Insights from MTN-032
Assessment of ASPIRE and HOPE
Adherence (AHA) : Phase 1

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Introduction

• MTN-020/ASPIRE and IPM-027/Ring Study proved that the dapivirine vaginal ring was safe and effective with consistent use.

• To optimize the impact of this promising female-initiated prevention method, adherence barriers need to be understood and addressed.

• MTN-032 explored women’s ring use challenges through open-ended discussion of their “objective” adherence data from stored plasma and returned rings.
MTN-032 Study Timeline

**MTN-032 (AHA)**

**Phase 1:** Former ASPIRE participants  
**Phase 2:** Former HOPE participants

- **ASPIRE Results Q1 2016**
- **AHA Phase 1 June – Oct 2016**
- **AHA Phase 2 Begins Q1 2018**

Timeline:
- **2012**: ASPIRE
- **2013**: ASPIRE
- **2014**: ASPIRE
- **2015**: ASPIRE
- **2016**: HOPE July 2016 – Sep 2018
- **2017**
- **2018**
Methods

In Phase 1, Former ASPIRE participants were:

• Stratified by age group (18-21; 22-45) and
• Randomly selected at 7 sites in Malawi, South Africa, Uganda and Zimbabwe
• 12-17 months after trial exit
Methods

- Ring use challenges were explored via in-depth interviews (IDI) or focus group discussions (FGD) using structured guides.
- Visual tools used included:
  - adherence trajectory tool and
  - Individual depiction of dapivirine levels detected in plasma and returned rings.
- Coding of transcribed interviews was conducted in Dedoose™.
Methods

ADHERENCE TRAJECTORY TOOL

A) Consistently adherent,
B) Consistently non-adherent,
C) Non-adherent at the beginning and adherent by end,
D) Adherent at the beginning and non-adherent by the end, or
E) Inconsistently adherent throughout the study.

Helped participant understand how participants may have used the ring differently
Methods

INDIVIDUAL DEPICTION OF RESULTS

MTN-032 Individual Drug Level Results Visual Tool

ASPIRE PTID

AHA PTID

Month 3  Month 6  Month 9  Month 12  Month 15  Month 18  Month 21  Month 24  Month 27
• The information gained from the Individual drug level results were divided into 4 analysis groups in terms of adherence
Results:

Participants

- Screened 229 women
- Enrolled 187 participants aged 19-48
- 37% were 18-21 at ASPIRE enrollment
  - Intentionally over sampled to address questions around adherence in young women

### Not enrolled (n=42)
- 13 Not available/time commitments
- 10 Relocated
- 9 No permission to contact
- 4 Not interested
- 2 Contacted but refused participation
- 2 Could not be reached
- 1 No show

<table>
<thead>
<tr>
<th>18-21 years old (n=38)</th>
<th>22-45 years old (n=51)</th>
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<tbody>
<tr>
<td>12 Focus Group Discussions (FGD) (n=89)</td>
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<th>18-21 years old (n=31)</th>
<th>22-45 years old (n=67)</th>
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<td>98 In Depth Interviews (IDI) (n=98)</td>
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Results:

Self Reported Use

- In IDIs, most women (80%) described their trajectory of ring use throughout the study as consistently high (58%), or high after the first few months (22%).
Use of these tools elicited participant descriptions of many instances of non-adherence, including removals from short-term, multiday, multi-week (often with reinsertion 1-3 days before the next visit).

Reasons for non-adherence included
- For sex or bathing
- Menses
- Worries about ring causing cancer or infertility;
- Experience of discomfort or side effects.
- Influence from peers and communities;
- Mistrusting researchers (particularly foreign)
- Non-disclosure to partners and partner objections;
Analysis

• Stratified analysis was done for the 4 adherence groups
• This was also done by age group and by IDI and FGD
  • Based on the many questions related to factors impacting adherence in younger women
• Allowed us to observe differences by adherence group and age
• Many of the reasons were the same across groups - motivators were different
## Results

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<td>Health Issue attributed to the ring</td>
<td>X</td>
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Results

FGDs

- ASPIRE result indicated younger women were less adherent
- Discussed during FGD
- Both younger and older women provided similar information with young women’s non-adherence attributed to being:
  - less “serious” about the future, HIV prevention and the study (and motivated predominantly by benefits);
  - more fearful of childbearing/fertility-related consequences;
  - more into partying;
  - not appreciating the potential consequences of non-use;
  - and to having less confidence and control in their partnerships
Motivators to Adherence

- A. Community
- B. Organizational/Group
- C. Household
- D. Individual
Motivators to Adherence:
Community

Information flow/beliefs
• Not susceptible to rumors or concerns expressed by others

Altruism
• Protecting future generations from HIV
• Believing in importance of proving efficacy

I think knowing that like in the future I am going to empower other young ladies like me not to be exposed to the HIV virus. That was my goal and it was at the back of my mind that I was doing this and I’m not going to remove the ring. (IDI #2031; Age 21; High Adherence Group; Johannesburg, South Africa)
Motivators to Adherence

Organizational/Group

Encouragement from other participants
• Others non-experiencing side effects
• Others wearing ring consistently

Trial Led Activities:
• Adherence workshops
• Site Level Adherence Feedback
• Waiting room talks
• Discussions/assurances from staff

I never had any fear because I would get confidence from friends who I often asked their experience and they would confirm that they haven’t had any problem and in a way it would make you strong. (IDI #6013; Age 23; Middle- High Adherence Group; Kampala, Uganda)
Motivators to Adherence: Household

Male Partner Support
• Disclosure to male partner
• Not feeling ring during sex

"Ah, he (male partner) just spoke- He even mentioned the names of staff and asked, "How are they? Don’t stop using the ring. You removed the ring in the first days. When I see them [staff] I will report that you removed the ring. Sopersevere in using the ring." (IDI #4005; Age 30; Middle-Low Adherence Group; Harare, Zimbabwe)
Motivators to Adherence:

Individual

Not experiencing side effects
Feeling protected
  • Regular HIV testing
  • Believing the ring is protective

While I was using the ring, I was very proud of myself, yes, that is what I am going to say! I used to pride myself in my ring use. I told myself that this ring that I am using, is protecting me. That is the first thing. (IDI #3001; Age 30; Middle-High Adherence Group; Durban, South Africa)
Conclusions

• Most women believed (or described) themselves to be adherent or mostly adherent to the ring, despite plasma and ring data demonstrating variable use.

• When presented with objective individual-level adherence data, participants provided numerous explanations/challenges resulting in non-adherence during ASPIRE:
  • Non-disclosure/disapproval of ring use by male partners,
  • Hygiene-related worries (especially related to menses) and
  • Concerns about side effects or adverse health effects

• Theses reasons were reported in almost all adherence and age subgroups
Conclusions

• Several motivators to consistent ring use were also identified, particularly a feeling of altruism among the high adherers.
• Motivators are equally as important as challenges to understand so as to encourage consistent use.

Overall, these data can be used to pre-emptively mitigate adherence challenges in future ring studies/activities
Acknowledgements

• All MTN-020 (ASPIRE) & MTN-032 (AHA) site staff and participants
• RTI International
• FHI 360
• MTN

The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.
Thank You!