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New study aims to empower teen girls and young women with choices in HIV prevention

Safety and acceptability of dapivirine vaginal ring and oral PrEP being assessed in REACH; researchers enroll first participant at trial site in Uganda

PITTSBURGH, Feb.7, 2019 – AIDS is already the leading cause of death among girls and young women in much of Africa, and matters could only get worse, given that for every day that passes, 1,000 more girls ages 15 to 24 are likely to become infected with HIV.

Ensuring that women and girls can have access to and benefit from safe and effective methods of prevention is imperative, say researchers from the National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN) who have launched a new study called REACH and enrolled its first participant.

In REACH (Reversing the Epidemic in Africa with Choices in HIV prevention), or MTN-034, researchers are focusing on two methods they believe could make a difference for many young women – a daily oral tablet called Truvada®, an approach often referred to as PrEP, short for pre-exposure prophylaxis, which is now approved in many countries; and a monthly vaginal ring containing an antiretroviral (ARV) drug called dapivirine currently undergoing regulatory review.

If approved, the dapivirine ring would be the first biomedical prevention method specifically for women, i.e., for women 18 and older. Additional information about the vaginal ring in girls under age 18, particularly about its safety, would be required before regulatory bodies would consider expanding approval to include a younger population.

REACH is a Phase IIa study that is designed to fill important gaps in information about the safety and acceptability of the dapivirine ring and oral PrEP, including in girls as young as 16. REACH also seeks to understand what young women will need to help them to use these products. Each must be used consistently and regularly to be effective – daily for oral PrEP, and monthly for the ring – which has been a challenge for younger women in clinical trials.

“With PrEP being made available in many countries and the possibility that the ring will be approved, we want to see that these products can work for and be made available to women and girls of all ages at risk of HIV acquisition, who both need and deserve methods of protection that are in their control,” noted Lulu Nair, MBChB, MPH, protocol chair of the REACH study, who is clinical research site leader at the Desmond Tutu HIV Centre (DTHC), University of Cape Town, in Cape Town, South Africa.

REACH will enroll 300 young women and girls ages 16 to 21 at five MTN-affiliated clinical research sites in Kenya, South Africa, Uganda and Zimbabwe. Two of the sites have begun the study: the Makerere University-Johns Hopkins University Research Collaboration in Kampala, Uganda, where the first participant was enrolled, and the University of Zimbabwe College of Health Sciences Spilhaus Clinical Research Site in Harare.

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All participants in REACH will use oral PrEP and the dapivirine ring, each for six months. After experiencing both approaches, participants will have a choice of using either the ring or PrEP – or neither – for an additional six months. REACH is expected to take about three years to conduct, with results anticipated in late 2022 or early 2023.

MTN researchers have already conducted a safety study of the dapivirine ring in the United States that enrolled 96 girls ages 15-17 who were randomly assigned to use the dapivirine ring or a placebo ring for a month at a time for a total of six months. Results of this study, referred to as MTN-023 /IPM 030, were reported in 2017 and found the ring was well-tolerated and acceptable. Adherence was also high – 95 percent of the rings returned after use had drug levels indicating consistent use during the previous month.

The dapivirine ring was well-tolerated and reduced the risk of HIV in two Phase III trials that together enrolled more than 4,500 women ages 18-45 from four African countries – ASPIRE , which was conducted by the MTN, and The Ring Study, led by the International Partnership for Microbicides (IPM), a non-profit organization that developed the dapivirine ring and is seeking its regulatory approval.

Yet, in ASPIRE, the dapivirine ring was not effective among younger women ages 18-21, who used the monthly ring least regularly. Similar results were seen among 18- to 21-year-old women in The Ring Study. Likewise, in studies with oral PrEP, it has been the younger participants who have struggled most with a daily pill-taking regimen. Results of a study, called HPTN 082, expected later this year, will shed additional light about PrEP use among girls ages 16-25 in South Africa and Zimbabwe.

As part of REACH, participants will receive extensive support and counseling focused on product adherence. They also will be encouraged to be open with study staff about any concerns or difficulties they may have.

“We have incorporated a number of supportive measures to help with adherence in REACH, but if girls aren’t willing or able to use the ring or PrEP, we want to understand why, so that we can learn what is needed to better support use,” explained Kenneth Ngure, Ph.D., M.P.H., associate professor and chair of the department of community health at Jomo Kenyatta University of Agriculture & Technology in Nairobi, Kenya, and REACH protocol co-chair. “At the same time, it’s important to recognize that these products won’t be for everyone, and the reasons why are just as important for us to understand.”

“Women need HIV prevention methods that are under their control, and their needs and preferences may change,” added Connie Celum, M.D., M.P.H., who is also a protocol co-chair, and professor of global health and medicine and director, International Clinical Research Center at the University of Washington in Seattle. “That’s why having different HIV prevention methods is so important, and why we have incorporated choice into the design of this study. It’s really quite exciting that we have come this far, to having PrEP, but also potentially the dapivirine ring.”

If approved, the ring could be available in some countries as early as 2020.

“Girls have told us that being able to protect themselves from HIV would be empowering, and that having choice would be especially empowering. They want and deserve to have control of their health, their lives and their destinies,” said Sharon Hillier, Ph.D., MTN principal investigator and professor and vice chair of the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine and Magee-Womens Research Institute.

In addition to the sites in Uganda and Zimbabwe, REACH will be conducted in Kisumu, Kenya at the Kenya Medical Research Centre (KEMRI) Centre for Global Health; and in South Africa at the DTHF’s Emavundleni Research Centre in Cape Town and the Wits Reproductive Health and HIV Institute in Johannesburg.

According to UNAIDS, young women comprised 26 percent of new HIV infections in eastern and southern Africa in 2017, despite making up only 10 percent of the population. Many factors may contribute to HIV susceptibility in adolescent girls and young women, including gender-based violence, cultural and economic inequities and biological or hormonal changes.

As a global priority, young women and girls need safe and effective biomedical HIV prevention strategies for use throughout their lifespan, including during times of pregnancy and breastfeeding, when the risk of infection is estimated to be three to four times greater than when not pregnant or nursing. Similar to REACH, the MTN is planning studies of the monthly dapivirine ring and oral PrEP in pregnant women (MTN-042, or the DELIVER Study) and breastfeeding women and infants (MTN-043, or B-Protected).

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More information about REACH is at mtnstopshiv.org/reach-study and www.mtnstopshiv.org/news/studies/mtn034,. Cliclk here to watch a short video.

About the Microbicide Trials Network

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. Based at Magee-Womens Research Institute and the University of Pittsburgh, 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 that are intended to prevent the sexual transmission of HIV – from the earliest phases of clinical study to large-scale trials that support potential licensure of these products for widespread use. More information about the MTN is available at www.mtnstopshiv.org/.

About the Dapivirine Ring

The dapivirine ring is made of a flexible silicone matrix polymer and contains dapivirine, a type of ARV known as a non-nucleoside reverse transcriptase inhibitors (NNRTI), this is slowly released over the course of a month. The ring delivers dapivirine directly at the site of potential infection, with low systemic absorption. Women insert the flexible, long-acting ring themselves into the vagina and replace it every month. The ring was developed by the International Partnership for Microbicides (IPM), a nonprofit with offices in the United States, South Africa and Belgium. IPM holds an exclusive worldwide license for dapivirine from Janssen Sciences Ireland UC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), which is designed to ensure that women in low-resource settings have affordable access to any dapivirine-based microbicide.

In 2016, two large clinical trials — The Ring Study (conducted by IPM) and ASPIRE (conducted by the MTN) — found the monthly dapivirine vaginal ring was well-tolerated and helped reduce the risk of HIV. Interim data from the DREAM and HOPE open-label studies, announced in March 2018, found increased adherence and suggest greater risk reduction. Final results of both open-label studies are expected in 2019. IPM is in the process of seeking regulatory approval for the ring's use by women 18 and older. If approved, the ring could be available in some countries around 2020 or 2021. It would be the first biomedical prevention option specifically for women. For more information about the dapivirine ring go to www.ipmglobal.org.

About Truvada for PrEP

TRUVADA® is the brand name for a tablet containing both tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg that is used for the treatment of HIV, in combination with other ARVs. TRUVADA was first approved for prevention of HIV-1 infection as daily oral pre-exposure prophylaxis (PrEP) by the US Food and Drug Administration (FDA) in 2012. TRUVADA, which is a registered trademark of Gilead Sciences of Foster City, California, is now approved as PrEP in several countries for ages 18 and older. In 2018, the FDA expanded the approval of TRUVADA as PrEP in the U.S for adolescents at risk of HIV – technically, for people weighing at least 35 kgs, a decision based on the ATN 113 study in US young men who have sex with men. The World Health Organization recommends oral PrEP for anyone at significant HIV risk. In some countries, such as Kenya, rollout includes those younger than 18.