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Women who took part in VOICE study speak up about why they didn't use the HIV prevention products being tested

Sub-study of VOICE sheds light on trial's results and women's poor adherence

CAPE TOWN, October 29, 2014 – Many of the women at first acted surprised. Some insisted the blood tests were wrong. But most conveyed to researchers why they had not used the study products assigned to them as participants in [VOICE](#), a large HIV prevention trial that, as a likely consequence, did not find any of the three products that were tested to be effective.

The women were among 127 former VOICE participants who, as part of a behavioral sub-study called [VOICE D](#), agreed to take part in in-depth interviews and/or focus group discussions after learning the results of blood tests indicating their actual patterns of product use during the trial. The researchers hoped that sharing individual test results would elicit candid discussion about the challenges women experienced in using the products during VOICE, and help to understand the study's disparate results, which were initially reported in March 2013.

Although behavioral measures of adherence, including women's own reports, indicated that 90 percent of the 5,029 women in VOICE had followed the daily regimens, tests to detect drug in stored blood samples conducted at the end of the trial revealed that less than 30 percent had actually used their product regularly (either tenofovir tablets, tenofovir/emtricitabine tablets – also known as Truvada® - or tenofovir vaginal gel).

Findings of VOICE D, which were presented at the [HIV Research for Prevention](#) (HIV R4P) meeting in Cape Town today, shed new and important light about women's use and nonuse of products in HIV prevention trials. Both VOICE and the VOICE-D sub-study were conducted by the U.S. National Institutes of Health-funded [Microbicide Trials Network](#) (MTN).

“We wanted women to open up, to feel comfortable and to talk candidly about their experience participating in VOICE. We hoped that providing women with their individual drug levels would be an impetus for them to be more forthcoming and frank. This is exactly what happened,” explained Ariane van der Straten, Ph.D., M.P.H., of the RTI International/Women's Global Health Imperative (RTI/WGHI) program in San Francisco, who led VOICE D and was the lead behavioral scientist on VOICE.

Dr. van der Straten described one woman who said she didn't use the vaginal gel because it leaked and she feared it would do harm to her uterus. She also admitted giving some to a friend who was a sex worker and pouring unused gel into the toilet. Another woman who had been assigned to one of the oral tablet groups said, among other things, that she was told by friends and family that taking the tablets would make her sick or give her HIV. This same woman insisted her blood tests were wrong, because she purposively took the pills prior to coming for her study visits so the drug would show up in her blood test.

“Even those who refused to admit nonuse provided insightful information,” commented Dr. van der Straten.

VOICE D was conducted at a third of the 15 VOICE sites in South Africa, Uganda and Zimbabwe and was designed to explore the contextual and trial-specific issues affecting actual and reported product use and sexual behaviors during women's participation in VOICE. Stage 2 of VOICE D, which was implemented in

response to VOICE final results, involved former VOICE participants who had been assigned to one of the active arms and then preselected based on drug levels: low (women whose tests detected no drug); inconsistent (those whose drug levels varied) and high (women who had drug detected in 75 to 100 percent of their blood samples). The cohort also included 13 women who had acquired HIV during VOICE.

Drug level results were presented to women by study staff who had not been involved in the conduct of VOICE using a simple visual tool. A teapot represented the pattern of adherence, depending on whether it was empty, full or half-full, while a teacup – 6 for every teapot – represented a study visit in which blood was collected and tested.

The reaction of women in the low adherence group was mostly surprise (41 percent) and disbelief (37 percent). Only 10 percent initially accepted their results; some remained in disagreement while others came to accept them. Among women in the high adherence group, 65 percent expressed happiness.

To help understand the reasons for not using the products, researchers asked participant to select among and rank order 20 theme cards (e.g., I was too busy to take the products every day; I had to hide when taking my products). Fears about the products and their side effects were the most common themes of low adherers and were fueled by peer participants, relatives and community members' negative attitudes about the products.

In total, seven presentations on different aspects of VOICE D are being reported at HIV R4P, including three oral presentations today on Stage 2 results and two oral presentations yesterday on Stage 1 results.

Stage 1 of VOICE D involved 88 women who took part in individual one-time in-depth interviews after exiting VOICE, most of whom were interviewed before the trial's results were publicly reported and shared with participants and communities. Stage 1 was designed in part to better understand women's perceptions and understanding of various risk behaviors, including anal sex. Yesterday, Zoe Duby, MPhil, from the Desmond Tutu HIV Centre, University of Cape Town, presented findings indicating there was widespread misunderstanding and misinterpretation by participants of questions being asked of them about anal sex.

In addition to Dr. van der Straten, VOICE D was also led by Barbara Mensch, Ph.D., of the Population Council, and Elizabeth Montgomery, Ph.D., also of RTI/WGHI.

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VOICE was funded by the National Institute of Allergy and Infectious Diseases (NIAID), with co-funding from the *Eunice Kennedy Shriver* Institute for Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The study products were provided by Gilead Sciences, Inc., of Foster City, Calif., and by CONRAD, of Arlington, Va. Viread (oral tenofovir) and Truvada are registered trademarks of Gilead Sciences. In 2006, Gilead assigned a royalty-free license for tenofovir gel to CONRAD and the International Partnership for Microbicides of Silver Spring, Md. For more on VOICE go to <http://www.mtnstopshiv.org/news/studies/mtn003>

HIV R4P abstract (OA15.04)

Disclosure of Pharmacokinetic (PK) Drug Results Promotes Open Discourse on Non-adherence among Women in VOICE

Ariane van der Straten^{1,2}, Petina Musara³, Juliane Etima⁴, Kubashni Woeber⁵, Elizabeth T. Montgomery¹, Miriam Hartmann¹, Lisa Levy⁶, Thola Benny⁷, Helen Cheng¹, Jeanna Piper⁸, Cynthia I. Grossman⁹, Barbara Mensch¹⁰, MTN-003D Study Team

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About the MTN

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 development and 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.

Also at HIV R4P HIV

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Tuesday, 28 October

- *Language, Terminology and Understanding of Anal Sex amongst VOICE Participants in Uganda, Zimbabwe and South Africa* (OA02.05)
- *Application of a Body Map Tool to Enhance Discussion of Sexual Behaviour in Women: Experiences from MTN 003D* (OA02.06)

Wednesday, 28 October

- *To Give or Not to Give PK Results: An Ethical Dilemma for Researchers & Regulators in Uganda* (OA15.02)
- *The Effect of Presentation of Pharmacokinetic (PK) Drug Results on Self-reported Study Product Adherence among VOICE Participants in Zimbabwe* (OA15.03)
- *Disclosure of Pharmacokinetic (PK) Drug Results Promotes Open Discourse on Non-adherence among Women in VOICE* (OA15.04)

Perceptions and Practice of Heterosexual Anal Sex amongst VOICE Participants in Uganda, Zimbabwe and South Africa
 (Poster #P46.03)