
FACT SHEET

The Microbicide Trials Network

Fast Facts

- The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases, with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The MTN brings together international investigators and community and industry partners whose work is focused on the rigorous evaluation of promising microbicides – products applied inside the vagina or rectum to help prevent the sexual transmission of HIV. These include multi-purpose products for preventing both HIV and unintended pregnancy and others to protect against HIV and different sexually transmitted infections.
- MTN studies are designed specifically to support the potential licensure and regulatory approval of these products for populations particularly vulnerable to HIV. Because effectiveness of a product is also dependent on use, behavioral science is integrated throughout MTN’s unique research portfolio.
- The MTN is led by Sharon Hillier, Ph.D., of the University of Pittsburgh and Magee-Womens Research Institute, who is principal investigator, and Jared Baeten, M.D., Ph.D., of the University of Washington, who serves as co-principal investigator. The MTN is comprised of a Leadership and Operations Center; a Laboratory Center with expertise in immunology, virology and microbiology; and a Statistical and Data Management Center.
- More than 25 clinical research sites on four continents have partnered with the MTN in the conduct of its clinical trials. Collectively, more than 12,000 research participants have taken part in MTN studies.

Research Highlights

- **Conducting key studies to support potential licensure of the dapivirine ring** – MTN has played a key role as clinical partner to the International Partnership for Microbicides (IPM), which developed the monthly dapivirine vaginal ring and is now seeking its approval for cisgender women 18 and older. Indeed, data from six MTN studies are included in IPM’s regulatory submissions. [ASPIRE](#) (MTN-020), which was conducted by MTN, is one of two Phase III trials contributing safety and efficacy data, along with The Ring Study, led by IPM. Other MTN studies, which were conducted in the U.S., are: [MTN-023/IPM 030](#), a Phase IIa safety study in adolescent girls; [MTN-024/IPM 031](#), a Phase IIa safety study in post-menopausal women; [MTN-012/IPM 010](#), a Phase I penile safety study; [MTN-029/ IPM 039](#), a safety and pharmacokinetic study in lactating women; and [MTN-013/IPM 026](#), which provides additional data on the safety and pharmacokinetics of the dapivirine ring. Data from the [HOPE](#) (MTN-025) open-label extension (OLE) study for former ASPIRE participants, as well as the DREAM OLE (for former Ring Study participants), may also be of interest to regulators. If approved, the dapivirine ring would be the first biomedical prevention method designed specifically for cisgender women and the first long-acting method.
- **Addressing the needs of adolescent girls and young women** – Adolescent girls and young women are among those especially vulnerable to HIV in sub-Saharan Africa. While oral pre-exposure prophylaxis (PrEP) and the dapivirine ring, should it eventually receive regulatory approval, could help curtail the rate of new infections, neither approach can be effective if not used with sufficient adherence. Studies have shown

-more-

adherence to be particularly challenging for younger women. Reducing HIV incidence in this vulnerable population is clearly a global priority. Launched in early 2019, [REACH](#) (MTN-034) is a study being conducted at four African sites that aims to understand how adolescent girls and young women ages 16-21 use Truvada as daily PrEP and the monthly dapivirine ring, and their preferences for either or both approaches after using each for six months. REACH will also collect much needed information on the safety of the approaches in these populations. The MTN has already completed a study called [MTN-023 /IPM 030](#), which involved 96 adolescent girls in the United States, that found the ring was acceptable and well-tolerated, and adherence to ring use very high. The REACH study will add to these data by contributing important information about ring use in African girls.

- Not to be forgotten: Pregnant and breastfeeding women** – The MTN has long recognized that women need products that will be safe and effective to use during all stages of life. As such, included in its scientific portfolio is a comprehensive research program purposefully designed to take incremental steps in determining whether HIV prevention products are safe to use by women during pregnancy and breastfeeding, when they are up to four times more likely to get infected. MTN’s first studies ([MTN-002](#) and [MTN-008](#)) focused on tenofovir gel. And, since 2008, researchers have collected data on 460 women and 413 infants through an observational study and registry called [MTN-016/EMBRACE](#), to understand the effects that antiretroviral (ARV)-based HIV prevention products may have on pregnancy and infant outcomes. Current studies are focused on the monthly dapivirine vaginal ring, which is under regulatory review, and Truvada as daily PrEP, an approach already approved in several countries. [DELIVER](#) (MTN-042), for pregnant women, and [B-PROTECTED](#) (MTN-043), for women who are breastfeeding, aim to collect the kind of information needed so that regulatory authorities and national programs can consider making these HIV prevention methods available to pregnant and breastfeeding women. Both studies are being conducted at four sites in Africa. DELIVER is the first study of the ring in pregnant women. An earlier study, [MTN-029/IPM 039](#), involving women who were no longer nursing their babies but still producing milk, found very low concentrations of dapivirine absorbed in breastmilk.
- The next generation of products: Multi-purpose prevention** – While a ring used for a month at a time may appeal to some women, others may prefer a product they replace every three months, or a ring that provides contraception in addition to protecting against HIV. Toward this end, [MTN-030/IPM 041](#) was a Phase I trial of a three-month dual-purpose ring containing both the ARV dapivirine and a hormonal contraceptive (levonorgestrel). As a first-in-human study, participants used the ring for only 14 days, with results finding the ring was well-tolerated and no safety concerns. A second Phase I trial of the dual purpose ring, [MTN-044/IPM 053/CCN019](#), in which participants used the dual-purpose ring for 90 days, will report results in late 2020. Additional trials of rings used for three-months at a time – one containing dapivirine ([MTN-036/IPM 047](#)) and another containing tenofovir ([MTN-038](#)), which was developed by CONRAD and designed to protect women against both HIV and herpes simplex virus type 2 (HSV-2) – are anticipating results in mid to late 2020 as well. Another study, [MTN-037](#), is evaluating the rectal safety of a multi-purpose gel, called PC-1005, that was developed by the Population Council to simultaneously prevent HIV, herpes simplex virus and human papillomavirus. The study has been completed, with results anticipated mid- to late 2020.
- Leading the way to a rectal microbicide** – MTN’s rectal microbicide research agenda is focused on evaluating diverse products and delivery methods as HIV prevention options for people who practice anal sex. Just as there are multiple options for contraception based on needs and lifestyles, rectal microbicides – formulated as gels, douches, suppositories and fast-dissolving inserts – could provide additional ways to reduce the risk of HIV infection from anal sex. The MTN has conducted three trials of a tenofovir-based gel as a rectal microbicide, including [MTN-017](#), the first Phase II study of a rectal microbicide product. Additional products and formulations are being evaluated in five MTN-led studies – two are ongoing, and three are completed and anticipating results in mid- to late 2020. In one unique study currently underway, participants are given the opportunity to use HIV prevention delivery approaches before actual products have been developed. The study, [DESIRE](#) (MTN-035), is the first to explore multiple placebo methods for delivering a rectal microbicide – a douche, suppository and fast-dissolving rectal insert.

-more-

Why Microbicides Are Needed

- Worldwide, nearly 38 million people are living with HIV. Almost 78 million people have been infected with HIV and about 32 million have died of HIV-related causes since the epidemic started in the early 1980s. Although significant strides have been made in the treatment of HIV, now, more than 30 years after HIV was first identified, prevention continues to be great a challenge. Nearly 2 million people are newly diagnosed with HIV annually – about 5,000 every day – with approximately one-third of these instances occurring among people ages 15-24.
- Cisgender women represent more than half of all people living with HIV worldwide, and account for 60 percent of those with HIV in sub-Saharan Africa. Across the globe, gay men and other men who have sex with men and transgender people also continue to be at especially vulnerable to HIV, with condomless anal sex the primary driver for the high prevalence in these populations. By some estimates, the risk of acquiring HIV through condomless receptive anal intercourse is at least 20 times greater than through condomless vaginal sex.
- Unlike other biomedical approaches that rely on systemic delivery of anti-HIV drugs, microbicides deliver drugs directly to the site of potential infection. Microbicide products could offer an additional option for people who, for various reasons, may not want to use or don't have access to proven methods, such as condoms or daily use of Truvada as PrEP to reduce their risk of HIV. Just as there are multiple contraception options to prevent pregnancy, microbicides could expand choices for HIV prevention by providing methods that are controlled by the user, non-systemic, and, in some cases, used around the time of sex.

###

The MTN is supported by U.S. National Institutes of Health grants UM1AI068633, UM1AI068615 and UM1AI106707.

More information about the MTN is available at www.mtnstopshiv.org.

More information about HIV can be found in the [UNAIDS Global HIV & AIDS Statistics – 2019 fact sheet](#), the Kaiser Family Foundation [Global HIV/AIDS Epidemic](#) fact sheet; and the amfAR [Worldwide Statistics](#) fact sheet.

21 April 2020