From the Editor
There’s a scene in the 2020 film *Becoming* where former First Lady of the United States, Michelle Obama, is hanging out with a group of Black women elders. She is reflecting on her time in the White House with President Barack Obama, and she tells the women, “Every time we showed up, it was to make you proud.” For whom do you show up every day? Whose pride in you fuels the way you show up in the world?

In this issue of *BTG News*, we continue our coverage of HIV prevention research and COVID-19 research—and much of it is good news! Cisgender women are closer than ever to being able to use a vaginal ring for HIV prevention. New HIV prevention studies with novel study products are opening for young people. The search for HIV and COVID-19 vaccines continues with revitalized emphasis on equity. And each of you has a role to play.

Through these often dark and challenging times, we at the Legacy Project remain committed to supporting you and your work. Share in our resources and stay in touch. Think of the generations past, present, and future, who are counting on us to be the generation to end the HIV epidemic. Let’s make them proud.

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The HIV Prevention Trials Network (HPTN) has launched its first study enrolling exclusively adolescents under the age of 18. This study, called *HPTN 083-01*, is evaluating whether a pre-exposure prophylaxis (PrEP) regimen containing the long-acting injectable drug, cabotegravir, is safe and acceptable for adolescents assigned male at birth. Twenty-one percent (21%) of new HIV cases in the U.S. occur among young people. Most of these cases are transmitted through sex, and about half of the youth who are living with HIV don’t know that they have it. Click here to view the study website.

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](http://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](#).
We're putting a dapivirine ring on it! We are excited to share that on Friday, July 24, the European Medicines Agency issued a positive opinion of the monthly dapivirine vaginal ring to reduce HIV risk. This opinion moves the ring closer to approval in African countries for use by cisgender women. Congratulations to our colleagues at the International Partnership for Microbicides (IPM) for achieving this milestone, and to study participants, researchers, site team staff, advocates and community members for the critical role they played in bringing us this far. IPM now plans to submit applications to national medical regulatory authorities in east and southern Africa, in collaboration with the WHO, and to the US FDA later this year. In addition to MTN’s press release, the opinion was also the topic of several other press releases from NIAID, IPM, UNAIDS and AVAC, as well as a joint statement issued by the International Community of Women Living with HIV, Advocates for the Prevention of HIV in Africa and Emthonjeni.

In other good news, the DESIRE study has been completed. This global study, also referred to as MTN-035, evaluated three placebo methods (douche, insert, and suppository) for the delivery of a rectal microbicide at sites in Malawi, Peru, South Africa, Thailand, and the US. An incredible effort by DESIRE study leadership, teams, sites, and participants enabled the safe and timely completion of the study in the midst of the COVID-19 pandemic. The study enrolled 210 participants: transgender men, transgender women, and cisgender men who have sex with men. We excitedly await results in 2021.
Results from MTN-041 (the MAMMA study) were published in the June 10 issue of JIAS. The MAMMA study explored community attitudes and perceptions about the use of two HIV prevention products – Truvada as daily oral PrEP and the monthly dapivirine vaginal ring – during pregnancy and breastfeeding. The study took place in Malawi, South Africa, Uganda, and Zimbabwe, and it involved group discussions with cisgender women who were pregnant and breastfeeding, as well as their male partners, mothers, and mothers-in-law. The study team also conducted interviews with community leaders, health care providers, midwives and traditional birth attendants, among others. Study results indicated that the participants welcomed options for HIV prevention that recognize personal preference and autonomy. These findings are helping to inform the implementation of the DELIVER (MTN-042) and B-PROTECTED (MTN-043) studies in cisgender women who are pregnant and breastfeeding, respectively.

As MTN approaches the end of our official tenure as an NIAID-funded HIV clinical trials network, we’re taking a look back at the communities, researchers, and participants who have made important contributions to the work of the network over the last 15 years. This is an occasional series of stories about the network’s accomplishments in HIV prevention and its legacy. Our first story, Baby Steps to Giant Strides, is focused on MTN’s research agenda in cisgender women who are pregnant and breastfeeding from its inception in 2006 to the present day. The story includes a sidebar piece, Pumped up for HIV Prevention, about a study participant who volunteered for an earlier clinical trial of the dapivirine vaginal ring in cisgender women who are lactating. As the global community initiates vaccine studies of COVID-19, the involvement of pregnant and breastfeeding women in clinical trials continues to be debated.

Bridget Gooden and her daughter Regin in 2020. Bridget participated in an early study of the dapivirine vaginal ring when Regin was 18 months old.
Office of HIV/AIDS Network Coordination (HANC)

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

- **COVID-19 Prevention Network**: a website with comprehensive information about COVID-19 vaccine and antibody research including a registry for people interested in participating
- **Action Alert**: a sign-on document by the Women’s HIV Research Collaborative asking for all to commit to scientific accuracy and cultural sensitivity in HIV and COVID-19 research communications
- **ART Adherence and the Promise of Long-Acting Injectable HIV Treatment**: a webinar recording featuring Dr. Michael Stirratt
- **Uniting to End COVID-19**: a webinar by the COVID-19 Prevention Network and the Urban Indian Health Institute focused on education and dialogue about COVID-19 prevention research in Native American communities
- **7 mil millones de razones: Unidos para poner fin a COVID-19**: a webinar by the COVID-19 Prevention Network and Latino Commission on AIDS. Also available in English.
- **COVID-19 Community Conversation**: a webinar featuring panelists from Treatment Action Group, AVAC, the COVID-19 Prevention Network, the Women’s HIV Research Collaborative, and community members discussing the state of our communities in relation to COVID-19 and coronavirus research.
- **Transgender Training Resources Homepage**: the Division of AIDS at the National Institute of Allergy and Infectious Diseases has put all its amazing resources related to research with transgender communities in one place. All resources are free; you may just need to create a free account if you don’t have one already.
- **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

- Friday, September 18: HIV/AIDS and Aging Awareness Day
- Sunday, September 27: National Gay Men’s HIV/AIDS Awareness Day
- Thursday, October 8 at 10 a.m. Pacific: The Youth Prevention Research Working Group (YPRWG) will host a webinar on the Adolescent Trials Network’s (ATN) iTech protocols. Presenters for the webinar include Dr. Lisa Hightow-Weidman and Dr. Travis Sanchez. To learn more about iTech, click here. For a current list of ATN studies, including iTech protocols, click here. An invite to the webinar will be sent to all HANC collaborators in the near future.
- Thursday, October 15: National Latinx AIDS Awareness Day
- October 19-21: United States Conference on HIV/AIDS (USCHA). This year’s conference will be virtual and free for most to attend. Keep an eye out for these workshop titles, where we will be presenting:
  - TRANSforming HIV Research: Systemic Change to Advance Transgender Inclusion
  - Words Matter: Using Non-stigmatizing Language in the HIV Field
  - Brother to Brother: Engaging Straight Black Men
  - The Impact of COVID-19 on NIH HIV/AIDS Research
  - Voices from Stolen Land in the Time of COVID-19
  - Long-Acting Antiretroviral Injectables (LAIs) and Broadly Neutralizing Antibodies (bNAbs) Messaging/Considerations for Women and POC
  - Historical Distrust Impact on Research Community Engagement
- October 25-28: American Public Health Association Annual Meeting (APHA). This year’s conference will be virtual. Join us for our sessions:
  - Monday, 10/26 at 7:30 a.m. Pacific: “Okay Ladies Let’s Get Information: Women & Biomedical HIV Prevention”
  - Monday, 10/26 at 9:30 a.m. Pacific: “Addressing the Intersection of Intimate Partner Violence and HIV in Women”
  - Tuesday, 10/27 at 12 p.m. Pacific: “Fostering Transgender Inclusion in Research”
- Tuesday, November 3: Election Day. PLEASE use the linked resource immediately to help you VOTE! Do not wait until November 3. This election will determine all of our futures; we cannot emphasize enough how important it is that you VOTE.
- Friday, November 20: Transgender Day of Remembrance
- Tuesday, December 1: World AIDS Day
In Memory

This issue is dedicated to David Hughes (November 1979 – August 2020). David was a leader in the Legacy Project family. He was our colleague and our friend. We are honored to be a part of the community he built and to continue living and working in his memory.