

# What motivates women to enroll in microbicide clinical trials? Results from the Phase 3 Carraguard® trial

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In March 2007, the Population Council completed a two-year Phase 3 clinical trial of Carraguard, a vaginal microbicide candidate. 6202 women were enrolled in the trial, which was conducted at three sites in South Africa.

The trial was conducted in collaboration with researchers from the University of Cape Town (UCT), the University of Limpopo (Medunsa Campus) and the Medical Research Council (Durban).



## DATA SOURCES

Two qualitative studies were conducted in which women were asked their primary motivations to join the Carraguard trial.

- Study 1: An Assessment of the Informed Consent Process**
- 83 in-depth interviews and 8 focus group discussions were conducted with trial participants from two sites.
  - Data were collected from November 2006-March 2007.
- Study 2: Socio-Cultural Determinants of Microbicide Acceptability**
- 65 in-depth interviews and 16 focus group discussions were conducted with trial participants from three sites.
  - Data were collected from May 2007- January 2008.

A sub-sample of trial participants (N=1601) answered a brief exit survey, which included questions about their motivation to join the trial.

## Desire to know one's HIV status was the primary motivation to join the clinical trial.

### EXIT SURVEY

Reasons for joining the trial	% of participants
HIV testing/counseling	56%
Help test a product that may prevent HIV	21%
Free exams	16%
Other (including compensation, chance to use/be protected by gel, STI treatment)	8%

"Something that made it easy is that I wanted to know my status. Yes it has been a long time I've been telling myself that I am going to test but end up not going. So I'm compelled here because my date is my date, yes."  
 Informed Consent, ID, UCT

"I can say I came here to check my HIV status because I was concerned that I might be infected. Before I came here I had a boyfriend who died of HIV and I only heard about it after he died. Then when I heard about Setshaba Clinic I got motivated to come since all the time I was scared to go to my local clinic."  
 Acceptability, ID, Medunsa



## HIV testing was stressful for most participants, even after a series of negative test results...

"... there is no way you cannot be anxious. I would be lying if I say so, because when you are given your results you always talk to yourself by saying that 'oh My Lord I wonder if I am not one of them, although you know your behaviour, but there is that anxiety, understand?'"  
 Informed Consent, ID, UCT

... However, most reported that routine testing was a key benefit of the trial.

## Routine HIV testing became part of a larger prevention strategy along with:

- condom use
- treatment for STIs
- encouraging their partners to be tested



"... I always explain to [my partner] that as long as we are still HIV negative, he must always go and get tested at the clinic so that we know when we get tested positive, the time in which we got it. I always tell him to take care of himself as long as we know our status... as a married couple. I always encourage him to use a condom even though he does not like it."  
 Informed Consent, ID, UCT

"I also like the fact that if I volunteer for two years here, my partner will behave well because if he does not he would be destroying my future... I told him to go to the clinic and test his status. I told him that I know my status and I told him that we were going to use gel. He tested negative and he said I should continue with the study and that he has thought about it well it has no problem and it does not disturb."  
 Acceptability, ID, MRC

## For many, participation in the trial allowed women to discuss HIV prevention differently with their male partners.

"This because we had to introduce the condom, and the reason I gave my partner was that the researchers are not sure if the gel is working or not... it is still on a testing phase so we have to use condoms. I also told him that he also needs to test so that he knows his status. My partner didn't like a condom but he was using it... sometimes when he really feels that we must not use condoms we always used the gel."  
 Acceptability, FGD, Medunsa

## Access to quality health care was also a significant motivator to join and remain in the trial.

"Before joining the study, [women] could not access services like pap smear from the local clinics, but now they have pap smear and know all that is to know about their health status."  
 Informed Consent, FGD, Medunsa

## Health care extends beyond medical services; participants noted the support and information provided by study staff was valuable to their overall health.

"... the personnel helped us with all problems and they did not only concentrate on Carraguard. They allowed us to speak about everything, our family problems, health problems and relationship problems."  
 Informed Consent, FGD, Medunsa

"Our participation here gives us our pride and self confidence... I maintain that I will live for the rest of my life being HIV negative. I know this because the staff at Setshaba taught me how to lead my life and protect myself from being infected..."  
 Informed Consent, FGD, Medunsa



## Financial compensation was also cited as a motivation to join the trial, although this was less salient than health care provision. Trial participants received R150 (equivalent of \$19, or 201 MXN). This amount was determined by the Medicines Control Council of South Africa.

"I was free when I was coming here because there was the voucher that we received here. You would think that you don't have soap at home but when you come here you know that you would be able to buy soap and other things, especially when you look at your money only. You know when the dates are at the 15th, the food boxes become dry."  
 Acceptability, ID, UCT



"INTERVIEWER: Why would the voucher make you decide to join the study?  
 PARTICIPANT: Because in my place it was very difficult because there is no income because there were days where we would go to bed with empty stomachs because I was entirely dependant to this childrens grant... the grant itself does not cover everything."  
 Acceptability, ID, UCT

## The motive of financial compensation was reported more frequently in the Acceptability study than in the Informed Consent study. The Acceptability study was conducted after the trial ended. We assume that due to issues of social desirability, participants were reluctant to report compensation as a primary motivation while the trial was ongoing.

## CONCLUSIONS

- HIV testing was perceived as a primary benefit of participating in the trial. However, even if test results were consistently negative, testing remained stressful for trial participants. In light of these findings, additional data are needed to explore why women are motivated to test at study clinics rather than VCT clinics.
- The desire to know one's HIV status indicates a significant concern of HIV infection. Risk perception was based primarily on the assumed sexual behaviors of their male partners, knowing someone with HIV infection, and having multiple sexual partners.
- The need and desire for access to free/low cost quality health care remains high in the catchment areas.
- Understanding the motives of trial participants is necessary to create more relevant recruitment materials and community awareness campaigns prior to the start of a trial. Enrolling participants who are primarily interested in testing a new product and being part of a clinical trial could improve overall adherence. More research is necessary to explore willingness to participate in clinical research.

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