Overview of the Integration of Clinical and Lab Procedures at the RHRU Site:

Nurses Perspective

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Outline

- Staff Competency
- Integration of lab testing procedures with clinical procedures
- Oversight
- Advantages and Disadvantages – Nurses Perspective
Pre-requisite Competency training

- World Courier
  - International Air Transport Association (IATA) Training

- Contract Laboratory Services (CLS) training
  - Good Clinical Laboratory Practice (GCLP) CLS training
    - Lab Safety training
    - Universal Precautions
    - Material Safety Data Sheets (MSDS)
  - Phlebotomy Training – Volume of Samples drawn
  - Health and Safety Training
Pre-requisite Competency training

- MTN-003 specific laboratory tests
  - Deemed Competent for the following:
    - Pregnancy Rapid Testing
    - Urine Dipstick
    - HIV Rapid Testing (Determine, Unigold, Oraquick) - Validation
    - Rapid *Trichomonas vaginalis* (TV) Testing
    - Rapid *Bacterial vaginosis* (BV) Testing
    - Microscopy training

- MTN Network Lab
  - KOH Wet Mount Testing – Online Proficiency Testing

- College of American Pathologists (CAP) Panels
  - CAP Schedule

- On-site training
  - Use of photomicroscope – KOH Wet Mount
  - Use of micropipettes
Integration of Lab, Clinical, Counselling and Sample Shipping Procedures

- Performed by Research Nurses

  - Lab and Clinical Stock Control
    - Inventory
    - Ordering

  - Benefits of greater understanding of timing of lab procedures
    - Urine collection timing
    - Separation of sample for hCG, dipstick, SDA – related to contamination reduction and reduce false positive results
Integration of Lab, Clinical, Counselling and Sample Shipping Procedures

- Performed by Research Nurses
  - Continuum of care - HIV counseling and testing by same nurse
    - Pre and post test counselling
    - Counselling and testing conducted per SOP
  - Pelvic exam and specimen collection is done by 2 nurses.
    - Nurse 1 labels, packages and ships to relevant laboratory as per SOP.
    - Nurse 2 completes CRF’s and lab logs, Nurse 1 reviews and countersigns for the procedures
Oversight: Quality Control and Quality assurance

- **Lab Quality Management (LQMP)**
  - **Quality Control (QC)**
    - Daily and Weekly QC of on-site tests – commercial controls
    - Daily dual/triple confirmation of results of lab tests
  - **Quality Assurance (QA)**
    - PI, Regulatory Compliance Officer (RCO) or authorized person.
      - 100% QA performed by RCO on all lab logs at the end of each month.

- **External Quality Assurance (EQA)**
  - Sending every 20th and/or last monthly HIV and pregnancy specimen to CLS
  - CAP Panel
  - External quarterly lab monitoring by Pharmaceutical Product Development (PPD) in accordance with DAIDS SOP
Oversight: Quality Control and Quality assurance

- Continuous Lab and clinical SOP training
  - Revision of package inserts

- Data Clarification Form (DCF) Resolution with outsourced labs – BARC/CLS

- Competency based training for all new staff and Refresher trainings
Nurses views on the lab involvement

- Disadvantages
  - Participant gets irritable due to time with one staff member
  - Requirement to leave ppt unattended – Wet mount in site lab
  - Duration of visit was lengthened
  - Requires other nurses to be available for second and third QC – delays result disclosure
  - More paper work e.g. completion of logs
  - Fatigue

- Motivation for employment of Medical Technologists
Nurses views on the lab involvement

- Advantages
  - Insight and experience was gained
    - Proficient in conduct of lab tests
    - Skill set broadened
  - Participants personally saw the results and readily accepted them
    - No risk of sample mix-up as seeing one ppt at a time
    - Real time testing - Reduction in time delay to a ppt receiving result
Thank You!