

Male partner involvement in the Carraguard Phase 3 Trial: Data from a qualitative study of the informed consent process

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BACKGROUND

The importance of male partner involvement in microbicides trials has been acknowledged by researchers, although most previous studies have focused on acceptability of study products

AIM

To evaluate the informed consent (IC) process and explore the influence of men on women's decision-making and study participation in the Phase 3 Carraguard trial

OBJECTIVES

- To investigate how, why and when women communicated trial participation to their male partners
- To examine how male partners responded to women's trial participation
- To explore the influence of male partners on the IC process

STUDY DESIGN AND METHODS



- IDIs and FGDs - Conducted in local languages, transcribed, and translated to English
- In-depth interviews (IDIs) with trial participants
- Focus group discussions (FGDs) with:
 - trial participants
 - male partners
 - trial participants and male partners (mixed gender)
- Data coded and analyzed collaboratively - modified grounded theory approach

RESULTS

Respondents

- Eight FGDs and 83 IDIs were conducted with Phase 3 participants
- Two male FGDs and one mixed gender FGD were conducted with male partners of trial participants

Trial Communication

When and how participants communicated trial participation varied by individual:

When?

- Before joining the study
- Immediately after joining
- Months after joining
- Never communicated participation

How?

- Expressing desire to join
- Providing information
- Asking for permission/ approval to join



Reasons for Disclosure

- Participants who discussed the trial with partners prior to enrolment were typically seeking partners' permission
- Participants who disclosed after enrolment used trial involvement as a means to discuss STI/HIV prevention
- Many women said fear of side-effects (for themselves and/or partners) motivated them to disclose
- Participants who never disclosed feared that partners would not give permission to join

Women were selective in communicating trial involvement to their partners, informing them about:

- Condom and gel use only
- The physical exam
- Availability of partner HIV test
- STIs results and knowledge gained

"He didn't have any problem, he liked the idea but, I had already finished with my heart that I am going to join even if he would not agree I would do it secretly."
[IDI, Medunsa]

"Yes, he was very supportive and he was actually always reminding me of my appointments at the center."
[IDI, Medunsa]

"I did not tell him exactly after I joined, I told him maybe after two visits, I was afraid of what his reaction would be."
[IDI, Medunsa]

"It was a problem from the beginning but he changed as the time goes. I also told him that I am not going to stop using them."
[IDI, UCT]

"...boyfriend said to me: 'You can't be serious, you are now bringing me Carraguard gel and a condom on top of that and in the meantime you are on an injectable, you are becoming too complicated for me.'
[FGD, female participant, Medunsa]

"I told him that if I use the gel then he has no choice but use the condom because no one is sure that the gel does indeed protect. So you can't use it alone."
[IDI, UCT]

"He was discouraging me to join because he said the gel was going to bring problems to our sex life but I kept on explaining to him until he was convinced."
[IDI, Medunsa]

"I never told my partner about the gel, we don't live together, and when I visit him I took the gel, inserted the gel, had sex and never told him. I have never told him, some men are impossible and I never knew whether he will agree or not."
[FGD, female participant, Medunsa]

Partners' opinions on trial participation

- Many men agreed to their partner's trial participation
- Typically men reacted positively when informed before their partners took the decision to join
- While some men agreed to use both condoms and gel, some would only agree to gel use
- Males who participated in FGDs expressed interest in increased involvement in future trials and worries about using the gel



"I never accepted this Carraguard, I would ask myself where does this thing come from, that we must now use?"
[FGD, male participant, UCT]

"The first response was against it. Remember, we nearly had a fight about this gel of hers. I told her that I was against these gels, you see. But with time she explained how the gel worked."
[FGD, male participant, UCT]

"I don't use condoms, we used the gels and my partner enjoyed sex when we use the gel, he used to remind me of getting more gels if they run out. He would even suggest that I ask from other study participants."
[IDI, Medunsa]

"I was always interested but I was never counseled or advised just like my wife."
[FGD, male participant, UCT]

Male partners' reactions

Women reported a range of partner reactions to their joining the trial:

- Acceptance (increased when involved in decision making from the start)
- Acceptance (over time and after receiving more information from partner)
- Indifference
- Anger (if informed after enrollment; wants to be involved in decision making)
- Refusal to get involved

"He was very angry. He got angry because I did not tell him before I started. I told him after a long time but he didn't take it that bad."
[IDI, Medunsa]

"He was not impressed and he said I must stop participating because from what he heard, these things (the gels) are making people sick, and a lot of people end up being infected."
[IDI, Medunsa]

"He did not accept it very well. I could see that he does not like it. I continued using the gel until at the end he agreed to use it (condom)."
[IDI, UCT]

CONCLUSIONS

- Partner involvement should always be considered and built into the social behavioural aspects of clinical trials.
- Women had varying reasons for communicating trial participation to their partners, although the decision to do so was often difficult because it introduced issues of:
 - Fidelity
 - Trust
 - Condom use
 - Gel use
 - Partner HIV testing and adherence to the trial protocol.
- Partner communication was an ongoing process. Over time, most men accepted and supported their partners' trial participation.
- Though most men accepted and supported their partners trial participation, most males who participated in the FGDs did not agree to condom use during the trial
- Recruiting men proved difficult; much of what we learned came from women's experiences, although men who did participate were responsive and FGD's were informative