

MTN 003D Overview: An Exploratory Study of Potential Sources of Efficacy Dilution in the VOICE Trial

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Outline

1. Study Team & Key Roles
2. Background
3. Study Objectives
4. Study Sites & Sample
5. Study Design and Data Collection Tools
6. Study Timeline and Updates

Study Team and Key Roles

Core/US

- **Chair:** Ariane van der Straten,
- **Co-chairs:** Liz Montgomery, Barbara Mensch
- **Operations (FHI 360):** Kaila Gomez, Stephanie Horn
- **Data coordination (RTI/WGHI):** Miriam Hartmann
- **MTN Core:** Beth Galaska Burzuk
- **DAIDS:** Jeanna Piper

Site Teams

- **UZ-UCSF:** Nyaradzo Mgodzi, Petina Musara, Imelda Makhala, Otilia Munaiwa
- **MU-JHU:** Clemensia Nakabiito, Carolyne Akello, Teopista Tibaijuka, Josephine Nabukerra
- **MRC:** Neetha Morar, Kubashni Woeber, Funeka Mthembu
- **DTHF:** Zoe Duby

Background: Dilution of Efficacy*?

- DSMBs futility results:
Tenofovir vaginal gel & oral tablet stopped



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FOR IMMEDIATE RELEASE

Microbicide Trials Network Statement on Decision to Discontinue Use of Oral Tenofovir Tablets in VOICE, a Major HIV Prevention Study in Women

PITTSBURGH, September 28, 2011 – VOICE, an HIV prevention trial evaluating two antiretroviral (ARV)-based approaches for preventing the sexual transmission of HIV in women – daily use of one of two different ARV tablets or of a vaginal gel – will be dropping one of the oral tablets from the study. The decision to discontinue use of tenofovir tablets in VOICE comes after a routine review of study data concluded that the trial will not be able to demonstrate that tenofovir tablets are effective in preventing HIV in the women enrolled in the trial. VOICE will continue to test the safety and effectiveness of the other oral tablet, Truvada®, a combination of tenofovir and emtricitabine, and of the vaginal gel formulation of tenofovir.



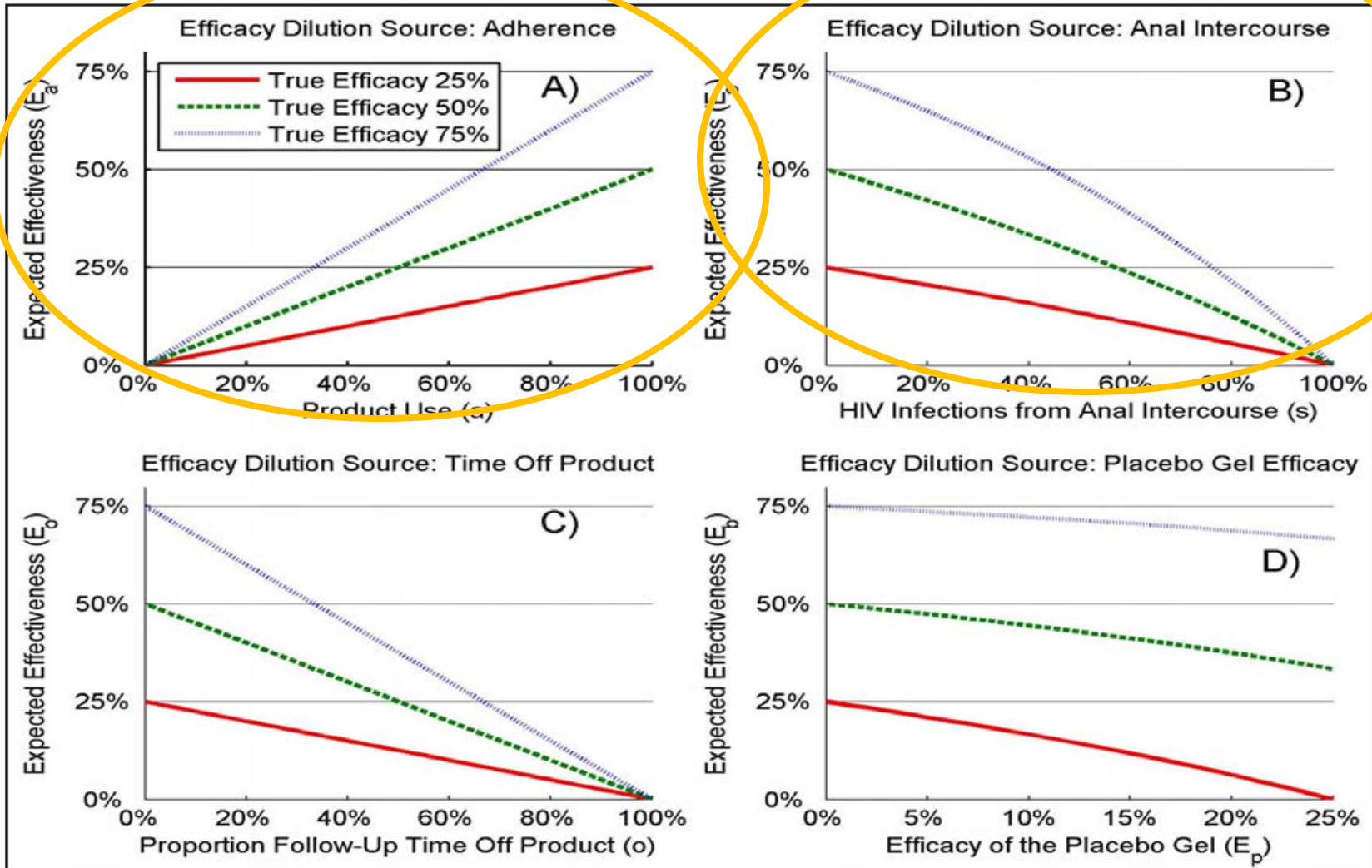
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FOR IMMEDIATE RELEASE

Microbicide Trials Network Statement on Decision to Discontinue Use of Tenofovir Gel in VOICE, a Major HIV Prevention Study in Women

PITTSBURGH, November 25, 2011 – VOICE, an HIV prevention trial that has been evaluating two antiretroviral (ARV)-based approaches for preventing the sexual transmission of HIV in women – daily use of one of two different ARV tablets or of a vaginal gel – will be dropping the vaginal gel from the study. The decision to discontinue use of the gel, which contains the ARV tenofovir, comes after a routine review of study data concluded that tenofovir gel was not effective in preventing HIV in the women enrolled in the trial.

Sources of Efficacy Dilution



Adherence



Getty Images

P24_1G. Please rate your ability, over the **past 4 weeks**, to insert gel exactly as you were instructed.

1. Very poor
2. Poor
3. Fair
4. Good
5. Very good
6. Excellent

We are most **interested in knowing on how many days you inserted gel. So if you cannot remember** which day(s) **exactly you** did insert gel, please guess. We **prefer that** you indicate that you missed **some** days, even if you cannot remember which **exact** days you missed.

NOTE: Q25aG repeats going backwards 7 days starting with yesterday.

25aG. Yesterday (x-day) did you insert gel?

1. Yes
2. No
3. Don't remember

MTN 001 Trial: discrepancy between self report and plasma drug level

- After observed dosing, ALL had detectable plasma TFV
- After 6 weeks of home dosing:

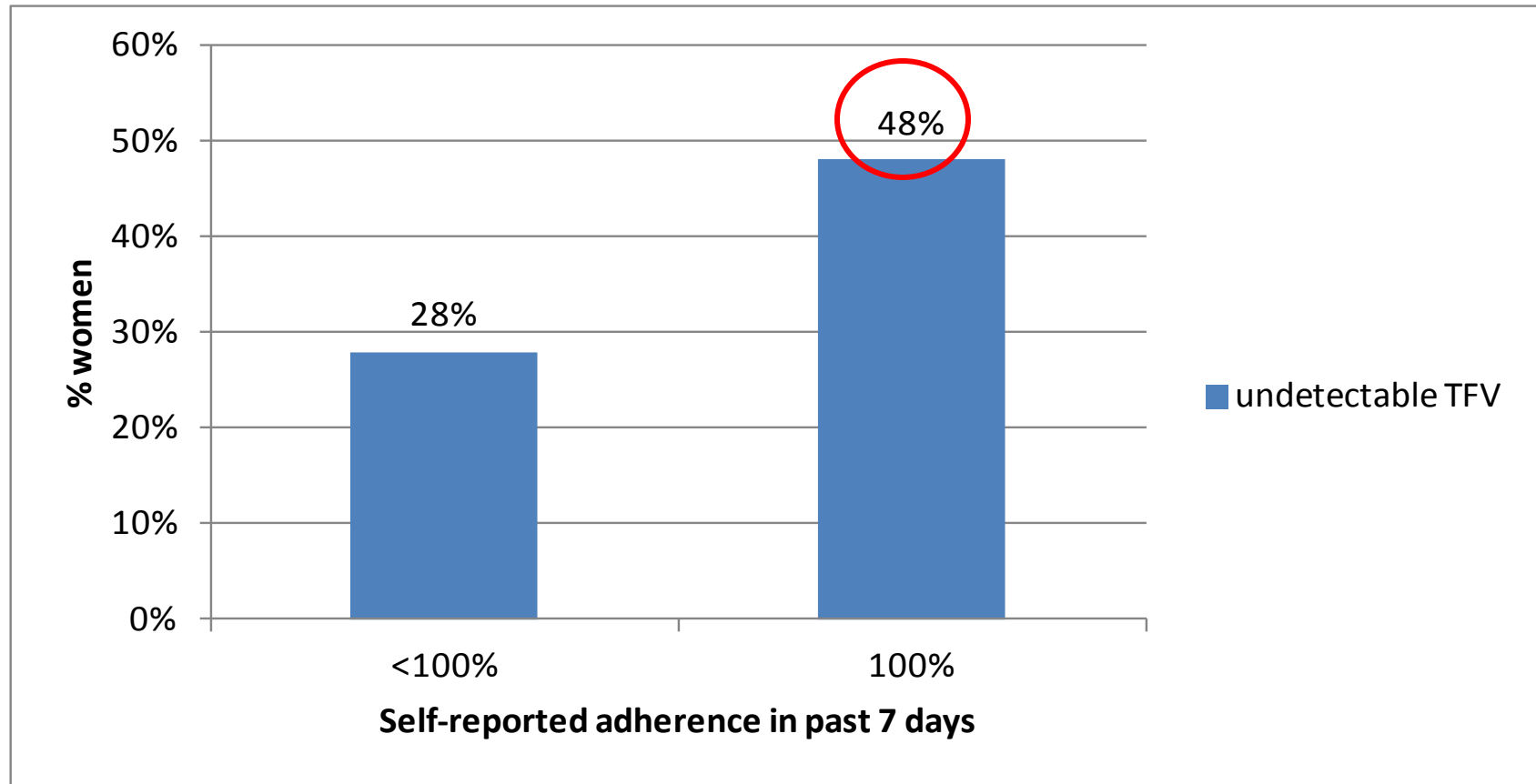
Daily TFV oral tablet

38% of participants:
had TFV plasma levels
inconsistent with daily dosing
BUT
reported 100% adherence

Daily TFV vaginal gel

48% of participants:
had undetectable TFV plasma
levels
BUT
reported 100% adherence

MTN-001: Adherence to Vaginal Gel



- Those reporting 100% adherence were **more** likely to have undetectable drug level ($p=0.02$)

Anal Sex

11. 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 → Skip to Q12

1

2

3

4

5

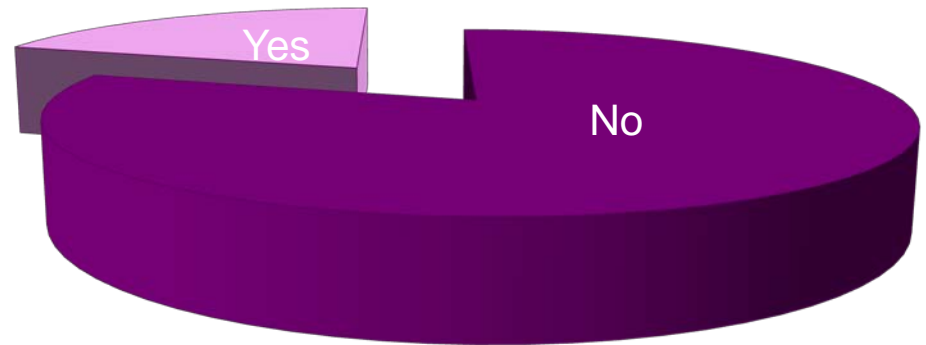
6

7 or more times

Version 5.0

March, 30, 2009

Reported 1 or More Anal Sex Acts in the Past 3 Months?





Study Objectives

□ Primary:

- to explore larger contextual issues and specific aspects of the VOICE trial that positively and negatively affected participants' actual and reported product use
- to explore the reasons, motivations, and context of engaging in receptive anal intercourse (and rectal use of gel among VOICE participants in the gel group)

□ Secondary:

- to explore participants' risk perceptions and motivations to participate in VOICE and the association of these factors with product use or non-use in a prevention trial setting

Study Sites & Sample

- Uganda
 - Kampala (MU-JHU, n=20)
- Zimbabwe
 - Chitungwiza (Seke South and Zengeza, n=20)
- South Africa
 - Durban (Isipingo and Overport, n=40)



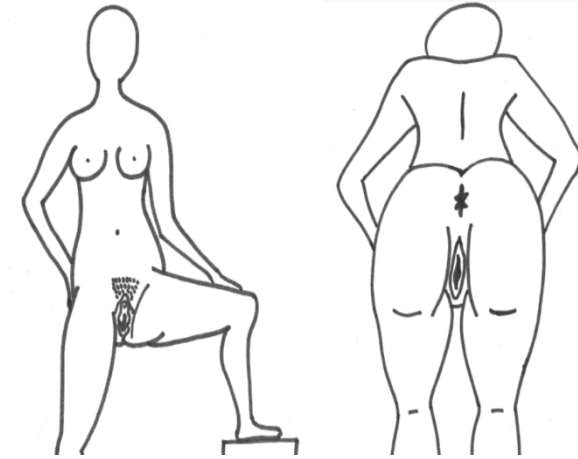
Population & Sample Size

- Former VOICE participants

Study group:	Tablet Users	Gel Users	Total
Reported Anal Sex	4	4	8
Sero-converters	4	4	8
All other women	32	32	64
Total	40	40	80

Study Design & Data Collection Tools

- Qualitative Exploratory Study
- Instruments:
 - Demographic survey
 - In-depth interview Guide
- Tools:
 - VOICE timeline
 - Rating Scale Show Card
 - Body Mapping Template



Repeat  Question

Please rate your ability, over the past 4 weeks, to take tablets exactly as you were instructed?

1	Very poor	4	Good
2	Poor	5	Very good
3	Fair	6	Excellent



Previous



Next

Study Timeline and Updates

