

# Prevention NOW!

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# HPTN Science: Focus on Women



Photo courtesy of the HPTN, Kampala, Uganda, 2017

For more than 30 years, the global HIV epidemic has severely affected families, communities and countries. Worldwide, HIV has taken its greatest toll on women of all ages. Nearly half of the 36 million people living with HIV (PLHIV) in the world are women. In sub-Saharan Africa, more than 60% of all PLHIV are women. Young women in southern Africa between ages 14 to 24 years are at alarming risk of and are most vulnerable to HIV infection.

In response to this compelling need, the HPTN is focused on the prevention of HIV in women at risk for infection. Nearly 40,000 women have been enrolled in HPTN trials in ongoing and recently completed studies worldwide. Many of the HPTN studies are evaluating interventions that - if proven to be effective-will empower women in protecting themselves from HIV infection. For example, appreciating the difficulty of adhering with daily oral pre-exposure prophylaxis (PrEP), the HPTN is evaluating new promising drugs for PrEP that do not need to be taken daily. These include injectable long-acting antiviral agents and monoclonal antibodies. In one study, HPTN 084, injectable long-acting cabotegravir will be evaluated for prevention of HIV among approximately 3,500 women from sub-Saharan Africa. In addition, the HPTN is collaborating with the HIV Vaccine Trials Network to evaluate the potential of monoclonal antibodies for prevention. More than 1,100 women from sub-Saharan Africa are already enrolled in the HVTN 703/HPTN 081 study.

The HPTN is also pursuing research to optimize the use of prevention methods that have been shown to work. This includes the optimization of oral PrEP using tenofovir/emtricitabine (Truvada) for young women in southern Africa. The HPTN 082 study is being conducted in Zimbabwe and South Africa to evaluate whether young HIV-uninfected women who are at risk for HIV infection will accept PrEP and achieve sufficient adherence using multiple interventions to enhance adherence.

Additionally, the HPTN 071 (PopART) study, the largest HIV prevention study ever conducted, is a community randomized study in Zambia and South Africa that includes door to door counseling and testing, as well as linkage to care and rapid initiation of treatment. More than 120,000 women have received this package of interventions in this study.

While women in sub-Saharan Africa have borne the burden of the HIV epidemic, women in the United States also continue to acquire new HIV infections. Therefore, the HPTN is committed to ensuring that new promising prevention interventions are safe and acceptable to women in the U.S. Recent HPTN studies have evaluated the safety and acceptability of injectable rilpivirine and cabotegravir among women in the U.S. as well as Africa.

Prevention of HIV infection among women is an urgent global priority. The HPTN is leading a vibrant research agenda to protect women worldwide from HIV infection.

# HPTN 084 Stakeholder Meeting

The HPTN and WITS RHI co-sponsored a stakeholder meeting for HPTN 084 (a study evaluating long-acting injectable cabotegravir for pre-exposure prophylaxis [PrEP] in women) in Cape Town, South Africa August 10-11, 2017. Approximately 150 attendees from seven countries attended the meeting which consisted of representatives from civil society groups, research staff, governmental and nongovernmental organization, and community members. The countries represented were Botswana, Kenya, Malawi, South Africa, Swaziland, Uganda, and Zimbabwe.

On the first day of the meeting, HPTN Leadership and Operations Center Director Dr. Nirupama Sista led a demonstration on basic clinical trial research concepts to address frequently-asked questions from research teams. These included concepts like placebo-controlled trials versus active-controlled trials and non-inferiority and superiority study designs. She also gave a presentation on PrEP and the potential of long-acting injectable cabotegravir as a new PrEP agent. Finally, the HPTN team from FHI 360 conducted a "Word on the Street" session which allowed attendees to discuss their prior knowledge of PrEP, injectables, HPTN 084, and other study-related topics.





Dr. Mina Hosseinipour and Dr. Sine ad Delany-Moretlwe

Day two of the meeting included a "real talk" session facilitated by Community Working Group co-chair Ntando Yola and Definate Nhamo from Pangaea Zimbabwe AIDS Trust (PZAT) which allowed attendees to ask questions about the study. Dr. Nyaradzo Mgodi from the Spilhaus CRS facilitated an interactive session on the study's objectives, focusing on the role of women in society and in the study. The protocol co-chairs Dr. Sinead Delany-Moretlwe and Dr. Mina Hosseinipour presented the details of the HPTN 084 study.





Dr. Nyaradzo Mgodiand Ntando Yola

HPTN 084 will be implemented throughout sub-Saharan Africa at 20 clinical research sites in seven countries. The study will enroll approximately 3,200 women ages 18-45 who are at risk for acquiring HIV. Learn more about HPTN 084 at <a href="https://hptn.org/research/studies/hpt

# 2017 HPTN Regional Meeting

The HPTN will hold a regional meeting for African sites October 18-20, 2017 in Johannesburg, South Africa. The intended audience includes African CTU/CRS staff participating in HPTN 071, 075, 076, 077, 081, 082, and 084; Principal Investigators/IORs; and CRS key study staff (study coordinators, study clinicians/nurses, laboratory representatives, pharmacists, and community staff responsible for community engagement and cohort recruitment & retention). Other attendees will include HPTN leadership, invited speakers, sponsors/NIH, and potential new partners, investigators, & sites.

The goals of the regional meeting are to:

- 1. Enhance and support new ideas generation by African investigators
- 2. Enhance partnership and foster engagement between HPTN leadership and site leadership and staff
- 3. Enhance the quality of study conduct through sharing successful experiences from sites implementing key HPTN trials in sub-Saharan Africa

Read more about the 2017 Regional Meeting at <a href="https://hptn.org/news-and-events/meetings/2017-hptn-regional-meeting">hptn.org/news-and-events/meetings/2017-hptn-regional-meeting</a>.



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# HPTN 065 Cost-Effectiveness Analysis Presented to Nobel Prize-winning Economists

On behalf of the HPTN 065 study team, Blythe Adamson, PhD candidate, Pharmaceutical Outcomes Research and Policy Program, University of Washington, presented findings from the <a href="HPTN 065">HPTN 065</a> cost-effectiveness analysis to a group of Nobel Prize-winning economists at the Lindau Nobel Laureate Meeting in Germany on August 26. Her analysis indicated that financial incentives for viral suppression, as used in HPTN 065, were cost-saving compared to standard of care using a societal perspective and

were cost-effective from a healthcare sector perspective. The economic model also estimated that financial incentives prevented eight percent of HIV transmissions to sexual partners during the two-year intervention. During the five-day meeting, Ms. Adamson discussed the HPTN 065 results and other research ideas with attendees who consisted of 19 Nobel prize winners and more than 200 economics PhD students from around the world.

# HPTN Substance Use Scientific Committee SUMI Tool Launches

The HPTN Substance Use Scientific Committee (SUSC) has developed a web-based, interactive Substance Use Measurement Identification (SUMI) tool to assist researchers to identify the proper biomarkers and behavioral survey tools to assess substance use in the HIV setting. The tool is free and is available to researchers around the world. Experts from different areas of the Network collaborated on the SUMI tool project. The tool is available at: <a href="https://hptn.org/researchtools">https://hptn.org/researchtools</a>. The SUSC is planning a webinar on the SUMI tool for November 21 from 3:00pm-4:30pm EST.

### HPTN Scholars Program is Now Accepting Applications

The HPTN Scholars Program, instituted in 2010 to involve more under-represented minority researchers into the HPTN, is now accepting applications for the 9<sup>th</sup> Domestic Cohort and the 4<sup>th</sup> International Cohort. If you are interested in applying, please review the **Domestic** and **International pages of the Scholars'** section of the HPTN website for preliminary eligibility information. Application materials are now available on the HPTN website on those same web pages. We look forward to reviewing your proposals and applications!



The Domestic Cohort 6 Scholars: (Left to right): Dr. Florence Momplaisir, Dr. Brandon Brown, Dr. Tonia
Poteat, Dr. Dustin Duncan, and Dr. Mandy Hill

### HPTN 068 Abstract Chosen to Be Part of UNAIDS' Science

#### Now and HIV This Month

The HPTN 068 mixed methods article by Co-Investigator Catherine MacPhail et al., "Cash transfers for HIV prevention: what do young womens pend it on? Mixed methods findings from HPTN 068" (BMC Public Health, 11 2017 July), was recently highlighted by UNAIDS Science Now. The abstract of the article was selected to be part of the 8th issue (August 2017) of HIV This Month, available at <a href="https://sciencenow.unaids.org/post/elimination-gender-inequalities-17">https://sciencenow.unaids.org/post/elimination-gender-inequalities-17</a>. There is an editorial preceding the abstract focused on eliminating gender inequalities, entitled "How to enhance adolescents' autonomy and self-esteem. Cash and schooling help." HPTN 068 was a Phase III study to determine whether providing cash transfers to young women and their household (conditional on school attendance) reduced their risk of acquiring HIV. Results showed that there was no difference in HIV acquisition between the young women who received the cash transfer and those who did not, however school attendance was high in both arms.

# Study Shout Outs

#### HPTN 074 Rolls Out Study Extension

HPTN 074, a vanguard study investigating an integrated intervention for People Who Inject Drugs (PWID) in Ukraine, Indonesia, and Vietnam, has begun re-enrolling some participants for a nine- to twelve-month study extension. Although the main study enrolled both HIV-positive index participants with up to five HIV-negative injecting network partners each, only the HIV-positive index participants are being re-enrolled in the study extension to assess the durability of the integrated intervention. The intervention includes ART at any CD4 count, psychosocial counseling and systems navigation. The Ukraine and Indonesia sites have already re-enrolled many of their index participants for the study extension, with Vietnam to follow this month. The study team has submitted baseline results for CROI 2018.

#### HPTN 075 Data Milestones

HPTN 075, a study assessing the feasibility of HIV prevention cohort studies among men who have sex with men (MSM) in sub-Saharan Africa (Cape Town and Soweto, South Africa; Kisumu, Kenya; Blantyre, Malawi), has completed data collection. The team concluded study visits and qualitative work as of August 25. The team has already disseminated early results (AIDS 2016 and IAS 2017) and plans to release data in the form of three oral presentations and one poster presentation at the upcoming AIDS Impact conference in Cape Town this November. The team also plans to develop the paper addressing the primary objectives of the study, among others. The HPTN Laboratory Center (LC) has submitted two abstracts on HPTN 075 for CROI 2018. Finally, in collaboration between the HPTN 075 team and the HPTN SUSC, a major review paper was recently completed: Sandfort, T. G. M., Knox, J. R., Alcala, C., El-Bassel, N., Kuo, I., & Smith, L. R. (2017). "Substance use and HIV risk among men who have sex with men in Africa: A systematic review." JAIDS, 76(2), 34-46. Be on the lookout for further results dissemination from the HPTN 075 team.

HPTN 078 To Utilize Mobile App Advertising for Recruitment

HPTN 078, a U.S.-based study to identify, recruit, and link MSM to HIV care and help them achieve and maintain viral suppression, will utilize mobile application advertising for recruitment. HPTN 078 takes place in four U.S. cities (Atlanta, Baltimore, Birmingham, and Boston) and will screen approximately 2,700 MSM over the age of 16. Of the 2,700 MSM screened, 356 HIV-infected MSM who are not virally suppressed will be enrolled into one of two study arms and followed for 24 months.



The advertisement campaign will target different demographic parameters of study participants and advertisements will be featured on apps such as Grindr, Jack'd, Adam4Adam, and Romeo.

Advertisements will navigate to a web-based contact form that will allow potential participants to enter their information so sites may contact them regarding participation in the study.

# Network Member Spotlight



Viet Anh Chu is the Research Manager at The University of North Carolina at Chapel Hill's office in Vietnam. He manages HPTN 074 at Pho Yen CRS in Thai Nguyen, Vietnam and HPTN 083 at Yen Hoa CRS in Hanoi, Vietnam. He holds an undergraduate degree in Public Health from Hanoi University of Public Health, Vietnam. He completed his Masters of Public Health at the University of Melbourne, Australia. His research focuses on HIV prevention for PWID, MSM, and transgender women.

#### How did you first get involved with the HPTN?

In 2014, our site (Pho Yen CRS in Thai Nguyen, Vietnam) was one of the three sites selected to implement the HPTN 074 study. I was the study coordinator for HPTN 074 in Vietnam. I provided technical support for the study's activities, supervised the study on a daily basis - including recruitment and retention activities - and provided technical and administrative support for the local Community Advisory Board. Since then I have been a member of the HPTN team - the most amazing team for HIV prevention.

#### Read More

# Awareness Days



National Latinx AIDS Awareness Day #NLAAD

October 15

# Hot off the Press

Stoner MCD, Edwards JK, Miller WC, Aiello AE, Halpern CT, Julien A, Selin A, Hughes JP, Wang J, Gomez-Olive FX, Wagner RG, MacPhail C, Kahn K, Pettifor A. <u>The effect of schooling on age-disparate relationships and number of sexual partners among young women in rural South Africa enrolled in HPTN 068.</u> J Acquir Immune Defic Syndr. 2017 Sep 11. doi: 10.1097/QAI.0000000000001544.

Bock P, Phiri C, Pwowar-Manning E, Kosloff B, Mandla N, Young A, James A, Schaap A, Scheepers M, Donnell D, Griffith S, El-Sadr W, Shanaube K, Beyers N, Hayes R, Fidler S, Ayles H; HPTN 071 (PopART) Study Team. <u>Understanding low sensitivity of community-based HIV rapid testing: experiences from the HPTN071 (PopART) trial in Zambia and South Africa</u>. J Int AIDS Soc. 2017 Aug 29;20(Suppl 6):19-27. doi: 10.7448/IAS.20.7.21780.

Ranganathan M, MacPhail C, Pettifor A, Kahn K, Khoza N, Twine R, Watts C, Heise L. <u>Young women's perceptions of transactional sex and sexual agency: a qualitative study in the context of rural South Africa.</u> BMC Public Health. 2017 Aug 22;17(1):666. doi: 10.1186/s12889-017-4636-6.







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