

Characteristics of non-disclosers of diaphragm use among Southern African women enrolled in an HIV prevention trial

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Background

- Adult HIV prevalence is 25% in Zimbabwe and 11-20% in South Africa (UNAIDS, 2003; HSRC, 2004)
- The diaphragm (DA) is a female-controlled contraceptive which covers the cervix
- DA is worn internally, and thus could be used without partner's knowledge
- DA used with Replens[®] lubricant gel is being evaluated as an HIV/STI prevention method in the MIRA trial in Zimbabwe and South Africa

Study Objectives

Among women enrolled in the MIRA trial:

- Examine characteristics of women who did not disclose DA and gel use to their main partner
- Assess attitudes towards discreet use of the DA and gel

Definitions:

Non-disclosure = woman did not tell her partner about use

Discreet use = self-reported use without partner's knowledge (woman did not tell him or he didn't feel it)

MIRA Trial Summary

- Ongoing randomized controlled trial to examine the effectiveness of the latex diaphragm and a lubricant gel for HIV/STI prevention
- Powered to detect effectiveness (biological efficacy combined with adherence) of 33%
- 5000 HIV negative, sexually-active, non-pregnant women will be randomized to receive condoms or condoms plus an All-Flex[®] diaphragm with Replens[®] gel
- All women receive risk reduction counseling, free male condoms and diagnosis and treatment of curable STIs
- Women are followed quarterly for 1-2 years
- Trial duration: September 2003 – September 2006

MIRA Trial Sites



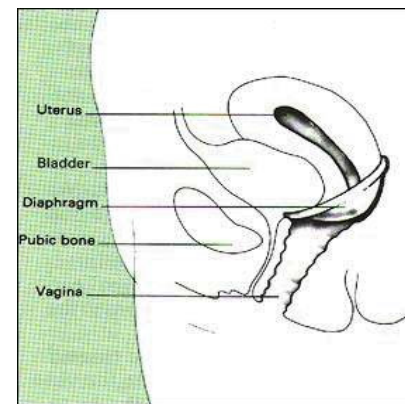
- UZ-UCSF, Harare, Zimbabwe (Epworth & Chitungwiza, periurban communities) target n=2500
- PHRU, Soweto, South Africa (urban area outside of Johannesburg) n=1100
- MRC, Durban, South Africa (Umkomaas & Bothas Hill, semi-rural communities) n=1400

Total enrolled (May 27, 2005): 4220

Study Products



Ortho All Flex Diaphragm and Replens[®] Lubricant Gel



Methods

Visit schedule

- Screening Visit:** interviews and laboratory testing
- Enrolment Visit:**
 - Eligible HIV seronegative women were examined, fitted for a diaphragm, and received an educational session on diaphragm and condom use
 - Women randomized to the intervention arm were given a diaphragm and gel (and condoms) and asked to use them every time they have sex
- 3-month follow-up:** interviews and laboratory testing

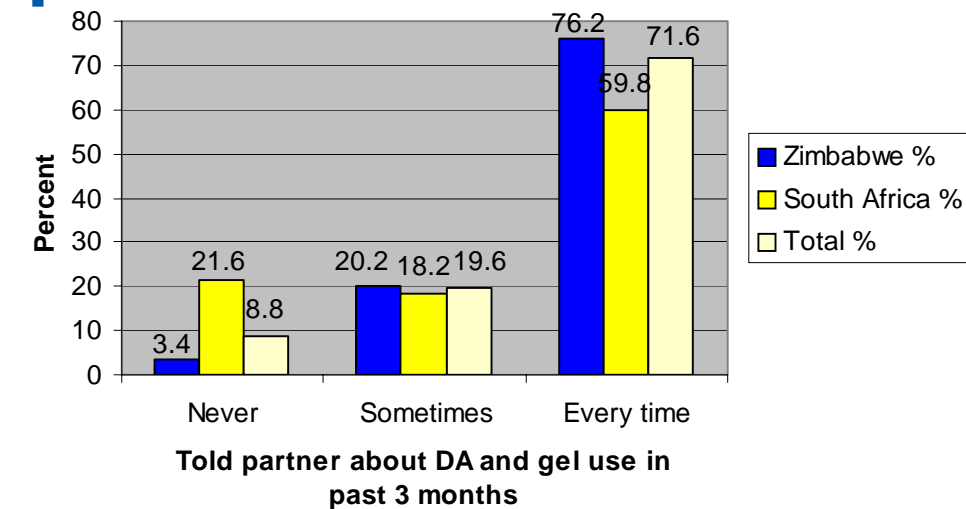
This preliminary analysis includes the first 716 women enrolled in the MIRA trial from August 2003 - October 2004 who reported DA use at their 3-month visit

- Analyses were conducted overall and by country (Zimbabwe and South Africa)
- The PHRU site in Soweto had just started enrolment at the time of this analysis and was combined with the Durban site

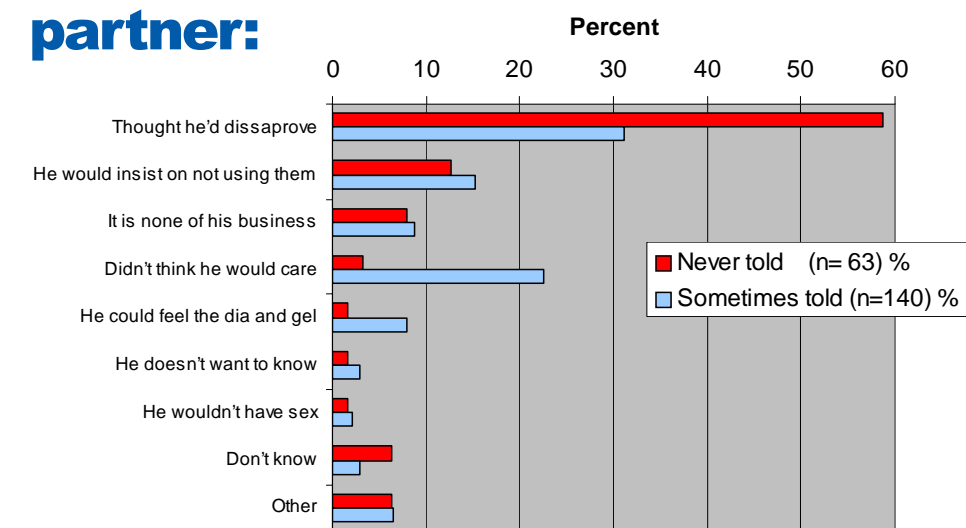
Sample characteristics

	Zimbabwe (n=502)	South Africa (n=214)	Total (N=716)	
	%	%	%	
Baseline variables				
Age mean (range)	28.7 (18-70)	27.4 (18-49)	28.3 (18-70)	*
Frequency of sex/month mean (range)	16.7 (4-112)	10.5 (4-48)	14.9 4-112	***
Education mean (range)	9.3 (0-16)	10.5 (0-14)	9.6 (0-16)	*
Married or has a regular partner	100	100	100	
Employed in past year	80.2	33.8	67	***
One or more children	97.8	87.5	94.8	***
On hormonal contraception	70.4	52.6	65.1	***
Ever used male condoms	92.8	82.6	89.7	***
Ever used diaphragms	<1	0	<1	
Symptoms of RTI (#)	9.8	39.4	18.6	***
More than 1 lifetime partner	22.9	72.9	37.8	***
Sex while partner intoxicated	39.8	25.5	35.5	***
Main partner has other partners				
Yes (knows or suspects he is)	19.7	39.2	25.6	
No	31.9	26.2	30.2	
Don't know	48.4	34.6	44.3	
Follow-up variable				
Reported new partner at follow up (#) identified by clinician	10.2	24.5	14.4	***
Chisquare test p value: * <0.05; ** <0.01, *** <0.001				

Disclosure of DA and gel use to partner



Main reason for not disclosing to partner:



Characteristics associated w/ non-disclosure of DA and gel use at 3-month follow-up (logistic regression)

	Never told partner (N=63) 8.8%	Adjusted OR (95%CI)
Age		1.06 (1.02-1.1)
Country		***
Zimbabwe	3.4%	ref
South Africa	21.6%	9.56 (4.90-18.53)
Main partner has other partners		
Yes	12.5	2.8 (1.1-7.1)
No	4.6	ref
Don't know	9.5	3.6 (1.49-8.67)
New partner at follow-up		
Yes	17.6	1.67 (0.86-3.27)
No	7.2	ref
Chisquare p val * < 0.05; ** < 0.01, *** < 0.001		

Attitudes towards discreet use by country and overall at 3-month follow-up

	Zimbabwe (n=502) %	South Africa (n=214) %	Total (N=716) %
How often did your regular partner know that you were using DA and gel? ***			
everytime	81.8	58.4	74.8
sometimes	13.6	19.6	15.4
never	3.4	8.41	4.9
don't know	1.2	13.5	4.9
How important is it to you that you could use DA and gel without your partner knowing? ***			
not at all important	32.5	45.8	36.5
somewhat important	16.4	5.6	13.5
very important	51.1	48.6	50.3
Do you think that women who are not in a study could use the DA and gel without their partner knowing? ***			
yes	60.7	53.7	58.6
no	33.1	30.4	32.3
don't know	6.2	15.9	9.1
Chisquare p val *** < 0.001			

Conclusion

Our preliminary analyses suggest that:

- Discreet use of DA and gel is possible and perceived as important by a majority of participants at 3 month of follow-up
- However, only a small minority had never told their partner about DA and gel use
- Non-disclosure was associated with older age, and with having a partner not perceived as monogamous
- Large differences between countries suggest the need to conduct stratified analyses when the full sample is available
- If found effective, DA and gel could help women protect themselves without their partner knowing about product use

