

VOICE

Screening Part 2 Visit

Operational Walkthrough
Johannesburg, South Africa
November 2008

Before the Visit

- Complete initial QC/QA review of visit documentation
- Receive, review, grade, and assess the clinical significance of Screening Part 1 lab test results
- Assess eligibility based on lab test results
- Assess Hepatitis B status
- Assess clinical management and referral needs
- Transcribe lab test results onto case report forms
- Document all review and action steps
- Complete additional QC/QA and eligibility reviews

Hepatitis B Status

- HBsAg+ and HBsAb–
 - Not eligible for study
 - Counsel and refer
- HBsAg- and HBsAb–
 - “Susceptible”
 - Offer vaccine if enroll
- HBsAg- and HBsAb+
 - Not susceptible
 - Vaccine not indicated

Protocol Requirements

- Administrative, Behavioral, and Regulatory Procedures
 - Participant identification
 - Check for co-enrollment in other studies

Protocol Requirements

- Administrative, Behavioral, and Regulatory Procedures
 - Behavioral eligibility information
 - Locator information
 - HIV post-test counseling (if indicated)
 - HIV/STI risk reduction counseling
 - Offer HIV counseling and testing for partners
 - Provision of condoms
 - Reimbursement
 - Schedule next visit (if applicable)

Protocol Requirements

- Clinical Procedures
 - Medical and menstrual history
 - Current medications
 - Urine collection
 - Weight
 - Height
 - Physical exam
 - Pelvic exam

Physical Exam Components

- Vital Signs
 - Oral temperature
 - Blood pressure
 - Pulse
 - Respirations
- Height
- Weight
- Clinical assessments of
 - Head and eyes
 - Ears, nose, and throat
 - Neck
 - Lymph nodes
 - Heart
 - Lungs
 - Abdomen
 - Extremities
 - Neurological
 - Skin
 - Breasts

Pelvic Exam Components

- Visual inspection of external genitalia, vagina, and cervix per WHO/CONRAD Manual
- Vaginal pH
- Vaginal fluid swabs for
 - Gram stain assessment at MTN NL
 - Trichomonas rapid test
 - BV rapid test *if clinically indicated*
 - KOH wet prep for candidiasis *if clinically indicated*
 - Biomarker analyses at the MTN NL
- Endocervical swab for biomarker analyses at the NL

Pelvic Exam Components

- Ecto- and endocervical cells for Pap smear
 - At sites where Pap smears are standard of care and where cytopathology and referral services for dysplasia are available
 - Not required if documented normal Pap result within the 12 months prior to enrollment
- Bimanual exam

Protocol Requirements

- Clinical Procedures
 - Blood collection if clinically indicated
 - Disclosure of available test results
 - Treatment for UTI/STI/RTI if clinically indicated
 - Offer of STI testing and treatment for partners if indicated
 - Contraceptive counseling
 - Provision of contraception if indicated per site SOP

Operational Considerations

- Clinical Procedures
 - Time/intensity of clinical procedures, especially baseline medical and menstrual history

Protocol Requirements

- Laboratory Procedures
 - Urine pregnancy test
 - Dipstick urinalysis if clinically indicated
 - Clinical indications include urinary symptoms at Screening Part 2 and detection of protein or glucose at Screening Part 1

Protocol Requirements

- Laboratory Procedures
 - Urine SDA for gonorrhea and chlamydia *if clinically indicated*
 - Syphilis serology *if clinically indicated*

Protocol Requirements

- Laboratory Procedures
 - Prepare and store Gram stain slides and swabs for biomarker analyses
 - Trichomonas rapid test
 - BV rapid test *if clinically indicated*
 - KOH wet prep for candidiasis *if clinically indicated*
 - Pap smear interpretation if applicable

Operational Considerations

- Laboratory Procedures
 - Coordination of clinic and lab
 - Days and hours of operation
 - Transporting and tracking specimens
 - Tracking result reports
 - Monitoring temperature and maintaining QC/QA for tests performed in clinic
 - Turnaround time for pelvic specimen testing and archive (freezing)

Operational Considerations

- Laboratory Procedures
 - Tracking dipstick urinalysis results across screening and enrollment visits
 - If 2+ or greater for protein or glucose at this visit ⇒ INELIGIBLE
 - If 1+ for protein at this visit and 1+ for protein at Screening Part 1 ⇒ INELIGIBLE
 - If 1+ for glucose at this visit and 1+ for glucose at Screening Part 1 ⇒ INELIGIBLE
 - If 1+ for protein at this visit and normal or trace for protein at Screening Part 1 ⇒ repeat at Enrollment Visit
 - If 1+ for glucose at this visit and normal or trace for glucose at Screening Part 1 ⇒ repeat at Enrollment Visit

Operational Considerations

- Scheduling next visit
 - 56-day screening and enrollment period
 - Number of Enrollment visits that can be scheduled on any one day
 - Time required to receive Pap result and any other clinically indicated lab test results
 - Current UTI/STI/RTI symptoms / time to resolution following treatment
 - Any other current exclusionary conditions / time to resolution
 - Continue current screening attempt?

Sequence of Procedures

- Pelvic exam procedures must be performed in the order shown on Screening Pelvic Exam Checklist
- Order procedures for maximum screening efficiency — perform procedures with highest expected screen-out rate first — and minimum waiting time during visit
- Stop when participant found to be ineligible

What are
your questions?

Questions for Site Input

- What study information materials would you provide to potentially eligible participants at the Screening Part 2 visit?
- Would you spend time explaining/discussing these materials at the Screening Part 2 visit, or wait until the Enrollment Visit?