



Network News • May 2013 • Issue No. 11

What's New in the HPTN?

HPTN: A Look Back and the Way Forward

At this juncture in the history of the HIV Prevention Trials Network (HPTN), we look back with pride on our many accomplishments. Since the Network's inception in 1993, we continue to evolve, as prevention science has evolved, but remain steadfast in our resolve to discover and develop new and innovative interventions and strategies to reduce the acquisition and transmission of HIV. This mission is evident in our completed, ongoing and proposed research agenda.



HPTN staff

A watershed moment for HPTN's research success was realized in 2011 when the HPTN 052 study showed that providing early antiretroviral therapy (ART) among serodiscordant couples reduced sexual transmission of HIV by 96 percent. HPTN 052 was named *Science* magazine's breakthrough of the year and was recognized as a "game changer" for HIV prevention. More recently, HPTN 043, another landmark study, demonstrated that community-based HIV testing was associated with an increase in testing rates and in detection of HIV infected individuals. (Full article on HPTN 043 on page 2.)

The success of these studies paved the way for expanding HPTN's portfolio to include the use of testing for and treatment of HIV infection as part of a comprehensive combination HIV prevention strategy. HPTN 071 (PopART) is evaluating the impact of an integrated strategy on HIV incidence at a community level in Zambia and South Africa. The experimental intervention package will include universal HIV counseling and testing through house-to-house testing and early initiation of ART for all those testing HIV positive combined with other interventions for linkage from HIV testing to HIV care and referral for male circumcision for HIV negative men. This ambitious study will provide rigorous evidence through a community-randomized clinical trial as to whether this strategy is effective for decreasing HIV transmission, and will also evaluate its cost-effectiveness.

HPTN JAIDS Supplement

The HPTN is excited to announce that it is sponsoring a special supplement to *Journal of Acquired Immune Deficiency Syndromes* (JAIDS) to be published in conjunction with the IAS 2013 Conference. The supplement titled, *State of the ART HIV Prevention*, will feature 24 manuscripts devoted to diverse aspects of HIV prevention with a critical analysis of science breakthroughs, promises and challenges. The supplement will be available online at www.jaids.org and www.hptn.org beginning June 25, 2013. The supplement is funded by NIAID and Office of Global AIDS Coordinator.

HPTN at IAS 2013

The HPTN is also proud to announce that four of its abstracts have been accepted at IAS 2013. HPTN scholars are well represented with three abstracts.

- *A Qualitative Analysis of HIV Testing Patterns among Black Men who have Sex with Men in Atlanta, Georgia, USA (HPTN 061)*
- *Prevalence and HIV Risk-Related Correlates of Emotional, Physical and Sexual Violence among Women at Risk for HIV in the United States: Data from HPTN 064 (The Women's HIV Seroincidence Study)*
- *Venues for Meeting Sex Partners*

Building on the concept of “test and treat”, the HPTN is planning a vanguard study (HPTN 074) to determine the feasibility of recruitment and retention of antiretroviral therapy in injection drug users in Asia with the ultimate goal of evaluation of treatment as prevention in this population.

The HPTN is also committed to the U.S. epidemic. In an ongoing study, HPTN 065 (TLC-Plus) is evaluating the feasibility of test, link to care, plus treat strategy in two U.S. communities, the Bronx, New York and Washington, DC. This study will provide invaluable information regarding the feasibility and effectiveness of specific interventions that may be utilized in future studies, including financial incentives for linkage to care and viral suppression that are being evaluated through a site-randomized clinical trial design. The area of behavioral economics is also receiving further attention in HPTN 068, an ongoing study in South Africa that is evaluating the efficacy of financial incentives for girls to stay in school to determine if it will reduce HIV acquisition in school-going girls.

Two other recently completed HPTN studies focused on the U.S. epidemic. HPTN 064 (ISIS) showed that the HIV incidence rate for U.S. women at risk living in communities defined by high HIV prevalence and high poverty rates was higher than the national overall estimated incidence rate in the U.S. for black adolescent and adult women. HPTN 061, a study conducted among at risk black men who have sex with men (MSM), revealed alarmingly high rates of HIV infection among young black gay and bisexual men, underscoring the urgent need to find efficacious interventions to reduce HIV acquisition in this population which bears a disproportionate burden of HIV infection.

MSM in sub-Saharan Africa also have alarming rates of HIV prevalence and endure high level of stigma, discrimination and criminalization. The HPTN is planning a vanguard study, HPTN 075, to determine the feasibility of recruitment and retention of African MSM in preparation for a future trial that will aim to evaluate the feasibility and efficacy of an integrated prevention study in this population. One such potential intervention is pre-exposure prophylaxis (PrEP). Alternative regimens and drugs are being evaluated for PrEP. HPTN 067 (ADAPT) seeks to determine the feasibility of intermittent dosing of Truvada® as PrEP to prevent HIV in heterosexual women and in men who have sex with men and transgender women.



HPTN 069, another PrEP study, is assessing the safety and acceptability of four different drug combinations including maraviroc and Truvada when used by MSM and women. Furthermore, HPTN 073 is evaluating the feasibility and acceptability of Truvada® when used for PrEP specifically among black MSM in the U.S. (Full article on HPTN 073 on page 6.) Another study under development, HPTN 076, will evaluate the safety of an injectable PrEP agent, TMC 278 LA in women in the U.S. and globally.

In the past several years, substantial advances have been achieved in prevention research. The HPTN is proud to have contributed to this body of work. This success would not have been possible without the many dedicated investigators, staff members, community groups and other collaborators over the years.

Former Secretary of State Hillary Clinton said, “As we continue to drive down the number of new infections and drive up the number of people on treatment, we will get ahead of the pandemic and an AIDS-free generation will be in sight.” The HPTN aims to continue to work diligently towards realizing this goal.

and Partner HIV Risk Characteristics: HIV Prevention Trials Network (HPTN 064) Women’s HIV Seroprevalence Study (ISIS)

- *Positive Social Impacts Related to Participation in a Multinational HIV Prevention Trial Involving Medication Assisted Treatment of People Who Inject Drugs (HPTN 058)*

HPTN Launches New Website

The HPTN is very excited about the launch of our new website. We hope you will visit us at www.hptn.org to see all of our new features. We now have an interactive map showing all of our study site locations and we have a new multimedia section where all of our presentations, webinars, videos and podcasts will be posted.

Prevention Now! Facebook Photo Share

In an effort to spread the word about the importance of HPTN’s HIV prevention research and to encourage others to become aware of the importance of ongoing research, we invited our partners and collaborators to post photos on the HPTN Facebook page at www.facebook.com/HIVpntn. Be part of our social media engagement and check out our Facebook Photo Share album.

Recognitions

Dr. Wafaa El-Sadr

HPTN Principal Investigator, Dr. Wafaa El-Sadr was named by the Huffington Post as one of the top 50 women who shaped America’s health. In honor of Women’s History Month, the Huffington Post wanted to honor the many health innovations pioneered by women in the sciences who have had the greatest impact in medicine and health research. In selecting Dr. El-Sadr the Post noted her career which has been spent focusing on underserved populations—from the inner city to sub-Saharan Africa—that require greater attention when it comes to preventing infectious disease.

After 20 years developing family-

HPTN 043 Study Results Released



Project Accept

(CROI).

NIMH Project Accept (HPTN 043) study results demonstrated that community efforts can increase HIV testing, reduce infection and detect previously undiagnosed HIV infections, especially among men and young people with HIV who might otherwise transmit the virus to others. The study results were presented at the 20th Conference on Retroviruses and Opportunistic Infections

NIMH Project Accept (HPTN 043) is the first community-randomized trial to test a combination of social, behavioral and structural interventions for HIV prevention and to assess the impact of an integrated strategy at the community level. The four major interventions were designed to: 1) increase access to voluntary counseling and testing and post-test services; 2) change community attitudes around HIV awareness, particularly the benefit of knowing one's HIV status; 3) remove barriers to knowing one's HIV status; and 4) increase the safety of testing and minimize the potential negative consequences of testing by providing various forms of support. Results showed a 14 percent reduction in new HIV infections in communities where the intervention arm was delivered compared to control communities. The study began in 2003 and was conducted in 34 communities in Africa (South Africa, Tanzania and Zimbabwe) and 14 communities in Thailand.

Many HIV prevention programs, especially in sub-Saharan Africa, have reported difficulty in reaching men; however, the NIMH Project Accept (HPTN 043) study was able to achieve a 45% higher rate of testing of men in intervention versus control communities. In addition, HIV-infected individuals in the intervention communities reported greater reductions in risky sexual behaviors. This effect was especially strong among HIV-infected men who reported 18% fewer sexual partners and 29% fewer concurrent sexual partners as compared to the control communities.

"These study results clearly demonstrate that high rates of testing can be achieved by going into communities and that this strategy can result in increased HIV detection which makes referral to care possible," said Dr. Thomas Coates, NIMH Project Accept (HPTN 043) Protocol Chair and Director of the Center for World Health at the University of California, Los Angeles. "This has major public health benefit implications by not only linking infected individuals to care but also by encouraging testing in entire communities and therefore also reducing further HIV transmission."

Study participants who learned they were HIV-infected were directed to the study's post-test services which included counseling, referrals to health care and social services assistance. Participants who tested HIV negative were also directed to post-test services for further counseling, referrals and support in staying HIV uninfected. Local health authorities were thoroughly briefed on the study findings and encouraged to continue implementation efforts.

focused and comprehensive services to prevent and treat HIV and tuberculosis as chief of the Division of Infectious Diseases at Harlem Hospital Center, Dr. El-Sadr is now the Director of the International Center for AIDS Care and Treatment Programs, known as ICAP. As head of ICAP, Dr. El-Sadr has helped an estimated 1,000,000 HIV patients receive the services they need and has helped 500,000 patients access the anti-retroviral treatment they require.

Dr. Sten Vermund

Congratulations also go out to former HPTN Principal Investigator, Dr. Sten Vermund. Dr. Vermund was recently elected to the American Pediatric Society (APS). Established in 1888, APS was the first honorary society to recognize pediatricians for their research and leadership contributions to the field. The APS will induct Dr. Vermund during an annual meeting in May. In addition, he will be awarded the Norman J. Siegel New Member Outstanding Science Award granted to one new member annually.

Dr. Vermund is recognized for his work on HIV treatment in countries such as Mozambique and Zambia, his leadership during the past six years within HPTN and his professorship at Vanderbilt University School of Medicine in the areas of Pediatrics, Medicine, Obstetrics, Gynecology and Preventive Medicine.

Dr. Quarraisha Abdool Karim

Congratulations are also extended to former HPTN Principal Investigator Dr. Quarraisha Abdool Karim for receiving the Order of Mapungubwe: Bronze by the South African State President. Dr. Abdool Karim, Associate Scientific Director of CAPRISA (Centre for the AIDS Programme of Research in South Africa), received the award in recognition of her "outstanding work in the field of HIV/AIDS and tuberculosis research and health policy development." The Order of Mapungubwe is South Africa's highest national honor.

HPTN 069 Update

Protocol Version 3.0 was approved in January for HPTN 069 to include the enrollment of at-risk women. HPTN 069 is a Phase 2 trial to assess the safety and tolerability of four antiretroviral (ARV) drug regimens used as pre-

What's New in HIV Prevention?

VOICE Study Results Released

The Microbicides Trial Network (MTN) announced results of its VOICE study at CROI. VOICE—Vaginal and Oral Interventions to Control the Epidemic—was designed to test whether antiretroviral (ARV) medicines commonly used to treat people with HIV are safe and effective in preventing sexual transmission of HIV in women as PrEP. The study was a phase IIB, double blind, placebo-controlled, five arm study evaluating daily dosing of oral tenofovir disoproxil fumarate (TDF) alone, and daily dosing of combination of oral TDF and emtricitabine (known as Truvada®) compared to oral placebo; and daily use of tenofovir gel (TFV) compared to the placebo gel.

Results released at CROI showed that the three products tested in the VOICE study (Tenofovir gel, and oral Tenofovir and Truvada) could not demonstrate efficacy because most participants did not use them daily as recommended. The study drug was detected in less than a third of blood samples from women who were assigned the oral tablets and in less than a quarter of samples from women assigned to use the gel. These results were discordant with self-reported adherence of about 90 percent.

“We applaud MTN, and their participating sites, investigators and study participants for their enormous effort in undertaking this critically important study,” said Dr. Wafaa El-Sadr, HPTN Principal Investigator. “These findings underscore the need for continued research to understand risk perception and adherence facilitators/impediments, to enhance adherence with drugs used for prevention as well as to find alternate efficacious PrEP agents.”

The VOICE study began in September 2009 and enrolled 5,029 women in Uganda, South Africa and Zimbabwe.

HPTN 073

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 073 will enroll a total of 225 HIV-negative men who have sex with men

(MSM) in 3 cities in the U.S.: Chapel Hill, NC; Los Angeles, CA; and Washington, DC. To enroll in the study participants must be at least 18 years old. Since HIV infection rates are highest among Black MSM aged 18 to 25, the study will strive to enroll participants from this age group.



A Closer Look

Network Profile Spotlight

Bonnie Dye

Before setting on her public health career path Bonnie held a variety of

exposure prophylaxis (PrEP) to prevent HIV transmission in a population of at-risk men who have sex with men (MSM) and in at-risk women. The study is enrolling participants at 13 domestic sites and 200 participants have been enrolled as of early April.

Coming Soon

HIV Vaccine Awareness

Day Saturday, May 18



National Asian & Pacific Islander

HIV/AIDS Awareness Day

Sunday, May 19



Hepatitis Test Day

Sunday, May 19



Caribbean American HIV/AIDS

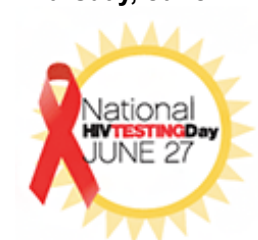
Awareness Day

Saturday, June 8



National HIV Testing Day

Thursday, June 27





jobs including: bank teller, sports photographer, camera saleswoman, and training manuals writer for the Virginia Department of Transportation. Bonnie likes to describe herself as a bit of a nomad without having a real “hometown”. She double majored in Political Science and Religion at Mary Washington College. Her first “real” job out of college was with Population Action International and from there she worked at a number of different places realizing that in order to do the kind of work she loved she needed an MPH. In 2002, she moved to New

York City and started her MPH at Columbia University. While there she worked at the Harlem Health Promotion Center/Project STAY (a group focused on providing HIV testing and counseling to at risk youth and services to HIV positive adolescents).

When Bonnie’s husband Tom was offered an opportunity to teach at Chiang Mai University in their architecture program she jumped at the chance to live outside of the U.S. and quickly found a job in HIV prevention. After spending two years in Thailand, Bonnie and Tom picked Durham, North Carolina as their new hometown. In May 2008 she was hired as a Protocol Research Specialist and worked on HPTN 058, HPTN 061 and supported the Ethics Working Group. Bonnie is currently a Clinical Research Manager and works on HPTN 067 and HPTN 074. She also supports the Women At Risk Group.

“My absolute favorite thing about working at HPTN are the amazing people I collaborate with at central—CORE, NL, SCHARP and at the sites.”

Bonnie says it’s hard to put into words why she is so committed to working in HIV prevention. “Over the last 10 years of working in HIV prevention and AIDS treatment programs I have met many people who are living with HIV and sadly some who have died from AIDS. I don’t feel like I have any choice but to use my skills in some way to help contribute to stopping this epidemic.”

Along with her awesome musician/architect husband Tom, Bonnie has two adorable little girls. When not running after them she enjoys long distance running. She’s been in more than 50 road races (four marathons). Bonnie enjoys knitting, cooking, photography (the old fashioned film kind), and is a voracious reader. She is also a born and bred Duke Blue Devils basketball fan and watches the games anytime and any way that she can.

In Memoriam:

LeTanya Johnson-Lewis

The HPTN is deeply saddened by the death of our beloved colleague LeTanya Johnson-Lewis. LeTanya passed away unexpectedly on February



20, 2013, in South Africa, while returning home from an HPTN meeting and site visits that she was attending and conducting on behalf of the HPTN Network Laboratory, Department of Pathology, Johns Hopkins University.

LeTanya was a Medical Technologist in the Department of Pathology and School of Medicine (SOM) for 14 years. She first joined Johns Hopkins in 1999 as a hospital employee and later transitioned to the SOM in 2008 as a Laboratory QA/QC Coordinator for HPTN. Working as a member the of HIV

[IAS 2013: 7th IAS conference on HIV Pathogenesis, Treatment and Prevention](#)

June 30-July 03, 2013

Kuala Lumpur, Malaysia



Hot Off the Press

Avery LB, Sacktor N, McArthur JC, Hendrix CW. [Protein-free efavirenz concentrations in cerebrospinal fluid & blood plasma are equivalent: Applying the law of mass action to predict protein-free drug concentration.](#) *Antimicrob Agents Chemother.* 2013;57(3):1409-14 PMID: 3591913.

Brookmeyer R, Konikoff J, Laeyendecker O, Eshleman SH. [Estimation of HIV incidence using multiple biomarkers.](#) *Am J Epidemiol.* 2013;177(3):264-72 PMID: In Process.

James MM, Laeyendecker O, Sun J, Hoover DR, Mullis CE, Cousins MM, Coates T, Moore RD, Kelen GD, Fowler MG, Kumwenda JJ, Mofenson LM, Kumwenda NI, Taha TE, Eshleman SH. [Antibody maturation and viral diversification in HIV-infected women.](#) *PLoS One.* 2013;8(2):e57350 PMID: 3583828.

Wendel SK, Mullis CE, Eshleman SH, Blankson JN, Moore RD, Keruly JC, Brookmeyer R, Quinn TC, Laeyendecker O. [Effect of natural and ARV-induced viral suppression and viral breakthrough on anti-HIV antibody proportion and avidity in patients with HIV-1 subtype B infection.](#) *PLoS One.* 2013;8(2):e55525 PMID: 3577851.

Want to Read More?

HIV Prevention Trials Network

Laboratory and HPTN Network Laboratory team, she worked tirelessly to effect changes in the attitudes concerning HIV and HIV transmission. Her efforts are captured in many abstracts and journal articles. She was involved directly as a protocol team member for HPTN protocols 043, 064, 068, 071, and 073 and performed specialized HIV testing for HPTN protocols.

LeTanya was well known for greeting everyone with a warm hello. Her infectious laughter and positive energy were endless. She will be dearly missed by all who were touched by her beautiful smile. LeTanya leaves behind her husband, Anthony Lewis, mother, brother, nephews and host of family and friends. In honor of LeTanya, a memorial fund has been set up which will be used for training Medical Technologists. Visit the HPTN website ([Network Lab section](#)) for more information.

Dr. Moses Sinkala



The HPTN also mourns the loss of Moses Sinkala (MChB, MPH), one of the leaders in policy and research for implementation of health care delivery in Zambia for more than a decade. Dr. Sinkala played an instrumental role as founder of the Centre for Infectious Disease Research in Zambia (CIDRZ). He held leadership roles within the Ministry of Health, most prominently as one of the longest serving Directors of the Lusaka Urban Health District. At the time of his death he

was the Country Director for the Catholic Medical Mission Board and was most active in the areas of HIV prevention and care and issues around services impacting maternal and child health.

While he was at the Lusaka Urban District, Dr. Sinkala launched some truly visionary initiatives including: the HPTN 024 protocol to prevent HIV transmission from mother to infant; HPTN 055 and HPTN 035 protocols to develop microbicides for women to prevent acquisition of HIV; the initiation of Zambia's first large scale effort to prevent mother-to-child HIV transmission through the Elisabeth Glaser Pediatric AIDS Foundation "Call to Action" program; the introduction of the first Zambian AIDS treatment program in the primary-care setting through the Columbia University "MTCT-Plus Initiative"; the integration of the first cervical cancer screening program in Zambia using appropriate technology; and the PEPFAR ART scale-up in the Lusaka Urban District. It was because of Dr. Sinkala's leadership that the Zambian ART scale-up was so successful; and it was he, among others, who insisted that the services be made available to all Zambians, free of charge, through sustainable national facilities.

Dr. Moses Sinkala was also a prolific researcher and co-author on more than 100 scientific papers, collaborating on clinical trials and implementation studies with scholars from multiple universities. He was passionate about effective integration and dissemination of evidence-based practice for the improvement of health outcomes in Zambia. He supported clinical training and public health education, playing key roles in the establishment of innovative task-shifting approaches such as the UNZA nurse prescribers program, and the Chainama College of Health Sciences Public Health certificate and diploma programs. He will be deeply missed.

Jimijika Batani

Jimijika Batani passed away suddenly on the morning of April 4, 2013. Well known to the international HPTN family, Jimijika was Study Coordinator for HPTN 052 at the Harare, Zimbabwe site. Working on HPTN 052 since its inception, Jimijika was critical to the success of the site and the study, particularly what became one of the top enrolling sites

<http://www.hptn.org/index.htm>

HPTN 043

http://www.hptn.org/research_studies/hptn043.asp

HPTN 046

http://www.hptn.org/research_studies/hptn046.asp

HPTN 052

http://www.hptn.org/research_studies/hptn052.asp

HPTN 064

http://www.hptn.org/research_studies/hptn064.asp

HPTN 065

http://www.hptn.org/research_studies/hptn065.asp

HPTN 067

http://www.hptn.org/research_studies/hptn067.asp

HPTN 068

http://www.hptn.org/research_studies/hptn068.asp

HPTN 069

http://www.hptn.org/research_studies/hptn069.asp

HPTN 071

http://www.hptn.org/research_studies/hptn071.asp

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for HPTN 052. As a result of her strong organization and leadership skills she was appointed the Parirenyatwa CRS coordinator in 2007 where her managerial skills were evident in the implementation of HPTN, IMPAACT, ACTG and non-DAIDS sponsored protocols.

Jimijika was trained as a registered nurse followed by certification in midwifery and acquisition of a Bachelor of Nursing Science degree. She worked as a midwife supervisor at Zimbabwe's busiest maternity unit at Harare Central Hospital for over 15 years where she taught nursing and medical students practical skills of obstetrics. Her passing is a great loss and her HPTN family will miss her very much.

Somkiati Sakooserksadee



The HPTN also mourns the loss of Somkiati Sakooserksadee. Described as kind, gentle and devoted, Somkiati was Chair of the Chiang Mai University Substance Abuse Community Advisory Board (CAB) and also Co-Chair of HANC Community Partners. Somkiati was a Chaing Mai businessman. He joined the CAB in 2003. He passed away July 4, 2012.