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# Researchers launch first study of a vaginal film that dissolves in 30 days to assess its acceptability as a potential HIV prevention method for women

*Study taking place in US and sub-Saharan Africa will also help inform final design of a monthly film containing dapivirine*

**PITTSBURGH – November 2, 2023** – A vaginal film designed to slowly dissolve over the course of 30 days is being put to the test for the first time in a study launched this week that aims to determine its feasibility and acceptability as a potential HIV prevention method for women.

The study, which is being conducted in the United States and Africa by MATRIX, a United States Agency for International Development (USAID)-funded project focused on the early research and development of innovative HIV prevention products for women, will help inform the final design of a monthly film containing the antiretroviral (ARV) drug dapivirine. The monthly dapivirine film is one of nine products being developed under MATRIX, which also includes a dual-purpose monthly film containing both dapivirine and a hormonal contraceptive to prevent pregnancy.

Similar to thin breath mint strips that dissolve in the mouth, vaginal films are products designed to dissolve after being inserted into the vagina. Previous studies exploring the use of vaginal films as a drug delivery method for HIV prevention have been of quick-dissolve films or films designed to dissolve within a week.

In the new study, known as MATRIX-002, researchers are assessing the acceptability, usability and safety of two prototype monthly vaginal films that contain no active drug. In this way, they will be able to learn what refinements may be needed in the film's design, including to its shape, before conducting a first-in-human study of the monthly dapivirine film.

MATRIX-002 will enroll 100 women, as well as 30 sexual partners, at five sites in Kenya, South Africa, Zimbabwe and the United States. Enrollment of the first participants took place at the US site, based at the University of Pittsburgh and Magee-Womens Research Institute (MWRI), which is also where the monthly dapivirine vaginal film products are being developed.

"By conducting a study of placebo films with no active drug, we will be able to answer fundamentally important questions. For instance, are women, especially African women, comfortable with the idea of using a vaginal film that takes 30 days to dissolve? What kind of support and counseling will they need to use it properly?," noted Nyaradzo Mgodi, MBChB, MMed, MATRIX-002 protocol co-chair and investigator of record at the Harare Health and Research Consortium (HHRC) Zengeza clinical research site (CRS) in Zimbabwe, one of the five sites conducting the study.

"We are fully aware of the urgent need for more HIV prevention methods for women, but we also don't want to rush into study of a new product with design features that may not be to the liking of women and could therefore impact product use. Something as simple as the shape of the film, or how it feels to the touch, are important considerations that are best resolved as early in the process as possible," added Alexandra Minnis, PhD, a behavioral scientist from RTI International, Berkeley, Calif., who is protocol co-chair.

A key focus of MATRIX is being responsive to end-user and stakeholder feedback during the earliest stages of product development to inform decisions about product design and improve the odds for success of the products in its portfolio, which is why a study like MATRIX-002 is being conducted and why it is designed the way it is – evaluating two prototype vaginal films, both of which are of similar size (2" x 2") but differ in their shape, one having straight corners and the other rounded corners. If not for the feedback that came out of stakeholder consultations convened in Kenya, South Africa, and Zimbabwe in 2022, during which prototype films were passed around, the MATRIX-002 study would have instead concentrated on the original square design. But upon learning that advocates and young women, in particular, disliked the straight corners of the film, researchers modified its shape by rounding the corners, recognizing also that this modification would result in a slightly higher product cost. While cost is an important factor to consider, so too are the preferences of women who will actually use the film, insight into which the MATRIX-002 study will provide.

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As such, women who enroll in the study will be randomly assigned to use one of the two placebo films – either a film with straight corners or one with rounded corners. Participants will use their assigned film twice, for one month each. During the first month of film use, women are to refrain from vaginal sex and vaginal product use. During the second month, when a new film will be used, there will be no such restrictions. Women will insert the films themselves in the clinic with study staff providing guidance and instructions. As part of the study, participants will be asked questions about their experiences, including likes and dislikes, with film use, and up to 35 participants will also be asked to participate in an in-depth interview so that the study can gain deeper insight into women's experience with and views about the film. In-depth interviews will also be conducted with approximately 30 sexual partners.

The study is expected to be underway at all five clinical research sites (CRS) by early 2024, which in addition to the University of Pittsburgh/MWRI and the HHRC CRS in Zimbabwe, includes the Kenya Medical Research Institute (KEMRI) Centre for Clinical Research Thika CRS and two sites in South Africa: the Aurum Institute Klerksdorp CRS and the Wits Reproductive Health and HIV Institute (Wits RHI) CRS in Johannesburg.

Follow-up of all participants is anticipated to be completed in July or August 2024, with study results anticipated by the end of the year (2024). MATRIX would then expect to be conducting the first-in-human study of the monthly dapivirine film in 2025.

Dapivirine is already known to be safe and effective for preventing HIV when formulated as a monthly vaginal ring, and in fact, the dapivirine vaginal ring has been recommended by the World Health Organization as an additional HIV prevention option for women and approved for use in several African countries, including Kenya, South Africa and Zimbabwe. The monthly film containing dapivirine is designed so that when it is placed inside the vagina and comes in contact with vaginal fluid, it will slowly begin to dissolve, and in doing so, release dapivirine. The drug would continue to be slowly released over the course of a month until the film completely dissolves and all of the drug has been delivered in the vagina. This means that there would be nothing to remove or discard before inserting a new film for another month of protection.

Development of both the monthly dapivirine film and the monthly dual-purpose dapivirine and contraceptive film is being conducted by a team of researchers at the University of Pittsburgh and MWRI under the direction of Lisa Rohan, PhD, professor of pharmaceutical sciences, University of Pittsburgh School of Pharmacy, and professor of obstetrics, gynecology & reproductive sciences, University of Pittsburgh School of Medicine. Both products are being developed in collaboration with the Population Council, a global nonprofit research organization, which acquired the dapivirine product pipeline from the International Partnership for Microbicides.

According to UNAIDS, women and girls accounted for 63 percent of all new HIV infections in sub-Saharan Africa in 2022, versus 46 percent globally. In much of Africa, daily oral PrEP (pre-exposure prophylaxis), which requires taking an ARV tablet every day, is the only biomedical prevention method available. Daily pill-taking has been especially challenging for adolescent girls and young women. Despite the dapivirine ring and cabotegravir long-acting injectable (CAB-LA) both being recommended by WHO and approved in several African countries, neither method is yet widely available. Even so, women have different preferences and needs, and at different times in their lives, which is why additional options are needed.

MATRIX is a five-year program funded by USAID in 2021 that aims to expedite the research and development of HIV prevention products for women – including products designed to protect against both HIV and pregnancy – that in addition to being safe and effective, will be acceptable, affordable, scalable and deliverable in the settings where they are needed most. MATRIX activities are focused on the early research and development of products, which involves both pre-clinical research and the first clinical trials of products. Through its North-South partnerships, MATRIX also aims to strengthen the capacity of African investigators to facilitate full and sustainable ownership of this work into the future. MATRIX is being implemented by Magee-Womens Research Institute (MWRI) in collaboration with partner organizations based in Kenya, South Africa, the United States and Zimbabwe. Leading the project is Sharon Hillier, Ph.D., of MWRI and the University of Pittsburgh School of Medicine, with Thesla Palanee-Phillips, Ph.D., from the Wits RHI and University of Witwatersrand, South Africa, serving as deputy director.

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To learn about MATRIX go to www.matrix4prevention.org. Click here to read a QA about the dapivirine film and MATRIX-002 study. Additional information about MATRIX-002 can also be found at www.matrix4prevention.org/activity-hubs/clinical-trials/matrix-002.

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