

New Approaches to reporting of Gel Adherence in Microbicide Trials

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Rationale: 035 Adherence Reports High

- In 035 women report high rates of adherence to gel and condoms at follow-up
- Compared to rates of condom use from national surveys these numbers appear high
- Raises concerns about potential over-reporting of gel and condom use in face-to-face interviews (FTFI)

Why Measuring Adherence a Challenge

Adherence difficult to measure in microbicide trials because:

- **Products not absorbed**
- **Participants may be unwilling to report gel non-use to interviewers**
- **Participants may be embarrassed to report about sexual behavior to interviewers**

Why Have Alternative to FTFI?

- **Mode of data collection previously shown to affect reports of sensitive behaviors**
- **Goal is to maximize accuracy of compliance reports in clinical trials &**
- **To increase participants comfort and willingness to report sensitive behavior such as non-use of gel or not following protocol**
- **Audio computer assisted self interviewing (ACASI) may increase reporting of sensitive behaviors.**

Studies Comparing FTFI to ACASI in Africa

| | | FTFI vs. ACASI* (%) | OR (95%CI) |
|---------------------------|-------------------|------------------------|-----------------|
| Zimbabwe | hormonal method | 67.5 - 53.3 | 0.6 (0.5-0.6) |
| | withdrawal | 1.2 - 3.4 | 2.7 (1.5-4.7) |
| | rhythm method | 0.5 - 8.9 | 17.8 (7.4-42.9) |
| | multiple partners | 0.4 - 2.4 | 5.7 (2.1-15.2) |
| Kenya ⁵ | sex with stranger | 3.7 - 13.9 | 3.45* |
| | ever forced sex | 6.0 - 15.8 | 2.73* |
| Kenya ⁹ | multiple partners | 20.7 - 34.9 | 2.35* |
| | sex with stranger | 3.7 - 14.2 | 4.25* |
| | ever forced sex | 12.9 - 31.3 | 3.35* |

*p<.05

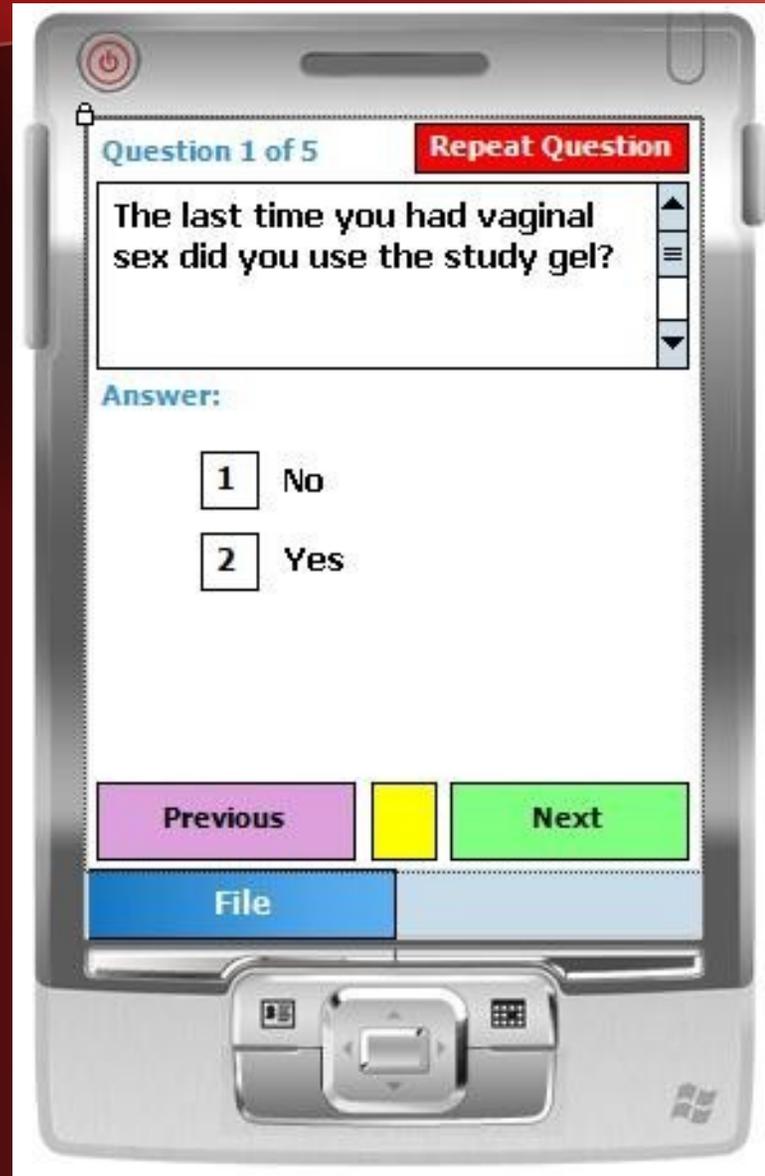
Research Objectives: 035b

- 1: Assess feasibility of using ACASI to collect data on gel adherence and condom use in MTN trials**
- 2: Determine whether ACASI yields higher reports of non-adherence to gel and condom use and a higher number of sexual partners**
- 3: Identify predictors of discrepancies in FTFI and ACASI reports**

Proposed Study Design (N=400)

- **Add a short ACASI measure of gel use and sexual behavior to 035 (10 questions) administered with headphones for privacy**
- **10 of the questions on gel use from 035 questionnaire will be included with a question on preference of interview mode**
- **Graphic response format allows all women to be able to participate**
- **Will be filled out AFTER the FBA questionnaire is completed by interview**

Handheld screen with 035 adherence question



Malawi – Pop Council School Study



Courtesy of Barbara Mensch, Population Council

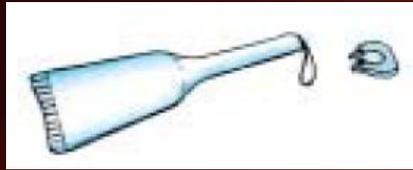
Why Handhelds

- Take up less space in busy clinics than desktops
- Run on batteries so do not need steady power source
- Less intimidating to participants who have never used a computer
- Allows data checking – between questions - built-in
- Audio & image options



Potential ACASI Graphics

The last time you had vaginal sex: did you use study gel?



'YES'



'NO'

In the past 3 months, how many sex partners have you had?



1



2



3

The number will increase each time the woman presses the image

Potential ACASI Graphics

In the past week, how many times did you use a male or female condom and not the study gel during vaginal sex?



In the past week, how many times did you use study gel and not a male or female condom during vaginal sex?



Do you prefer answering questions to the computer/ machine or to a person?



Self- Administered Questions: FBA

| | 035 FBA question# | Question |
|----|-------------------|--|
| 1 | 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 | 2 | In the past week, how many times did you have vaginal sex? |
| 3 | 2b | In the past week, how many times did you use a male or female condom and not the study gel during vaginal sex? |
| 4 | 2c | In the past week, how many times did you use study gel and not a male or female condom during vaginal sex? |
| 5 | 2d | In the past week, how many times did you use study gel with a male or female condom during vaginal sex? |
| 6 | 2e | 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 | 4a | did you or your partner use a male condom? |
| 8 | 4c | did you use study gel? |
| 9 | 5 | In the past 3 months, did you have anal sex? |
| 10 | N/A | Do you prefer answering questions to the computer or to a person? |

Data Management

- **ACASI data will be downloaded onto desktop computers from the hand-held devices on a daily basis**
- **A program to convert the data into a format that will fill in the boxes on a CRF form - similar to the forms currently used in 035 is in development**
- **The CRF forms will be printed and faxed to SCHARP for entry into the database**

Conclusions

- **ACASI shown in other studies to increase reporting of sensitive behaviors – not a new concept but new to clinical trials**
- **ACASI in developing country contexts is feasible – we will test its feasibility in a clinical trial context**
- **Alternatives to face-to-face interviews may enhance accuracy of reported adherence in MTN trials**

Final Points

- **Study has separate budget – sites will receive some funding for participating to cover extra costs required to conduct the study**
- **Sites interest in participating?? 400 women needed – at least 1 site**