MTN-038 Behavioral Measures

WGHI/RTI International
San Francisco, CA
Overview of Behavioral Measures

• Behavioral CRFs – covered by SCHARP
  – Ring Insertion and Removal: ease or difficulty with ring insertion, reason for not inserting it herself
  – Ring Adherence: Number, timing, duration or removals and expulsions, with reasons

• CASI questionnaires – covered by SCHARP & RTI at later date
  – Enrollment, Visit 6 (Day 28), Visit 8 (Day 56) and Visit 9/PUEV (Day 91)
    • Administer Visit 9/PUEV survey if early PUEV or early termination
## Overview of Behavioral Measures

- **CASI questionnaires – topics**

<table>
<thead>
<tr>
<th>Topics</th>
<th>ENR</th>
<th>V6 (Day 28)</th>
<th>V8 (Day 56)</th>
<th>V9/PUEV (Day 91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motivation to Join</td>
<td>✓</td>
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<tr>
<td>Demographics</td>
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<tr>
<td>Vaginal Practices</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Sexual History &amp; Partners</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Recent Sexual Behavior</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Drug/alcohol</td>
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<tr>
<td>Other HIV px methods</td>
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<tr>
<td>Adherence (frequency of removal/expulsions)</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Acceptability</td>
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<td></td>
<td>✓</td>
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<tr>
<td>Preference (attributes, dual indication, duration)</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
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</tbody>
</table>
Overview of Behavioral Measures

• By the way! New CASI uses “Illume” and will be online instead of an app on handheld tablets.
  – Here’s a peak at the new format:
  – Separate training will be provided by SCHARP and RTI to review format and content in more depth
Overview of Behavioral Measures

• Qualitative: In-depth Interviews
• Conducted at Visit 9/PUEV or Early Termination Visit
• Topics
  – Degree to which participants like/dislike using the IVR
  – Attitudes about ring attributes, dosing regime, willingness to use IVR in future
  – Effect on sex and partners’ reactions
  – Challenges using IVR in relation to hygiene, menses, sex
  – Interest/preference in single vs. dual-purpose indications (MPTs)
  – IVR in comparison to other HIV prevention methods
In-depth Interviews (IDIs)

• Subset of participants invited to IDI
  – Ideally 8 IDI participants per site, ~24 total
  – Eligibility: penile-vaginal sex in past year.
  – We expect that 1/3 to 1/2 may not meet eligibility criteria.
  – Randomization at Pitt: 16/24
  – Randomization at Bridge and UAB: TBD*
    *Randomization will be over sampled to account for participant ineligible or unwillingness to participant in the IDI.

• Selection procedure at Enrollment Visit:
  – SCHARP will provide a list of randomization IDs (outside of Medidata) to indicate whether the participant is randomized to an IDI.
  – Site staff will confirm eligibility based on response to question 7 (penile-vaginal sex in past year) on DEM CRF
  – If eligible, site staff will invite participant to participate in IDI
  – Document randomization, invitation, and response on Enrollment CRF
In-depth Interviews (IDIs)

- Interviewers at RTI will conduct IDI over BlueJeans
  - IDI will be audio recorded but not video recorded

- Site staff will:
  - Email interviewers and mtn038IDI@mtnstopshiv.org to notify them of scheduled interviews in advance (preferably when scheduled at Enrolment)
  - Hand Visual Ring Comparison Tool to participants before IDI
  - Be responsible for setting up and closing down IDI during PUEV
In-depth Interviews (IDIs)

• IDI set up:
  – Download BlueJeans (free software)
  – Quiet, private space, out of earshot
  – “Interview in Progress, Do Not Disturb” sign on door
  – Stable internet connection (supported by ethernet if necessary)
  – Webcam connected to computer
  – Landline phone next to computer
    • Connect on computer first and select “Phone audio”
    • “Dial in” or have BlueJeans call the landline
    • Ideally use headset, or speakerphone if necessary (hands should be free)
  – Comfortable space, not in front of a bright window or light (which would disturb camera)
In-depth Interviews (IDIs)

• Next steps:
  – Assemble any necessary equipment: computer, webcam (we use Logitech brand), landline, headset optional, ethernet cable
  – Schedule mock interview for site study staff with interviews to test set-up/equipment and guide soon after activation or first enrolment

• Questions? Thank you!
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