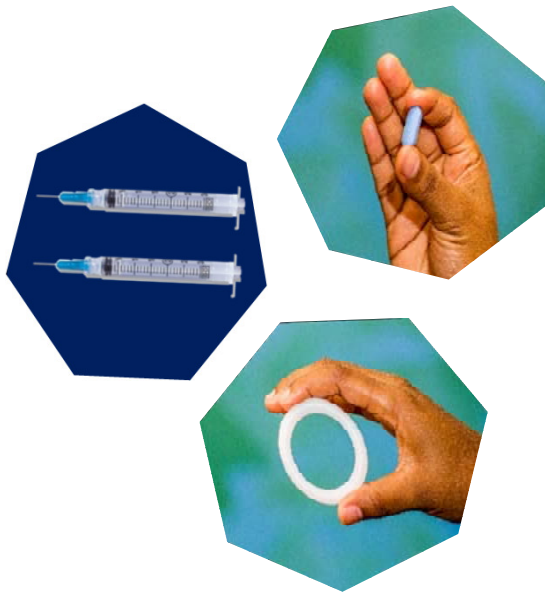




TRIO Study: Key Insights from Research with Female End-Users of MPT and HIV Prevention Products

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Washington DC

BILL & MELINDA
GATES foundation

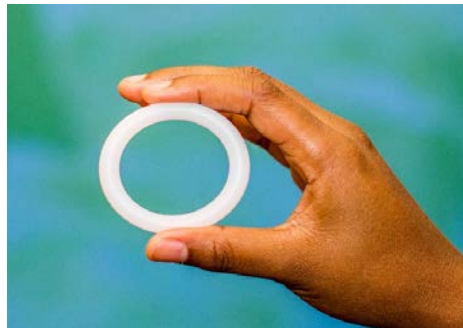


TRIO: Three Multi-purpose Prevention (MPT) Placebo Products

TRIO = *Tablet, Ring, and Injectable as Options for women*



Daily oral tablet



Monthly silicone ring



Monthly saline injections
(2x 2ml)

Objectives and Approach

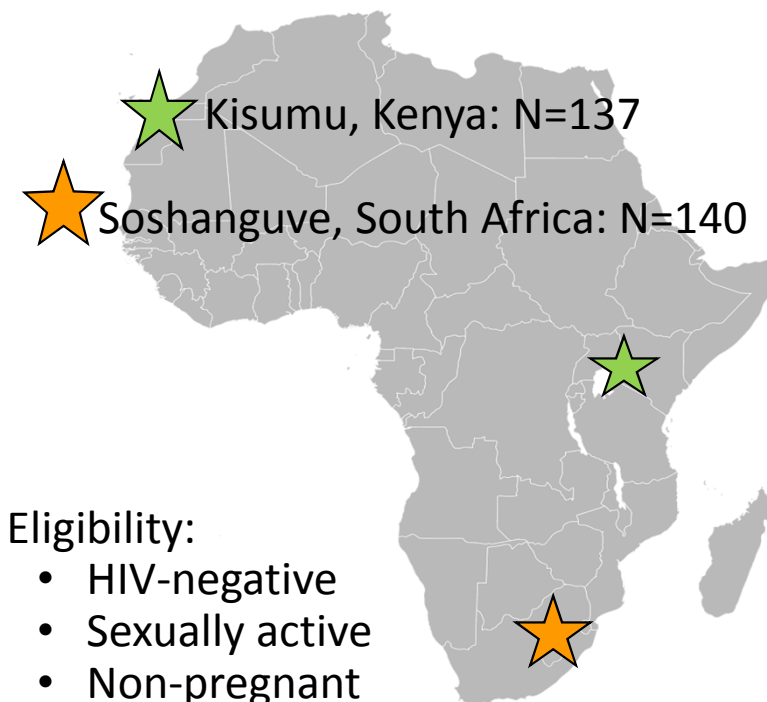
1. Inform early-stage development of three potential HIV prevention/MPT approaches among young women end-users:

- Placebo products to focus on delivery form
- Assess relative preference among products
- Changes in preferences with increased exposure to products
 - Baseline: pre and post baseline video
 - After 1 month of use
- Salient product attributes

2. Mixed-methods design intended to engage participants as co-designers

3. Stakeholder engagement & feedback

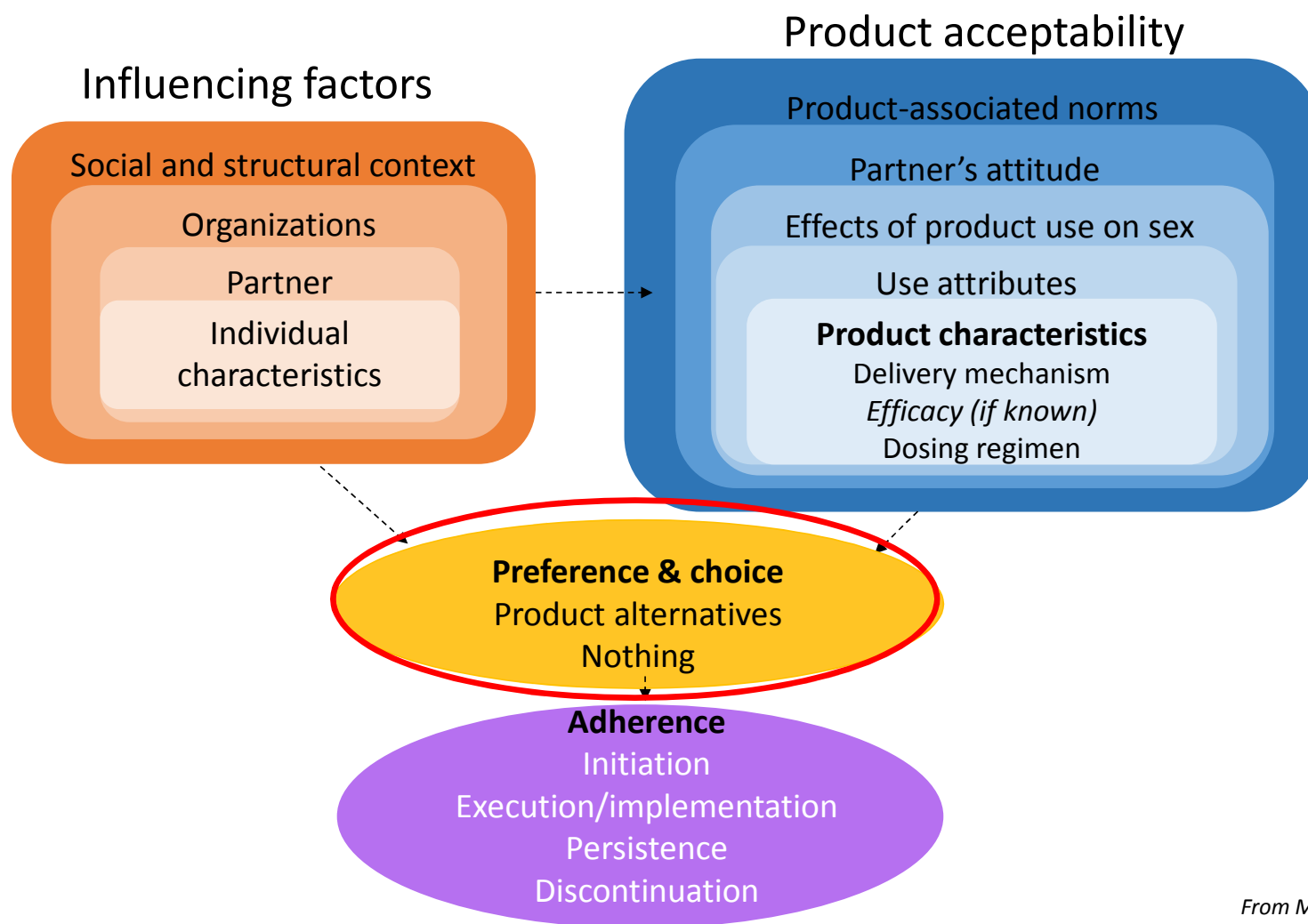
- Male partners
- Health providers



Eligibility:

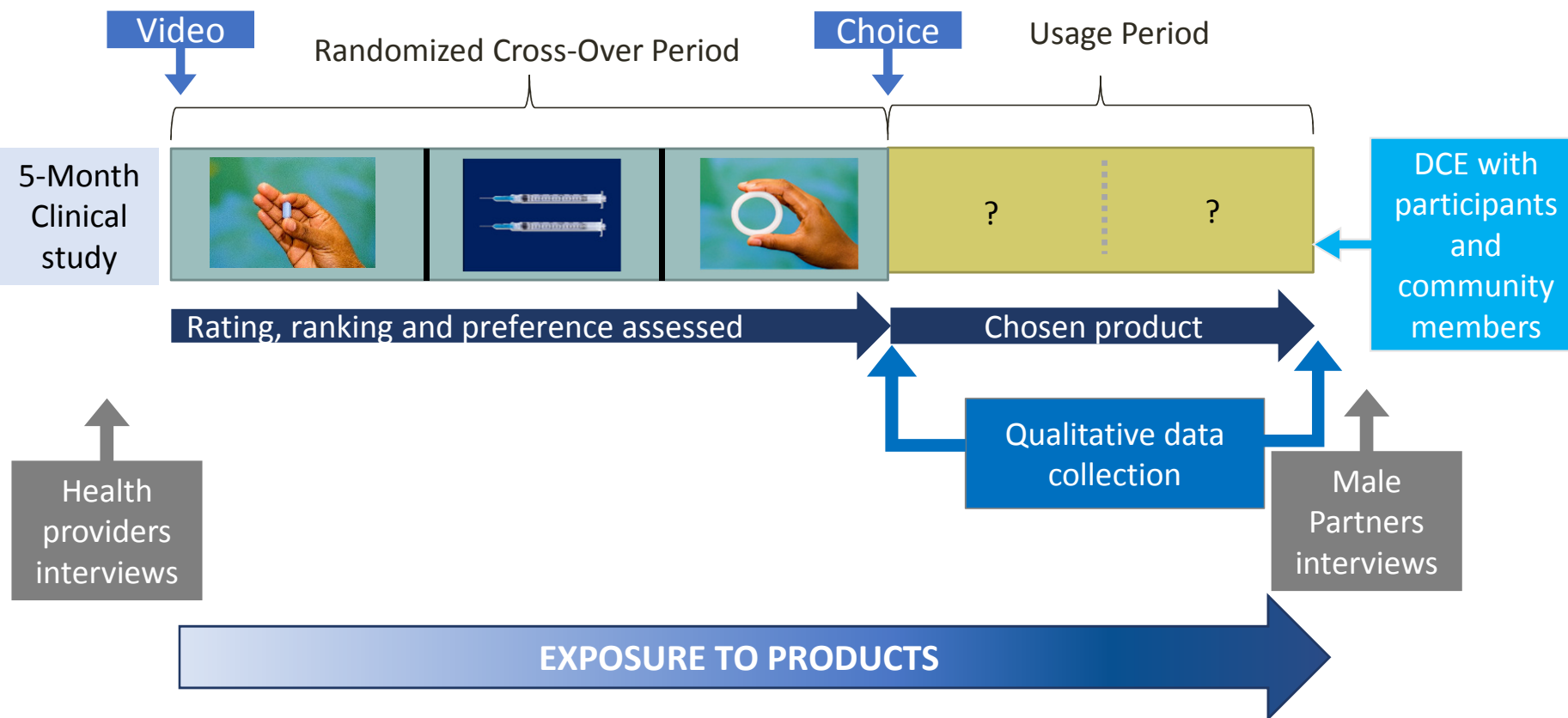
- HIV-negative
- Sexually active
- Non-pregnant
- Aged 18-30 years
- Microbicide and PrEP naïve

PrEP/Microbicide Acceptability Framework

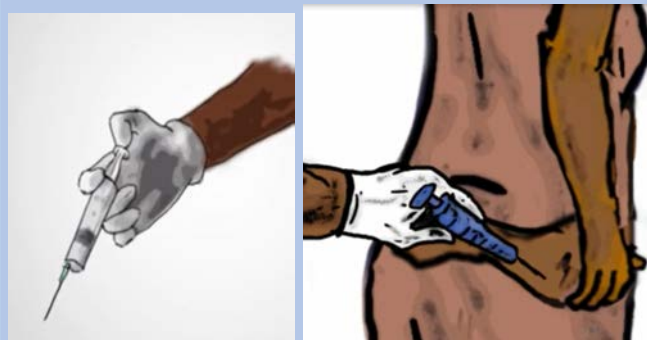
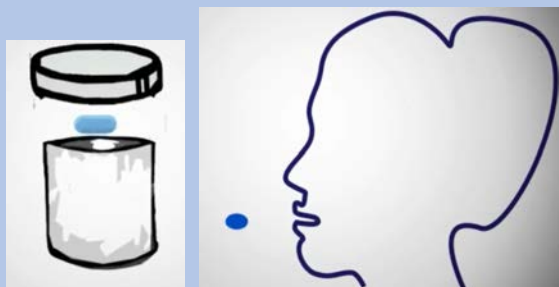


From Mensch, et al C.O.H 2012

TRIO Study Design and Timeline



4 minutes Educational Video at Enrollment



Key Results Addressed

1. Rating – product satisfaction- Effect of educational video
2. Ranking and preferences – among study products
3. Choice – (revealed preference) after trying each product for one month
4. Adherence – self-report, directly observed dosing in the clinic + Wisepill electronic monitoring
5. MPT interest
6. Product attributes - Discrete choice experiment (DCE)

Publications: Agot K., International Journal of Women's Health, in press., Lutnick, A., Journal of the International Association of Providers of AIDS Care, 2019., Minnis, A.M., AIDS and Behavior, 2018., Minnis, A.M., Journal of Acquired Immune Deficiency Syndromes, 2019., Shapley-Quinn, M.K., International Journal of Women's Health, 2019., van der Straten, A., Journal of the International AIDS Society, 2018., Weinrib, R., AIDS and Behavior, 2018.



TRIO Participant Characteristics in clinical study (N=277)

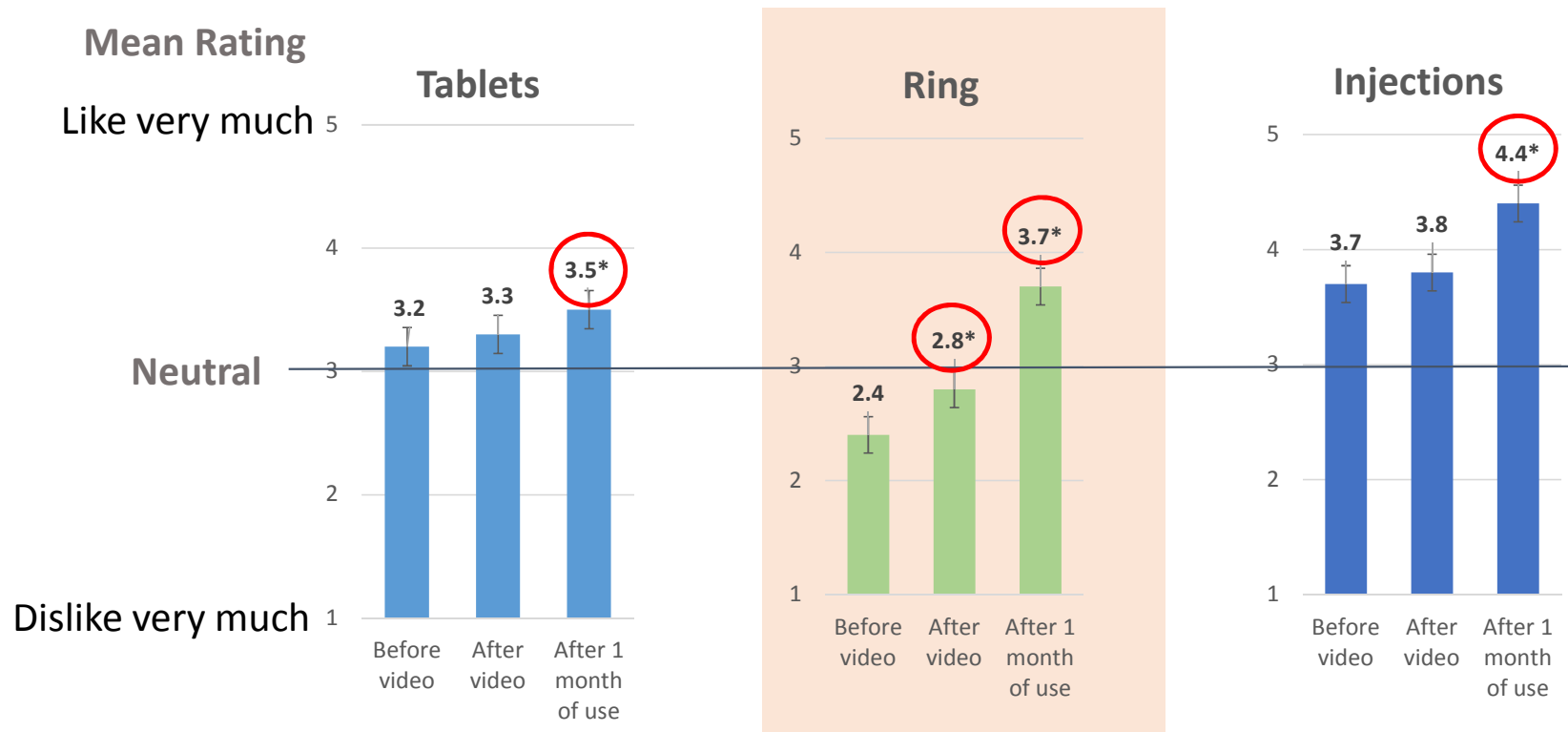
	Soshanguve, South Africa (N=140) %	Kisumu, Kenya (N=137) %
Median age (IQR)	23 (21-26)	24 (21-26)
Currently have a primary partner	96	92
Married or cohabiting*	9	48
Parity >0	78	78
Completed secondary school*	61	42
Earns an income*	13	50

*p<0.05

- 89% Completed the 5-month clinical study

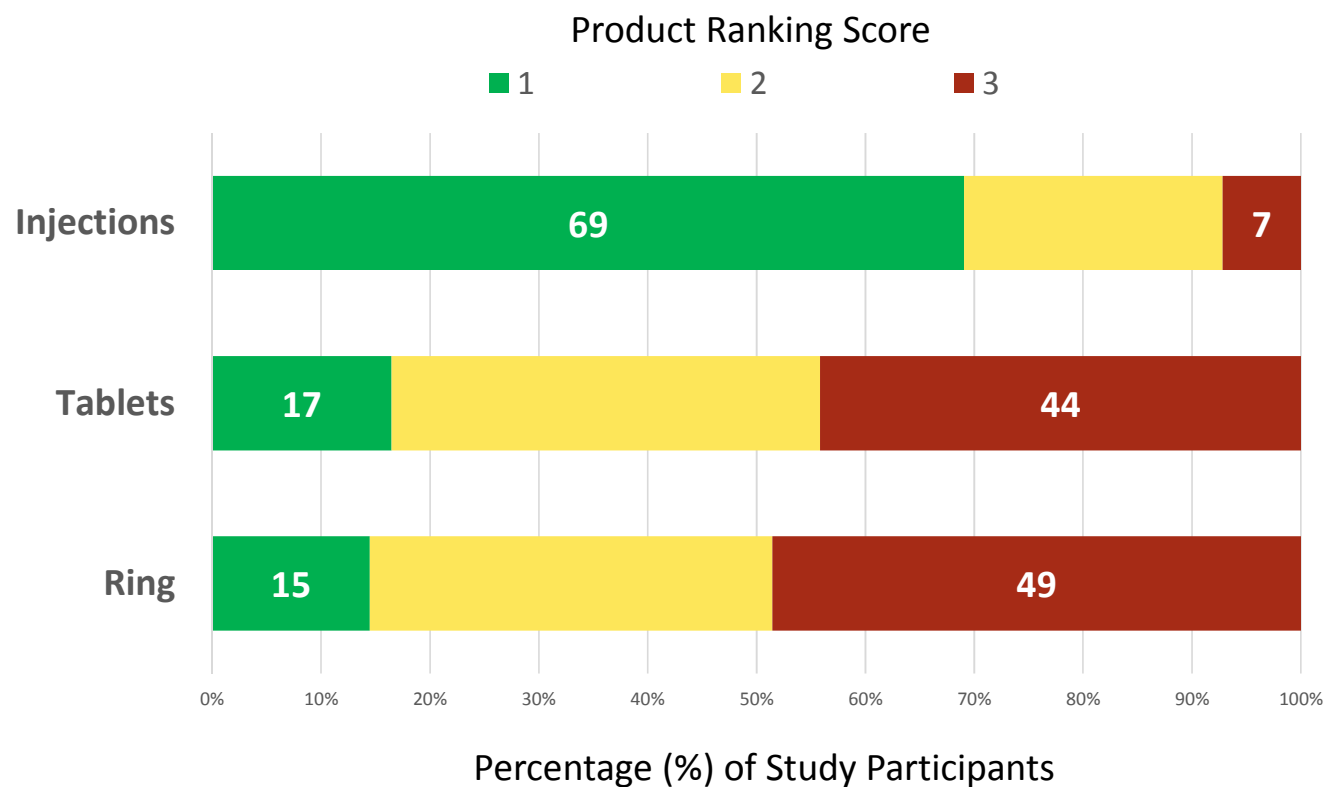
1. Product rating changed with exposure: CO Period (N=249)

- All rating were significantly higher post 1-mo use vs. before video ($p < 0.001$)
- Higher rating post-video (vs. pre-) only for the most unfamiliar product: ring



2. TRIO Product Preference: Rankings after CO period (N=249)

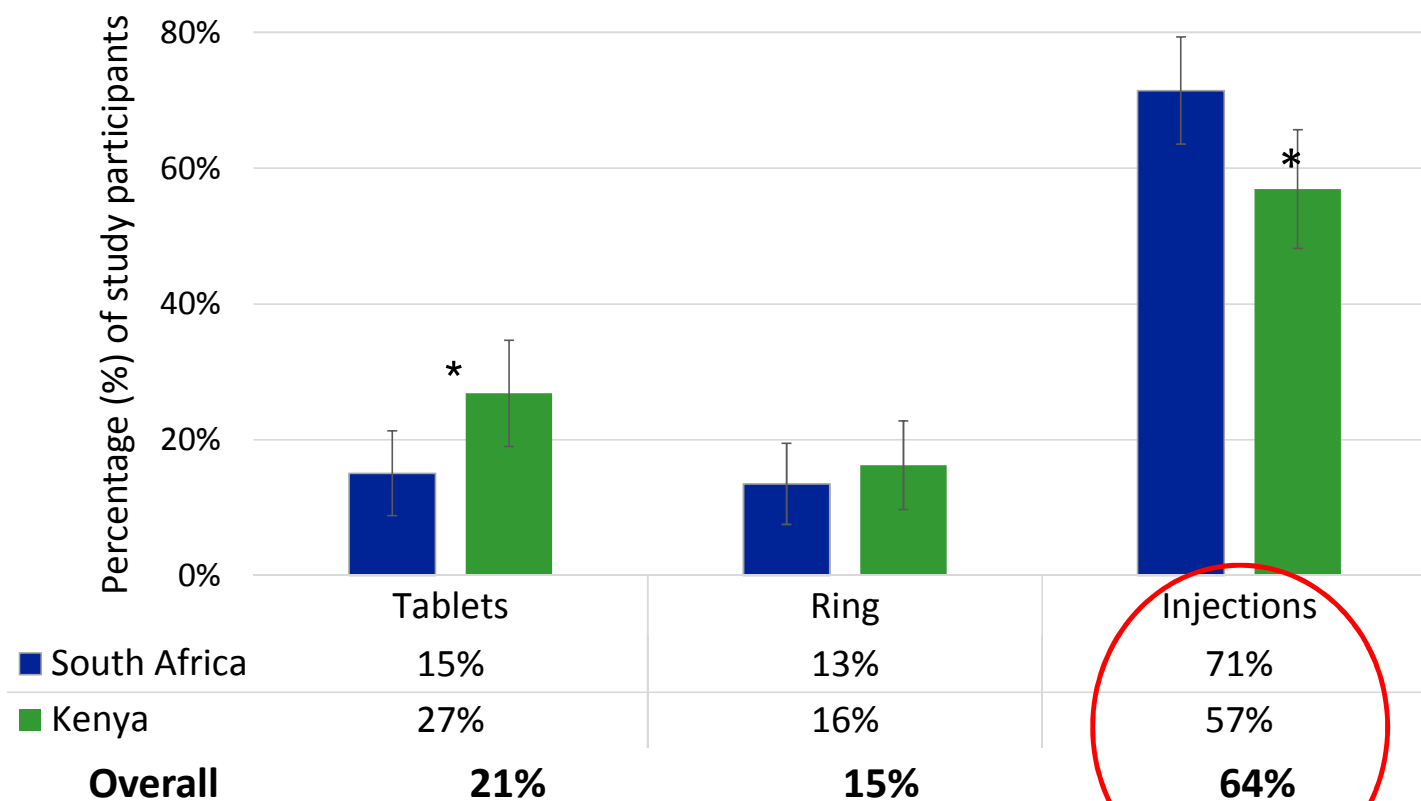
Please rank the three study products in order of your preference for using them for both pregnancy and HIV prevention.



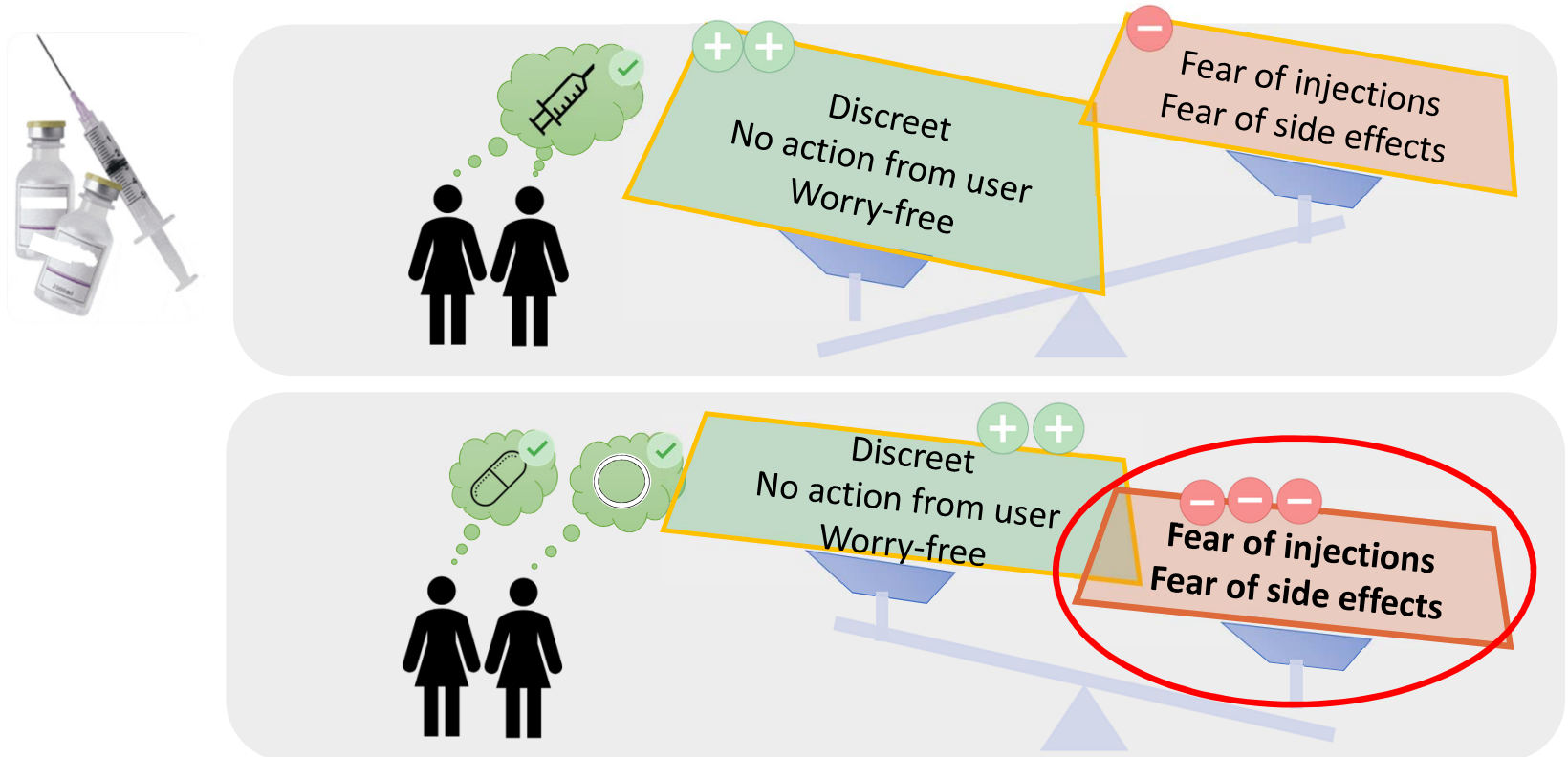
2. Women changed their mind re: preferred product (rank #1)

- Overall, **50%** of women changed their mind about their most preferred product after crossover.
- Those who chose the ring had biggest change in opinion

3. Choice by site for usage period (N=249)



3. Barriers shaped TRIO product choice (n=87 qualitative component)



- Overall, women described the same pros and cons of each product
- However, the “cons” weighed more heavily in **decision NOT to choose**

4. We assessed **All** components of adherence in TRIO

Adherence components	Tablets	Ring	Injections
Initiation- at clinic	Direct observation (DO) of first ingested tablet 97	Pelvic exam after vaginal ring insertion 97	2x 1ml saline injected in glutei 100
Completion- at clinic	DO of last ingested dose 97	Ring in situ at return 81	NA
Execution	WISEPILL: (EM) 10%	Self report 70	NA
Persistence	At M-4 visit, continue or switch to another product		
	96	96	89

5. Preference for a “2-in-1” MPT product

At the end of TRIO, most participants indicated **preference for a 2-in-1 product over using two separate products.**

South Africa



98%

Kenya









86%

This was strongly corroborated by qualitative findings with participants

6. Discrete Choice Experiment (N=536)

- ½ Clinic sample and ½ community sample.
- Each participant answered 8 HIV prevention product choice questions.
- Participants randomized to one of 6 sets of choice questions.

Please look at these two products and choose Product A or Product B:

	Product A	Product B
HIV Prevention	 7 of 10 women remain HIV negative	 7 of 10 women remain HIV negative
Pregnancy Prevention	✓ Prevents pregnancy <i>May stop having monthly menstrual period</i>	✓ Prevents pregnancy <i>May stop having monthly menstrual period</i>
Product Form	Vaginal ring 	Injection 
How often it is used	Use one time <u>per month</u>	Use one time per <u>week</u>
Side Effects	 Mild headache/dizziness	 No side-effects

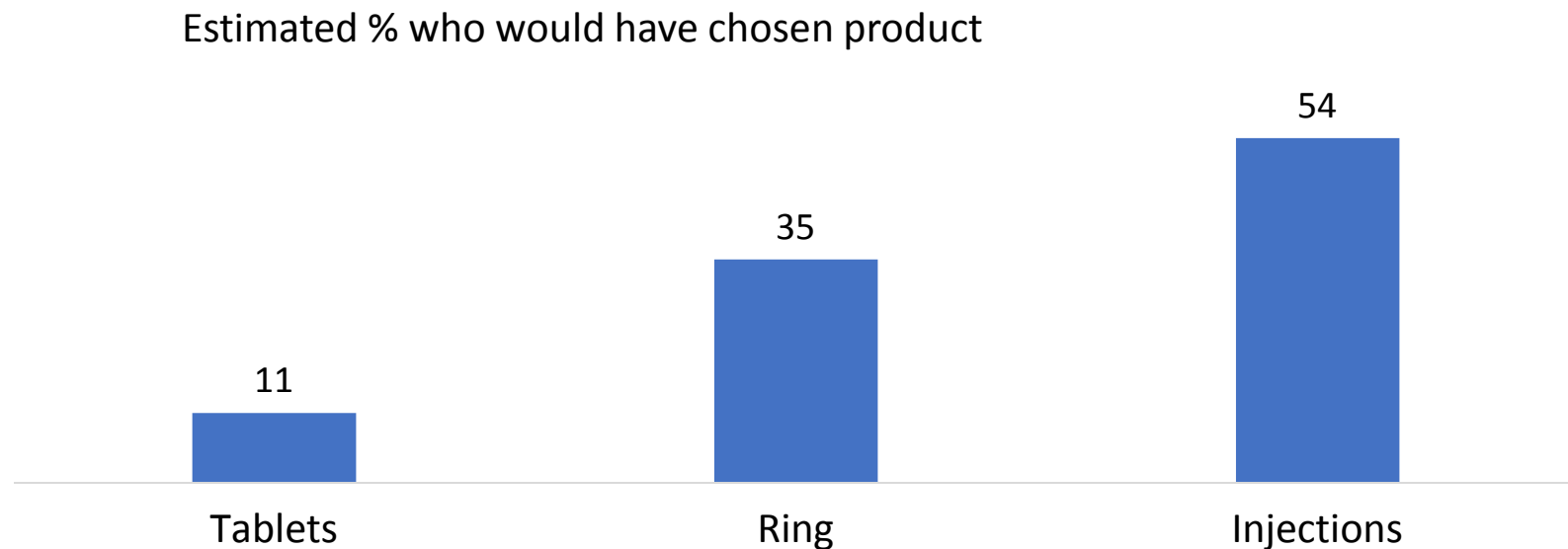
6. Attributes Influential to Product Choice



- **Product efficacy** most important attribute.
 - More influential to choice among Kenyan than South African women.
- Other attributes influential to choice:
 - **Pregnancy prevention (MPT feature)**
 - **Product delivery form** more influential to choice in South Africa than in Kenya.
 - Injections favored; daily tablets disliked.
- Side effects played minor role in choice.

6. Predicting product choice based on DCE preferences (South Africa)

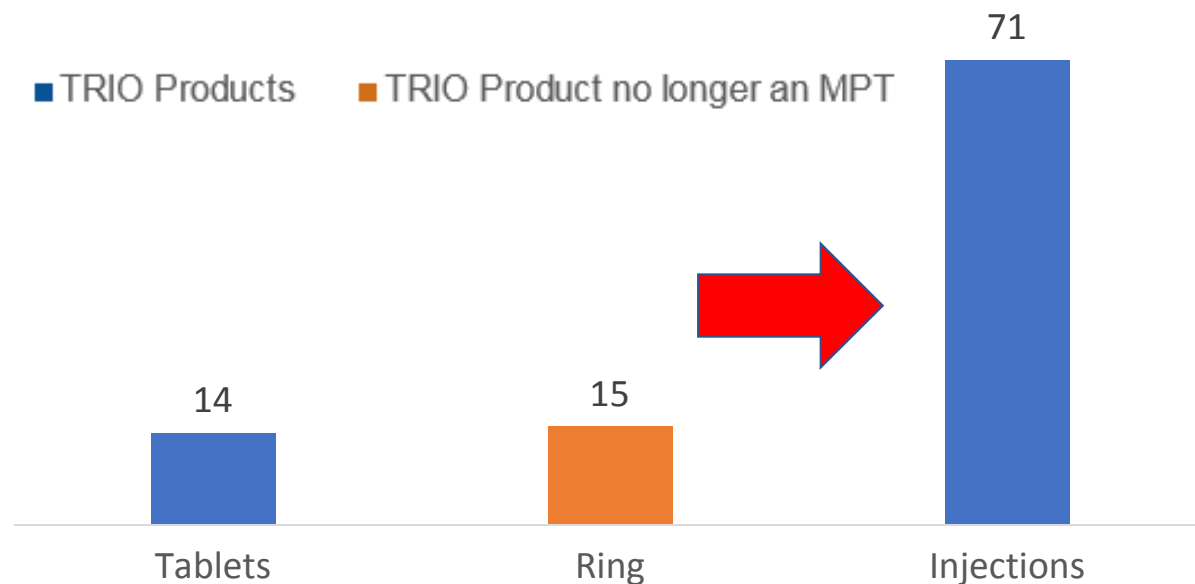
- **Scenario #1:** Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.



6. Predicting product choice based on DCE preferences- SOUTH AFRICA

- Scenario #1: Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.
- Scenario #2: same as #1 *except* one product is no longer an MPT.

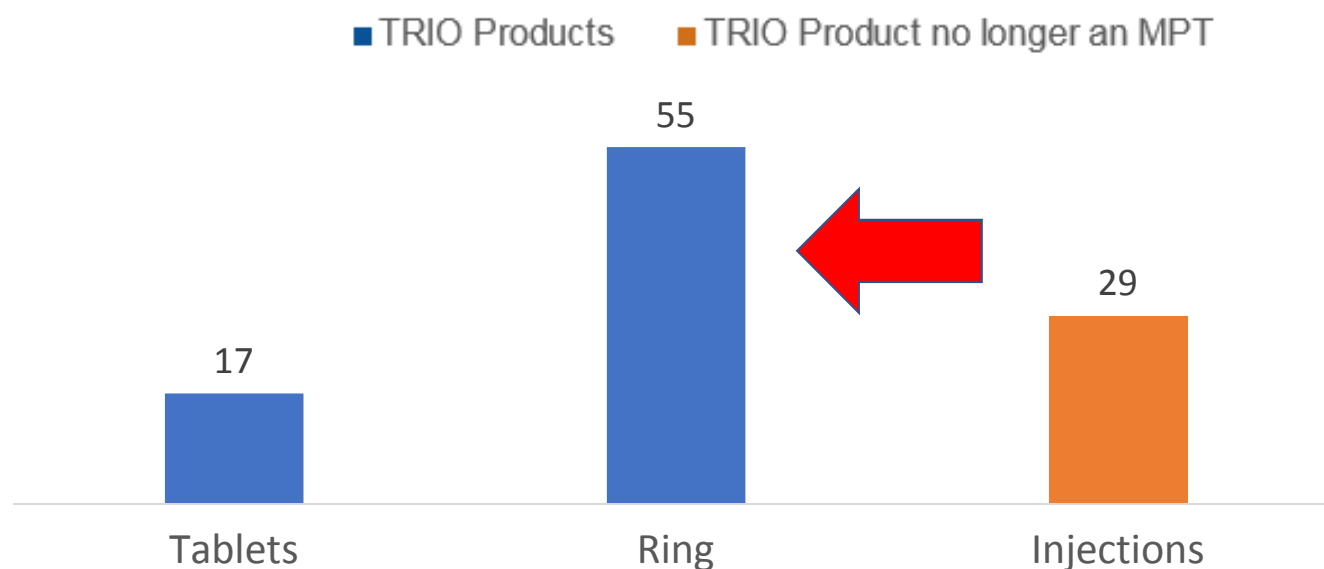
Estimated % who would have chosen product



6. Predicting product choice based on DCE preferences- SOUTH AFRICA

- Scenario #1: Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.
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Estimated % who would have chosen product



Lessons learned from TRIO

1. **Young women are interested in a MPT product**
2. **Users recognize they are different and desired multiple options**
 - Familiarity, simplicity, discretion favored injections
 - **Key + attributes were not product specific:** Low burden, stress-free, lifestyle congruent
3. **DCE:**
 - Efficacy is necessary but not sufficient.
 - Suggests higher preference for ring compared to tablets as MPT - Actual choice in clinical study showed no difference with tablets
4. **Experience with product use (and familiarity) informed choice**
 - Video and education material critical (mostly for the unfamiliar product)
 - For individuals, opinion changed with product experience
 - Residual reluctance with most unfamiliar product (ring);
 - Choice of tablet may have been driven by disinterest to use;
5. **Downside of products are real and must be discussed-** keep them as inconvenience vs. no becoming barriers
6. **Placebo use studies:**
 - Feasible and acceptable
 - Allow to measure the full product “lifecycle” from awareness to persistence
 - Valued by participants and helped to get insights by gaining their engagement as “co-designers”

Acknowledgements



Thank you!
All our study participants



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Erica Browne, Alexandra Minnis



BILL & MELINDA
GATES *foundation*

BMGF
Lut Van Damme

IPM
GILEAD