

# Prevention NOW!

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December 1 is World AIDS Day, a day for people worldwide to unite in the fight against HIV, show support for people living with HIV and commemorate those we lost from the disease. This year's theme is "Increasing Impact Through Transparency, Accountability, and Partnerships". As we look back on 2017, we are reminded of the need to develop and evaluate new prevention interventions to help reach the Joint United Nations Program on HIV/AIDS' (UNAIDS) ambitious 90-90-90 goals. With nearly two million new HIV infections worldwide in 2016, the HPTN research agenda remains focused on the use of integrated strategies to achieve a successful public health impact and the development of new options for preexposure prophylaxis (PrEP).

During the past year, findings from two HPTN studies evaluating PrEP options were published. HPTN 076 demonstrated long-acting injectable rilpivirine was safe and acceptable among HIV-uninfected women. HPTN 077, a study to evaluate the safety, tolerability, pharmacokinetics and acceptability of long-acting injectable cabotegravir (CAB LA), demonstrated the drug was well-tolerated in HIV-uninfected low-risk men and women. This study provided critical information that informed the selection of the dose of cabotegravir to be used in the two recently-launched HPTN studies evaluating the efficacy and safety of CAB LA in men who have sex with men (MSM) and transgender women who have sex with men (HPTN)

083) and among women in sub-Saharan Africa (HPTN 084). If found to be safe and effective, CAB LA may be easier for some people to adhere to than daily oral tenofovir/emtricitabine (Truvada®). At the same time, another study, HPTN 074, which evaluated treatment as prevention combined with harm reduction strategy among people who inject drugs, completed follow-up. Preliminary results are expected to be available over the coming weeks.

Other active HPTN studies are addressing important questions regarding the use of antiretroviral therapy (ART) for prevention among MSM with unsuppressed viral loads in the U.S. (HPTN 078), the evaluation of daily oral Truvada® as PrEP as a primary prevention strategy for young southern African women (HPTN 082), and the feasibility of HIV prevention cohort studies among MSM in sub-Saharan Africa (HPTN 075).

The Network's collaboration with the HIV Vaccine Trials Network (HVTN) continues with two ongoing studies investigating the safety and efficacy of VRC01, a broadly neutralizing monoclonal antibody (bnAb). HVTN 703/HPTN 081 and HVTN 704/HPTN 085, collectively known as the Antibody Mediated Prevention-or AMP-studies, are the first to evaluate whether a bnAb will be effective in the prevention of HIV among at-risk populations.

Finally, <u>HPTN 071</u> (PopART), a large study engaging nearly one million people in Zambia and South Africa, will reach an important landmark by the end of December with completion of the last round of its combination prevention strategy. PopART is anchored in universal household HIV testing and linkage to immediate antiretroviral treatment initiation with the goal of reducing HIV incidence. The landmark study will be completed next year, with primary results anticipated by early 2019.

On this World AIDS Day, let us take a moment to celebrate our collective achievements while reaffirming our mission and commitment to the successful elimination of HIV acquisition and transmission, and a world free from the threat of HIV and AIDS.

Myron Cohen, MD Wafaa El-Sadr, MD, MPH HPTN Principal Investigators

A World AIDS Day Vide o Message



# Giving Women Control of HIV Prevention: How Injectable PrEP Could Change Everything





By Sinead Delany-Moretlw e

As a South African, HIV prevention is a very real and personal issue. I completed my medical training in

South Africa at a time when HIV incidence was rising. The hospital wards were full of young people, including women who should have had futures ahead of them and yet for whom we could do very little. Antiretrovirals were in their infancy and had not yet reached South Africa. That experience for me as a clinician was profound. Even now, it is impossible to ignore the impact that HIV has on women in our region, particularly young women. Nearly half of the 36 million people living with HIV (PLHIV) in the world are women, and in sub-Saharan Africa, more than 60 percent 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 the infection.

As a mother of a young woman myself, I am inspired by the idea that she and her generation will have something we were not able to offer their mothers: a choice of safe and effective HIV prevention products that are under the control of women.

Over the years, the field has advanced tremendously and we now have a wealth of technologies that we are evaluating. We have learned a lot about how to do HIV prevention research with women in sub-Saharan Africa, and finally we have a prevention product, oral pre-exposure prophylaxis (PrEP), which is directly under women's control. Unfortunately, many of the same factors that shape women's risk for HIV like gender inequality and violence against women, stigma and poverty, also influence their ability to access and use existing prevention products effectively. While there is still much work to do to change the underlying social context within which women live, there are things we can do now to evaluate strategies to improve the uptake and adherence to oral PrEP, and use the lessons from oral PrEP to help us plan for the introduction of new HIV prevention products.

Women need HIV prevention products they can integrate into their busy lives. Condoms or pills may be appropriate for some women at some stages of their lives, but many desire a longer acting product that is discrete and does not require daily use. For many women in sub-Saharan Africa, storage of prevention products is an issue where privacy is limited, and where violence or stigma may be the consequence of inadvertent disclosure. A safe and effective long acting injectable could add to the HIV prevention tool kit, and would be highly acceptable in populations that already have extensive experience of injectable contraception.

It is very exciting we are undertaking HPTN 084, a trial to assess the safety and efficacy of long-acting injectable cabotegravir compared to oral tenofovir/emtricitabine (Truvada®). HPTN 084 is an incredibly important study for women in the African region, and will enroll 3,200 women from 20 sites in seven countries in sub-Saharan Africa. Women will be randomly allocated to receive either cabotegravir or tenofovir/emtricitabine and will be followed up for an average of three and a half years. We will learn an enormous amount about both products through this trial, as well as women's preferences for each of them.

It is a huge privilege for me to work on such a collaborative effort across communities, countries and continents. This week we took an important first step and enrolled our first participant. The enrollment marks the start of a long journey together that we hope will ultimately yield an important result for HIV prevention for women in Africa.

Sinead Delany-Moretlwe, MBBCh, Ph.D., DTM&H, HPTN 084 protocol chair and research director at Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg, South Africa

#### HPTN Hosts Second Regional Meeting





The HPTN held its second regional meeting October 18-20 in Johannesburg, South Africa for Network sites located in sub-Saharan Africa. The meeting focused on study progress, as well as visions for the future of the HPTN's mission.

HPTN Co-Principal Investigator Mike Cohen explained how the Network must be adaptive to changing strategies and new prevention products, explaining that there are now different messages for different populations. Wafaa El-Sadr, HPTN co-principal investigator, also echoed this statement saying it is important for the HPTN to be very precise in the populations targeted at this stage of the HIV epidemic. It is a challenge, she said, because HIV incidence is enormous.

The two-day meeting included protocol meetings, community meetings, interactive breakout sessions, plenaries, facilitated discussions, and a State of the Network address. Attendees consisted of investigators, site staff, and community stakeholders from Kenya, Uganda, Malawi, Botswana, Zambia, Zimbabwe, Swaziland and South Africa. HPTN's partners and funders included colleagues from the NIH, Bill and Melinda Gates Foundation, USAID, ViiV Healthcare and more.

View the Regional Meeting presentations here and check out the photos.

### HPTN Scholars Update



Linda-Gail Bekker addressing audience at HPTN International Scholars information session

The HPTN International Scholars Program held an information session for potential applicants at the recent HPTN Regional Meeting in Johannesburg, South Africa. Speakers included Sten Vermund and David Serwadda from the Scholars Leadership team, Jesne Kistan, a Cohort 1 International Scholar, and Linda-Gail Bekker, a mentor in the program. Applications are now being accepted for the next cycle of scholars. To learn more, click <a href="here">here</a>.

Following the HPTN Regional Meeting, current Scholars convened in Seattle, Washington at the fifth annual HPTN Scholars' Workshop. Scholars met with statisticians, reviewed and presented accomplishments on their projects since the HPTN Annual Meeting in April, learned about statistical design in clinical trials, and engaged in networking opportunities.

#### Shout Outs





Zambia's National Science and Technology Council (NSTC) recently recognized two HPTN members for their contribution to science in the country. Kwame Shanaube and Musonda Simwinga received the 2017 Individual Science and Technology Merit Award at a ceremony in Livingstone, Zambia. Both are based at ZAMBART in Lusaka, Zambia and currently support HPTN 071 (PopART); Kwame is a study manager and Musonda is a social scientist and community coordinator.



Helen Ayles (right) receiving award from AIDS Healthcare Foundation (AHF) representative

Helen Ayles received an award from the AIDS Healthcare Foundation (AHF) as part of the organization's  $10^{th}$  annivers ary celebrations. Helen, HPTN 071 (PopART) site principal investigator at ZAMBART, was recognized for her contribution to the fight against HIV and tuberculos is.

## Network Member Spotlight



Mina Hosseinipour is HPTN 084 protocol co-chair and professor of medicine at the University of North Carolina (UNC) at Chapel Hill School of Medicine and the scientific director of UNC Project-Malawi in Lilongwe, Malawi. After completing her training in internal medicine, infectious diseases, and epidemiology, Mina moved to Lilongwe in 2001 to begin preparations for the HPTN 052 study. In the last 16 years, she has been active in HIV prevention and treatment studies through the NIAID networks as well as independent research. She is also active in training the next generation of Malawian investigators through the UJMT Fogarty Global Health Fellowship and other training programs.

Why is HPTN 084 important to you?

Women represent the largest group of new HIV infections in sub-Saharan Africa. If effective, HPTN 084 has the potential to be a game-changer for HIV prevention in women by providing a choice in prevention products. An injectable prevention product allows an easy, discreet, and female-oriented method that can help women stay uninfected. This puts a woman in control of her own future.

#### Read More

#### Hot off the Press

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