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## What's New in the HPTN?

### HPTN Launches First Black MSM PrEP Study

HPTN is excited to announce the start of HPTN 073, a demonstration study designed to see if Black Men who have sex with men (BMSM) are willing to use Truvada® for pre-exposure prophylaxis (PrEP).



Palm Card for HPTN 073

"While other studies have shown promise for PrEP, this will be the first study to specifically look at PrEP acceptability and use among BMSM in the United States," said HPTN 073 Protocol Co-Chair [Sheldon D. Fields, PhD, RN](#). "Considering BMSM make up nearly 30 percent of all new infections in the U.S. it is imperative that we explore prevention strategies that might help Black men better protect themselves and their communities."

HPTN 073 will enroll a total of 225 HIV-negative BMSM in three U.S. cities: Chapel Hill, NC; Los Angeles, CA; and Washington, D.C.

"This is an exciting study that will provide us with critical information about whether Black men will accept PrEP," said HPTN 073 Protocol Chair [Darrell Wheeler, PhD, MPH](#). "It will also help us better understand under what conditions they are willing to accept taking PrEP and how health care providers and researchers, might be able to better support their efforts to achieve optimal health outcomes."

To help raise awareness about the study, HPTN hosted a webinar: [Introducing HPTN 073: A PrEP Demonstration Project for Black MSM](#) featuring presenters Greg Millett, MPH, Sr. Policy Advisor in the Office of National AIDS Policy; Myron Cohen, MD, HPTN Principal Investigator; Darrell Wheeler, PhD, MPH and Sheldon Fields, PhD, RN, HPTN 073

## HPTN JAIDS Supplement



The HPTN special JAIDS supplement, [State of the ART HIV Prevention](#), is now available online. The supplement features 24 manuscripts devoted to diverse aspects of HIV prevention with a

critical analysis of science breakthroughs, promises and challenges. The supplement is funded by NIAID and the Office of Global AIDS Coordinator.

### HPTN at USCA

Want to learn more about the latest advances in HIV prevention research? How to get involved in all levels of clinical research? Join representatives from HPTN for an exciting lineup of presentations at the U.S. Conference on AIDS (USCA) September 8-11 in New Orleans, Louisiana. Click [here](#) for details.

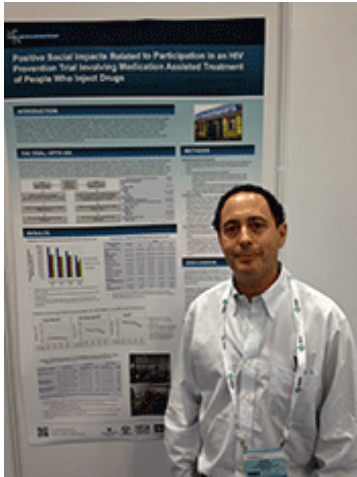
## Study Updates

### 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

Protocol Chairs; Christopher Chauncey Watson, HPTN 073 Black Caucus Chair; and Jonathan Paul Lucas, MPH, HPTN 073 Community Project Manager.

## HPTN at IAS 2013



Jeremy Sugarman at IAS 2013

The HPTN had four abstracts accepted at the International AIDS Society conference in Kuala Lumpur, Malaysia. Three of the four posters were presented by HPTN scholars.

Sophia Hussen, MD presented her poster on the need to increase HIV testing rates among Black MSM if access to HIV prevention and treatment is to be scaled up. Four HIV testing patterns were described among black MSM 1) maintenance testers (those who test as part of routine self-care), 2) risk-based testers (test after sexual activity or after a change in the relationship), 3) convenience testers (are influenced by location and cost of testing), 4) test avoiders (avoid testing for fear of a

positive result). The authors recommended multi-pronged testing strategies to reach Black MSM who are disproportionately impacted by HIV.

Jeremy Sugarman, MD, MPH, MA presented a poster on the positive social impacts related to participation in HPTN 058, a phase III randomized trial assessing the safety and efficacy of a drug treatment intervention in decreasing HIV transmission and mortality among people who inject drugs at four sites, three in China (Xinjiang, Nanning and Heng County) and one in Thailand (Chiang Mai). In addition to providing medication-assisted treatment for drug addiction, drug- and risk-reduction counseling was conducted with participants and social impact assessments (both positive and negative) were obtained at regular follow-up visits.

Although the study was closed early because it was not able to provide sufficient evidence to answer the study's primary objectives, HPTN 058 provides important information regarding social impacts of research participation. While research measures typically focus on direct benefits, indirect benefits (such as medical care and other services) can be profoundly important for participants and may motivate some people to enroll in research studies. However, indirect benefits experienced during research are rarely measured during clinical trials. Consequently, very little is known about the influences on participants' well-being outside of the direct outcomes of the intervention or other secondary outcomes that are measured in a trial.

"It has been really interesting to learn what participants consider a positive social impact," said Sugarman. "Normally you would not think of decreased drug use as a social impact, but in an area where drug use is so stigmatized, it makes sense that study participants view this as a positive social impact."

Participants in HPTN 058 experienced numerous positive social impacts (PSIs). However, these declined over time. Since this correlated with discontinuation of active medication assisted treatment of drug use, this finding may be linked to resumption of drug use. Multivariate analyses indicate that individuals in the long-term medication assisted treatment arm were more likely to report a drug-related PSI in the second year of the

HIV-infected people who inject drugs (PWID) will reduce HIV transmission to HIV-uninfected injection partners, compared to routine care as recommended by the 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 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 participants 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 agent for pre-exposure prophylaxis (PrEP) among approximately 120 healthy, HIV-uninfected women. The study will have two sites in the United States along with one site each in Cape Town, South Africa and Harare, Zimbabwe. Sites are expected to begin enrollment in early 2014.

### HPTN 061

HPTN 061 recently had three publications accepted. A manuscript lead by Typhanye Penniman looking at the differences in psychological, social, substance use and HIV sexual risks between urban Black Men who have Sex with Men Only (BMSMO) and Men who have Sex with Men and Women (BMSMW) was accepted by the Journal of Urban Health. HPTN 061 Protocol Chair, Beryl Koblin lead an article accepted by [PLoS One](#) looking at the correlates of HIV acquisition in HPTN 061. Manya Magnus lead a manuscript accepted by the Journal of Public Health Management and Practice that examines lessons learned in HPTN 061, specifically looking at engaging, recruiting, and retaining black MSM in research studies.

### HPTN 064

HPTN 064 continues to publish important findings. Ada Adimora led a manuscript looking at the characteristics of multiple and concurrent partnerships among the participants in HPTN 064.

study when compared to the short-term arm. This is logical considering that individuals in the long-term arm received treatment up to a year versus up to 18 days on two occasions for the short-term arm.

"While research rightly focuses on direct benefits, assessing indirect benefits such as PSIs is also arguably important in ensuring the well-being of participants," said Sugarman. "Future research should embed assessments of negative and positive social impacts experienced by study participants not only to ensure their well-being, but also to inform policy and conceptual work related to the ethics of research."

Click [here](#) for a full list of all of the HPTN IAS 2013 abstracts as well as links to the posters.

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## What's New in HIV Prevention?

### New WHO HIV Guidelines

At the 2013 International AIDS Society (IAS) Conference the World Health Organization (WHO) issued new HIV treatment guidelines.

The WHO recommends offering antiretroviral therapy (ART) earlier and encourages all countries to initiate treatment in adults living with HIV when their CD4 cell count falls to 500 cells/mm<sup>3</sup> or less. The previous WHO recommendation, set in 2010, was to offer treatment at 350 CD4 cells/mm<sup>3</sup>.

The new recommendations also include providing ART, irrespective of CD4 count, to all children with HIV under age five, all pregnant and breastfeeding women with HIV, and to all HIV-positive partners where one partner in the relationship is uninfected. "The results of the HPTN 052 study strongly support the use of ART to prevent HIV transmission among HIV serodiscordant couples. The Guidelines Development Group therefore endorsed the recommendations established in the 2012 WHO guidance on HIV testing and counseling including ART for treatment and prevention in serodiscordant couples that the sexual partner with HIV in such couple should be offered ART regardless of CD4 count." HPTN 046 was also cited for early ART initiation. HPTN 043 was cited in relation to recommending community based HIV testing and counseling with linkage to prevention, care and treatment services in addition to provider initiated testing and counseling.




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### CDC—Thailand PWID PrEP Study

The U.S. Centers for Disease Control (CDC) released results of the [Bangkok Tenofovir Study](#)—the first study to examine PrEP use among persons who inject drugs (PWID). The study demonstrated that daily oral tenofovir-disoproxil fumarate (TDF) was able to lower HIV infection risk by 49 percent in PWIDs in Bangkok, Thailand.

"The exciting study finding in this very important population highlights the need for continued PrEP research in order to optimize use of PrEP and identify new PrEP agents," said Wafaa El-Sadr, MD, HPTN Principal

Investor.

The Bangkok Tenofovir Study began in 2005 and enrolled 2,413 HIV-negative PWIDs. It was conducted in Bangkok at 17 drug treatment clinics. Participants were randomized to receive either 300 mg of oral tenofovir daily or placebo. The primary endpoint was HIV seroconversion during follow-up.

"These study results build upon previous PrEP trials and provide

### HPTN Annual Meeting



Thank you to everyone who made the 2013 HPTN annual meeting a great success.

Protocol team

meetings, trainings, community working group workshops, scholars' presentations—it was a busy and productive few days in Washington, D.C. Some highlights from the plenary sessions (HPTN and joint IMPAACT) included NIMH Project Accept (HPTN 043) study results, an overview of HPTN 071 (PopART), making sense of oral and topical PrEP trials, hormonal contraception and HIV, cost effectiveness of PMTCT and a special presentation from NIAID Director, Dr. Anthony Fauci, "Getting to an AIDS Free Generation—What Will it Take?" Dr. Fauci applauded the HIV prevention research that is underway but noted that the levels of access to testing, entry and retention in care, and initiation and adherence to ART remain inadequate in many settings. He also noted that some of the challenges in improving implementation of existing interventions include, validating the concept of treatment as prevention, optimizing adherence to PrEP regimens, scaling up medical male circumcision, and eliminating mother-to-child transmission. He underscored there is much to do in a time of serious fiscal constraint and suggested that all networks must prioritize research with a "laser focus." He also advocated that all studies must be kept current so they are relevant when completed and that partnerships—such as those exemplified in HPTN 071 (PopART)—are essential. You can access the annual meeting PowerPoint presentations on the [HPTN](#) website.

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## Coming Soon

[National HIV/AIDS and Aging Awareness Day](#)  
September 18



researchers with additional important information about effective HIV prevention strategies for this key population at risk for HIV," said Myron Cohen, MD, HPTN Principal Investigator.



Intravenous drug use in the U.S. accounts for about eight percent of all new HIV infections, however it is the key mode of HIV transmission in some regions of the world such as Central Asia and Eastern Europe. It is also a growing concern in sub-Saharan African countries. Based on the study results, the CDC has issued interim guidance for use of PrEP as one of the options for prevention of HIV transmission in PWIDs at risk for HIV infection.

## A Closer Look

### Network Profile Spotlights Sam Griffith



Sam's career path took many turns before ending up at HPTN. He spent time as a carpenter, lab technician, high school teacher, software sales person and even a writer for a TV quiz show.

Sam grew up in the suburbs of Chicago, but went to college in Massachusetts. When he graduated in the early 90s he says he wanted to do something worthwhile with his work life and thought either teaching or working on

AIDS seemed like a good fit. He just didn't know how to work on the AIDS part so he decided to become a high school science teacher. That wasn't the exact fit Sam hoped for so he tried a number of different jobs.

After spending three years at a dot.com start-up working on the sales team and then managing a software development project Sam says, "I realized I just didn't care how many software licenses we sold, and needed to get back into work I could feel good about." Sam took an entry-level position at FHI and started working on HPTN 039 with Scott Rose as his mentor. "That Christmas when I went home to Chicago, and people asked me what I was doing now, I enjoyed saying I'm working on an international research project to slow the spread of HIV rather than I'm selling software that helps people save money on test tubes."

Within a few months of starting at HPTN, Sam attended a training for HPTN 039 in Lusaka, Zambia—his first trip to Africa. After HPTN 039, Sam worked on HPTN 061, the first HPTN study to focus on Black MSM in the U.S. Now most of Sam's time is spent working on HPTN 071. "I am very excited to work on this study, which has the chance to be a real game-changer in the fight to reverse the expansion of HIV/AIDS. If HPTN 052 was the *Science* breakthrough of the year in 2011, I hope HPTN 071 can be the discovery of the year in a few short years!"

Along with meaningful work, Sam says the best part of his job is the people he works with. "This field is full of smart, committed, compassionate people, who could be making a lot more money doing something else, but they do this because they believe in it, and that's the kind of people it's great to work with around the world."

When not at work Sam likes to cook, play ultimate Frisbee, take walks



**National Gay Men's HIV/AIDS Awareness Day**  
September 27



## Hot Off the Press

Fogel JM, Wang L, Parsons TL, Ou S-S, Piwowar-Manning E, Chen Y, Mudhune VO, Hosseinipour MC, Kumwenda J, Hakim JG, Chariyalertsak S, Panchia R, Sanne I, Kumarasamy N, Grinsztejn B, Makhema J, Pilotto J, Santos BR, Mayer KH, McCauley M, Gamble T, Bumpus NN, Hendrix CW, Cohen MS, and Eshleman SH. **Undisclosed antiretroviral drug use in a multi-national clinical trial (HPTN 052).** *J Infect Dis.* 2013.

Kintu K, Andrew P, Musoke P, Richardson P, Asiimwe-Kateera B, Nakyanzi T, Wang L, Fowler MG, Emel L, Ou SS, Baglyos L, Gurnathan S, Zwierski S, Jackson JB, Guay L. **Feasibility and Safety of ALVAC-HIV vCP1521 Vaccine in HIV-Exposed Infants in Uganda: Results from the First HIV Vaccine Trial in Infants in Africa.** *J Acquir Immune Defic Syndr*201363(1):1-8. PMID: 23221981

## Want to Read More?

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

HPTN 052

with his two rescue dogs, consider finishing the home renovation he began shortly after joining FHI 360, and stay connected with family and friends. As you read this, Sam is on his first cruise with his mom to the fjords of Norway. Before setting sail Sam was in search of a good sweater. Let's hope he found one...

### Leslie Cottle



Leslie Cottle started at the Fred Hutchinson Cancer Research Center in 1987 as a data control technician working on the Hutchinson Smoking Prevention Project and went on to become the Data Manager. She joined SCHARP (formerly HIVNET) in 1998 as a Project Manager and has worked on a number of studies in the HIVNET, AIEDRP, and CHAVI networks.

In 2004 she was asked to sit in on a meeting in D.C. where logistics surrounding the new, not-yet-open HPTN 052 study were being discussed; she has been the project manager on the study ever since. Until recently, she has spent the vast majority of her time keeping the operations of HPTN 052 running smoothly, addressing emerging data management and operations challenges that come with such a long, complex study.

Meeting and working with the dedicated study site staff and contributing to such a landmark study has been a highlight of her time at SCHARP. She also currently acts as PM for HPTN 069, and performs operational reviews of new HPTN protocols for the Science Review Committee.

Leslie was born and raised in Anchorage, Alaska but has been living in Seattle since 1986. She and her partner, Heidi, have two children Doria (age 9) and Leo (age 2). Outside work she enjoys gardening, taking photographs, biking, and exploring the outdoors with her family. You can find her outside in the very early morning hours in a boot camp exercise class with several other crazy women.

[http://www.hptn.org/research\\_studies/hptn052.asp](http://www.hptn.org/research_studies/hptn052.asp)

HPTN 061  
[http://www.hptn.org/research\\_studies/hptn061.asp](http://www.hptn.org/research_studies/hptn061.asp)

HPTN 064  
[http://www.hptn.org/research\\_studies/hptn064.asp](http://www.hptn.org/research_studies/hptn064.asp)

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