MTN 003 SCREENING PART 1
PRESENTATION
JOHANNESBURG
LILONGWE SITE
12 NOVEMBER 2008
CLIENT FLOW

RECEPTION

• Welcome participant
• Confirm identity- confirm whether VOICE PTID was assigned before
• Determine screening attempt
• Check for co-enrollment
• Refer participant to the interview room
CLIENT FLOW

INTERVIEW ROOM

• Determine legal age of participant
• Obtain informed consent
• Assign PTID
• Obtain locator information
• Administer demographics form
• Administer screening part 1 eligibility form
• Refer exam room
CLIENT FLOW (cont’d)

EXAM ROOM

• Measure weight
• Collect urine and do PT
• Send urine to Lab for dipstick urinalysis and for GC and CT
• Refer participant to counseling room
CLIENT FLOW (cont’d)

COUNSELLING ROOM

- Provide HIV pre-test counseling
- Do risk reduction counseling
- Draw blood for HIV testing and remaining for CBC, Liver and renal function test, Hepatitis B surface antigen and antibody and Syphilis serology testing
CLIENT FLOW (cont’d)

COUNSELING ROOM

- Provide rapid HIV test results and post test counseling
- Transcribe rapid results onto screening and enrolment HIV test results forms
- Offer for HIV counseling and testing for partner
- Provide condom and refer to clinician
CLIENT FLOW (cont’d)

CLINICIAN

• Medical eligibility determination
• Disclosure of available results
• Treatment for STI/UTI if clinically indicated
• Refer for contraception if clinically indicated and back to reception room for review of visit and reimbursement
SPECIMENS

ADMINISTRATIVE

• Specimens requiring ASAP results will be immediately taken to Lab next door

• Tests will be run from Mondays to Friday, between 7:30am and 4:30pm and emergencies on weekends and public holidays
SPECIMENS (cont’d)

TRANSPORTATION AND TRACKING

- Transported to Lab in cooler boxes
- Specimen collection tracked through duplicate Lab request forms
SPECIMENS (cont’d)

TRANSPORTATION AND TRACKING

• In clinic pH and PT tracking logs
• Daily reconciliation of archived samples between Lab and clinic.
• Daily posting of results in the MTN 003 folder based in the Lab
SPECIMENS (cont’d)

QA/QC

• Daily monitoring of temperature in clinic

• Random selection and testing of samples by Lab staff - QA/QC monitoring

• Weekly positive and negative controls done in clinic, results documented in QC logs and reviewed monthly

• Monthly review of all in clinic logs by Lab personnel
STUDY PRODUCT

RANDOMIZATION

• Review randomization procedure with participant
• Assign next sequential envelope
• Open envelop in front of participant
• Complete prescription in front of participant
STUDY PRODUCT contd

• If Gel or tablets nurse escorts participant to pharmacy with prescription
• Duplicate remains in folder
• Product adherence counseling

PRODUCT EXCHANGE

• Continuous counseling
• Use of color coded ribbons
FORMS

• Locator
• Demographics
• Screening Part 1 Eligibility
• Safety Laboratory Results
• STI Laboratory results
• Screening and Enrollment HIV Test Results