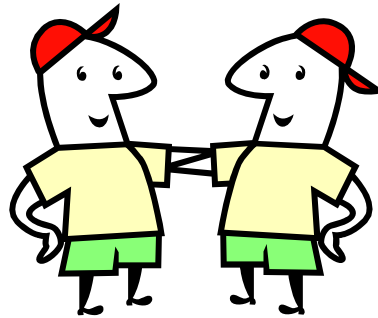


VOICE

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)

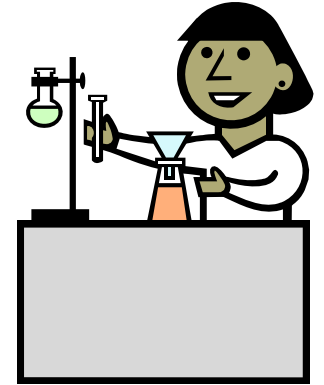
Protocol Requirements

- 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 nodes
- 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 trichomonas 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?