VOICE
Month 3 and Quarterly Visits

Operational Walkthrough
Johannesburg, South Africa
November 2008
Looks very similar to the...

Month 1 Visit
Protocol Requirements

- **Administrative, Behavioral, and Regulatory Procedures**
  - Participant identification
  - Check for co-enrollment in other studies
  - Locator information
  - Behavioral and study product adherence assessment (CRF & ACASI)
  - Study product sharing assessment (CRF & ACASI)
  - Intravaginal practices assessment (ACASI)
  - Social harms assessment (CRF)
Protocol Requirements

• Administrative, Behavioral, and Regulatory Procedures
  – HIV pre- and post-test counseling
  – HIV/STI risk reduction counseling
  – Offer of HIV counseling and testing for partners
  – Provision of condoms
  – Provision of study product supplies, instructions, and adherence counseling
  – Reimbursement
  – Schedule next visit
What is different from a regular monthly visit?

- Different behavioral and adherence assessment CRFs
- Study product sharing assessment
- Intravaginal practices assessment
- Social harms assessment
Protocol Requirements

• **Clinical Procedures**
  – Interval medical and menstrual history
  – Current medications
  – Contraceptive counseling
  – Provision of contraception if indicated
  – Physical exam + weight
  – Pelvic exam *only if clinically indicated*
  – Urine collection
  – Blood collection
Blood Collection
(approximate volumes)

• 1 x 10 mL lavender top (EDTA)
• 1 x 5 mL lavender top (EDTA)
• 1 x 5 mL red top (no additive)
Protocol Requirements

• Clinical Procedures
  – Disclosure of available test results
  – Treatment for UTI/STI/RTI if clinically indicated
  – Offer of STI testing and treatment for partners if indicated
  – Hepatitis B vaccination if indicated
What is different from a regular monthly visit?

• Physical exam + weight
Protocol Requirements

• **Laboratory Procedures**
  – Urine pregnancy test
  – Dipstick urinalysis for protein and glucose
  – Dipstick urinalysis for nitrites and leukocyte esterase *only if clinically indicated*
  – HIV serology
  – Serum chemistries: AST, ALT, phosphate, creatinine
  – Plasma archive
Protocol Requirements

- Other lab procedures that may be done if clinically indicated
  - Tests and specimen archive associated with pelvic exams
  - Urine SDA for gonorrhea and chlamydia
  - Syphilis serology
  - Complete blood count with differential and platelets
  - Hepatitis B tests (surface antigen, surface antibody)
What is different from a regular monthly visit?

- **Dipstick urinalysis for protein and glucose**
- **Serum chemistries** (AST, ALT, phosphate creatinine)
- **Plasma archive**
What is the quarterly plasma archive used for?
Is there really no pelvic exam at quarterly visits?

• Yes, really!

• Pelvic exams are required
  – Semi-annually
  – At PUEV
  – And when clinically indicated

• Let’s review the follow-up pelvic exam components ...
Pelvic Exam Components

• Palpate inguinal lymph notes
• Inspect external genitalia
• Insert speculum
• Vaginal pH – at all exams
• Vaginal fluid swab for Gram stain slides (stored) – at all scheduled exams
• Vaginal fluid swab for BV rapid test – only when clinically indicated
• Vaginal fluid swab for KOH wet mount for candidiasis – only when clinically indicated
Pelvic Exam Components (cont)

- Vaginal fluid swab for trichomomas rapid test – annually and when clinically indicated
- Vaginal fluid swab stored for biomarker analyses at the MTN NL – at all exams
- Endocervical fluid swab stored for biomarker analyses at the MTN NL – at all exams
- Inspect cervix and vagina
- Ecto- and endocervical cells for Pap smear – at PUEV and when clinically indicated
- Bimanual exam
What are your questions?