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## What's New in the HPTN?

### HPTN Scientific Agenda

The HPTN is excited to continue its work in identifying interventions and strategies that will reduce HIV transmission in populations disproportionately impacted by the HIV epidemic. The HPTN recently received a seven year, multi-million dollar award from the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). Moving forward the award will allow the network to focus on its core research priorities—integrative strategies and pre-exposure prophylaxis (PrEP).

Integrative strategies will address: 1) strategies to find at-risk populations; 2) HIV testing and counseling, since knowledge of HIV status is the decision point for determining the tailored integrated package of interventions; 3) linkage to care and initiation of a package of biomedical, behavioral and/or structural interventions based on the particular population and situation; and 4) adherence and retention.

The HPTN scientific agenda will also include research on new PrEP agents. Currently, only the daily use of oral FTC/TDF (combination of emtricitabine and tenofovir disoproxil fumarate) that is FDA-approved for PrEP. Studies evaluating oral FTC/TDF for PrEP have consistently shown an association between adherence and efficacy. Planned HPTN studies will look at adherence challenges and evaluate alternative PrEP agents such as long-acting injectables.

As HIV prevention strategies continue to evolve, the HPTN

Scientific Committees (SCs) develop and guide the scientific agenda of the HPTN. The Men who have Sex with Men Scientific Committee (MSMSC), the Substance Use Scientific Committee (SUSC), the Adolescents at Risk (ASC) and the Women at Risk (WAR) committees are playing an important role in ensuring that the HPTN remains on the cutting edge of prevention strategies and interventions.



## Upcoming Events

### HPTN Annual Meeting

Mark your calendars! The HPTN annual meeting will be held June 13-20 at the Crystal Gateway Marriott Hotel in Crystal City, VA. Last year more than 500 people attended. Join HIV prevention researchers, advocates and collaborators from around the world to learn the latest about HPTN's exciting scientific agenda. Reservation and agenda information coming soon. Look for updates at [www.hptn.org](http://www.hptn.org).

### HPTN 061

HPTN 061 will continue its webinar series in April. Researchers will highlight results from the study and recently published work from the study team including HPTN scholars. The study showed that the overall rate of new HIV infection among Black MSM in the study was nearly 50 percent higher than in white MSM in the U.S. Young black men—those 30 years of age or younger—acquired HIV infection at a rate of 5.9 percent a year, three times the rate among U.S. white MSM.

The webinar series started January 8, 2014 with a report on what has been learned from the study since initial results were released in 2012. A recording of the webinar, as well as PowerPoint presentation slides, can be found at [hptn.org](http://hptn.org).

### Strategic Working Group Meeting

HPTN leadership presented at the Strategic Working Group Meeting (SWG) held January 28th and 29th in Washington DC. The SWG provides advice on the scientific priorities of the

Under the leadership of Kenneth Mayer, MD and Darrell Wheeler, PhD, the MSMSC is working on additional data analyses from HPTN 061 and 063, designing studies in the U.S. that focus on how to best engage black MSM and determine PrEP uptake for prevention in this population, and developing strategies for prevention strategies for MSM in sub-Saharan Africa.

"HPTN studies are unique because they are premised on an understanding that HIV prevention for MSM does not involve a single strategy," said Mayer. "Rather, it involves a careful assessment of the appropriate package of potential interventions that may be relevant for different subgroups of MSM at different stages of their lives."

The SUSC, led by Steffanie Strathdee, PhD, and Steve Shoptaw, PhD, is collaborating with other SCs and also providing expertise in protocols in development such as HPTN 074. The SUSC and MSMSC are also collaborating to develop an HIV prevention project that will address the key problem of substance misuse among U.S. MSM and the transmission of HIV. In addition, the SUSC is working with the Ethics Working Group (EWG) on a manuscript to provide guidelines for assessing the minimum acceptable package of interventions that should be in place prior to site selection for future HPTN trials.

Populations at highest risk for HIV include adolescent females in sub-Saharan Africa and adolescent MSM in the U.S. The Adolescents at Risk Committee, led by Audrey Pettifor, PhD and Frances Cowan, PhD, was established to develop interventions that can protect these most at risk groups during their most vulnerable periods. The committee is currently working with the Integrated Strategies SC in developing a comprehensive concept that uses multiple strategies to support HIV negative young women in sub-Saharan Africa. The proposed concept is expected to have multiple phases from vanguard/formative work through a Phase III trial.

The WAR committee chaired by Adaora Adimora, MD and Elizabeth Bukusi, MBChB, MMed, MPH, PhD collaborated with HPTN's 069 protocol team to include women in that trial and proposed a vanguard concept that uses qualitative research to examine the barriers and facilitators to PrEP adherence among women participants. WAR is also working to develop research collaborations with pharmaceutical companies that will advance HIV prevention research for women and is working with epidemiologists and biostatisticians on development of research design strategies that will facilitate evaluation of interventions to prevent HIV infection among women.

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## Network Leadership

HPTN is led by Principal Investigators Wafaa El-Sadr, MD and Myron Cohen, MD. David Serwadda, MD serves as the International Lead Investigator. Other members of the Executive Committee include:

**Nirupama Sista, MSc, PhD** leads the development and implementation of all ongoing HPTN research studies as the Project Director for HPTN. She also focuses on strategic partnerships with funding agencies and collaborative partners. Dr. Sista is a senior research scientist at FHI 360 with more than 20 years of experience in the academic, pharmaceutical and non-profit sectors. Before joining FHI 360 Dr. Sista was a Senior Clinical Research Scientist for Triangle Pharmaceuticals, now Gilead Sciences, where she served as a Medical Team Leader for a novel ARV molecule. She earned her PhD in microbiology from the University of Tennessee, with post-doctoral training at the University of North Carolina at Chapel Hill.

**Susan H. Eshleman, MD, PhD** serves as the Principal Investigator of

NIAID-funded HIV/AIDS Clinical Trials Networks. Specifically, the SWG provides guidance on scientific priorities for future high resource trials, input regarding budget allocation for future funding of the networks and sites, and facilitates communication among all stakeholders relevant to the NIAID-sponsored HIV/AIDS Clinical Trials Networks. The SWG meets two to three times a year, and members include the network principal investigators, NIAID-appointed external advisors, representatives from the Community Partners, and the director of DAIDS.

A video cast of day one of the meeting is available [here](#).

## HIV R4P Conference

HIV Research for Prevention will host its inaugural scientific conference dedicated exclusively to biomedical HIV prevention research October 28-31, 2014 in Cape Town, South Africa. Organizers say the conference will support cross-fertilization between research on HIV vaccines, microbicides, PrEP, treatment as prevention and other biomedical prevention approaches. The abstract submission deadline is May 2. For more information visit [hivr4p](#).

## DAIDS Learning Portal

DAIDS has launched a new website. The [DAIDS Learning Portal](#) (<https://www.daidslearningportal.com/>) will offer two web training sessions through April 2014. The sessions include, Discovering the DAIDS Learning Portal, and Exploring the DAIDS Social Learning Community. Sign up for a session [here](#).

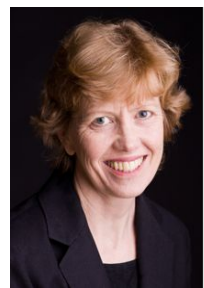
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## Study Updates

### HPTN 052 Study Featured in The Lancet

The latest data from HPTN 052 is featured in [The Lancet Infectious Diseases](#). HIV-serodiscordant couples were randomly allocated to either early initiation of highly active antiretroviral treatment (HAART) (i.e., at a CD4 count of 350–550 cells per  $\mu$ L) or delayed antiretroviral treatment (i.e., starting treatment when their CD4 count fell below 250 cells per  $\mu$ L). Fewer individuals who were assigned to early HAART had primary clinical events,

the Laboratory Center (LC) and oversees all lab activities for HPTN trials. She is a Professor of Pathology at the Johns Hopkins University School of Medicine and has directed the HPTN LC Virology Core since 1999. Dr. Eshleman plays an active role in protocol development and has served as a study team member on many HPTN protocols. Dr. Eshleman is board-certified in Clinical Pathology. She directs JHU HIV Genotyping Lab and JHU HIV Specialty Lab, and is the Associate Director of the Blood Bank at Johns Hopkins Hospital. Her LC group has developed novel laboratory methods relevant to HIV prevention trials, including novel methods for HIV incidence determination.



**Deborah Donnell, PhD**, serves as Principal Investigator of the Statistical and Data Management Center (SDMC) for the HPTN. Dr. Donnell has extensive experience in the design and analysis of clinical trials for HIV prevention, providing statistical leadership for studies of prevention of mother to child transmission, prevention in injection drug user populations, and U.S. based prevention and epidemiology, including behavioral prevention in MSM and PrEP approaches to HIV prevention. Dr. Donnell is a Principal Staff Scientist in the Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center and an affiliate associate professor, Department of Global Health, University of Washington. Dr. Donnell has been lead protocol statistician on six Phase III HIV prevention trials, both domestic and international, including the Partners PrEP trial that supported FDA approval of TDF/FTC.



**Kathy Hinson, BS** serves as HPTN Associate Director for Finance and Administration and is responsible for the financial management of the HPTN LOC agreement, for establishing and monitoring contractual agreements for protocol implementation funds, and for the financial management of sub-agreements. Ms. Hinson provides programmatic, managerial and administrative guidance for the HPTN and serves a critical role in the governance of the Network.

## HPTN at CROI

The HPTN had four accepted abstracts at the 2014 Conference on Retroviruses and Opportunistic Infections (CROI).



1.) HPTN 066 results were presented regarding the directly observed dosing of tenofovir (TFV) disoproxil fumarate (TDF)/emtricitabine (FTC). In this study 39 healthy, HIV-negative men and women were randomized 1:1:1:1 to 4 oral TDF 300 mg/FTC 200mg regimens: 1 tab daily, 2 tabs twice weekly, 1 tab twice weekly, or 1 tab weekly, each for 5 weeks with all doses observed. Steady-state plasma TFV concentrations from daily dosing were consistent with concentrations reported in the Partners, TDF2 and Thai IDU PrEP studies (high levels of HIV protection); higher than in iPrEX (moderate protection), and far higher than in FEM-PrEP and VOICE (no protection). Oral pre-exposure prophylaxis trials have yielded varying efficacy results attributed largely to

new-onset AIDS events, and tuberculosis. In an editorial which accompanied the findings, *The Lancet* noted, "These data show a clear benefit to patients of starting HAART early, when the CD4 count is well above 400 cells per  $\mu\text{L}$ . The debate about the value of early HAART initiation should now be viewed as settled from both patients' and public health perspectives."

## HPTN 067

The Harlem site expects to complete enrollment in April. HPTN 067/ADAPT 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 and transgender women. In the first part of the study, pill-taking is directly observed to determine an objective measure of drug exposure for each participant. Participants are then randomized to receive daily dosing, time-driven dosing, or event-driven dosing. They are also 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.

## HPTN 073

A total of 79 participants (35%) have been enrolled in the study to date. UNC has enrolled 22, UCLA 31 and GWU 26 participants. HPTN 073 is a demonstration project designed to determine acceptability of PrEP in Black men who have sex with men (BMSM). Although 28% of all new HIV infections in the U.S. occur in BMSM, they have been underrepresented in HIV research trials. HPTN 073 aims to find out how consistently BMSM are able to take one tablet at approximately the same time during each day of the week, and what that experience is like for them.

## HPTN 074 (under development)

HPTN 074 will determine the feasibility of a future trial that will assess whether an integrated intervention combining facilitated antiretroviral therapy (ART) at any CD4 cell count, substance use treatment, and behavioral counseling for HIV-infected people who inject drugs



variable adherence. HPTN 066 data can be used to benchmark adherence estimates in oral TFV PrEP trials, and assist in interpreting clinical outcomes.

2.) The Laboratory Center and HPTN 061 findings were presented regarding the antiretroviral (ARV) drug resistance among HIV-infected Black Men Who have Sex with Men (MSM) in the U.S. Understanding the current prevalence and patterns of ARV drug resistance in this population, which is disproportionately impacted by HIV, is important since ARV drug resistance can lead to treatment failure and limit treatment options. The study found that ARV drug resistance, including multi-class and transmitted drug resistance, is common among Black MSM in the U.S. In three of the six cities studied, >40% of the men had resistance. Overall, 11.3% of the men had multi-class resistance. Furthermore, 25% of the newly-infected men (acute infection, recent infection, seroconverters) had resistance, which most likely reflects transmission of resistant HIV strains. These findings underscore the public health importance and urgency of scaling up culturally appropriate and acceptable programs to engage Black MSM in care and promote adherence to ARV treatment.

Two additional lab related abstracts were also presented at CROI:

3.) The Impact of HIV Subtype on Specificity of Cross-Sectional HIV Incidence Assays in Rakai, Uganda

4.) Incorrect Identification of Recent HIV Infection Using a Limited Antigen (Lag)-Avidity Assay in Adults in the U.S.

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## In the Community



and



### HPTN's Community Engagement Partnership with Black AIDS Institute Inc.

In 2013, HPTN entered into a community engagement partnership with Black AIDS Institute, Inc. (BAI). As part of the collaboration, the HPTN agreed to provide research education support for BAI's Brown Bag Leaders program, which aims to improve national HIV prevention services, care engagement and treatment adherence through information sharing, networking, and mobilization of local community members. To achieve these aims, BAI recruited a cohort of leaders from 20 cities across the U.S. that included individuals working in the public health field, front line HIV service providers and people living with HIV/AIDS.

Leaders participated in a series of train-the-trainer webinars that provided them with the resources to conduct a series of "Brown Bag Lunch" events in their communities. BAI provided technical assistance, including study fact sheets and other materials from the HPTN, as well as other networks and agencies. Researchers affiliated with the HPTN, and the HPTN core staff members and site representatives, provided presentations for four Brown Bag Leaders webinars in 2013. HPTN 061 Protocol Co-Chair Ken Mayer, MD delivered a presentation on the integration of biomedical and behavioral interventions, HPTN Senior Community Engagement Officer Georgette King spoke about confronting barriers to Black leadership in HIV/AIDS education and advocacy, HPTN 073 Black Caucus Chair Christopher Chauncey Watson provided information about various aspects

(PWID) will reduce HIV transmission to HIV-uninfected injection partners, as compared to routine care dictated by World Health Organization (WHO) and/or national guidelines for HIV-infected PWID. Sites are currently being selected.

### HPTN 075 (under development)

HPTN 075 is an observational cohort study that will determine the feasibility of recruiting and retaining roughly 400 men who have sex with men (MSM) at four sites in sub-Saharan Africa in a preparation for future HPTN studies in the region. Although HIV infection status is not a factor in inclusion and exclusion criteria, a total of 20 HIV-infected individuals will be allowed to enroll at each of the four sites.

### HPTN 076 (under development)

HPTN 076 will evaluate the safety and acceptability of a long acting injectable pre-exposure prophylaxis (PrEP) agent among approximately 132 healthy, HIV-uninfected women. The study will have two sites in the United States (Newark, New Jersey and Bronx, New York) along with sites in Cape Town, South Africa and Harare, Zimbabwe. Sites are expected to begin enrollment in early 2014.

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## FHI 360 has moved

A reminder that the HPTN Leadership and Operations Center (LOC), FHI 360, moved to a new location. Our new office is located at 359 Blackwell Street, Suite 200 Durham, NC 27701.

Email addresses and telephone numbers of LOC staff remain the same.

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## Coming Soon

### National Native HIV/AIDS Awareness Day

**Thursday, March 20**

of HIV prevention research, and HPTN Principal Investigator Dr. Wafaa El-Sadr led a national webinar focusing on HPTN's combination care engagement and viral suppression research.

As 2013 came to a close, HPTN's community engagement partnership with BAI expanded to provide members of a second BAI group with research updates. BAI coordinates the Black Treatment Advocates Network (BTAN) chapters in 16 cities across the U.S. BTAN seeks to increase patient access and utilization of treatment and care to strengthen local leadership and to advocate for policy change in Black communities. Through this expanded partnership, HPTN core staff provided research updates at a series of onsite workshops for experienced BTAN chapters, as well as during a BTAN webinar that provided an initial introduction to PrEP and treatment as prevention for new BTAN chapter volunteers.

In 2014, the HPTN is excited to continue these partnerships to commemorate National Black HIV/AIDS Awareness Day and to launch a new series of Brown Bag Leaders webinars. These education opportunities will once again provide community members with a greater understanding of the research that can shape life changing HIV prevention and treatment efforts in their communities.

For more information about the Black AIDS Institute, Inc.'s programs visit [www.blackaids.org](http://www.blackaids.org) and follow BAI on [Facebook/blackaids](https://www.facebook.com/blackaids) and [Twitter/@blackaids\\_org](https://twitter.com/blackaids_org). Remember that HPTN is @HIVptn on [Facebook](https://www.facebook.com/blackaids) and [Twitter](https://twitter.com/blackaids_org).

## A Closer Look

### NAESM Award



The HPTN extends its congratulations to Jonathan Paul Lucas, MPH who was honored at the 2014 National African American MSM Leadership Conference on HIV/AIDS and Other Health Disparities in Orlando, Florida. Mr. Lucas received the Gerald A. Ludd Lifetime Achievement Award which is given to emerging leaders annually by the National AIDS Education and Services for Minorities (NAESM). The Ludd Award honors an individual for his/her outstanding community service, dedication and contributions to remove HIV/AIDS and other health disparities from

African American Men Who have Sex with Men (MSM) communities. Mr. Lucas is a Senior Community Programs Associate at FHI 360, the Leadership and Operations Center for HPTN.

"Jonathan is a very deserving recipient of this honor," said Melissa Turner, MSW, LICSW, HPTN U.S. Community Working Group Chair. "He is an outstanding leader in the field of HIV research and community advocacy. He is a strong ambassador for community engagement in clinical trial processes and for bridging community members with researchers for meaningful science collaboration."

To be eligible for the Ludd Award, a nominee must have at least seven years of work and/or volunteer contributions in HIV/AIDS prevention or other health disparities, targeting the African American MSM community. Candidates also must have provided significant efforts in HIV prevention and/or other health disparities or show exceptional leadership.

"Jonathan was recognized for his endless energy, dedication, commitment and hard work," said Kathy Hinson, HPTN Associate Director for Finance



**HIV R4P Conference**  
**October 28-31, 2014**

**Cape Town International Conference**  
**Centre, South Africa**



## Hot Off the Press

### HPTN 061

Magnus M, Franks J, Griffith S, Arnold MP, Goodman K, Wheeler DP; for the HPTN 061 Study Group. [Engaging, Recruiting, and Retaining Black Men Who Have Sex With Men in Research Studies: Don't Underestimate the Importance of Staffing-Lessons Learned From HPTN 061, the BROTHERS Study.](#) Journal of Public Health Management and Practice, 9 Jan 2014.

Mayer KH, Wang L, Koblin B, Mannheimer S, Magnus M, et al. (2014) [Concomitant Socio-economic, Behavioral, and Biological Factors Associated with the Disproportionate HIV Infection Burden among Black Men Who Have Sex with Men in 6 U.S. Cities.](#) PLoS ONE 9(1): e87298. doi:10.1371/journal.pone.0087298

### HPTN 071

Hayes R, Ayles H, Beyers N, Sabapathy K, Floyd S, Shanaube K, Bock P, Griffith S, Moore A, Watson-Jones D, Fraser C, Vermund S, Fidler S. [HPTN 071 \(PopART\): Rationale and design of a cluster-randomised trial of the population](#)

and Administration. "We congratulate Jonathan for his many contributions to the HIV/AIDS prevention field and for helping communities worldwide."

Mr. Lucas works with the HPTN and the Microbicides Trials Network. His public education experience in the community health arena spans almost two decades. His focus has primarily involved non-traditional HIV/AIDS programs and community based organizations which provide services and support to populations deemed vulnerable and hard to reach.

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## Contact Us

We would love to hear your comments on the newsletter, answer any questions you have about its content, or consider your ideas for future articles. Please contact us at [news@hptn.org](mailto:news@hptn.org).

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[impact of an HIV combination prevention intervention including universal testing and treatment - a study protocol for a cluster randomised trial.](#) *Trials* 2014, 13 Feb 2014.

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