

VOICE Overview

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MTN-003 (VOICE) Summary

- Description: *Phase 2B Study of Tenofovir 1% Gel, Tenofovir Tablet and Truvada Tablet for the Prevention of HIV Infection in Women*
- Designed to Estimate:
 - Effectiveness of tenofovir gel compared with placebo
 - Effectiveness of oral tenofovir and oral Truvada compared with placebo
- Examine extended safety of the products
- Secondary aims include: adherence/behavioral, drug resistance, PK, delayed seroconversion



Behavioral Aims

- To evaluate:
 - a) Adherence to daily product regimens
 - b) Change in sexual behavior, condom use and vaginal practices

Locations & Procedures



- 3 Countries: Uganda, Zimbabwe, South Africa
- 15 sites
- 5 arm trial
- Study duration: 12 -36 months on study product
- Monthly visits



Background: Adherence

- Adherence in biomedical trials tends to be lower than desired:
 - Self-report tends to produce high estimates of adherence (with FTF interview or ACASI)
 - Clinic based product counts tend to be high
 - But, drug detection suggests adherence is lower than any of these indicators

Adherence is Critical

- Differential effectiveness in as treated analyses suggest adherence is critical ... *& lower than desired*

- Partners PrEP:

- 81% adherence **75%**

- CAPRISA 004

- Overall end study effectiveness: **39%**

- **>80% Adherence** **54%**

- 50-80% Adherence 38%

- <50% Adherence 28%



38% of participants

- iPrEx

- Overall end study effectiveness: **44%**

- **>=90% Adherence** **68%**

- 50-90% Adherence 34%

- <50% Adherence 16%

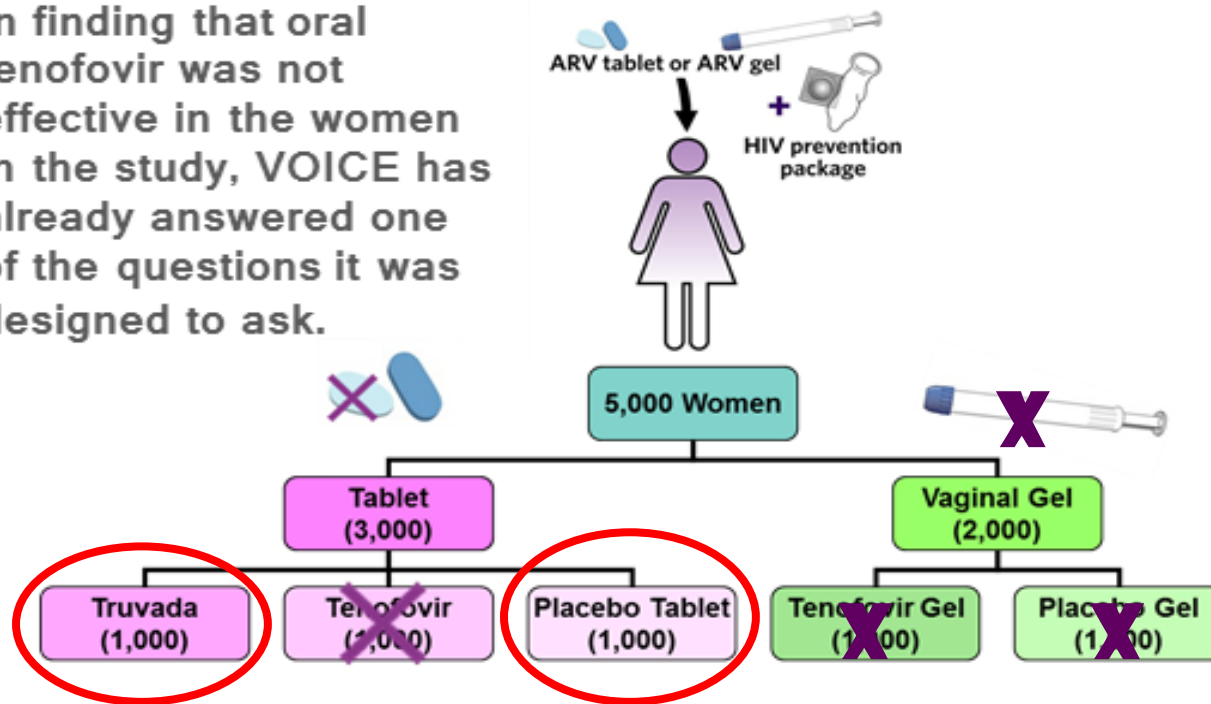


49% of visits

VOICE: Post-DSMBs (Sept & Nov 2011)

The VOICE Study Today

In finding that oral tenofovir was not effective in the women in the study, VOICE has already answered one of the questions it was designed to ask.



- DSMB futility results: 3 arms discontinued early (N=3000)
- 2 arms continued (Truvada/placebo) until completion (N=2000)



VOICE Behavioral Components

- Behavioral & Adherence Assessments
 - CRFs
 - ACASI
 - Product counts
- Adherence Support Program
 - ASP
 - VASP (6/2011)

Mode of Administration: Behavioral Questions in VOICE

Behavioral questions	CRF (FTF interview)	ACASI
FREQUENCY	Monthly + Quarterly	Quarterly/Annually
Vaginal sex	●	●
Condom use	●	●
Anal sex		●
Vaginal practices		●
Product use	●	●
Adherence rating scale	●	●

Anal Sex Questions

Repeat



Question

In the past 3 months how many times have you had anal sex? By anal sex we mean when a man puts his penis inside your anus.

 [0](#) [4](#) [1](#) [5](#) [2](#) [6](#) [3](#) [7 or more times](#)

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Product Use Calendar Question



Repeat  Question

6 days ago (Tuesday), did you insert gel?

Yesterday Sunday	2 days ago Saturday	3 days ago Friday	4 days ago Thursday	5 days ago Wednesday	6 days ago Tuesday
					
 Yes	 Yes	 Yes	 Yes	 Yes	 Yes
 No	 No	 No	 No	 No	 No
 Do not remember	 Do not remember	 Do not remember	 Do not remember	 Do not remember	 Do not remember

Previous



Next

Key Revisions to ASP (6/2011)

Original Adherence Counseling Approach (ASP)	New Adherence Counseling Approach (VASP)
<ul style="list-style-type: none"> Used product count from pharmacists to inform the counseling session; reconciled product count and self-reported adherence. 	<ul style="list-style-type: none"> Counselors will NOT review product count prior to counseling session or probe about discrepancies in product count versus self report.
<ul style="list-style-type: none"> Asked the participant how often she had been able to use the product and then based counseling on reported level of adherence. 	<ul style="list-style-type: none"> Counseling will focus on participant's experiences using the product, and what makes using product easier or harder, regardless of how much she used it.
<ul style="list-style-type: none"> Adherence plan/strategies based on overcoming barriers to product use. 	<ul style="list-style-type: none"> Adherence plan/strategies based on addressing adherence-related needs.
<ul style="list-style-type: none"> Used reported adherence to determine the focus of the session (i.e. page 2 of the counseling worksheet options). 	<ul style="list-style-type: none"> All sessions will follow the same 8 steps, regardless of how much the participant has been using the study product.
<ul style="list-style-type: none"> Reinforcement of product use instructions (10 key messages) by the adherence counselor. 	<ul style="list-style-type: none"> Product use instructions (10 key messages) removed from the counseling session.
<ul style="list-style-type: none"> Positive reinforcement of good adherence. 	<ul style="list-style-type: none"> Maintain a neutral counseling approach.
<ul style="list-style-type: none"> Goals focused on perfect adherence. 	<ul style="list-style-type: none"> Goals focused on making product use manageable.

VOICE Adherence Support Program (VASP)

1	WELCOME Greet/Rapport; Thank participant; Check-in
2	FRAME Explain purpose of discussion; Seek permission to continue discussion.
3	EXPLORE Explore product use <u>experiences</u> (facilitators/challenges); Discuss efforts on strategies from last session.
4	SUMMARIZE Summarize Context/Experiences
5	IDENTIFY NEEDS Explore needs for adherence given experiences; What would make it easier?
6	STRATEGIZE Explore how participant could increase ease/comfort/efficacy.
7	NEGOTIATE Agree on a goal identified by the participant.
8	CLOSE Summarize; Thank participant, Document

VOICE Timeline

