

Male Involvement in VOICE

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Why Partner Involvement is Crucial

Support from male partner could facilitate higher product adherence, prevent early study withdrawal, and prevent social harm

- Low adherence to product use results in efficacy dilution (efficacy-effectiveness gap)
- Participant withdrawal from study can negatively affect study end-points
- Social harm on VOICE participant may occur when male partner discovers her enrolment accidentally

Major Impact: Early Study Termination

- As of Sep 2010, we have 20 women who have voluntarily terminated their participation in VOICE
- 11 of these early terminations cite partner issues; 6 reported social harm
- Early terminations result in lost women-years of follow-up on product, which could reduce the power of the study to detect a difference in effectiveness between study arms.

What are some of the partner-related issues cited by women who terminated early?

- ❑ Stopped by husband after a long stay at the clinical that resulted in late home arrival
- ❑ Stopped by husband who is not comfortable with her taking part in a ARV based study
- ❑ Stopped by husband after he read IC form because of several potential side effects of product use
- ❑ Many of the early terminations occurred within 1 month of joining study

Strategies used to increase male involvement in VOICE

- Engagement of Community Advisory Board members to sensitize men about partner support in VOICE study
- Study team members visiting target male audiences at workplaces, market places, beerhalls, social gatherings
- Some participants who agree for study team members to visit male partner at home or workplace (very essential to get permission beforehand)

Strategies used to increase male involvement in VOICE

- Increase local media coverage (print, radio, TV, leaflets) about VOICE study and the role men play in the study
- Planned retention meetings that study team invites all participants, male partners, and CAB members
- Assess site impact after retention meetings

Strategies used to increase male involvement in VOICE

- Encourage potential participant (at screening) to discuss VOICE study with their primary male partner
- Encourage participants to discuss study participation after enrolment with their male partner (ongoing process)
- Sites should carefully work on estimates of how much time each visit takes, so they can let participants know what to expect ahead of time for planning purposes

More to come on this topic!

- Betty Kamira will give a presentation on Uganda's experience with male involvement in VOICE:
 - Tuesday October 6th morning plenary
- Adherence/Male Involvement Workshop
 - Tuesday October 6th afternoon
 - Part I: Focus on Adherence 1:30-3:00 PM
 - Part II: Focus on Male Involvement 3:30-5:00 PM