NATIONAL HEALTH LABORATORY SERVICE

# GeneXpert MTB/RIF

## Progress Report

October 2013

NATIONAL HEALTH LABORATORY SERVICE

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Disclaimer: This is a dynamic dataset requiring regular updating and although correct in the vast majority cases, the reader should be aware that the figures reported can change slightly as the linkages are updated

## 1. Background to Project

This project was initiated at the request of the Honorable Minister of Health, Dr Aaron Motsoaledi, in early 2011, following the World Health Organization's strong recommendation published in December 2010 which stated that "the new automated DNA test for TB be used as the initial diagnostic test in individuals suspected of MDR-TB or HIV/TB". In essence this comprises the majority of TB suspects in South Africa. A pilot study was proposed by the TB Cluster within the National Department of Health (NDoH) while a project feasibility study was being performed with due diligence.

The pilot study was initiated in microscopy centres. The NDoH requested that at least 1 instrument be placed in each province, preferably in high burden districts. Selections were made by the TB cluster, with twenty-five microscopy centres being selected and a total of 30 instruments placed.

The NDoH funded 9 GX16 and 14 GX4 instruments for the project. FIND (The Foundation for Innovative New Diagnostics) donated 6 GX4 analysers and the Infinity or GX48 was supported by PEPFAR Right to Care funds. All instruments were placed by World TB day March 24 2011. This placement represented about 10% of national coverage. The basis for the calculations was an assumption that 2 smears at diagnosis would be replaced by 1 Xpert® MTB/RIF assay. All instruments were interfaced to the NHLS Laboratory Information System (LIS) allowing for troubleshooting and data collection.

Since then, 283 GeneXpert instruments of varying sizes (GX4: 95; GX16:186; GX48: 1; GX80:1) have been placed in 207 sites – both urban and rural settings, by the National Priority Programmes of the NHLS and the NDoH, the progress of which is described in point 6 below.

## 2. Assays performed to date

In summary, a total of 2,144,333 specimens have been processed to date (31 October 2013). In October 166,366 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 11.63% (19,341). As a reflection of Xpert MTB/RIF's superior sensitivity over microscopy, the average national TB positivity rate among suspects was found to be

8% using microscopy but up to 16-18% in the first year and 13-14% in the second and third year, after introduction of Xpert® MTB/RIF assay. To date Kwa-Zulu Natal (KZN) has performed the greatest number of tests which is probably as a result of the number of instruments placed (refer to tables 1 & 2). Average Rifampicin resistance detection rates have remained around 7% since project inception (Refer to tables 3 & 4).

**Table 1: GeneXpert MTB Results by province (cumulative)**

| Province | Year | MTB Detected | MTB Not Detected | Test Unsuccessful | Total | % MTB Detected |
|---|---|---|---|---|---|---|
| Eastern Cape | 2011 | 3 296 | 15 413 | 555 | **19 264** | **17.11** |
| Eastern Cape | 2012 | 16 040 | 85 575 | 2 892 | **104 507** | **15.35** |
| Eastern Cape | 2013 | 35 468 | 249 903 | 8 218 | **293 589** | **12.08** |
| Free State | 2011 | 2 844 | 14 831 | 33 | **17 708** | **16.06** |
| Free State | 2012 | 11 631 | 77 087 | 280 | **88 998** | **13.07** |
| Free State | 2013 | 12 146 | 116 454 | 1 035 | **129 635** | **9.37** |
| Gauteng | 2011 | 3 049 | 18 727 | 424 | **22 200** | **13.73** |
| Gauteng | 2012 | 10 960 | 72 349 | 2 267 | **85 576** | **12.81** |
| Gauteng | 2013 | 23 806 | 168 153 | 6 570 | **198 529** | **11.99** |
| Kwa-Zulu Natal | 2011 | 12 226 | 45 944 | 1 729 | **59 899** | **20.41** |
| Kwa-Zulu Natal | 2012 | 24 446 | 138 967 | 6 116 | **169 529** | **14.42** |
| Kwa-Zulu Natal | 2013 | 34 155 | 238 081 | 13 623 | **285 859** | **11.95** |
| Limpopo | 2011 | 1 975 | 17 261 | 172 | **19 408** | **10.18** |
| Limpopo | 2012 | 3 993 | 30 710 | 688 | **35 391** | **11.28** |
| Limpopo | 2013 | 11 161 | 157 344 | 5 326 | **173 831** | **6.42** |
| Mpumalanga | 2011 | 2 639 | 12 763 | 1 107 | **16 509** | **15.99** |
| Mpumalanga | 2012 | 4 044 | 21 959 | 1 118 | **27 121** | **14.91** |
| Mpumalanga | 2013 | 7 728 | 46 563 | 1 908 | **56 199** | **13.75** |
| North West | 2011 | 3 476 | 14 887 | 657 | **19 020** | **18.28** |
| North West | 2012 | 5 174 | 29 005 | 1 976 | **36 155** | **14.31** |
| North West | 2013 | 9 974 | 76 885 | 4 117 | **90 976** | **10.96** |
| Northern Cape | 2011 | 2 864 | 16 117 | 735 | **19 716** | **14.53** |
| Northern Cape | 2012 | 4 440 | 23 653 | 1 192 | **29 285** | **15.16** |
| Northern Cape | 2013 | 6 524 | 42 922 | 2 220 | **51 666** | **12.63** |
| Western Cape | 2011 | 2 204 | 10 093 | 31 | **12 328** | **17.88** |
| Western Cape | 2012 | 13 202 | 68 428 | 596 | **82 226** | **16.06** |
| Western Cape | 2013 | 25 454 | 137 681 | 2 515 | **165 650** | **15.37** |
| **Total** | | **294 919** | **1 947 755** | **68 100** | **2 310 774** | **12.76** |

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**Table 2: GeneXpert MTB Results by province (01-31 October 2013)**

| Province | MTB Detected | MTB Not Detected | Test Unsuccessful | Total | % MTB Detected |
|---|---|---|---|---|---|
| Eastern Cape | 3 713 | 27 568 | 788 | **32 069** | **11.58** |
| Free State | 1 220 | 11 198 | 117 | **12 535** | **9.73** |
| Gauteng | 2 900 | 18 864 | 516 | **22 280** | **13.02** |
| Kwa-Zulu Natal | 4 279 | 31 131 | 1 210 | **36 620** | **11.68** |
| Limpopo | 1 168 | 15 869 | 390 | **17 427** | **6.70** |
| Mpumalanga | 1 075 | 6 758 | 214 | **8 047** | **13.36** |
| North West | 1 146 | 9 103 | 414 | **10 663** | **10.75** |
| Northern Cape | 625 | 4 528 | 178 | **5 331** | **11.72** |
| Western Cape | 3 215 | 18 012 | 167 | **21 394** | **15.03** |
| **Total** | **19 341** | **143 031** | **3 994** | **166 366** | **11.63** |

**Table 3: Provincial GeneXpert RIF Results in MTB detected cases (01-31 October 2013)**

| Province | Inconclusive | Resistant | Sensitive | No Rif Result | Total | % RIF Resistant |
|---|---|---|---|---|---|---|
| Eastern Cape | 146 | 250 | 3 311 | 6 | **3 713** | **6.73** |
| Free State | 23 | 55 | 1 138 | 4 | **1 220** | **4.51** |
| Gauteng | 154 | 174 | 2 562 | 10 | **2 900** | **6.00** |
| Kwa-Zulu Natal | 130 | 372 | 3 693 | 84 | **4 279** | **8.69** |
| Limpopo | 16 | 47 | 1 096 | 9 | **1 168** | **4.02** |
| Mpumalanga | 18 | 103 | 953 | 1 | **1 075** | **9.58** |
| North West | 32 | 70 | 1 044 | | **1 146** | **6.11** |
| Northern Cape | 17 | 48 | 560 | | **625** | **7.68** |
| Western Cape | 69 | 159 | 2 987 | | **3 215** | **4.95** |
| **Total** | **605** | **1 278** | **17 344** | **114** | **19 341** | **6.61** |

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**Table 4: Provincial GeneXpert RIF Results in MTB detected cases (cumulative)**

| Province | Year | Inconclusive | Resistant | Sensitive | No RIF Result | Total | % RIF Resistant |
|---|---|---|---|---|---|---|---|
| | 2011 | 33 | 251 | 2958 | 53 | **3 295** | **7.62** |
| | 2012 | 213 | 1096 | 14597 | 134 | **16 040** | **6.83** |
| Eastern Cape | 2013 | 1054 | 2364 | 31920 | 130 | **35 468** | **6.67** |
| | 2011 | 28 | 154 | 2661 | 1 | **2 844** | **5.41** |
| | 2012 | 162 | 736 | 10707 | 26 | **11 631** | **6.33** |
| Free State | 2013 | 339 | 681 | 11107 | 19 | **12 146** | **5.61** |
| | 2011 | 25 | 174 | 2849 | 1 | **3 049** | **5.71** |
| | 2012 | 135 | 760 | 9995 | 70 | **10 960** | **6.93** |
| Gauteng | 2013 | 757 | 1540 | 21461 | 48 | **23 806** | **6.47** |
| | 2011 | 107 | 923 | 11134 | 62 | **12 226** | **7.55** |
| Kwa-Zulu | 2012 | 434 | 2207 | 21553 | 252 | **24 446** | **9.03** |
| Natal | 2013 | 925 | 2984 | 29953 | 293 | **34 155** | **8.74** |
| | 2011 | 25 | 148 | 1777 | 25 | **1 975** | **7.49** |
| | 2012 | 52 | 267 | 3599 | 75 | **3 993** | **6.69** |
| Limpopo | 2013 | 272 | 588 | 10197 | 104 | **11 161** | **5.27** |
| | 2011 | 31 | 210 | 2392 | 6 | **2 639** | **7.96** |
| | 2012 | 57 | 407 | 3504 | 76 | **4 044** | **10.06** |
| Mpumalanga | 2013 | 187 | 792 | 6727 | 22 | **7 728** | **10.25** |
| | 2011 | 40 | 304 | 3128 | 4 | **3 476** | **8.75** |
| | 2012 | 66 | 390 | 4704 | 14 | **5 174** | **7.54** |
| North West | 2013 | 254 | 563 | 9128 | 29 | **9 974** | **5.64** |
| | 2011 | 28 | 197 | 2637 | 2 | **2 864** | **6.88** |
| | 2012 | 64 | 273 | 4093 | 10 | **4 440** | **6.15** |
| Northern Cape | 2013 | 157 | 356 | 5724 | 287 | **6 524** | **5.46** |
| | 2011 | 15 | 106 | 2082 | 1 | **2 204** | **4.81** |
| | 2012 | 150 | 657 | 12393 | 2 | **13 202** | **4.98** |
| Western Cape | 2013 | 618 | 1288 | 23547 | 1 | **25 454** | **5.06** |
| **Total** | | **6 228** | **20 416** | **266 527** | **1 747** | **294 918** | **6.92** |



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## 3. Rif Condordance

Rifampicin concordance is good for both LPA and culture. The data is skewed by reporting the GeneXpert immediately, but still have to wait for MGIT and LPA results.

**Table 5: Rif Concordance by LPA or DST**

| Province | Rif Resistant Cases | GeneXpert Confirmation & Rif Concordance | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Cultures | | | | | LPA | | | | |
| | | Confirmed | | Rif Concordance | | Pre-analytical | Confirmed | | Rif Concordance | | Inderterminate |
| | | # | % | # | % | | # | % | # | % | |
| EC | 3 814 | 186 | 4.9% | 109 | 58.6% | 0 | 648 | 17% | 588 | 90.7% | 2 |
| FS | 1 476 | 78 | 5.3% | 38 | 48.7% | 0 | 342 | 23% | 233 | 68.1% | 57 |
| GP | 2 765 | 99 | 3.6% | 76 | 76.8% | 0 | 425 | 15% | 364 | 85.6% | 7 |
| KZN | 5 318 | 1 227 | 23.1% | 1 140 | 92.9% | 0 | 1 247 | 23% | 981 | 78.7% | 40 |
| LP | 998 | 74 | 7.4% | 66 | 89.2% | 0 | 184 | 18% | 123 | 66.8% | 2 |
| MP | 1 330 | 232 | 17.4% | 220 | 94.8% | 0 | 355 | 27% | 286 | 80.6% | 3 |
| NW | 1 051 | 50 | 4.8% | 40 | 80.0% | 0 | 186 | 18% | 146 | 78.5% | 13 |
| NC | 770 | 65 | 8.4% | 39 | 60.0% | 2 | 146 | 19% | 100 | 68.5% | 11 |
| WC | 1 832 | 25 | 1.4% | 3 | 0.0% | 0 | 1 239 | 68% | 1 162 | 93.8% | 4 |
| **National** | **19 354** | **2 036** | **10.5%** | **1 731** | **85.0%** | **2** | **4 772** | **25%** | **3 983** | **83.5%** | **139** |

## 4. Errors

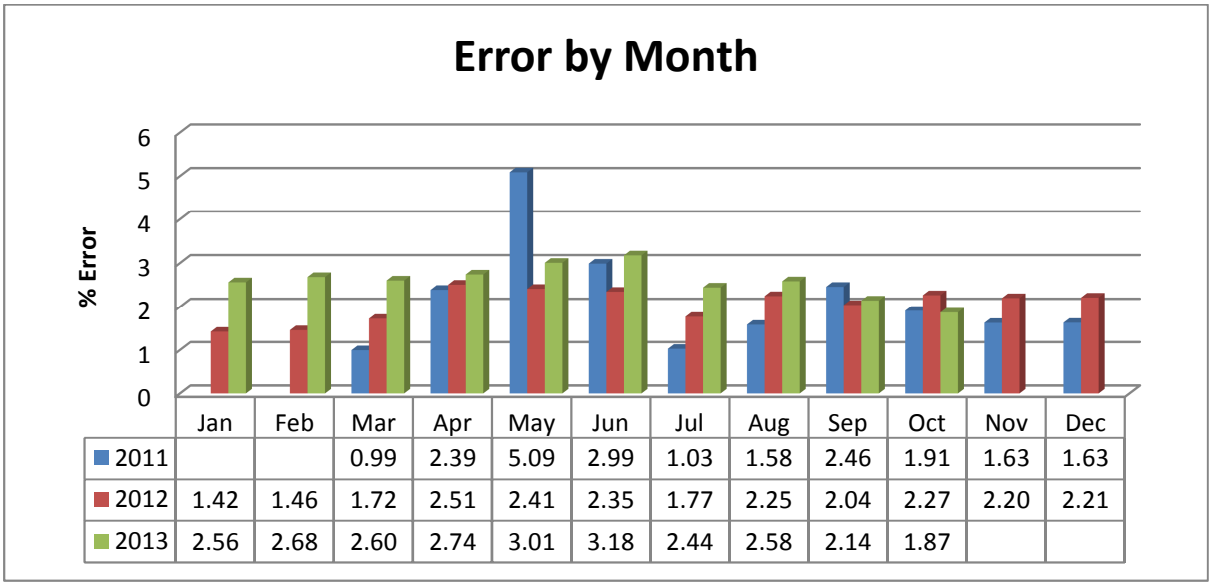
Average error rate has ranged consistently below 3%, however 1/9 provinces reported error rates above 3% in the month of October. There has been a significant improvement in the in the number of errors reported due to hardware failures of the modules reported by laboratories. Details of the invalid results, which likely represent sample issues remains below 1%. These are being monitored regularly and corrective action implemented where necessary.

**Table 6: Number of Unsuccessful Tests and Reasons (1-31 October 2013)**

| Province | ERR | INV | NORES | NULL | MTB Results | Grand Total | % Error |
|---|---|---|---|---|---|---|---|
| Eastern Cape | 585 | 85 | 118 | | 31 313 | 32 101 | 1.82 |
| Free State | 103 | 14 | | | 12 423 | 12 540 | 0.82 |
| Gauteng | 450 | 51 | 15 | | 21 773 | 22 289 | 2.02 |
| Kwa-Zulu Natal | 882 | 276 | 50 | 2 | 35 558 | 36 768 | 2.40 |
| Limpopo | 310 | 71 | 9 | | 17 078 | 17 468 | 1.77 |
| Mpumalanga | 177 | 33 | 4 | | 7 835 | 8 049 | 2.20 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| North West | 369 | 31 | 14 | | 10 254 | 10 668 | 3.46 |
| Northern Cape | 94 | 81 | 3 | | 5 153 | 5 331 | 1.76 |
| Western Cape | 139 | 22 | 5 | 1 | 21 811 | 21 978 | 0.63 |
| **Grand Total** | **3 109** | **664** | **218** | **3** | **163 198** | **167 192** | **1.86** |

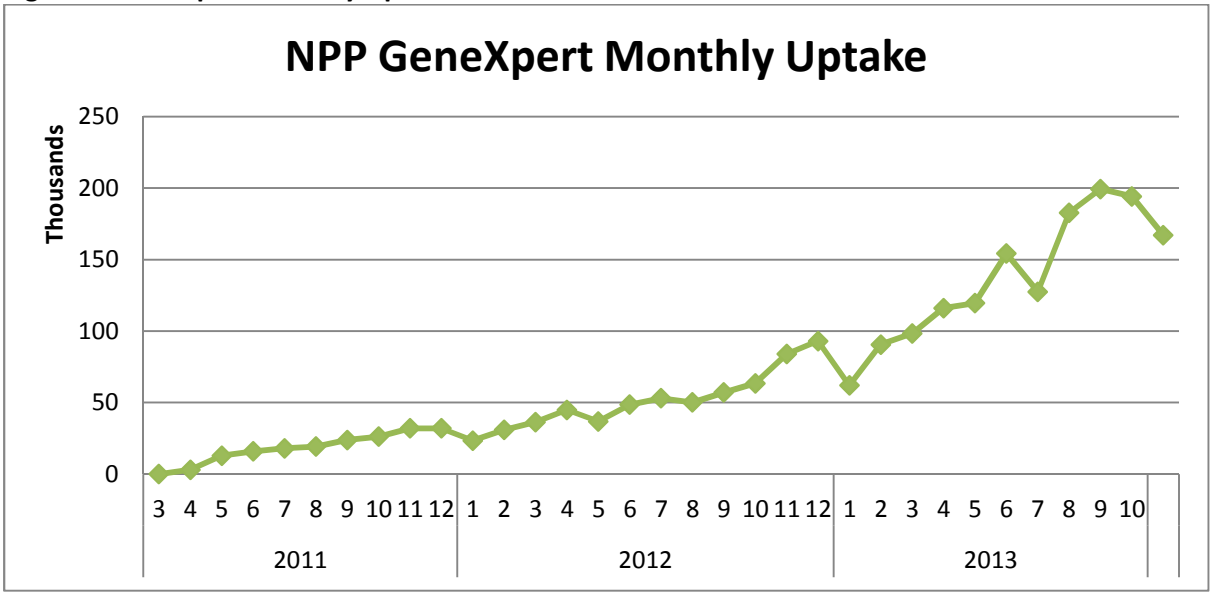
**Figure 1: GeneXpert Error by Month**




| | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2011 | | | 0.99 | 2.39 | 5.09 | 2.99 | 1.03 | 1.58 | 2.46 | 1.91 | 1.63 | 1.63 |
| 2012 | 1.42 | 1.46 | 1.72 | 2.51 | 2.41 | 2.35 | 1.77 | 2.25 | 2.04 | 2.27 | 2.20 | 2.21 |
| 2013 | 2.56 | 2.68 | 2.60 | 2.74 | 3.01 | 3.18 | 2.44 | 2.58 | 2.14 | 1.87 | | |

## 5. Monthly uptake since implementation started

**Figure 2: GeneXpert Monthly Uptake**



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Monthly uptake increased steadily since program inception. There was a significant decrease in the number of tests conducted in the month of September and October. CDW experienced problems with data loading from TrakCare Lab since the beginning of November. The problem has since been rectified however CDW is still loading the backlog of data. Once all the data has been loaded, CDW will then re-run and re-distribute the dashboard. The main reason for interruptions is due to the variation in work practices which is expected during the December period.

## 6. Further project phases as defined in the NTCM model

**Phase I** completed and reported on in the section above.

**Phase IIa** involves full capacitation of existing labs: Completed

**Phase IIb:** Full capacitation of high burden districts. Completed

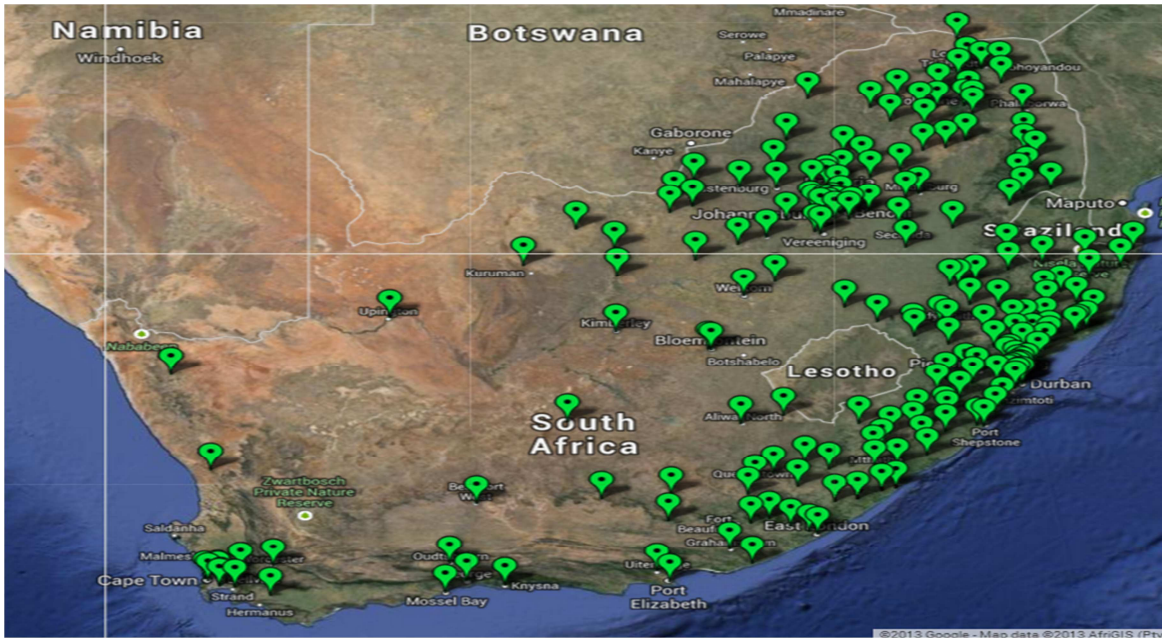
**Phase IIIa and b:** Gates funded study (Gauteng, EC and Free State). Completed

**Phase IIIc:** ensuring all districts have a minimum of 1 instrument per district: Completed

**Phase IIId:** Completion of all current microscopy and clinic sites: Completed

## 7. Phased Implementation Progress

**Figure 3:** Current GeneXpert Placement (207 testing centers, 283 **analysers, Gx4:** 95; Gx16-8: 1**; Gx16:** 185; GX48:1; GX80-80: 1) *20 clinic placements





Disclaimer: This is a dynamic dataset requiring regular updating and although correct in the vast majority cases, the reader should be aware that the figures reported can change slightly as the linkages are updated

## 8. Training: Laboratory and Clinical

A total of 976 laboratory staff and 4,987 health care workers have been trained since December 2011. This will be an ongoing process to support NDoH training on clinical algorithm. Laboratory staff received both clinical and technical training.

30 participants from 30 GeneXpert testing laboratories within the NHLS across the nine provinces attended a four day HBDC Advanced GeneXpert Training organized by the National Priority Programs of the NHLS in collaboration with Cepheid. The course conducted from 15 to 18 October 2013 at Wits Medical School, Johannesburg, South Africa.

**Back**: Nozipho Qakaza (Rustenburg), Tsholofelo Maditse (Moses Kotane), Yonas Ghebrekristos (Grooteschuur), Dawn Kennedy (Port Elizabeth), Tania Dolby (Greenpoint), Thabo Mashupye (Edenvale), Mpila Modungoa (Mmametlhake), Sanele Masina (Ermelo), Nhlanhla Dlamini (Addington), Tsoaeli Tsoaelinyana (Bethlehem), Cecil Napier (Kokstad), Ezekiel Kubheka (Kroonstad), Benjamin Rademeyer (Carletonville),
**Middle**: Mona Johnson (Kimberley), Lydia Matlala (Polokwane), Mpho Nkhahle (Huhudi), Matshidiso Makoala (Welkom), Florah Shibambo (TAD), Precious Nyathikazi (Madadeni), Zandile Mbotho (Bela-Bela), Sipho Xulu (Piet Retief)
**Front:** Nandi Rooi (Queenstown), Dinah Marobela (Tzaneen), Nazley Matthews (Universitas), Puseletso Tlaka (Tambo Memorial), Sonwabo Solo (St Barnabas), Leana Gertse (Oudtshoorn), Simphiwe Buthelezi (Eshowe), Sivuyile Yamba (Cofimvaba)

The Advanced GeneXpert Training course was intended to give participants knowledge of the GeneXpert technology and its applications in diagnostic and research settings, highlighting differences between this technology and the currently available TB diagnostic tools in South Africa. Topics covered by this comprehensive training course include regulatory compliance and adherence to good laboratory practices, personnel qualifications and responsibilities, establishment and verification of test performance specifications, preparation and processing of clinical molecular samples, quality control practices, proficiency testing and alternative performance assessment, test reports and quality management practices.

## 9. Challenges identified during the course of the project to date

- Delay in training health care workers, especially doctors whose availability is limited, on clinical algorithm: is being addressed
- Rollout of EGK to avoid duplications
- Multiple specimens submitted for initial diagnosis using the GeneXpert in the Free State: being addressed with the provincial coordinator.

## 10. Literature Update For GeneXpert

There has been an expansion of the literature with respect to the assay performance. The highlights are summarized in the table below:

**Table: Recent publications (GeneXpert for pulmonary TB and extrapulmonary TB)**

| Manuscript | Aim/Sample population and specimen type (n=…) | Results | |
|---|---|---|---|
| | | Sensitivity | Specificity |
| Boulware DR. PloS Med, 2013 | Review article | Discusses the challenges of diagnosing tuberculous meningitis and the implications of the study by Patel and colleagues using the Xpert MTB/RIF assay for diagnosis. | |

| | | | |
|---|---|---|---|
| Theron et a, Lancet, 2013 | Pragmatic, randomised, parallel-group, multicentre trial: recruited adults with symptoms suggestive of active tuberculosis from five primary-care health-care facilities in South Africa, Zimbabwe, Zambia, and Tanzania<br>Randomly assigned n=758 patients to smear microscopy (182 culture positive) and 744 to Xpert MTB/RIF (185 culture positive). | • Point-of-care MTB/RIF had higher sensitivity than microscopy (83% vs 50%) but similar specificity (95% vs 96%).<br>• Xpert at POC had similar sensitivity to laboratory-based MTB/RIF (83%) but higher specificity (92%).<br>• N=34 (5%) of 744 tests with point-of-care MTB/RIF failed.<br>• N=82 (6%) of 1411 with laboratory-based MTB/RIF failed (p=0·22).<br>• Compared with the microscopy group, more patients in the MTB/RIF group had a same-day diagnosis | |
| Kwak et al, PloS One, 2013 | N=681 patients in whom Xpert MTB/RIF assay was requested were retrospectively reviewed | Xpert sensitivity for diagnosis of PTB = 79.5%<br>PPV = 100% | Xpert specificity = 100.0%<br>NPV = 94.0% |
| | | Median time to treatment after initial evaluation was 7 (4-9) days in patients with Xpert MTB/RIF assay, but was 21 (7-33.5) days in patients without Xpert MTB/RIF assay | |
| Walusimbi S et al, BMC Infect Dis, 2013 | A systematic review and meta-analysis of publications on GeneXpert, or MODS, or the WHO 2007 algorithm for diagnosis of SN-PTB, using culture as reference test was performed. | The pooled sensitivity for detection of smear-negative pulmonary tuberculosis:<br>67% for GeneXpert,<br>73% for MODS, 61% for WHO 2007 algorithm | The pooled specificity for detection of smear-negative pulmonary tuberculosis:<br>98% for GeneXpert<br>91% for MODS<br>69% for WHO 2007 algorithm |
| Patel et al, PLoS Med, 2013 | N=235 CSF specimens from South-African patients with a meningeal-like illness. Comparison to a smear and a clinical score | Sensitivity of Xpert MTB/RIF = 62% Sensitivity of smear microscopy = 12% Sensitivity of CS =30% | |
| | | MTB/RIF sensitivity was higher when centrifuged versus uncentrifuged samples were used (82% [62%-94%] versus 47% [31%-61%]; p = 0.004). | |

| | | | |
|---|---|---|---|
| Ablanedo-Terrazas Y et al, Laryngoscope, 2013 | N=68 cervical lymph nodes from HIV positive patients. | Xpert MTB/RIF sensitivity = 100% (95% CI, 74.65%-100%) | Specificity = 100% |
| Lawn et al, BMC Med, 2013 | N=602 ambulatory patients enrolling for antiretroviral treatment in South Africa | sensitivity of sputum microscopy was 26.7% overall. Rapid diagnosis from sputum (Xpert) and/or urine (TB-LAM) samples was possible in >80% of patients in sub-groups with poor prognosis (either CD4 counts <100 cells/uL, advanced symptoms, CRP concentrations >200 mg/L or hemoglobin <8.0 g/dl) | |

## 11. Update on GeneXpert Research projects:

### 11.1. *GeneXpert Verification and EQA program using Dried Culture spots (DCS)*

- n=250 DCS panels are in the process of being produced for verification of the India GeneXpert program.
- Phase 3 of the national NHLS GeneXpert EQA has been manufactured for early November roll-out.
- In collaboration with PATH we are in the process of commercialisation of the verification and EQA material for TB Xpert testing globally. This has the support of both the NHLS and the University of the Witwatersrand, the WHO and the CDC.
- TBGxMonitor™ (www.tbgxmonitor.com) is about to undergo an upgrade to include EQA reporting functionality for national and international EQA programs along with a minor functionality upgrade.
    - The first of the minor updates has been completed.
    - The national reporting template has been finalized and will be implemented in November along with a number of system upgrades to automate the reporting process for EQA.
    - The website content is to be updated with SOP's, training material and additional information regarding the EQA programme.

### 11.2. *Diagnosis of Extrapulmonary TB (EPTB) using the GeneXpert MTB/RIF*

A study to determine whether a modified GeneXpert protocol which will not involve addition of SR buffer, can be used to increase the diagnostic sensitivity of the Xpert MTB/Rif assay for clear watery fluid types among aspirates and fluids.

- To date: approximately 170 EPTB clear watery fluids have been tested.

**11.3.** ***Connectivity solutions for the GeneXpert***

- Connectivity: Collaboration with Cepheid ongoing
    i. Remote connectivity – System deployed on 180 instruments to date with over 1,291,320 results live on the dashboard. The NHLS are currently underway with completing the national enrolment of laboratories on the dashboard.
    ii. Cepheid are finalizing a list of sites to participate in a new pilot program to test and evaluate the new Xpert Monitor Software and Dashboard which is to be compatible with the NHLS proxy.

## 12. Update on other projects

***Grand Challenges Canada project: Multiple POC HIV/TB integration feasibility project***

GCC is a three year project to investigate the feasibility of integrating multiple POC testing for HIV and TB (using the Xpert MTB/RIF test) integration of services in an active ARV treatment clinic. This will involve a randomized controlled trial at 3 clinic sites to compare standard of care and Point of care. Enrolment is complete and patients are being followed-up for one year.

- *Sub-studies within GCC*
    - **Investigating blood volumes obtained from finger stick**: In collaboration with Northwestern University. Aim of the study is to investigate if 150ul of blood can be obtained from a new finger stick collection device.
    - Investigating **alternative media** (Hemaform plates, Primestore tubes and a thicker DBS cards) **for blood specimen collection/storage and transport** to centralized laboratories for VL testing. Patient recruitment complete. Abbott testing of media is underway.
    - **Laboratory validation** of a rapid strip based test for **HIV/Syphilis** (SD Bioline):

  - n=170 syphilis samples tested
  - n=160 HIV samples tested
  - A external HIV and syphilis panel has also been tested

  Results will be compared to routine lab testing.
- **Laboratory validation** of a new POC chemistry system the **Epoc** (Alere): Protocol complete and ethics obtained. Awaiting instrument from Alere
- **Clinical validation** of nurse operated **Liat (IQuum)** VL testing at POC on finger stick specimens: Protocol is complete and ethics obtained. n=100 patients have been recruited into the study and tested on-site for VL. Data analysis is underway with comparison to laboratory VL Roche platform
- **Laboratory validation of Primestore technology with flocked swabs** to determine the ease and accuracy of flocked swab technology for collecting and transporting finger stick blood specimens for centralized VL testing. Study ongoing.
- **Laboratory Comparison of Genotype MTBDRplus versions 1 and 2 using DCS.** This comparison will be performed using DCS material in order to determine the reproducibility of results using either version of the MTBDRplus assay. This will be initiated during October.
- **DNAGenotek Evaluation.** A novel liquification, storage and nucleic acid extraction reagent set for sputa will be evaluated in the laboratory and clinically. Protocol and ethics is under development

- GCC Connectivity
  - Data analysis on the captured information for the connectivity is underway.
  - AegisPOC and Conworx will be review in an attempt to identify the transcription error rate present when manually capturing results.

## 13. Funding

**Table 9: Total and Percentage Contribution to date by Donor**

| Donor | % Contribution |
|---|---|
| NDoH | 24.04 |
| Bill & Melinda Gates Foundation | 7.20 |
| TB Reach | 1.42 |
| MSF | 0.90 |
| FIND | 0.45 |
| USAID | 2.45 |
| CDC NHLS 2010/11 | 14.78 |
| CDC NDoH | 0.72 |
| CDC NHLS 2011/12 | 1.39 |
| Dr. Niebauer | 0.20 |
| Gobal Fund NDOH | 40.91 |
| Global Fund RTC | 2.78 |
| CDC NDoH | 2.77 |
| **Subtotal** | **100** |

CDC has contributed 19, 65% towards the program to date.

## 14. Recent Campaigns

NHLS collaborated with the DOH in organizing and providing services in support of the Parliament HIV Counseling and Testing (HCT) Campaign Launch that was held on 22-23 October 2013.