Participant report of ring use in ASPIRE – Zim Site strategy

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Outline

- VOICE experiences and lessons learnt
- Plans for ASPIRE
- Promoting honest reporting of ring use
- Promoting honest reporting of non-use

VOICE Experience

| Initial adherence counselling approach | VASP approach |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Counselling was guided by pharmacy returned counts and self report of product use | Counselling was focused on participant's experiences in using the product and what made product use easier or harder, regardless of how much she used. |
| Probing was done for any discrepancies | A neutral counselling Approach was used |
| Counselling was based on how often participant was able to use product | Adherence plan was based on addressing Adherence related need |
| Goal was focused on perfect Adherence | Goal was focused on making product use manageable |
| | |
| | |

Lessons from VOICE

- Participants open up if you address their needs.
- An approach that is centred on perfect adherence results in biased reporting
- Focusing on perfect adherence creates anxiety for participants and they will only report what the researcher expects to hear
- Participants should be respected for their effort.
- Partner involvement should be done from the start

Plans for ASPIRE COMMUNITY

- Community perceptions of a new product –ARV based vaginal ring – can significantly impact product use
- CAB members were engaged/ consulted right from the start via protocol trainings bi-monthly meetings led by Mrs Ngani.
- Community education very critical to deal with misconceptions, fears and purpose of the study
- Community sensitisation has started with outreach workers.
- Outreach team is taking the sample ring to the community and capturing concerns about the ring.
- Outreach team is giving out fliers that will address the fears of the community with ring use

Promoting honest reporting of ring

• We are going to use the Adherence Counselling Education Approach which is client-centred.

- Create a comfortable environment by creating good relationships between participants and research staff.
- Participant education is key. There is need to find out if participants understand the objectives of the study and how they can be achieved.
- Pay special attention to addressing participant needs vs efficiency of the process
- Encourage open dialogue always
- Follow-up with participants after enrolment visit- courtesy call.
- Partner Involvement.

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continued:

Promoting honest reporting of ring

use

- Address all the potential issues/fears that may affect one's willingness to use the study product.
 - 1. Fear of side effects
 - 2. ring sticking in the body
 - 3. ring coming out during sex
 - 4. Partner feeling ring during sex
 - 5. wearing ring during menses
 - 6. difficulty in inserting or removing ring
 - 7. ring uncomfortable during normal daily activities
 - 8. partner not approving ring use
 - 9. community perceptions

Promoting honest reporting of non-use

- Respect for the participant will be our MOTTO
- Participants shall be respected for their effort even if they report non-use
- Study staff shall always encourage product use without coercion.
- Study staff shall address needs of Participants individually.
- Study Clinic should always have a friendly atmosphere to make participants feel at home

Conclusion:

- In conclusion, i would like to say it is very important to have a good study staff participant relationship. A good relationship promotes honest reporting.
- Respect for the participant shall be our MOTTO

I would like to say THANK YOU!!! to CAB Members, Zim site Staff, MTN, NIH

THANK YOU!!!!!!!!

Acknowledgements







University of Zimbabwe, School of Medicine

UZ - UCSF Collaborative Research Programme in Women's Health

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University of California, San Francisco, School of Medicine Acknowledgements Zimbabwe MTN 003 Research Participants CAB Members UZ-UCSF Staff MTN Protocol Team MTN is funded by NIAID (SUMIAIO68633), NICHD and NIMH, All of the U.S National Institutes of Health