



Whats New in the HPTN?

Injectable Agents for PrEP

Reducing the number of new HIV infections requires innovative and evolving prevention strategies. As the HPTN moves forward with its research agenda, one strategy the network is exploring is the use of injectable agents for pre-exposure prophylaxis (PrEP). Previous studies have shown that when taken properly, daily oral PrEP is effective in reducing the transmission of HIV. However, in several studies not all participants took their medication as directed and the trials did not demonstrate efficacy.

“Previous PrEP studies have demonstrated that drugs work only if people take them as required,” said Dr. Nirupama Sista, HPTN 076 Co-Chair and Director, HPTN at FHI 360. “The HPTN is interested in exploring alternative methods of drug delivery for PrEP, and particularly the safety, acceptability and efficacy of long-acting injectable agents.”

The HPTN is launching two studies to evaluate long-acting injectable agents for safety, tolerability, acceptability, and drug metabolism properties. HPTN 076 will evaluate injectable rilpivirine, TMC278LA, in HIV-uninfected women at two sites in the United States (New York, NY and Newark, NJ) as well as at a site in Cape Town, South Africa and Harare, Zimbabwe. HPTN 077 will evaluate injectable cabotegravir, GSK1265744, in HIV-uninfected men and women and will include one site in Brazil, three sites in sub-Saharan Africa, and four sites in the U.S.

“One of the greatest challenges and criticisms of daily oral PrEP is the need for regular daily adherence to pill taking,” said HPTN 077 Protocol Chair Dr. Raphael Landovitz. “This has been prohibitively difficult or just plain unacceptable to some populations. A long acting (every 2 to 3 month) injectable removes the need for daily pill taking, and may be more acceptable to some groups. If we are able to show that it is safe and effective, this could be a real game-changing innovation for HIV prevention.”

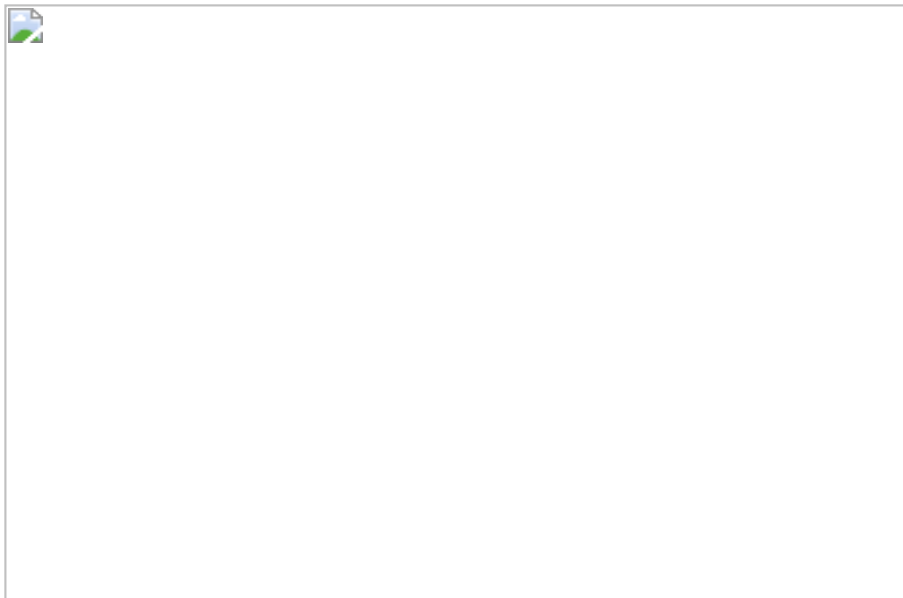
Dr. Landovitz says HPTN 077 and its “sister” study ÉCLAIR (a GSK/ViiV sponsored study) represent the next steps forward in developing injectable cabotegravir for HIV prevention but he cautions that unlike other drugs which have been studied for PrEP to date, cabotegravir is a new drug, and is not yet FDA approved for HIV treatment. Therefore, evaluation of safety and tolerability is the first step.

HPTN 076 and HPTN 077 are expected to begin enrolling later this year.

Study Updates

Enrollment Completed for HPTN 067

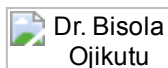
Congratulations to the HPTN 067/ADAPT study team for completing enrollment on May 6. HPTN 067/ADAPT is a Phase II study to determine the feasibility of intermittent dosing of Truvada as pre-exposure prophylaxis (PrEP) to prevent HIV in heterosexual women and in men who have sex with men and transgender women. In the first part of the study, pill-taking was directly observed to determine an objective measure of drug exposure for each participant. Participants were then randomized to receive daily dosing, time-driven dosing, or event-driven dosing. Participants are 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. The Emavundleni Centre enrolled heterosexual women in Cape Town, South Africa and the Harlem Prevention Center in New York and Silom Community Clinic in Bangkok, Thailand enrolled MSM/TGW.



HPTN 061 Results Webinar

The HIV Prevention Trials Network (HPTN) hosted a special webinar, [HIV and Black MSM in the U.S.: More Findings from HPTN 061](#). Study team members and HPTN scholars provided information on some of the drivers of the HIV epidemic, what part drug and alcohol use play in HIV incidence in Black Men who have Sex with Men (BMSM), who gets tested, who doesn't and why it matters. The webinar recording is available on the HPTN website at www.hptn.org.

HPTN 2014-2015 Scholars Announced



Dr. Bisola Ojikutu

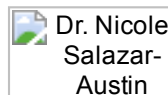
The HPTN is pleased to announce the selection of its newest scholars.

Dr. Bisola Ojikutu, Brigham and Women's Hospital will work with mentors Dr. Steven Safren, Harvard Medical School, Mass General Hospital and Dr. Ken Mayer, Harvard Medical School, The Fenway Institute. Her project is HPTN 063: Community Level Cultural Beliefs and Sexual Transmission Risk Behaviors in HIV Infected Women Enrolled.



Dr. Tiarney Ritchwood

Dr. Tiarney Ritchwood, University of North Carolina at Chapel Hill will work with mentor Dr. Audrey Pettifor, UNC Chapel Hill. She will work on two projects, HPTN 068: The relationship between partner age and sexual risk among South African adolescent girls and the impact of partnership status on risk, and HPTN 062: Understanding individual motivations to reduce risky sexual behaviors after HIV diagnosis and the impact of depression, coping, and social support on perceived infectiousness and risk behaviors



Dr. Nicole Salazar-Austin

Dr. Nicole Salazar-Austin, Johns Hopkins University School of Medicine will work with mentors Dr. Tom Coates, UCLA School of Medicine and Dr. David Celentano, Johns Hopkins University Bloomberg SPH, Her project is NIMH Project Accept (HPTN 043): Social norms and the effects of sociodemographic factors on HIV testing in youth age 18-24.

Dr. Laramie Smith, University of California San Diego will work with mentors Dr. Carl Latkin, Johns Hopkins University Bloomberg SPH and Dr. Steffanie Strathdee, University of California San Diego. Her project is HPTN 037: Evaluation of factors through which a peer-delivered intervention facilitate HIV risk behavior change.

HPTN 043

HPTN 043 (NIMH Project Accept) was featured in the peer-review journal The Lancet Global Health. The study demonstrated that a combination of social, behavioral and structural HIV-prevention intervention efforts increased the number of people tested for HIV and resulted in a 14 percent reduction in new HIV infections, compared with control communities. The study was conducted in Africa and Thailand. Study Principal Investigator Thomas Coates, PhD says the study clearly demonstrated that high rates of testing can be achieved by going into communities. "This strategy can result in increased HIV detection which makes referral to care possible."

HPTN 073

A total of 140 participants (62%) have been enrolled in the study to date. HPTN 073 is a demonstration project designed to evaluate the acceptability of PrEP in BMSM. Although 28% of all new HIV infections in the



Dr. Laramie Smith

The [HPTN scholars program](#) is funded through a supplement from the National Institute of Allergy and Infectious Diseases (NIAID). It is offered to early career U.S. minority investigators and seeks to increase opportunities for scientists from groups traditionally underrepresented in HIV prevention research. The scholars work with mentor scientists in the Network to complete a research project based upon an existing HPTN research study. The program seeks to provide scholar recipients with the knowledge, skills and abilities to further their careers as independent investigators in the HIV prevention research field.

New Executive Committee Members

Following the completion of the site recompetition process, the HPTN Executive Committee was expanded to include representative investigators from the sites. The HPTN welcomes Steve Shoptaw, PhD Director, Center for Behavioral and Addiction Medicine and Professor and Vice Chair for Research, Department of Family Medicine at UCLA in Los Angeles, California and Dr. Newton Kumwenda, Field Director for the Johns Hopkins University Research Project in Blantyre, Malawi and the Blantyre CRS Leader.

New Scientific Committee Members

The HPTN is pleased to announce the newest members of the current Network Scientific Committees and Working Groups. We extend our thanks to all of those who have served on committees in the past and those who nominated themselves or others to be members of our scientific committees. The membership of the scientific committees is reconstituted and we look forward to working with our new members.

Adolescents at Risk	Women at Risk	Substance Users	MSM
Audrey Pettifor		Steffanie Strathdee	Ken Mayer
Frances Cowan	Ada Adimora	Nabila El-Bassel	Darrell Wheeler
Linda-Gail Bekker	Elizabeth Bukusi	Apinun Aramrattana	Chris Beyrer
Sarah Dlamini	Judy Auerbach	Raquel de Boni	Bob Remien
Sybil Hosek	Sevgi Aral	Pedro Gonzales	Theo Sandfort
Sophia Hussein	Gina Brown	Adeeba Kamarulzaman	Beatriz Grinsztejn
	Sally Hodder	Irene Kuo	Tim Holtz
	Angela Kashuba	David Metzger	Patrick Sullivan
	Nelly Mugo	Vu Minh Quan	

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 (in 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 (PWID) will reduce HIV transmission to HIV-uninfected injection partners, as compared to routine care recommended by World Health Organization (WHO) and/or national guidelines for HIV-infected PWID. Study sites include Indonesia, Vietnam and Ukraine.

HPTN 075 (In development)

HPTN 075 is an observational cohort study that will evaluate 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. A total of 20 HIV-infected MSM will be allowed to enroll at each of the four sites.

Coming Soon

HIV R4P Preview

Chitra Singh

Ron Stall

Jorge
Sanchez

Integrated Strategies	Ethics	Community
Connie Celum	Jeremy Sugarman	Janet Frohlich
Susan Buchbinder	Jerome Singh	Melissa Turner
Peter Cherutich	Alex London	Charles Chasakara
Sinead Delaney-Moretlwe	Anant Bhan	Shipeng Chen
Tim Hallett	David Borasky	David Galetta
Mina Hosseinipour	Florence Luna	Daniel Gondwe
Risha Irvin	Kate MacQueen	Craig Hutchinson
Heidi Van Rooyen	Mark Barnes	Ernest Moseki
Valdilea Veloso	Robert Klitzman	Agnes Nondo
	Steven Wakefield	Fatima Zulu
	Yali Cong	

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 HPTN has submitted several abstracts. The deadline for late breaker abstracts opens August 1 and closes August 17. For more information visit [hivr4p](http://hivr4p.org).

[AIDS 2014: 20th International AIDS Conference](#)

July 20-25, 2014
Melbourne, Australia

In the Community

HPTN works with more than 20 research sites in 15 countries. These sites play a critical role in the successful implementation of our studies. In this Prevention Now issue we profile one international and one domestic site.

UNC Project in Lilongwe Malawi

The UNC Project in Lilongwe Malawi is a research, training and service organization that is a collaboration between the University of North Carolina at Chapel Hill and the Malawi Ministry of Health's Kamuzu Central Hospital. Established in 1999, the mission of UNC Project-Malawi is to identify innovative, culturally acceptable, and affordable methods to improve the health of the people of Malawi, through research, health systems strengthening, prevention, training, and care. While initially the site's research was primarily focused on HIV and STI prevention and treatment, in recent years the site has expanded activities to include maternal health, surgery in resource limited settings, cancer treatment, and treatment for malaria and other infectious diseases. The project is multidisciplinary with faculty and collaborators from the school of medicine in multiple departments including public health, geography, pharmacy, radiology and pathology.

"We offer a broad range of research activities," said Dr. Mina Hosseinipour, Clinical Director, UNC Project-Malawi and HPTN 052 Protocol Co-Chair. "Given our central leadership structure, we are able to apply our basic principles for conducting high quality research across disciplines. We are fortunate to have many long-serving staff members that have supervised the growth phase of our organization."

UNC Project-Malawi points to its work on the HPTN 052 study as one of its proudest accomplishments. Dr. Hosseinipour and her team have worked



[USCA: 18th Annual United States Conference on AIDS](#)

October 2-5, 2014
San Diego, CA

Recent Event

[National HIV Testing Day](#)

with the HPTN for many years. “The other sites and their investigators and staff are exceptional. We are always able to learn and improve our activities through the network affiliation. And of course, by now, most of these investigators are also our dear friends.”

UNC Project-Malawi is looking forward to participating in the HPTN 077 study. It has also been selected as an HVTN site. “I think our staff has seen the benefits of prevention and treatment research and how our work has transformed the HIV epidemic in Malawi,” said Dr. Hosseinipour. “We are hopeful these studies will prove effective to transform the HIV prevention landscape in much the same way as HPTN 052.”



UNC Project - Malawi Team



UNC Project - Malawi Team

George Washington University

George Washington University (GWU) was one of the first groups in Washington, DC to work with the community on HIV prevention studies. As of one of the cities in the U.S. most affected by HIV GWU Associate Professor Dr. Manya Magnus says the site is excited to be part of the HPTN. “We are pleased to be able to partner with other scientists and with communities affected by HIV. As we strive together, we are hopeful that in some way the work we are doing will allow us to see a day before too long when HIV is no longer a health threat for any population.”

Dr. Magnus points to GWU’s partnerships with members of affected communities, as well as with other scientists and medical providers throughout the area, as some of the sites greatest assets. “We collaborate with a wide variety of people and professions to ensure that everything from our recruitment and retention methods to our educational programming is appropriate to meet the needs of those with whom we work. We also work within the context of a city-wide Developmental Center for AIDS Research (D-CFAR), which allows us myriad services and expertise of other scientists.”

Another point of pride for the site is the strong relationship it has built with community members. The Community Advisory Board is very active and provides valuable insight into local needs. Dr. Magnus says one of the biggest challenges for the site was migrating from cross-sectional studies such as CDC National HIV Behavioral Surveillance and then moving into

Webinar

The HPTN and Black AIDS Institute are partnered to present two presentations on National HIV Testing Day, June 23 2014, at 1:00 p.m. EDT. HPTN Principal Investigator, Dr. Myron Cohen provided an overview of HPTN 052, including the most recent results from the study and the impact of early ART initiation on HIV transmission. Dr. Eugene Gooden Martin, Professor of Pathology and Laboratory Medicine at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School in New Brunswick shared information about the advances that have been made in early detection of HIV infections through fourth generation testing technology. You can watch a video of the webinar [on the HPTN website](#).

Hot Off the Press

Corneli A, Pettifor A, Kamanga G, et al. [HPTN 062: A Feasibility and Acceptability Pilot Intervention to Reduce HIV Transmission Risk Behaviors Among Individuals with Acute and Early HIV Infection in Lilongwe, Malawi](#). AIDS and behavior. Feb 13 2014.

Grinsztejn B, Hosseinipour MC, Ribaud HJ, et al. [Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial](#). The Lancet infectious diseases. Apr 2014;14(4):281-290.

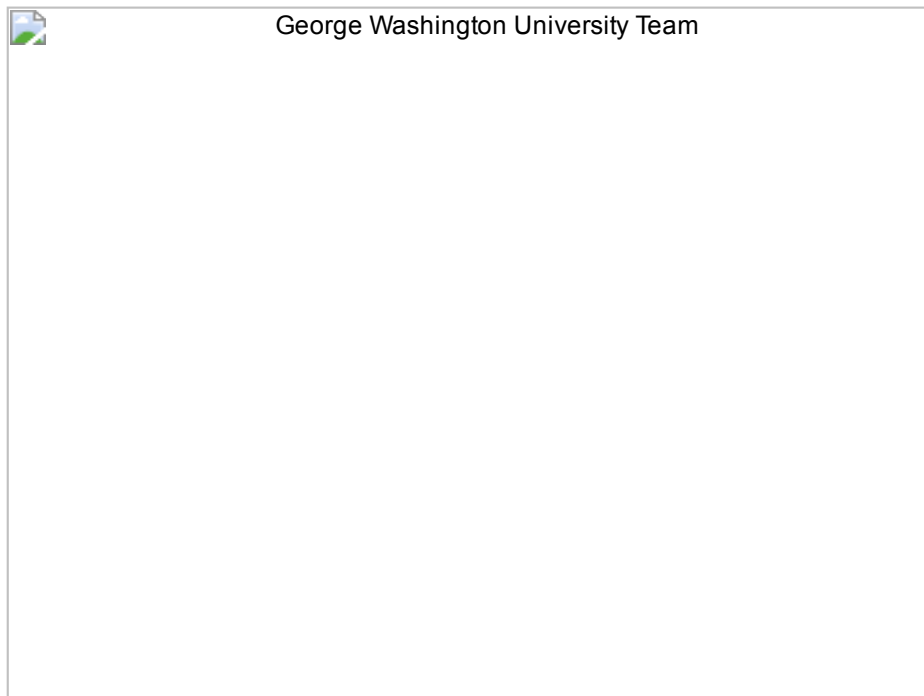
Jackson JB, Wei L, Liping F, et al. [Prevalence and seroincidence of hepatitis B and hepatitis C infection in high risk people who inject drugs in china and Thailand](#). Hepatitis research and treatment. 2014;2014:296958.

longitudinal observational studies (with HPTN 061 and HPTN 064) and as well as treatment trials (HPTN 069, HPTN 073 and, soon, HPTN 077).

“Early on, it was a steep learning curve to develop effective retention methods to keep people on study,” says Magnus. “But we learned quickly and received a lot of support in this domain from our community and the HPTN network. These methods are critical to success in clinical trials, and are serving us well as we enter new biomedical intervention trials such as 077, which hold so much promise for a future without HIV.”

Dr. Magnus credits the wonderful staff at GWU as a key to the site’s success. The team is able to interface effectively with the community for recruitment, implementation, and retention yet also work seamlessly with medical personnel. “This dual ability is critical especially in working on biomedical prevention trials. Our staff is outgoing, compassionate, dedicated to research and the community, and have outstanding research skills. Our participants adore them, and they are the reason we have achieved such excellence to date!”

In addition to the infrastructure support provided by HPTN Dr. Magnus says it is a joy to work in the multisite environment of the network. “We learn so much from other scientists and staff, and appreciate the collaborative nature of the work. Working with the HPTN also provides opportunity to develop new collaborations and mentor future generations of scientists. This is a great honor and one which is supported by the collegial HPTN network. “



GWU Team

Harawa N, Wilton L, Wang L, et al. [Types of Female Partners Reported by Black Men Who Have Sex with Men and Women \(MSMW\) and Associations with Intercourse Frequency, Unprotected Sex and HIV and STI Prevalence.](#) AIDS and behavior. Feb 13 2014.

Sugarman J, Rose SM, Metzger D. [Ethical issues in HIV prevention research with people who inject drugs.](#) Clin Trials. 2014;11(2):239-45
PMCID: 3972281

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.

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www.facebook.com/HIVptn

www.twitter.com/HIVptn



A Closer Look

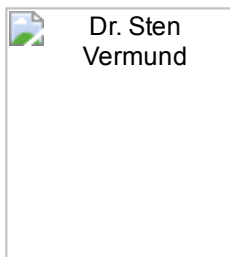
HPTN at IAS 2014

The HPTN has eight accepted abstracts at the 20th International AIDS Conference in Melbourne, Australia July 20-25.

- Measuring Preventive Misconception in HIV Prevention Trials (HPTN 069/ACTG 5305)

- Characteristics of Young Black Men Who Have Sex with Men Enrolled in HPTN 061
- Presence at the Table (PAT): A Cultural Competency/Humility Workshop for Anyone Working with BMSM in Clinical Research
- Self-Reported Experience with Financial Incentives for Virologic Suppression among HIV-infected Adolescents on Antiretroviral Therapy and Guardians of HIV-infected Pediatric and Adolescent Patients on Antiretroviral Therapy (HPTN 065)
- When Your Life is Threatened, HIV is a Peripheral Concern: Qualitative Perceptions of Crime/Violence in Nine HPTN 071 (PopART) Community Sites in South Africa
- Reflections on the Broad Brush Survey (BBS) Research Methodology: A Rapid, Qualitative, Mixed-Method Set of Research Activities Used to Inform a Community Based Randomized Controlled Trial HTPN 071 (PopART)
- Intruders with Questions and Justified Fears: Reflections on the Experiences of Research Staff Implementing Rapid, Qualitative Research in Nine HPTN 071 (PopART) Community Sites in Western Cape Province, South Africa
- “What is this ‘Universal Test and Treat’ (UTT)?” Community Understandings of Key Concepts Linked to a Combination HIV Prevention Strategy in 21 Zambian and South African Communities

HPTN Congratulates Dr. Sten Vermund and Dr. Richard Hayes



Dr. Sten Vermund

Former HPTN Co-Principal Investigator Sten Vermund is the 2014 recipient of the Allan Rosenfield Alumni Award for Excellence. Dr. Vermund, who is Director of the Vanderbilt Institute for Global Health and the Amos Christie Chair of Global Health and Professor of Pediatrics, was recognized for his “extraordinary contributions to the field of public health in the area of HIV infection prevention and HIV/AIDS infrastructures to improve cancer screening and treatment for women

in low income countries since the late 1980s.” Dr. Vermund was also honored for his devotion to addressing public health disparities and his remarkable efforts to improve women and children's health on a global scale.

The Allan Rosenfield Alumni Award for Excellence was established in 2009 to honor the memory of Dr. Allan Rosenfield who served as dean of the Columbia Mailman School of Public Health from 1986 to 2008. The award recognizes the achievements of the School's outstanding alumni and their leadership in the field of public health.



Dr. Richard Hayes

HPTN 071 Protocol Chair Richard Hayes was awarded the 2014 George Macdonald Medal in recognition of his research leading to the improvement of health in tropical countries. “Professor Hayes has been a leading figure in tropical epidemiology for over 30 years, and has conducted ground-breaking research on a wide range of public health problems in developing countries, including sickle cell disease, malaria, HIV and TB.”

The medal will be formally presented at the Royal Society of Tropical Medicine and Hygiene biennial meeting in Oxford in September.

Please contact us at news@hptn.org