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

Ariane van der Straten 1,2, Rachel Weinrib 1, Kwangwo Agot 3, Kathia Ahmed 3, Erica Brownie 1, Kaghlisho Manenzhe 3, Fredrick Owino 4, Jill Schwartz 3, Alexandra Minnis 1,4, on behalf of the TRIO Study Team

1. Women’s Global Health Imperative (WGH) RTI International, San Francisco, CA, USA; 2. Center for AIDS Prevention Studies, Department of Medicine, UCSF, San Francisco CA, USA; 3. Impact Research and Development Organization, Kisumu, Kenya; 4. Sesheke Research Centre, Soshanguve, South Africa; 4. CONRAD/EPIVAX, Arlington VA; 5. School of Public Health, UC Berkeley, CA, USA

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
- 59% of people living with HIV in SSA are women
- 40-60% of pregnancies are unintended

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.

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

Cross-Over Test Period
Choice
Usage Period
Persistence

Participants randomized to a product use sequence, and use each study product for one month

Participants use their chosen product for 2 months; could switch products at month 4

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: IAS 2017 abstract #WEPEC0978 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 @ M4 and M5).

Adherence components: Tablets, Ring, Injections

Initiation/compliance - at clinic:
- Direct observation (DO) of first ingested tablet
- Pelvic exam after vaginal ring insertion

Completion - at clinic:
- DO of last ingested dose
- Ring in situ at return

Execution:
- Self report

Persistence:
- At M4 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 377 women enrolled
- 249 (90%) completed cross-over period and chose a product
- None declined to choose a product at M3 visit
- Loss to follow-up during cross-over 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.

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.

Preference, choice & adherence summary

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

ADHERENCE (%)

Table: Preference of three MPTs by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Tablets</th>
<th>Injections</th>
<th>Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya (N=123)</td>
<td>25%</td>
<td>64%</td>
<td>15%</td>
</tr>
<tr>
<td>South Africa (N=126)</td>
<td>17%</td>
<td>72%</td>
<td>11%</td>
</tr>
</tbody>
</table>

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

Pharmac 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.
- Tablets 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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