

Decision Making and the Influences of Others in the Informed Consent Process: A Qualitative Investigation in the Phase 3 Study of Carraguard®

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BACKGROUND

The informed consent (IC) process poses particular challenges in microbicide trials, which often draw from vulnerable populations naive to medical research. A qualitative study was conducted to assess the holistic IC process used in the Carraguard® Phase 3 trial.

STUDY OBJECTIVES

- To evaluate participants' comprehension and understanding of the purpose of the Carraguard trial.
- To determine primary motivations for enrolling and continuing in the trial.
- To explore the influence of HIV risk perception on decision making.
- To evaluate the involvement of male partners, family, community members, and study staff in the IC process.

STUDY DESIGN

Study conducted at two sites in South Africa:

- Gugulethu (University of Cape Town, Empilisiweni)
- Shoshanguve (University of Limpopo, Medunsa Campus)

83 IDIs

Sample questions:

- Why did you choose to join the trial?
- Who did you discuss the trial with before you joined? What was their response?
- How would you explain the purpose of the study to a friend who has not been involved in the trial?
- Which materials were most helpful for understanding the trial? Least helpful?

8 FGDs

Sample questions:

- For female-only groups*
- How important is financial compensation for most women in the trial?
 - Do you think most women used the gel consistently while in the trial?
- For mixed-gender and male-only groups*
- What did your partner tell you about the trial? How would you recommend men be involved in the IC process?

ANALYSIS

Participants in a clinical trial make sense of information they are given in unexpected ways. The decision to join a trial is less linear than prior theoretical frameworks predict.

Traditional models predict:



Our experience suggests:



DECISION MAKING: AUTONOMY

- Respondents often made the decision to join the trial before attending a screening visit.
- Participation encouraged feelings of empowerment and altruism.



"We were excited because this was the first time we experienced participating in this type of a trial. We always go to clinics for many things but this is the first of its type to us where we are involved in research and we are proud to be part of it." (FGD, Medunsa)

Interviewer: Did you discuss this issue with someone before you came and join?
Respondent: No, I just felt in my spirit that I should come because this issue is being discussed on radios, and TV's everyday that people must get tested. I only talked to my friends after I came here trying to encourage them to come and get checked." (IDI, Medunsa)



DECISION MAKING: SOCIAL NETWORKS

- While support networks (partners, family, etc.) provided valued encouragement to participants, they were rarely cited as influencing an individual's decision to join the trial.
- Participants enrolled in the trial based on their own determination to do so.

Interviewer: Did you feel pressurized to join this study?
Respondent: Yes, the pressure was from me because I wanted to know where I am. I didn't want to be in the dark." (IDI, UCT)

"This was my sole decision. She [staff] did not have any influence because she only made me aware of the trial and nothing else." (IDI, Medunsa)

"There was no influence from his side, I am the one who decided to join." (IDI, Medunsa)

COMPREHENSION

- Although explanations of risks, challenges, and benefits is a crucial component of the IC process, participant's understanding appears to be determined by their own experiences and observations.
- What may be misinterpreted as lack of comprehension may instead be a woman's perception that potential risks do not apply to her, and that other concerns (e.g., access to health care) are more significant.

"The thing that I see as a risk is that when you have to come for testing you are found to be HIV positive. Perhaps you are not ready yet or you have told yourself that you don't have it... In my understanding the benefits was that the outcome of the trial was that the gel is going to benefit the future generation of women because we know most men don't want to use a condom." (IDI, UCT)

"I think the Carraguard gel cannot be a risk because they cannot give us something that can make us sick. I think before they gave us the gel they did research to know that it is alright for us to use." (IDI, Medunsa)



"For me it was very easy... because I wanted to know my status, and since I joined the study, I really enjoyed using these gels. Now that I no longer have them I don't like being sexual active anymore because I had so much faith and trust in this gel." (IDI, Medunsa)

MOTIVATIONS

- Reasons to join a trial vary by participant and change over time; however concern and perceived risk about HIV infection remain salient motivations for most participants.
- Receiving quality health care is more important than financial compensation for most participants.

"I say being in the Carraguard study is helpful, we get a full medical examination and if there is something wrong with you, you get referred for further treatment... you know what is wrong with you." (FGD, Medunsa)

"No, even though the money is helpful, I did not join for that. For me it was important to know my status, because if you are positive there is a support group, if you have any other disease they treat you. I thought that being [at Setshaba] you are safe." (IDI, Medunsa)

"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." (IDI, UCT)



INFORMATION PROVISION

- Participants find different types of IC materials (illustrated booklet, video, IC form) more or less useful based on individual preference and literacy levels.
- Regardless of materials preferred, participants highly value consistent and compassionate information provided by study staff throughout the trial.

"...what you saw on the video was in the form that we were given. The purpose of the form was to read the things you didn't understand at your own leisure at home and you end up understanding." (IDI, Medunsa)

"It was very good to participate in the trial because the people who were giving us the information and the services were so patient and full of respect. They took their time to explain everything in detail... They prepared us to be ready to live a positive life irrespective of what the results were [infected or not infected]." (FGD, Medunsa)

DISCUSSION

- Participants understand clinical research through of their own perspectives and experiences.
- Participants' own motives informed the decision making process as much as, and often more than, the influence of others. This "sense of self" cannot be discounted.
- Many participants feel empowered by their participation in the trial. Respondents suggested that this sense of empowerment improved communication about HIV prevention between themselves and their partners, at least while in the trial.
- Information provided by the study staff was highly valued by participants.

RECOMMENDATIONS

- Staff-participant interaction is not typically subjected to the same level of scrutiny and pre-testing as written or visual materials. More attention should be paid to the role of staff in the IC process.
- IC materials must speak to the lived experience of trial participants. A variety of tools should be employed to compensate for differences between participants' preferences, experiences, and literacy levels.
- The greatest concern for participants throughout the trial was the HIV test, both being tested and hearing the results. Ongoing counseling and support is a critical part of the IC process.