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About the REACH Study (MTN-034)

In a nutshell

- ▶ Adolescent girls and young women are especially vulnerable to acquiring HIV. In much of Africa, it is estimated that 1,000 young women ages 15-25 are infected every day.
- ▶ A vaginal ring containing an antiretroviral (ARV) drug called dapivirine that women use for a month at a time was found to be safe and help protect against HIV in two large trials that together enrolled more than 4,500 women ages 18-45 from four African countries. ASPIRE was conducted by the National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN). The Ring Study was conducted by the International Partnership for Microbicides (IPM), a non-profit organization that also developed the dapivirine ring.
- ▶ Based on the results of ASPIRE and The Ring Study, and several supporting studies, IPM is seeking regulatory approval of the dapivirine ring for women ages 18-45. If approved, the ring could be available in some countries around 2020.
- ▶ Regulatory authorities would need information about the safety of the ring in girls under age 18 to consider expanding approval in this population. The MTN has already conducted a study in the United States that found the ring to be safe and acceptable in girls ages 15-17.
- ▶ The REACH study (MTN-034) will provide additional information on the safety of the ring in young African women, as well as of an approach called PrEP, which involves daily use of an ARV tablet. REACH will also assess how young women use the monthly ring and daily PrEP and their preferences for either or both approach.

About REACH

[REACH](#) (Reversing the Epidemic in Africa with Choices in HIV prevention, or MTN-034/IPM 045) is a study that seeks to understand the HIV prevention needs and preferences of adolescent girls and young women in Africa. Specifically, the study will evaluate how adolescent girls and young women use the monthly dapivirine vaginal ring and Truvada as daily pre-exposure prophylaxis (PrEP), and their preferences for either or both approaches. REACH will also collect information on the safety of these approaches.



REACH will enroll 300 young women and girls – at least 100 girls ages 16-17 and 200 young women ages 18-21 – at five MTN-affiliated sites in Kenya, South Africa, Uganda and Zimbabwe. Pending ethics and in-country approvals, REACH is expected to begin early 2019 and take about three years to conduct.

The study is funded by the National Institute of Allergy and Infectious Diseases (NIAID); the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and National Institute of Mental Health, all components of the U.S. National Institutes of Health.

How is REACH designed?

REACH is a type of clinical trial called an open-label study in which all participants use an active product. In REACH, there are two products: the dapivirine vaginal ring, which is used for a month at a time, and an oral tablet called Truvada® taken daily, a regimen often referred to as PrEP.

All participants will use each product for six months. Random assignment will determine whether PrEP is used for the first six months and then the ring for the following six months, or the ring first and then PrEP. After experiencing both approaches, participants will have a choice of using either the ring or PrEP – or neither – for an additional six months.



To evaluate the safety of each approach, researchers will conduct medical exams and do laboratory tests of blood, urine and vaginal fluid. To evaluate adherence to and acceptability of PrEP and the vaginal ring, participants will answer questions about their use and experience with each product, both on a computer and in face-to-face conversations with site staff. In-depth interviews and focus group discussions will also help understand what motivates or is challenging about using each product.

Why is a study like REACH needed?

No one HIV prevention method will suit everyone, nor suit everyone at all times. As with contraception, the more HIV prevention options available to women, the more likely one will and can be used.

Daily pill taking (PrEP) was challenging for young women in clinical trials of PrEP. And, while the monthly ring helped protect against HIV among women older than 21 in ASPIRE, it was not effective among those 18-21, who used the ring least regularly. Researchers need to understand the challenges young women face in using these products, so strategies can be identified that can help.

Truvada as daily PrEP is approved in several countries for ages 18 and older, although the World Health Organization recommends it for anyone at significant risk. In some countries, such as Kenya, rollout includes those younger than 18. The U.S. Food and Drug Administration (FDA) recently expanded approval of Truvada as PrEP for adolescents – technically, for people weighing at least 35 kgs, a decision based on the ATN 113 study in young men who have sex with men in the United States. Though the FDA decision is very encouraging, African regulators will likely need more data about PrEP safety in young African women. To date, there is very little safety data on PrEP in African adolescent girls and no safety data on the ring in younger African women. The MTN has already completed a safety study of the dapivirine ring in the United States that enrolled 96 girls between the ages of 15-17. Results of this study, referred to as [MTN-023 /IPM 030](#), found the ring to be safe. Adherence to ring use was also high.

REACH will add to this data by contributing important information about both PrEP and the dapivirine ring in African girls.



What exactly is the dapivirine ring?

The dapivirine ring is similar to vaginal rings commonly used for contraception except that it contains an ARV drug, dapivirine, instead. Dapivirine belongs to a class of ARVs called non-nucleoside reverse transcriptase inhibitors (NNRTIs) that prevent HIV from making copies of itself. The ring, which is made of a flexible material, sits high inside the vagina, where it slowly releases the drug over the course of the one month the ring is worn. Women can insert and replace the ring themselves.

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More information about REACH can be found at <https://mtnstopshiv.org/reach-study> and www.mtnstopshiv.org/news/studies/mtn034, and about the dapivirine ring at www.mtnstopshiv.org/news/studies/mtn025; and www.ipmglobal.org.

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