



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

May 2015





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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, 309 GeneXpert instruments of varying sizes (GX4: 110; GX16:190; GX48: 1; GX80:8) have been placed in 221 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.

The programme is being further expanded to directly support the annual screening for TB and HIV of a quarter of a million people in special risk populations in correctional centres and in peri-mining communities.

1.1. Correctional Services

In order to improve TB control in all 242 correctional facilities in South Africa, the NHLS is working in partnership with the Department of Correctional Services (DCS), NDoH, Aurum Institute, TB/HIV Care Association and Right to Care to ensure access to regular HIV- and TB-related screening, testing and treatment of up to 150,000 offenders through the Global Fund programme. Xpert MTB/Rif testing is being provided either on-site, or at the nearest referral laboratory. During 2014, Xpert MTB/RIF testing facilities have been established on-site at the following Correctional Facilities:

- KgošiMampuru Management Area II
- Barberton Management Area
- Johannesburg Management Area
- Groenpunt Management Area
- Pollsmoor Management Area
- St Albans Management Area
- Durban-Westville Management Area

1.2. Peri-Mining Communities

NHLS, together with the Aurum Institute, has been appointed by NDoH (under the Global Fund grant) to provide services to implement interventions aimed at improving TB and HIV/AIDS management for vulnerable peri-mining communities (estimated at around 600,000 people) in 6 main mining districts. Six staffed and GeneXpert-equipped mobile TB units will be provided within the communities to undertake Xpert MTB/RIF testing for TB. In addition, persons newly identified as HIV-infected through the clinical partner will be staged for HIV-treatment using CD4 tests provided by the closest NHLS lab in the district. The 6 districts with a high proportion of mines in South Africa that have been identified for focused attention are:

- Lejweleputswa (Free State),
- Dr K K Kaunda & Bojanala Districts (North West),
- West Rand (Gauteng)
- Waterberg & Sekhukhune (Limpopo)

2. Assays performed to date

In summary, a total of 6 020 602 specimens have been processed to date (31 May 2015). In May 223, 005 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 7.94% (17,705). 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 year, 10-11% in the third and fourth years and has reduced to 9% in the 5th 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	3 252	15 235	549	19 036	17,08
EASTERN CAPE	2012	15 880	84 755	2 862	103 497	15,34
EASTERN CAPE	2013	45 469	320 022	10 046	375 537	12,11
EASTERN CAPE	2014	48 900	382 950	11 369	443 219	11,03
EASTERN CAPE	2015	20 016	180 840	4 998	205 854	9,72
FREE STATE	2011	2 811	14 532	35	17 378	16,18
FREE STATE	2012	11 660	76 863	288	88 811	13,13
FREE STATE	2013	14 758	139 299	1 020	155 077	9,52
FREE STATE	2014	14 030	125 554	997	140 581	9,98
FREE STATE	2015	5 098	46 731	476	52 305	9,75
GAUTENG	2011	3 094	18 881	443	22 418	13,80
GAUTENG	2012	11 120	72 979	2 305	86 404	12,87
GAUTENG	2013	31 432	215 064	7 690	254 186	12,37
GAUTENG	2014	38 537	303 844	7 423	349 804	11,02
GAUTENG	2015	14 787	143 018	3 366	161 171	9,17
KWAZULU-NATAL	2011	7 546	30 575	896	39 017	19,34
KWAZULU-NATAL	2012	23 963	135 973	5 915	165 851	14,45
KWAZULU-NATAL	2013	42 294	293 200	15 003	350 497	12,07
KWAZULU-NATAL	2014	57 323	519 674	18 683	595 680	9,62
KWAZULU-NATAL	2015	22 800	243 274	8 508	274 582	8,30
LIMPOPO	2011	1 973	17 253	173	19 399	10,17
LIMPOPO	2012	4 004	30 924	689	35 617	11,24



LIMPOPO	2013	13 927	188 932	6 086	208 945	6,67
LIMPOPO	2014	14 376	211 956	7 688	234 020	6,14
LIMPOPO	2015	5 034	85 561	2 692	93 287	5,40
MPUMALANGA	2011	2 629	12 683	1 100	16 412	16,02
MPUMALANGA	2012	4 035	22 226	1 133	27 394	14,73
MPUMALANGA	2013	10 406	63 030	2 210	75 646	13,76
MPUMALANGA	2014	14 650	112 752	4 210	131 612	11,13
MPUMALANGA	2015	5 355	48 371	1 964	55 690	9,62
NORTH WEST	2011	3 429	14 557	644	18 630	18,41
NORTH WEST	2012	5 499	29 977	2 052	37 528	14,65
NORTH WEST	2013	13 301	100 512	4 926	118 739	11,20
NORTH WEST	2014	17 001	150 584	6 638	174 223	9,76
NORTH WEST	2015	6 420	66 425	2 265	75 110	8,55
NORTHERN CAPE	2011	2 727	15 527	712	18 966	14,38
NORTHERN CAPE	2012	3 830	21 728	1 038	26 596	14,40
NORTHERN CAPE	2013	7 912	53 728	2 529	64 169	12,33
NORTHERN CAPE	2014	8 685	63 062	2 891	74 638	11,64
NORTHERN CAPE	2015	3 396	26 045	962	30 403	11,17
WESTERN CAPE	2011	2 173	9 897	47	12 117	17,93
WESTERN CAPE	2012	13 206	68 045	689	81 940	16,12
WESTERN CAPE	2013	28 653	155 003	2 343	185 999	15,40
WESTERN CAPE	2014	33 717	180 294	1 992	216 003	15,61
WESTERN CAPE	2015	12 407	73 497	710	86 614	14,32
TOTAL		673 515	5 185 832	161 255	6 020 602	11,19

Table 2: GeneXpert MTB Results by province (01-31 May 2015)

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	3 935	41 706	1 148	46 789	8,41
Free State	1 001	10 024	74	11 099	9,02
Gauteng	2 870	32 706	831	36 407	7,88
Kwa-Zulu Natal	4 446	51 943	1 297	57 686	7,71
Limpopo	949	18 892	356	20 197	4,70
Mpumalanga	1 034	10 577	309	11 920	8,67
North West	1 167	14 313	338	15 818	7,38
Northern Cape	592	5 414	212	6 218	9,52
Western Cape	1 711	15 051	109	16 871	10,14
Grand Total	17 705	200 626	4 674	223 005	7,94



Table 3: Provincial GeneXpert RIF Results in MTB detected cases (01-31 May 2015)

Province	Inconclusive	Resistant	Sensitive	No Rif Results	Grand Total	% Rif Resistant
Eastern Cape	50	224	3 659	2	3 935	5,69
Free State	12	50	938	1	1 001	5,00
Gauteng	35	152	2 681	2	2 870	5,30
Kwa-Zulu Natal	60	341	4 044	1	4 446	7,67
Limpopo	16	68	857	8	949	7,17
Mpumalanga	17	74	943		1 034	7,16
North West	19	40	1 108		1 167	3,43
Northern Cape	6	33	553		592	5,57
Western Cape	21	104	1 586		1 711	6,08
Grand Total	236	1 086	16 369	14	17 705	6,13

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

Province	Year	Inconclusive	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
EASTERN CAPE	2011	33	248	2 919	52	3 252	7,63
EASTERN CAPE	2012	213	1 077	14 456	134	15 880	6,78
EASTERN CAPE	2013	1 274	2 969	41 073	153	45 469	6,53
EASTERN CAPE	2014	1 248	2 983	44 620	49	48 900	6,10
EASTERN CAPE	2015	242	1176	18585	13	20 016	5,88
FREE STATE	2011	28	155	2 626	2	2 811	5,51
FREE STATE	2012	162	755	10 717	26	11 660	6,48
FREE STATE	2013	372	800	13 564	22	14 758	5,42
FREE STATE	2014	367	816	12 843	4	14 030	5,82
FREE STATE	2015	62	280	4753	3	5 098	5,49
GAUTENG	2011	25	179	2 889	1	3 094	5,79
GAUTENG	2012	136	766	10 142	76	11 120	6,89
GAUTENG	2013	921	2 008	28 433	70	31 432	6,39
GAUTENG	2014	818	2 293	35 399	27	38 537	5,95
GAUTENG	2015	177	861	13742	7	14 787	5,82
KWAZULU-NATAL	2011	64	592	6 875	15	7 546	7,85
KWAZULU-NATAL	2012	417	2 166	21 128	252	23 963	9,04
KWAZULU-NATAL	2013	1 076	3 704	37 079	435	42 294	8,76
KWAZULU-NATAL	2014	1 512	4 962	50 646	203	57 323	8,66
KWAZULU-NATAL	2015	361	1775	20626	38	22 800	7,79
LIMPOPO	2011	25	148	1 775	25	1 973	7,50
LIMPOPO	2012	52	268	3 609	75	4 004	6,69
LIMPOPO	2013	299	715	12 803	110	13 927	5,13



LIMPOPO	2014	328	706	13 294	48	14 376	4,91
LIMPOPO	2015	52	270	4695	17	5 034	5,36
MPUMALANGA	2011	30	207	2 386	6	2 629	7,87
MPUMALANGA	2012	57	401	3 501	76	4 035	9,94
MPUMALANGA	2013	238	1 024	9 116	28	10 406	9,84
MPUMALANGA	2014	380	1 281	12 969	20	14 650	8,74
MPUMALANGA	2015	73	428	4852	2	5 355	7,99
NORTH WEST	2011	39	303	3 083	4	3 429	8,84
NORTH WEST	2012	75	414	5 000	10	5 499	7,53
NORTH WEST	2013	325	730	12 219	27	13 301	5,49
NORTH WEST	2014	504	909	15 579	9	17 001	5,35
NORTH WEST	2015	96	332	5988	4	6 420	5,17
NORTHERN CAPE	2011	28	186	2 511	2	2 727	6,82
NORTHERN CAPE	2012	50	236	3 536	8	3 830	6,16
NORTHERN CAPE	2013	175	422	7 025	290	7 912	5,33
NORTHERN CAPE	2014	200	448	8 022	15	8 685	5,16
NORTHERN CAPE	2015	30	179	3187		3 396	5,27
WESTERN CAPE	2011	15	107	2 050	1	2 173	4,92
WESTERN CAPE	2012	153	653	12 397	3	13 206	4,94
WESTERN CAPE	2013	636	1 409	26 606	2	28 653	4,92
WESTERN CAPE	2014	678	1 766	31 272	1	33 717	5,24
WESTERN CAPE	2015	117	610	11678	2	12 407	4,92
Total		14 163	44 717	612 268	2 367	673 515	6,64

3. Rif Concordance

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

		GeneXpert Confirmation & Rif Concordance									
Province	Rif Resistant Cases	Cultures					LPA				
		Confirmed		Rif Concordance		Pre-analytical	Confirmed		Rif Concordance		Inderterminate
		#	%	#	%		#	%	#	%	
Eastern Cape	5 514	213	3,9%	138	64,8%	3	1 393	25%	1 290	92,6%	5
Free State	1 903	166	8,7%	95	57,2%	0	643	34%	523	81,3%	146
Gauteng	4 116	160	3,9%	109	68,1%	4	1 067	26%	968	90,7%	20
Kwazulu-Natal	9 673	2 221	23,0%	2 069	93,2%	0	2 117	22%	1 857	87,7%	80
Limpopo	1 451	85	5,9%	69	81,2%	2	335	23%	260	77,6%	9
Mpumalanga	2 369	532	22,5%	523	98,3%	0	870	37%	749	86,1%	2
North West	2 506	143	5,7%	103	72,0%	0	799	32%	681	85,2%	31
Northern Cape	962	202	21,0%	152	75,2%	3	367	38%	281	76,6%	22
Western Cape	3 281	96	2,9%	26	0,0%	0	2 583	79%	2 403	93,0%	2
National	31 775	3 818	12,0%	3 284	86,0%	12	10 174	32%	9 012	88,6%	317

4. Errors

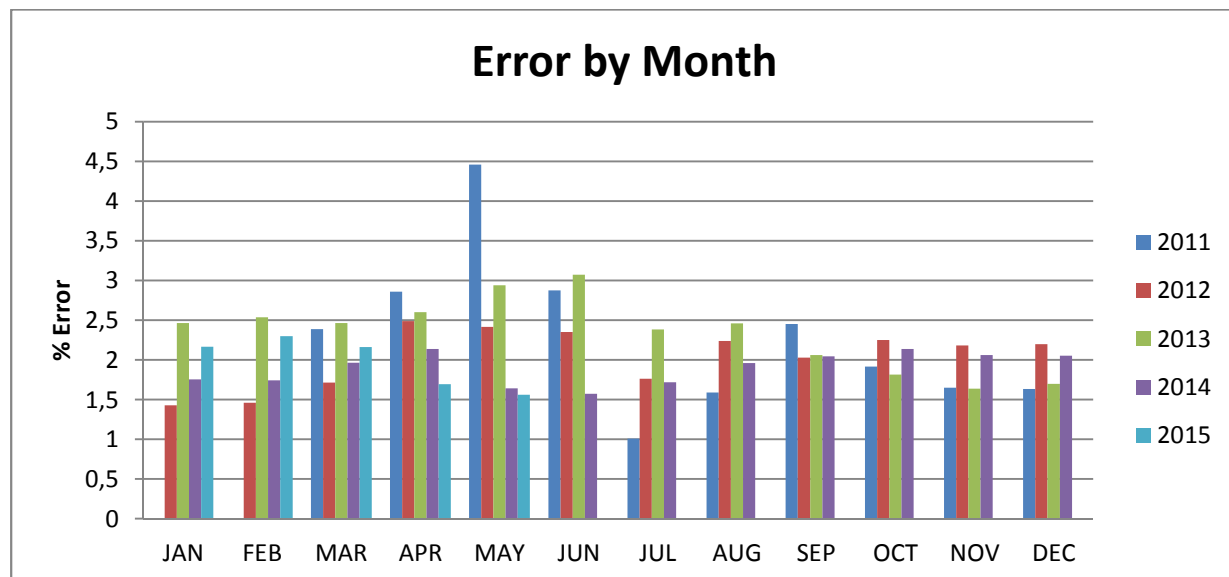
Average error rate has ranged consistently below 3%, however Mpumalanga reported error rates above 3% in the month of March. Details of the invalid results, which likely represent sample issues remains below 1%. These are being monitored regularly and corrective action implemented where necessary.

Table 6: Number of Unsuccessful Tests and Reasons (1-31 May 2015)

Province	Errors	Invalids	No Results	MTB Results	Grand Total	% Error
Eastern Cape	848	158	140	45 718	46 864	1,81
Free State	63	10	1	11 035	11 109	0,57
Gauteng	705	104	22	35 627	36 458	1,93
Kwa-Zulu Natal	865	298	134	56 443	57 740	1,50
Limpopo	263	72	21	19 851	20 207	1,30
Mpumalanga	216	76	17	11 618	11 927	1,81
North West	285	42	11	15 483	15 821	1,80
Northern Cape	123	82	7	6 007	6 219	1,98
Western Cape	81	20	8	16 870	16 979	0,48
Grand Total	3 449	862	361	218 652	223 324	1,54

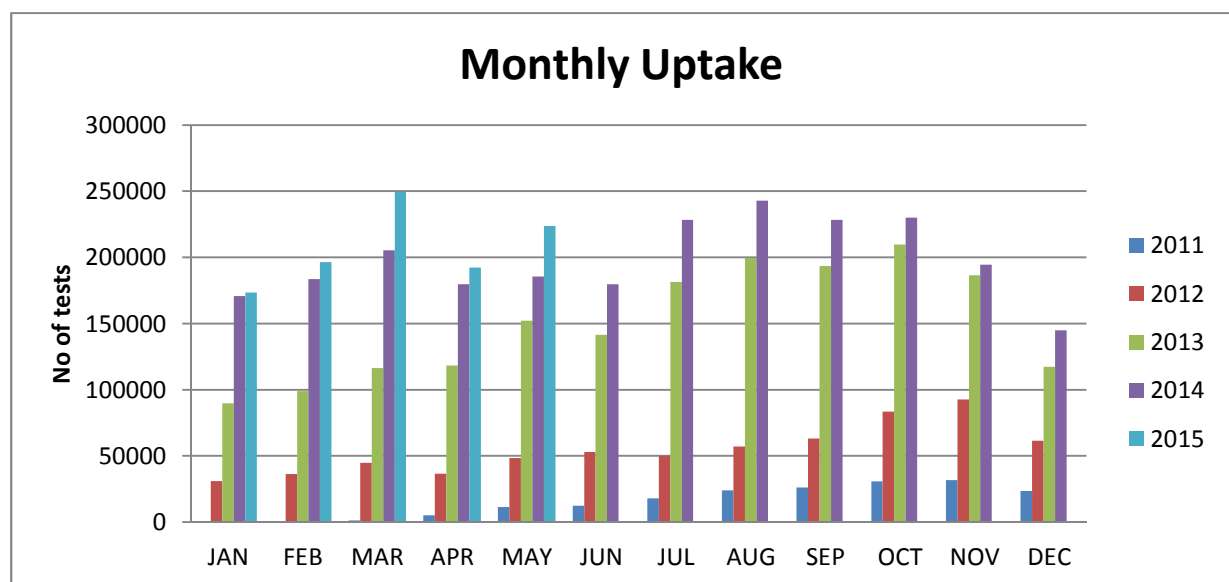


Figure 1: GeneXpert Error by Month



5. Monthly uptake since implementation started

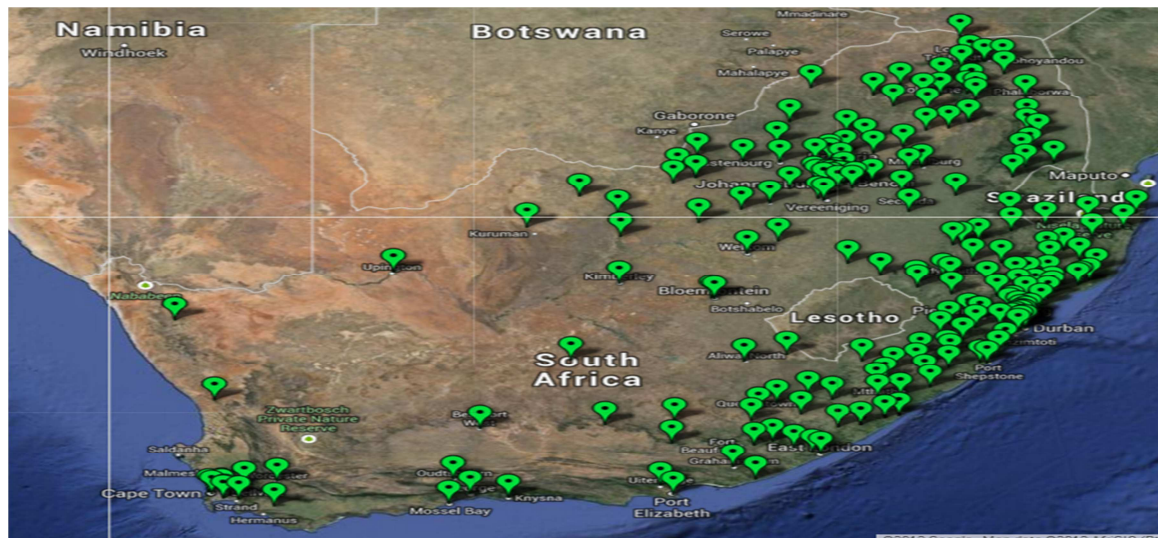
Figure 2: GeneXpert Monthly Uptake



Monthly uptake increased steadily since program inception. The main reason for interruptions is due to the variation in work practices which is expected during the December period.

6. Phased Implementation Progress

Figure 3: Current GeneXpert Placement (221 testing centers, 309 analysers, Gx4: 110; Gx16-8: 1; Gx16: 189; GX48:1; GX80-80: 8) *20 clinic placements *7 Correctional Facilities *6 Mobile Vans



7. Training: Laboratory and Clinical

A total of 1,716 laboratory staff and 8,280 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.

8. Challenges identified during the course of the project to date

- Rollout of EGK to avoid duplications
- Implementing WHO recommended guidelines for Xpert testing on EPTB and paediatric samples: being addressed
- EPTB training to be expanded to correctional facilities to ensure compliance
- Hospital staff not complying to the GXP testing algorithm because trainings has not been conducted in most of the hospitals- being addressed
- Staff rotation in hospital wards posing a challenge in the implementation and compliance to the TB algorithms resulting to delay in initiating patients on TB Treatment



9. 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
Abdurrahman et al, JCM 2015	Assessed a pooled testing strategy to optimise the affordability of Xpert for the diagnosis of TB in Nigeria n=718 valid specimens	• 115 (16%) MTB-positive. • Pooled testing detected 109 (96%) of 114 individual MTB-positive samples, with 99% overall agreement. • The strategy saved 31% of cartridge costs. • Savings were higher in the community, where the proportion of specimens positive was low.	
Gu et al, Int J Infect Dis	Investigated the diagnostic utility of Xpert and Genotype MTBDRplus techniques for bone and joint TB (BJTB) versus the composite reference standard (CRS)	• 50/60 had BJTB by CRS • Sensitivities: - o smear 26% (13/50) - o culture, 48% (24/50) - o Xpert 82% (41/50) - o MTBDR 72% (36/50) • Specificities of all of the tests were 100% (10/10) • Xpert was 100% concordant with MGIT for detection of rif resistance. • MTBDR had a sensitivity of 83.3% and a specificity of 100% for the detection of rifampicin resistance and a sensitivity of 85.7% and specificity of 100% for the detection of isoniazid resistance	
Sachdeva et al, PloS 2015	This study assessed the impact of up-front Xpert MTB/RIF testing on detection of pulmonary tuberculosis (PTB) and rifampicin-resistant PTB (DR-TB) cases in 8 sub-district level TB programme units (TUs) in India	• Implementation of Xpert MTB/RIF associated with increases in both notification rates of bacteriologically confirmed TB cases (adjusted incidence rate ratio [aIRR] 1.39; CI 1.18-1.64), and proportion of bacteriological confirmed TB cases among presumptive TB cases (adjusted risk ratio (aRR) 1.33; CI 1.6-1.52). • Xpert MTB/RIF implementation increased rifampicin resistant TB case detection by over fivefold	
Daum et al, Int J Tuberc Lung	Investigated molecular detection of MTB from sputum transported from	• 132 patients, 23 (17%) were positive on microscopy, 39 (30%) on Xpert and 44	



Dis. 2015	rural settings using PrimeStore(®) Molecular Transport Medium (PS-MTM)	(33%) by PS-MTM/PM-PCR • Of 107 microscopy-negative samples, 22 (21%) were positive using PS-MTM/PM-PCR • 11/91 (12%) Xpert-negative samples were PS-MTM/PM-PCR-positive • PCR testing of specimens transported in PS-MTM would enhance TB diagnosis and could provide an alternative in settings where Xpert testing is not available.
Shrestha et al, Tuberc Res Treat, 2015	Determined the possibility of additional case detection for PTB by offering Xpert on a fee-paying basis to smear-negative patients in a low-HIV burden setting with no M.tb culture facilities • n=258 smear-negative patients were included	• 55/258 (21.32%) M.tb positive. • Using standard clinical assessment for selection, testing 5 patients detected one case of smear-negative PTB. • These results demonstrate that fee-paying Xpert service in low-income setting can increase TB case confirmation substantially

10. Update on GeneXpert Research projects:

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

- TBGxMonitor™ (www.tbgxmonitor.com) upgrade specification finalized.
 - o First set of developments published live and working.
 - o Continued developments will be published at a later stage.
- Results for EQA panel 1 for 2015 have been submitted, analysed and released. New enrollments include sites in Australia, Cameroun and Kilimanjaro.
- In collaboration with CHAI, 18 news sites in India will be included as of panel 2015-2 and 2015-3.
- Additionally, a trial is being initiated to pilot the DCS EQA program on the line probe assay in collaboration with ACTG. 14 sites to be included in trial.

11.2. Connectivity solutions for the GeneXpert

- Connectivity: Collaboration with Cepheid ongoing
 - i. Cepheid RM Dashboard commercial version now available.

11.3.mHealth solutions for MDR-TB

Emocha

The emocha MDR-TB mHealth project officially began its implementation on **19 March 2015**. Three facilities were implemented in the Ugu District of Kwa-Zulu Natal (Murchison Hospital, Kwa-Mbunde Gateway Clinic and Gamalakhe Clinic). Implementation was conducted by the NPP (Lynsey Isherwood, Floyd Olsen and Portia Madumo), Eموcha, Jphiego and Johns Hopkins University.

During the month of May, following was conducted:

- Re-training on requisition forms at Gamalakhe, Murchison Hospital and Kwa-Mbunde.
- Requisition forms from the above facilities were audited against TrakCare.
- Data between emocha and TrakCare were further troubleshooted.
- Barcode matching between TrakCare and Eموcha has increased from 45% to >90%.
- 18-20 May: Eموcha software updated was implemented (together with Jphiego, South Africa). Refresher training of data capturing was conducted at Murchison Hospital and Port Shepstone laboratories.

To date, 2,000 patients have been screened and successfully registered onto emocha between the three facilities. Fifteen of these patients were diagnosed with as RIF resistant; 12 were linked to treatment in <5 days (two patients deceased before accessing treatment; one patient was already on MDR-TB treatment).

Treat-TB

An APP has been designed by the NPP to measure the turn-around-time from the diagnosis of RIF-R on GXP to the time of treatment initiation. Three facilities in the Ekurhuleni district of Gauteng were training and implemented:

Table 8: mHealth Publications/abstracts/presentations:

Title	Publication type	Authors	Journal/conference
Novel Package of Integrated Mobile Applications Reduces Time to Treatment Initiation for Patients with MDR-TB	Oral Presentation	Mani Naicker, Jane McKenzie-White, Sebastian Seiguer, Annatjie Peters, Lynsey Isherwood, Floyd Olsen,, Wendy Stevens, Jason Farley	NDoH 90-90-90 Symposium 7 th SA AIDS Conference, Durban, South Africa
Driving mHealth	Oral Presentation	Lynsey Stewart-	7 th SA AIDS Conference,



Programmes from the Laboratory		Isherwood	Durban, South Africa
m-Health: intervention to rapidly link Xpert MTB/RIF rifampicin resistant patients to treatment initiation in South Africa	Poster Presentation	Lynsey Stewart-Isherwood, Floyd Olsen, Portia Madumo, Lesley Scott, Leigh Berrie, Wendy Stevens ^{1,2}	8 th IAS Conference on HIV Pathogenesis, Treatment and Prevention

11. Update on other projects

- **Evaluation of the GeneXpert to Diagnose Paediatric TB using stool specimens:** (In collaboration with David Alland and FIND). The laboratory R&D component to determine appropriate stool processing protocol has started. Phase 1a completed and involved 30 spiked TB positive and 30 TB negative specimens tested using 6 different stool processing and filtration protocols. Phase 1b completed (25 positive and 25 negative specimens processed). Phase 1c has started – 18 negative specimens have been run to date. Phase IIA (clinical phase) has started – 90 patients enrolled.
- **Longitudinal follow up of Dried Blood Spots for viral load monitoring:** Longitudinal collection of DBS from n=100 HIV-positive patients on ARV's over 72 weeks. Interim data analysis is underway and will be presented as an oral at the 7th SA HIV AIDS conference.
- **Laboratory validation of new TB diagnostics:** 1). A validation protocol is underway, for evaluation of the updated Abbott MTB-RT high throughput TB assay. The clinical study has begun: n=239 patients have been recruited to date and tested on the new Abbott assay for comparison to MGIT culture and smear.
- **Laboratory validation of new HIV diagnostics:**
 - Pilot evaluation of Alere q VL POC instrument (Alere, Inc) on a longitudinal cohort of whole blood specimens: Performance will be compared to plasma VL on Abbott and DBS VL on Abbott to determine the place for POC. Study start June 2015.
 - Laboratory evaluation of the Cepheid HIV-1 Quantitative VL cartridge on plasma, DBS and whole blood: n=111 patients have been recruited to date; plasma,



whole blood and DBS tested. Interim data analysis is underway and results will be presented at a Cepheid Symposium at the 7th HIV AIDS conference.

- o R&D is underway to investigate new materials for a molecular HIV EQA program such as Dried Plasma spots.
- o A new high throughput HIV VL platform, the Hologics Aptima HIV- 1 assay will be validated: Protocol in development

- **GCC Connectivity**

- o No specific update. The connectivity solutions are not being used at present since the study is not recruiting any further patients or performing new tests.

12. 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.

13. Recent Campaigns

None in May