

Prevention NOW!

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Jonathan Lucas presenting on stakeholder engagement for HVTN 703/HPTN 081 (The AMP Study)

AIDS 2016: ICYMI

The HPTN presented findings from six studies: HPTN 068, 069, 071, 073, 075, and HVTN 703/HPTN 081 (AMP) at AIDS 2016 - 21st International AIDS Conference which brought together about 18,000 people from 180 countries with a focus on implementation – moving scientific advances into practice. With more than 60% of people living with HIV remaining without antiretroviral therapy; including women and girls, men who have sex with men, transgender people, sex workers, young people, and people who use drugs and other marginalized groups remain under-prioritized in the response; investments in HIV prevention research appear to have flattened; and widespread violations of human rights including criminalization continue to undermine effective responses, this year's theme was Access Equity Rights Now. It's a call to action to work together and reach the people who still lack access to comprehensive treatment, prevention, care and support

HPTN Oral Presentation Highlights

Kathleen Kahn presented <u>The Impact of a Cash Transfer on Young South African Women's Mental Health: HPTN 068</u>, which concluded that <u>HPTN 068</u> did not show an impact of receiving a cash transfer (conditional on school attendance), on depression, anxiety or hope for the future.

HPTN 069 released results on the women's cohort in the study. Roy Gulick presented HPTN 069/ACTG

A5305: Phase II study of Maraviroc-Containing Regimens for HIV PrEP in United States (U.S.) Women, which concluded that maraviroc-containing regimens were safe and well-tolerated compared to the control regimen of tenofovir + emtricitabine (Truvada). Although only 2/3 of the women had detecable study drug concentrations, no HIV infections were identified.



Darrell Wheeler, LaRon Nelson and Christopher Hucks-Ortiz

HPTN 073 had three oral presentations; Darrell Wheeler presented Correlates for Levels of Self-reported PrEP Adherence Among Black Men Who Have Sex with Men (BMSM) in 3 U.S. Cities. HPTN 073 demonstrated consistency between self-report and biological markers of adherence for oral PrEP among BMSM in the U.S. The new findings confirm the prior study report at CROI 2016 that showed high uptake and self-report of adherence of oral PrEP by participants in this study. Christopher Hucks-Ortiz presented <u>HPTN 073:</u> Successful Engagement of Black MSM Into a **Culturally Relevant Clinical Trial for Pre-Exposure** Prophylaxis (PrEP) and Lisa Hightow-Weidman presented Incidence and Correlates of STIs Among Black Men Who Have Sex With Men Participating in a US PrEP study.

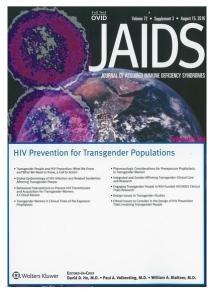
HVTN 703/HPTN 081 (The AMP Study) held <u>The Amazing World of Antibodies: Secrets That Could Spell the End of The HIV Epidemic</u>, a presentation and Q&A session in the Global Village. Along with this session Jonathan Lucas presented <u>Engaging Community Stakeholders in Preparation for HVTN 703/HPTN 081, an Antibody Mediated Biomedical HIV Prevention Trial in sub-Saharan Africa (SSA).</u> As Jonathan mentioned in his presentation, "Stakeholder engagement enables generous local insight into successful implementation of complex, biomedical HIV prevention interventions, and adds value to transparent, authentic dialogue about a wide range of HIV trial considerations."

Injectable PrEP: Where are We? Perspectives and Ways Forward

Along with the accepted abstracts, the HPTN hosted <u>Injectable PrEP: Where are We? Perspectives and Ways Forward</u>, a satellite session to discuss ongoing and planned studies that utilize injectable PrEP agents and monoclonal antibodies. The two-hour event also included the design of the various studies and timelines for anticipated results. More than 175 people participated in an excellent session that included presentations from Wafaa El-Sadr, Kenneth Mayer, Nyaradzo Mgodi, Mike Cohen, and Tonia Poteat. The session concluded with the launch of the HPTN JAIDS Supplement <u>HIV Prevention for Transgender Populations</u>.



Kenneth Mayer, Nyaradzo Mgodi, Wafaa El-Sadr, Myron Cohen and Tonia Poteat at the HPTN Satellite Session



HIV Prevention for Transgender Populations

The HPTN has been committed to the rights and health of transgender persons. To help reinforce the network's focus on the state of the HIV epidemic among transgender individuals, the HPTN has published the JAIDS Supplement HIV Prevention for Transgender Populations. The articles in the supplement build on presentations and discussions from the transgender workshop held at the 2015 HPTN Annual Meeting. HPTN investigators Kenneth Mayer, MD and Beatriz Grinsztejn, MD, PhD along with HPTN coprincipal investigator, Wafaa EI-Sadr were guest editors for the supplement. The following articles are included in the supplement:

- Transgender People and HIV Prevention: What We Know and What We Need to Know, a Call to Action.
- Global Epidemiology of HIV Infection and Related Syndemics
 Affecting Transgender People.
- <u>Behavioral Interventions to Prevent HIV Transmission and Acquisition for Transgender</u> Women: A Critical Review.
- Transgender Women in Clinical Trials of Pre-Exposure Prophylaxis.
- Pharmacologic Considerations for Preexposure Prophylaxis in Transgender Women.
- Integrated and Gender-Affirming Transgender Clinical Care and Research.
- Engaging Transgender People in NIH-Funded HIV/AIDS Clinical Trials Research.
- Design Issues in Transgender Studies.
- Ethical Issues to Consider in the Design of HIV Prevention Trials Involving Transgender People.

HPTN 052 Final Results
Published in New
England Journal of
Medicine

Final results from HPTN 052 were published in the New England Journal of Medicine on July 18. The final results showed a 93 percent reduction of HIV transmission when the HIV-infected person started ART when their immune system was relatively healthy. HIV



ORIGINAL ARTICLE

Antiretroviral Therapy for the Prevention of HIV-1 Transmission

Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H., Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D., Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D., Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Filotto, M.D., Sheela V. Godbole, M.D., Suwat Chariyalertsak, M.D., Breno R. Santos, M.D., Kenneth H. Mayer, M.D., Irving F. Hoffman, P.A., Susan H. Eshleman, M.D., Ph.D., Estelle Piwowar-Manning, M.T., Leslie Cottle, B.S., Xinyi C. Zhang, Ph.D., Joseph Makhema, M.B., B.Ch., Las A. Mills, M.D., Ravindre Panchia, M.B., B.Ch., Sharlaa Faesen, M.B., B.Ch., Joseph Eron, M.D., Joel Gallant, M.D., Diane Havlir, M.D., Susan Swindells, M.B., B.S., Vanessa Elharrar, M.D., David Burns, M.D., Taha E. Taha, M.B., B.S., Karin Nielsen-Saines, M.D., David D. Celentano, Sc.D., Max Essex, D.V.M., Sarah E. Hudelson, B.S., Andrew D. Redd, Ph.D., and Thomas R. Fleming, Ph.D., for the HPTN 052 Study Team July 18, 2016 [DOI: 10.1056/NEJMoa1600693

transmission from HIV-infected study participants to their partners was not observed when viral replication in the treated individual was stably suppressed by ART. HPTN 052 was a randomized, controlled trial designed to evaluate the effectiveness of antiretroviral therapy (ART) to prevent the sexual transmission of HIV in serodiscordant couples. Learn more about HPTN 052

SHOUTOUTS

Finals words on the 2016 HPTN/IMPAACT Annual Meeting: "The HPTN/IMPAACT Annual Meeting provides an opportunity to learn about efforts to expand the HIV prevention toolkit while recommitting ourselves to research to understand, treat and ultimately end the HIV/AIDS pandemic," said Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases. "I applaud the many volunteers, researchers, community members and health professionals working with the HPTN and IMPAACT Network to support and participate in this vital area of scientific research."



Dr. Fauci at the 2016 HPTN/IMPAACT Annual Meeting

Congratulations to the HPTN 075 team for completing enrollment on July 12! HPTN 075 aims to determine the feasibility of recruiting and retaining MSM in a multicountry prospective cohort study in preparation for HIV prevention studies in sub-Saharan Africa.

All four <u>HPTN 078</u> sites were activated in the spring and both deep-chain respondent-driven sampling (DC-RDS) and case management activities are underway. To date, 72 individuals have participated in the DC-RDS activities and 4 people have been enrolled into the randomized case management intervention. We are on target for DC-RDS and plan to expand our recruitment activities to include both DC-RDS and direct recruitment beginning in September 2016.



The AMP Studies have enrolled a combined 337 participants with <u>HVTN 703/HPTN 081</u> enrolling 44

The HPTN 082 team is preparing for study start and held study trainings in Harare, Zimbabwe (Spilhaus CRS) and Johannesburg (Ward 21 CRS) and Cape Town (Emavundleni CRS), South Africa. HPTN 082 is designed to assess characteristics of young women who accept versus decline pre-exposure prophylaxis (PrEP) at enrollment. The study will also compare adherence to PrEP between women who are randomized to receive standard adherence support and those receiving enhanced adherence support.

participants. The AMP Studies are testing whether giving people an investigational anti-HIV antibody called VRC01 as an intravenous infusion every eight weeks is safe, tolerable and effective at preventing HIV infection.

NETWORK MEMBER SPOTLIGHT

Dr. Chirenje is a professor of obstetrics and gynecology at the College of Health Science at the University of Zimbabwe in Harare. His main research interest is HIV prevention clinical trials in women with particular emphasis on microbicides and pre-exposure prophylaxis development and cervical cancer screening/treatment of pre-cancer lesions in low resource settings. He is also principal investigator for a large U.S. National Institutes of Health-funded HIV clinical trials unit (UZ-UCSF).

How did you first become involved with the HPTN?

I first became involved with the HPTN when I joined the HPTN 035 protocol writing team and was a site principal investigator (PI) for HPTN 035 during its execution. As Clinical Trials Unit (CTU) PI during HPTN 052, I assisted our site with study conduct. I was a member of the protocol writing teams for HPTN 076 and HPTN 082. Currently I am a member of the HPTN 084 protocol writing team. I am site PI for HPTN 076 and Co-Investigator for HPTN 081. Read more



HOT OFF THE PRESS

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