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?