

ASPIRE CWG Update

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MTN Annual Meeting

Sunday, 23 February 2014

Bethesda, Maryland





Overview

- Current ASPIRE challenges
 - Strategies to address challenges
- Anticipated future challenges
- Additional feedback for the protocol team



Current ASPIRE Challenges

- Rumors and misconceptions about the ring
 - Causes infections, including HIV
 - Disappears or dissolves inside the body
 - Causes cancer, particularly cervical cancer



Current ASPIRE Challenges

- Rumors and misconceptions about the ring
 - Affects fertility and libido
 - Causes birth defects
 - Prevents HIV infection, researchers already know the ring works

Current ASPIRE Challenges

- Rumors and misconceptions about the study/study staff
 - Organize men to ensure sexually active women are enrolled
 - Participate in Satanic activities, and reimburse participant for their participation in the same



Current ASPIRE Challenges

□ General challenges

- Non-disclosure of study participation to male partners
- Male partners' interference with and disapproval of study participation
- Relocation of participants and informal settlement communities
- Limited access to high risk populations



Current ASPIRE Challenges

- General challenges
 - Participants permanently discontinued from product use influence others to do likewise
 - Screen-outs speak negatively and inaccurately about the study to discourage other women from screening



Current ASPIRE Challenges

□ General challenges

- Expectation of personal goods and health services at community sensitization events
- Anxiety about possibly receiving HIV positive test results





Strategies to Address Challenges

- Community sensitization
 - Targeted and broader communities
- Re-sensitizing all CBOs about ring use
- Waiting room education
- Couples workshops
- One-on-one participant education



Strategies to Address Challenges

- Hosting adherence and retention workshops with participants
- Hosting male involvement workshops
 - Supporting participants who choose to disclose study participation to male partners
- Hosting a “social responsibility day” and partnering with CBOs





Anticipated Future Challenges

- Study fatigue
- Decreased product adherence
- Increase in missed visits and early terminations
- Intense expectation of immediate product access from participants and community pending study results of safety and effectiveness



Additional Feedback

- Begin planning for end of study participant and community meetings to discuss post-ASPIRE research plans
- Stakeholder engagement has been important in the ASPIRE study – more resources are needed



Additional Feedback

- Budget constraints and accrual timelines confine community sensitization to targeted communities at the expense of the broad community sensitization – a key source of rumors

Additional Feedback

- Tokens for couples events should be considered to help improve participation
- CRSs need waiting room posters with ring-related messages to encourage adherence
 - ‘power is in your hand keep the ring inside’



Additional Feedback

- Refresher training for community education staff regarding contraceptive implants
- CRSs need education about anal sex, transgender issues, and related standard of care



Summary

- From the CWG's perspective, the most prevailing challenges to ASPIRE are derived from rumors and partner issues
- Diverse strategies are used to address challenges including increased community sensitization and education workshops

Summary

- Participant fatigue is the greatest foreseeable challenge facing ASPIRE
- Provision of education to CRS on sensitive topics; early end-of-study planning; and support for innovative outreach strategies are requested to enable continued successful community engagement in ASPIRE



Acknowledgements

The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.



