MTN-020 Qualitative Update

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RTI International
San Francisco, CA, USA

ASPIRE Protocol Team Meeting, MTN Annual Meeting 23 February 2014
Agenda

1. Accrual Update
2. Overview of Themes to Date
3. Interesting Case Selection
   • Single IDIs
   • Serial IDIs
# Accrual Update

<table>
<thead>
<tr>
<th>Site</th>
<th>SIDI1</th>
<th>SIDI2</th>
<th>SIDI3</th>
<th>Single IDI</th>
<th>FGD</th>
<th>Total # of IDIs / FGDs</th>
<th>Total # of Women Interviewed</th>
</tr>
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<td>DTHF</td>
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<td>15</td>
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<td>18</td>
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<td>10</td>
<td>10</td>
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<tr>
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<td>2</td>
<td>0</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>52</strong></td>
<td><strong>22</strong></td>
<td><strong>0</strong></td>
<td><strong>15</strong></td>
<td><strong>0</strong></td>
<td><strong>89</strong></td>
<td><strong>67</strong></td>
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## Accrual Progress

<table>
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<tr>
<th></th>
<th>SIDI1</th>
<th>SIDI2</th>
<th>SIDI3</th>
<th>Single IDI</th>
<th>FGD**</th>
<th>Total # of Women Interviewed</th>
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</thead>
<tbody>
<tr>
<td><strong>Target # / Site</strong></td>
<td>12-14</td>
<td>12-14</td>
<td>6-7*</td>
<td>≥3</td>
<td>2</td>
<td>~35</td>
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<td><strong>Target # all sites</strong></td>
<td>72-84</td>
<td>72-84</td>
<td>72-84</td>
<td>18</td>
<td>12</td>
<td>~210</td>
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<tr>
<td><strong>Total to date</strong></td>
<td>52</td>
<td>22</td>
<td>0</td>
<td>15</td>
<td>0</td>
<td>67</td>
</tr>
</tbody>
</table>

*Anticipate that not all women will take part in 3 SIDIs

**Estimated 10 women per FGD
OVERVIEW OF SELECT THEMES
Motivations for Participation

I feel at risk for HIV and want to know my status

I value the health care benefits
Ring Acceptability/Adherence

- Generally high reported adherence
- Discreteness facilitates use
- Non-adherence associated with negative influence from other participants and some side effects
- Expulsion associated with defecating
- Participant engagement activities reported to improve adherence
Male Partners/Sex

- Promiscuity of partners motivates participation
- Differing opinions and levels of disclosure to partners
- Concerns
  - Partner will feel ring during sex
  - Associate ring use with infidelity
  - May cause harm to partner
Rumors

Did you hear that ASPIRE is Satanic?

No, but did you hear that the ring causes cancer?
Understanding Study/Procedures

- Placebo concept still confusing to some
- Ring use inspections
  - Confusion over purpose and what is done
  - Belief that it demonstrates lack of trust
Single IDIs and Purposively Selected Serial IDIs

INTERESTING CASE
SELECTION
Single IDI Cases

- 15 Single IDI cases
  - 14 sero-convertors
  - 1 termination due to partner
Reported Adherence

- Few adherence problems reported
- One woman reported a single instance of ring expulsion while defecting with immediate re-insertion
- Only one woman reported removing ring prior to sex, attributed improper ring and condom use to her sero-conversion
Responses to Product

- Initial belief that ring is protective/using active ring
- Retrospective comments on lack of side effects support belief that they were using placebo
- One participant believed she alternately received placebo and active ring during study
Responses to Study

- Generally sad, but appreciative of the study
- At least one woman expressed disappointed that the ring did not protect her
Interviewing Sero-Convertors

- Generally gone well, but some sensitivity

- Important for participant to be aware that the interviewer knows her HIV positive status.
  - Before Interview/Introduction: To inform participants about shared confidentiality regarding her HIV status.
  - During Interview: Introduce when discussing Acceptability and Adherence topic [before question 5 on IDI].

“As I mentioned before we will be talking about your experience in ASPIRE and your HIV status...”
Questions on Single IDIs

- Have any sites had other early terminators (i.e. not sero-convertors) they’ve considered enrolling?
- Any additional issues encountered with conducting single IDIs?
- What other themes have emerged related to the study/ring use with this sample?
‘Interesting’ Serial IDI Cases

- 4 cases purposively selected to date
  - 2 interviewed at MU-JHU
  - 2 selected at MRC

- Example indicators of interesting cases
  - Disclosure of widespread or situational non-use (e.g. before sex)
  - Shift in overall attitude towards study
  - Demonstrates unique behavior (e.g. able to bring partner into clinic, different from peer group, etc.)
Example Interesting Case

- Selected based on:
  - Self-reported perfect adherence.
  - After adherence workshops, reported not using product.
  - Concerned about HIV risk because partner is promiscuous.
  - Through workshop realized HIV risk and decided to use ring.

- Upon being interviewed as a serial IDI case:
  - SIDI1: she reported the ring coming out once while washing her vagina, but did not report widespread non-adherence.
  - SIDI2: reported non-adherence prior to adherence workshops.
Final Topics for Discussion

- Site input:
  - Are we getting interesting, useful information?
  - Are there topics we should be exploring further/less?