



VOICE
OPERATIONAL
WALKTHROUGH
NOVEMBER 2008

MONTH 3 VISIT
CLINIC FLOW

Presented By
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Blantyre Site

Administrative Nurse

- Confirm the participant's identity and PTID
 - In 035 we used the appointment card and link log to confirm PTID
 - We plan to use finger print technology as well for VOICE (this will also tell us if she has enrolled in FEM-PrEP and in future we can link the database to other studies conducted at the site)
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Research Nurse 1

- Check co-enrollment in other studies
 - Ask participant if she is taking part in any other study and explain the issues of co-enrollment
 - Explain procedures for the day
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Pharmacy

- Participant returns study product to pharmacy
 - Participant will be accompanied by a clinic staff member
 - Local form to be designed for pharmacy staff to record information on returned products as source for Product Returns and Dispensations Form
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Research Nurse 1

- Review previous visit documentation (Done while the participant is at the pharmacy)
 - Review elements of informed consent with participant as needed
 - Review locator information and update if there are changes
 - Administer Oral or Vaginal Product Adherence and Behavior Assessment form
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Research Nurse 2

- ACASI interview
 - To be done by a different nurse from the one who administered the Product Adherence and Behavior Assessment form
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Research Nurse 3

- HIV pre-test counseling, risk reduction counseling, and provision of condoms
- Blood specimen collection and HIV testing
 - Results recorded in clinic testing logs
- HIV post-test counseling
 - Provide referrals as needed and offer partner testing
 - Test results transcribed onto Follow-up HIV Rapid Test Results Form
- Remaining blood sent to lab for liver and renal function tests and plasma archive
 - LDMS Specimen Tracking Form completed for plasma archive
 - Collect information on date and time of last study gel application or last dose of each tablet for Specimen Storage/PK form

Research Nurse 3

- Urine specimen collection
 - Pregnancy testing
 - Record result in clinic testing log and transcribe result onto Follow-up Visit Form
 - Dipstick urinalysis for protein and glucose
 - If clinically indicated, dipstick urinalysis for nitrites and leukocyte esterase, provide treatment if needed
 - Record dipstick urinalysis results on clinic result form and transcribe results onto Safety Laboratory Results Form
 - Remaining urine to be refrigerated for possible gonorrhea and chlamydia testing
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Research Nurse 3

- Collect interval medical and menstrual history
 - Document on Participant-reported Follow-up Medical and Menstrual History form
 - If complaints raised, refer to clinician
- Collect information on current medications
 - Document on Concomitant Medications Log
- Provide contraceptive counseling and contraception
 - Document counseling on Contraception Flow Sheet
 - Document contraception on Contraceptive Medications Log
 - Complete Follow-up Family Planning Form

Research Nurse 4

- Physical examination including weight (document on Physical Exam form)
- If clinically indicated, conduct pelvic examination per the Follow-up Pelvic Exam Checklist (document findings on Pelvic Exam Diagram and Vaginal Test Results forms)
- Clinician will be called when abnormalities are noted
- If RTI/STI diagnosed, provide treatment and offer testing and treatment for partner
- Administer Hep B vaccine (if indicated)

Research Nurse 3/Clinician

- Assess eligibility to continue product use
 - If continuing with product, provide product use instructions, adherence counseling, and complete Study Product Request Slip
 - Schedule next visit and remind participant to bring unused study product
 - Remind participant about site contact information
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Pharmacy

- Participant to collect study product
 - Again, participant will be accompanied by a clinic staff member
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Administrative Nurse

- Targeted QC review of file
(To be done while the participant is at the pharmacy)
 - All issues requiring participant input to be resolved before she leaves the clinic
 - Provide transport reimbursement to participant
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After the Visit

- Completion of Remaining Forms
 - Product Returns and Dispensations
 - Rest of the Follow-up Visit Form
 - Specimen Storage/PK Form
 - Safety Lab Results Form
 - Other forms as needed
 - Complete QC of file
 - Faxing of Forms
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ANY QUESTIONS?

