From the Editor

I began the last issue of BTG News with a reflection on recent hurdles in our movement—hurdles like the exclusion of cis women and trans people from PrEP trials and a failed HIV vaccine candidate. As if these obstacles weren’t enough, we now have a new global pandemic to contend with: COVID-19. Those of us working to end the HIV epidemic in the US are watching our social determinants of health play out all over again. Our indigenous communities, Black communities, and Latinx communities bear a disproportionate burden of the COVID-19 epidemic—no different from the HIV epidemic. We don’t even have data on how this new virus is impacting LGBTQ communities because the decision-makers are not collecting these data—an erasure of our people that our community is all too familiar with. But June is Pride Month, and with it comes two vital reminders: 1) the power to seize justice lies within us, and 2) we can’t leave anyone behind. The co-occurring HIV and COVID-19 epidemics call upon the resilience and solidarity of our movement. While much of our HIV research has been stymied by the COVID-19 pandemic, many of our HIV research teams and community members are stepping up and pivoting to join in the COVID-19 response. Read on to learn how our HIV prevention research networks are handling this crisis with commitment to the health of our communities. Let’s keep our hopes up and remember who we are: the generation that will end the HIV epidemic. Share our resources and stay in touch. We’re in this together!

Brian Minalga &
The Legacy Project

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Some of the most exciting news in HIV prevention research in recent years came out of the HPTN in May: an injectable form of PrEP works to prevent HIV in cisgender men (MSM) and transgender women who have sex with men! Another HPTN study evaluating the same injectable PrEP agent in cisgender women is ongoing, and we can’t wait to see how these results turn out for our “cisters.” This announcement is just the beginning; we still have much to learn about injectable PrEP and how it may be used outside the context of HIV clinical trials. In the meantime, let’s celebrate these results as a much-needed win for our movement. Thank you to the study participants and the entire HPTN community for not only conducting a high-caliber study with the potential to change the HIV prevention landscape, but for doing so in a way that is meaningful for transgender women and African American cis MSM. 12% of the overall study participants were transgender women, and 50% of the US participants were Black. The significance of these accomplishments cannot be over-emphasized!

The HPTN has the mission of conducting HIV prevention research at the highest scientific and ethical standards. The updated *HPTN Ethics Guidance for Research* aims to facilitate the Network’s mission by raising awareness of the associated ethical considerations, engaging all network members in a discussion about those considerations, and promoting the integration of ethical considerations into the design and implementation of HIV research.
Dr. Jeremy Sugarman, chair of the HPTN Ethics Working Group and Harvey M. Meyerhoff Professor of Bioethics and Medicine at the Johns Hopkins Berman Institute of Bioethics in Baltimore, and Dr. Brandon Brown, 2015-16 HPTN Domestic Scholar and current associate professor in the School of Medicine at the University of California, Riverside, led the revision with extensive input from the HPTN Ethics Working Group. HPTN Leadership and the Executive Committee provided additional support. To read more, click here.

HIV Vaccine Trials Network (HVTN)

The latest HVTN Community Compass is now available! Each edition of this publication is a collection of stories conveying the passion and unwavering commitment of our pursuit for a safe and globally effective preventive HIV vaccine. We hope every edition will be an informative read to grow your knowledge and understanding of the HIV prevention field and to celebrate how you are making an impact! Community Compass is available in English, Spanish, Portuguese, and French.

The Mosaico Study is an ongoing HIV vaccine trial. We have now launched a website for this study for U.S. audiences: www.mosaicostudy.com. The website is currently being developed to incorporate the other regions where the study is taking place, and that upgrade will be released soon. Stay tuned!

The NIH-funded HIV Vaccine Trials Network (HVTN) and HIV Prevention Trials Network (HPTN) initiated their first clinical trial in response to COVID-19. The study, HVTN 405/HPTN 1901, is underway at clinical trial sites across North and South America and will describe immune responses in study participants with a history of having SARS-CoV-2, the virus that causes COVID-19. HVTN 405/HPTN 1901 aims to enroll approximately 400 study participants aged 18 and older who tested positive for SARS-CoV-2 and have since recovered. Access the official press release here: HVTN Media room
The EMBRACE (MTN-016) study enrolled its first participant more than a decade ago. Now, the final participant in this study has completed follow-up! This was an observational study and registry to understand any effects that antiretroviral-based HIV prevention products may have on pregnancy and infant outcomes. A total of 460 cisgender women and 413 infants have participated in EMBRACE, which has paved the way for a multitude of studies at MTN focused on the need for safe and effective HIV prevention products for all stages of life -- including during pregnancy and breastfeeding.

MTN is delighted to report the first births coming out of the DELIVER study. Four participants being followed by the Wits Reproductive Health and HIV Institute (Wits RHI) Shandukani Research Centre in Johannesburg recently delivered. Participants and babies are doing well. All continue to be followed by the study team in accordance with local guidelines for protecting against COVID-19. The study is otherwise paused. DELIVER (MTN-042) is assessing the safety & acceptability of HIV prevention products used during pregnancy – the dapivirine vaginal ring and Truvada as PrEP – in 750 cisgender women in Malawi, South Africa, Uganda, and Zimbabwe. Wits RHI is the only DELIVER site that has been activated to date.

The DESIRE study (MTN-035), is a behavioral study of three different rectal microbicide placebo products: a douche, suppository, and insert. This study includes transgender men and women and cisgender men who have sex with men. This study has now completed enrollment! This milestone was reached in mid-March, just prior to the pausing of study enrollment across the MTN to protect staff and participants from COVID-19 and to prevent its spread. The 210 participants were enrolled at sites in Malawi, Peru, South Africa, Thailand, and the U.S., with approximately 50 participants remaining in study follow-up. To enable study follow-up to safely continue at sites where clinics are closed, remote data collection procedures have been instituted. The study team is optimistic that these necessary changes will allow DESIRE to be completed on time – anticipated at the end of June/early July – and ultimately help answer important questions about preferences for future rectal microbicide products.
On May 14, MTN leadership made the decision to lift the blanket pause in study enrollment across network trials, which was instituted on March 18 in response to the COVID-19 pandemic. The decision regarding when study enrollment can begin at individual sites will be governed by the management team for each study, in concert with local and regional guidelines and stay-at-home orders. The MTN looks forward to completing studies while honoring the continued commitment to the safety of our global network of participants and study teams. As this is an ever-changing situation, MTN has developed a COVID-19 Response page to keep study participants, staff, teams, and community members updated on any new developments. Read more about the inspiring efforts of the MTN to maintain its commitment to HIV prevention research during these challenging times.

In the interest of safety and public health, MTN leadership has announced the cancellation of the 2020 MTN Regional Meeting this October in Cape Town. This decision was not made lightly as it was to be the last MTN Regional Meeting as a network. Please read message from Sharon Hillier and Jared Baeten.

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

- **COVID-19 & HIV Research Update**: a webinar recording featuring Drs. Carl Dieffenbach, Manizhe Payton, Sarah Read, and Jeff Schouten
- **Can Treatment as Prevention End the HIV Epidemic**: a video hangout (recording) with Brian Minalga, MSW, who walks us through four studies to help answer this hot-topic question
- **Tuberculosis Vaccine Research Update**: a webinar recording featuring Mike Frick and Jim Kublin
- **Characterizing Loneliness among Young Black MSM**: a webinar recording featuring speaker Cory Bradley, PhD
- **National Native HIV/AIDS Awareness Day**: a webinar recording featuring speakers Harlan Pruden and Tyler Adamson
- **National Women & Girls HIV/AIDS Awareness Day infographic**: a resource created by the Women’s HIV Research Collaborative featuring recent developments in HIV research focused on cis and trans women
• **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 free downloadable training
• **Biomedical HIV Prevention for Women**: a free downloadable training
• **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)
• June 5: **HIV Long-term Survivors Awareness Day**
• June 8: **National Caribbean American HIV/AIDS Awareness Day**
• June 27: **National HIV Testing Day**
• August 20: **Southern HIV/AIDS Awareness Day**
• August 30: **National Faith HIV/AIDS Awareness Day**