



The MTN-016 Pregnancy Registry: Baseline Characteristics of Enrollees from the VOICE Study and Reasons for Non- enrollment of Eligible Women

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Outline

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Background

- Many HIV prevention trials target reproductive age women. If HIV prevention agents come to market, women of reproductive age will use them, highlighting the importance of safety assessments before licensure in both non-pregnant and pregnant women.
- The Microbicide Trials Network (MTN) initiated the MTN-016 study, a prospective observational cohort enrolling participants who became pregnant during MTN effectiveness studies or those with planned exposures in pregnancy safety studies.

Background cont'd

- MTN-016 collected data on exposure to investigational HIV prevention agents during pregnancy, potential confounding and/or relevant factors such as maternal age, disease status during pregnancy, gestational age at exposure, pregnancy outcomes, genetic history and infant outcomes during the first year of life
- Our abstract describes participant enrollment in MTN-016 from MTN-003 (VOICE), a phase 2B double-blinded, placebo-controlled, five arm safety and effectiveness trial of daily use of tenofovir 1% vaginal gel, oral emtricitabine/tenofovir disoproxil fumarate for prevention of HIV acquisition in women.

Methods

- The VOICE trial was conducted between 2009-2012 at 15 sites in Uganda, South Africa and Zimbabwe.
- Women who became pregnant while participating in VOICE and met eligibility criteria were invited to enroll in MTN-016
- Pregnant women were eligible to participate if they were able and willing to provide informed consent, provided adequate locator information and had a confirmed pregnancy.

Methods cont'd

- Baseline demographic and behavioral characteristics were captured on standardized case report forms at enrollment in MTN-016 and were summarized using descriptive statistics.
- We collected data monthly on reasons for non-enrollment of potentially eligible women who chose not to participate.

Results

- Among 5,029 VOICE participants with over 5,425 person-years (py) of follow-up, there were 424 pregnancies (7.8/100 py) and 201 live births. The average age of participants who became pregnant during VOICE was 24 years, with 24% of pregnant participants being married at baseline.
- Among women who became pregnant during VOICE, 261 (62%) were eligible to enroll in MTN-016. Of these, 213/261 (82%) women and 185/201 (92%) of their infants enrolled in MTN-016. Baseline characteristics of MTN-016 enrollees from VOICE are summarized in Table 1.

Table 1. Baseline characteristics of women enrolled in MTN-016 from MTN-003

Characteristics	N(%)
Age category	
18-24	115(54.0)
25-34	91(42.7)
35 and above	7(3.3)
Currently married	69(32.6)
Participant earns an income of her own	90(42.3)
Some secondary education or higher	191(89.7)
Participant or relative owns the home the woman lives in	134(62.9)

Results cont'd

- The most common reasons for non-enrollment into MTN-016, as reported to site investigators by potentially eligible pregnant women, included the following:
 - Additional study visit burden associated with participating in two protocols at the same time (co-enrollment in MTN-003 and MTN-016) or continuing obligations to complete MTN-016 study visits after exiting from the parent protocol.
 - Employment considerations/conflicts.
 - Cultural customs related to women's temporary relocation to rural areas/family homes during the perinatal periods.
 - Beliefs that public access to newborns and movements outside of the home should be limited during the postnatal periods.

Conclusion

- Similar to participants in other HIV prevention studies, the majority of women who enrolled in VOICE were young, reproductive age women.
- The majority of eligible women from VOICE and their infants chose to enroll in MTN-016; however, among those who declined enrollment, study visit burden and local cultural customs were common barriers to enrollment that may also impact enrollment of mothers and their infants into other pregnancy-related studies.

Conclusion cont'd

- Efforts to assist women with some of these barriers could foster increased prospective enrollment into MTN-016. Doing so will augment the amount and quality of data gathered in this unique population with early pregnancy exposures to candidate HIV prevention agents.
- Data regarding the impact of early pregnancy exposure to candidate HIV prevention agents is a critically important component of the overall safety profile of HIV prevention agents.

Thanks

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