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One Size Doesn't Fit All When It Comes to Products for Preventing HIV from Anal Sex

PITTSBURGH, 6 March 2021 – After “trying on” three placebo methods for the delivery of a rectal microbicide, study participants said they could see all of them – a douche, rectal suppository and fast-dissolving rectal insert – fitting into their daily lives. These results, which also identified the product attributes most important to participants, underscore the importance of developing a range of HIV prevention products for people who practice anal sex.

The initial insights from the study, aptly named DESIRE (Developing and Evaluating Short-acting Innovations for Rectal Use), are being reported on March 6 in a Science Spotlight session at the virtual meeting of the [Conference on Retroviruses and Opportunistic Infections](#) (CROI), March 6-10. The presentation will be available for registered participants and media to view throughout the meeting.

Conducted by the National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), DESIRE focused on potential delivery methods for rectal microbicides – topical products being developed and tested to reduce a person’s risk of acquiring HIV and other sexually transmitted infections from anal sex. MTN researchers are particularly interested in on-demand options – used around the time of sex – and behaviorally congruent options that deliver anti-HIV drugs via products people may already be using as part of their sex routine.

“DESIRE stands out as a unique study because we took a step back and said, ‘Let’s figure out the modality without automatically pairing it with a drug’,” explained José A. Bauermeister, Ph.D., M.P.H., study protocol chair and Albert M. Greenfield Professor of Human Relations at the University of Pennsylvania. “It gave us the ability to manipulate the delivery method without having to worry about how reactions to a particular drug might confound the results. We also had people trying out these methods in their own lives, and only then asked them to weigh the attributes of each.” As such, he said, participants weren’t making choices based on theoretical concepts, but instead using real experiences to guide their preferences.

Launched in 2019, DESIRE, also referred to as [MTN-035](#), is the first study to explore multiple placebo methods for delivering a rectal microbicide. The three delivery methods assessed included a [fast-dissolving placebo insert](#) approximately two-thirds of an inch in length, a [placebo suppository](#) approximately

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an inch and a half in length, and a commercially available 120 mL [douche bottle](#) that participants were instructed to fill with clean tap or bottled water prior to use.

The study enrolled 217 participants who used each rectal delivery method for a month at a time, with a week-long break in between. Study participants, whose average age was 25 years, included cisgender men who have sex with men (79 percent) as well as transgender women (19 percent) and transgender men (2 percent) who have sex with men. The participants, based in Malawi, Peru, South Africa, Thailand and the United States (Birmingham, Pittsburgh and San Francisco), were instructed to use each method between 30 minutes and 3 hours prior to engaging in receptive anal sex, or once a week if they had not engaged in receptive anal sex in a given week.

To evaluate the acceptability of each method, participants were asked to complete a four-item survey once a week by text, commonly referred to as short message service (SMS), in their preferred language. After a month of using a particular delivery method, they were asked to complete a computer-assisted interview, with a subset of participants also completing an in-depth interview led by one of the study researchers.

At their final study visit, participants ranked attributes of a hypothetical product for preventing HIV from anal sex, and researchers used conjoint analysis – a market research approach that measures the value consumers place on features of a product or service – to calculate the percentage of weight participants gave to each attribute. They found that efficacy was the strongest determinant of participants’ stated modality choice at 30 percent, followed by delivery method (18 percent) and side effects (17 percent). Other factors – timing of use before sex, duration of protection, frequency of use, and the need for a prescription – were not weighted as having as much importance by study participants. Through further analysis, researchers identified the participants’ most preferred package based on the product features: A douche used 30 minutes before sex with 95 percent efficacy that offers three to five days of protection. This ideal product would also only need to be used once a week, have no side effects, and be available over the counter.

While this market research approach offered insights into the most common package of features, participants also underscored how each of the modalities could offer unique advantages in their daily lives.

“As you might expect, the context of the participants’ lives informed their product choice,” said Dr. Bauermeister. “When asked to rank the most preferred product attributes, they based their answers on their own experiences and the tradeoffs they might make in real-life situations.” In some instances, he explained, discretion might be important, so a small tablet in the form of a fast-dissolving rectal insert that could be carried in your pocket might be the best option. At other times, hygiene may be a priority and a douche would be preferred. As a pre-lubricated product, even the suppository had unexpected advantages with some participants commenting about its potential as an alternative to sexual lubricant.

“The lesson we learned from MTN-035 is that even though the douche was preferred overall, we shouldn’t assume it’s right for everyone every time they plan to have sex,” said Dr. Bauermeister.

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“Depending on who you are, what you do and where you live, it may not be a viable, or even a desirable, option for HIV prevention. At the end of the day, people could see all three of these modalities fitting into their lives.”

Researchers like Dr. Bauermeister are hopeful these results will inform the development of rectal microbicides moving forward, and lead to expanded choices in preventing HIV from anal sex.

MTN-035 was conducted at the following clinical research sites (CRSs): the College of Medicine-Johns Hopkins Research Project in Blantyre, Malawi; the IMPACTA CRS in Lima, Peru; the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa; the Chiang Mai University HIV Prevention CRS in Thailand; and, in the United States, the University of Pittsburgh CRS, Bridge HIV CRS in San Francisco, and University of Alabama at Birmingham CRS.

The MTN is funded by the National Institute of Allergy and Infectious Diseases (NIAID), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all part of the NIH. The placebo rectal insert used in the study was developed by CONRAD, a not-for-profit research and development organization based at Eastern Virginia Medical School in Norfolk, Va.

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Dr. Bauermeister’s presentation “*Developing and Evaluating Short-Acting Innovations for Rectal Use (Desire): Acceptability and choice for three placebo products used with receptive anal intercourse among young MSM and TG people*” will be viewable beginning at 12:01 a.m. (EST), Saturday, March 6. Please visit www.croiconference.org for more information.

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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 <https://mtnstopshiv.org>.

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