



ASPIRE CWG Update

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Bethesda, Maryland

Acknowledgements

- Community
- ASPIRE Study Participants
- ASPIRE CWG
- MTN CWG
- FHI 360

Overview

- Responses to Study Close-out Announcement
 - CAB and Stakeholders
 - Male Partners
 - Study Participants
- Messages to Encourage Product Return
- ASPIRE CWG Comments Regarding FACTS 001 Results
- Summary

Responses to Study Close-out Announcement

CAB and Stakeholders

- Eagerly anticipating and hoping for favorable study results
- Concerned about the absence of routine HIV counseling and testing, easy access to condoms, and a potentially effective product between the end of ASPIRE and the beginning of HOPE

Male Partners

- Sites will include male partners in the groups to be informed about study close-out plans in hopes of avoiding confusion and misinterpretation about the status of the trial (*i.e. the study is ending because of futility*).

Study Participants

- Daily waiting room education sessions are convened to discuss close-out plans and timeline
- Some participants have expressed concern about not having access to the ring after the study ends. Staff are reminding participants that we don't know if the ring works to prevent HIV infection nor which participants are using the placebo ring. Condom use is encouraged.

Study Participants

- Participants are not looking forward to obtaining health services from public health facilities due to long queues and concerns about the quality of care compared to that received through the study
- Some sites are continuing adherence workshop to maintain motivation about study participation and adherence

Study Participants

- Recently published VOICE manuscript and the FACTS 001 results are being used as adherence motivators
- Site teams have brainstormed how to counsel participants who hesitate to return rings

Five Points Message to Encourage Product Return

Five Points Message to Encourage Product Return



1. When the ring is in the vagina the amount of dapivirine gradually decreases over the month. Eventually there won't be any dapivirine in the used ring.

Five Points Message to Encourage Product Return

2. When worn correctly and consistently with every sex act, condoms work well to reduce the risk of becoming infected with HIV.



Five Points Message to Encourage Product Return

- Until the study ends and results are made available, we don't know:
 3. if the dapivirine ring works better than the placebo ring at reducing HIV infections
 4. who is wearing a placebo ring or a dapivirine ring

Five Points Message to Encourage Product Return

5. We don't know the health effect of wearing the ring well beyond the period of time the ring is intended to be worn. Please return all rings to the clinic.

ASPIRE CWG Comments Regarding FACTS 001 Results

- Study staff should be congratulated for a job well done, and participants should be thanked for their volunteerism – even those who didn't use the gel because we learned something through their non-adherence.
- Results were disappointing, but not completely surprising considering the VOICE study results.

ASPIRE CWG Comments Regarding FACTS 001 Results

- The results have raised questions, ‘why did participants adhere in CAP 004, but not in FACTS 001’? and ‘does adherence vary amongst different age groups’?
- Education about the meaning of research and adherence, and the consequences of non-adherence must be on-going.

ASPIRE CWG Comments Regarding FACTS 001 Results

- The results might cause communities and male partners to discourage potential participants from joining future research.
- “... we need to find an HIV prevention method that is non-coitally dependent, can be used covertly, long-acting, and convenient.”

ASPIRE CWG Comments Regarding FACTS 001 Results

- “... the ring is the real deal.”
- The results will motivate ASPIRE participants to continue adhering to the end of the study.

Summary

- Access to health benefits within the trial continues to be important for women.
- Despite on-going education about research, participants perceive that the ring protects them from HIV infection. Thus, some are concerned about no longer using the ring after study close-out.

Summary

- Community members and participants have come to appreciate the importance of product adherence in order to find an effective HIV prevention method for women.
- Though FACTS 001 did not provide the results we had hoped for, the ASPIRE CWG sees these results as an opportunity to encourage ring adherence in ASPIRE.

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