

BE THE GENERATION

TO END THE AIDS EPIDEMIC

BTG News

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From the Editor

2020: a new year, a new decade, a fresh start to the commitment to ending the HIV epidemic. So why does my mind feel clouded? Why does my heart feel heavy? When the clock struck midnight on January 1st, the fireworks were supposed to usher in a new era, right? But when I woke up that morning, I was still living in an unequal society. People of color, women, and transgender people are still being excluded from HIV research—with [real-life consequences](#). One of our research networks dedicated to finding safe and effective [microbicides](#) for HIV prevention will soon lose funding. We still don't have a scale-able cure for HIV. And a major HIV vaccine study has been [stopped early](#) because the potential vaccine did not work to prevent HIV. If you're feeling demoralized about the recent hurdles in our movement, you have every right to feel that way. But if you keep reading, you'll see that we have many more reasons to be hopeful for the future of HIV research. One of the injectable PrEP studies is fully enrolled having exceeded expectations for enrollment of Black MSM and transgender women. The vaginal ring is closer yet to being approved as the first biomedical HIV prevention tool designed specifically for cisgender women. Two other major HIV vaccine studies are well underway. And we have more resources than ever focused on improving community representation in HIV research. We must mourn our losses, but we must also celebrate our victories. Share our [website](#), drop us a post on [Facebook](#), and stay strong with us. We are still the generation that will end the HIV/AIDS epidemic!

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HIV Prevention Trials Network (HPTN)

The [first major study of injectable PrEP](#) is now fully enrolled! This study is iconic not only because it's testing to see if a drug given by injection every other month will work to prevent HIV. It's also iconic because advocates had the study team set enrollment goals for Black men who have sex with men (MSM) and transgender women. Recognizing the underrepresentation of these populations in HIV research, advocates convinced the researchers to write two requirements into the study: at least 10% of the overall study participants enrolled should be transgender women, and at least 50% participants enrolled in the US sites should be Black cisgender men. We applaud the community advocates and study teams who made this happen.

We also congratulate the [HPTN 083-01](#) and [HPTN 084-01](#) study teams for finalizing plans for these two important studies. Both are sub-studies of the two ongoing injectable PrEP studies, [HPTN 083](#) and [HPTN 084](#). HPTN 083-01 will investigate an injectable drug as HIV prevention in adolescent men who have sex with men in the US (HPTN 083-01), and HPTN 084-01 will do the same in adolescent women in sub-Saharan Africa. Screening and enrollment are expected to begin in February 2020 for HPTN 083-01 and May 2020 for HPTN 084-01.



HIV VACCINE
TRIALS NETWORK

HIV Vaccine Trials Network (HVTN)

The HVTN 706/HPX3002 study, also known as [Mosaico](#), is underway, with the first study participants receiving study injections at sites in Houston, Washington D.C., and Philadelphia. Mosaico evaluates an investigational vaccine based on mosaic immunogens—vaccine components made from elements from multiple strains of HIV—that aim to induce immune responses against the wide variety of global HIV strains. We look forward to the support and participation of study participants and communities globally.

As Mosaico gears up, the HVTN's Social and Behavioral Sciences and Community Engagement Unit (SBS/CEU) is hard at work training and preparing sites. The SBS/CEU conducts training on community education, recruitment, and retention to enhance the skills and tactics study teams employ to encourage community

involvement in the study. The SBS/CEU team has recently traveled to sites in the U.S., Europe, and South America to prep sites for Mosaico. In the HVTN model of community engagement, community education is a critical component that involves spreading information throughout local communities relating to HIV, HIV vaccine science, and the study. “Our community engagement model helps to ensure that interested study participants hear accurate information from their trusted voices: persons who they go to for information and advice,” says Dr. Stephaun Wallace, Social and Behavioral Sciences Junior Investigator Liaison for the HVTN.



HVTN staff at the Vila Mariana CRS in Sao Paulo, Brazil after a site preparation visit. Left to right: Patricia Segura, Dr. Valdez Madruga, Dr. Stephaun Wallace, Shelly Ramirez, Luciana Kamel

Teams at trial sites educate communities about the study, the broader HIV prevention landscape, and HIV vaccine science, paving the way for study participants and communities to be involved and meaningfully participate in Mosaico. Community engagement and outreach activities are critical, and underscore how the local study teams gain an intimate understanding of the structural and social drivers of HIV in their communities.

On January 28-29 in Harare, Zimbabwe, the MTN held its final in-country stakeholder meeting for the [DELIVER](#) (MTN-042) and [B-PROTECTED](#) (MTN-043) studies that will be evaluating the safety of the dapivirine vaginal ring and Truvada as daily oral PrEP in pregnant and breastfeeding cisgender women, respectively. Approximately 60 stakeholders, advocates, former study participant and researchers attended the meeting, which was co-hosted by AVAC as well as the Pangea Zimbabwe AIDS Trust and the Organization for Public Health Interventions and Development. The meeting was coordinated with the Zengeza Clinical Research Site of the University of Zimbabwe College of Health Sciences – Clinical Trials Research Centre, which will be conducting the study.



Participants dance at MTN's DELIVER and B-PROTECTED stakeholder engagement meeting in Harare.

A few weeks later, a woman who is eight months pregnant was the first participant enrolled into DELIVER, which launched mid-February at the Wits Reproductive Health and HIV Institute Shandukani Research Centre in Johannesburg, South Africa. In addition to the Wits site, DELIVER is taking place at clinical research sites in Malawi, Uganda, and Zimbabwe. The study is enrolling

750 HIV-negative pregnant women ages 18-40 who are being randomly assigned to use either the monthly dapivirine vaginal ring or Truvada as daily oral PrEP.

Other studies the MTN has launched include [MTN-039](#) and [MTN-045](#). MTN-039 is a Phase I study evaluating whether a fast-dissolving insert containing the antiretroviral drugs tenofovir alafenamide (TAF) and elvitegravir (EVG) is safe to use in the rectum. The study is including 20 HIV-negative individuals at two sites in the United States. MTN-039 will help determine whether further testing on the rectal insert can be conducted in a larger population.

MTN-045 is a cross-sectional study using questionnaires and other measures to assess cisgender heterosexual couples' preferences for dual purpose prevention products to prevent unintended pregnancy and HIV. The study is enrolling 400 couples in Uganda and Zimbabwe, and it will help inform the future design and delivery of products.



Clare Collins (right) accepts an award for her exceptional service to the MTN and greater HIV community. Clare is MTN's Associate Director of Communications and External Relations as well as co-chair of the Women's HIV Research Collaborative and member of the Legacy Project Working Group. For her dedication to women and all underrepresented populations, Clare is loved by all.

The MTN held its final annual meeting February 9-12 at the Crystal Gateway Marriot in Arlington, Virginia. Topics covered at the [2020 MTN Annual Meeting](#) included HIV prevention in pregnant and breastfeeding women and adolescents, an update on rectal microbicides, and a lively and fun debate about the future of topical products for HIV prevention. The meeting concluded with an awards ceremony and gratitude for all who have contributed to the MTN's research agenda for nearly a decade and a half.



Office of HIV/AIDS Network Coordination (HANC)

HANC is pleased to share these webinar recordings, articles, video interviews, and other resources:

- [Including Women in HIV Cure-Related Research](#): a video interview (with transcription) of Brian Minalga discussing this topic at the recent Association of Nurses in AIDS Care conference
- [Women in HIV Cure-Related Research](#): a downloadable training
- [Stepping Up the Search for a Cure](#): an article about HIV cure-related research and the inclusion of women and transgender people
- [Biomedical HIV Prevention for Women](#): a downloadable training
- [Transgender People Must Be Included in Every Aspect of HIV Research](#): a conversation between Brian Minalga and Mathew Rodriguez in Thebodypro.com
- [Blood, Hair, Saliva: Addressing Mistrust in Medical Research and Demystifying how HIV Lab Researchers Use and Store Samples](#): a new webinar recording
- [Our People, Our Stories: A Conversation about Black Gay Men, Research, and the CDC](#): a new webinar recording
- [National Black HIV/AIDS Awareness Day](#): a statement released by the Legacy Project and Women's HIV Research Collaborative
- [Webinar Library](#): a collection of over 30 of our webinar recordings on topics such as HIV & race, HIV & women, HIV genetic sequencing, HIV & aging, outreach & marketing, Native Americans & HIV, microbicides research, pregnancy & lactation in HIV research, HIV in the Latinx community, community engagement, and more.

Important Dates (check our [Facebook](#) for important updates)

- March 10th: National Women and Girls HIV/AIDS Awareness Day
- March 20th: National Native HIV/AIDS Awareness Day
- April 10th: National Youth HIV/AIDS Awareness Day
- April 18th: National Transgender HIV Testing Day
- May 18th: HIV Vaccine Awareness Day
- May 19th: National Asian-Pacific American HIV/AIDS Awareness Day
- May 27-29: [HIV Vaccine Trials Network Full Group Meeting](#) in Washington, DC (see you there)
- May 30 – June 3: [HIV Prevention Trials Network annual meeting](#) in Washington, DC (see you there)