Activating for Off-site Visits

MTN Regional Meeting 2012
Next step is to think about how and when to utilize off-site visits and prepare for activation for these procedures.
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
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
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.
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
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
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
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.
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
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?