

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



Nurses Perspective

Lebogang Modise (Dip. in Nursing)

Clinical Trial Nurse

MTN 003 Regional Meeting

Cape Town, South Africa

06 October 2010



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!