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: 3

- No. of visits from Sponsor Monitor (PPD): 1
- No. of visits from FHI/ SCHARP: 1
- No. of visits from Network Lab: 1
- No. of visits from PAB: 1
MTN Stakeholders meeting at MUJHU, 2008
Sessions about VOICE study with Men in community
Study Updates

- Total No. of Participants
  - Pre-screened: 1348
  - Screened (part 1): 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

**Strategy**

- 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

Strategy

- 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

**Strategy**

- 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

Strategy

- 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

**Strategy**

- 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.
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- Site Research Team
- FHI/MTN CORE/Network LAB/SCHARP
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