as soon as the Ministry of Health approves the trial. A third site is planned in Zambia, if government approval can be obtained there. HPTN 063 is an observational study that will inform the development of an intervention to reduce the behaviors that put HIV-positive men and women at risk of transmitting the virus to their sexual partners.

Enrollment Nearly Complete for HPTN 064

The dedicated efforts of the [HPTN 064](#) recruitment teams have paid off! More than 2,000 women have enrolled in the study—a huge step toward the target of 2,100 participants. The study is estimating the risk of HIV among U.S. women from 10 distinct geographic communities with high levels of HIV infection and poverty. Its findings should help determine whether future large-scale domestic trials can use HIV incidence as an endpoint for measuring the effectiveness of an HIV prevention intervention.

Hot Off the Press

HPTN's Expertise Highlighted in *Clinical Infectious Diseases*

The HPTN is well represented in a recent [supplemental issue](#) of the journal *Clinical Infectious Diseases*, which the Special Libraries Association considers one of the "100 most influential journals in biology and medicine" of the past 100 years. The special issue, which focuses on confronting the global HIV and tuberculosis epidemics, was published in May 2010. Congratulations to all the HPTN members who contributed articles to this supplement or to other journals over the past few months!

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levels of the research process. Panel discussions at the forum will focus on participant recruitment and retention, effective use of community advisory boards, and the challenges sites face when they are involved in multiple research networks.

The HIV/AIDS Network Coordination (HANC) Legacy Project, in partnership with Sisterlove, Inc., will also host an "Expert Consultation on Women and Research" immediately following the HPTN annual meeting. On June 11–12, 2010, experts and members of community advisory boards from six research networks (all funded through the National Institute of Allergy and Infectious Diseases) will discuss issues related to HIV research with women in the United States.

A Closer Look

HPTN 064: Innovative Strategies for Recruitment and Retention

As hard as a study team works to maintain uniform procedures and standards throughout an HIV prevention trial, unique site-specific challenges inevitably emerge. As the recruitment and community coordinator for the HPTN 064 sites in New York, Ms. Noranik Zadeyan has been faced with some of these challenges. In response, she and her team have developed several innovative strategies for improving participant recruitment and retention.

Also known as the Women's HIV Seroincidence Study (ISIS), HPTN 064 is estimating the incidence of HIV among U.S. women from 10 distinct geographic communities with higher levels of HIV infection and poverty than surrounding areas. More than 2,000 women are being enrolled from these high-risk "hot spots," including the Bronx and Harlem in New York, where Ms. Zadeyan helped establish recruitment procedures.



Ms. Zadeyan and her team have found that even small issues, like venue location and weather, can slow down recruitment. Larger issues, such as participant mobility, present challenges for both recruitment and retention.

"Many people no longer have landlines today, and mobile phones are easily lost or turned off," Ms. Zadeyan says. "Also, people who are at higher risk of contracting HIV are often more transient because of less social and economic stability." This can be a particular problem in studies like HPTN 064, which will include the women who are believed to be at the highest risk for acquiring HIV in their communities.

To compensate for these challenges, the recruitment team in the Bronx tried to recruit and enroll women on the same day. This effort included escorting the women from the recruitment venues to the study site for enrollment. In Harlem, recruitment dates and enrollment dates are not the same, but the team tries to schedule them as close together as possible (within three days of each other) to minimize the number of women who miss their enrollment appointments.

Monthly phone calls, text messaging, flyers, and postcards are just some of the strategies used to help participants remember to return for their follow-up appointments. The teams also conduct home visits if retention starts to be a problem.

"We always ask permission to visit participants at their home, as a last

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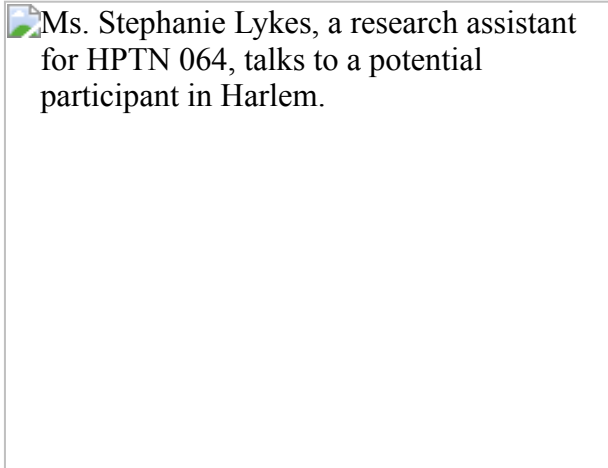
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resort, and this strategy has been very effective for eventually contacting otherwise unreachable participants," says Ms. Zadeyan.

The Bronx and Harlem sites have also taken steps to make sure participants feel welcome during study visits. For example, the same research assistants who recruit the women are involved in enrolling and retaining them. The study offices are located in the community, and participants are encouraged to drop by and say hello. To improve consistency between the sites, the outreach worker who helped recruit women in the Bronx is also helping recruit women in Harlem. This same worker conducts home visits in both communities to encourage participants to return for their follow-up appointments.



Ms. Stephanie Lykes, a research assistant for HPTN 064, talks to a potential participant in Harlem.

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Ms. Zadeyan knows that many of these strategies are in place thanks to the close communication between the recruitment teams at the two sites, who have shared information and learned from each other along the way.

"Although each community in each study is unique, sites should be encouraged and willing to share challenges and successes with other sites," Ms. Zadeyan says. "Communication is key."

The Bronx-Lebanon Hospital Center and Harlem Prevention Center, both affiliated with the International Center for AIDS Care and Treatment Programs (ICAP) at Columbia University, are the two official HPTN 064 sites in New York. Additional sites are located in Atlanta, GA; Decatur, GA; Durham, NC; Raleigh, NC; Washington, DC; Baltimore, MD; and Newark (North and South), NJ.

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Want to Read More?

HIV Prevention Trials Network
www.hptn.org/index.htm

HPTN Community Working Group
www.hptn.org/community_program/community_working_group.asp

HPTN 061
www.hptn.org/research_studies/hptn061.asp

HPTN 064
www.hptn.org/research_studies/hptn064.asp

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