

Assessing the Reporting of Adherence and Sexual Activity in a Simulated Microbicide Trial

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Background: Adherence in Carraguard Phase 3 Trial

- Adherence measured by self reports & staining assay indicating whether applicators inserted in vagina
 1. Self-reported gel use based on last sex 96%
 2. Sex acts covered by gel use 42%
 - Numerator: inserted applicators
 - Denominator: sex acts in prior 2 weeks, aggregated across all visits
- Discrepancy between two estimates of gel use highlights challenge of obtaining accurate measures of adherence

Research Question:

- Does audio computer-assisted self-interviewing (ACASI) produce more accurate reporting of adherence in a placebo trial than conventional face-to-face interviewing (FTFI)?

Why use ACASI in microbicide trials?

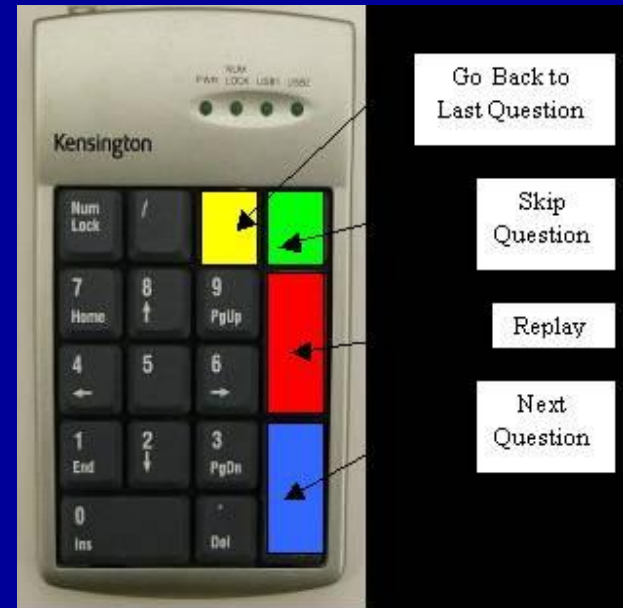
- Methodological research indicates interviewing methods affect answers to sensitive questions
- Increased **privacy** and **confidentiality** may yield more honest reporting of:
 - adherence
 - sexual behavior

Study Design

Study Sites	Carraguard Phase 3 sites - Medunsa, MRC, UCT
Product	Methylcellulose (placebo gel Carraguard trial); instructed to use prior to sex for 3 months
Hardware	Laptop computers, headphones, keypads
Study Design	Randomization ACASI vs. FTFI; Visits at screening, enrollment, months 1, 2, 3
Sample	848 HIV negative women, aged 18–40
Special Features	Biomarkers to validate self-reports: RSID at enrollment, months 1, 2, 3; Applicator test (>40,000 applicators distributed, 90% returned)

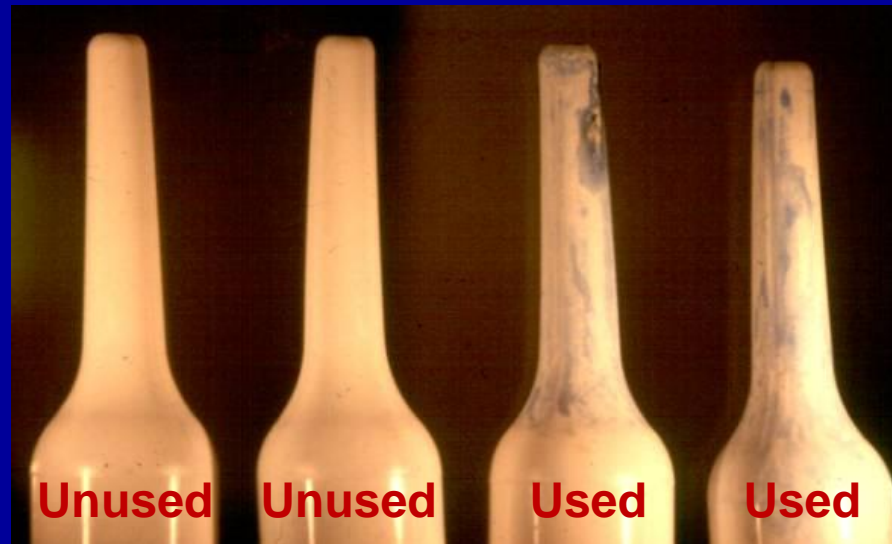
Population Council ACASI Software V.1

- Custom Microsoft Visual Basic and Access application
- Question/response displayed on laptop screen & recorded in audio files translated into 3 languages (Xhosa, Zulu, Setswana)
- External numeric keypad for response entry
- No consistency checks (range checks for continuous responses)
- Laptops secured, only permitted to run ACASI software, data encrypted



Biomarkers

- *Rapid stain identification of human semen (RSID)*
 - detects semenogelin
 - indicates unprotected sex within prior 48 hours
- *Applicator test*
 - indicates gel insertion into vagina
 - does not indicate whether sex occurred after insertion or frequency of sex without gel



Selected Behaviors: Month 1 and Month 3

	Month 1			Month 3		
	ACASI	FTFI		ACASI	FTFI	
>1 partner, last month	9	1	***	7	2	**
Told partner(s) about gel	76	87	***	75	87	***
Anal sex, last month	5	2	**	5	2	**
Ever had sex without gel, last month	60	41	***	47	31	***
Gel use, last sex	79	82		80	83	
Condom use, last sex	55	56		57	62	
Squeezed gel into vagina without sex, last month	21	13	**	13	9	

Biomarker results: Month 1 and Month 3

	<u>Month 1</u>		<u>Month 3</u>		
	ACASI	FTFI	ACASI	FTFI	
Mean difference, reported and tested applicators, last month	3.2	2.3	4.1	3.8	
Tested RSID positive...					
...reported no sex in past 2 days	12	17 †	14	18	
... reported unprotected sex in past 2 days	11	7 †	12	5 **	

† P<.10

Selected GEE Results: Effect of ACASI

Reported Behavior	Adjusted Odds Ratio
>1 sex partner, last month	7.0***
Told partner(s) about gel	0.4***
Anal sex, last month	4.0***
Ever had sex without gel, last month	2.0***
Gel use, last sex act	1.0
Condom use, last sex act	1.0
Squeezed gel into vagina without having sex, last month	1.5**
Washed vagina after sex, last vaginal sex	5.8***

Controlling for age, site, ethnic group, marital status, education, male interviewer

GEE Results for Biomarkers: Effect of Interview Mode

Behavior	Adjusted coefficient
Mean difference in reported and tested applicators, last month	.05
	Adjusted Odds Ratio
Tested positive for RSID... ...reported no sex in past 2 days	0.8 †
...reported unprotected sex in past 2 days	1.6 **

Controlling for age, site, ethnic group, marital status, education, male interviewer.

† $p < .10$

Summary and Conclusion

- Significantly higher reporting of sexual behavior and vaginal hygiene practices with ACASI
- Reported applicators inserted > tested applicators for both ACASI and FTFI
- Validation of reports on unprotected sex with RSID indicates ACASI slightly more accurate
- Effect of ACASI on reporting diminishes over time
- Electronic data capture introduces additional complexities

Donors

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