

# Ring Acceptability and Adherence: Results from US and Indian Women Enrolled in MTN 005

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Happy Halloween



# MTN 005: Expanded safety and adherence study of a nonmedicated intravaginal ring

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- ❑ Sites: Birmingham, Alabama; Bronx, NY; Pune, India
- ❑ Design: Open label, 2-arm randomized control trial comparing IVR to no IVR, with 2:1 randomization
- ❑ Study duration: 16 weeks per woman; IVR use 12 weeks
- ❑ Sample : Sexually active HIV negative women 18-45
- ❑ ACASI behavioral assessments: enrollment, 4, 8, 12, & 16 weeks

# Study Product

- Silicone elastomer ring
  - Manufactured by Andromaco for the Population Council (IND holder)
  - 58mm outer diameter, 8.4mm cross section
  - (ASPIRE: 56mm and 7.7mm )



# Objectives

## □ Primary

- Evaluate safety of study IVR in HIV uninfected women over 12 weeks of use
- **Evaluate adherence to study IVR in HIV uninfected women over 12 weeks of use**

## □ Secondary

- Describe changes in sexual behavior and in vaginal hygiene practices in study IVR vs. no IVR group over 12 weeks of use/non-use
- **Evaluate acceptability of the study IVR in HIV uninfected women over 12 weeks of use**
- Measure vaginal flora characteristics, and descriptively examine changes in these characteristics over the course of study IVR use

# Study Sample

	Total	Alabama & Bronx, US		Pune, India	
		IVR	No IVR	IVR	No IVR
Proposed	252	68	34	100	50
Actual	195	68	34	63	30



# Spotted Rings

- 27 of 69 recovered rings from NARI site had spots
- Inspection by MTN and Pop Council labs revealed bubbles and flashing
- No safety issues or bacterial or fungal contamination
- Manufacturing issue; spots due to surface imperfections discolored by accumulation of biological fluids
- NARI site enrollment suspended June 2012 (51 women put on product hold)

# Study population: Demographics

	US	India
Mean age	32	30
Marital Status:		
Married	31%	99%
Unmarried with primary sex partner	68%	1%
Highest level of education completed:		
<High school	6%	46%
High school	20%	20%
Some college	75%	33%



# Adherence: IVR in vagina at all times as instructed

Country	#of IVR participants	% adherent	#of days (of 30) IVR out <sup>a</sup>
US	67	60	2.8
India	63	56	2.9 <sup>b</sup>

<sup>a</sup> Limited to those not perfectly adherent (US N=27; India N=28)

<sup>b</sup> Due to product hold, based on ~ 9 wks of IVR use (on average)

Differences between India and the US sites not significant

## Adherence: Comparison at 4 and 12 weeks, among those who used IVR for 12 weeks and interviewed at both time periods

Time period (week)	Ring ever out past month (%)		Had sex with ring out (%)		Ring out during menses (%)		Sex during menses (%)	
	US	India	US	India	US	India	US	India
4	35	13	6	7	10	3	6	17
12	24	0	8	0	12	0	7	15

US N=45-49; India N=30

Differences between 4 and 12 weeks not significant

# Adherence: IVR Out of Vagina

## 4-week follow-up assessment (India N = 59, US N = 66)

Reported IVR Out	India 22%	US 36%
Came out on its own	10%	11%
Took it out	12%	26%

### What participant was doing when IVR came out on its own

	India	US
defecating	0%	8%
urinating	3%	2%
having sex	2%	1%
menstruating	5%	0%

\* of those who reported reinsertion, all reported washing or rinsing before reinserting

### Why IVR taken out (multiple responses possible)

	India	US
pain/discomfort	7%	12%
not in place	2%	9%
wanted to clean	5%	11%
because of menses	3%	14%
ppt/partner felt it interfered with sex	2%	7%

### What did you do after IVR was out\*?

	India	US
reinserted immediately	14%	21%
left out awhile; reinserted before next appointment	5%	12%
waited for next appointment	2%	3%

## Acceptability: responses from 12 and 16 week assessments

	U.S. (%) N=67	India (%) N=60
Prefer not to wear every day	16	13
Prefer not to wear during menses	25	25
Not acceptable to primary partner	1	10†
Worry about ring falling out	10	32**
Dislike wearing during sex	16	20
Would not wear, if partner doesn' t like	3	32***
Changes the feeling of sex	18	8
Difficult to use	4	3
Overall dislike	9	20
If at risk of HIV, definitely would not use	0	20***

Differences between the US and India significant at

\*\*\* p<0.001 \*\*p<0.01 †p<0.10

## Comparison of acceptability at 4 and 12 weeks, among those who used IVR for 12 weeks and interviewed at both time periods

Response	U.S. (%) N=46-49		India (%) N=27-30	
	4 weeks	12 weeks	4 weeks	12 weeks
Aware of the ring during daily activities	22	12	33	23
Ring usually comfortable	82	88	73	77
Felt during sex	45	39	37	22
Partner felt during sex	29	31	23	23
Check that ring inside	63	45	37	40
Worried ring would get lost inside	10	0†	23	10

Within country, difference between 4 weeks and 12 weeks significant at †p<0.10



## Association between reported acceptability and adherence (ring out of the vagina past month): US sites only, week 12

### Ring out past month:

- 6 of 23 participants who “prefer to wear the ring every day”
- 7 of 27 participants who “prefer not to wear the ring every day” or who “have no preference”
- $p=1.00$
  
- 8 of 21 participants who “don’ t mind wearing the ring during menses”
- 4 of 22 participants who “prefer not to wear the ring during menses”
- $p=0.19$
  
- 8 of 43 participants who “do not mind wearing the ring during sex”
- 5 of 7 participants who “do not like wearing the ring during sex”
- $p=0.01$

# Conclusions: Adherence

- 100% adherence achieved in >56-60% of participants
- Fewer than 10% of participants report sex when ring out, although ~ 20% dislike wearing ring during sex
- About 10% of participants report ring out during menses, although ~ 25% prefer not to wear during menses
- Although differences between 4 and 12 wks not significant (small sample size), adherence appeared to increase over time

# Conclusions: Acceptability

- Few participants report ring difficult to use
- Over 75% report ring usually comfortable
- Between 20% and 50% report feeling ring during sex and >25% report partner feeling during sex
- Acceptability significantly lower in India; 20% would “definitely” not use every day if at risk of HIV compared to 0% in US
- Although differences between 4 and 12 weeks not significant (small sample size), acceptability appeared to increase over time



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