

VOICE-D (MTN-003D) stage 2: Truth & consequences

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Outline

1. VOICE-D stage 2 study overview
2. “truths”: what have we learned about tablet and gel use in VOICE?
 1. VOICE-D preliminary findings
 2. Case studies- narratives of use
3. “consequences”: women’s stated preference for different hypothetical HIV prevention product formulations

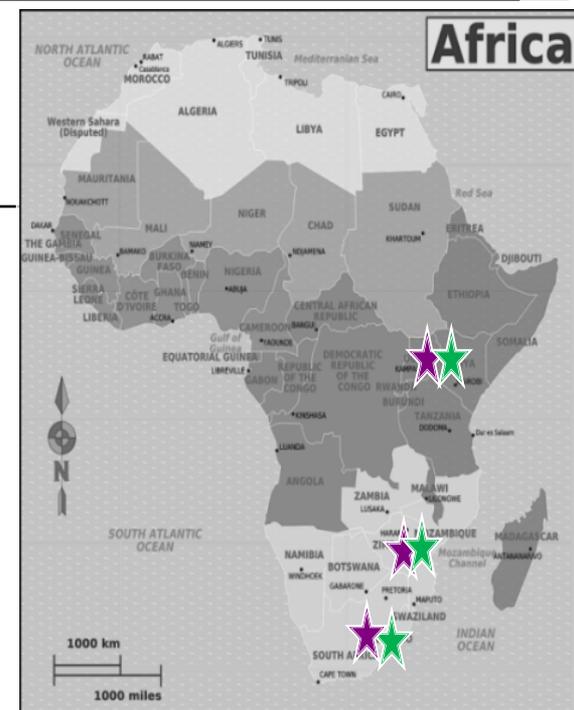


Study objectives

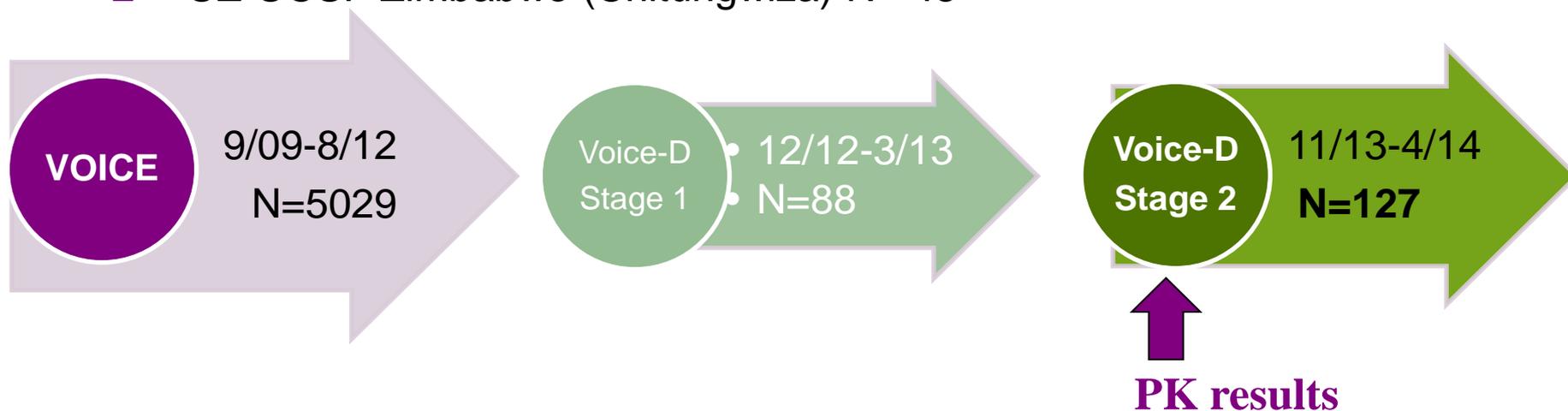
- ❑ To explore contextual and trial specific issues affecting actual and reported product use
- ❑ To assess whether disclosure of PK results retrospectively encouraged candid discussion of low adherence and product use challenges

Background

- ❑ Multisite (n=4)
- ❑ Qualitative exploratory study (N= 127)
- ❑ Former active-arms VOICE participants
- ❑ 3 Countries:
 - ❑ MU-JHU Uganda (Kampala) N= 49
 - ❑ MRC South Africa (Durban) N= 30
 - ❑ UZ-UCSF Zimbabwe (Chitungwiza) N= 48



★ VOICE ★ VOICE-D



Methods

- Sample pre-selected based on:
 - Being on active product ≥ 3 months during VOICE
 - Study product (tablets & gel)
 - HIV status
 - TFV PK detection level
 - Low = 0% samples with detectable PK**
 - Inconsistent = 1- 74%
 - High = 75-100% (positive deviants)**
- IDIs & FGDs (debriefing reports; transcripts thematically coded and analyzed)
- CRFs (demographic and socio-behavioral info, reactions to PK results)

Study tools

DailyNews

Home Daily News home **News** Sport Business Tonight Opinion Lifestyle Motoring Consum

KwaZulu Natal South Africa World Africa

Aids pills not taken

March 5 2013 at 09:11am
By LIZ CLARKE

Related Stories

➔ HIV trial tests fail after participants shun regimen

It was hoped that it would be the solution to one of the world's worst pandemics and the end to a global scourge of death and disease.

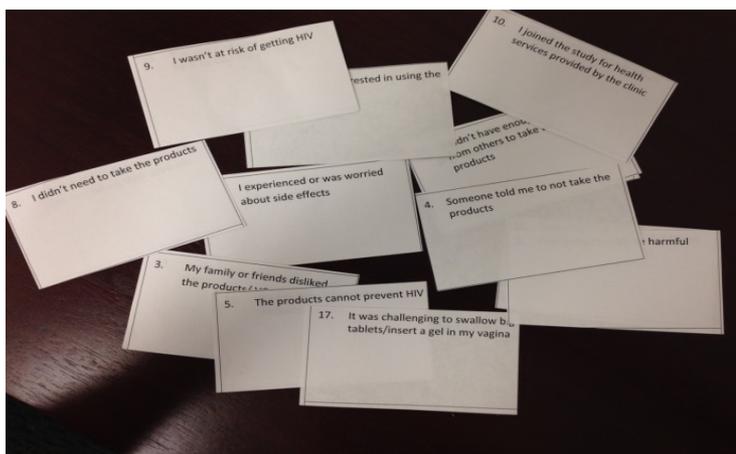
But the study failed because most of the women participating in the trials, including at sites in KwaZulu-Natal, did not take the medication.

Disappointment and dismay have come in the wake of the announcement that one of the largest HIV prevention trials did not find the answer to contain

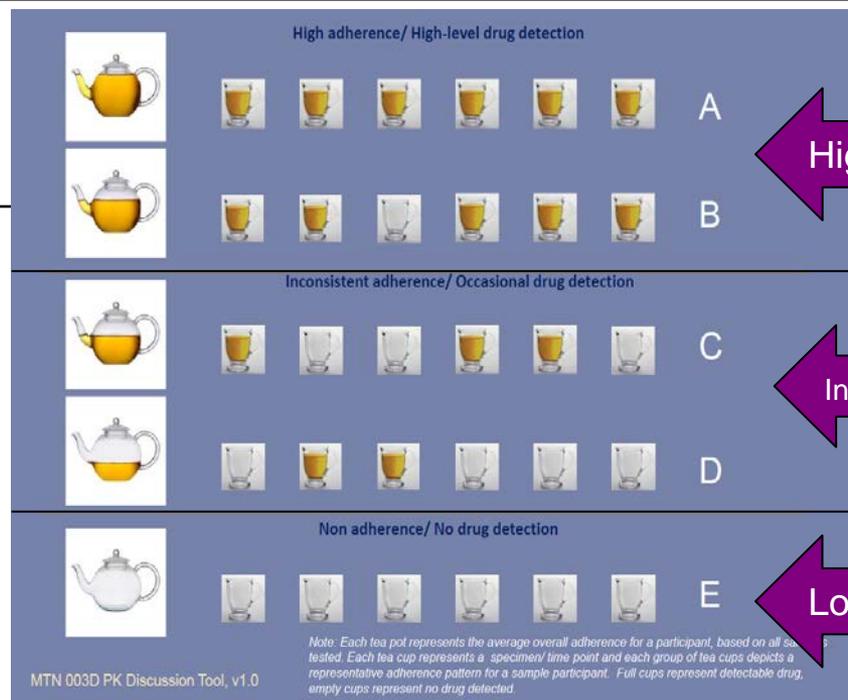


EX-QDMS

Local press clippings



Adherence challenge theme cards



PK result 'Teapot' tool



Potential HIV Product formulations

Study Sample (N=127)

Characteristic		Percent
PK group	Low	62%
	Inconsistent	22%
	High	16%
Study products	Gel	50%
	Tablets	50%
HIV seronegatives (N=114)		90%
Median PK visits (range)		6 (3-11)
HIV seroconverters (N=13)		10%
Median PK visits (range)		4 (1-9)
Interview type	IDI	43%
	FGD	46%
	Both	10%

Demographics

Characteristic		Percent (N=127)
Country (CTU)	South Africa (MRC)	24%
	Uganda (MU-JHU)	39%
	Zimbabwe (UZ-UCSF)	38%
Enrolled in Stage 1		35%
Median age (range)		28 (21-41) years
Median lifetime partners (range)		3 (1->100)
Same male partner as in VOICE		79%
Married		57%
≥ Completed secondary school		37%
SES indicator level	Low	41%
	Middle	39%
	High	20%

Adherence during VOICE by PK group

VOICE Adherence data	Low % (N= 79)	Inconsistent % (N= 28)	High % (N= 20)
PK detected at month 3	0%	46%	85%
VOICE ACASI mean adherence *	94%	89%	98%
VOICE FTFI mean adherence *	95%	91%	100%
CPC clinic product returned*	93%	93%	92%

(*) matched on PK visits

Product non-use: preliminary findings

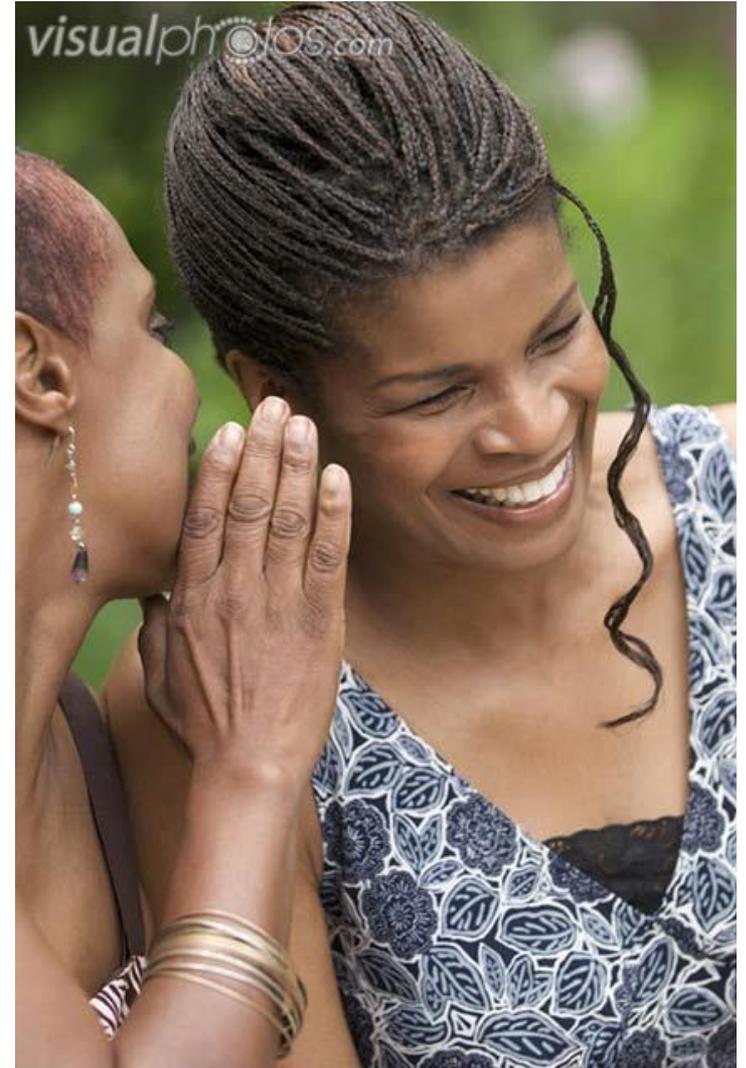
❑ **Stories of poor execution**

- ❑ Never used (outside the clinic)
- ❑ Tried initially, then stopped early
- ❑ Used occasionally or intermittently:
 - ❑ Forgot, life style, events, access to food, partner disapproval
 - ❑ Used purposively prior to study visits (white-coat effect)
 - ❑ Adjusted regimen or dosing to suit personal circumstances

❑ **Elaborate stories of product disposal:**

- ❑ Thrown away (garbage, toilet, water bucket); wrapped and sent to rural area
- ❑ Given/shared with friends, family members who wanted them
- ❑ Stock piled in case the product would show later to work

Case studies



Tablet group, low PK (0/6 visits)

Durban, South Africa

Reasons for joining: health benefits

“...because you were able to go to the clinic and check your health status. [...]They were able to see something that you had not seen and give you medical help.”

Reaction to PK results

Participant admitted she had not used product

Adherence narrative

- Never took tablets apart from two administered at clinic.
- Assumed she was on placebo because she had been on placebo in CAP004

“Taking a tablet was not nice especially since you were not sick.”

- Thought she would have been able to use the gel every day.

Tablet group, low PK...Continued

Product disposal

- She would count out the tablets and then throw the excess away.

Suggestions for future studies

- Would be nice but not feasible to get daily motivation from staff.
- Better not to tell people about placebo because it discourages adherence.

Top Theme Cards

- I was not interested in using the products.
- It was boring to take the products daily
- I joined the study for health services

Preferred HIV products

- Injection and ring (both are administered at the clinic)

Gel group, low PK (0/6 visits)

Zimbabwe

Reasons for joining : altruism

- Wanted the product successful to benefit people in the future.
- Felt at risk:

“As a single mother, I am in the high risk category, very susceptible to the risk of contracting diseases.”

Reaction to PK results

- Not surprised

“perhaps, the absence of any evidence of the product in my blood also contributed to the poor study results.”

Adherence narrative

- Afraid of “chemicals” that are the same as ARVs and can cause “cooked bones” & “dark skin complexion”.
- Gel was too slippery during sex.
- Afraid of side effects & had rash on her thighs.
- Intentionally modified dosing

“I had a principle that I should not use [gel] every day as I was worried it might have side effects in future... My thinking was that, if sometimes I use the products; maybe things would work [I would be protected].”

Gel group, low PK...Continued

Product disposal

- Counted the product; threw extras in a bin or burn them.

Suggestions for future studies

“They must deal with participants privately, because from my own experience, when women share ideas, they negatively influence each other... [They] would start by criticizing the whole purpose of the study. Then also talk about the possible side effects of the study products. In the case of VOICE, the rumors in the community were that the products were being given to the participants and the products have HIV.”

Top theme cards

- I experienced or was worried about side effects
- The products decreased sexual pleasure
- Too busy to take product everyday

Preferred HIV products

- Gel (you can insert it and leave it there)

Tablet group, high PK (8/8 visits)

Uganda

Reasons for joining

- For reimbursements
- Because she and her children got health care, and family planning services.

Reaction to PK results

- Disagreed: should be 75% (not 100%):
- She sometimes missed using the product when she forgot and when she fell sick and was unable to take tablets.

Adherence narrative

- Had no problems using the tablets because she knew they checked for drug in her blood
- Took tablets right after supper.
- Hid tablets in a bag at home because they looked like ARVs.
- Not worried about side effects:

“I was not worried about that because they could not bring a product that would cause harm on our bodies....”

Tablet group, high PK... Continued

Product disposal

- Returned tablets she did not use.

Suggestions for future studies

- Modify containers & tablets so they don't look like ARVs.
- Give participants effective birth control because some got pregnant and would use someone else's urine for the pregnancy test.

Top theme cards

- Other participants told her not to use the products
- The products cannot prevent HIV
- Products may be harmful.

Preferred HIV products

- Injection and Implant (do not have to be used daily)

HIV prevention products preferred (IDI=68)

8 formulations presented (2 known)*



Vaginal Gel



Oral Tablets



Injectables



Vaginal Film



Vaginal Ring



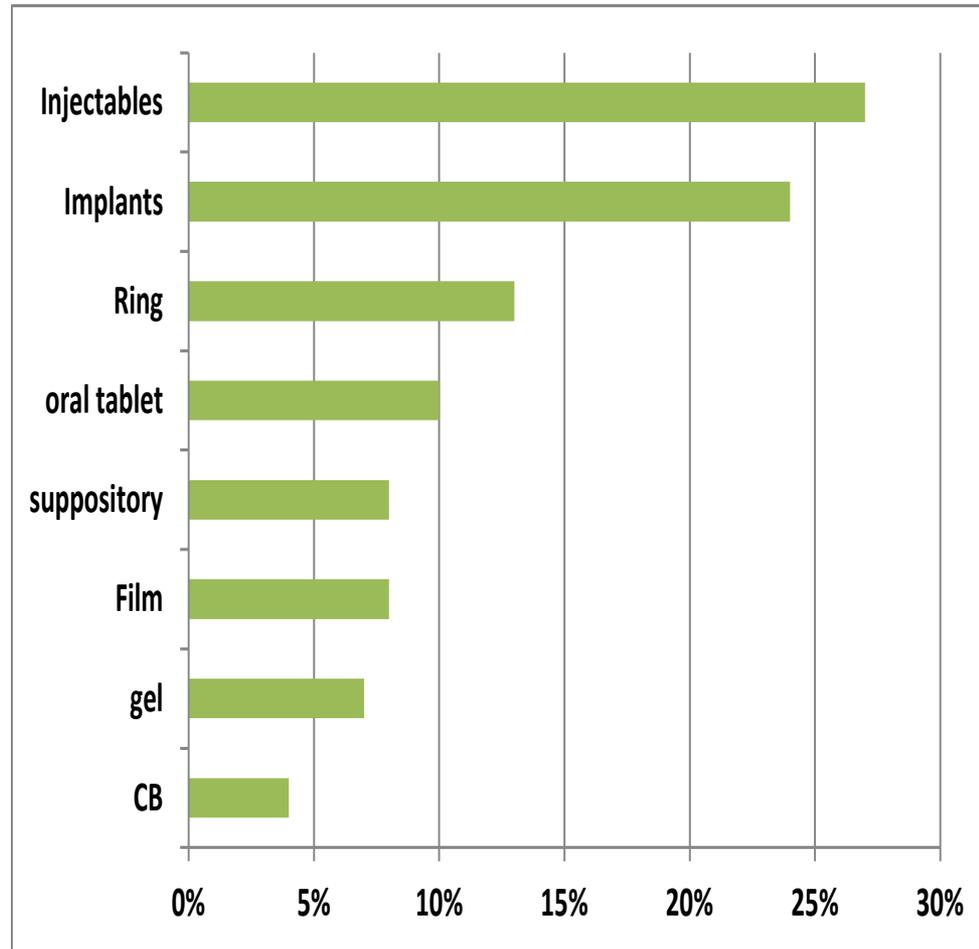
Barrier Methods



Vaginal Suppository/Tablets



Implants

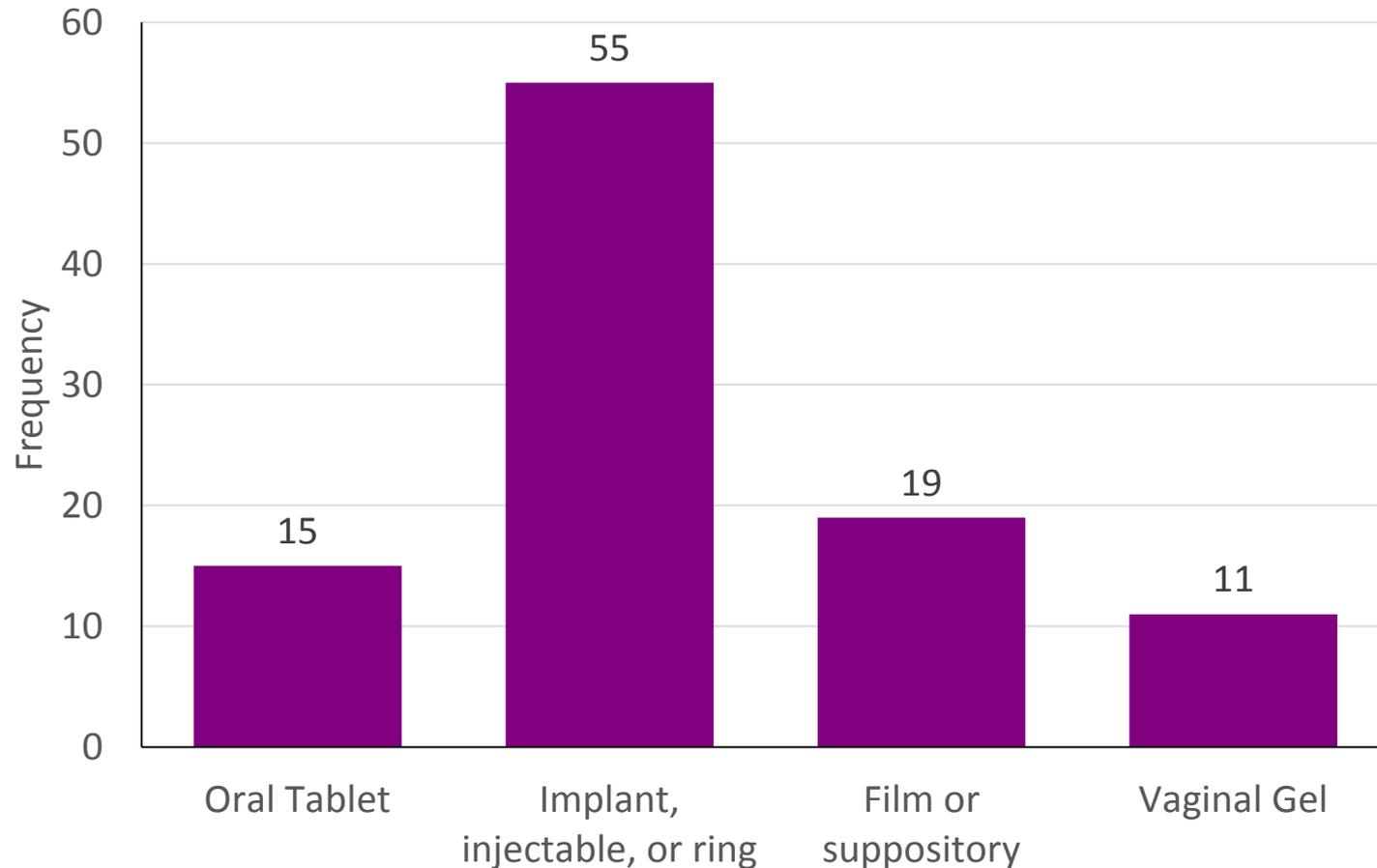


MTN-003D Stage 2: Pictures of Possible Prevention Products

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* Multiple selections allowed: Median preferred methods selected = 2 (range 0-6)

Preferred Product Outcome Groups



Based on exploratory factor analyses and latent class analyses

Note: cervical barriers removed

Conclusions

- ❑ Retrospective provision of PK results promoted candid discussions about product non-use and challenges.
- ❑ Study tools were useful for generating discussion and getting insights into various topics
 - ❑ Poor execution; product discontinuation
 - ❑ Unused products disposal
 - ❑ Trial experience and (negative) sources of influence on use
- ❑ Different types of women selected each HIV product group
 - ❑ Preferences varied by country and other demographic information
 - ❑ Multiple options will help meet women's varied HIV prevention needs
 - ❑ Further analysis of the data will clarify why formulations were selected & contribute to informing future prevention studies

Study Team and Key Roles

Core/US

- **Chair:** Ariane van der Straten,
- **Co-chairs:** Liz Montgomery, Barbara Mensch
- **Operations (FHI 360):** Lisa Levy, Kristy Alston
- **Data coordination (RTI/WGHI):** Ellen Luecke, Nicole Laborde, Helen Cheng, Jonah Leslie, Ariana Katz, Miriam Hartmann
- **MTN Core:** Beth Galaska Burzuk
- **DAIDS:** Jeanna Piper
- **NIMH:** Cynthia Grossman

Site Teams

- **UZ-UCSF:** Nyaradzo Mgodi, Petina Musara, Imelda Makhala, Otilia Munaiwa
- **MU-JHU:** Clemensia Nakabiito, Juliane Etima, Teopista Nakyanzi, Josephine Nabukeera
- **MRC:** Sarita Naidoo, Kubashni Woeber, Funeka Mthembu, Nozipho Vilakazi

Behavioral Consultants

- **DTHF:** Zoe Duby, Thola Bennie