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A Study to Prevent Infection with a Ring for Extended Use


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Activating for Off-site Visits

MTN Regional Meeting 2012

MTN microbicide trials network

9 Sites Activated!

Next step is to think about how and when to utilize off-site visits and prepare for activation for these procedures

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Why go off-site?

- Promote good adherence
  - A participant can't use the product if she doesn't have it
- Ensure good retention and data quality
  - Conduct what can be done off-site; getting at least *some* of the required procedures conducted, and better data for the visit overall
- Reduce participant burden
  - Recognizing that it is difficult to come to the clinic (sometimes more than once a month) may help build rapport and appreciation for the clinic

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But the draw-backs?

- Takes up staff time away from the clinic
- A trip for an off-site visit could take a long time, depending on where she lives
- Confidentiality concerns
- Staff safety concerns
- Collecting and testing specimen restrictions
- Difficulty with transport of study product and/or specimens
- Coordination of materials/planning

Clear benefits, clear drawbacks…

- In-clinic assessments are always the best so full safety assessment can be completed
- Conduct as a last resort
- Critical option to have available when needed

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What are the options… and benefits of each?

- Scenario 1: Off-site visits specifically for VR delivery and collection
- Scenario 2: Collection of specimens (for HIV and pregnancy for example)- will consider the participant 'retained'
- Scenario 3: The above, plus sample *testing* off-site

Conducting other visit procedures can be added to any of these scenario's- questionnaire administration, clinical assessments, specimen collection for other tests required for the visit

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Scenario 1: VR delivery and collection

- Considerations:
  - Staff: Available for adherence counseling, ring use instructions off-site
  - Prep Work: Ensuring no symptoms *prior to* ring delivery (verification by clinician)
  - Equipment: Min/max thermometer that can be reset to capture the max temperature reached for duration of time between pharmacy and participant delivery

Scenario 1: VR delivery and collection

- Considerations:
  - Study Product: Pharmacy will prepare product but will not dispense until immediately before departure.
    - *If for any reason the product is not given to the participant it should be returned to the pharmacy as soon as possible.*
  - Documentation: very similar to in-clinic procedures; recording temperature and off site visit log are additional
  - Discussed in more detail in the pharmacy breakout session

Scenario 2: Sample collection

- Considerations:
  - HIV pre-test and risk reduction counseling (if done with pre-test): worksheets/chart notes
  - Processes in place for collection of blood and urine samples off-site
  - Need to return to the participant after testing in the lab/at the clinic with HIV rapid test results and to conduct post-test counseling
    - Staff and time required should be considered

Scenario 2: Sample collection

- Chain of custody considerations:
  - How will you track the transfer of specimens from the off-site team to the lab?
  - Will there be a hand off to a driver and then the lab? Or will the same people collecting the samples deliver to lab directly?
- Safety considerations, including details on how biological specimens and bio-waste will be handled and procedures to prevent and respond to specimen accidents

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Scenario 2: Sample collection

- Adhering to allowable time intervals to get specimens to testing laboratories (remain the same whether in clinic or off site)
- Specimen handling and transport methods
  - Specimens kept at proper temperatures and labeled as biohazard
  - Preventing jostling to preserve specimen quality
- Equipment and supplies

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Scenario 3: Specimen Testing

- Considerations:
  - Source documentation for test results
  - Staffing: 2 staff members qualified in HIV rapid testing will be required to perform and review HIV testing results
  - Safety considerations: including details on how biological specimens and bio-waste will be handled and procedures to prevent and respond to specimen accidents
  - Equipment and supplies
  - Appropriate area

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Scenario 3: Specimen Testing

- Considerations for HIV rapid testing:
  - If your site is already performing in clinic FS rapid HIV testing, there are not additional considerations for offsite testing to those steps previously outlined.
  - If your site is not already performing in clinic FS rapid HIV testing, site staff experienced in FS rapids from other studies can train ASPIRE staff and perform competency assessment.
  - If no site staff have FS HIV rapid experience, a validation will be required-contact the NL.

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Scenario 3: Specimen Testing

- Considerations for fingerstick HIV rapid:
  - The lab must provide oversight for any lab testing done by non-lab staff.
  - Source Documentation must have all the same elements (kit lots, start and stop times, etc…)
  - One staff member can start the test; two qualified staff must read the test within the allowable read times.

Adding other visit procedures

- Considerations:
  - Questionnaire administration: time/space and appropriate staff, appropriate CRFs
  - Abbreviated physical exam: appropriate equipment/space/staff, Physical exam CRF
  - Contraceptive counseling: appropriate worksheet/chart notes, visual aids if necessary
  - Additional specimen collection: considerations all similar to those listed for blood and urine collection previously

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Preparing for any off-site visit

- Confirm consent has been provided
- Confirm time/date/location with the participant:
  - Ensure that she does not have any current symptoms prior to the visit
  - Check that confidentiality can be ensured
- Prepare according to the type of visit that will be conducted
  - It is recommended that checklists are put in place for this!

Not a One Size Fits All!

- Each IoR may choose to approach off-site visits differently, but please consider at least offering the delivery of the ring off-site to your participants → ACCESS TO PRODUCT IS CRITICAL
- We want to hear from you as you work through these systems!
  - How is it working?
  - Are there any challenges?
  - How do participants respond?

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