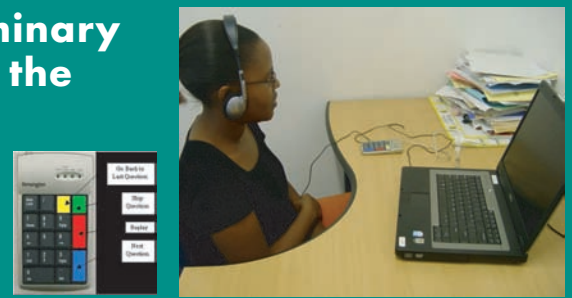


Assessing the Reporting of Adherence and Sexual Activity in a Simulated Microbicide Trial: Preliminary Results from an Interview Mode Experiment in the Phase 3 Carraguard® Sites, South Africa

Barbara Mensch¹, Paul Hewett¹, Johanna Rankin¹, Sarah Littlefield¹, Sharon Abbott¹, Khatija Ahmed², Nazira Cassim², Smruti Patel³, Vuyelwa Mehlomakulu³, Gita Ramjee⁴, Thesla Palanee⁴, Stephanie Skoler⁵, Marlena Gehret¹, Sumen Govender⁶

¹Population Council, New York; ²University of Limpopo/Medunsa Campus, Setshaba Research Centre, Soshanguve; ³University of Cape Town, Empilweni Centre for Wellness Studies, Gugulethu; ⁴Medical Research Council, Isipingo Clinic, Isipingo; ⁵Memorial Sloan Kettering Cancer Center, New York; ⁶CRS Consulting, Durban



BACKGROUND

Misreporting of product use and sexual behavior can undermine the ability to detect an association between HIV status and microbicide use in clinical trials. Given the explicit expectations that participants comply with project protocols, accurate data on sensitive topics—such as frequency of unprotected vaginal, anal and oral sex in conjunction with the use or non-use of the candidate microbicide during sex acts—may be difficult to obtain. Furthermore, since trial participants are counseled to use gel as part of study procedures, they may be unwilling to admit that they have not been compliant due to courtesy bias, fear of being excluded from the trial and/or embarrassment. Improving self-reports reduces the possibility that a candidate microbicide would be deemed ineffective when in fact low adherence is the underlying issue.

Those who advocate computerized administration of questionnaires assume that the more private and standardized the interview the better the quality of the data. The advantage of audio computer-assisted self-interviews (ACASI) over face-to-face interviews (FTFI) is that neither the investigator nor anyone else in the area where the interview is being conducted hears the question or response, presumably reducing social desirability bias. Moreover, unlike self-administered questionnaires, which require literacy, ACASI can be conducted without the respondent reading the questions on the computer screen. In addition, the researcher does not have to be concerned with differences in the characteristics or interviewing styles of the interviewers.

METHODS

- An ongoing study in the three South African clinics that participated in the Population Council's phase 3 Carraguard® trial is investigating whether ACASI produces more "accurate" reporting of adherence and sexual behavior than FTFI.
- External validation of reporting is assessed through two biomarkers: the Population Council's applicator test, which indicates whether the applicator has been inserted in the vagina, and Rapid Stain Identification of Human Semen (RSID), which detects the presence of semen in the vagina and is a biomarker of sex without a condom in the prior 48 hours.

STUDY DESIGN

- At enrollment 848 women were randomly assigned to FTFI or ACASI and instructed to use applicators filled with a placebo gel together with condoms in each sex act.
- At three monthly follow-up visits women return used applicators, receive condoms, have a physical exam, and complete a behavioral interview using one of the two interviewing techniques. At month one, 371 FTFI and 384 ACASI were completed.
- Acceptability of ACASI and FTFI methods is being assessed with a subgroup of 45 ACASI and 30 FTFI participants in in-depth interviews after completion of the quantitative behavioral interview.

APPLICATOR TEST:

Does indicate: Instances of applicator insertion

Does NOT indicate:

- Whether gel was inserted prior to sex.
- Frequency of sex without gel.
- Whether applicator used by study participant or someone else.



RSID TEST:

- Detects human semenogelin (protein produced by seminal vesicles) sampled from the vagina.
- Is species-specific.
- Will not cross-react with blood, urine, saliva, or vaginal products.
- Sensitivity – 2 nl up to 48 hours.
- Can be done in the clinical setting.
- Results are available in 10 minutes.



PRELIMINARY ANALYSIS (MONTH 1):

- Differences in reporting of sensitive behaviors were compared by interview mode using descriptive statistics.
- RSID test results were compared by interview mode for women who reported no sex in the past 48 hours.
- Self-reported gel use was compared by interview mode to tested applicators.

PRELIMINARY RESULTS (N=755):

I. Self-Reported Behavior (see Table 1)

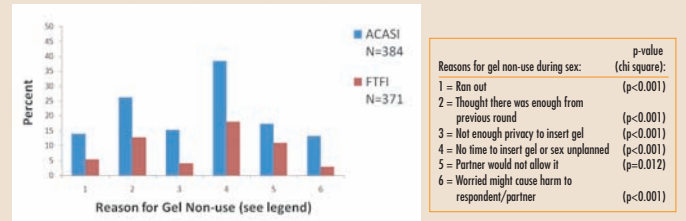
- Compared to FTFI, ACASI produces significantly higher reporting of sensitive behaviors, including multiple partners and anal sex.
- ACASI participants reported significantly higher frequency of washing or cleaning the vagina after sex.
- No difference is found between ACASI and FTFI in reporting of condoms or gel use.
- FTFI participants reported significantly more vaginal sex acts in the past month.

TABLE 1: Self-reported behavioral results – Month 1

	ACASI N=384	FTFI N=371	p
>1 partner last month (%)	8.9	1.4	<0.001
Anal sex last month (%)	5.2	1.6	0.007
Used condom during last sex act (%)	56.7	55.9	0.81
Always use condoms (%)	36.4	36.1	0.94
Ever squeeze gel into vagina without having sex last month (%)	21.1	12.9	0.003
Use study gel last round of vaginal sex (%)	81.5	82.0	0.86
Washed/inserted something in vagina after last sex (%)	61.2	34.2	<0.001
Sex yesterday, today (%)	31.4	21.5	0.002
Mean # vaginal sex acts in past month	7.8	9.3	0.03
Mean partners in last 6 months	1.42	1.08	<0.001

- ACASI participants significantly more likely to report non-use of gel (Figure 1).

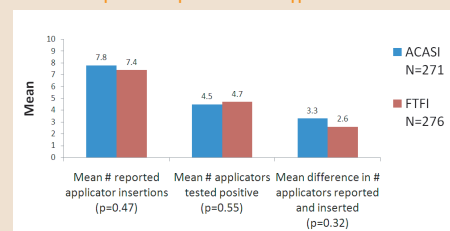
FIGURE 1: Percentage reporting nonuse of gel during sex for specified reasons



II. Applicator Insertion Test

- Applicator test results indicate overreporting of sex acts where gel was used is greater in ACASI than in FTFI, although difference is not significant ($p=0.32$; see Figure 2). ACASI women were not asked about inconsistencies between questions about gel-covered sex acts and number of total sex acts, whereas in FTFI, interviewers may have reconciled inconsistent answers. There is no difference by interview mode in the number of inserted applicators ($p=0.55$; see Figure 2).

FIGURE 2: Comparison of reported and tested applicator use – Month 1¹

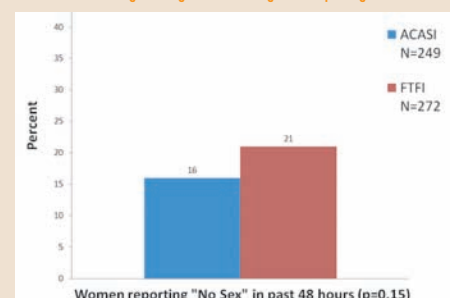


¹ Women excluded for whom no applicator test data available or for whom applicator tests were flawed.

III. RSID Test Results

- RSID results are comparable for FTFI and ACASI participants (28% and 26% testing positive respectively, $p=0.63$; data not shown). However, among women reporting no sex in the past 48 hours, 21% of FTFI compared to 16% of ACASI participants had a positive RSID ($p=0.15$; $N=521$). Although this difference is not quite significant, it suggests that FTFI respondents are less likely to report honestly about sex in the past 48 hours.

FIGURE 3: Percentage testing RSID + among those reporting "no sex" in the past 48 hours



STUDY LIMITATIONS

- Lack of consistency checks in ACASI is a likely explanation for higher levels of overreporting gel-covered sex acts compared with FTFI; although interviewers were not explicitly instructed to reconcile inconsistent answers, they may have done so in FTFI.
- Because of a desire to match applicators tested to self-reported gel use, women were asked to recall behavior during previous month. Had a more restricted time frame been used, e.g. the past week, recall bias would likely have been minimized.
- RSID analyses were restricted to women who reported no sex in the past 48 hours. Such subgroup analyses cannot guarantee randomization of measured and unmeasured confounders. Analyses could not be conducted on women who reported sex because questions about condom use were asked only for the last sex act and not for all sex acts in prior 48 hours.

CONCLUSIONS

- Compared to FTFI respondents, ACASI respondents were significantly more likely to report multiple partners, anal intercourse, and vaginal washing after sex.
- ACASI respondents were significantly more likely to report squeezing gel into vagina without having sex and nonuse of gel during sex for variety of reasons.
- Applicator test results suggest women overreport gel use, somewhat more so with ACASI, although differences by interview mode are not significant.
- RSID results suggest FTFI respondents may be less likely to report honestly about sex in prior 48 hours than ACASI respondents, although difference is not significant.
- These preliminary findings suggest ACASI may improve the validity of self-reported behavioral data in microbicide trials, although more research is needed.

RECOMMENDATIONS

- Future studies using ACASI would benefit from built-in consistency checks. Although such consistency checks would not guarantee greater validity, participants may be forced to think more carefully about their responses when asked to reconsider their answers.
- A monthly reporting period is likely too long for accurate behavioral reporting; future trials using the applicator test to validate reporting could distribute multiple plastic bags at study visits so that applicators could be labeled and grouped weekly.

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