A World AIDS Day Message from the HPTN

On this World AIDS Day, people worldwide are rededicating themselves to raising awareness of the continuing AIDS epidemic. We at the HPTN are reminded of the great strides made in recent years to develop treatment and prevention options for HIV, while remaining grounded and steadfast in our commitment to innovation and identification of new interventions to prevent HIV transmission. Most importantly, we are indebted to the remarkable partnerships, most importantly with the communities we serve, which have enabled our continued success.

With more than two million new HIV infections worldwide in 2015, the need for developing and evaluating new prevention interventions remains critical. Our research agenda is focused on the use of integrated strategies to achieve public health impact and the development of new options for pre-exposure prophylaxis (PrEP).

During the past year, three HPTN research studies were completed. In July, the New England Journal of Medicine (NEJM) published final results of HPTN 052. The findings from HPTN 052 have helped to galvanize a worldwide commitment to a universal “treatment as prevention” strategy for combatting the HIV/AIDS epidemic. Additionally, key results from HPTN 073 were announced at the International AIDS Conference (AIDS 2016) in Durban, South Africa. This study, which assessed uptake of and adherence to oral PrEP for the prevention of HIV infection among Black men who have sex with men (MSM) in the U.S., demonstrated consistency between self-report and biological markers of adherence. HPTN 069/ACTG 5305 results presented at the 23rd Conference on Retroviruses and Opportunistic Infections (CROI) in Boston and AIDS 2016 in Durban, South Africa found maraviroc-containing regimens were as safe and well-tolerated as TDF/FTC in women and MSM.

We have much to look forward to and many studies will be ongoing in 2017. HPTN 071 (PopART), a landmark effort to determine the impact of a combination prevention package on HIV incidence at a community level, continues in the field utilizing a large research team and including an impressive array of stakeholders in South Africa and Zambia where it is being conducted. And HPTN 074 focuses on people who inject drugs, comparing an integrated intervention, including antiretroviral therapy (ART) for prevention with other harm reduction support, to standard of care. The study will complete follow up in 2017.

Several studies evaluating PrEP options will be ongoing or completed in 2017. We eagerly anticipate findings from our two ongoing safety studies of long-acting injectable PrEP candidates, rilpivirine in HPTN 076 and cabotegravir in HPTN 077. Two Phase 3 studies to be initiated in 2017 will
build on the findings from HPTN 077 aiming to evaluate the efficacy and safety of injectable cabotegravir in MSM and transgender women who have sex with men (HPTN 083) and women in sub-Saharan Africa (HPTN 084). In addition, our successful collaboration with the HIV Vaccine Trials Network (HVTN) to study the safety and efficacy of VRC01, a broadly neutralizing monoclonal antibody (bnAB), continues in HVTN 703/HPTN 081 and HVTN 704/HPTN 085. Also known as Antibody Mediated Prevention (AMP), the global Phase 2b clinical trials are the first studies to evaluate whether bnAbs are effective in reducing acquisition of HIV-1 infection among at-risk populations.

Other ongoing HPTN studies are aimed at answering important questions regarding use of ART for prevention among MSM with unsuppressed viral load in the U.S. (HPTN 078) and the uptake and adherence with FTC/TDF PrEP among young women in southern Africa (HPTN 082) as well as the feasibility of enrolling MSM in Africa (HPTN 075).

On this World AIDS Day, to help reach the Joint United Nations Program on HIV/AIDS' (UNAIDS) ambitious 90-90-90 goals (90 percent of people with HIV diagnosed, 90 percent of them on ART and 90 percent of them virally suppressed by 2020), let us celebrate our collective achievements and reaffirm our mission and commitment to a world without AIDS.

Myron Cohen, MD
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HPTN Principal Investigators

Community Sensitization and AMP: A UZ-UCSF CTU Site Visit Report

By Ntando Yola

My recent visit to three research sites in Zimbabwe revealed how teamwork between the community, clinical and other support staff results in trials that are run like well-oiled machines with results bearing praise. The visit highlighted the reason why most of us attending the 2016 HPTN Annual Meeting were wowed by how Spilhaus Clinical Research Site (CRS) maintained 100 percent participant retention on top of other notable achievements. What I saw helps explains why trial participants are so motivated to be associated with their sites.

At the Parirenyatwa CRS we briefly settled down in a meeting with a very passionate Elizabeth Magada, better known as Liz, a Community Liaison Officer (CLO) for both Parirenyatwa and Spilhaus. She gave an account of an intense process that began in January 2016 to sensitize the community to a new concept in HIV prevention known as antibody mediated prevention (AMP). In preparation for this study, they conducted a series of stakeholder sensitization sessions across all participating communities. This is where almost nine months of community preparedness contributes to a strong ground work for the success of the study.
Liz described accomplishments made through this sensitization process including: 1) Community Advisory Board (CAB) information and discussion sessions that facilitated an understanding of the concept, effectively gaining support in the community, 2) Connections to various strategic community groups and stakeholders, 3) Broad community discussions and interactions regarding the study, which goes a long way in preparing both the site and the community for the study, and 4) Lists of women and at times their male partners who showed interest in participating in this and other studies. With regards to the latter, both Liz and Emilder Chihota, Seke South CLO, have collaboratively built a database of more than 500 potential participants. We all agreed that this process should be included in a best practices manual of community preparedness before a study as well as an abstract for a publication with the next target being the 2017 HPTN Annual Meeting.

Attending two of the sensitization meetings on day two of my visit was another exciting experience that exhibited how community collaboration has the potential of achieving good participatory practices (GPP). A mid-week stakeholder meeting as well as a session with a women’s community club were held back to back and in a very successful manner. In addition to providing community support, I commend the clinical trial unit’s collaboration as one of the meetings was not only attended by community outreach staff members, but also an investigator, pharmacist and site coordinator who also engaged with stakeholders. This teamwork is bound to produce good results. In addition, when community members experience engagement with clinical staff early on, they are not total strangers when they visit the clinical site during the study.

In both my community working group co-chair role as well as my role as a research site staff, this experience was very beneficial and I encourage and advocate for it to happen across sites whenever possible. It made me see that learning from each other as research community staff cannot be limited to conference rooms as there are tangible benefits in experiencing it in the field, in real-time, as I did.

Heartfelt gratitude to all the University of Zimbabwe - University of California San Francisco (UZ-UCSF) site staff, particularly Charles Chasakara and team who welcomed me, took me around and fed me during my visit. I am grateful for the warm welcome I received from each and every staff member I came across at the sites including Dr. Nyaradzo Mgodi, AMP’s protocol chair, and Dr. Zvavahera (Mike) Chirenje, principal investigator of the UZ-UCSF CTU, whom I refer to as Uncle Mike. I hope this story goes a long way to highlight the great work done by this research unit of excellence and encourages other colleagues and peers as it did me. Thanks to HPTN’s community programs at FHI 360 for being open to and supporting this kind of effort.
Ntando Yola is a community liaison and education officer with the Desmond Tutu HIV Foundation (DTHF) in Cape Town, South Africa. He works closely with national and international HIV prevention networks and various community stakeholders, developing and implementing community education programs, forming partnerships with health service providers and other community-based organizations.

SHOUTOUTS

Congratulations to Jonathan Lucas, Dazon Dixon Diallo, and Blake Rowley for being hailed as two of POZ Magazine’s "POZ 100: Celebrating the South", celebrating people working to end the HIV/AIDS epidemic. Jonathan is a senior community programs manager with the HPTN LOC in Durham, North Carolina. Dazon Dixon Diallo is president/CEO of SisterLove, an organization focused on women of African descent in the fight against HIV/AIDS and the struggle for human rights and reproductive justice. Based in Atlanta, Georgia, Dazon is a member of the HPTN’s Community Working Group, Scientific Advisory Group and Women at Risk Scientific Committee. Blake is a senior manager of health equity at the National Alliance of State and Territorial AIDS Directors (NASTAD) in Washington, DC and serves as a member of the HPTN’s Black Caucus. POZ magazine and POZ.com reach more than 70 percent of all people living in the United States who are aware they are HIV positive.

Congratulations to the HPTN 075 sites for achieving high retention rates. Soweto and Kenya reached 100% retention at Week 52, Cape Town 91%, and Malawi reached 100% at Week 39.

Bridge HIV (San Francisco) hosted an educational, engagement event to teach the Oakland-San Francisco Bay Area about HPTN 083. "PrEP & Vogue" was a 2-hour forum with presentations, performances, community discussion, dinner, and a raffle.

NETWORK MEMBER SPOTLIGHT
Roy (“Trip”) M. Gulick, MD, MPH, is the Rochelle Belfer Professor in Medicine and chief of the Division of Infectious Diseases at Weill Cornell Medicine, and attending physician at the New York Presbyterian Hospital in New York City. He serves as the co-chair of the U.S. Department of Health and Human Services (DHHS) Panel on Clinical Practices for Treatment of HIV Infection and chairman of the National Institutes of Health (NIH) Office of AIDS Research Advisory Committee (OARAC). In the HPTN, he serves as protocol chairman of HPTN 069, a Phase 2 study of maraviroc-containing regimens for HIV pre-exposure prophylaxis (PrEP).

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

I have spent most of my career designing and conducting studies of HIV treatment. When the first prep studies with TDF/FTC were reported, I became interested in strategies using other antiretroviral drugs for PrEP. I had some initial discussions with Ken Mayer and we began to explore studying maraviroc-containing regimens for PrEP — these ultimately became HPTN 069 (with co-sponsorship from the ACTG as A5305).

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