

Disclosure of Vaginal Ring Use to Male Partners in an HIV Prevention Study: Impact on Adherence

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Background

- HIV prevention strategies for women have thus far focused on strategies that women can use discreetly that do not require partner awareness of use or approval for adherence.
- However, disclosure of study product use to supportive male partners may increase uptake and adherence to HIV prevention strategies.
- To this end considerable effort was made to engage male partners in the ASPIRE trial.

Objective

- To describe the characteristics of women who did not disclose vaginal ring use to male partners and the association between disclosure and adherence in the MTN 020 (ASPIRE) trial.

Methods

- The MTN-020/ASPIRE trial was a phase III randomized, double blinded, placebo controlled trial evaluating the effectiveness and safety of the dapivirine vaginal ring for HIV prevention. The study enrolled 2,629 women between 2012-2015 in Malawi, South Africa, Uganda and Zimbabwe.
- At enrolment and quarterly visits women were asked whether their primary partner (PP) knew: 1) that they were participating in ASPIRE 2) were using a vaginal ring as part of the trial.
- Women who did not have behavioral assessments (n =29) and a primary partner (n=12) during follow up were excluded from the analysis.
- Plasma drug concentrations were measured at quarterly visits and adherence was defined as dapivirine levels >95pg/ml.
- During follow-up, women were categorized as “always”, “sometimes”, or “never” disclosing ring use to their primary partner.
- The impact of over 20 baseline sociodemographic and behavioral factors on ring disclosure patterns were evaluated using Poisson regression models with robust standard errors. Final multivariate models include all variables significant at p<0.05.
- GEE Poisson regression models with robust standard errors were used to estimate the visit-level association between ring disclosure and low adherence.

Results

- At enrolment, 2616 women (99,54%) reported having a primary partner
- Disclosure of both study participation and ring use was higher during follow up in comparison to disclosure at the enrolment visit (**Figure 1**).
- Three quarters of women (73,26%) reported partner knowledge of study participation at every quarterly visit (“always” disclosed), 18,39% reported partner knowledge at some visits (“sometimes” disclosed), and 8,35% reported partner having no knowledge at any visit (“never” disclosed) (**Figure 2**).
- Ring use disclosure followed the same pattern but was lower at enrolment (**Figure 2**).
- Following multivariate modelling, variables significantly associated with “never” disclosing ring use during follow up were country; partner having no knowledge of study participation and ring use at enrolment; and having no knowledge of partner HIV status (**Table 1**). In addition to those associated with “never” disclosing, variables predictive of “sometimes” disclosing included younger age, being unmarried, and worries that the PP would not like or approve of the ring (**Table 2**).
- After adjusting for age, site and time in study, the risk of low adherence did not differ by disclosure status (RR=1.08, 95% CI 0.91-1.30, p=0.38) (**Table 3**).

Results (continued)

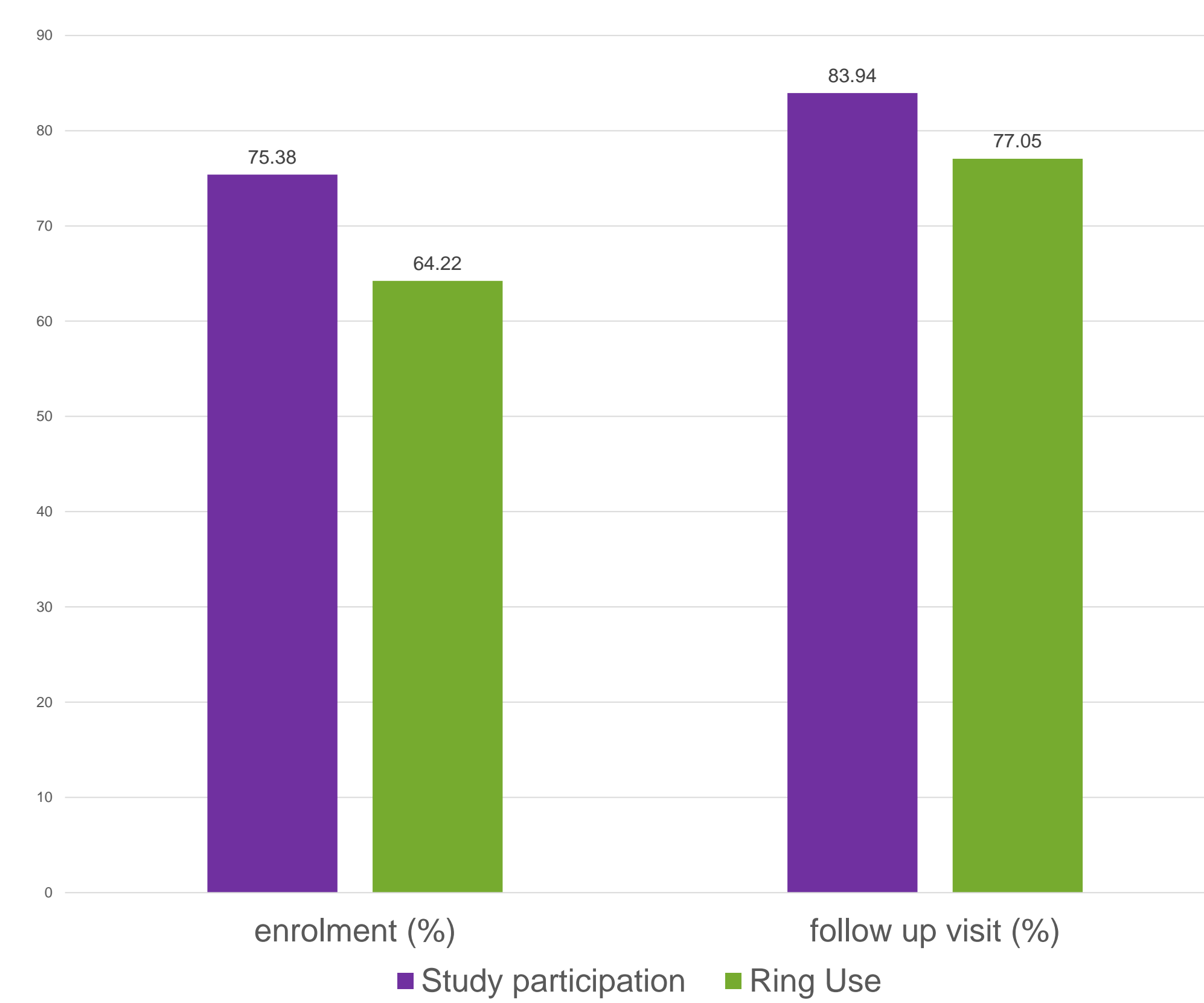


Figure 1: Disclosure of ASPIRE Study Participation and Ring Use

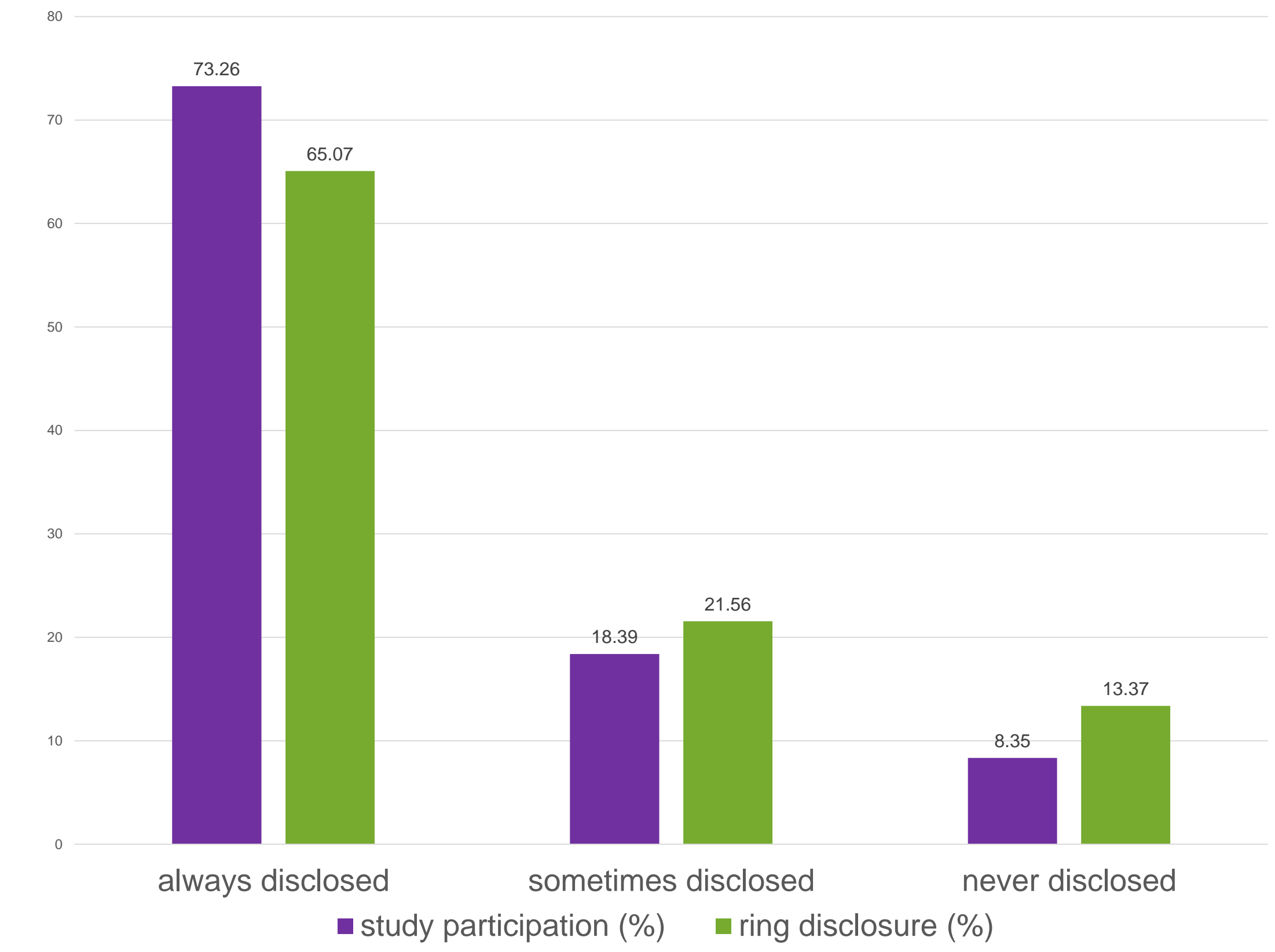


Figure 2: Patterns of Study and Ring Disclosure by Disclosure Status

Table 1: Multivariate Analysis of Correlates of Never Disclosing Ring Use (versus Always Disclosing)

		Total # (n=2588)	# never disclosed (n=346)	% never disclosed (13.4%)	RR	95% CI	P
Country	Malawi	268	5	1.9	0.62	0.28–1.38	<0.001
	Uganda	249	152	61.0	2.54	2.16–2.98	
	Zimbabwe	671	57	8.5	1.78	1.37–2.31	
	South Africa	1400	132	9.4	Ref		
Partner aware of study participation*	Not aware	632	253	40.0	2.06	1.61–2.65	<0.001
	Aware	1946	91	4.7	Ref		
Partner aware of ring use*	Not aware	920	302	32.8	7.76	5.26–11.43	<0.001
	Aware	1658	42	2.5	Ref		
Partner HIV status*	HIV positive	35	3	8.6	0.90	0.42–1.88	0.02
	Ppt does not know	1122	189	16.8	1.23	1.06–1.42	
	HIV negative	1421	152	10.7	Ref		

Table 2: Multivariate Analysis of Correlates of Sometimes Disclosing Ring Use (versus Always Disclosing)

		Total # (n=2588)	# sometimes disclosed (n=558)	% sometimes disclosed (21.6%)	RR	95% CI	P
Age	18-21	507	155	30.6	1.29	1.09–1.53	0.002
	22-26	832	168	20.2	0.97	0.82–1.15	
	27+	1249	235	18.8	ref		
Country	Malawi	268	28	10.5	0.83	0.57–1.22	<0.001
	Uganda	249	64	25.7	2.37	1.90–2.96	
	Zimbabwe	671	120	17.9	1.35	1.05–1.72	
	South Africa	1400	346	24.7	Ref		
Marital status^	Yes	1061	157	14.8	0.71	0.56–0.89	0.003
	No	1525	400	26.3	Ref		
Partner aware of study participation*	Not aware	632	217	34.3	1.38	1.15–1.66	0.001
	Aware	1946	336	17.3	Ref		
Partner aware of ring use*	Not aware	920	309	33.6	2.20	1.79–2.70	<0.001
	Aware	1658	244	14.7	Ref		
Partner HIV status*	HIV positive	35	4	11.4	0.78	0.32–1.89	0.001
	Unknown	1122	277	24.7	1.29	1.12–1.48	
	HIV negative	1421	272	19.1	Ref		
Worried partner will not like or approve of ring**	Yes	249	73	29.3	1.26	1.05–1.51	0.02
	No	2338	485	20.7	Ref		

* Excludes 10 women with missing data; ^ Excludes 2 women with missing data; ** Excludes 1 woman with missing data

Table 3: Visit-level association between ring disclosure and adherence (n=8654)

Partner knows about ring use	# of visits	N (%) with low adherence	Adjusted for age, site and time in study		
			RR	95% CI	P
Yes	6694	999 (14.9%)	ref		
No/not sure	1990	311(15.6%)	1.08	0.91–1.30	0.4

Conclusions

- The majority of women reported using the vaginal ring with their partner's knowledge, but substantial proportions reported non-disclosure at some or all visits.
- Disclosure at baseline predicted disclosure through out the study: women who did not disclose study participation or ring use at enrolment were less likely to disclose ring use throughout follow up.
- Changes in disclosure could occur due to partner change, delayed disclosure or reporting error.
- Delayed disclosure or staggered disclosure, where women disclose study participation and then study product use, has been reported in other studies.
- In contrast to findings of other studies women in this study considered study participation and ring use to be two distinct topics. Disclosure of participation was not necessarily accompanied by disclosure of ring use.
- Disclosure did not impact on study product adherence. In contrast to PrEP or vaginal gel use, a vaginal ring may allow for covert use and thus partner disclosure may not significantly impact on adherence to study product.