

HPTN 035 & ACASI: Do We Always Tell the Truth?

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High Reporting of Adherence in Microbicide Trials of Coitally Dependent Gels in Africa

Self-reported gel use at last sex

- HPTN 035
(0.5% PRO 2000 and Buffer gel) = 81%
- MDP 301 (0.5% PRO 2000) = 80–85%
- Population Council (Carraguard) = 96%

Is there over-reporting of gel use in face to face interviews?

Reporting of Condom use at Last Sex: HPTN 035 vs. National Surveys

HPTN 035: **72%**

Demographic and Health Surveys:

- Malawi DHS 2004 **5%**
- Zambia DHS 2007 **13%**
- Zimbabwe DHS 2005-6 **8%**

National HIV Prevalence, Incidence, Behaviour & Communication Survey

- South Africa 2005 **36%**
- South Africa 2008 **63%**

HPTN 035B Objectives

1. Assess feasibility of ACASI with graphics in microbicide trials
2. Develop a method for self-administered adherence questionnaires for nonliterate women
3. Determine if reports of gel and condom use are lower, and sexual partners and anal sex higher, in ACASI than in FTFI
4. Determine whether women prefer to be interviewed by a person or a computer

035b Study Design

Trial Sites	Lilongwe, Blantyre
Hardware	Handheld computers
Study Design	ACASI interview at quarterly visit after behavioral CRF administered FTF; Single visit; 9 of 10 ACASI questions identical to those in FTFI
Sample	663 HIV negative women, 18+; 586 completed ACASI & CRF on same day
Special Features	Pictorial format; Consistency checks programmed

ACASI Questions

- 1 In the past 3 months, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal sex?
- 2 In the past week, how many times did you have vaginal sex?
- 3 In the past week, how many times did you use a male or female condom and not the study gel during vaginal sex?
- 4 In the past week, how many times did you use study gel and not a male or female condom during vaginal sex?
- 5 In the past week, how many times did you use study gel with a male or female condom during vaginal sex?
- 6 In the past week, how many times did you use neither study gel nor a male or female condom during vaginal sex?

The last time you had vaginal sex:

- 7 did you or your partner use a male condom?
- 8 did you use study gel?
- 9 In the past 3 months, did you have anal sex?
- 10 Do you prefer answering questions to the computer or to a person?

035B ACASI Features

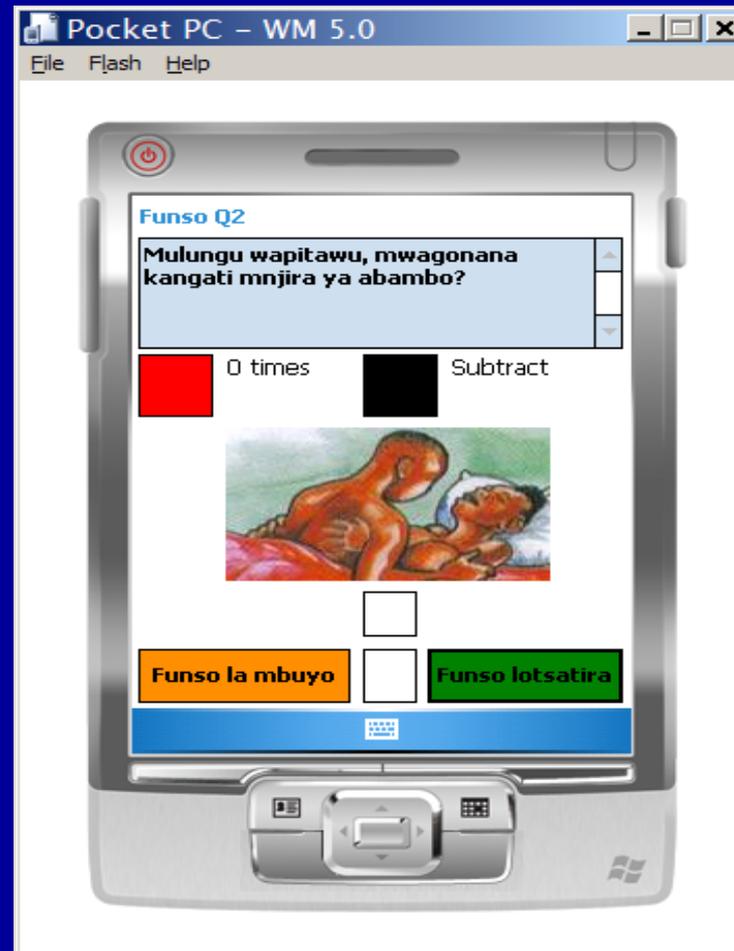
- ACASI with images and audio
- Three sections
 - Administrative questions
 - Practice questions
 - Survey questions
- Type of survey questions
 - Colored-boxes
 - Pictures
- Consistency checks
 - Question repeated if sex acts reported ...
 - With condom, no gel
 - With gel, no condom
 - With condom and gel
 - With neither condom nor gel
 - ... are > than total sex acts

Number of Sex Partners



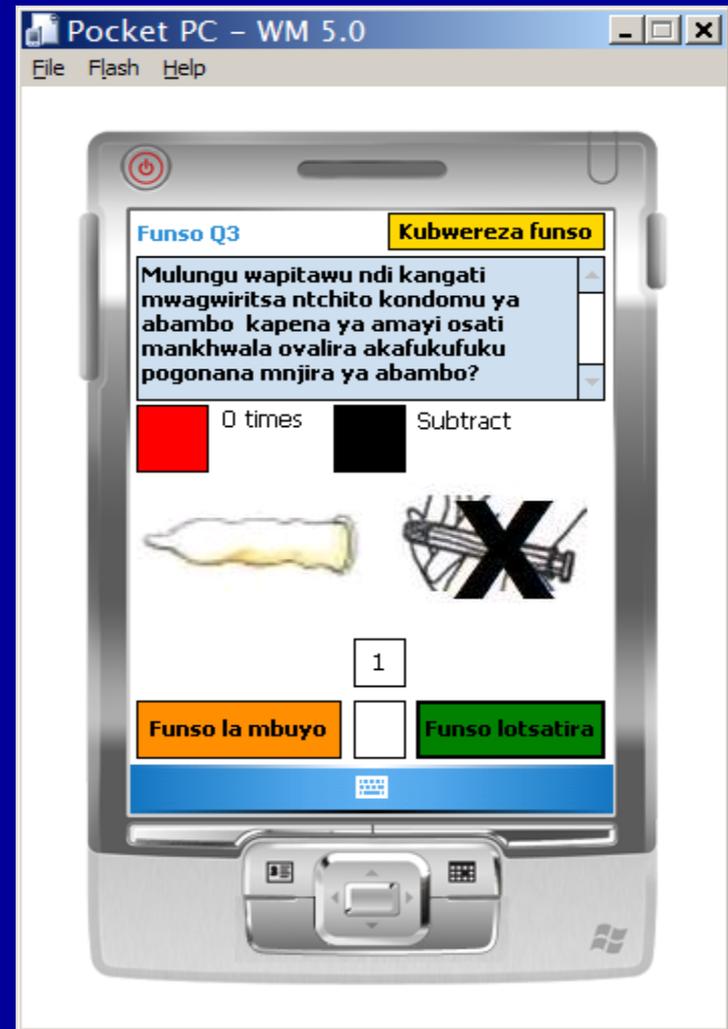
Images change as participant selects more partners.
Number shown on screen & audio "reads" number.

Number of times had sex past week

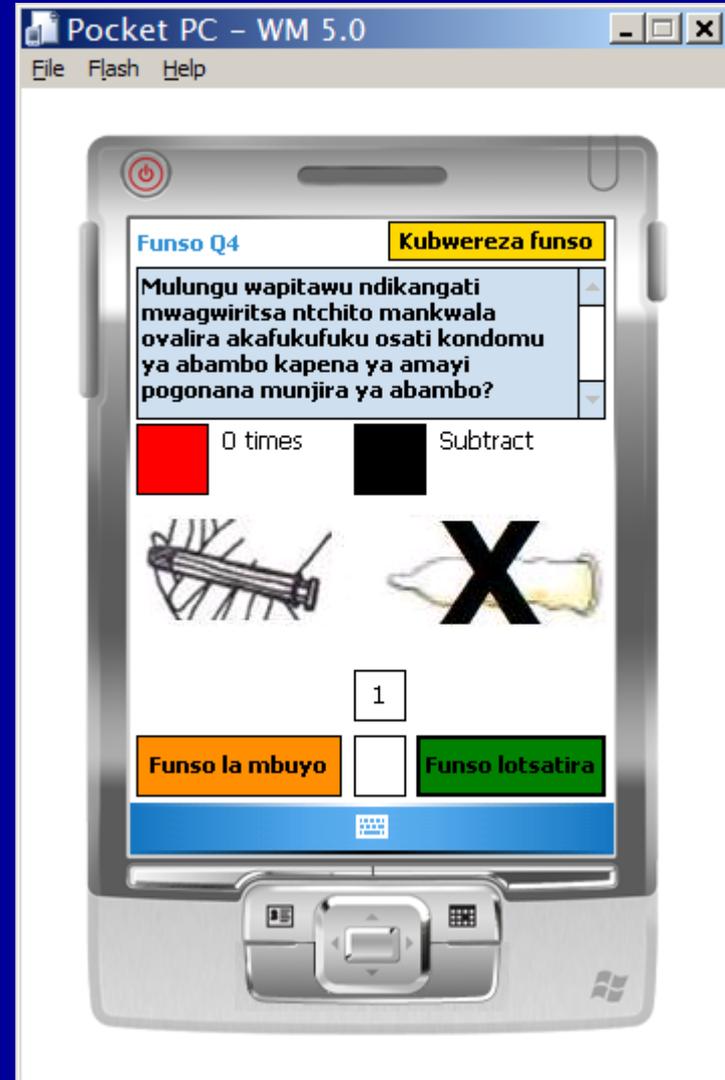
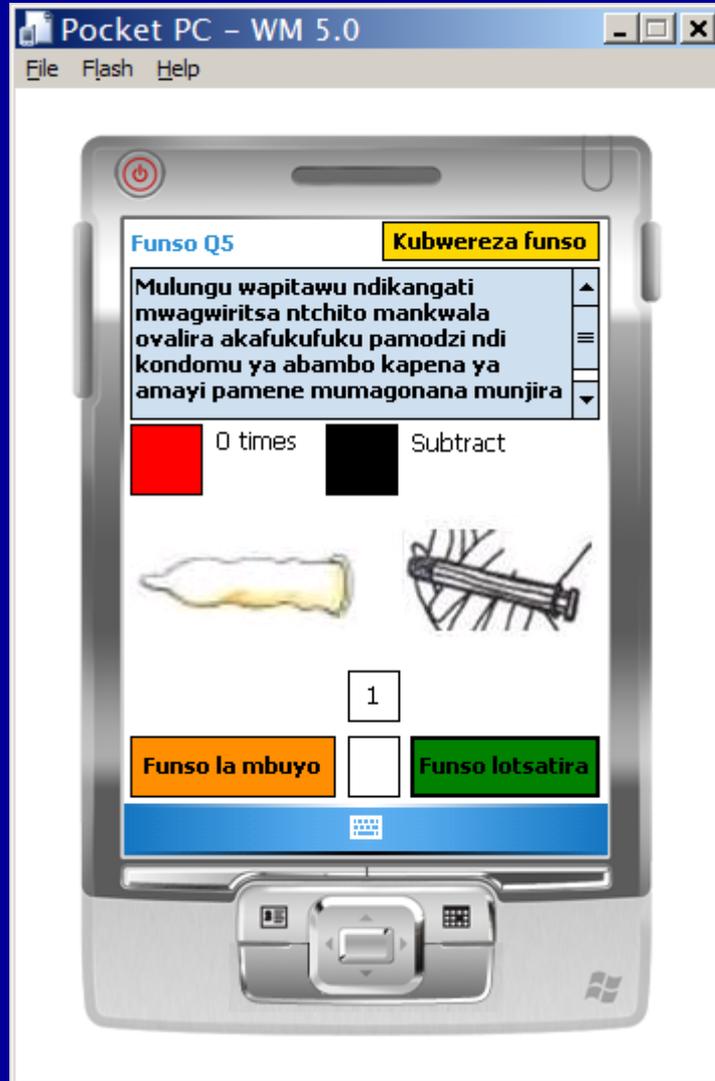


As participant indicates more sex acts, the number is shown on screen & audio “reads” number.

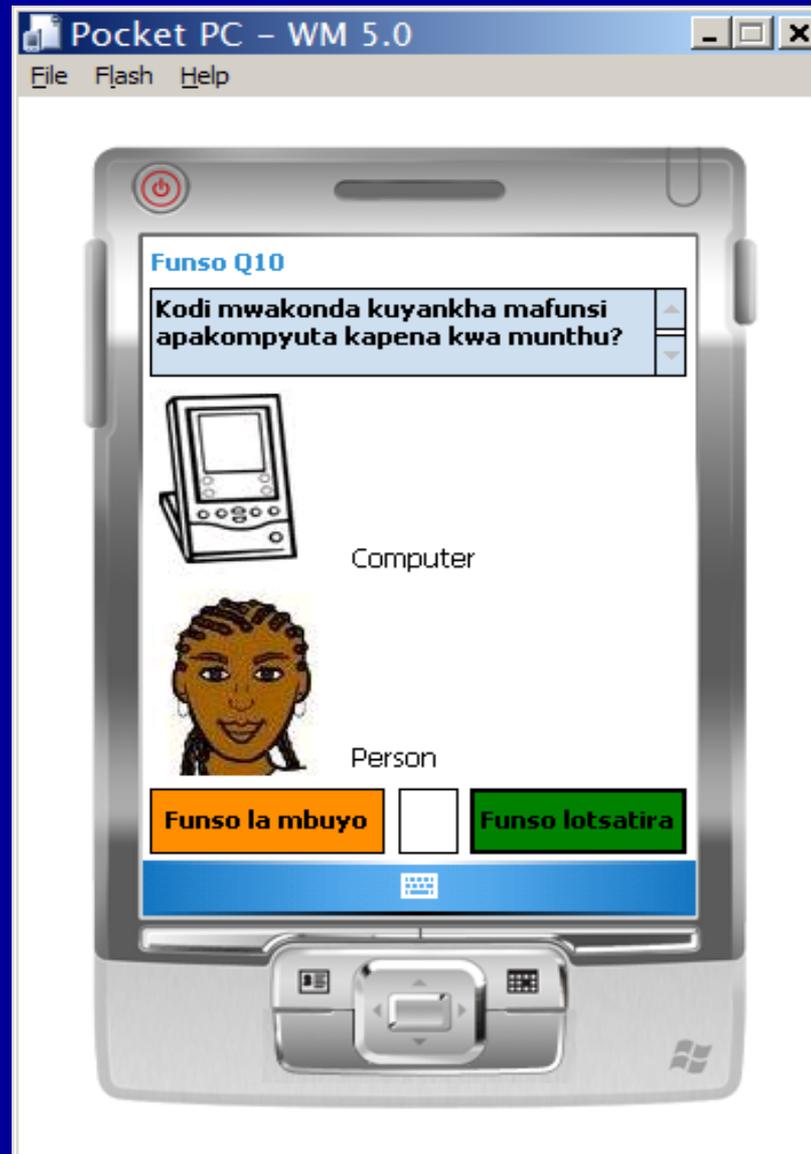
Condom Use



Gel Use: With and Without Condoms



Preference for Interview Mode



Data Management

- ACASI data were uploaded to laptop computers from handheld devices daily
- Data sent electronically to SCHARP Atlas Portal



Comparison of Gel and Condom Use

	CRF – FTFI	ACASI
Gel Use Last Sex Act†	77.4%	73.5%
Condom Use Last Sex Act*	65.7%	60.3%

† p<.10

* p<.05

Microbicide Trial ACASI Experiments

	PC Study	HPTN 035b
Trial Sites and Product	Carraguard clinics South Africa – Post Phase 3 (Placebo gel only)	Lilongwe, Blantyre (Buffer Gel, 0.5% PRO 2000)
Hardware	Laptop computers	Handheld computers
Study Design	Randomization ACASI vs. FTFI; Visits at screening, enrollment, months 1, 2, 3	ACASI interview at quarterly visit after behavioral CRF administered FTF; Single visit; 9 questions about gel use and sexual behavior from CRF
Sample	848 HIV negative women, 18–40	663 HIV negative women, 18+
Special Features	Biomarkers to validate self-reports: RSID at enrollment, months 1, 2, 3; Applicator test (>40,000 applicators distributed, 90% returned)	Pictorial format; Consistency checks programmed

Biomarkers Used in PC Study

- **Rapid stain identification of human semen (RSID)**
 - Detects semenogelin
 - Marker of unprotected sex 48 hours prior
 - Does not cross-react with blood, urine, saliva or vaginal products
- **Applicator test**
 - indicates gel insertion into vagina
 - does not indicate whether sex occurred after insertion or frequency of sex without gel



ACASI: Experiment Results

	PC Study (Enrollment/Month1)			HPTN 035b		
	FTFI (%)	ACASI (%)	Sig.	FTFI (%)	ACASI (%)	Sig.
Gel use, last sex act	81.7	79.3		77.4	73.5	†
Condom use, last sex act	42.2	38.5		65.7	60.3	*
Zero partners, last 3 months	—	—		4.8	12.3	*
> 1 partner	1.7 <i>(last month)</i>	14.0	***	0.0 <i>(last 3 months)</i>	1.0	*
Anal sex	1.9 <i>(last month)</i>	7.8	***	0.2 <i>(last 3 months)</i>	4.8	***
Interview preference	—	—		14.9	85.1	***
Inconsistencies:						
At least one answer					28.7	
Reported more acts of gel use than sex acts	3.3	19.2				

*** p<.001; ** p<.01; * p<.05; † p<.10

Additional Results (Enrollment, Month 1) – PC Study

	FTFI (%)	ACASI (%)	Sig.
Ever had sex without gel, last month (M1)	36.0	54.5	***
Squeezed gel into vagina without having sex, last month (M1)	12.8	20.6	**
Washed vagina after sex, last vaginal sex (E)	25.8	61.1	***
Mean difference in reported and tested applicators, last month (M1)	2.29	3.16	†
RSID tested positive, reported no sex in past 2 days (E)	17.1	11.5	*
RSID tested positive, reported unprotected sex in past 2 days (E)	6.7	12.9	**

***p<.001; **p<.01; *p<.05; † p<.10 ;

Summary

- 035b** Lower gel and condom use in ACASI compared to FTFI
- PC** No difference in gel and condom use at last sex; Higher reporting of sex without gel in ACASI compared to FTFI
- 035b and PC** Higher reporting of anal sex and multiple partners in ACASI compared to FTFI
- PC** Biomarker of unprotected sex indicates ACASI reports slightly more credible in month 1
- 035b and PC** Greater inconsistency in ACASI than in FTFI

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