Tenofovir-Based PrEP for African Women

VOICE
### Study Design: VOICE

- **N = 5029 women**
- **Age 18-45**
- **Setting:** 14 sites in South Africa, Uganda, and Zimbabwe
- **Eligibility:**
  - Women who reported vaginal sex in previous 3 months
  - Not pregnant or breastfeeding
  - Willing to use effective contraception
- **Regimens**
  - Tenofovir 1% gel daily (TFV gel)
  - Tenofovir 300 mg po daily (TFV tablet)
  - Tenofovir 300 mg-emtricitabine 200 mg po daily (TDF-FTC tablet)
Tenofovir-Based PrEP for African Women
VOICE Trial: Background

Women randomized
n = 5,029

HIV+ at enrollment
n = 22

Lost to follow-up
n = 38

TDF tablet
n = 993

TDF-FTC tablet
n = 985

Placebo tablet
n = 999

TFV gel
n = 996

Placebo gel
n = 996

Abbreviations: TDF = tenofovir; TDF-FTC = tenofovir DF-emtricitabine

Vaginal and Oral Interventions to Control the Epidemic

VOICE Trial: Timeline

September 2009 to June 2011: accrual period
Independent DSMB review every 3-6 months

September 2011: oral TDF arm stopped
Deemed safe but not effective

November 2011: vaginal TFV gel arm stopped
Deemed safe but not effective

August 2012: follow-up completed for oral TDF-FTC arm
Deemed safe but not effective
Adherence shown to be low in all arms

Vaginal and Oral Interventions to Control the Epidemic
VOICE Trial: Results

*Data censored at time that oral TDF arm stopped

Vaginal and Oral Interventions to Control the Epidemic
VOICE Trial: Adherence

Mean Proportion of Quarterly Samples with Tenofovir Detected (%)

Conclusions: “None of the drug regimens we evaluated reduced the rates of HIV-1 acquisition in an intention-to-treat analysis. Adherence to study drugs was low.”
The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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