

WITS RHI GENEXPERT EXPERIENCE

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2017

MTN Lab Breakout
Session



University of the Witwatersrand

WITS RHI

Background

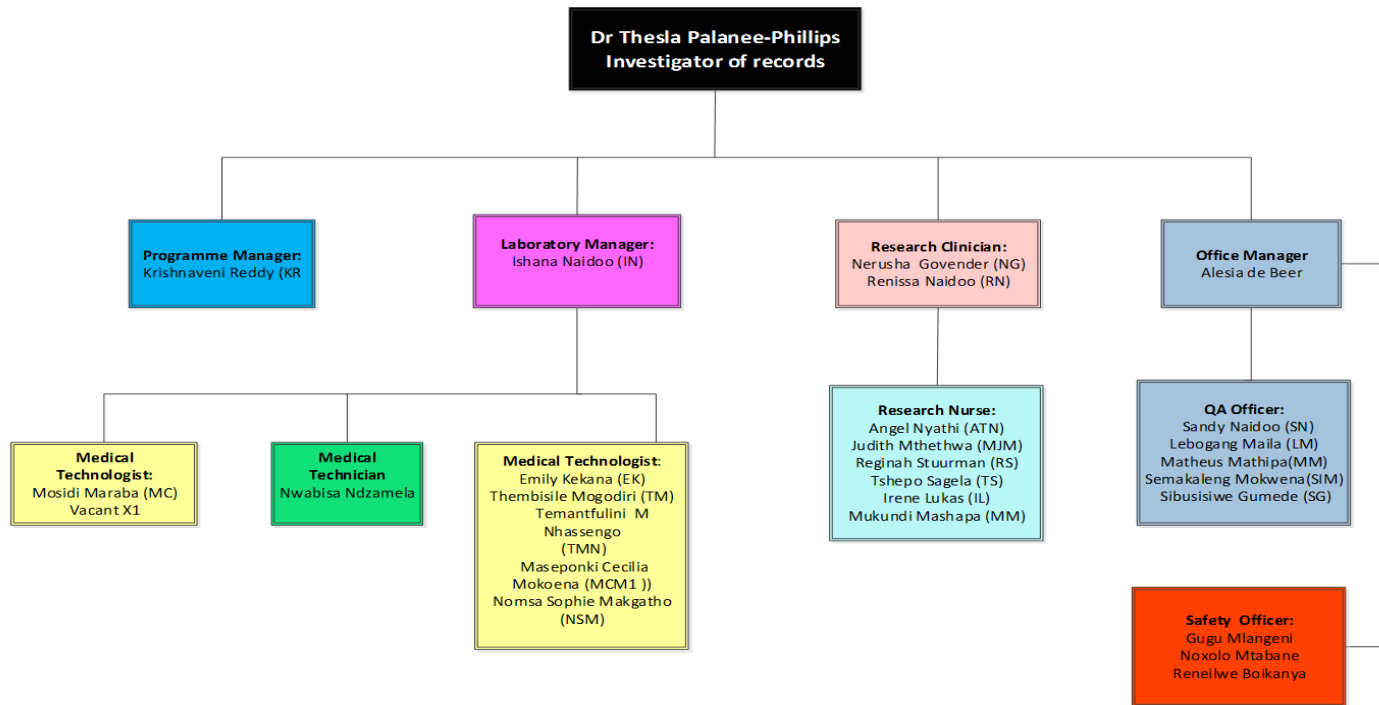
- Early in 2016 , the Wits RHI laboratory oversight group (LOG) embarked on an expansion initiative with the intention to build site capacity to conduct on-site testing for STIs.
- GeneXpert was identified as one of the technologies that would be relevant for set –up.
- An internal organizational inventory review lead to identification of 4 GeneXpert instruments in storage.
 - These were previously used for the TB program so no costs were incurred to purchase instruments.
- Cepheid - evaluated instruments and completed setup.
- Two adjacent clinical rooms were renovated to house the new equipment.
- Calibration and set up of 2 instruments were completed in June 2016.

Validation pathway

- Target Analytes :
GC/CT , HIV Viral load , HPV and TV
- Thus far we have completed validation on
 - GC/CT (N=47)
 - HIV Viral Load (approved for MTN 025 testing).
- EQA - VQA for Viral load
 - CAP HC-7 Panel for GC/CT

Lab Organogram

Wits Reproductive Health and HIV Institute
Lab Organogram



- Director
- Medical Technician
- Medical Technologist
- Office Managers, QA Officer
- Medical Technologist,
- Research Nurse
- Clinician
- Safety Officers
- Counsellors

RC ORG 001
 Edition: 01
 DRAFT under review

Wits RHI GeneXpert Bench Team



Lessons learnt

- GC/CT : Sourcing validation samples was a challenge, we gained permission from the ECHO study to use residual sample.
- Very few positives this posed a challenge with the sample size.
- Sample size - 47 (10 GC positive , 22 CT positive).
- HIV Viral load – We acknowledge and are grateful for the assistance from the MTN Laboratory Centre with providing validation samples to complete this validation.
- Lab staff were all new to this technology , however with support and training from Cepheid we achieved competency .

Experience thus far

- Currently we are processing:
 - GC/CT: ≈ 60 Urine samples per month
 - HIV -1 Viral load: ≈ 20 samples per month
- CPU issue - The CPU required replacing . Issue was related to storage over a long period.
- We have had a few sample rejections for the VL assay (6 Invalid samples). Possibly due to poor pipetting.
- Outsourced lab experience : We had a number of our ECHO study GC/CT swab samples rejected on the BARC GeneXpert . BARC has indicated that this is related to mucoid vaginal swab samples. The ECHO study has requested repeating these samples on the Abbott.

Wits RHI Studies

RESEARCH CENTRE CRS	WARD 21 CRS
MTN 025/HOPE	HPTN 082
MTN 015	CHOICES
ECHO + ECHO Ancillary	EMPOWER
TRANSFORM	HPTN 084(Pending start-up)
HPTN 081/AMP	
MTN034/REACH (Pending start-up)	

Note : Red Font - These studies are using the GeneXpert.

Acknowledgment

- MTN LC for their continued support.
- ECHO Study for approving use of residual samples.
- Dr Thesla Palanee – Phillips
- WITS RHI laboratory team and Laboratory Oversight Group (LOG).
- BARC Laboratory .