Social science and humanities in HIV research

Janet Seeley
THE TREATMENT TARGET

- Diagnosed: 90%
- On treatment: 90%
- Virally suppressed: 90%
Women’s Experiences with Oral and Vaginal Pre-Exposure Prophylaxis: The VOICE-C Qualitative Study in Johannesburg, South Africa

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Abstract

Background: In VOICE, a multisite HIV pre-exposure prophylaxis (PrEP) trial, plasma drug levels pointed to widespread product nonuse, despite high adherence estimated by self-reports and clinic product counts. Using a socio-ecological framework (SEF), we explored socio-cultural and contextual factors that influenced participants’ experience of daily vaginal gel and oral tablet regimens in VOICE.

Methods: In Johannesburg, a qualitative ancillary study was concurrently conducted among randomly selected VOICE participants assigned to in-depth interviews (n = 41), serial ethnographic interviews (n = 21), or focus group discussions (n = 40). Audio taped interviews were transcribed, translated, and coded thematically for analysis.

Results: Of the 102 participants, the mean age was 27 years, and 96% had a primary sex partner with whom 48% cohabited. Few women reported lasting nonuse, which they typically attributed to missed visits, lack of product replenishments, and family-related travel or work. Women acknowledged occasionally skipping or missing doses because they forgot, were busy, felt lazy or bored, feared or experienced side effects. However, nearly all knew or heard of other study participants who did not use products daily. Three overarching themes emerged from further analyses: ambivalence toward research, preserving a healthy status, and managing social relationships. These themes highlighted the profound and complex meanings associated with participating in an blinded HIV PrEP trial and taking antiretroviral-based products. The unknown efficacy of products, their connection with HIV infection, challenges with daily regimen given social risks, lack of support from partners and significant others—and the relationship tradeoffs entailed by using the products appear to discourage adequate product use.

Conclusions: Personal acknowledgment of product nonuse was challenging. This qualitative inquiry highlighted key influences at all SEF levels that shaped women’s perceptions of trial participation and experiences with investigational products. Whether these impacted women’s behaviors and may have contributed to ineffective trial results warrants further investigation.


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Competing Interests: MTN-VOICE complied with all National Institutes of Health (NIH) data sharing policies. This does not alter the authors’ adherence to all the PLOS ONE policies on sharing data and materials.

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The Effect of Presentation of Pharmacokinetic (PK) Drug Results on Self-reported Study Product Adherence among VOICE Participants in Zimbabwe

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Background: Honest reporting of participant product use is critical to understanding challenges to adherence in HIV PrEP trials. Previous studies, like VOICE, have shown a huge gap between self-reported adherence and actual PK data. MTN-003D study was conducted after VOICE trial to elicit truthful reports about product non-use in VOICE. The study was conducted in 2 stages, the first without PK drug results provided to participants, the second with.

Methods: We conducted in-depth interviews and focus group discussions. Guides included questions assessing factors affecting women’s use of study product. We enrolled 74 women at 2 Zim
Notes and Quotes

VOICE reveals the need to improve adherence in PrEP trials

In a new study of preexposure prophylaxis (PrEP) in African women, Murenza et al. [1] found little effect of oral or vaginal treatments on prevention of new HIV-1 infection. They also revealed a critical need for study designs that address social and cultural barriers to PrEP adherence in women.

The Vaginal and Oral Interventions to Control the Epidemic (VOICE) trial was a randomized, placebo-controlled trial to evaluate the effectiveness of oral tenofovir, alone or in combination with emtricitabine, and vaginal tenofovir in preventing new HIV-1 acquisition in a population of 829 women at 15 sites in South Africa, Uganda, and Zimbabwe. The primary endpoint was new HIV-1 infection, which was tested monthly.

The study also included a case-cohort study to analyze plasma tenofovir levels in infected and uninfected participants.

There was no difference in the rate of HIV-1 seroconversion among any of the treatment groups or compared with placebo. Resistance to tenofovir was only present in three participants, and no participants had resistance to tenofovir. Adherence to the study treatment appeared to be high on the basis of product returned at each visit (packed pills, empty pill bottles, unused vaginal applications; 86%), a monthly questionnaire (98%), and a quarterly audio computer-assisted self-interview (ACASI; 88%). However, plasma tenofovir levels in the case-control subsample were low with tenofovir detected in only 23–58% of samples in the treatment groups. These findings were consistent with those of a previous study, the Preexposure Prophylaxis Trial for HIV Prevention among African Women (FEM-PrEP) trial [2], which also had a low adherence rate and showed no effect of tenofovir-based treatments on reduction of new HIV-1 infection.

There was a high level of interest in PrEP among VOICE participants, with more than 90% remaining in the study through the final visit. Yet, participants were not taking the study medication, even as they were reporting high adherence and even returning product to suggest high adherence. A small ancillary study by the investigators found that VOICE participants were unsure about the efficacy and safety of treatments in uninfected individuals and were concerned about the social stigma of being identified as HIV-1 infected because they were taking the medication [3]. Plasma tenofovir was more likely to be detected in participants who were married, 25 years of age or older and monogamous; this suggested that the predominantly young, unmarried population in the VOICE trial may have had less social and family support, leading to lower adherence and lack of efficacy.

The authors concluded that future PrEP study designs must not only include methods to ensure accurate reporting of adherence, such as real-time monitoring or use of products with sustained delivery rather than daily use, but also take into account social and cultural barriers to improve adherence among women.

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Conflicts of interest

There are no conflicts of interest.

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References

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Dear Prof. Seeley

# BMJ.2016.033807 entitled "A qualitative study of the xxxx trial (xxxx): is it acceptable to xxxx?"

Thank you for sending us your paper. I am sorry to say that we do not think it is right for the BMJ. We do not send out for external peer review manuscripts whose subject matter, design or topic do not meet our current priorities and are unlikely to make it through our process. We hope that this will allow you to promptly submit this manuscript elsewhere.

ANALYSIS

qualitative

Editors to reconsider their policy challenge the journal to develop with its stated mission

Excerpt from rejection letter tweeted by McGill Qualitative Health Research Group (@MQHRG), 30 September 2015

Thank you for sending us your paper. We read it with interest but I am sorry to say that qualitative studies are an extremely low priority for The BMJ. Our research shows that they are not as widely accessed, downloaded, or cited as other research. We receive over 8000 submissions a year and accept less than 4%. We do therefore have to make hard decisions on just how interesting an article will be to our general clinical readers, how much it adds, and how much practical value it will be.

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Quick Links

CROI 2017: Seattle

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CROI 2017 will be held from February 13 to February 17 in Seattle, Washington, at the Washington State Convention Center. Webcasts, abstracts, electronic posters, and other electronic resources from CROI 2017 will be now available online.

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