

# Measuring Recall and Understanding of Informed Consent: Results from a randomized controlled trial of the diaphragm for HIV prevention

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## I. Background

Informed consent is integral to clinical trials research. There is debate on how to ensure that participants understand the proposed research and the implications of participation. Evidence indicates that often individuals do not understand major aspects of the research in which they consent to participate and/or concepts such as randomization, double-blinding and the difference between research and treatment.

Research has shown that asking potential participants to repeat information about procedures verbally can improve recall of concepts (Wadey & Frank 1997; White *et al.* 1995) and that having to write information may significantly increase understanding (Sorrell 1991). More information is needed regarding techniques for improving and measuring participants' retention and understanding of study-related concepts.

We present preliminary results from implementation of a quiz used to assess retention and understanding of concepts at enrollment and after 12 months of participation in the Methods for Reproductive Health in Africa (MIRA) trial, a randomized controlled trial of 5045 women conducted in Zimbabwe and South Africa from 2003 to 2006 which evaluated the diaphragm, Replens® gel, and condoms (intervention) versus condoms alone (control) for HIV/STI prevention (Padian *et al.*, 2007).



MIRA study sites: Harare, Durban, Johannesburg

## II. Methods

Before enrolling in the trial, all eligible women underwent an informed consent session where a staff member read the consent aloud and facilitated discussion of its contents. Women were given the opportunity to ask questions and to take the consent home and consider it before signing.

After introduction of the Informed Consent Quiz (ICQ) in November 2004, researchers administered it to enrolled participants at the enrollment visit (after the consent was signed) and at month 12 to assess short and long term retention of study-related information.

The ICQ comprised 18 True/False questions. All incorrect responses were corrected and explained to the participants. Incorrect responses to Key Questions triggered re-review of relevant sections of the consent. If more than six responses were incorrect, the entire consent was re-reviewed.

**A Total Score (TS) (# and % correct of total) and Key Score (KS) (# and % correct of 6 key questions) were calculated for each ICQ completed.** Frequencies/analysis were conducted using SPSS (v14.0).

## Informed Consent Quiz – True or False?

**Bold = Key question (Answer in brackets)**

- The main purpose of the study is to see if using a diaphragm and gel can protect women from getting HIV. (T)**
- Women in both study groups are asked to use a diaphragm and gel throughout the duration of the study. (F)
- You can use a male condom with the diaphragm. (T)
- You will come to the clinic every three months for the duration of the study to be tested for HIV and other sexually transmitted infections. (T)
- Women who are pregnant can join the MIRA trial. (F)
- Doctors know that using the diaphragm will prevent women from getting HIV and other sexually transmitted infections (STIs). (F)**
- Doctors know that using condoms will prevent women from getting HIV and other sexually transmitted infections (STIs). (T)
- During the study, you will get free health care at the study clinic for ANY health problems you may have (like a broken leg or pneumonia). (F)
- You can choose which study group you are in, EITHER diaphragm, gel and condoms OR condoms alone. (F)**
- The study staff will not tell your partner or your family members the results of your tests without your consent. (T)
- Once you have decided to join the study, you cannot quit. (F)**
- You will be reimbursed for your travel costs and time when you come for scheduled study visits. (T)
- It is possible that you could become infected with HIV while participating in this study. (T)**
- Women in both study groups are asked to use male condoms to prevent HIV and STIs. (T)
- The diaphragm and gel prevent pregnancy 100% of the time. (F)
- Having a pelvic examination may cause some discomfort and bleeding. (T)
- The study staff will show personal information of women in the study to anyone who asks to see it. (F)**
- You can choose whether or not to store your blood for future research. (T)

## III. Results

4452 women, or 88.4% of all MIRA participants, completed at least one ICQ. 1779 women completed the ICQ at enrollment; 3814 completed it at month 12; and 1514 completed it at both time points. The following tables present median scores by site and by study arm.

### A. Enrollment visit – Median # (and median %) correct by site

	Harare, Zimbabwe (n=698)	Durban, South Africa (n=818)	Johannesburg, South Africa (n=263)
<b>Total score (% correct of 18 questions)</b>	16 (88.89%)	16 (88.89%)	16 (88.89%)
<b>Key score (% correct of 6 key questions)</b>	6 (100.00%)	5 (83.33%)	5 (83.33%)

### B. Enrollment visit – Median # (and median %) correct by arm

	Diaphragm, gel and condoms (n=891)	Condoms only (n=888)
<b>Total score (% correct of 18 questions)</b>	16 (88.89%)	16 (88.89%)
<b>Key score (% correct of 6 key questions)</b>	5 (83.33%)	5 (83.33%)

### C. Month 12 visit – Median # (and median %) correct by site

	Harare, Zimbabwe (n=1765)	Durban, South Africa (n=1213)	Johannesburg, South Africa (n=836)
<b>Total score (% correct of 18 questions)</b>	16 (88.89%)	16 (88.89%)	17 (94.44%)
<b>Key score (% correct of 6 key questions)</b>	5 (83.33%)	5 (83.33%)	6 (100.00%)

### D. Month 12 visit – Median # (and median %) correct by arm

	Diaphragm, gel and condoms (n=1873)	Condoms only (n=1941)
<b>Total score (% correct of 18 questions)</b>	16 (88.89%)	16 (88.89%)
<b>Key score (% correct of 6 key questions)</b>	6 (100.00%)	5 (83.33%)

The five most commonly incorrect answers are listed below. They were all cases where women thought a “False” statement was “True”. The two most common errors were misconceptions about the effectiveness of the diaphragm for HIV/STI and pregnancy prevention. The most commonly correct questions concerned confidentiality, reimbursement, and the study purpose (i.e. testing the diaphragm for HIV prevention).

### E. Questions most often answered incorrectly (Percent incorrect)

Question (See full text for questions in table at bottom left)	Enrollment visit (n=1779)	Month 12 visit (n=4064)
<b>Q2 – Both arms use D's</b>	27.7%	30.4%
<b>Q6 – It is known that D prevents HIV</b>	35.0%	32.7%
<b>Q8 – Free healthcare for any ailment</b>	23.6%	16.8%
<b>Q11 – Cannot quit study after joining</b>	17.0%	19.0%
<b>Q15 – D&amp;G prevent pregnancy</b>	45.1%	35.4%

D = diaphragm, D&G = Diaphragm and gel

## V. Conclusion

Retention of the information presented in the consent forms was high at enrollment and month 12. However, the most often incorrectly answered questions pertained to key study concepts such as the efficacy of the diaphragm and gel in preventing HIV.

Women correctly answered that the purpose of the study was to test the effectiveness of the diaphragm and gel in preventing HIV; however, about one third incorrectly reported that doctors already knew that the diaphragm and gel prevents HIV/STIs. These types of contradictions between correct/incorrect questions suggest that recall doesn't always reflect understanding.

Different approaches to the consenting or reviewing processes may have caused the differences in scores across study sites or study arms. The experience of being in one study arm over time might also have influenced women's scores. Additional analyses are underway to explore these differences.

