



MTN-003D
***An Exploratory Study of Potential
Sources of Efficacy Dilution in VOICE
Trial***

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Presentation Overview

1. **Background & Rationale**
2. **Objectives**
3. **Population & Sample Size**
4. **Study Design**
5. **Data Collection Methods**
6. **Site burden**
7. **Timeline**
8. **Next Steps**

Dilution of Efficacy?



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FOR IMMEDIATE RELEASE

Microbicide

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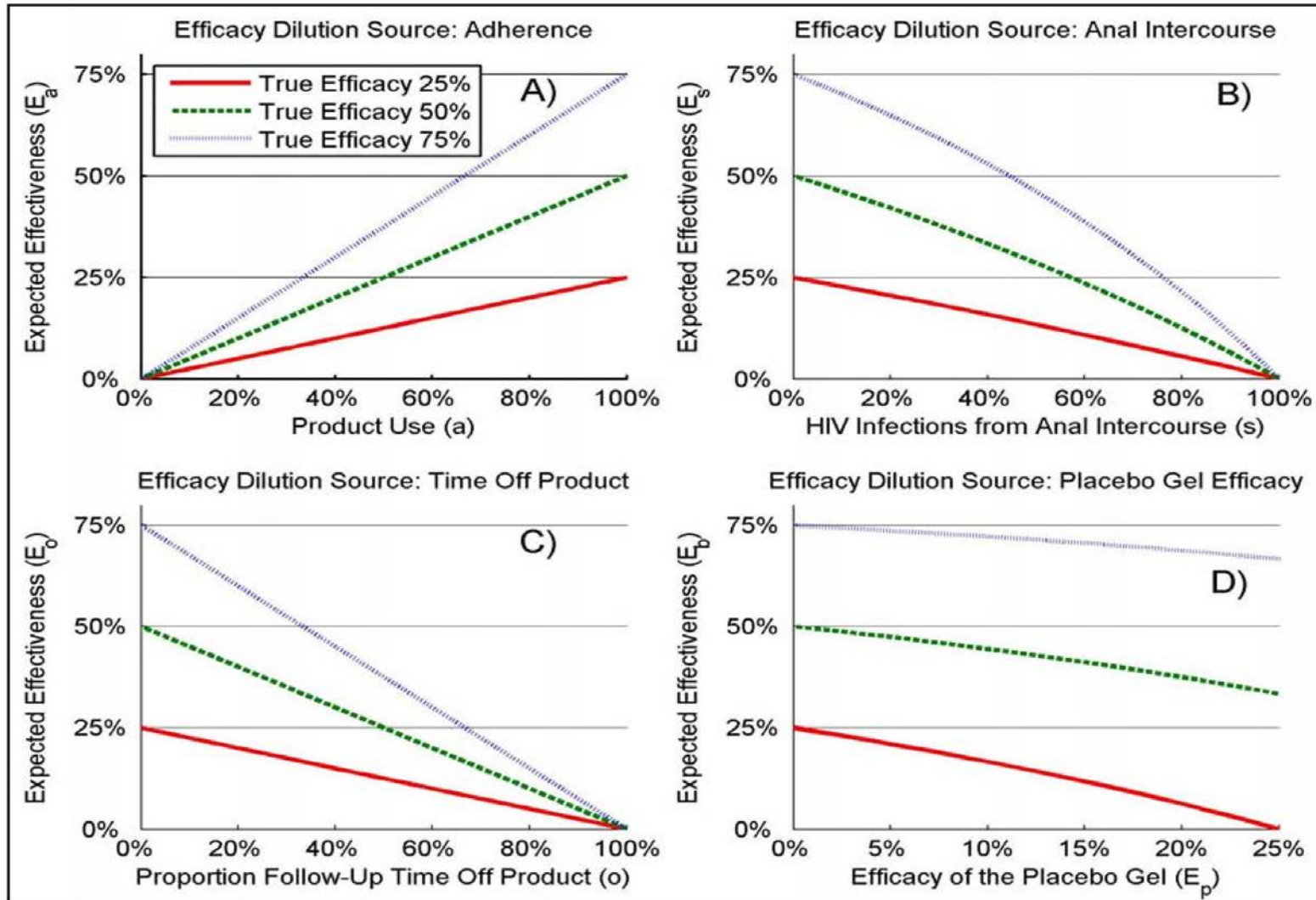
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Microbicide Trials Network Statement on Decision to Discontinue Use of Tenofovir Gel in VOICE, a Major HIV Prevention Study in Women

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

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

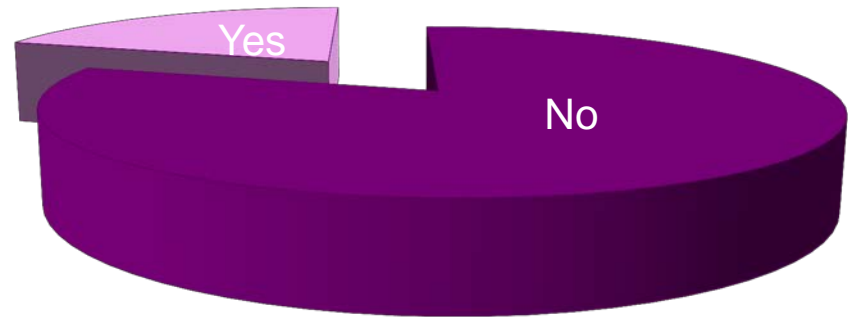
4

5

6

7 or more times

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



Primary & Secondary Objectives

- Explore larger contextual issues and specific aspects of the VOICE trial that positively and negatively affected participants' actual and reported product use.
 - 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.



- Explore the reasons, motivations and context of engaging in receptive anal intercourse, (and rectal use of gel among VOICE participants in the gel group).

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

Sites

- TBD
- Proposed: 3-4 Sites



Study Design

- Exploratory sub-study of VOICE using qualitative in-depth interviews (IDIs)



Asking the Hard Questions: Adherence

- Discuss motivations/risk perceptions
- Present visual displays/scenarios
 - Different adherence measures
- Role of context on adherence
 - Trial context
 - Social context

What did these responses mean to you?

Excellent



Very Good



Good



Fair



Poor



Very Poor



Asking the Hard Questions: Anal Sex

- Define 'anal sex'
- Normative statements / scenarios
 - Anal sex behaviors
 - Rectal gel use



...a woman in your community who is participating in an HIV trial like VOICE. She has a partner who doesn't like to wait until she finishes menstruating to have sex...

Anticipated site burden

VOICE site responsibility

- **Preparatory**
 - IRB submission

- **Study Implementation**
 - Re-contact, and refer participants
 - Possible limited infrastructure support (e.g. clinic space)

- **Post-study**
 - Archive participant files

Not VOICE site responsibility

- **Preparatory**
 - Full responsibility for development of protocol, SSP, SOP, data collection instruments

- **Study implementation**
 - Informed Consent
 - Conduct IDIs
 - Transcribe and translate
 - Manage data entry/ QC

- **Post-study**
 - Data analysis and dissemination

Estimated Timeline: 2012-2013

Activity	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Development of Research Protocol and Data Collection Tools and Regulatory Approvals	X	X	X	X												
Site Training/Preparation				X	X											
Data Collection & Management				?	X	X	X	X	X	X	X					
Data Analysis								X	X	X	X	X	X	X		
Preparation and Dissemination of Study Results													X	X	X	X



Next Steps

- Finalize protocol
- Select chair(s) and site(s)
- Initiate study



Any Questions?