Abstract #WEPEC0978

Choice, use and persistence with three MPT delivery forms: tablets, ring, injections - among young African women

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Background

Preventing HIV and unintended pregnancies are key health priorities in sub-Saharan African (SSA) women:

- Rates of HIV infection are over 2x higher among women age 18-30, compared to men[1]
- 59% of people living with HIV in SSA are women[1]
- 40-60% of pregnancies are unintended[2]

A dual-purpose product may facilitate uptake, use and acceptability among at-risk women compared to a single indication product.

To understand attributes of future multipurpose prevention technologies (MPTs) associated with choice, use and persistence, we evaluated 3 different placebo MPTs with young Kenyan and South African women.

1. UNAIDS 2014
2. Mc Phail ., BMC Med. 2007; Kott, A. Int Pers Sex R. H. 2011

The TRIO study (2014-2017)

To improve understanding of the acceptability of potential MPTs among young women through assessment of preference, choice and use

Three placebo MPTs:

- Daily oral tablets,
- Monthly vaginal ring
- Two monthly injections

Clinical study among young sexually active women

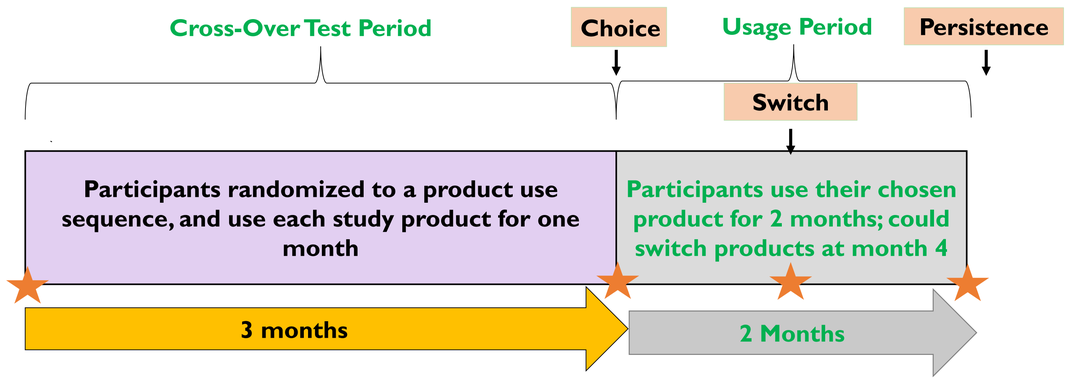
TRIO 5-month clinical study (2015-2016)

☆ Kisumu, Kenya: N=123*
☆ Soshanguve, South Africa: N=126*

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

* = Total who chose a product at Month 3

Study design



Objectives: to assess product choice at the end of the cross-over period, and use and persistence during the usage period.

★ Time points contributing data to this analysis; see IAS 2017 abstract #WEPEC0940 for results from the cross-over period.

Measures

- **Choice:** At month 3 visit, participants chose one product for an additional 2-month usage period.
- **Use:** Adherence to chosen product for up to 2 months (assessed @ M-4 and M-5).

Adherence components	Tablets	Ring	Injections
Initiation/compliance - at clinic	Direct observation (DO) of first ingested tablet	Pelvic exam after vaginal ring insertion	2x 1ml saline injected in glutei
Completion - at clinic	DO of last ingested dose	Ring in situ at return	NA
Execution	Self report	Self report	NA
Persistence	At M-4 visit, continue or switch to another product (for 1 month)		

- We used multinomial logistic regression to determine if choice differed by site

Study retention and safety endpoints

Total of 277 women enrolled

- 249 (90%) completed crossover period and chose a product
  - None declined to choose a product at M3 visit
  - Loss to follow-up during crossover period was not associated with product sequence
- 246 (89%) completed the 5-month clinical study

Product-related AE during use period: 1 mild AE (vaginal pruritis) associated with ring use.

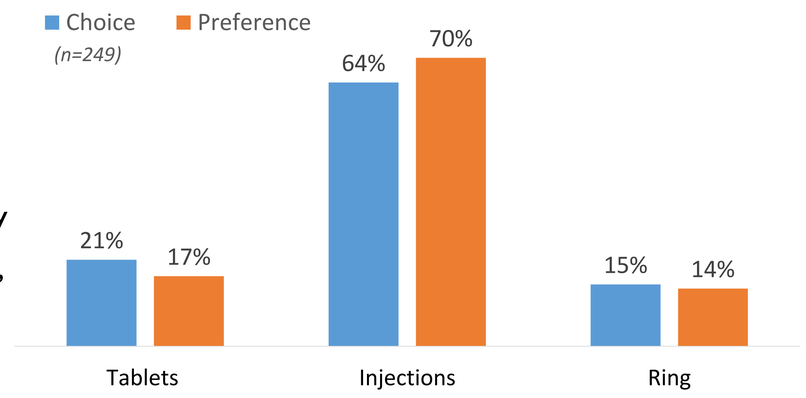
Table 1: Sample characteristics by country

	Soshanguve, SA (n=126)	Kisumu, Kenya (n=123)	Overall (N=249)
Age group			
18-24	67%	67%	67%
25-30	33%	33%	33%
Married	4%	46%	25%
Currently has a primary partner	96%	92%	94%
Lives with partner/spouse	7%	48%	27%
Contraceptives ever used			
Male condoms	94%	90%	92%
Pills	25%	28%	27%
Injectables	82%	59%	71%
Implants/IUD	39%	61%	38%
Transactional sex ever	6%	20%	13%

Choice is a good proxy for product preference

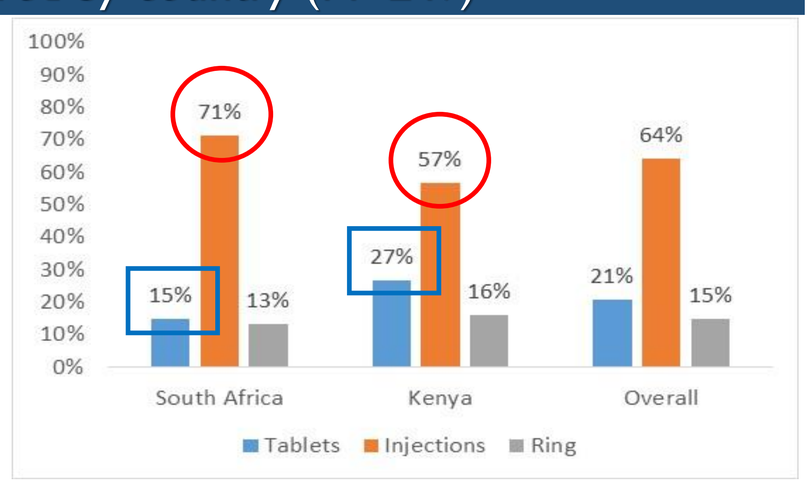
91% chose the product they would most prefer to use now for both pregnancy and HIV prevention

- Note: 3 participants (1%) chose to use a product they "would definitely not consider using in the future" (2 tablets, 1 ring)



Product choice differed by country (N=249)

- Kenyan women were more likely than South African women to choose tablets or rings compared to injections; & less likely to choose rings compared to tablets.
- Choice was not associated with age, marital status, education, AEs or with last product used in the crossover period.

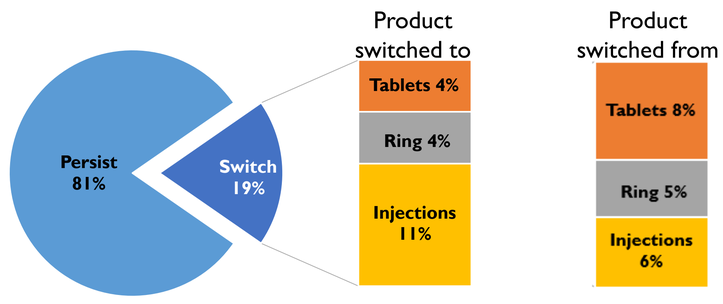


	Tablets (vs Injections) RRR (95% CI)	Ring (vs Injections) RRR (95% CI)	Ring (vs Tablets) RRR (95% CI)
Kenya (vs South Africa)	2.23** (1.73 – 2.87)	1.52* (1.15 – 2.02)	0.68* (0.49 – 0.96)

RRR: relative risk ratio; * p<0.05 ** p<0.001

Persistence

- 81% continued with their chosen product; 19% switched after first use month (M3-M4)



Preference, choice & adherence summary

			ADHERENCE (%)			
MPT Delivery Form	Preference	Choice	Initiation	Completion	Execution	Persistence
Injectables	1st	1st	100	n/a	n/a	89
Oral tablet	2nd	2nd	97	97	61	96
Vaginal ring	3rd	3rd	97	81	70	96

Note: differences in adherence components were not statistically significant.

Limitations

- Use in TRIO may not fully reflect active product experiences, including side effects, lead-in and lead-out dosing (injections), and likely 3-month duration (ring).
- One month of product use provides an opportunity to try the product, but does not mimic sustained use period.
- Adherence measures were not comparable across the three products; perfect adherence to injections once initiated was a given.

Conclusions

Placebo MPT product preference and choice were highly correlated.

- Injections were chosen most often, followed by tablets and then rings
- The strongest factor associated with choice was "country". Socioeconomic and behavioral differences in the populations at each site likely underlie this finding.

While all placebo MPT products were used during the usage period, findings suggest different adherence levels (though not statistically significant):

- Adherence appeared higher with injections; however persistence appeared lower.
- Tablet and rings appeared to have similar levels of adherence, with lower completion for the ring, and conversely, lower (self-reported) execution for the tablets.

Future studies with active products may further inform product choice, use and persistence in these and other settings.

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