



MTN 003

MONTHS 1 & 2 VISIT PRESENTATION

ZIMBABWE TEAM

JULIET MOYO – RESEARCH NURSE

MARTHA MASAWI - COUNSELLOR

CLINIC CLERK

- Greet participant. Create rapport
- Confirm PTID with Screening and Enrollment Log vs Participant's appointment card
- Check co-enrollment N.B If participant is not co-enrolled proceed
- If co-enrolled inform clinic manager → medical officer → IoR, immediately withhold study product use and seek assistance from the Protocol Safety Review Team (PSRT)

PHARMACY

- Greet participant
- Unused product supplies returned
- Check PTID and study product label

COUNSELLOR

- Verify participant's binder & review previous documentation
- Greet participant & assure confidentiality
- Review elements of the IC
- Explain the content and sequence of procedures for the day
- Review/ update locator information

RESEARCH NURSE

- Welcome and greetings
- Explain to participant procedures to be done
 - Urine collection
 - Questionnaire
 - Physical exam
 - Blood draw
- Collect urine for pregnancy test and urinalysis

Continued – RESEARCH NURSE

- Dipstick urinalysis for protein and glucose → Month 1 (Month 2 if clinically indicated).
- Dipstick urinalysis for nitrites and leukocyte esterase if clinically indicated.
- Negative pregnancy result → proceed
- Positive pregnancy result → inform clinic manager
 - Complete a pregnancy Report and History Form
 - Inform participant that she must stop product use and arrange to collect product supplies

Continued – Research Nurse

- Collect interval medical and menstrual history
- Administer monthly Product Adherence and Behavior Assessment form
- Document accordingly

COUNSELLOR

- Pretest HIV counselling
 - Aim is to prepare participant for any HIV test result.
 - Reassure confidentiality
 - Discuss basic facts about HIV and AIDS
 - HIV/STI risk reduction
 - Inform participant that results will be ready in about 20-40 minutes

RESEARCH NURSE

- Blood draw
 - Month 1
 - 1 x 5ml lavender top (ETDA) for HIV testing
 - 1 x 5 ml red top tube for LFTs and RFTs
 - Month 2
 - 1 x 5 ml lavender top (ETDA)
- Transcribe HIV Test results

N.B Verify results first before collection from lab

RESEARCH NURSE

- Perform and document physical exam and weight measurement → Month 1 (Month 2 if clinically indicated)
- If clinically indicated, perform and document pelvic exam per follow up pelvic exam checklist
- Provide and explain all available findings and results

Continued – Research nurse

- Contraceptive counselling and provide contraception per site SOP
- Provide treatment for STI for participant and partner if applicable
- Administer Hepatitis B vaccine if clinically indicated
- Complete AE log if required based on medical history, clinical examination and any results from the lab

Continued – Research Nurse

- Assess eligibility to continue product use
- If eligible, provide product request slip, offer adherence counselling
- If ineligible, complete study product request slip marked 'Hold' or 'Permanently Discontinued.' Check if unused product has been returned to pharmacy
- Remind participant to bring all unused study product supplies and any medication she is currently taking

COUNSELLOR

Post-Test & Adherence

Counselling

- Check if results are in the binder
- Call the participant and assure confidentiality
- Assess readiness to receive the HIV test results
- Inform participant and show her the result.
- If both tests are negative → proceed. Discuss the meaning of result including the window period.
- Discuss risk reduction and partner testing issues, condom use.
- Offer study product adherence counselling

COUNSELLOR - Continued

- Find out if she is using the study product correctly and consistently
- If there are any challenges on adherence, discuss how she can overcome them.
- Emphasise the importance of adhering to study product whilst in the study
- Inform participant to come back to the clinic if she has any symptoms and for more supplies
- Remind her to bring all unused product on next visit

COUNSELLOR – Continued

Positive Result

- Discuss meaning of results and implications to self, partner and family.
- Explore her feelings and address them accordingly.
- Inform participant that a WB test will be done on the same sample for confirmatory purposes.
- Inform her that she will stop product use and that she continues in the study.

COUNSELLOR – Continued

- Discuss positive living issues
 - Diet
 - Risk reduction
 - Health issues, psychological and physical
- Inform her that she is welcome for further counselling when needed. Offer condoms
- Inform clinic manager about the seroconversion

PHARMACY

- Product supply
- Adherence counselling based on product count
- Clinic manager informed if there are any challenging issues on adherence e.g. product sharing or selling before participant leaves the clinic

CLINIC CLERK

- Schedule next visit
- Complete registration Log
- Reimburse participant

- Thank You!
- Bayadhanki !
- Zi komo!
- Si yabonga!
- Mwebal e nnyo!
- Tatenda!

