

# Male Involvement in VOICE

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# Why Partner Involvement is Crucial

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*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

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- 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?*

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- ❑ 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*

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- 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*

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- 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*

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- 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!

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