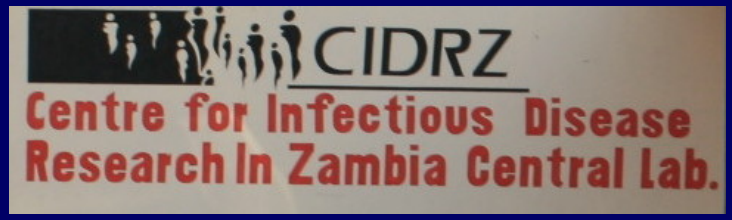
OVERVIEW OF MTN 015 AND LESSONS LEARNED

Peter Mutale

MTN Study Laboratory Supervisor

October 2009



- A pioneer non-governmental organization in HIV research and training
- CIDRZ work extends to other infectious diseases – e.g. TB
- Three arms of CIDRZ:
  - Training
  - Research
  - Service

CIDRZ

TRAINING

- Training health providers in HIV care
- Training in HIV treatment
- Training in HIV/TB care and treatment
- Research Methodology and Management [interns and medical licentiates]

CIDRZ

RESEARCH

- ACTG
- IMPAACT
- Viral Load
- MTN

CIDRZ

SERVICE

- PMTCT – In partnership with the Zambian Ministry of Health to reduce HIV infection to new born infants.
- ART – In partnership with the Zambian Ministry of Health to provide ART
- TB – Management of TB/HIV co-infection

FOCUS FOR DISCUSSION

CIDRZ RESEARCH

MTN 015 – Protocol under discussion

- Chain of custody
- Challenges
- Solution process
- Lessons learned
- Successes to be maintained

THE CHAIN OF CUSTODY

- The satellite laboratory (AKA “sat-lab”) receives samples from the clinic examinations rooms.
- The sat-lab technologists inspect the specimens to ensure that the samples are of good quality, adequate quantity, collected in right containers, correctly and clearly labeled.

THE CHAIN OF CUSTODY

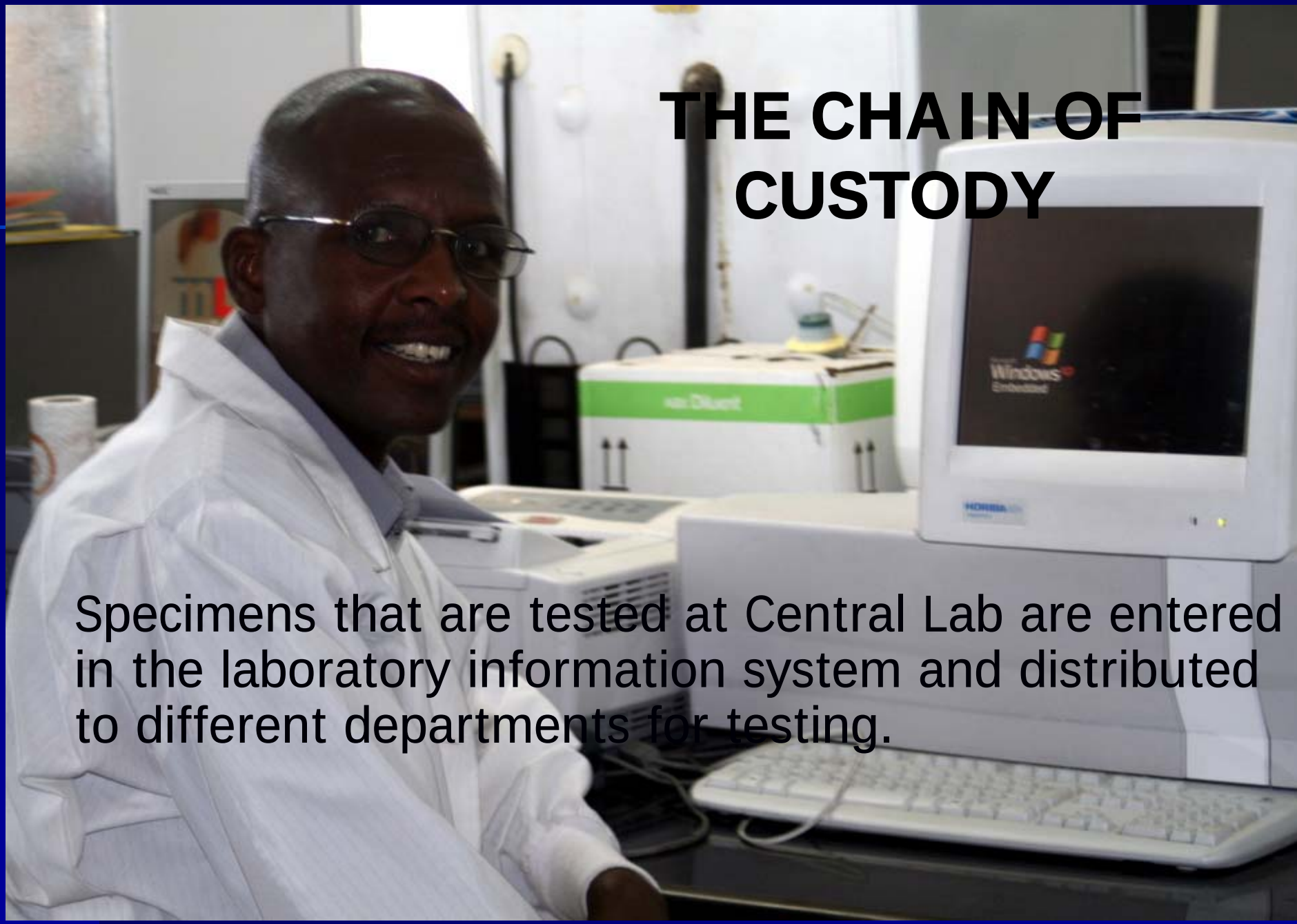
- Sat-lab techs will sign the clinical examination room report form (CER) when they are sure that everything is done according to the protocol.
- All samples are listed on transport log and then stored at appropriate temperature until transport.
- Transport of specimens occurs twice a day.

THE CHAIN OF CUSTODY

- The tests that are performed at sat-lab:
  - ❖ RPR
  - ❖ Wet mount preparation
- Specimen that are referred to central lab for testing:
  - ❖ CBC
  - ❖ CD4
  - ❖ LFT
  - ❖ RFT
  - ❖ Viral Load
  - ❖ TPHA
  - ❖ GC and CT
- Specimen are referred to central lab for storage.

THE CHAIN OF CUSTODY

At central lab all specimens are checked to insure that they have been transported at the correct temperature, are properly labeled, are of good quality and quantity for required testing.



THE CHAIN OF CUSTODY

Specimens that are tested at Central Lab are entered in the laboratory information system and distributed to different departments for testing.

THE CHAIN OF CUSTODY

- Specimens for storage are entered into laboratory data management systems and stored in the -80 freezers.

John Mwale, Archivist

CHALLENGES

The study faced a lot of challenges at inception mainly due transitions ranging from the changing of stuff, lack of understanding the protocol, etc.

The following are some of the specific challenges that were faced.

CHALLENGES

- The satellite lab technologists indicated the number of aliquots on the satellite laboratory report before the actual aliquots were made. As a result there were discrepancies between the actual number of aliquots and the number indicated on the satellite laboratory report.

CHALLENGES

- Sat-lab techs made fewer aliquots than the minimum required by the protocol.
- Sat-lab techs also made wrong volumes of aliquots
- Nurses drew smaller volumes of blood than allowed, making it difficult for sat-lab techs to make the correct number of aliquots

CHALLENGES

At Central Lab, the study specific laboratory assistants ordered the wrong tests in LIS.

The laboratory assistants also entered wrong volumes of aliquots in the LDMS.

Solution process

- Held a process improvement meeting in which we went through every step of a participant's visit: from specimen collection to the clinic receiving lab results. Areas of improvement were identified.
- Conducted retraining for sat-lab techs in areas were they did not understand well.

Solution process

- We performed “100% QC” process which went through all the documentation since the start of the study to check for errors. We reviewed all sample information that was entered into LIS to identify errors so as to clean the data by putting all necessary corrective documentation in place.

Solution process

Checked through all the specimens in storage and errors identified were corrected.

All the documentation was cc'ed to the network laboratory depending on the nature of the error.

Solution process

We have documented all errors that occurred and put the corrective action in place for those errors that had the verifiable source.

For those errors that had no verifiable source, we wrote memos to file and maintained the original documentations.

LESSONS LEARNED

- We have learned that the number of aliquots should only be indicated on the sat-lab report after the actual aliquots have been made.
- We cannot assume that one or two trainings before starting a protocol is adequate.

LESSONS LEARNED

- We have learned to keep constant communication between the sat-lab techs and the study laboratory supervisor so that issues that concern the protocol are clarified.
- Technologists have learned to consult the nurses on any issues so that things like collection of smaller volumes of blood are addressed.

LESSONS LEARNED

- We have learned to always consult the SSP manual so that procedures are performed accordingly.
- We have also learned that a second person should always verify specimens ordered in LIMS and entered in the LDMS, especially when the regular staff is on leave.

LESSONS LEARNED

We have found that putting aliquots with the same volume into separate specimen bags with the aliquot volume clearly marked on the bag helps to avoid errors when putting them into LDMS and then in the freezers.

LESSON LEARNED

- Our QC performance has improved if each person carefully reviews their own work, ensures correct PTIDs, collection dates and correct lab requests are made.
- Better identify errors, omissions and fix them before requests are entered into the LIMS and LDMS.

LESSONS LEARNED

- It is always important to help each other to perform better.
- QC improvement is an on going process

LESSONS LEARNED

- We can consistently keep the error rate low by logging the storage samples in LDMS as they are received.
- We must continue to do this as this is a good marker for our quality system.

LESSONS LEARNED

- With all lessons learned, we are very optimist that this information will help us in the future research studies.

SUCCESS THAT WE WILL ENDVOUR TO MAINTAIN

- Low rates or if possible eliminate LDMS queries/errors
- Effectiveness and efficiency in everything that we do
- Quality lab results being sent out within turn-around-time
- Being specific and thorough in what we do in all areas in the lab.

SUCCESS THAT WE WILL ENDVOUR TO MAINTAIN

- Continue to improve communication between the study clinic, satellite lab and our central laboratory.
- Continue to improve the work process by constantly identifying the areas for quality improvement.

THANKS for your time!

Any Questions???