

# **Participant Adherence Workshops: Kampala Site Experience**

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# Presentation outline

- ▣ Introduction/ origin of adherence workshops?
- ▣ Structure of the workshops
- ▣ Lessons learnt
- ▣ Impact of adherence workshops on clinic operations
- ▣ Challenging and successful case scenarios
- ▣ Male involvement workshop
- ▣ Conclusion
- ▣ Acknowledgements

# Introduction/origin of adherence workshops

- ▣ Hints of possible non-adherence
  - VOICE results dissemination meeting to community contact persons
  - Dissemination of VOICE results to individual ASPIRE Participants
  
- ▣ Differing opinions on handling this;
  - Group adherence session for all participants
  - Terminating the suspected “non adherent” participants

# Introduction/origin of adherence workshops cont'd

- ▣ Terminating suspected participant would:
  - send wrong messages into the community
  - raise more suspicions and misconceptions
  - sabotage against recruitment & retention activities
  - missed opportunity for establishing root cause of non-adherence
  
- ▣ Final decision was to hold small group adherence sessions for all enrolled participants
  
- ▣ Workshops held every Thursday since 27Mar13

# Structure of adherence workshops

- ▣ Self introductions by participants & study staff
- ▣ Purpose of the adherence workshop
  - Reminder about participant responsibilities with reference to the ICFs, & the importance of fulfilling their obligations
  - Importance of adherence in clinical trials with a preview of varying results from VOICE, Partners PrEP, etc
  - Participants experience with ring use with emphasis on the importance of honest reporting
- ▣ Explanation of placebo concept & effect of non-adherence using the illustration of car seat belts
- ▣ PK results from initial analysis

# Structure of the workshops cont'd

## ▣ Other topics discussed

- Research achievements especially PMTCT where the MU-JHU site has been heavily involved
  - The Big picture; HIV/ AIDS epidemic globally and in Uganda (350-400 new infections everyday)
  - HIV/ AIDS in our own families - personal testimonies by staff and participants
  - Vaginal cleansing and sexual practices
- ▣ Q & A session on what has been discussed
- ▣ Feed back or participant concerns about the study implementation including customer care

# Key Lessons Learnt

- ▣ General lack of understanding of importance of research in the community
- ▣ Even the most well intentioned participant can be affected by rumors & misconceptions
  - Majority of participants cautioned by family members & friends on safety; possibility of cancer, HIV/ AIDS, infertility e.t.c.
- ▣ Participants remove the ring especially in the 1<sup>st</sup> month due to:
  - Anxiety about partners feeling the ring during foreplay & sexual intercourse
  - Fear of side effects
  - cleaning ring especially during menses

# Key Lessons Learnt Cont'd

- ▣ Anxiety goes down after the first month
- ▣ Most partners do not feel the ring during sexual intercourse
- ▣ Low rates of disclosure for study participation
- ▣ Spouses made to believe that the ring is a contraceptive option
- ▣ Some women have come to appreciate their HIV risk levels & their behavior modified accordingly
- ▣ Douching is a common practice douching among women



# Lessons Learnt Cont'd

Before enrollment day, I was so worried about side effects of the ring. I inquired from another participant who assured me that the ring is not harmful. I am not worried any more and I am comfortable with wearing the ring

After enrollment, I wanted to find out if my primary partner would feel the ring but he called and told me that he couldn't come back home. I went to experiment with my secondary partner and had sex with him. He felt the ring but I told him that it was a family planning method.

# Impact of workshops on clinic operations

- ▣ Key outcomes from workshops discussed during the weekly staff meetings
- ▣ Staff have come to appreciate participants' challenges
  - Participants are not judged but listened to. Their needs are identified and encouraged to work on their goals
- ▣ More honest reporting realized, more rings looking used
- ▣ Reduced incidence of reported ring expulsions & douching

# Impact of workshops on clinic operations cont'd

- ▣ Flagging of charts for special participant categories
  - IoR's list: Suspected non adherent participants
  - Comes from far (CFF): Reside upcountry, islands.
- ▣ Staff scheduled to come in earlier for CFFs, VIP treatment given
- ▣ Participants with medical complaints are followed up immediately in the clinic
- ▣ Ppt feed back requested during clinic visits to evaluate the workshops - reports of better understanding of need for adherence

# Case Scenarios

# Challenging Case I

- ▣ Participant found partner & brother-in-law reading her ICFs. They later bought her beer which made her drunk. The next day, she realized that she didn't have the ring. Feared to confront the partner, & Later she came to the clinic to be given a new ring. She reported that the partner was not aware of the her visit to the clinic and has not commented about the incident or felt the new ring.
- ▣ **Plan:** Encourage her to clear the air with the partner since he seems to know about the study

# Challenging Case II

- ▣ **A suspected non-adherent participant came for an interim visit to receive DMPA. The IoR requested for a spot check, and established that the participant was not wearing her ring. Participant initially said she had left the ring at home but later retrieved it from her hand bag and showed it to the IoR. Invited for an adherence workshop where she admitted that she removes the study ring when is travelling long distances for fear of dying with the ring inside her body.**

## Challenging Case II cont'd

- ▣ After the workshop, other participants volunteered information that this participant was not using the ring. Her returned rings continuously to looked unused. She was invited to attend a follow-up workshop. Unfortunately, we still got reports that she does not use the ring because she thinks it's not safe. The IoR had made a decision to terminate she thinks her at her next scheduled visit (M13). However, at this visit participant was found to be pregnant and study product was held. She seemed happy about the pregnancy, and intends to carry it to term. Had changed from DMPA to CoC's. Non-adherence possibly due to intention to conceive.
- ▣ **Plan:** Minimize her interaction with other participants by scheduling her on Thursdays

# Successful Case I

Participant reported that before attending the workshop, she used to remove the ring because she didn't want the secondary partner to feel it. She wanted to maximize the fun they had together since they never used to meet very often. She would let him touch every part of her body unlike the primary partner. When she attended the 1<sup>st</sup> workshop, she realized that she was at a high risk of acquiring HIV from the secondary partner who refuses using condoms. She then decided to end extramarital relationship and use the ring as counseled.



# Successful Case II

A participant reported that before enrollment, another participant told her the ring came out on the partner's penis during sex. This made her to feel very scared because she had not disclosed to her partner. After enrollment, she was anxious and didn't want her partner to come back home.

At night, she was very anxious because she didn't want to have sex with him but he insisted. She was surprised when he didn't feel the ring and since then she is comfortable with the ring.

# Male involvement workshop

- ▣ Pilot workshop held on 17 Oct 13
- ▣ Targeted partners of participants who have disclosed investigational ring use
- ▣ Men invited through their participating partners
- ▣ 4 men out of 10 men invited turned up
- ▣ Agenda included:
  - Introductions
  - Feed back from male partners/ what they know about ASPIRE
  - Back ground of MU-JHU and importance of research
  - Overview of the ASPIRE study
  - Questions & way forward – how can we involve other me?
  - Discussion of services offered to male partners

# Male involvement workshop cont'd

## ▣ Site experience

- A very tense session, very careful not to cause social harms
- Many questions were asked
  - ▣ Is the ring safe?
  - ▣ Won't the women think the ring works and start engaging in risky behavior?
  - ▣ The study seems to be for low SES women, why do not the researchers participate as well?
  - ▣ Is it okay for their women to conceive while in the study?
  - ▣ Will the women access the product at no cost once it's proven to work?

# Male involvement workshop cont'd

## ▣ Lessons learned

- Men admitted difficulty in using male condoms
- All the 4 men reported feeling the ring during sex
- One partner said the ring smells for the 1<sup>st</sup> 2 weeks following the clinic visits
- One male partner was willing to take an HIV test

## ▣ After the workshop

- Follow up calls made to the study participants - partners felt honored to be invited for the workshops, recommended a similar session for other men

# Statistical Summary

- ▣ No. of workshops held: 20
- ▣ Attended one workshop: 187 / 201 enrollees
- ▣ Attended a follow-up session: 73
- ▣ Male partner workshops: 01

# Conclusion

- ▣ Given the general lack of understanding about importance of research in communities, there is need to support participants
- ▣ Adherence workshops have been crucial
- ▣ Peer support from each other through sharing experiences
- ▣ Participants are empowered with knowledge
- ▣ Confidence built between participant & researchers leads to more honest reporting

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