VOICE study- Experiences from Uganda Site

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Outline

- Study updates at the site
- Experiences (Challenges & Strategies)
 - Recruitment
 - Retention
 - Adherence
 - Clinic and Pharmacy
 - Logistics
 - Customer Care



MU-JHU Research Collaboration









Study Updates

- Site activated on 07 Oct 2009
- First participant was screened on 13 Nov 2009
- First enrollment was on 07 Dec 2009
- As of 15 March 2010:
 - Number of participants enrolled: 87
 - Average enrollment per week: 6.2



Study Updates

No. of Study Related Trainings:

- Pre-initiation
 16
- Ongoing training
 11
- No. of CAB Trainings & Meeting:
- No. of visits from Sponsor Monitor (PPD): 1
- No. of visits from FHI/ SCHARP:
- No. of visits from Network Lab:
- □ No. of visits from PAB:



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MTN Stakeholders meeting at MUJHU, 2008



CAB meeting at MUJHU

Sessions about VOICE study with Men in community

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Study Updates

- Total No. of Participants
 - Pre-screened: 1348
 - Screened (part I): 199
 - Screened (part 2): 138
 - Enrolled: 87
 - In Follow-up:
 - □ Month 1 68
 - □ Month 2 28
 - Month 3
 6
 - Withdrew from study: 1



Recruitment

- Recruitment sites: Community vs. Health Clinics
- Misconception & Negative Attitudes: Information about research and current results (e.g. MDP 301)
- Seasonal effect: Rainy season vs. Dry season
- Weekend Coverage: community recommendation for recruitment over the weekend vs. week days

- Arranged for more community recruitment by having a contact person in each area
- Arranged meetings with CAB, contact persons, and sister-organization to formulate common strategies
- Met with participants & potential participants to explain the results from MDP 301 vs VOICE
- Re-budgeting to account for the weekend costs ...



Retention

As of March 15, 2010, the retention has been over 98%

- 1 participant withdrew because of MDP 301 results
- 1 participant missed visit due to re-location & challenges with family members acceptance of her participation

- More sessions for results dissemination was held and it is on-going
- Close monitoring of the target visit dates for participants to prevent potential missed visits
- Invited the family members to come to clinic for more education



Adherence

- Forgetting to take the study product
- Partner's objection
- Discrepancy in information provided to staff

- Emphasize the use of various methods of reminders
- Encourage to disclose study participation to male partners and if possible come with partners to clinic.
- Use the study product adherence form
- Weekly Adherence Committee meeting



Logistics

- Need for more space for counselors
- Need for more staff in the areas of Counseling, and Quality Control.
- Need to accommodate for long hours of work by staff

- Created more rooms
- Recruited 2 counselors, and 1 QC staff.
- In the process of hiring full time Adherence coordinator.
- Changed team meeting times to accommodate the participants early arrival and late departures



Customer Care

Need for improvement in customer care

- Providing Child play area with Peer-mother supervision
- Showing entertaining programs in the waiting area
- Providing Refreshment (water, soda) and/or lunch depending on their appointment time



Summary

- VOICE study is a challenging study at our site.
- We are using our experiences from previous clinical trials (e.g. MTN 001) to conduct VOICE successfully.



Acknowledgements

- Study Participants
- Site Research Team
- FHI/MTN CORE/Network LAB/SCHARP
- □ Sponsor (NIH)

MTN is funded by NIAID (5U01AI068633), NICHD and NIMH, all of the U.S. National Institutes of Health

