

BE THE GENERATION

TO END THE AIDS EPIDEMIC

BTG News

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From the Editor

If you support people living with HIV, women, the LGBTQ+ community, and all people affected by HIV, put your cell phone light up! Here, we are all about positivity, equity, and *science*—not stigma. We recognize stigma and structural violence as primary factors in HIV transmission, and we know that science alone is not enough to end the epidemic. We work in the interest of justice and quality of life for all—and we strive to align HIV prevention research with these priorities.

This issue of *BTG News* takes us back to our roots: underrepresented populations. The [International Covenant on Social, Economic, and Culture Rights](#) defines “the right of everyone to enjoy the benefits of scientific progress and its applications.” When populations are left out of research, their ability to claim this human right becomes compromised. Read on to learn what our research networks are doing to center underrepresented populations such as adolescents, transgender people, and women.

As always, share our [resources](#) and [stay in touch](#). Thank you for all you do to **be the generation** to end the HIV/AIDS epidemic!

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HIV Prevention Trials Network (HPTN)

Adolescents are often overlooked when it comes to biomedical HIV prevention research. However, adolescents are heavily impacted by HIV and should be prioritized in the HIV response, including as participants in HIV prevention research. The HPTN has designed two studies of injectable PrEP that are exclusively enrolling people under the age of 18. These studies are the focus of the HPTN's latest feature story, [Community Insights and Lessons Learned \(So Far\) From Two HPTN Studies Targeting Young People](#). Check out the story today!



HIV VACCINE
TRIALS NETWORK

HIV Vaccine Trials Network (HVTN)

The HVTN has some disappointing news as well as some exciting and hopeful news. First, the [Imbokodo Study](#). This was a large, Phase IIb study testing a potential HIV vaccine among cisgender women in 5 African countries. Results were recently announced, showing that the vaccine candidate was very safe. However, we also learned that the HIV vaccine candidate did not work to prevent HIV as we had hoped. Sixty-three participants in the placebo arm of the study acquired HIV, compared to fifty-one participants who acquired HIV in the vaccine arm of the study. This comes to 25.2% vaccine efficacy—a number that is both low and statistically insignificant. This means that the Imbokodo Study will be discontinued, but all is not lost! We learn a lot from studies that don't work out as we hope for, and this study will inform our next move in the search for an HIV

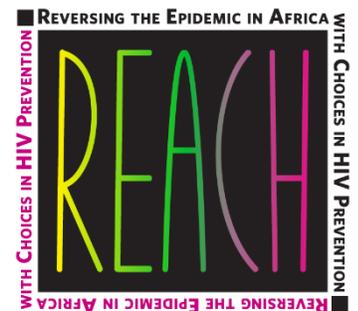
vaccine. We also have a large Phase III study of another HIV vaccine candidate that is still ongoing, the Mosaico Study!

[The Mosaico Study](#) is a multi-country HIV vaccine study testing whether an investigational HIV vaccine regimen can prevent HIV acquisition in cisgender men and transgender persons who have sex with cisgender men and/or transgender persons. This is one of the first HIV vaccine studies to explicitly name gender non-conforming people in the study protocol as an eligible population to participate in the study! The study is being conducted in Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain, and the United States. As of July 2021, the study was over 85% enrolled, and Argentina, Brazil, Mexico, Poland, and Spain have reached their full enrollment commitments. The study is expected to complete enrollment in September 2021. The communities and research teams involved in this study are hard at work to find an answer to the scientific questions about safety, immune response, comfort with injections, and how well the vaccine regimen works to prevent HIV. Answers to these questions are expected in 2024.



Microbicide Trials Network (MTN)

Interim results of the [REACH](#) (MTN-034) study, which is evaluating Truvada as daily oral PrEP and the monthly dapivirine ring in cisgender adolescent girls and young women in three African countries, were among those featured at [IAS 2021](#) (which took place virtually in July). The bottom line? Adolescent girls and young women can and will use HIV prevention products with consistency.

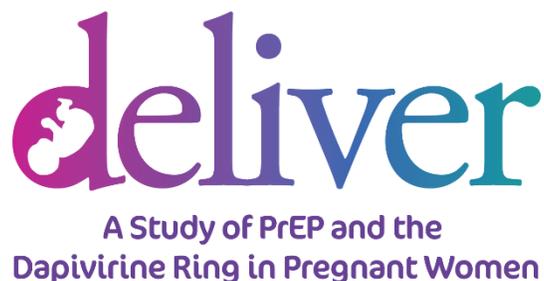


Unlike in previous studies of oral PrEP and the ring, the vast majority (97 percent) of the 247 participants in REACH, who were between ages 16 and 21 when they enrolled, used the vaginal ring and daily oral PrEP some or all of the time. Fewer than three percent of participants used neither of the products, according to laboratory tests for adherence. The research team gives credit to the ongoing support measures, tailored for this population, and nonjudgmental counseling approach provided as part of the study.

[The results](#) are from the study's first two periods, during which participants were asked to use each of the products for six months. During the final six months of the study, participants will be able to choose which product to use, or to use neither. Follow-up is expected to be completed in October and final results available by mid-2022.

The dapivirine ring was developed by the nonprofit [International Partnership for Microbicides](#) (IPM), which is seeking its approval in several African countries as well from the US Food and Drug Administration. The ring's [first approval](#) – in Zimbabwe – came just days before the IAS meeting. Yet, for the ring to even be considered as an option for adolescent girls, specific data about its safety in this population is needed – data that REACH, as well as the MTN-023 study conducted in the US among young women ages 18-21, intends to provide.

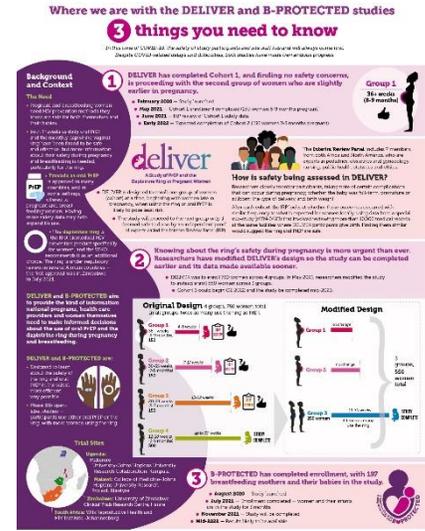
Similar studies – [DELIVER](#) (MTN-042) and [B-PROTECTED](#) (MTN-043) – are evaluating the safety and acceptability of Truvada as oral PrEP and, in particular, the dapivirine ring, when used during pregnancy and breastfeeding, respectively. As of 30 July, B-PROTECTED had met its target enrollment, with 197 breastfeeding mothers and their 6-12-week old babies in the study, and is on track to be completed in November. Final results will likely be available mid-2022.



Meanwhile, in May, the DELIVER study completed follow-up of its first cohort of participants, who were 8-9 months pregnant when they enrolled. Finding no safety concerns in its review of Cohort 1 data, the independent Interim Review Panel recommended the study proceed to enroll the next group, who are between 7-8 months pregnant. (Safety outcomes from Cohort 1 were presented at IAS 2021 as a late-breaker e-poster.)

Researchers have modified the design of DELIVER so that the study can be completed earlier and its data made available sooner. DELIVER was to enroll 750 women across 4 groups. In May 2021, researchers modified the study to instead enroll 550 women across 3 groups. Cohort 3 could begin in Q2 2022 and the study be completed mid-2023.

To get a better picture of these study milestones, take a look at this infographic, [The DELIVER and B-PROTECTED studies: 3 things you need to know.](#)



Office of HIV/AIDS Network

Coordination (HANC)

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

- [Be the Generation website](#): the best place to go for trustworthy information on biomedical HIV prevention research. Features sections on PrEP, U=U, Microbicides, HIV vaccine research, inspiring videos from researchers and community members, and even a quiz to test your knowledge of HIV prevention research.
- [Biomedical HIV Prevention for Women](#): a free downloadable training
- [Women in HIV Cure-Related Research](#): a free downloadable training
- [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.
- [COVID-19 Community Resources](#): In 2020, HANC formed the COVID-19 CAB Coalition (CCC). The CCC includes folks from the COVID-19 Prevention Network's Community Engagement Group, ACTG's ACTIV-2 CAB, AVAC's COVID-19 Advocates Advisory Board, The National CFAR Coalition, Stony Brook's COVID-19 CAB, Community Partners, and DAIDS. This resource page includes links to prevention and therapeutic studies, general information on COVID-19, links to webinars, and social media accounts to follow.

- [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

- Saturday, September 18th: [National HIV/AIDS and Aging Awareness Day](#)
- Monday, September 27th: [National Gay Men's HIV/AIDS Awareness Day](#)
- Friday, October 15th: [National Latinx AIDS Awareness Day](#)
- October 18-20: [HVTN Conference](#)
- October 28-31: [United States Conference on HIV/AIDS](#)
- Saturday, November 20th: [Transgender Day of Remembrance](#)