Provision of Residual Drug Level Results from the Dapivirine Ring Open Label Extension Study: Participant Reactions and Explanations during a Qualitative Ancillary Study (MTN-032)

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Background

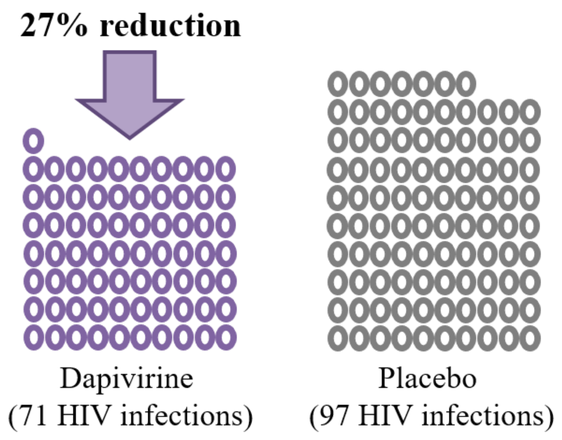


Figure 1: MTN-020 (ASPIRE) – Phase 3 clinical trial of dapivirine vaginal ring – Primary Result

- MTN-020 (ASPIRE) study assessed the efficacy and safety of the dapivirine vaginal ring for the prevention of HIV-1 acquisition in women. MTN-025 (HOPE) was an open label extension study of ASPIRE.
- Understanding ring adherence barriers and motivators in the context of known safety, partial efficacy and choice is imperative to ensure the dapivirine vaginal ring's potential success.
- MTN-032/AHA study was a two-phase exploratory sub-study of the ASPIRE (Phase 1) and HOPE (Phase 2) studies. AHA utilised qualitative in-depth interviews (IDIs) and focus group discussions (FGDs) to explore socio-contextual and trial specific issues.
- Participants were presented with their residual drug level (RDL) results (captured from month 1 - month 12) and their reactions and adherence challenges were discussed.

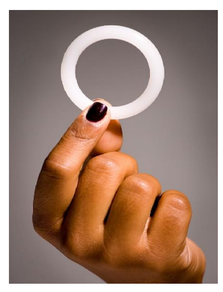


Figure 2a: Dapivirine vaginal ring

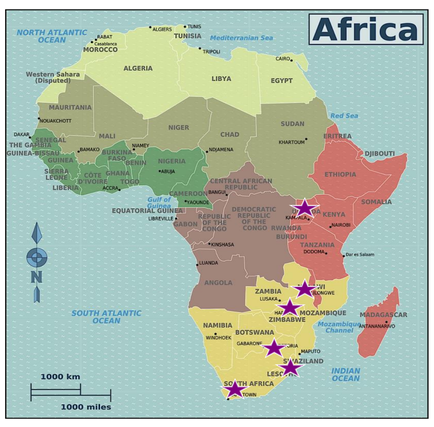
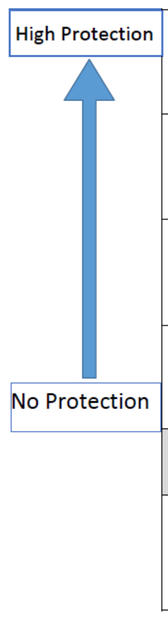


Figure 2b: MTN-025 (HOPE) – open label extension study – site locations

Methods

- AHA (phase 2) randomly selected 10 former HOPE participants at each of the six HOPE sites within three strata of Month 1 adherence (low, middle, high; using a 1:3:1 ratio).
- Sixty participants were enrolled (age 23-48) at 0-9 months after exiting HOPE and participated in the IDIs; two participants were not included in the analysis due to inappropriate enrolment (n = 58).
- IDIs explored ring experiences and challenges and included presentation of monthly RDLs categorized from zero (no use) to three (high use) (Figure 3).
- Interviewers discussed the participants' adherence challenges and responses to their RDLs and assessed whether they believed the RDLs matched their actual use throughout study participation and if they trusted the RDL testing methods.
- Interviewers summarized experiences in debrief reports and quantitatively categorized the RDL reactions on forms.
- IDIs were audio-recorded, transcribed and translated with quality control checks.
- Analysts summarized qualitative data using Dedoose software and quantitative data was tabulated using Stata.



3					x	x	x				x	x
2								x	x			
1	x	x		x						x		
0			x									
Ring Use Period:	Enr-M1	M1-M2	M2-M3	M3-M4	M4-M5	M5-M6	M6-M7	M7-M8	M8-M9	M9-M10	M10-M11	M11-M12
Notes:												

Figure 3: Example of the tool used to capture residual drug level results which was then presented to the participant

Results

Table 1: Results of trusting/not trusting the method used to test the ring vs residual drug level results matching/not matching how the participant used the ring

Trust/does not trust the method used to test the ring	Participant thinks her residual drug level (RDL) match/do not match how she used the ring		
	RDL matched how the participant used the ring	RDL did not match how the participant used the ring	Total
	N (%)	N (%)	N (%)
Trusts the method	18 (94.7)	15 (38.5)	**33 (56.9)**
Does not trust the method	1 (5.3)	24 (61.5)	**25 (43.1)**
Total (Row %)	**19 (32.8)**	**39 (67.2)**	**58 (100.00)**

- Approximately two-thirds of the women, (n=37; 63.8%), had all twelve months of RDL scores to review.
- Most women (n=39; 67.2%) felt that their RDLs did not match their ring use. On average, this group had varying RDLs, but reported using the ring.
  - Of the 39 women, 24 (61.5%) indicated that they distrusted the RDL testing method and theirs explanations for the discrepancy included: delays in changing the ring monthly, body did not absorb the drug, blood type/stress influenced amount of drug being released, the ring having less drug or not working as required, not inserting the ring correctly, use of traditional medication and faulty testing machines.
- Those who felt their RDLs matched their ring use (n=19; 32.8%) predominantly trusted the RDL testing method (18/19 women; 94.7%). These participants were generally consistent ring users but occasionally described ring non-use because of menses, vaginal itching, pelvic pain, increased wetness in the vagina, partner feeling the ring, partner objection, cleaning of the ring and community myths. The most common reason cited for adherence was wanting HIV protection.

Conclusions

- Women in this study sample, with variable adherence levels, felt that they were more consistent ring users than the RDL signified.
- Understanding participants' barriers and motivators beyond the RDL scores provides insight into how the ring is understood to work and is incorporated into women's lives, which will help facilitate successful real-world implementation of the ring.

MTN-020 (ASPIRE), MTN-025 (HOPE) and MTN-032 (AHA) studies were designed and implemented by the Microbicide Trials Network (MTN) and 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. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The vaginal rings used in ASPIRE and HOPE were developed and supplied by the International Partnership for Microbicides (IPM).