We aimed to assess the frequency of HIV-1 drug resistance in women from MTN-003 (VOICE) who acquire HIV infection while using study product by standard genotype analysis.

**Genotype:** Q58E

**Objective**

- **Aim:** To assess the frequency of HIV-1 drug resistance in women from MTN-003 (VOICE) who acquire HIV infection while using study product by standard genotype analysis.

**Study Design**

- **Participants randomized to:**
  - Oral tenofovir (n=1007)
  - Oral placebo (n=1009)
  - Gel placebo (n=1003)
  - Oral TDF (n=1007)
  - Gel TDF (n=1006)

- **Drug regimen:**
  - Oral tenofovir/emtricitabine (TDF-FTC)
  - Oral placebo
  - Gel placebo

- **Randomization arm:**
  - TDF-FTC
  - Placebo

- **Drug use period:**
  - Oral drug: daily
  - Gel drug: twice weekly

- **End visit:**
  - Oral drug: 12 months
  - Gel drug: 8 months

- **Follow-up visits:**
  - Mid-Sep (study enrollment) – Early Aug
  - Mid-Sep (study enrollment) – Mid-Sep

- **Additional visits:**
  - Acutely infected post enrollment
  - Enrollment visit – mid-Sep
  - Enrollment visit – early Aug

- **HIV RNA levels:**
  - Undetectable
  - Negative serology
  - HIV RNA > 200 copies/ml

- **Resistance to tenofovir or emtricitabine:**
  - Acquired resistance to PrEP ARVs is rare
  - No resistance to oral tenofovir or tenofovir gel

- **Drug resistance testing:**
  - PCR amplification failure
  - Insufficient copies of HIV-1 RNA for extraction
  - No result due to:
    - Acquired HIV-1 after product use end visit
    - Acquired HIV-1 after enrollment

- **Drug resistance outcome:**
  - Of 355 seroconverters genotyped in VOICE (212 on active product arms):
    - No resistance to oral tenofovir or tenofovir gel
    - 9 cases (2.5%) of transmitted resistance with major NNRTI mutations
    - 3 cases (0.8%) of FTC resistance; all from TDF-FTC arm (3/71; 4.2%)

**Conclusions**

- Acquired resistance to PrEP ARVs is rare
- Transmitted NNRTI resistance (2.5%) more likely than acquired resistance to product (3/212; 1.4%)
- Better point-of-care tests are needed to exclude acutely infected individuals from prevention trials
- Limitations:
  - Low product use in VOICE may underestimate resistance selection
  - Evaluation of low frequency resistance (>20% of population) is needed

**Summary**

- Of 355 seroconverters genotyped in VOICE (212 on active product arms):
  - No resistance to oral tenofovir or tenofovir gel
  - 9 cases (2.5%) of transmitted resistance with major NNRTI mutations
  - 3 cases (0.8%) of FTC resistance; all from TDF-FTC arm (3/71; 4.2%)

**HIV-1 Resistance Outcomes from the MTN 003 (VOICE) Study**

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  - To assess the frequency of HIV-1 drug resistance in women from MTN-003 (VOICE) who acquire HIV infection while using study product by standard genotype analysis.

- **Study Design**
  - Participants randomized to:
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- **Drug regimen:**
  - Oral tenofovir/emtricitabine (TDF-FTC)
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  - Oral drug: daily
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  - Mid-Sep (study enrollment) – Early Aug
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  - Acquired resistance to PrEP ARVs is rare
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