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What's New in the HPTN?

HPTN 071 Randomization Event

Zambia and South Africa selected twenty-one communities for the new HPTN 071 study. HPTN 071, also known as PopART (Population Effects of Antiretroviral Therapy to Reduce HIV Transmission), is a planned six



HPTN 071 randomization event in South Africa

year study to test the impact of a combined package of several HIV prevention interventions on population-level HIV incidence. The study seeks to determine how well universal house-to-house voluntary testing and earlier provision of treatment, called the “treatment as prevention” approach, can work on a large community scale and whether it is possible and affordable to deliver.

Twelve communities across three provinces in Zambia and nine in the Western Cape, South Africa, were randomly assigned to one of three different study arms in a public randomization event. One group of communities will receive house-to-house voluntary HIV counseling and testing with the offer of immediate ART to all individuals who test HIV positive, together with other prevention methods; promotion of male medical circumcision, prevention of mother-to-child transmission for pregnant women with HIV, referral to care for individuals with sexually transmitted infections, and distribution of condoms.

The second group of communities will receive all of the HIV prevention methods in the study, but HIV treatment will only be offered to those eligible according to respective national guidelines. The third group of communities will not receive new health care interventions other than the current standard of health care services offered in each country. However,

HPTN Annual Meeting

The HPTN annual meeting will be held May 2–8 at the Marriott Washington Wardman Park Hotel in Washington, DC. 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.

HPTN at CROI 2013

HPTN 043 study results will be presented at the 20th Conference on Retroviruses and Opportunistic Infections in Atlanta, Georgia, March 3-6. HPTN 043 is the first community-randomized trial to test a combination of social, behavioral and structural approaches for HIV prevention and to assess the impact of an integrated strategy at the community level. The study was conducted in 34 communities in Africa (South Africa, Tanzania and Zimbabwe) and 14 communities in Thailand. Three other [HPTN abstracts](#) (046, 052 and 061) were also accepted at CROI.

Harlem Site Activated for HPTN 067



Congratulations to the HPTN 067/ADAPT study team for activating the Harlem Prevention Center in New York City on January 14. The Harlem

the research team will endeavor to ensure that all standard health services are present and available. The groups will be replicated in each country and the rate of new HIV infections will be compared between the groups at the end of the study.

"We are not coming to terms with this epidemic. At the moment, for every one person on treatment there are two new infections. We need a complete re-think of the way we deliver prevention and care," said Dr. Helen Ayles, Project Coordinator for ZAMBART.

"PopART will make it possible for universities, departments of health, non-governmental organizations and communities to work together to find novel ways of reducing the transmission of HIV — and we hope it will result in better health for our people," said Professor Nulda Beyers, the Director of the Desmond Tutu TB Centre (DTTC) at Stellenbosch University.

HPTN 071 is led by investigators at the London School of Hygiene and Tropical Medicine (LSHTM) in collaboration with Imperial College London, the Zambia AIDS Related Tuberculosis (ZAMBART) Project and the Desmond Tutu TB Centre (DTTC) at Stellenbosch University, South Africa.

HPTN 068 Completes Enrollment

Can financial incentives encourage young women to stay in school and reduce their HIV risk? That's a question the HPTN 068 study is trying to answer. Nearly 2,500 young women (aged 13-20 years) from the Mpumalanga province of South Africa have been enrolled in HPTN 068. The study is trying to determine whether providing cash transfers to young women and their household, conditional on school attendance, (known as Conditional Cash Transfer, or CCT), can reduce structural barriers to education, increase school attendance, and as a result, decrease HIV risk. Research has shown that CCTs have been used successfully for improving other health outcomes; however, their use for HIV prevention is new.

"This type of innovative approach to HIV prevention among young women in high prevalence areas is urgently needed," says Audrey Pettifor, MD, HPTN 068 Protocol Chair. "In South Africa, young women are infected with HIV at 3-4 times the rate of young men. Preventing HIV infection in this population is essential to stopping the cycle of new infections and dramatically reducing the cost of HIV treatment and its impact on society."

Studies in Africa have shown that young women who do not complete high school are almost four times more likely to be HIV-infected compared to those who do complete their secondary education. Research has also demonstrated that better educated women are more likely than their less educated peers to delay having sex, to use condoms more often, to delay marriage and childbearing, to have fewer children and healthier babies, and to enjoy better earning potential.



Many poor families are unable to send their children to school because of the financial burden. In South Africa, 65% of young people who are not in school say they do not have enough money to continue their education. Providing CCTs to

Prevention Center will be enrolling 180 men who have sex with men and transgender women (MSM/TGW). 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. The Harlem Prevention Center joins the Emavundleni Centre enrolling women who have sex with men (WSM) in Cape Town, South Africa and the Silom Community Clinic enrolling MSM/TGW in Bangkok, Thailand. The Cape Town site has completed enrollment and Bangkok expects to complete enrollment in May.

HPTN 069 Launches Website

The HPTN 069/ACTG 5305 NEXT-PrEP website www.nextprepstudy.org is up and running. Available in English and Spanish, the new site is designed to provide information about the study and help with recruitment efforts. NEXT-PrEP (Novel Exploration of Therapeutics for Pre-Exposure Prophylaxis), is an HIV prevention study designed to learn more about the safety and acceptability of four different drug combinations when used as PrEP by men who have sex with men and by women who have sex with men. The drugs are maraviroc (also called Selzentry or MVC), emtricitabine (also called Emtriva or FTC), and tenofovir (also called Viread or TDF). The NEXT-PrEP study is an important next step in helping to determine if future research should be done to see if different ARVs can be used as PrEP. This will be the first study to see if maraviroc is safe and tolerable when used by HIV-negative people as an



HIV testing station for HPTN 068

families to help young women attend school makes it more likely that they will be able to complete their high school education.

“We know reducing economic barriers to an education by providing a cash stipend, conditional on school attendance,

increases school attendance,” says Pettifor. “What HPTN 068 is trying to determine is if increased school attendance will also result in fewer HIV infections. What we learn from this study will be instrumental in determining future HIV prevention strategies for young women who are most at risk for HIV.”

Enrollment for HPTN 068 began in March 2011. The study is expected to be completed in December 2014.

HPTN 067 (ADAPT) Uses Next Step Counseling to Support Open-Label PrEP Adherence

The HPTN 067 (ADAPT) study completed training at all sites on the use of Next Step Counseling (NSC) as a brief, discussion-based, participant-centered strategy to support study product use. The team identified NSC as an adherence support approach in the original protocol and to-date no modifications have been necessary. HPTN 067 is a behavioral study to evaluate the feasibility of intermittent dosing of a pre-exposure prophylaxis (PrEP) regimen. The study aims to identify dosing regimens that foster healthy sexual practices and pill-taking behavior in people at high risk of HIV acquisition. ADAPT is an acronym for Alternative Dosing to Augment PrEP Pill-Taking.

NSC was developed originally by the iPrEx trial’s Adherence Working Group as an alternative to prescription-persuasion based approaches that emphasize expectations for perfect compliance. NSC assumes that adherence is a function of how well informed participants are, how positively (or negatively) they feel about the regimen and the real-world burdens they experience trying to adhere to it, and how skilled they are at negotiating those challenges. NSC uses a process-discussion to help participants identify adherence-related facilitators, barriers, needs and strategies, while intentionally avoiding telling participants what they ‘must’ or ‘should’ do.

HIV prevention strategy. The results of the NEXT-PrEP study will help researchers decide if maraviroc should be tested further to see if it prevents new HIV infections when it is used as PrEP.

Awards

Congratulations to HPTN 043 Protocol Chair Dr. Thomas Coates for his 2013 Elizabeth Fries Health Education Award. Dr. Coates was recognized for his “pioneering



research on HIV related volunteer testing and counseling which has improved HIV related health care, reduced risk behavior and saved lives in vulnerable populations worldwide.” In a letter of congratulations, Fries Foundation Chair James Fries wrote, “We hope that this award will stimulate and inspire more health educators to become advocates and opinion leaders for improved national health and that your role model will further challenge them in these directions.” The award will be featured at the 64th annual SOPHE (Society for Public Health Education) meeting in Orlando, Florida in April. The 2012 conference theme is *The Magic of Health Education: Vision, Imagination & Transformation*.

Coming Soon



20th

[Conference on Retroviruses and Opportunistic Infections \(CROI 2013\)](#)

March 3–6, 2013
Atlanta, GA



National

Women & Girls
HIV/AIDS Awareness Day
Sunday, March 10



National Native

HIV/AIDS Awareness Day
Tuesday, March 20

Hot Off the Press

Hodder SL, Justman J, Hughes J, Wang J, Haley DF, Adimora AA, Del Rio C, Golin CE, Kuo I, Rompalo A, Soto-Torres L, Mannheimer S, Johnson-Lewis L, Eshleman SH, El-Sadr WM, HIV Prevention Trials Network 064 (ISIS) Study Team. **HIV acquisition among women from selected areas of the United States.** *Ann Intern Med.* 2013 Jan 1;158(1):10-18. PMID:23277896

Want to Read More?

HIV Prevention Trials Network
<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

1	INTRODUCE Greet/Rapport, Explain Purpose of Discussion, Seek Permission to continue discussion
2	REVIEW Progress made on strategies identified last visit
3	EXPLORE Explore Product Use Experiences (Facilitators/Challenges); Summarize Context/Experiences
4	TAILOR
5	IDENTIFY NEEDS Explore Needs for Adherence Given Experiences; WHAT would or does make it easier?
6	STRATEGIZE Explore HOW participant could meet or is meeting the needs identified in step 5
7	AGREE Agree on WHICH strategy discussed the participant will continue with or try out; Action plan
8	CLOSE and DOCUMENT Summarize, Thank Participant, Document

GOAL: Create a comfortable environment to talk about experiences with the product

CLIMATE: Supportive, non-judgmental, neutral, reinforcing of open discussion/efforts, avoidance of "fixing," recognition of limited role, and emphasis on participant as a whole person.

METHOD: Exploration of context (experiences, thoughts, beliefs, feelings; information, motivation, skills) to identify needs and promote movement towards building a context that supports product use.

IMPLICIT ASSUMPTION: Participants choose whether or not, or how much, to use the study product. We cannot make them use it, but can support open frank discussions about it.

Using several strategies developed in Motivational Interviewing, counselors work to have participants identify their own reasons for adherence or clarify their reasons for non-adherence. To date, counselors have positively evaluated NSC as appropriate for their participant populations and feasible to implement. Formal evaluation of the approach will include interviews with all counselors to determine acceptability and feasibility from a counselor perspective, while participants will be asked to provide some information about their experiences with NSC at their final CASI survey assessment.

HPTN 067 will provide valuable information about the implementation, feasibility and acceptability of NSC in diverse settings and cultures.

Expanding HPTN's Global Following

The HPTN's Facebook and Twitter social media platforms are helping to draw attention to the Network's research agenda. As of December, 2012 the number of Followers on [Twitter/HIVptn](#) topped 2,700.

[Facebook/HIVptn](#) had more than 900 Likes. The majority of HPTN's Facebook connections are people living outside the U.S. with Thailand, Brazil and Uganda topping the list. Nearly 40 percent of all of HPTN's Facebook Friends state that their primary language is one of 16 languages other than English. A quick look at HPTN's list of Twitter Followers shows a similar trend. The diversity of HPTN's social network connections are likely due in part to support from HPTN's international Community Working Group members and site staff members. That trend is likely influenced by that fact that HPTN posts and shares information about international HPTN studies as well as news of other global HIV prevention research efforts.

The HPTN entered the world of social media in November 2009. Twitter and Facebook pages were originally designed to draw attention to HPTN's domestic research agenda, with the goal of increasing engagement with U.S. AIDS service organizations, advocacy groups, civic organizations and other community groups or individuals who wanted to know more about HIV prevention research in the U.S. That objective was accomplished by sharing updates related to HPTN's domestic study activities, as well as HIV-related news from partner organizations, HPTN's U.S. sites and other appropriate sources. Because social media is designed to build a dialogue and to develop new opportunities to form connections, the HPTN's social media presence has provided the network

with greater insight into questions and concerns about HPTN research, as well as information about new community engagement opportunities. HPTN both organized and participated in twitter chats, webinars and in-person community presentations as a direct result of connections that were established through social media involvement.

Help spread the word and continue to grow our “virtual” audience. If you haven’t done so already, you can start by following [Twitter/HIVpntn](#) and [Facebook/HIVpntn](#), and by sharing posts from both pages within your own social network. When you share the link to HPTN’s website, www.hptn.org, please also include links to [Twitter/HIVpntn](#) and [Facebook/HIVpntn](#). Social media engagement is a dynamic way to foster meaningful dialogue and we value your feedback. If you have suggestions about our social media outreach or any other HPTN community engagement efforts, please send your comments to gking@fhi360.org.



HPTN at NAESM: CWG Members Receive Emerging Leaders Award

The HPTN congratulates community working group members Christopher Watson and Blake Rowley for receiving Emerging Leaders Awards at the 10th annual National African American MSM (NAESM) Leadership Conference on HIV/AIDS and other Health Disparities in Atlanta, Georgia. Watson received the Gerald Ludd Award and Rowley received the Harold Philpot Award. Both were recognized for their significant efforts in HIV/AIDS prevention targeting the African American MSM community.

HPTN was proud to support the 2013 NAESM Conference. This year’s conference leadership theme was “10 Years and the Dialogue Continues: HIV Prevention as Social Justice for Black Gay Men/MSM 2013 and Beyond.” The HPTN presented two oral abstracts: *Exploring the HPTN’s U.S. scientific agenda: Are PrEP studies and community-wide test and link to care strategies the key to curbing the HIV epidemic among Black men who have sex with men*, and *Developing a cultural humility training model for use at clinical research sites that conduct studies focusing on Black MSM*.



A Closer Look

Network Spotlights

Jim Hughes

Jim Hughes joined SCHARP and the HPTN in 2000. He’s been the lead statistician on HPTN 039, 064, 067, and 068. He was also the lead statistician on Connie Celum’s Partners/HSV2 clinical trial in discordant couples and the PREVEN community randomized trial of STD prevention in Peru. Jim chairs the SMC for the HPTN.

In addition to HIV prevention trials, Jim teaches introductory statistics for public health majors, both graduate and undergraduate.

Jim received his undergraduate degree in Wildlife Biology from the University of Maine and his PhD in Statistics from the University of Washington in 1993. He has been on the faculty of Biostatistics at University of Washington since 1993.

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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Jim can't say that he always wanted to be a statistician, but he did always want to be a scientist. "The great thing about being a statistician is that you can participate in and contribute to so many different areas of science. As John Tukey (a famous statistician) said –'The great thing about statistics is that you get to play in everyone's backyard'."

Jim is married to Pat Livingston and has two children (Paul and Riley), and two cats. When he's not working, Jim enjoys fishing (particularly fly-fishing), hiking and skiing.

Ayana Moore



Ayana is a Senior Clinical Research Manager at HPTN. Prior to HPTN, she was a regulatory consultant to pharmaceutical and biotech companies. Since joining the HPTN, she has managed numerous clinical research studies in the U.S., Africa, Asia, Europe, and South America. She has overseen the development of a number of clinical research protocols, developed data collection instruments, performed on-site trainings for clinic staff, and provided general study management and oversight throughout the trials.

Ayana is currently enjoying her work on HPTN 071 (PopART). "It will test a fascinating integration of numerous HIV prevention strategies on a very large scale. If effective, it has the potential to completely change the HIV prevention landscape and make an indelible mark on prevention strategies worldwide."

Ayana says she was drawn to HIV prevention work because it gives her the opportunity to help combat a number of social ills such as stigma, discrimination, and gender inequality. "The fight against HIV has brought with it the fight for improved social justice."

Ayana has a background in mathematics, with a Master's degree in Applied Math. After completing her master's thesis on mathematical modeling of molecular motors, she transitioned into cell and molecular biology research and earned a PhD in Physiology and Biophysics.

Away from the office, Ayana enjoys volunteer work, sports (running and tennis), and attending live music and theater performances.