

# EFFECT OF ACASI ON REPORTING SEXUAL BEHAVIOR, CONDOM USE AND ADHERENCE TO GEL USE IN A MICROBICIDE CLINICAL TRIAL (HPTN 035)

P. Gorbach<sup>1</sup>, B. Mensch<sup>1</sup>, A. Coly<sup>1</sup>, A. Young<sup>1</sup>, B. Masse, B<sup>1</sup>. Makanani, C<sup>1</sup>. Nkhoma, L<sup>1</sup>. Chinula, T. Tembo<sup>1</sup>, S. Mierzwa<sup>1</sup>, K. Reynolds, S<sup>1</sup>. Hurst, A<sup>1</sup>. Coletti, <sup>1</sup> A. Forsyth<sup>2</sup>. <sup>1</sup>The Microbicide Trials Network and <sup>2</sup>NIMH.

## Objective:

Assess differences in sexual behaviors, condom use, and gel use reported via audio computer assisted self interviewing (ACASI) compared to face-to-face interview (FTFI) in a microbicide clinical trial.

## Background:

- Measured effectiveness of a microbicide is a function of efficacy and product adherence
- Adherence is difficult to measure in microbicide trials because participants may be embarrassed or otherwise unwilling to report certain sexual behaviors (e.g. anal intercourse, multiple partners)
- Sub-study of HPTN 035: "Safety and Effectiveness of the Vaginal Microbicides BufferGel and 0.5% PRO 2000 Gel for the Prevention of HIV Infection in Women"

## Methods:

- 663 women enrolled in a microbicide safety and effectiveness trial (HPTN 035) who were randomly assigned to use vaginal gels (gel arm) or no gel (no gel arm) consented to complete an ACASI survey on sexual behavior, and use of condom and study gel.
- 10 questions from standardized case report forms (CRFs) used in the clinical trial were asked via ACASI after CRFs – mostly on the same day.
- Pictorial format facilitated use by illiterate women

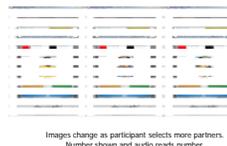


- Conducted in Lilongwe and Blantyre, Malawi
- 585 paired ACASI and FTFI surveys completed on same day were compared using bivariate analyses; multivariate models assessed characteristics associated with differences by mode of interview.



Number of times had sex past week

As participant selects more partners, number shown and audio reads number.



Images change as participant selects more partners. Number shown and audio reads number.

- ACASI with images and audio
- Pre-programmed with consistency checks
- Could repeat questions & change previous answer; could pause survey

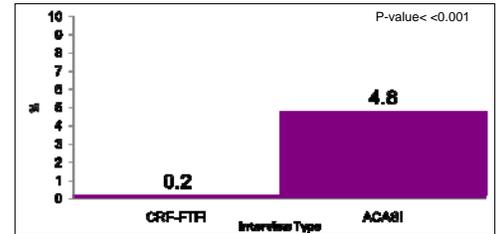
**Results:** Mean age was 26 years; 67.1% had not completed primary school and 14% had no education. There were significant differences in demographic characteristics and reported sexual behavior between sites.

Bivariate analyses of adherence reporting across interview modes indicated that those in Blantyre and those with secondary education were more likely to give same response in both modes; those who own home less likely.

**Table 1: Behaviors by Interview Mode**

	CRF – FTFI	ACASI	p-value
Gel Use Last Sex Act*	77.4%	73.5%	0.06
Condom Use Last Sex Act	65.7%	60.3%	0.04
% Women Reporting 0 partners last 3 months*	4.8%	12.3%	<0.05
% of Women Reporting >1 partner last 3 months*	0	1%	<0.05

**Figure 1: Anal Intercourse in Last 3 months: ACASI vs FTFI/CRF**



**Table 2: Interview Preference**

	FTFI	ACASI
Interview Preference	99 (15%)	567 (85%)



To be eligible for the study, women were required to be sexually active. Thus, reporting no partner could have been sensitive as was having >1.

**Table 3: Multivariate Models: Same Response Reported ACASI & FTFI -Women interviewed on same day**

	Gel and Condom Use Gel arm (N=411)		Gel Use Gel arm (n=411)		Condom Use Both arms (n=586)	
	AOR	95% CI	AOR	95% CI	AOR	95% CI
Blantyre	1.50	0.95, 2.36	2.41	1.29, 4.49	1.19	0.78, 1.82
Education						
Some primary	1.21	0.67, 2.16	1.04	0.51, 2.15	1.27	0.75, 2.15
Some 2ndary school	2.28	1.06, 4.87	1.26	0.49, 3.25	2.46	1.21, 5.01
Owens home	0.71	0.44, 1.15	1.27	0.70, 2.31	0.58	0.37, 0.92
Electricity in home	1.10	0.50, 2.39	1.34	0.47, 3.79	1.13	0.55, 2.33

## Conclusions:

Reported adherence to coitally dependent products was lower and more women reported anal intercourse via ACASI than FTFI, especially women of lower socio-economic status. The study suggests ACASI may provide more accurate reports of product adherence and sexual behavior in HIV prevention trials.



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