Tenofovir-Based PrEP for African Women

VOICE
Tenofovir-Based PrEP for African Women
VOICE Trial: Study Design

- **Background**: Randomized, placebo-controlled trial to assess daily treatment with oral tenofovir disoproxil fumarate (TDF), oral tenofovir-emtricitabine (TDF-FTC), or 1% tenofovir (TFV) vaginal gel as HIV PrEP in women in South Africa, Uganda, and Zimbabwe

- **Participants** (n = 5029) women
  - Age 18-45 years
  - Cisgender women
  - Reported vaginal sex in previous 3 months
  - Not pregnant or breastfeeding
  - Willing to use effective contraception

- **Regimens**
  - Tenofovir mg PO daily (TDF tablet)
  - Tenofovir-emtricitabine PO daily (TDF-FTC) tablet
  - Tenofovir 1% gel daily (TFV gel)

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

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<th>Event</th>
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<tr>
<td>September 2009 to June 2011: accrual period</td>
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<td>Independent DSMB review every 3-6 months</td>
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<td>September 2011: oral TDF arm stopped</td>
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<tr>
<td>Deemed safe but not effective</td>
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<tr>
<td>November 2011: vaginal TFV gel arm stopped</td>
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<tr>
<td>Deemed safe but not effective</td>
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<tr>
<td>August 2012: follow-up completed for oral TDF-FTC arm</td>
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<td>Deemed safe but not effective</td>
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Vaginal and Oral Interventions to Control the Epidemic
VOICE Trial: Results

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.”

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