ASPIRE CWG Update

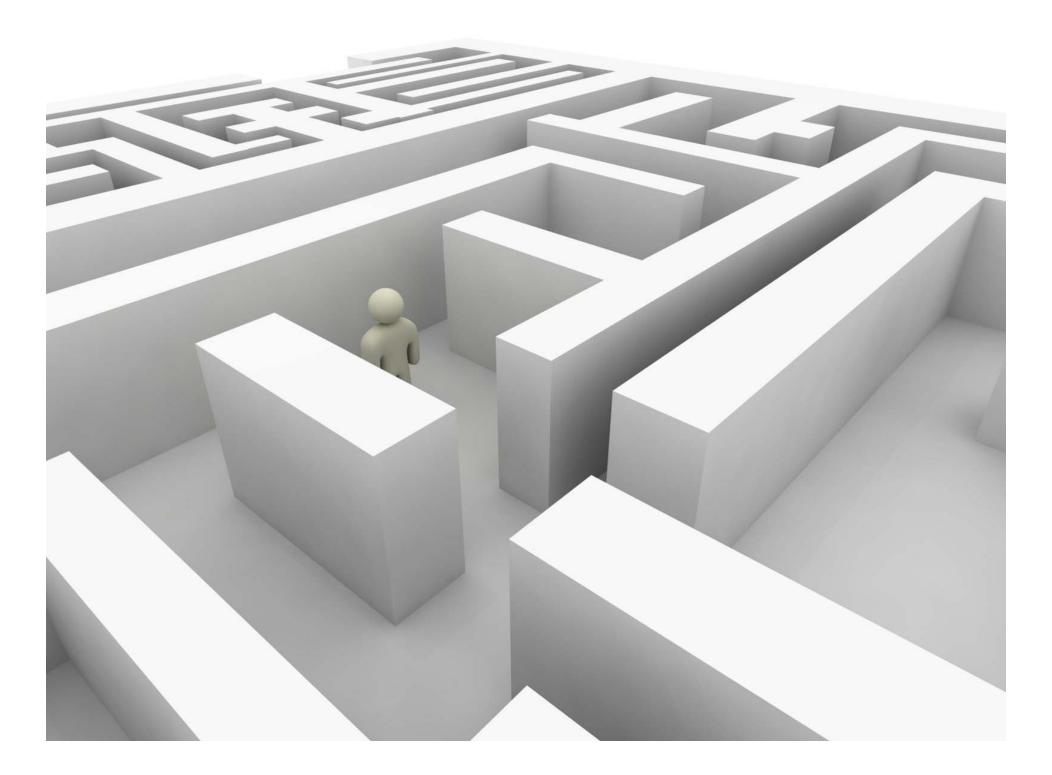
Charles Chasakara
MTN Annual Meeting
Sunday, 23 February 2014
Bethesda, Maryland



Overview

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





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



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



- 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



- 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



- 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



- 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



- 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



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



- 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'



- 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



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