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**TUBERCULOSIS
PROGRAM
SOUTH AFRICA**

Annual Report (1 October 2013 to 30 September 2014)

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LIST OF ACRONYMS

3Is	Intensified case finding, Isoniazid preventive therapy and Infection control
ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral treatment
BC	Bacteriological Coverage
CAT	Community Action Team
CBO	Community-Based Organization
CBS	Community Based Services
CCMT	Comprehensive Care Management and Treatment
CCW	Community Health Care Workers
CDC	Center for Disease Control
CHC	Community Health Centre
COPC	Community Oriented Primary Care
c-PMDT	Community Programmatic Management of Drug-resistant TB
CPT	Co-trimoxazole Preventative Therapy
CSIR	Council for Scientific and Industrial Research
CWD	Cape Winelands District
DCS	Department of Correctional Services
DENOSA	Democratic Nurses Organisation of South Africa
DHIS	District Health Information System
DOH	Department of Health
DOL	Department of Labour
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short-course
DRAT	District Rapid Assessment Tool
DRS	Drug Resistant Survey
DR-TB	Drug Resistant Tuberculosis
DS- TB	Drug Susceptible TB
DST	Drug Susceptibility Testing
DTTC	Desmond Tutu TB Centre
EC	Eastern Cape Province
EDR	Electronic Drug Resistance Register
ETR	Electronic TB Register
FS	Free State Province
GP	Gauteng Province

GXP	GeneXpert
HAST	HIV, AIDS, and Sexually Transmitted Infections and TB
HCT	HIV Counselling and Testing
HCW	Health Care worker
HIV	Human Immunodeficiency Virus
HOSPERSA	Health & Other Services Personnel Trade Union of South Africa
HST	Health Systems Trust
IC	Infection Control
ICF	Intensified Case Findings
IEC	Information, Education, and Communication
ILO	International Labour Organization
IPT	Isoniazid Preventive Therapy
IR	Intermediate Results
IYA	Imbume Yamakhosikazi Akomkhulu
JHHESA	John Hopkins Health and Education South Africa
KZN	Kwa-Zulu Natal Province
LOP	Life of Project
LP	Limpopo Province
M&E	Monitoring and Evaluation
MDR-TB	Multi-drug Resistant Tuberculosis
MIS	Management Information System
MOU	Memorandum of Understanding
MPU	Mpumalanga Province
NC	Northern Cape Province
NDOH	National Department of Health
NEC	National Expansion Coordinator
NGO	Non-Governmental Organization
NHLS	National Health Laboratory Service
NMBHD	Nelson Mandela Bay Health District
NTCP/ NTP	National Tuberculosis Control Program
NW	North West Province
PEPFAR	President Emergency Plan for AIDS Relief
PHC	Primary Health Care
PMDT	Programmatic Management of DR TB
PMTCT	Preventing Mother to Child Transmission
PPM	Public – Private Mix
PSA	Public Service Announcement

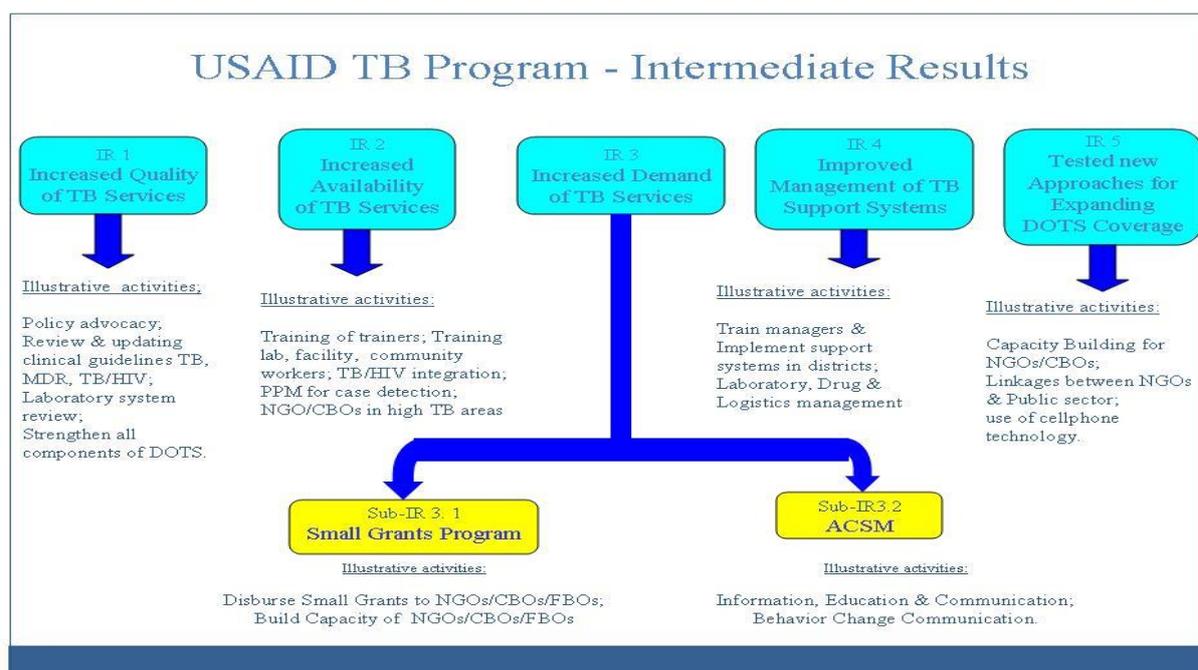
PTB	Pulmonary Tuberculosis
SABCOHA	South African Business Coalition
SAG	South African Government
SCR	Smear Conversion Rate
SND	Smear Not Done
SO	Strategic Objectives
SS+	Smear Positive
STI	Sexually Transmitted Infections
TAT	Turn Around Time
TB	Tuberculosis
The Union	International Union against Tuberculosis and Lung Disease
THP	Traditional Health Practitioners
TOT	Training of Trainers
TSR	Treatment Success Rate
URC	University Research Co., LLC
USAID	United States Agency for International Development
VCT	Voluntary Counselling and Testing
WAD	World AIDS Day
WC	Western Cape Province
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

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data captureurs, etc.)*

Organogram Updated: 1 October 2014

1 EXECUTIVE SUMMARY

This report details the activities undertaken, results achieved, and challenges encountered by the USAID TB Program South Africa from October 2013 to September 2014 (FY14), year 5 of the project. The activities implemented were guided by the Strategic Objectives (SO) and the related Intermediate Results (IRs) of the USAID TB Program as reflected below:



During FY14, the USAID TB Program continued intensified support to targeted districts to address identified gaps and challenges to improve performance. A summary of the project performance results according to the expected IRs is provided below.

1.1 IR 1: Increased Quality of TB Services

Project performance: The overall TSR achieved in FY14 is 78.9% compared to 78.6% in FY13, 77% in FY12, and 71% in FY10 respectively for the new smear positive (SS+) cases.

For smear conversion rate (SCR), the project reported 73% in FY14, compared with 75.5% in FY13 and 74.2% in FY12. The loss-to-follow up rate was 7% in FY14, compared to 7.1% in FY13, and 7.8% in FY12.

1.2 IR 2: Increased availability of TB services

Capacity building: In FY14, a total of 7,670 health care workers (HCW) and community health workers (CHW) were trained in all nine provinces, achieving the targets set for both USAID (3,500) and PEPFAR (4,000). To support implementation of infection control (IC) guidelines, training was conducted for 1,075 HCW and CHW in seven provinces in conjunction with TB risk assessments, which were conducted in 73 facilities. In FY14, the USAID TB Program facilitated a High Level MDR-TB Course for local facilitators together

with the International Union Against Tuberculosis and Lung Diseases (The Union). This was the final course for the seven doctors who have been trained and mentored by The Union.

Ensure functional TB/HIV Integration: In FY14, a total of 524,595 HIV positive patients were screened for TB, an increase from 378,900 in FY13. During FY14, there was 131,213 TB patients registered, 113,523 (86.5%) of whom were tested for HIV and had their status recorded in the TB registers. A total of 165,482 HIV patients found to be without TB were initiated on Isoniazid Preventive Therapy (IPT). Co-trimoxazole Preventative Therapy (CPT) uptake increased from 76.3% in FY13 to 83.9% in FY14. Antiretroviral Therapy (ART) uptake increased from 56.2.6% to 67.6%.

Multi-drug Resistant (MDR) TB: South Africa has among the largest MDR TB programs in the world and the USAID TB Program supported the strengthening and expansion of quality MDR TB diagnostic and care services through multi-pronged strategies including assisting to expand access to diagnostic services through GeneXpert and support for comprehensive, decentralized community-based care. In FY14, the project facilitated training of 475 HCWs (doctors, nurses, and hospice nurses) on PMDT. In addition, the project supported the establishment of DR TB clinical review committees at the provincial and district levels, focusing on high-burden districts in Free State, KZN, Gauteng, and North West, to improve DR TB program management and patient outcomes. Small grant partners were assisted to further expand the network of community-based care for MDR TB patients. Five NGOs are currently providing care and treatment support to 244 MDR TB patients and 21 XDR TB patients.

Laboratory Diagnostics: In FY14, the project completed the scale-up of GeneXpert (GXP) training which began in 2013, with 179 individuals trained in Eastern Cape, Limpopo, and North West provinces. A session on TB diagnostics has been incorporated into the DS and DR TB management trainings, and the impact of the GXP on the key indicators including bacteriological coverage (BC) and treatment outcomes is continuously addressed during trainings.

The TB Program hosted two national summits on TB Diagnostics. One was in November 2013 in joint collaboration with the National Department of Health (NDOH) in November 2013. A total of 100 local and international participants attended from the DOH, USAID, Department of Science and Technology, and other key stakeholders from the public and private sector. Likewise, the TB Program supported the Child TB Diagnostics Summit held on September 18, 2014, in collaboration with the Department of Health and University of Pretoria. This was a one-day seminar to address the diagnosis of TB in children, bringing together 80 experts at the Council for Scientific and Industrial Research (CSIR) in Pretoria.

1.3 IR 3: Increased Demand of TB services

Advocacy, Communication and Social Mobilization (ACSM): During FY14, a total of 1,033 participants were reached by ACSM trainings in six provinces. To rally support for the campaign on TB in children launched in FY13, the USAID TB Program focused in FY14 on developing frontline support through district ACSM workshops with Department of Health (DOH) promoters from Kwa-Zulu Natal, Gauteng, and Free State.

Small grants: In FY14, the Small Grants program focused on aligning the grantees' activities with the DOH's PHC Re-engineering Strategy. The TB Program also collaborated with the NTP and World Health Organization (WHO) Engage –TB on activities that improved data management and measured community contribution from HCWs to TB control. Nine NGOs also presented at the 4th SA TB Conference held in Durban from 10 – 13 June, 2014.

The Small Grants programs this FY14 focused on capacity building for the NGOs, funded six research projects, scaled-up the management of TB in children, and intensified case findings. Currently, the TB Program has closed out 39 NGOs in FY14.

1.4 IR 4: Improved Management of TB Support Systems

Procurement of Park Homes: In FY14, USAID TB Program procured and installed eleven (11) park home modular units to be used as an addition to existing health facilities/clinics in Eastern Cape, KwaZulu-Natal (KZN), and Mpumalanga to improve their infrastructure capacity to deliver quality TB services.

DVE and TB/HIV collaborative workshops: The implementation of data verification exercises (DVE) in supported districts resulted in improvements in the identification of program challenges. Electronic TB Register (ETR) support followed by facility supportive supervision continues. To improve the quality of the TB/HIV program, quarterly TB/HIV collaborative workshops were conducted.

1.5 IR 5: Tested New Approaches for Expanding DOTS Coverage

Activities for public-private mix (PPM) in FY14 included strengthening TB services in mines, correctional services and private sector. The USAID TB Program strengthened public-public collaboration with the Departments of Transport and Labour. Trade unions were capacitated to provide adequate support to their members on TB and HIV management. In collaboration with SABCOHA and the NDOH, the TB/HIV workplace toolkit was developed and finalized. The activities with THPs were continued in Limpopo, while Durban University of Technology was funded to support (KZN).

2 INTRODUCTION

In 2013, South Africa reported 328,896 cases of tuberculosis (TB) – 312,380 new TB cases and 16,516 previously treated, excluding relapse, TB cases. The incidence for 2013 was 860/100,000. The treatment success rate (TSR) for new smear positive (SS+) cases was 77% in 2012, slightly lower than the 79% reported in 2010. For TB/HIV indicators, HIV testing for TB patients is at 90%, with 62% of TB patients co-infected with HIV. Co-trimoxazole uptake for co-infected patients is 81% while antiretroviral therapy (ART) uptake is 66%. The United States Agency for International Development (USAID) TB Program South Africa continues to provide technical assistance to the South African Government (SAG) in line with the National Strategic Plan (NSP).

The USAID TB Program South Africa supports the National TB Control Program (NTP) strategies for improving early case detection, increasing access to diagnostics, ensuring treatment support for patient on TB treatment and ensuring that there is provision of appropriate and timely HIV care for TB patients and ART treatment for all TB/HIV co-infected patients. Overall, the USAID TB Program continues to develop its multi-level support working closely with:

- ***The NTP*** – to build national support by mobilizing resources and creating a conducive environment for expansion of TB services. This includes policy support, support for TB/HIV integration, expanding diagnostic networks, developing strategic interventions that could rapidly address MDR/XDR TB threats, building systems for monitoring programmatic progress, and increasing access to TB services vulnerable populations such as children.
- ***Provincial and district health departments*** – to support the collaborative development of need based strategies to combat TB, TB/HIV and DR TB, as well as communities to create appropriate social mobilization and service delivery models for rapid directly observed treatment short-course (DOTS) expansion in the country.

The Project's technical and financial inputs contribute to the following expected results:

- Treatment success rate of 80%;
- Improved capacity to plan and implement TB DOTS at community, facility, district, municipality, provincial and national levels;
- Improved surveillance system resulting in early detection of TB cases, MDR TB cases, co-infected patients for ART as well as to prevent treatment defaulters and reduce mortality.
- Improved understanding and support among the general population regarding TB and TB/HIV signs, symptoms, referral, and treatment.

The Project works to align its planned activities with the strategic policies of the South African Government (SAG). These key strategic policies include the following:

- Health Sector 10 Point Plan, in which Point 7 specifically emphasizes accelerated implementation of the National Strategic Plan for HIV and AIDS, sexually transmitted infections (STI) and TB (HAST) 2012-2016 reduction of mortality due to TB;

- Decentralization of services to Primary Health Care (PHC) and nurse initiated diagnosis, treatment, and monitoring of HIV infected patients including management of TB/HIV co-infected patients. The criteria for initiation of ART for co-infected patients which changed to allow ART initiation for all co-infected patients.
- Revised the National DR TB Control Policy: amendment addressing decentralization of DR TB care and community based management of DR TB;

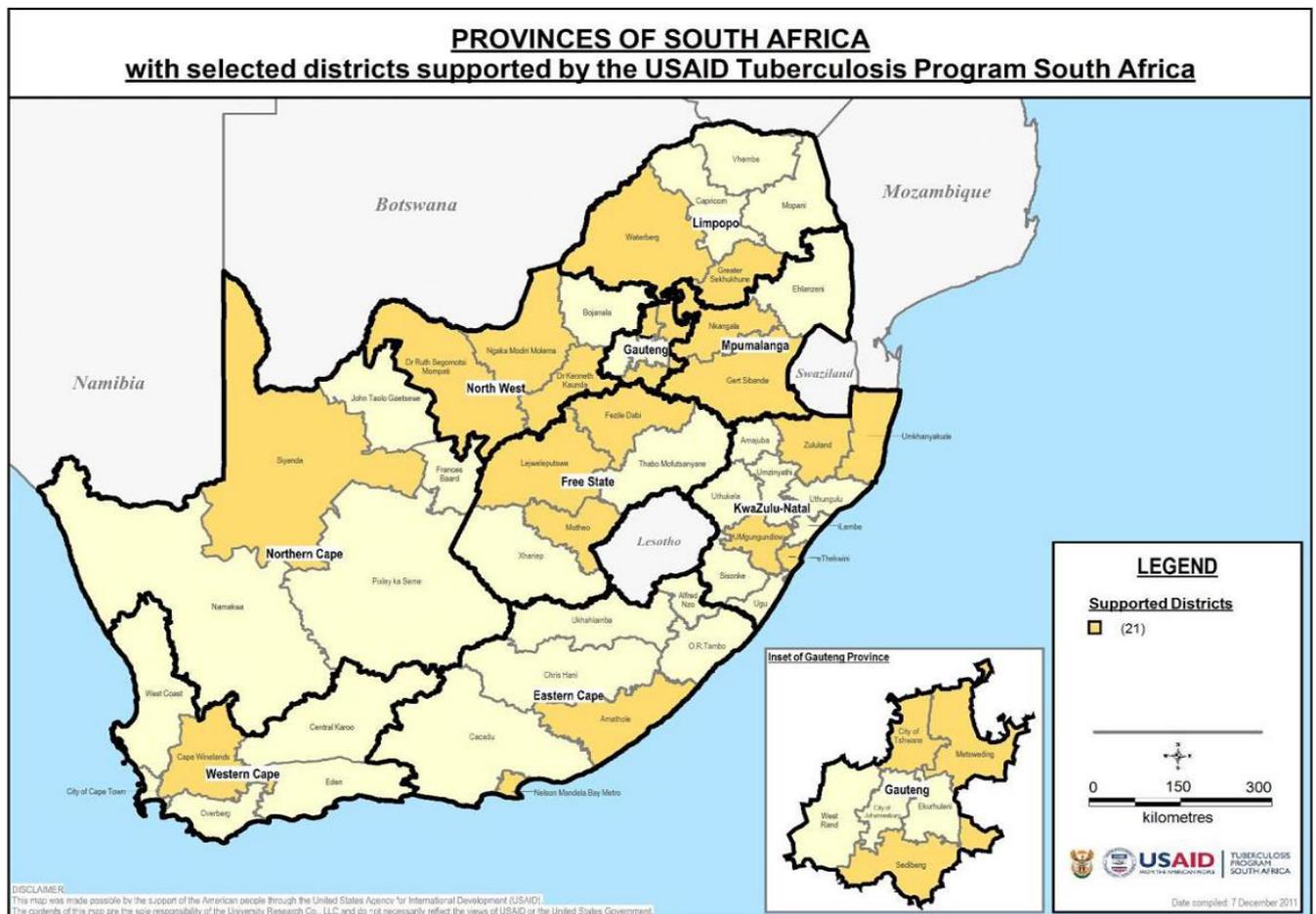
Activities in FY14 will be implemented in all the 24 supported districts. See **Figure 1: USAID TB Allocated District by Province on page 12.**

3 OVERALL PROJECT PERFORMANCE

3.1 Performance by Geographic Coverage

The project geographical coverage represents 46% (24/52) of all the districts in the country as reflected in the map below.

Figure 1: USAID TB Program Allocated Districts by Province



3.2 Progress on USAID overall Targets

Progress on the key indicators is presented in *Table 1* below.

Table 1: Project Overall - Indicators progress summary, FY14

Indicator	Baseline	Target (FY14)	Achieved (FY14)
Number of improvements to laws, policies, regulations or guidelines related to improved access and use of health services drafted with USG support		2	2
Number of people trained in DOTS with USG funding		3500	3558
Number of TB cases reported to NTP by USG-assisted non-MoH sector		3500	1375
% of all registered TB patients tested for HIV through USG-supported programs		90%	86.5%
% of registered new smear positive pulmonary TB cases that were cured and completed treatment under DOTS (i.e. treatment success rate) in USG-supported areas	74%	85%	78.9%
SCR rates for new smear positive cases	63%	75%	73%
Cure rates for new smear positive cases	62%	75%	72.3%
Defaulter rates for new smear positive cases	8.3%	≤5%	7.0%

3.2.1 TB Case Finding

A total of 135,318 TB cases were reported in FY14, out of which 125,095 were new TB cases, and 10,223 (7.6%) were re-treatment TB cases (see **Figure 2**). Of these, 111,349 (89%) were pulmonary TB cases (PTB), while 13,746 (11%) were extra-pulmonary TB cases (**Figure 3**).

Figure 2: FY14 TB Case Notification

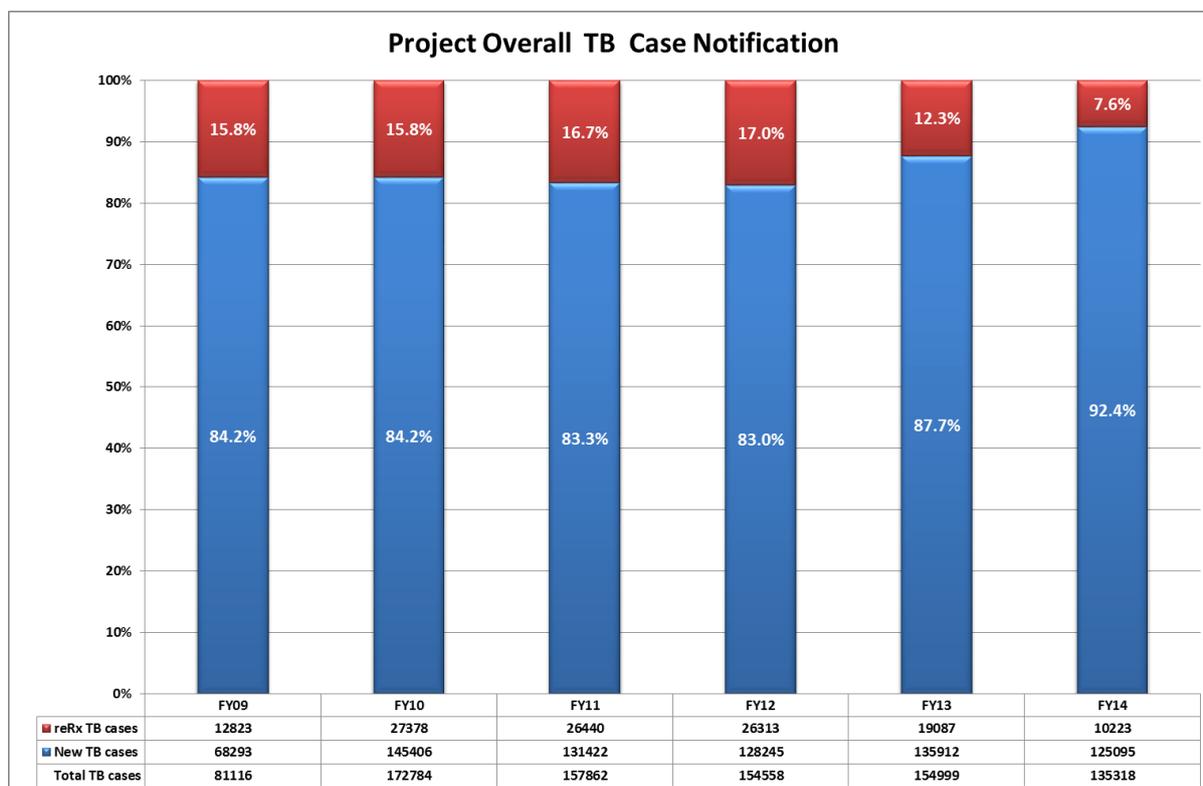
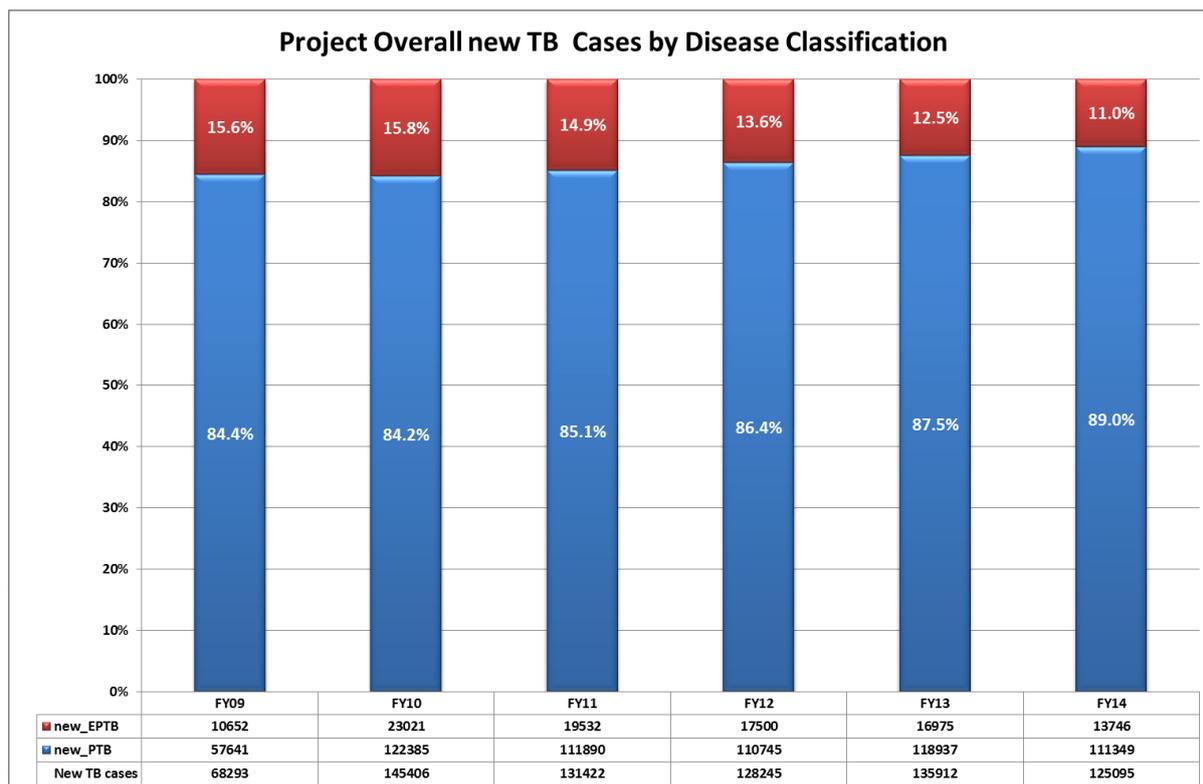


Figure 3: FY 14 New TB Cases by Disease Classification



3.3 Performance by Intermediate Results

3.3.1 IR 1 – Improved quality of TB services:

3.3.1.1 Support for Improved TB Policies and Guidelines

Updates to TB/HIV Policy and Guidelines: The USAID TB Program continued to support the DOH in the revision of National TB Management Guidelines, Guidelines for the Management of TB in Children, and the IPT Guidelines and associated training materials. The national TB management guidelines and the guidelines for the management of TB in children were launched and are being used in facilities, following project support for training and dissemination. The updated IPT guidelines and training materials are currently awaiting National Department of Health (NDOH) final approval. The project is supporting the DOH in reviewing the monitoring and evaluation plan for the IPT programme. Draft IPT clinical stationary was developed by the project and presented to the DOH for approval.

Updates to MDR TB Policies and Guidelines: The USAID TB Program continued to support the DOH (DR-TB Cluster) and provide technical support in exploring possible changes for consideration in the current DR-TB treatment guidelines to introduce newer generation second line agents such as Linezolid, Bedaquiline, and Delaminate to strengthen the current treatment regimen. The USAID TB Program South Africa provide ongoing support for the National Bedaquiline Clinical Trial Access Program currently running in South Africa.

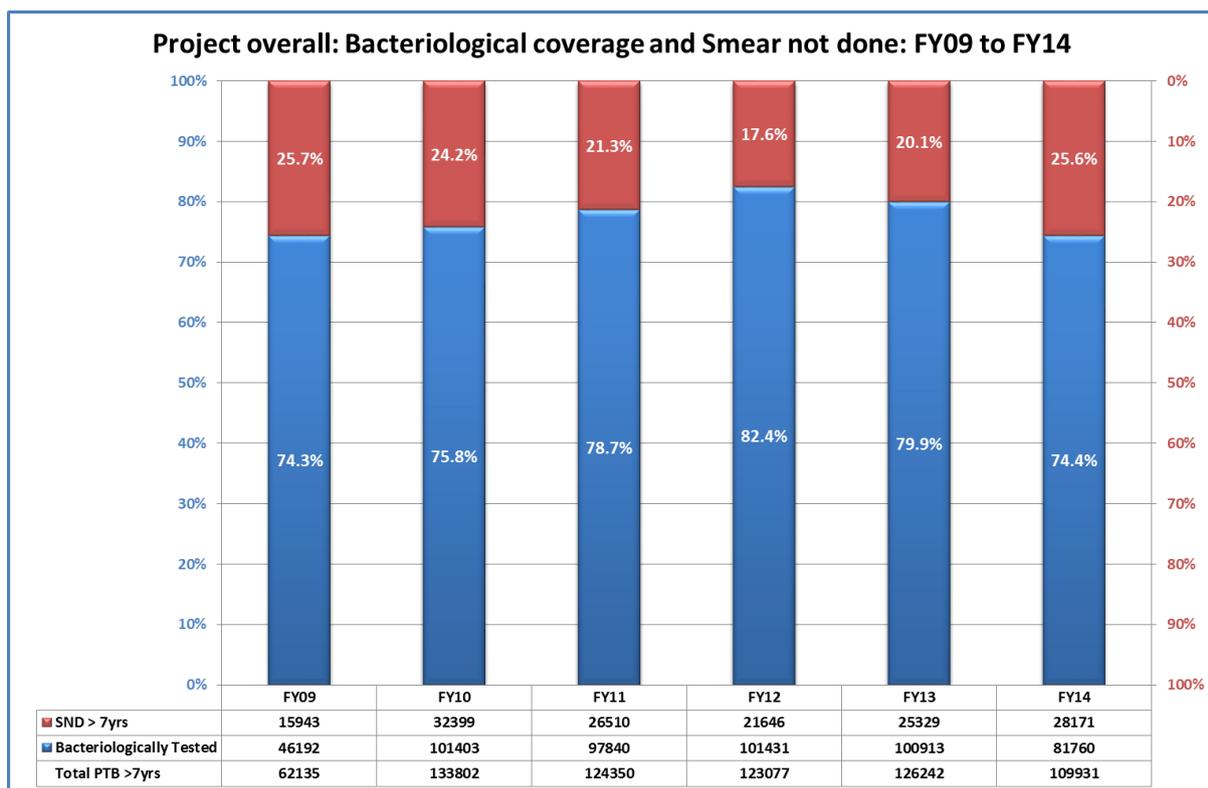
3.3.1.2 Support for DOTS expansion: In FY 14, the TB Program small grants program and the Public-Private Mix (PPM) activities supported DOTS expansion. This included PPM activities for strengthening TB services in mines, correctional services and the private sector. Under the small grants program, one of our grantee, Durban University of Technology supported training and activities for traditional health practitioners (THPs).

3.3.1.3 Monitoring of diagnostic indicators

Bacteriological Coverage (BC)

BC has declined since peaking at 82.4% in 2012. The decline has coincided with the rollout of the GXP program, for which the USAID TB Program played a leading role. The ETR system was not updated simultaneously to accommodate diagnosis by the GXP. This resulted in an artificially high rate of smear not done. The GXP algorithm addressed this issue by recommending repeating smears for clients diagnosed by GXP; however, the smear result needs to be uploaded into the ETR system within 48 hours. The USAID TB Program is supporting the NDOH in rolling out the amended ETR.V2 which addresses most of these technical issues.

Figure 4: BC and Smear not done FY09 to FY14



Smear Conversion Rates

The sputum conversion rate report, like BC report, is plagued with similar technical challenges with sputum results not available constituting the biggest determinant of the low sputum conversion rate. (Figure 5)

Figure 5: Project overall: Sputum Conversion Report- FY09 to FY14

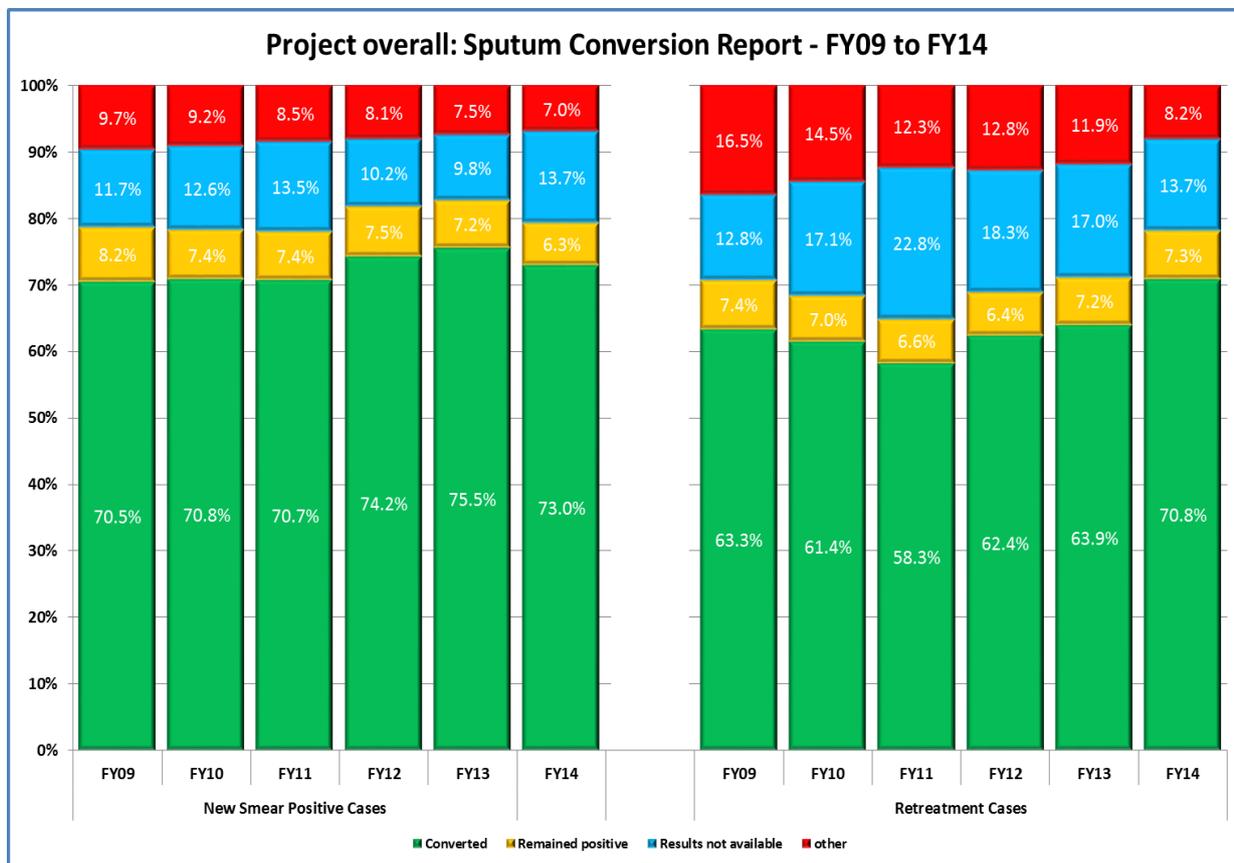


Figure 6 below illustrating some of the other technical challenges experienced by the ETR, which included incompatible algorithms resulting in incorrect summations (top row does not add up to total new sputum smears/GXP positive cases, with 8% of cases not accounted for) The new ETR.v2 being rolled out has addressed this challenge and the rollout process has started. Retreatment cases only constitute 8% of the reported TB cases. During FY14, eight reporting units out of 25 were able to report SCR of above 80%.

Figure 6: ETR.Net Technological Snapshot



Report on New and Retreatment Sputum Smear Positive TB Cases

RAMOTSHERE MOILOA (NGAKA MODIRI MOLEMA, NORTH WEST)

QUARTER 1 of 2014

Created By: KARABO SENOSI

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Table 1: New Sputum Smear / Gene Xpert Positive - Conversion at 2 months

New sputum smear / gene xpert positive cases	Sputum conversion at 2 months (negative)	Not converted (sputum results still positive) at 2 months	Not Evaluated* 2 months	Died before sputum conversion	Transferred out before sputum conversion	Defaulted before sputum conversion
80	31	4	37	1	0	1
%	38.8%	5%	46.2%	1.2%	0%	1.2%

Table 2: New Sputum Smear Positive - Conversion at 3 months

Number not converted (sputum results still positive) at 3 months	Sputum conversion at 3 months (negative)	Not converted (sputum results still positive) at 3 months	Not Evaluated* 3 months	Died before sputum conversion	Transferred out before sputum conversion	Defaulted before sputum conversion

Treatment Outcomes

The treatment outcomes for the new SS+ have shown improvements since the beginning of the project with the most important contributor being improved patient retention. Declines in death rates and treatment failure have also contributed to the improved treatment outcome. The project continues to focus on assisting reporting units to improve the quality of data to decrease the number of cases that are not evaluated; continued support is needed in this area. Two reporting units, uMgungundlovu and Tshwane achieved the target of >85% treatment success rate and 11 achieved treatment success rates of above 80%.

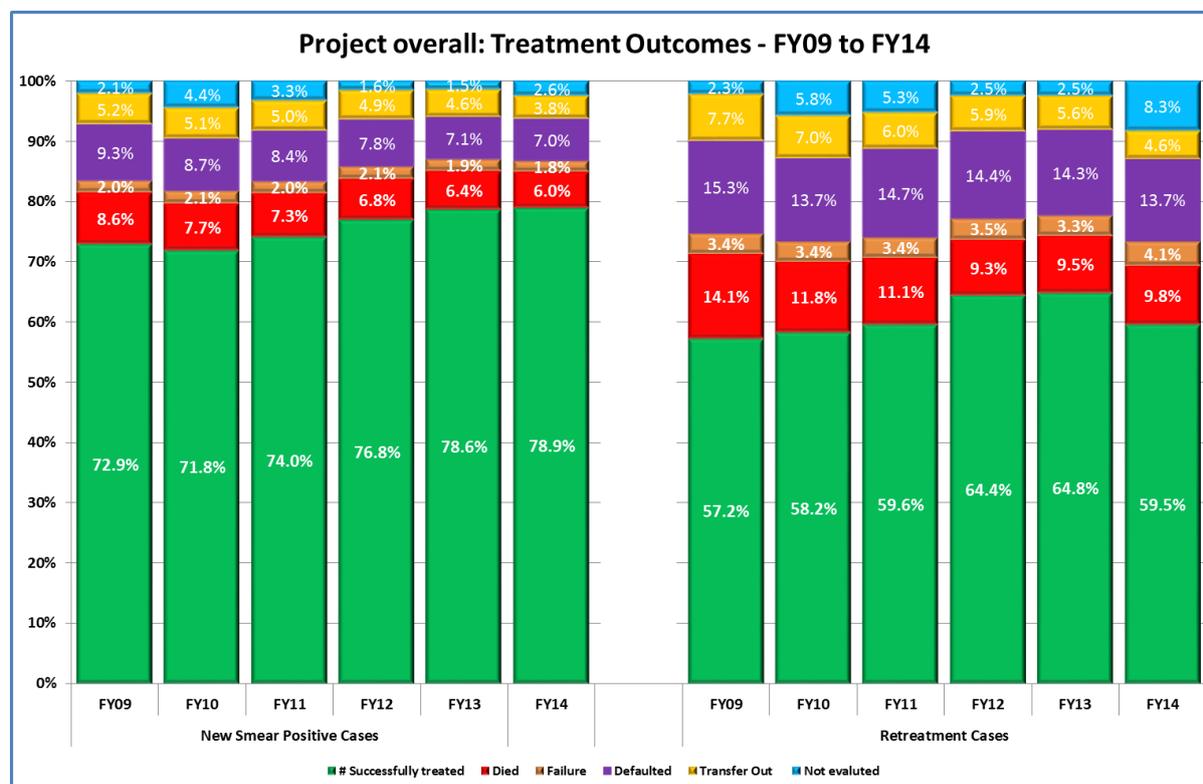


Figure 7: Treatment Outcomes- FY09 to FY14

3.3.2 IR 2 – Increased availability of TB services

3.3.2.1 Capacity Building

In FY14, a total of 7,670 health care workers (HCW) and community health workers (CHW) were trained in all nine provinces, achieving the targets set for both USAID (3,500) and PEPFAR (4,000). Under USAID, the project reached 3,558 doctors, professional nurses, and non-professional nurses, and CHW working in both public and private health sector with training on basic TB management as well as clinical and programmatic management of DR TB. Under PEPFAR, a total of 2,004 HCW were trained on the care of co-infected TB/HIV patients and TB/HIV collaborative activities.

Table 2: Summary of trainings conducted in FY14

Numbers for PEPFAR			Numbers for TraiNet / USAID		
Indicator	Target	Reached	Indicator	Target	Reached
<i>Number of HCWs trained on TB IPC</i>	<i>1000</i>	<i>1075</i>	<i>Number of people trained in DOTS using USG funds</i>	<i>3500</i>	<i>3558</i>
<i>Number of HCWs trained on TB/HIV</i>	<i>2000</i>	<i>2004</i>			
<i>ACSM</i>	<i>1000</i>	<i>1033</i>			
TOTAL	4000	4112	TOTAL	3500	3558

Infection control and facility risk assessments: To support implementation of infection control (IC) guidelines, training was conducted for 1,075 HCW and CHW in seven provinces. Facility TB risk assessments were conducted in 73 facilities in FY14. The results of these risk assessments revealed that only 26 facilities (36%) had designated either a person or committee responsible for TB IPC. Only 27 facilities (37%) had a TB IPC plan.

National Level Trainings: The project also supported a number of national level capacity building activities.

DR-TB - In FY2014, the USAID TB Program facilitated a High Level MDR-TB Course for local facilitators together with Dr. Jose Caminero from The Union. This was the final course for the seven doctors who have been trained and mentored by The Union in March 2014.

Diagnostics - In November, 2013, the project conducted a National TB Diagnostic Summit with 99 attendees.

TB HIV- From 17 – 19 March 2014, the project’s provincial and national team were trained on Nurse Initiated Management of Anti-Retroviral Treatment (NIMART), which aimed at supporting the health facilities in providing comprehensive care for TBHIV co-infected patients and to improve ART uptake in co infected patients.

NTP - Starting in 2012, the project has collaborated on a National Trainers Task Team was under the guidance of the National TB Program (NTP). The project has assisted the Task Team to develop, pilot and revise a comprehensive training manual to be used in a standard five-day TB and HIV Care and Management Course for Health Care Workers. The interactive didactic curriculum includes ten sessions, focusing on how to diagnose, care, manage and treat HIV/AIDS and TB, including drug resistant TB. The objective of the training will be to enhance and strengthen the role of health care professionals in providing /quality care to patients infected with HIV and TB. The project also continued to train staff the latest comprehensive TB and TBHIV manuals for HCWs, covering topics including TB diagnosis and HIV, management of TB, Drug Resistant TB, management of TB in an HIV

infected patient, TB Infection Prevention and Control and case scenarios, which are being used in provincial and district level capacity building efforts.

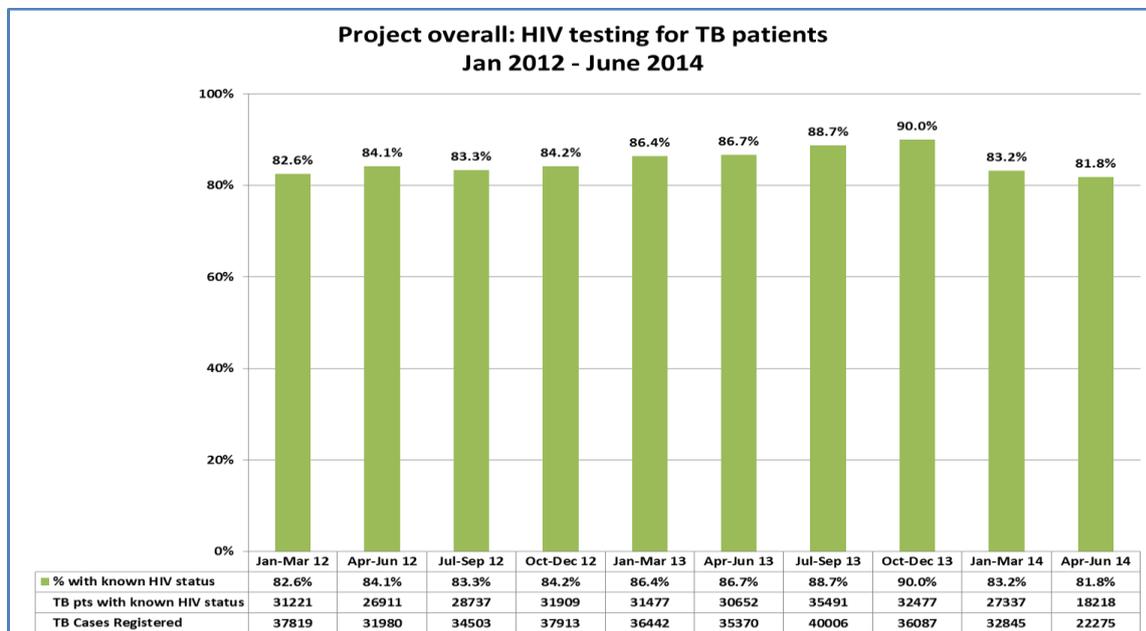
3.3.2.2 TB/HIV Integration

The TB/HIV indicators presented below monitor the quality of care in TB HIV co-infected patients received from health facilities. The data represents overall performance from all the 24 reporting units. The project continued with routine mentoring and coaching activities in the supported districts, strengthening the provision of HIV services for TB patients and TB services for HIV positive clients.

TB Entry Point: HIV testing among TB patients; CPT and ART uptake for co-infected patients

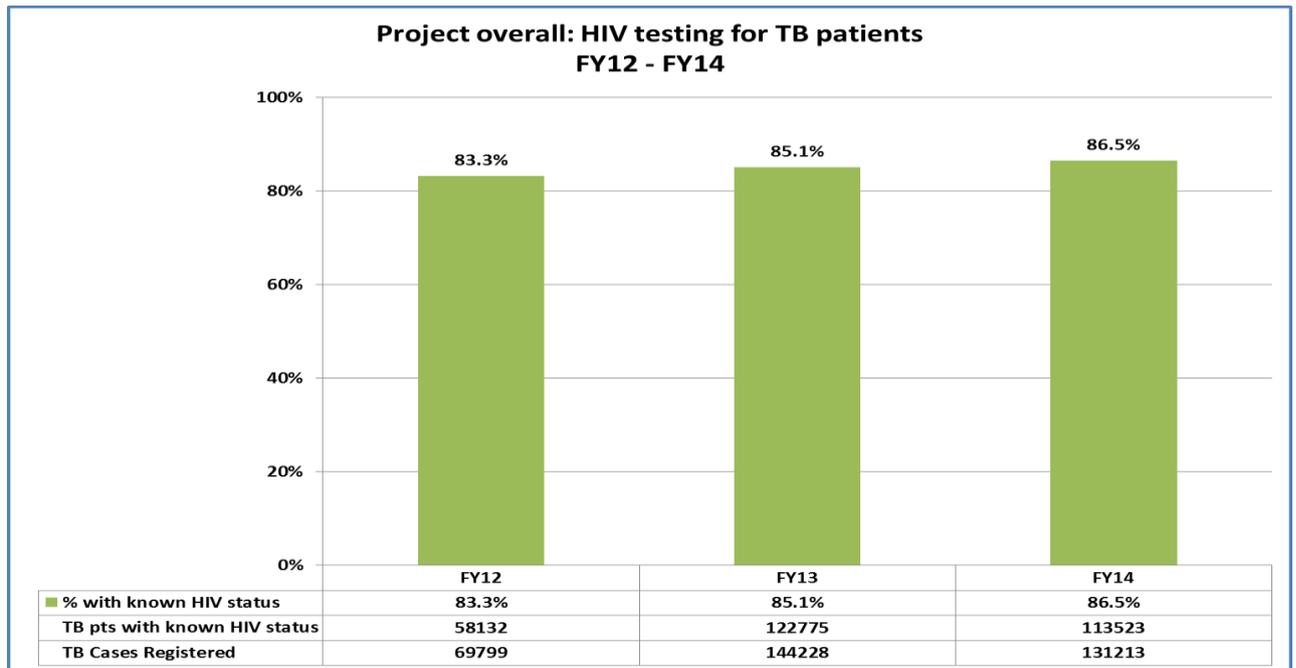
HIV Testing in TB patients: During the FY14, a total of 131,213 patients were registered for TB. This was decline from 144,228 in FY13, which could be explained by the general national trends in the decline of registered numbers of TB patients. The breakdown of the numbers registered per quarter are as shown in **Figure 8** below.

Figure 8: HIV testing for TB Patients (Jan 2012-June 2014)



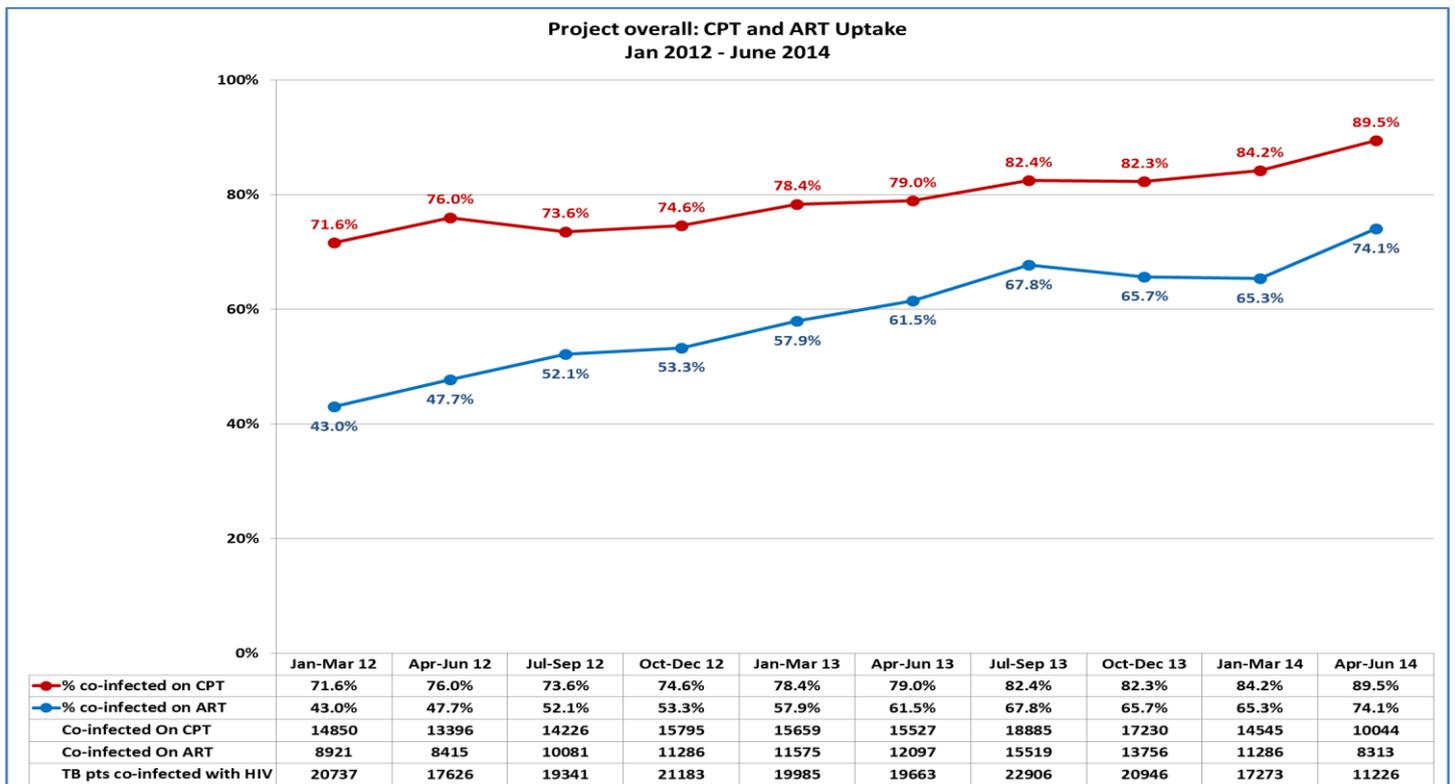
In South Africa, TB HIV co-infection is 65%, in different provinces. In the project supported districts ranges from the lowest 30.4% in Cape Winelands and the highest 78.4% in Gert Sibande HIV testing is recommended for all TB patients, and continues to expand at TB service sites. HIV testing among TB patients increased from 85.1% in FY13 to 86.5% in FY14 as shown in **Figure 9** below.

Figure 9: HIV testing for TB patients FY12-FY 14



CPT and ART uptake: CPT and ART uptake for TB/HIV co-infected patients continue to increase, reaching 89.5% and 74.1% respectively in April – June 2014 as shown in **Figure 10** below.

Figure 10: CPT and ART uptake Jan 2012 to June 2014 by quarter



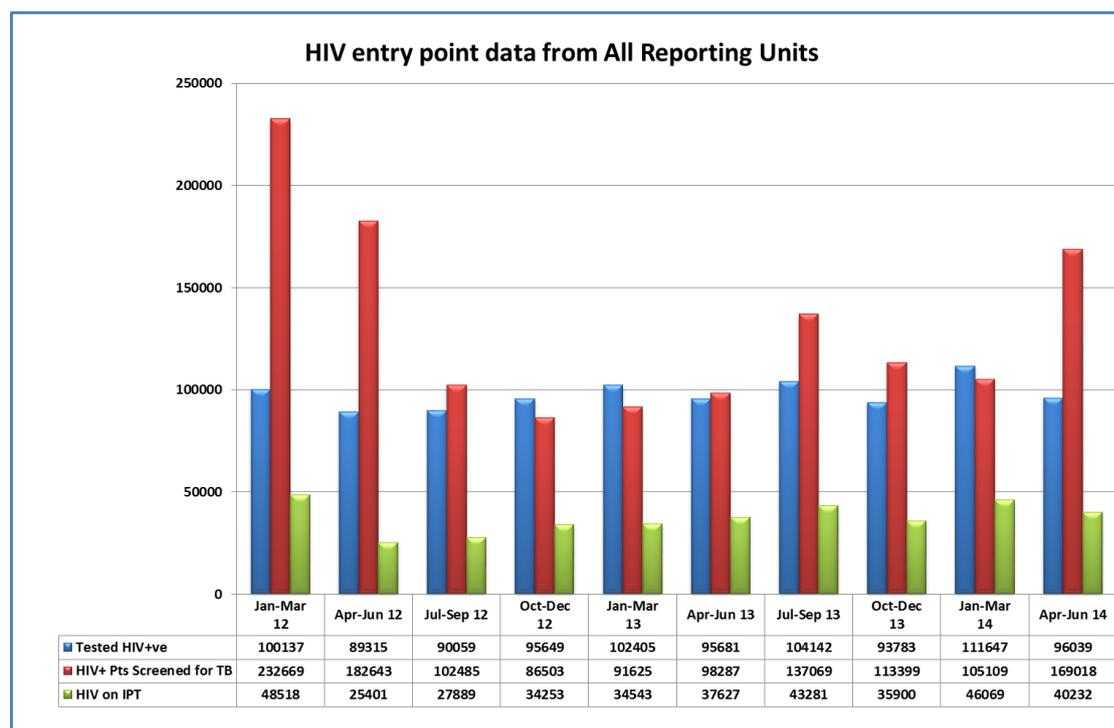
The increase in the ART uptake in supported districts is attributed to the project’s continued engagement with programme managers at district and sub-district levels to allocate NIMART trained nurses to TB services in order to improve TB HIV integration in facilities. Poor data quality and incomplete records also contribute to the poor performance for ART uptake. The project will continue to support the training of nurses on TB/HIV integration and advocate for NIMART trained nurses to be allocated to the TB services. In addition data validation exercises (DVEs) have been conducted throughout the year to assist to improve data quality.

HIV Entry Point: (Screening for TB in HIV+ Clients and Provision of IPT)

TB Screening in HIV patients

The DOH recommends that all patients be screened for TB whenever they visit the facility to improve active case finding. Challenges have arisen regarding reporting of TB screening among HIV positives as HCWs in most facilities count both new and known HIV patients screened for TB (rather than only new HIV cases as intended) hence the number of patients screened for TB is more than the number of those tested for HIV. The USAID TB Program has been educating the HCWs on the correct reporting of the indicator during the support visits and DVEs. **Figure 11** below shows project performance on TB screening among HIV positive patients and the provision of IPT.

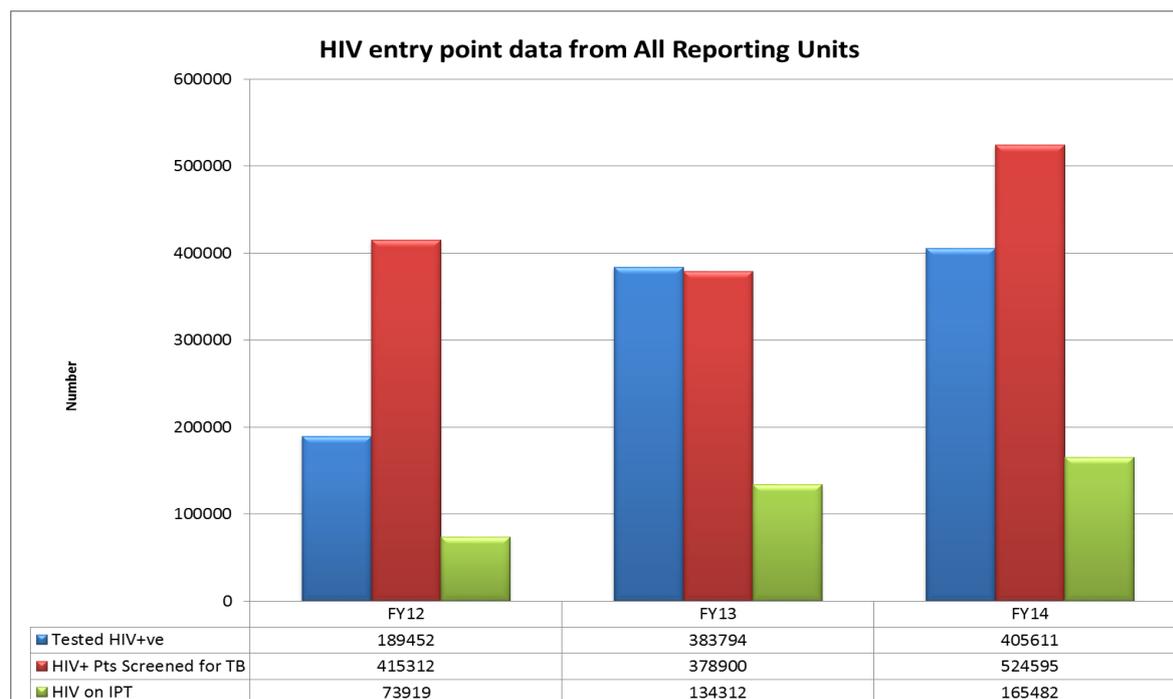
Figure 10: HIV entry point data Jan 2012 to June 2014



The number of HIV positive patents screened for TB significantly increased to 169,018 between April and June 2014 from 105,109 in the same quarter in 2013. In 2014, a total of 524,595 HIV positive patients were screened for TB.

This was an increase from 378,900 patients in 2013 as shown in **Figure 12** below.

Figure 11: HIV entry point data FY12-FY14



IPT uptake: Improvements were noted in patients initiated on IPT as compared to 2013, with IPT numbers increasing from 134,312 to 165,482 in 2014. The project provided IPT training to health care workers and strengthened IPT initiation through the supervisor visits and mentoring activities. The project will continue to build the capacity of HCWs to improve the management of TB and HIV, including initiating targeted support for identified challenges, such as inconsistent use of the screening tools, HCW not initiating patients on IPT, and poor documentation for patients on IPT. Although tools are available in facilities, HCWs are not using the tools to screen patients. The other main challenge in IPT uptake remains the unavailability of standardized tools nationally to document patients on IPT. In addition, the current system does not provide information on follow up patient until they complete IPT making it difficult to know how many patient complete IPT or default IPT.

Strategies to Improve IPT uptake: To improve the use of TB screening tools, the programme is supporting TB coordinators to strengthen supervision. In addition, the USAID TB Program has supported provincial DOH in developing and updating the TB screening tools currently used in facilities. The project printed and distributed the TB screening tools in supported districts thus contributing to the improved performance. The USAID TB Program is currently supporting the NTP in developing patient monitoring tools to be used in the management of patients started on IPT. These tools will help to improve patient management and recording of IPT. The project has also supported non-governmental organizations (NGOs) to conduct campaigns in partnership with the NDOH and other partners where TB screening was conducted. The NTP programme is finalizing the new IPT guidelines and training has commenced. The USAID TB Program is part of the core team finalizing the guidelines with the NDOH. The project will continue to roll out IPT training in the supported district build capacity of health care in initiating IPT.

Joint TB, HIV and Preventing Mother to Child Transmission (PMTCT) National Program Review:

The USAID TB Program participated in the Joint TB, HIV and Preventing Mother to Child Transmission (PMTCT) National Program Review that was conducted in October 2013. The reviewed primarily focused on programme performance and the secondary objective was to foster integration between these programmes. Best practices were noted and shared, so were challenges observed. Most of the challenges had previously been reported on an ongoing basis by the project, ranging from staff shortages in facilities, incorrect or lack of recording and reporting especially related to GXP results, vertical paper and electronic tools that are not interfaced such as ETR.net, Tier.net, etc., all of which the key recommendations were to address as a matter of urgency. The report of this review was developed by the organizers, in collaboration with project staff.

District TB/HIV summits: The project participated in three separate TB/HIV summits in Xhariep and Thabo Mofutsanyane and Fazile Dabi districts in Free State, both of which were aimed at discussing the social and structural drivers of TB, HIV and STI with various stakeholders. The summit also focused on integrating TB, HIV and maternal and child health (MCH) programmes. In Fazile Dabi, the project was part of the team that developed an integrated plan to address identified challenges faced by the three programmes.

3.3.2.3 MDR TB Management

South Africa is implementing the largest programmatic management of DR TB (PMDT) program to address the increasing number of MDR/XDR TB cases, and has introduced the GXP as first line of TB diagnosis countrywide to replace smear microscopy. These two interventions are attributed to a strong political commitment and large financial investment in the country. South Africa reported 26,023 laboratory-confirmed cases of MDR TB cases in 2013, with only 10,663 (41%) on treatment. During FY14, the USAID TB Program supported several activities to increase the capacity to decentralize MDR/XDR TB patients care and support, which are summarized below.

Training on PMDT: In FY14, the project facilitated training of 475 HCWs (doctors, nurses, and hospice nurses) on PMDT.

DR TB Clinical Review Committees: The project is providing technical support for the establishment of DR TB clinical review committees at the provincial and district levels, focusing on high-burden districts, to improve DR TB program management and patient outcomes. These multidisciplinary committees will be responsible for providing leadership and guidance in all aspects of PMDT, including further management of DR TB treatment failures, in line with national policy guidelines. The project is working with the PDOHs to develop and finalize terms of reference, standard operating procedures for these committees. Planning and orientation activities are underway in Free State, North-West, KZN, and Gauteng.

Support to Grantees Managing DR TB Patients: The USAID TB Program South Africa team is continuing to provide technical support to 12 NGOs/grantees in five provinces who are supporting MDR management activities in their communities. Grantee activities include cPMDT, contact tracing, tracing of treatment interrupters, and DOT support.

Five NGOs provided care and treatment support to 288 MDR TB patients and 24 XDR TB patients. By end of September, 2014, 128 MDR-TB patients had converted to culture negative with grantees reporting 94% adherence to treatment.

Palliative Care for MDR TB Patients: The Program funded a mission by a global palliative care expert to assess the provision of palliative care services for patients with incurable MDR/XDR TB and to catalyze the development of a framework with short- and long-term programmatic interventions. The mission consisted of field visits and discussions with key stakeholders, including representatives from the NTCP, Provincial departments of health, Hospice Palliative Care Association of South Africa and MSF, and included a seminar attended by Program staff, representatives from the NDOH and from several provinces. The field visit were done in three different provinces which includes Free State, KwaZulu Natal, and Western Cape Province.

3.3.2.4 Support for TB Diagnostics

National Summit on TB Diagnostics, 18-19 November 2013

The TB Program South Africa hosted a National Summit on TB Diagnostics in joint collaboration with the NDOH in November 2013. A total of 100 local and international participants attended from the DOH, USAID, Department of Science and Technology, public and private laboratory service providers, diagnostic product manufacturers, funders, researchers, implementing partners, academics and other stakeholders. The objective of the meeting was to provide a forum for these stakeholders to review and discuss the state of TB diagnostics in South Africa, and create a roadmap for improving laboratory diagnosis of TB in the country. The focus areas for the panel sessions are summarized in the diagram below.

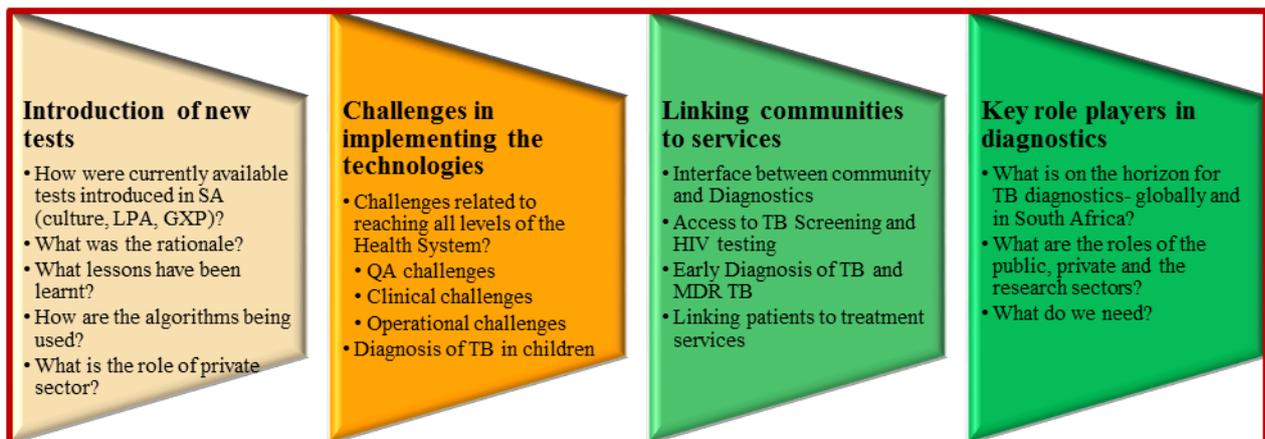


Figure 12: Session topics for the National Summit on TB Diagnostics, 18-19 November 2013

Key recommendations that came out of the summit include:

- Development of a generic national implementation framework for future review and rollout of new diagnostic tests.
- Establishment of a multi-stakeholder national task team of experts to provide ongoing advice / guidance on introduction of new tests and other diagnostics matters.
- Regular (annual) meetings of this nature to follow up implementation of recommendation of this summit.

The report is finalized by the USAID TB Program and NTP. Draft action plans have already been put together by NTP. A copy of the report is available on request for further details, and

the final copy will be distributed to all URC staff and summit participants. All presentations from the summit are available on: <http://tbsouthafrica.org/node/267> .

Waterberg District Data Review, 18 – 20 June 2014

The second GXP impact review was conducted since the baseline assessment, data is being analyzed and will be shared with the district once completed. The following observations were made:

- ✓ GXP increased the number of TB diagnosed cases mainly in the hospitals
- ✓ TAT in hospitals also improved.
- ✓ There was no impact on both TAT and diagnosed cases for samples collected from the clinics.
- ✓ Lab diagnosed DR-TB (Rif resistant) also increased in the district.

Childhood TB Seminar, 18 September 2014

The USAID TB Program, in collaboration with the Department of Health and University of Pretoria, hosted a one-day seminar to address the diagnosis of TB in children, bringing together 80 experts at the CSIR in Pretoria. The theme of the event, “Childhood TB: The Elephant in the Room,” aptly captures the nature of pediatric TB – overlooked in the past but increasingly recognized as an important challenge for National TB Control Programs to address. The DOH will continue to strengthen implementation of the full TB diagnostic cycle – to ensure that rapid TB testing results in early treatment initiation for TB patients.

3.3.3 IR 3 – Increased demand of TB services

3.3.3.1 ACSM

Advocacy to Build DOH capacity in ACSM: To rally support for the campaign on TB in children launched in FY13, the USAID TB Program focused in FY14 on developing frontline support through district ACSM workshops with DOH promoters from KZN, Gauteng, and Free State. The training workshops were designed to support the implementation of strategic evidence-informed ACSM plans that will strengthen community response in actively finding TB cases and preventing the spread of TB in children. In total, 90 people participated in these ACSM capacity building sessions.

Mass Media: In FY14, the USAID TB Program continued to air PSAs developed by the project to reinforce messages and awareness raising on TB in children. Project subcontractor Mediology reported that through May 2014, 15,498,700 members of the target population (Blacks, ages 16-64) were reached through TV messages, while 17,878,740 were reached through radio messages.

World TB Day Commemorative Activities: To celebrate World TB Day in 2014, the USAID TB Program worked with the NTP to redesign the national TB screening tool to include symptomatic screening of children. This tool was used for screening at the national and provincial TB Day events. In Gauteng, Eastern Cape, and KZN, the project partners with DOHs and local partners to lead health walks and door-to-door outreach to encourage communities to make public pledges to stop the spread of TB in children. At the national level, the project worked with the NDOH to develop educational and promotional material to highlight the national World TB Day theme: *Find, Treat, and Cure TB in hard-to-reach communities.*



Mobilization Against TB in Children: The USAID TB Program took the opportunity to highlight TB in children at the 4th annual National TB conference, which was held in Durban from June 10-13, 2014. On June 10, 2014, in the run up to the conference, the TB Program South Africa hosted a “We Beat TB in Children” walk in partnership with the mayor of eThekweni district of KZN. This event promoted awareness of TB in children and linked with a conference satellite session facilitated by the project entitled “We Beat TB in Children: Getting to Zero TB Deaths in Children.” At the project exhibition booth, conference participants were given the opportunity to learn more about TB in children and take a pledge to help stop TB in children – and 951 attendees signed up to do so.



The project, in partnership with the NDOH, also conducted a satellite workshop on Childhood TB at the 2014 UNIPATH Congress hosted by the University of Pretoria on September 18, 2014 at CSIR International Convention Centre.



Materials Development: In FY14, the project developed a series of communication materials to increase awareness in communities and improve interpersonal support for people with TB and their families. Materials developed and distributed included: TB Screening Tool (10,000), Daily Appointment TB Diary (5,000), Smart Cards (225,000) and Posters (over 130,000). Promotional materials (such as caps, water bottles, conference bags, etc.) branded with key TB messages were distributed at various events.

3.3.3.2 Small Grants

In FY14, the small grants program focused on intensifying the current efforts aimed to align the grantees with the government PHC Re-engineering Strategy. The TB Program collaborated with the NTP and WHO Engage-TB on activities to enhance the systems to improve data management and measure the contribution of community – based HCWs to TB control. The purpose of this alignment was to ensure sustainability of the work done and improve community-based care for the served areas, also looking at the main activities that will benefit the communities beyond the funding period; e.g. intensified case finding, ACSM and treatment adherence to both TB and HIV.

There were 48 NGOs active at the beginning of FY14. At the end of FY14, 39 have been successfully closed out.

Short – term grant allocation was provided for a period of 1-month to nine NGOs, selected from a pool of completed contracts under Wave 4.

Capacity building for NGOs

A post award workshop was conducted for the last two organizations to be awarded grants in FY13 (Mpilonhle and University of Pretoria). On-site mentoring was provided to all 48 NGOs during quarterly visits by the Provincial Coordinators and close out visits by the Grants team.

The revision of the “TB Adherence Flipchart” was completed and launched during the World TB Day in the Cape Winelands.

There were nine grantees that presented at the 4th SA TB Conference held in Durban, 10 – 13 June, 2014, (Seven in the USAID TB Program sessions and four (two research projects) in the main conference plenary sessions)

Research projects

The six funded research projects have been completed:

1. Medical Research Council: Both research projects presented at the 4th SA TB Conference in Durban
 - Community-based care vs. centralised hospitalisation for MDR-TB patients KwaZulu-Natal, South Africa
 - Investigating the diagnosis of TB/MDR-TB and comparing models of treatment.
2. Human Sciences Research Council: presented at the SA 4th TB Conference
 - A multi-faceted intervention to improve adherence to tuberculosis treatment at three urban clinics in the Eastern Cape Province
3. Desmond Tutu TB Centre (DTTC), Stellenbosch University
 - - Strengthening the paediatric cycle for TB care. The research project will be presented as an e-Poster at the 45th Union Conference in Barcelona, 2014
4. University of Pretoria
 - - Community Oriented Primary Care (COPC): A municipal ward based primary care intervention to increase TB case detection and improve TB cure rates

Scaling up the management of TB in children

The project had identified two focus districts with high TB caseloads for scaling – up management of TB in children (NMBM and BCM). Three organizations were identified to intensify case detection among children. In addition, the project funded DTTC to test a model of care to improve management of TB in children. From a total of 920 child contacts <5years screened for TB, 52 (6%) were confirmed and started on TB treatment while 566 were started on IPT.

Intensified Case Finding

ICF continued to be a key activity for the funded grantees in FY14. A total of 81,331 people were reached with TB messages, this includes 13,855 learners reached during various school based activities. Of the 9,157 TB presumptive, 690 (7%) were confirmed with TB, 12 with

MDR-TB, of which 6 were school learners. Contact tracing was intensified for the 6 learners where another case of MDR was identified (grandmother to the learner)

Data management

The project's participation in the WHO/NTP engagement of community based organizations and monitoring contribution of these to TB control has culminated in the finalization of draft data collection tools for Civil Society Organizations. These will be formally presented to the Chief Directorate: TB Control for approval in the next quarter.

3.3.4 IR 4 – Improved Management of TB Support Systems

For FY14, key priorities for management support were to scale up TB/HIV collaborative model, conduct data verification, and continue ETR.net support. Training of managers and HCWs on TB program management, TB/HIV and analysis of data continued. The TB Program continued the joint quarterly DRAT; facility support visits with on-site mentoring and coaching.

Procurement of Park Homes: In FY14, USAID TB Program procured and installed eleven (11) park home modular units to be used as an addition to existing health facilities/clinics in Eastern Cape, KZN, and Mpumalanga to improve their infrastructure capacity to deliver quality TB services. Infection control implementation remains a challenge in some facilities being supported by the USAID TB Program due to infrastructure challenges. In most of the instances, the size of the facility does not allow for patient triaging or cross ventilation, and there is lack of space to be used as a waiting area for TB patients. This situation creates a risk to both patients and health care workers, resulting in nosocomial transmission of TB. In one facility in KZN, nine health care workers were found to have contracted TB within the facility. The project provided the temporary structures to high case load facilities to decongest facilities and improve infection control in the facilities identified as having infrastructure problems which compromise implementation of infection control. Park homes will also be utilized to improve integration of TB/HIV services, which is a priority for NSP on HIV STI and TB 2012-2016. In some of the facilities, TB patients diagnosed with HIV currently have to be referred to other facilities for ART, despite the fact that there are NIMART trained nurses within the facility.

TB Think Tank Meeting: The project participated in the TB Think Tank Meeting to reduce the incidence of TB: The meeting reviewed key research findings by various local researchers and key findings of the integrated TB/HIV/MCH program review conducted in October 2013. The following were identified as priority areas for intensified focus and scale up to meet the MDGs by 31 December 2015:

- Implement an integrated approach at community level to reduce transmission;
- Conduct TB prevalence survey;
- Improve programmatic reporting;
- Implement a patient-centred approach;
- Accelerate the use of unique patient identifiers.

Mentorship and Supportive Supervision: The USAID TB Program Coordinators continued to work with other NGO partners in order to optimize TB-HIV support at facility level through focused capacity building of nurse mentors and NGOs' community health care workers to enable them to provide focused support at facility level thus contributing to overall improvement in TB-HIV program outcomes. Ongoing mentoring and coaching was provided to facility staff on the importance of HCT for TB patients, TB screening for PLHIV, and CPT and ART provision for HIV co-infected TB patients.

Peer Review and TB/HIV Collaborative: The USAID TB Program continued to support the Quarterly District TB/HIV collaborative meetings in all supported districts. The workshops reviewed TB HIV programme progress, challenges and mapping the way forwards to achieve programmatic goals. New approaches were discussed on improving the care of TB/HIV patients in the community and on strengthening linkages between facilities and communities and contact and defaulter tracing.

Data Verification Exercise (DVE): In 2014, the project in partnership with DOH conducted six DVEs in Mahikeng Sub-district (Ngaka Modiri Molema District), Matlosana Sub-district (Dr Kenneth Kaunda District), East London Sub-district (Buffalo City Metro Health District), Mnquma Sub-district (Amathole District), Bloemfontein Sub-district (Mangaung Metro Health District) and EThekweni District.

The objectives of these exercises are to improve TB & HIV data management and quality through identifying good practices, identifying gaps in data management and identifying interventions to be implemented to improve data quality. The findings from the DVEs showed that the standardized NTCP data collection tools were being implemented across sub-districts and districts. The health facility staff demonstrated a positive attitude towards the exercise, learning and to be corrected in accordance with the NTCP guidelines. Filing at sub-district and district levels was generally satisfactory.

However, challenges were also learnt in the data management and patient management processes. These include:

- Incomplete and incorrect recording of information in the TB registers and patient files;
- Data review/data checks not done regularly at local level;
- No feedback provided to facilities on their performance;
- ETR.net technical challenges and its alignment with the current TB programme guidelines;
- Poor integration of TB and HIV services and data management processes;
- Untimely collection of sputum smears;
- Low suspicion rates in the facilities;
- Limited understanding of the management of TB in children by health care workers; and
- Allocation of junior category staff in the TB service points which leads to sub-optimal management of patients.

The USAID TB Program shared recommendations with DOH and will be offering technical assistance in the areas supported for betterment of the TB and TB/HIV programme. In particular:

- To continue with the data verification and encourage sense of ownership of the activity by programme supervisors for sustainability;

- Conduct training on data collection tools and recording for TB focal nurses where applicable;
- Data checks to be run and updated before data are submitted to the next level;
- Feedback should be provided to facilities on their performance and data quality issues on a monthly and quarterly basis;
- Support supervision of health care workers should ensure timely collection of sputum smears by the use of the TB diary -- USAID TB Program may assist in training HCWs on the same;
- Continuous training and emphasis on the GXP algorithm reinforces the proper implementation the GXP algorithm;
- Training HCW on the Childhood TB Guidelines and Childhood TB Management Job Aid distributed to facilities for guidance on diagnosis and management of TB in children; and
- Where possible, advocate for professional nurses to be allocated to the TB focal area, or should closely supervise the junior staff to ensure optimal management of TB patients.

HAST strategic planning meetings: The programme participated in the HAST strategic planning session in Gauteng and Western Cape provinces. The provinces were developing their 5 year strategic plans and the project provided technical input to the development of the plans.

3.3.5 IR 5 – Tested New Approaches for Expanding DOTS Coverage

USAID South Africa TB Program Public Private Mix (PPM) Approach for TB Control

PPM is one of the strategies that the USAID TB Program uses to address challenge of access to TB care, treatment and support in the private sector. The TB Program applies PPM to promote new approaches and partnerships for delivery of TB care by engaging various health care providers that exist in South Africa. Involvement of private providers and NGOs in the delivery of TB care not only expands the number of delivery points making it convenient for TB clients, but most importantly expands the resources available to them. The activities in FY14 included the following:

- Building capacity through knowledge and skills enhancement of health care workers;
- Improving systems for case management at facility level by private health care providers;
- Strengthening linkages between health facilities and laboratory networks;
- Improving DOTS implementation strategies to reduce multi-drug resistant TB (MDR-TB) as well as improved management of MDR TB patients;
- Improving capacity of HIV testing sites to provide TB screening to all HIV+ clients;
- National and local advocacy; and
- Supporting private sector involvement (e.g. mines, industries, and medical schemes) in TB service delivery.



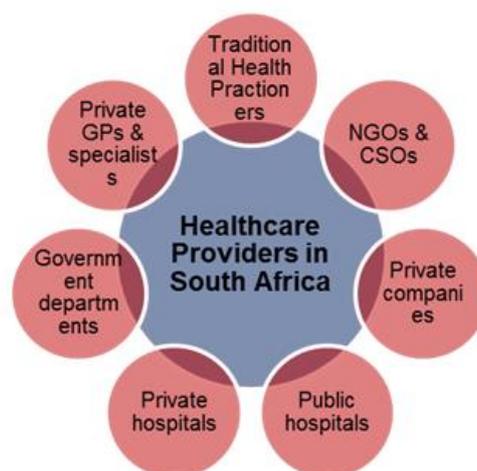
Addressing TB within private and public health care providers in South Africa

Although the public sector provides health services for the majority of the South African population, private for-profit providers serve a significant portion of the population. The USAID TB Program is collaborating with the service providers to deliver a comprehensive approach for their systematic involvement in TB control.

The World Health Organization (WHO) has documented that not all health care providers are actively involved in early TB detection, diagnosis, treatment and referral of TB patients. The perception and understanding of TB as a public health challenge varies across providers and stakeholders; and that delay in the timely diagnosis of patients with pulmonary TB remains a serious challenge in the health care sector. There are other difficulties affecting the quality of health care, which include cost of living expenses and decreases in take home pay for patients (i.e. medicines, transportation, lost work hours), as well as complications related to the poor adherence to treatment and loss of life due to health problems that are often treatable or curable.

The NTP has an insufficient number of providers to address the serious health threat caused by TB. The participation of other health providers is essential in order to join forces and achieve more effective TB care and control. This can be accomplished through the use of best practices and guidelines that are clearly outlined in international documents and reiterated in official NTP tools.

TB in the mining sector is a massive challenge and a top priority for DOH. South Africa has at least half a million mine workers, with the highest TB incidence in the world. In FY14, the USAID TB Program supported initiatives aimed at addressing the scourge of TB in the mines. The activities included providing technical advice in the development of the Mining-Led Stop Project Business Case, which was presented to chief executive officers from some mining companies. The USAID TB Program's approach has emphasized developing programs, and TB service linkages within small and medium size mines in Limpopo and



Gauteng Provinces. Jointly with the DOH, the project also facilitated local community based TB awareness and treatment services with mining communities. Technical support provided to small and medium size mines included:

- Technical assistance on integrating TB into HIV workplace policies
- Conducting assessment of TB management in selected mines in Limpopo province
- Strengthen TB programme management in the mining sector
- Capacity building of clinical staff
- Provision of Information, Education, and Communication (IEC) materials on TB

The TB Program's support for improving TB services within the mining sector focuses on developing lasting multi-sectoral partnerships geared around the following activities:

- **Advocacy and consensus building** among mine operators, mine health services, mine labourers' representatives, and district DOH on practical steps to implement the objectives within the declaration;
- **Development of service linkages between TB and other health and social support** agencies working with current and ex-miners and mining communities; and
- **Assistance to develop and expand TB workplace programs** in small and medium sized mines.

Completion of TB/HIV workplace toolkit: Towards the end of the fiscal year, the project began focusing on assembling and inventorying putting together the tools and documents developed over the life of the project. The TB toolkit, developed in collaboration with South African Business Coalition on Health & AIDS (SABCOHA), the NDOH and with inputs from International Labor Organization (ILO), was completed in the second half of the year.

TB Awareness Campaign at Medupi Power Station: The USAID TB Program conducted a one-day workplace TB awareness campaign at Eskom's Medupi power station in Lephalale in the Limpopo Province during the four day event TB and HIV event in September. During this campaign, 3,324 employees screened for TB; 477 were presumptive of TB; 422 sputum were collected from those who were presumptive of TB, four were employees were positive for TB, 51 samples were not tested because the sputum was insufficient, 19 had unsuccessful results, and three were put on TB treatment.

Improved screening, diagnosis, care and treatment of TB and TB/HIV cases by Traditional Health Practitioners (THP) in selected areas of KZN:

Zululand District:

- In Phongola, THPs have seen 2,873 patients overall, 60 TB suspects were screened and showed symptoms for TB and 12 TB suspects were referred to clinic. 96 suspects presented with HIV related symptoms and 43 were referred to clinic. One was referred for medical male circumcision.
- In eDumbe, 90 patients were seen by THPs. Five (5) TB suspects were referred to clinic. Twenty-one (21) patients presented with HIV/AIDS related symptoms, and all 21 were referred to the clinic. Of these, nine were referred for MMC and four were referred for PMTCT.

Amajuba District:

- In Newcastle, THPs have seen 656 patients. Here are some of the results: 30 TB suspects were identified; 21 patients presented with HIV/AIDS related symptoms; 6 were referred to clinic; five PMTCT referred and 2 MMC.

- In Danhasser, THPs have seen 153 patients. The results include: 11 TB suspects were identified and referred to the clinical for testing; 10 patients presented with HIV/AIDS related symptoms, of whom three were referred to the clinic for PMTCT.

Management of TB in the workplace: This quarter, the USAID TB Program team were invited by the Department of Labour (DOL) to share best practices and lessons learned about management of TB in the workplace. DOL partners present, including the Human Resource Management Team and the Director of the Employee Health and Wellness Team discussed challenged they are currently facing given the rising number of TB cases in their labour centres.

4 CHALLENGES

4.1 Implementation Challenges and Planned Resolution:

Data quality and verification at facility level remain a challenge. Generally all the challenges related to both the versions of ETR.net system are constantly being escalated to the Provincial and eventually NTP for further rectification with the next ETR version iterations.

Investigation by the USAID Program M&E team to know how the system works and findings based on the challenges already highlighted have been formally communicated to the NTP; and the changes/corrections have been incorporated in the latest iteration (version 2.0.15) of ETR.net system. The NTP is currently collaborating with the ETR.net system developer and the trainings on the revised version have re-started. Progress on the rollout of this corrected version to the various province/districts will be reported

5 COMMON AGENDA ITEMS

5.1 Project Website

The USAID TB Program manages a project website, www.tbsouthafrica.org, to share updates, stories and successes, disseminate news about events or partnership opportunities, and to serve as a library of TB-related materials. Working with our web-development partner, BEA Enterprises, the team tracks usage of the site to more effectively tailor content. Statistics from this quarter are as follows:

Website Statistics	Oct. 1, 2013 – Sept. 30, 2014
Visits	9,915
Unique visitors	8,200
Page views	18,686
New visitors	18%
Average pages per visit	1.88
Average minutes : seconds per visit	02:28
Mobile device visits	3,795
Arrived by search engine	74%
File downloads	582

5.2 Conferences

USAID TB Program South Africa Hosts National TB Diagnostic Summit

The USAID TB Program South Africa hosted a National TB Diagnostic Summit in Pretoria on November 18 – 19, 2013, bringing together key stakeholders to discuss the role of TB diagnostics in achieving the Stop TB Partnership goal of zero TB deaths. A high-quality laboratory system employing modern diagnostic techniques is critical to early, rapid, and accurate detection and treatment of TB. While South Africa has been at the forefront of countries of replacing traditional smear microscopy with rapid Xpert MTB/RIF (GeneXpert) testing for all patients presenting with TB symptoms, continued evaluation and improvement is needed. “There has not been a formal platform to review the introduction of these tests, development of diagnostic algorithms, lessons learned and how best to improve diagnostics or inform policy changes in the country hence we need this forum to harness efforts and work in partnership,” said South African Health Minister Aaron Motsoaledi, who chairs the Stop TB Partnership Coordinating Board.

South Africa is one of 12 countries identified by WHO as having a high burden of both TB and MDR-TB. With approximately 500,000 incident cases of TB per year, South Africa has the third largest TB epidemic in the world, after India and China. “These statistics stress the need for strengthening laboratory capacity, quality assurance measures and linkages between the laboratory and clinical components of the National TB Control Programme to ensure early diagnosis and treatment of the majority of these estimated cases,” Motsoaledi said.

The summit was attended by 120 key stakeholders, representing the National Department of Health, public and private laboratory service providers, TB diagnostics product manufacturers, researchers, and TB implementing partners. Topics of discussion included a review of newly-introduced diagnostic tests, challenges faced in implementing new technologies across all levels of the health system, how best to link communities to services, and the roles of the public, private, and research sectors in advancing laboratory diagnostics as part of the country’s overall health agenda. The summit coincided with the release of a public service announcement (PSA) on TB in children on television and radio, sponsored by the USAID TB Program South Africa. The PSA is designed to engage families and communities to recognize the risk and signs of TB in children and encourage them to seek diagnosis and treatment at local health facilities.



USAID TB Program South Africa Participation in National TB Conference in Durban

The USAID TB Program South Africa participated at the 4th annual national TB conference in Durban from June 10-13, 2014. The conference centred around the theme “working together to eradicate TB” feature three thematic tracks to address key issues hampering elimination of TB – detection and prevention of TB, TB treatment, and TB management. More than 1500 participants attended. The USAID TB Program South Africa had a strong presence at the conference, highlighting its work in TB over the past five years and assisting the NDOH and other partners to map the way forward for TB eradication in the country.

On June 10, the TB Program South Africa hosted a “We Beat TB in Children” walk in partnership with the mayor of eThekweni district of KwaZulu-Natal. This event promoted awareness of TB in children and linked with a satellite session the project facilitated at the conference on the morning of June 10 entitled “We Beat TB in Children: Getting to Zero TB Deaths in Children.” On June 11, the USAID TB Program South Africa facilitated a session on community-based management of drug-resistant TB (DR TB), highlighting lessons learned and project achievements to date in strengthening and scaling up DR TB support at the community level. On June 12, the TB Program South Africa also facilitated a third satellite session on engaging community-based and civil society organizations in TB and TB/HIV control. This session reflected on work done by NGOs in supporting the National TB Control Program’s efforts to improve case detection, TB treatment outcomes, and integrating TB/HIV services. The USAID TB Program South Africa presented the achievements lessons learned from its small grants program, which has provided 85 small grants to 67 NGOs since 2009. A number of these small grantees also participated in the conference through oral and poster presentations of their work.

The project developed a series of technical briefs on project achievements around key thematic areas, including TB/HIV, MDR TB, TB diagnostics, and small grants, which were also on display and disseminated. Please see **Annexure 3**.



USAID TB Program Supports Child TB Diagnostics Summit

On September 18, 2014 the USAID Tuberculosis (TB) Program South Africa, in collaboration with the Department of Health and University of Pretoria, hosted a one-day seminar to address the diagnosis of TB in children, bringing together 80 experts at the CSIR in Pretoria. The theme of the event, “Childhood TB: The Elephant in the Room”, aptly captures the nature of pediatric TB – overlooked in the past but increasingly recognized as an important challenge for National TB Control Programs to address.

The first session focused on current gaps in diagnosis of TB in children, as well as progress made to date. Participants discussed the South African TB diagnostic algorithm, and the impact of Xpert MTB/RIF rapid testing technology (GeneXpert) on diagnosis of pediatric TB. Diagnosis of TB in children occurs most easily when health care workers ask the right questions; however, it was agreed that additional training and support of health care workers is needed to ensure they know the right questions to ask and what to do with that information. The second session built off lessons learned during the National Diagnostics Summit held in November 2013, and addressed key issues of regulation and standardization, access and affordability, priorities for operational research, and development of public-private partnerships to further support the development of TB diagnostics. The final portion of the summit focused on advocacy – building the momentum to get to zero TB transmission in children – by asking if children are receiving the attention they deserve and if policy is effectively translating into practice. Participants explored ways to raise community awareness of TB in children and to improve the management of childhood TB at the facility and community levels.

TB diagnostics still have a long way to go – there is no rapid test that can diagnose TB similar to those that exist for HIV, nor is there a diagnostic instrument specifically designed to diagnose TB in children. However, the South Africa Department of Health remains at the forefront of championing new diagnostics – particularly in the roll out of GeneXpert. The Department of Health will continue to strengthen implementation of the full TB diagnostic cycle – to ensure that rapid TB testing results in early treatment initiation for TB patients.



6 GOING FORWARD

At the end of FY14, the project completed five years of implementation. In order to avoid gaps in delivery of technical assistance going forward, a short (5 month) extension period is planned, extending in Q2 FY15. During this period, the project will continue supporting critical activities at the provincial and district level, and will also focus on transition and sustainability of activities conducted with small rants partners and the NDOHs through future project support mechanisms, including the USAID TB CARE II project. An additional critical focus during this period will be to further document and translate successes and challenges experienced during the life of the project, to further describe and develop technical assistance strategies.

7 ANNEXURES



USAID
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**TUBERCULOSIS
PROGRAM
SOUTH AFRICA**



ANNEXURE 1: FY2014

MONITORING & EVALUATION REPORT (OCTOBER 2013 TO SEPTEMBER 2014)

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Report submitted:
30 October 2014

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List of Acronyms

AFB	Acid Fast Bacilli
ART	Antiretroviral Therapy
BC	Bacteriological Coverage
CCW	Community Care Worker
CPT	Co-Trimoxazole Prophylaxis Therapy
DoH	Department of Health
DOTS	Directly Observed Treatment Short-course
DVE	Data Verification Exercise
EPTB	Extra Pulmonary Tuberculosis
ETR	Electronic Tuberculosis Register
GXP	GeneXpert
KZN	KwaZulu Natal
M&E	Monitoring and Evaluation
MDR-TB	Multidrug-Resistant Tuberculosis
NHLS	National Health Laboratory Services
NIMART	Nurse Initiated Management of Anti-retroviral Therapy
NMBHD	Nelson Mandela Bay Metropolitan
NTCP	National Tuberculosis Control Program
NW	North West
PHC	Primary Health Care
PICT	Provider Initiated Counselling and Testing
PTB	Pulmonary Tuberculosis
reRx	Re-treatment
SA	South Africa
SCR	Smear Conversion Rate
SND	Smear Not Done
SS+	Smear Positive
TB	Tuberculosis
THP	Traditional Health Practitioner
TSR	Treatment Success Rate

I. Introduction

The monitoring and evaluation (M&E) on USAID Tuberculosis (TB) Program South Africa (SA) attempts to address issues of transparency and accountability as comprehensively as possible. This report focuses on the presentation of data, interrogation of the same and districts' activities planned to address challenges indicated by the data. The reporting period is Oct 2013 to Sep 2014. Insight into the districts program performance is described below and comparisons are made between the various groups. In areas where there was no consistent fielding of a provincial coordinator, indirect support such as training on Basic TB Management including the GeneXpert (GXP) Algorithm was provided. The affected reporting units include Lejweleputswa, Fezile Dabi, Siyanda, Tshwane, Cape Winelands and uMkhanyakude.

A. Progress on Performance

The report will focus on the overall USAID TB Program progress as well as comparing district and group performances against agreed targets.

The results presented focuses on the main TB indicators that cover the output level of:

- *Bacteriological coverage (BC)*
- *Sputum smear conversion rates (SCR)*

and treatment outcome indicators comprising:-

- *Cure rates*
- *Treatment success rates (TSR) and*
- *Lost to follow-up rates (defaulter rates);*

II. Overall Program Performance: FY14

The M&E report presents district-level data employing a number of methods to give a broader picture of the performance of the project in different districts. Comparison of different groups will also be made to highlight improving trends following interventions. In all nine provinces, there are 24 districts and sub-districts that are supported. These reporting units are grouped according to the time of initial intervention:

- ✓ Group 1: Eleven districts (Amathole, Buffalo City Metropolitan (BCMHD), Nelson Mandela Bay (NMBHD), eThekweni, Nkangala, Sedibeng, Greater Sekhukhune, Dr Kenneth Kaunda, Ngaka Modiri Molema, Dr Ruth Semogotsi Mompoti, and Waterberg). These are the districts which were identified as having unsatisfactory performance; indicated by the performance at initial support. Despite being lower than the target, improving trends have been observed.
- ✓ Group 2: Seven districts (Fezile Dabi, Tshwane, Lejweleputswa, Gert Sibande, Mangaung, Zululand, uMkhanyakude)
- ✓ Group 3: Two districts (uMgungundlovu, Siyanda)
- ✓ Group 4: Four districts (Xhariep, Cape Winelands, Thabo Mofutsanyane, Chris Hani)

It should be noted that due to focused support rendered in North West, sub-districts that receive support are reporting as individual units; hence in Dr Kenneth Kaunda District, there are two reporting units i.e. Matlosana and Ventersdorp Sub-districts, while in Ngaka Modiri Molema, there are also two sub-districts (Mahikeng and Ramotshere Moiloa).

Due to recurrent challenges with Greater Taung Sub-district Management and no provincial coordinator in the area, there were no support activities and data were not provided for reporting.

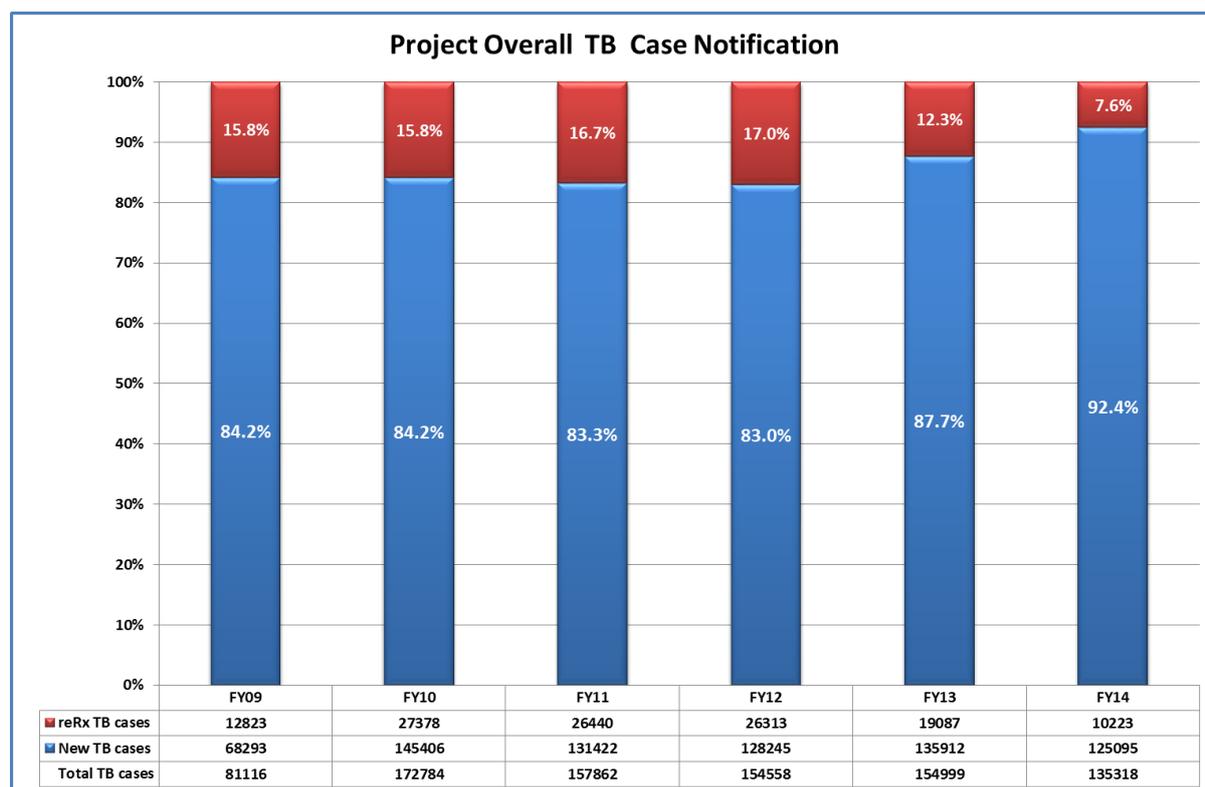
Generally all the challenges (detailed in this report per corresponding indicator performance affected) related to both the versions of ETR.net system have been escalated to the Provincial and eventually the National TB Control Program (NTCP) for further rectification as the system is updated from one ETR.net version iteration to the next.

III. TB Case Notification

The reporting year 2014 has also seen a decline in case notification (by 14.5%) a trend that has been observed since 2009. The reason for the decline despite the high reported TB incidence in South Africa has not been fully explained. South Africa rolled out one of the largest GeneXpert programs in the world to improve case detection including adopting a new diagnostic algorithm supported by the USAID TB program.

Possible reasons for the decline include the scale up of ART in South Africa, which is also the largest in world, increasing from 32 893 in 2005 to 2.4 million in 2014. The use of infection control and isoniazid prophylactic therapy are likely to have played a role as well.

Figure 1: TB Case Notification



In 2014 the number of new TB cases are disproportionately higher than the previous years. This is because, all clients diagnosed by the GeneXpert machine (rifampicin sensitive), were treated by the six month regimen which is captured as a new TB case in the Electronic TB register (ETR). As GeneXpert was being rolled out this artefact has increased (FY13 and FY14).

There is a proportional increase in pulmonary tuberculosis (in both new and retreatment with the later showing only 3.7% of the cases being extra pulmonary). The reasons for this requires some investigation. The hypothesis that clients with higher CD4's are less likely to have extra pulmonary tuberculosis needs to be tested. The median CD4 of a South African client being initiated in 2009 was 149cells/μL and while the data is currently not available for 2014, the revision of South African guidelines in 2011 to increase ART initiation criteria to <350cells/μL.

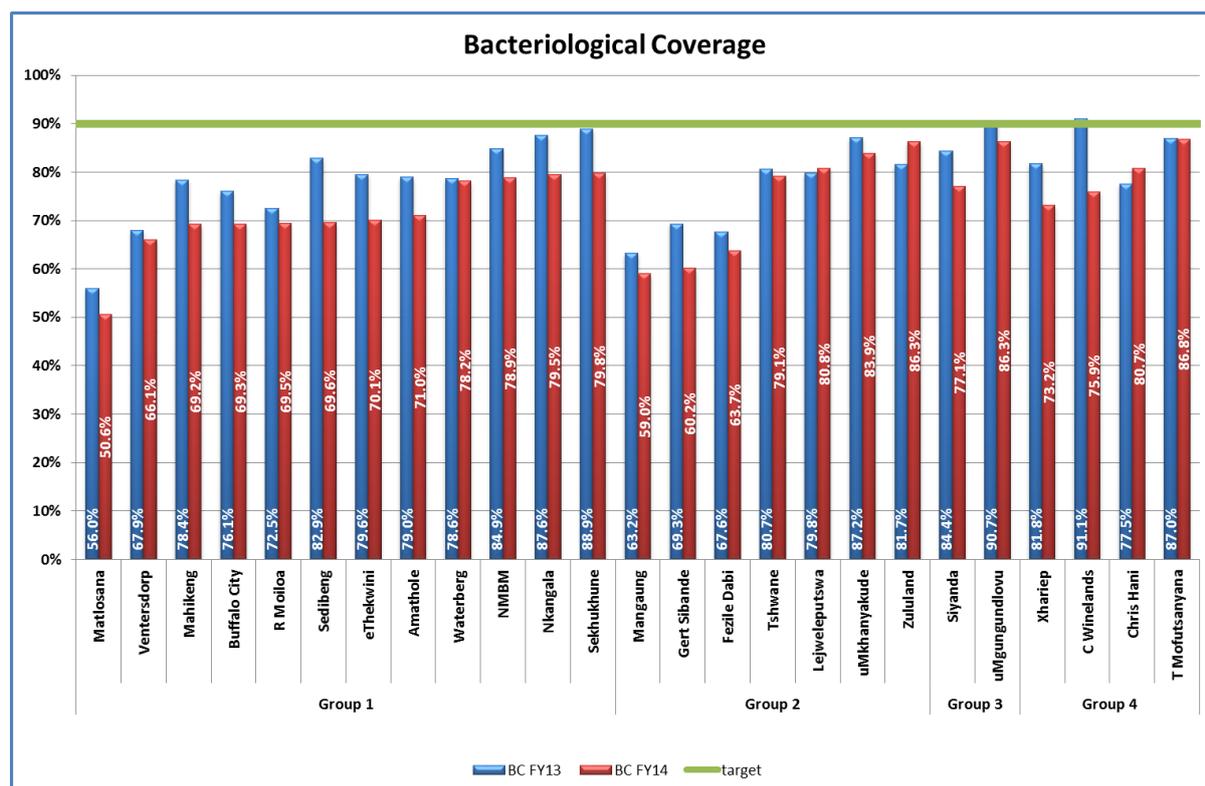
IV. Bacteriological Coverage

There have been perpetual challenges around sustaining and/or improving bacteriological coverage (BC) nationally. The project's bacteriological coverage has been declining since last year due to various challenges (see the annual report); mostly these challenges were around the issues associated with the introduction of GXP. The challenges include, but are not limited to: acid fast bacilli (AFB) smears taken after TB treatment initiation not being recognized by the electronic TB register (ETR) in the BC calculation – according to TB guidelines, pre-treatment AFB smears should be conducted within the first 28 days of

TB treatment initiation. Lack of uniformity in reporting GeneXpert (GXP) has also been a challenge – districts that report low BC are those that are capturing the GXP results correctly as guided by the National TB Control Program (NTCP) but ETR doesn't include those test results in the calculation of BC. Since the GXP rollout; health information personnel have been instructed to record the GXP results under culture while the recording tools are being revised.

Some districts are still resorting to collecting two specimens at once; one for GXP and another for smear microscopy, this is in order to mitigate the challenge with pre-treatment AFB smears that are not done for all GXP positive cases. NTCP has also been working with the ETR.net developers to reprogram the system based on the issues identified as system errors and also for alignment with the TB program clinical developments, etc.

Figure 2: BC districts' snapshot: FY13 and FY14



The project BC dropped significantly from a peak of 82.4 in FY12 to 74.4% in FY14; this is a further 5% drop from the 79.9% reported in FY13. Though none of the reporting units reached the target of 90% in FY14; eight of them reported BC of at least 80% and above. It is to be noted however that; except for Chris Hani, Lejweleputswa and Zululand districts; all the other units reported a BC performance drop from the FY13 period. The most affected districts with close to 10% decline being Sekhukhune, Nkangala, EThekwini, Sedibeng and Mahikeng. The project will continue to strengthen efforts to mitigate and address this issues by continuing to:-

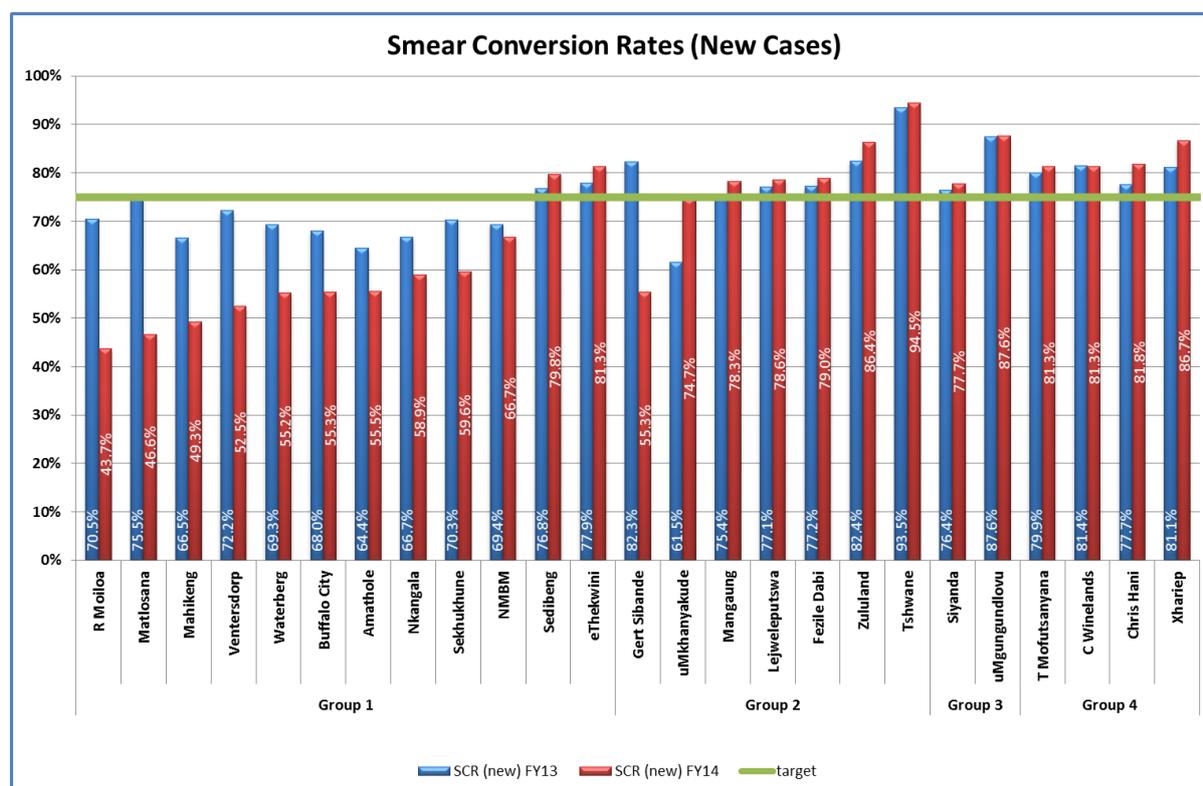
- Distribute related job and monitor sputum posters
- Partner with National Health Laboratories to train HCW on the latest diagnostics algorithms (including GXP)
- Conduct regular Data Verification Exercises
- Strengthen support to consistent peer review sessions
- Assist the NTP with the rollout of ETR.net V2 latest iteration

V. Smear Conversion Rates

The sputum conversion rate report, like bacterial coverage report, is plagued with similar technical challenges with sputum results not available constituting the biggest determinant of the low sputum conversion rate.

The project overall smear conversion rates (SCR), are still below target, recording 73% (see the annual report) for new smear positive cases in FY14. This is a drop in performance from the 75.5% reported in the FY13. This below target performance is due mostly to the challenges already highlighted with the migration of districts data to the new ETR.net version. SCR for retreatment cases are now above the target at 70.8% for this reporting period. Despite the ETR.net system challenges; the TB program still faces a number of challenges such as AFB smears not being collected particularly in hospitals, late (not within the range according to the guideline) collection of AFB smears at the end of intensive phase. Consequences to these include the ETR omitting those results in the calculation of the SCR and/or a higher proportion (14% this year) of smear results not available at the end of the intensive phase.

Figure 3: Smear conversion rates - districts' snapshot FY13 and FY14



More than half (14 of the 25) of the reporting units did manage to reach and surpass the smear conversion rates (SCR) targets of 75% for new smear positive cases. Notably, there are still challenges with Limpopo (LP) districts i.e. Greater Sekhukhune and Waterberg; Mpumalanga (MP) districts i.e. Nkangala and Gert Sibande; as well as NW reporting units. These districts/ reporting units have all rolled out ETR version 2. Smear conversion reports run from this new version are significantly different from version 1 reports. It is hoped that the situation will improve once this reporting units are now updated to the latest iteration which has been re-programmed accordingly.

TB diaries have also been found not to have been used properly in some facilities in the Waterberg area. There were also reported cases of clients remaining smear positive after completion of the TB treatment intensive phase. This was primarily in the North West and Limpopo districts. The project overall proportion of patients remaining positive at the end of intensive phase was 6.3% this reporting period; a slight decline for the above 7% from the previous years since FY10.

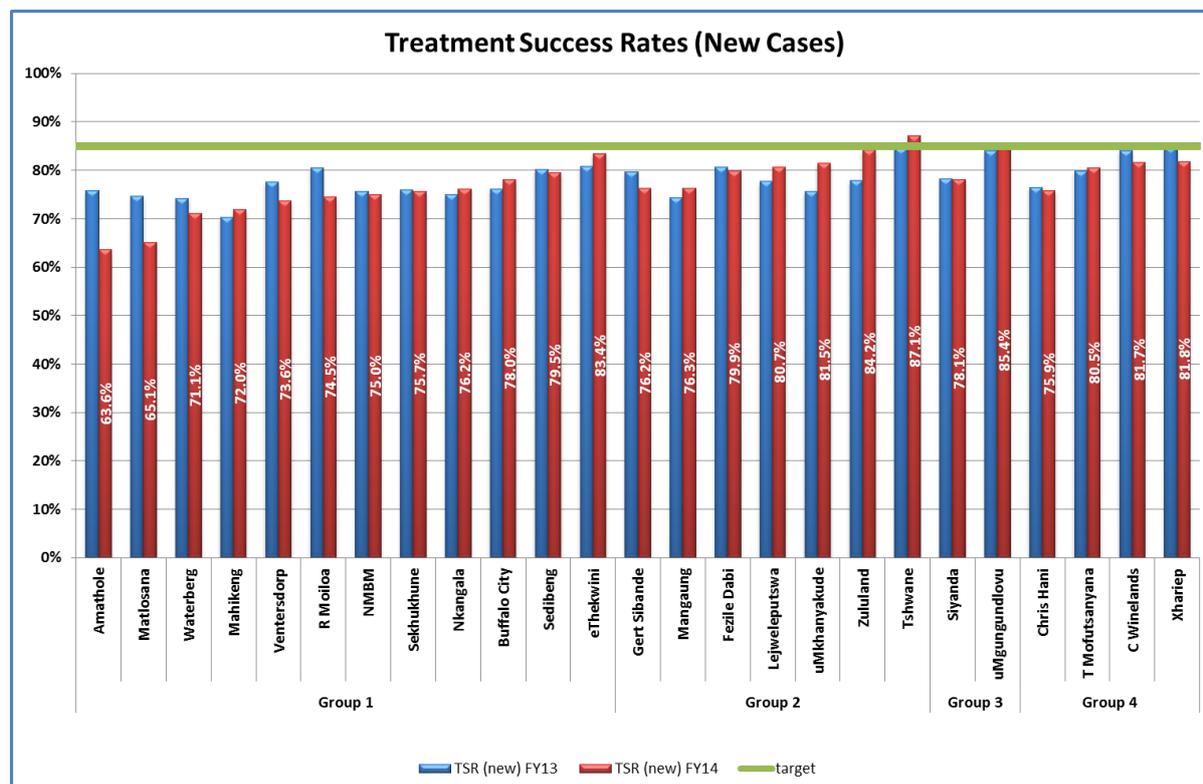
The project continues to distribute, train on and emphasize the use and importance of the TB appointment diary in attempt to alleviate the above mentioned challenges. The data capturers in various supported districts are also encouraged to generate reports to pro-actively identify smears due for collection. There is also a need to involve ward based outreach teams and small grants; and also

conduct ACSM training for health promoters in order to reduce curb the numbers of patients presenting very late to facilities by improving health seeking behaviour through ACSM health education.

VI. Treatment Outcomes

The treatment outcomes for the new smear positives have shown improvements over the years with the most important contributor being improved patient retention (see the annual report). Declines in death rates and treatment failure have also contributed to the improved treatment outcome. The quality of data as has been explained has resulted in increased Not Evaluated cases.

Figure 4: Treatment success rates - districts' snapshot: FY13 and FY14



The USAID TB Program's life of project target for treatment success rate (TSR) is 85% for new smear positive cases. Tshwane and uMgungundlovu Districts achieved this project target, with 11 units achieving treatment success rates of above 80%.

The overall TSR for new smear positive cases remained stable above 75%; recording 78.9% this year compared to 78.6% recorded in FY13 (refer to the annual report). However, the TSR for retreatment cases decreased to 59.5% from 64.8% recorded in the FY13. Patients lost to follow up and the ones who died make up 13% of the cases reported. The provinces affected by the high death rates are Limpopo, North West and the uMkhanyakude district in Kwazulu-Natal

Program interventions designed to improve TSR include:

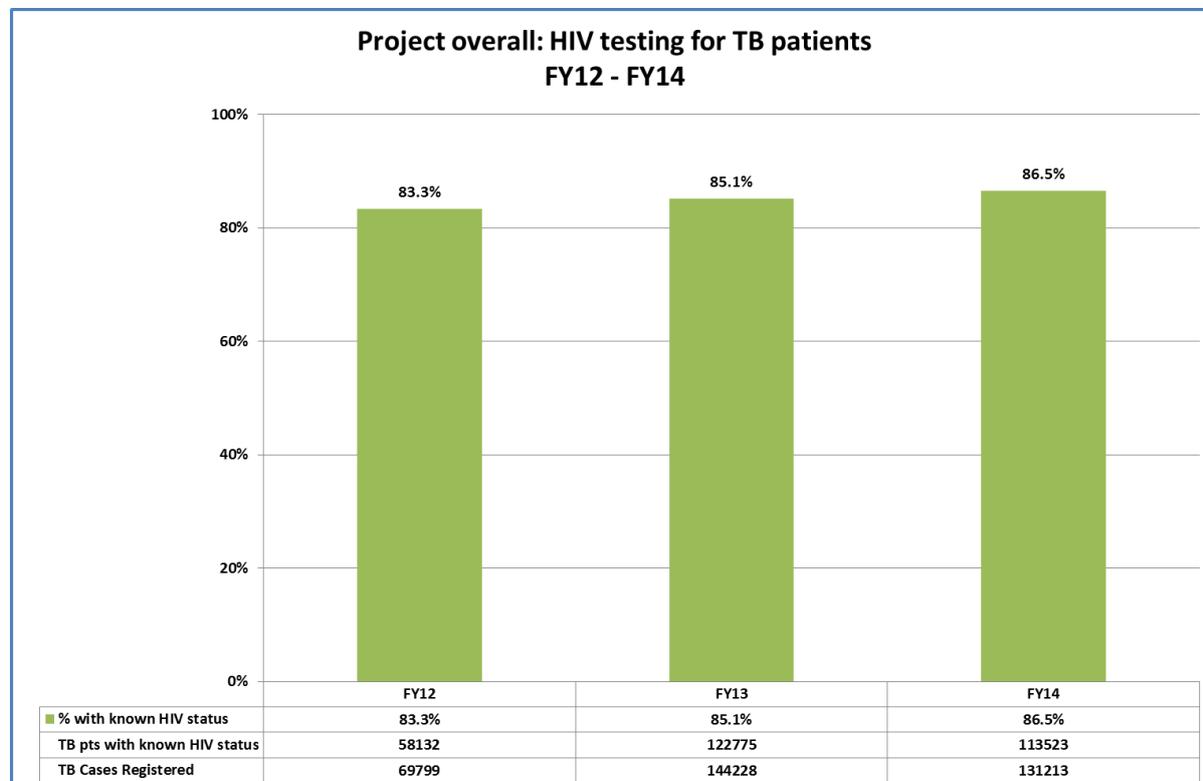
- ensuring proper use of the TB diary,
- scale-up ART uptake to lessen mortality
- data verification and clean up
- actively support supervision by programme managers
- Intensify THP program
- Identifying opportunities for increasing knowledge in communities
 - o ACSM and racing of treatment interrupters by NGOs

VII. TB/HIV Data: Overall Project

A. TB Entry Point Data

HIV testing among TB patients¹ gradually increased towards the 90% program target. During the FY14, a total of 131,213 patients were registered for TB. This was decline from 144,228 in FY13, which could be explained by the general national trends in the decline of registered numbers of TB patients.

Figure 5: HIV testing for TB patients – FY12 to FY14



In South Africa, TB HIV co-infection is 65%, in different provinces. In the project supported districts ranges from the lowest 30.4% in Cape Winelands and the highest 78.4% in Gert Sibande HIV testing is recommended for all TB patients, and continues to expand at TB service sites. HIV testing among TB patients increased from 85.1% in FY13 to 86.5% in FY14 as shown in Figure 5 above.

Antiretroviral therapy (ART) and Co-Trimoxazole Therapy (CPT) uptake recorded significant changes in this reporting period, particularly the ART uptake now slightly below the 70% mark for the 1st time since the beginning of 2012. CPT and ART uptake for TB/HIV co-infected patients continue to increase, reaching 89.5% and 74.1% respectively in April – June 2014 as shown in Figure 6 below.

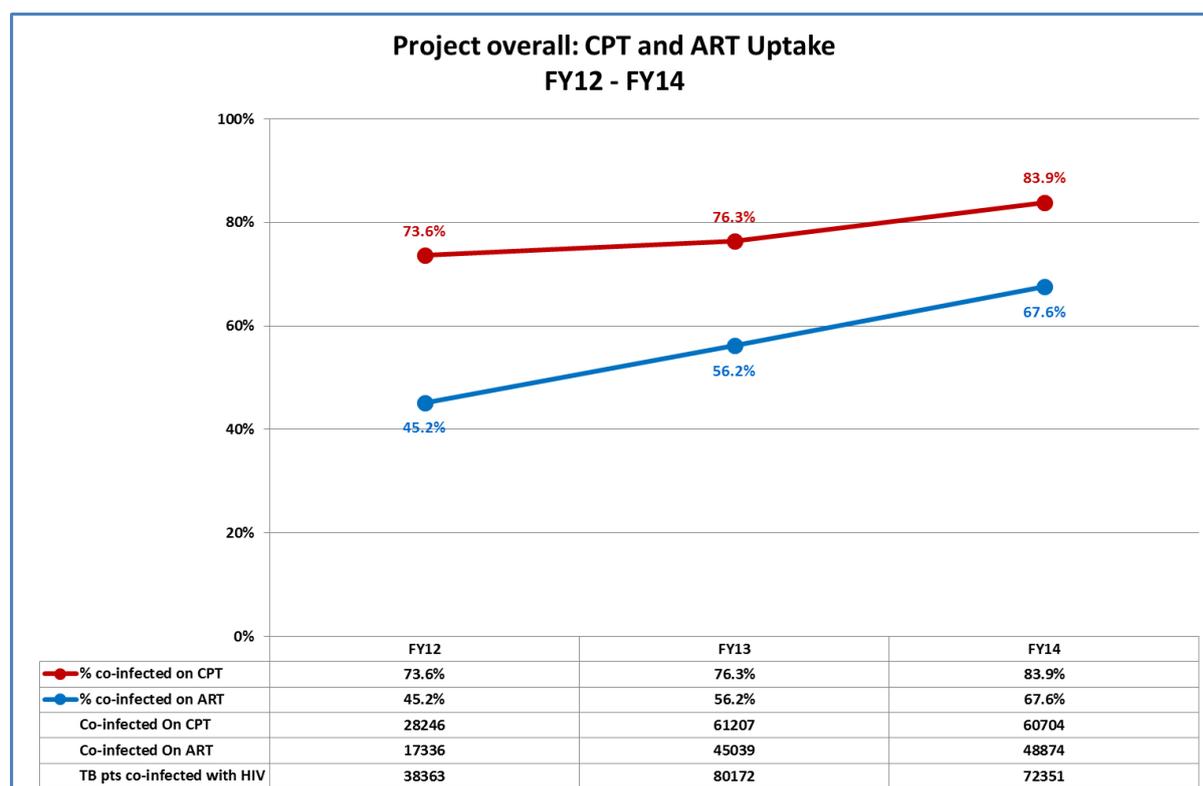
This increases in ART and CPT uptake are noted though they still do not mirror one another, as the services should simultaneously be offered to the HIV positive patients. There are still some facilities and/or TB nurses who do not initiate ART for TB clients. This poor integration of services at one point then leads to patients being initiated on ART in another room or clinic but data updates are not made back into the TB records. This also points to poor data management as a factor contributing to these variances and a relatively lower ART uptake

The project continues to closely monitor this and strengthen support for district specific interventions. This interventions include but not limited to:-

- Advocating for allocation of NIMART-trained professional nurses in TB rooms (Including the mentorship program)
- Assisting NDoH to use implement a unique identifier for interoperability of electronic data systems
- Conducting data verification and clean ups and consistent peer review session.

¹ Referring to TB patients with a 'known' HIV status in the ETR (all who tested HIV positive or HIV negative)

Figure 6: ART and CPT uptake - FY12 to FY14

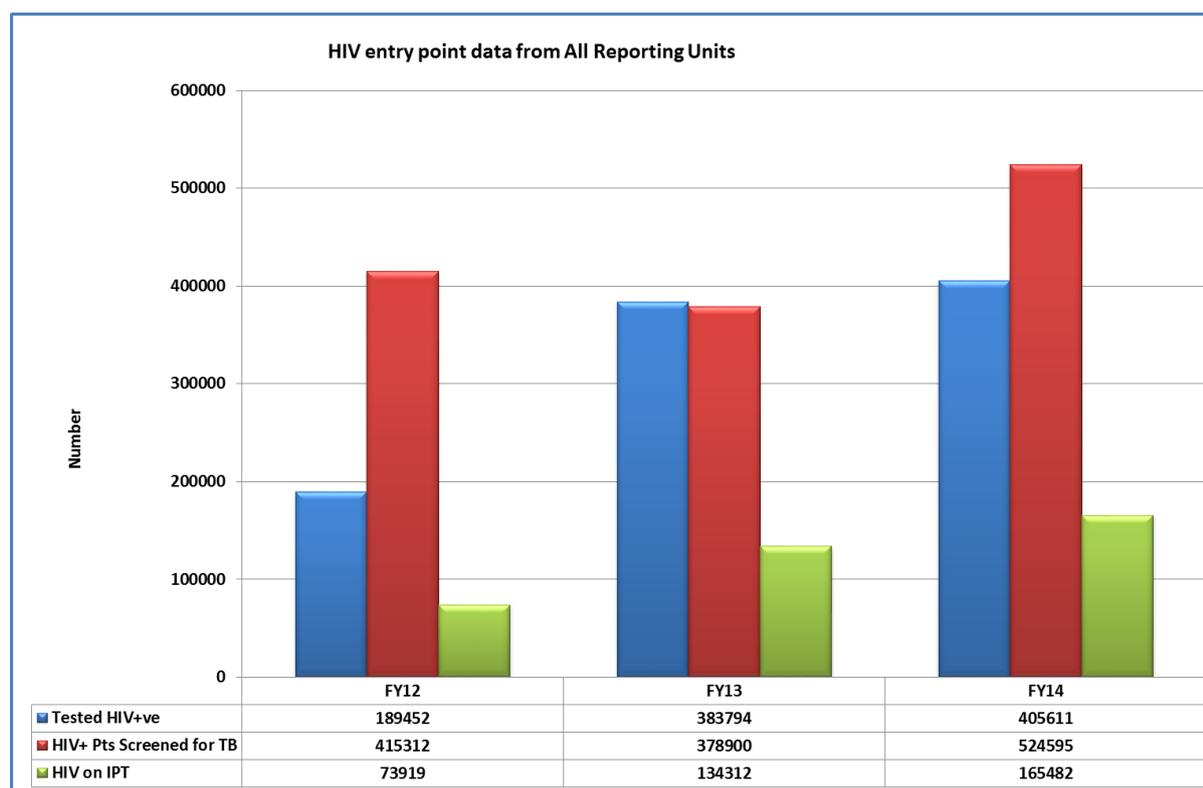


B. HIV Entry Point Data (Screening for TB in HIV+ Clients and Provision of IPT)

TB Screening: The DOH recommends that all patients be screened for TB whenever they visit the facility to improve active case finding. Challenges have arisen regarding reporting of TB screening among HIV positives as HCWs in most facilities count both new and known HIV patients screened for TB (rather than only new HIV cases as intended) hence the number of patients screened for TB is more than the number of those tested for HIV. The USAID TB Program has been educating the HCWs on the correct reporting of the indicator during the support visits and DVEs. In FY14, a total of 524,595 HIV positive patients were screened for TB. This was an increase from 378,900 patients in FY13. Figure 7 below shows project performance on TB screening among HIV positive patients and the provision of IPT.

IPT uptake: Improvements were noted in patients initiated on IPT as compared to FY13, with IPT numbers increasing from 134,312 to 165,482 in FY14. The project provided IPT training to health care workers and strengthened IPT initiation through the supervisor visits and mentoring activities. The project will continue to build the capacity of HCWs to improve the management of TB and HIV, including initiating targeted support for identified challenges, such as inconsistent use of the screening tools, HCW not initiating patients on IPT, and poor documentation for patients on IPT. Although tools are available in facilities, HCWs are not using the tools to screen patients. The other main challenge in IPT uptake remains the unavailability of standardized tools nationally to document patients on IPT. In addition, the current system does not provide information on follow up patient until they complete IPT making it difficult to know how many patient complete IPT or default IPT.

Figure 7: TB screening and IPT - FY12 to FY14



VIII. Conclusion

A. Summary

The USAID TB Program overall performance this year has slightly dropped for certain key indicator such as bacteriological coverage and sputum conversion rates. A number of challenges and key successes, detailed in this report, have been identified through the program support activities. General program management shortfalls, including recording and reporting, have also been identified through the project initiated activities such as DVEs. There was however supported districts that have shown marked improvements despite the said challenges. These districts included:

- C Winelands, Chris Hani, T Mofutsanyana, Lejweleputswa, uMkhanyakude, Zululand, Siyanda and uMgungundlovu that reported at least 80% for BC,
- Sedibeng, eThekweni, uMkhanyakude, Mangaung, Lejweleputswa, Fezile Dabi, Zululand, Tshwane, Siyanda, uMgungundlovu, T Mofutsanyana, C Winelands, Chris Hani and Xhariep for achieving the 75% target for SCR
- Tshwane and uMgungundlovu achieved the 85% target for TSR and

The BC for the program continues to drop further below the target this year, with the overall performance reported at 74.4 in FY14

The program SCR decreased from 75.5% to 73% for new smear positive cases. This is still below the 75% target for the overall program performance.

The TSR was maintained above the 75% mark with the overall project performance recorded at 78.9% again this year, just 6% short of the life of project target (85%).

Meanwhile, re-treatment cases continue with unfavourable outcomes; higher mortality, lost to follow-up and treatment failure rates compared to new smear positive cases.

TB\HIV indicators have also shown significant performance improvements with ART uptake 2% shy of the 70% mark and IPT being provided to more clients compared to last year.

B. M&E Issues and threats to data validity

1. Challenges

As highlighted on the BC section, there have been perpetual challenges around sustaining and/or improving BC nationally. These challenges include: AFB smears taken post TB treatment initiation being omitted by the ETR in the BC calculation.

More and more districts and/or sub-districts implementing the ETR version 2 as highlighted in the previous quarters. Investigation by the USAID Program M&E team to know how the system works and findings based on the challenges already highlighted in the previous reports have been formally communicated to the NTP; and the changes/corrections have been incorporated in the latest iteration (version 2.0.15) of ETR.net system. NTCP will however rollout this "corrected" version to the various provinces/districts in the next coming quarters. Progress thereof will be reported in the next reporting periods.

Recording of TB information in the TB registers in general, both electronic and paper, remains a challenge. This is apparent not only in the TB program but across the various health programs such as HIV, etc. Records in many facilities remain incomplete; and at times, health workers record some data erroneously. This is especially a challenge for low category staff such as enrolled nursing assistants. In some facilities, particularly during DVE's or records reviews by the sub-districts, AFB smear results were available in the patients records (blue files) but not updated in the TB registers; a situation that saw reduction in related the TB program indicators.

2. Proposed Solutions

The program will assist the NTCP with the speedy rollout of the latest version of ETR.net for uniform and accurate reporting in all the districts.

The project will continue with other intervention activities such as: distribution of the job aid; identification of under-performing districts, distribution of sputum posters and monitoring of their implementation; repeated training on GXP algorithm; quarterly data verification exercise (DVEs) and training for data capturers on the new version of ETR.net and strengthening support to supervision by provincial, district and sub-district level program managers.

The program will also continue to encourage the facilities to regularly validate and update accordingly the patient records/registers against the two data systems, Tier.net and ETR.net, before submission to the next level.



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TUBERCULOSIS
PROGRAM
SOUTH AFRICA

NATIONAL SUMMIT ON TB DIAGNOSTICS

18-19 NOVEMBER 2013 / SHERATON HOTEL, PRETORIA



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The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development (USAID) or the United States Government.

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Executive Summary

Thanks to strong political commitment, South Africa has been at the forefront of the roll out and use of new TB diagnostics, including liquid culture, Line Probe Assay and the Xpert MTB/RIF for rapid diagnosis of TB and resistance to rifampicin. Recent implementation of new diagnostic technology, coupled with ongoing local research, has generated a great deal of information and operational experience. Results have been shared at international conferences, but to only a limited extent locally. To that end, the National Department of Health (NDOH) and the USAID TB Program South Africa convened a National TB Diagnostics Summit as a platform/forum to facilitate the sharing of research findings to inform policy.

The National TB Diagnostics Summit took place on November 18-19, 2013. The purpose of the summit was for key stakeholders to review and discuss the state of TB diagnostics in South Africa and to create a roadmap for improving laboratory diagnosis of TB throughout the country. More than a hundred local and international participants attended, including representatives from the NDOH, the Department of Science and Technology, USAID, public and private laboratory service providers, diagnostic product manufacturers, funders, academics and researchers, and implementing partners.

Representatives from the NDOH, the USAID Mission in South Africa and University Research Co., LLC (URC) highlighted the relevance of effective TB diagnostics towards attainment of National Strategic Plan on HIV, STIs and TB 2012-2016 (NSP) targets. Public and private sector partners were urged to collaborate to achieve the desired sustainable results. The persistent challenge of high TB incidence in South Africa necessitates the use of new diagnostic tools to improve early identification, ensure faster initiation of treatment, and provide better support for patients.

The Summit was broken down into four main sessions as follows:

■ Session 1: Introduction of new tests

This session included an overview of new tests, and presentations on the uptake of TB laboratory diagnostics, the role of the private sector, testing in rural settings, and the introduction of new diagnostic technologies. Discussions centred on the utilisation of new algorithms, including costs, involvement of the medical aid schemes, non-compliance with the algorithm, the feasibility of

the target of reducing time to treatment initiation to two days for DS-TB and five days for MDR-TB, and lack of inter-system operability of various patient databases, making difficult to track previous test results. It was agreed that improving the efficacy of the diagnostic processes in both the public and private sectors requires a combination of interventions.

■ Session 2: Challenges in implementing the technologies

Presentations included the clinical challenges in implementing the new technologies, challenges related to reaching all levels of the health system, measuring the challenges, evaluating GeneXpert rollout, and diagnosis of TB in children. Discussions covered the roll-out of a quality assurance programme for GeneXpert, the effect of GeneXpert on case detection, clinical lead times, location of the test, remote calibration, an effective algorithm, and issues related to cost effectiveness as a public health intervention.

■ Session 3: Community, patients, civil society: Linking communities to services

Presentations included issues related to access to health care, early diagnosis of TB and MDR TB in the community setting, the high proportion of initial defaulters, the infectiousness of patients, the interface between community and PHC facilities, ineffective referral mechanisms between HIV clinics and TB clinics, the need for community-based integrated TB and HIV services, data quality, the need for an enabling policy, and revisiting the decentralization process. Discussions also addressed the role of NGOs working in the decentralized model and the amount of excellent TB operations research being undertaken across the country.

■ Session 4: Key players in diagnostics: researchers, academics, private sector, manufacturers and medical schemes

This session looked at what is in the pipeline for TB diagnostics both local and globally. It highlighted progress towards affordable point-of-care (POC) tests in resource-limited settings, early phase technology and biomarkers, and the importance of showing the impact of new tests on the burden of disease. Manufacturers BD Diagnostics (POC technology, collaboration with the NHLS to bring in second line drugs), Hain Life Science (new assays) and Cepheid HBDC (future molecular diagnostics, extended

warranty worldwide, on-site preventative maintenance, web-based training) all presented. The Department of Science and Technology (DST) reported on examining ways of supporting local research, development and innovation capacity in diagnostics and treatment for HIV, TB and malaria. South Africa is currently validating a new TB rapid test which is easy to use and will provide results in 30 minutes that will cost less than \$4. This test will hopefully be available by 2015. The discussion covered training, health systems strengthening, early diagnosis and linkages to care and treatment, identifying research gaps, and strengthening relationships with academia. The role of TB diagnostics in reaching “zero TB deaths” was also emphasized.

■ **Key recommendations**

Key recommendations generated from the 2013 Summit were as follows:

1. Develop a generic national implementation framework for review and roll out of new diagnostic tests.
2. Establish a multi-stakeholder national task team of experts to provide on-going guidance on the introduction of new tests/diagnostic procedures.
3. Convene annual meetings to follow up on implementation.

This report on the 2013 Summit provides a summary of the session presentations, issues discussed, and recommendations reached.

Welcome

Mr. David Mametja, National Department of Health (DOH)

The National Strategic Plan on HIV, STIs and TB 2012-2016 (NSP) informs the interventions by the Department of Health on the management and control of TB in the country. We are almost halfway through the implementation of this strategic plan. The targets are ambitious but we need to work towards attaining these targets in order to reduce the scourge of TB in South Africa. This is an important summit and the need to improve on the performance of the diagnostics is acknowledged. It is also important that the private sector is participating as the linkages between the public and private sector in relation to the management of TB have not received adequate attention in the past.

The expected outputs of this Summit are to:

- Provide recommendations on optimization of existing TB diagnostic technology;
- Provide recommendations on strengthening TB diagnostic and clinical management systems;
- Identify research priorities; and
- Reach consensus on a national TB diagnostic task team.

USAID Support

Ms. Catherine Brokenshire-Scott, United States Agency for International Development (USAID)

The United States Agency for International Development (USAID) is keen to support this important collaboration and commitment in tackling the scourge of TB. This event is supported by USAID, the South African National Department of Health (DOH) and the University Research Company (URC). The Summit provides the opportunity to review efforts made thus far on the management and control of TB with a special focus on diagnostics to make informed changes and improve future outcomes. A dedicated effort is needed amongst all partners to achieve the sustainable results that are so necessary.

TB Diagnostics – The Global Context

Dr. Refiloe Matji, University Research Co., LLC (URC)

The high incidence of TB remains a serious challenge in South Africa. While the focus for diagnosis has been on microscopy in the past, there have been many important developments such as Xpert MTB/RIF. Where these new diagnostic tools are placed is important. Patients at the community level therefore need to be considered in this planning.

One of the main challenges is that by the time people present at a facility, they already show evidence of serious symptoms. They then have to wait for testing to be done and again for the results of the tests. For MDr. TB, this can take a month or more from the time they present. There are many variables in the process resulting in these delays, in particular, transportation of specimens and results to and from the laboratory affecting the turnaround time.

While some people are close to a health facility, there are many who live some distance from a clinic and transport costs can be high. Many people cannot afford transport at all. There have been a number of local and international studies that highlight the high cost of accessing free health services. There may also be geographical impediments. The role of the community needs to be assessed since they can promote education on signs and symptoms, and encourage prevention and infection control.

Health care facilities need to focus on early identification, faster initiation of treatment, and support for patients. The key questions to be addressed include:

- Are we bringing services closer to the communities we serve?
- Can we reduce the high (30%) initial default rates?
- How can we reduce MDr. TB?

In Tanzania, there has been an interesting development in the use of African giant pouched rats which were trained to detect TB in patient sputum. This may not be ideal but the point is to begin to think creatively about the tools that are needed to promote the treatment and reduction of TB.

General Comments

1. Noting that initial screening is critical, and currently we screen ten people to identify one positive. We need a cost-effective way of screening to exclude expensive testing on the majority ($\pm 95\%$) of people who do not have TB. This would enable us to then use the expensive test for the identified high risk people.
2. There is currently no screening test available that has been validated and is suitable to screen patients and assist in narrow down the field to patients at highest risk on whom the Xpert MTB/RIF could then be used. Therefore it is best to focus on what is available and optimize its use. To manage TB into the future, a screening test at community level is needed.
3. Community health care workers should be encouraged to participate more actively in screening of TB. Communities should be encouraged to become more proactive in seeking TB screening services, while noting that limited finances often prevent people being able to access a health care facility for screening.
4. The NSP stipulates a further objective which is to ensure that all South Africans are screened for TB at least once a year, but how this will be achieved remains a challenge. The numbers needing to be screened could significantly escalate.
5. The use of GeneXpert has made a difference but not enough. People still have to go home and wait for their results and then come back to the health facility. The coverage of the National Laboratory Health Service (NHLS) is good but the roll-out of GeneXpert has not yet been evaluated. The placement of the GeneXpert should be assessed as well.
6. TB is a public health problem, so the focus must be both on the individual and on the health system overall.
7. New products are constantly being developed and tested and improved screening tools are expected in 2014.

Panel Discussion – Introduction of New Tests

Panel Chair: Dr. Giorgio Roscigno

Introduction and Overview

Professor Mark Nicol, UCT/NHLS

Better testing is needed for the diagnosis of HIV-associated TB and early diagnosis of drug-resistant TB. In Gugulethu, it was shown that 25% of HIV positive patients commencing ARVs have TB despite having few symptoms and 80% had smear negative TB. There is a growing concern around the increase in Multi-Drug-Resistant TB (MDR-TB) and the threat to public health. While there have been improvements, in the reduction of time taken to treatment initiation, in Khayelitsha about 53% of patients died while waiting for results between Jan 2008 and June 2009.

A low cost triage test with high level of sensitivity is needed to rule out TB in the primary health care setting especially for HIV positive patients in care. A definitive test with a high sensitivity and specificity can then be used to diagnose TB and screen for MDR-TB in the identified high risk patients.

GeneXpert performance thus far has been good but its limitation is that it cannot be used as an exclusion test for TB in a patient with HIV. There is a need for further testing in HIV positive, Xpert negative patients. The main concerns with GeneXpert are that it i) has had no clear effect on mortality/outcome (Theron G, Lancet; XTEND results awaited), ii) has shown no substantial increase in case notification, iii) the impact on reducing time to treatment initiation is not yet clear. Therefore it needs to be used in a strong health care system with good follow up systems to improve linkage to care.

GeneXpert has limited applicability for POC use and much more expensive compared to laboratory placement.

A study conducted in Khayelitsha has shown how the introduction of the rapid assays (LPA and Xpert MTB/RIF) has reduced the time to treatment initiation for drug resistant TB. The LPA however can only be used for direct testing of smear positive sputum or cultured isolates. There are new tests - MTBDRplus v2 which can be used on smear negative sputum, and MTBDRsl for second line DST.

There is a need to examine the indicators that must be measured in order to determine the impact of GeneXpert on mortality and outcomes, in particular MDR-TB.

Uptake of TB laboratory diagnostics

Professor Koleka Mlisana, UKZN/NHLS

The testing had previously been smear-based but with the increase in the HIV epidemic (high co-infection rates (65%), in medical wards this could be as high as 90%), the sensitivity of microscopy has dropped, with detection rates as low as 43%.

Introduction of the more sensitive tests (liquid culture, LPA and Xpert MTB/RIF) has improved the diagnosis of TB in HIV positive patients, while also improving the turnaround time for the diagnosis of drug resistant TB.

LPA (Version II) would be preferable for smear negative testing but evidence is limited and it is unclear where it will fit in the diagnostic algorithm. An analysis conducted in KZN showed that 50% of patients confirmed by Xpert as Rif resistant TB had a confirmatory test conducted within two weeks and 75% cumulatively within four weeks. The time to treatment initiation was within two weeks of diagnosis for 68% of the patients.

Challenges

- Lab safety issues
- High contamination rates (10 – 15%) with liquid culture
- High setup costs for the PCR lab
- Staff training
- Lack of political drive – no clear policy and lab request for Ms. never finalised (incorporating LPA)
- Clinical training lagged behind introduction of the rapid assays, therefore most clinicians did not know what to do with the test results
- With the phased implementation, two algorithms (smear and Xpert MTB/RIF) were used causing confusion for both clinicians and laboratory personnel
- Lack of a system to check duplicate testing.
- There was no EQA program on implementation of the rapid assays.

The role of the private sector

Dr. Suleiman Hajee, Toga Laboratories

The sensitivity, rapid turnaround time, and technological advances of the molecular tests make compelling arguments for their widespread use as first-line tests. However, in the private sector, cost is the major barrier to more widespread utilization of the commercially available molecular tests like the GeneXpert. The Toga solution is to use a cheaper in-house molecular test as a screening

test, and if positive proceed with a commercial assay for confirmation of MDR-TB. Microscopy for AFB should be retained, for public health and infection control purposes.

Dr. Keshree Pillay, Lancet Laboratories

The GeneXpert has been used since 2009. The main challenge relates to the high costs of testing. There is pressure from clinicians and hospitals to conduct rapid specific and sensitive tests on smear negative patients because of the HIV prevalence. Since the endorsement of the use of GeneXpert by the WHO in 2010 the uptake has increased from 4 000 in 2009 to 60 000 in 2012. The algorithm is different from the DOH one in that microscopy is still the first line test and is followed by the Xpert MTB/RIF for all specimens.

Challenges

- Coordination and communication between public and private sector
- Standardisation of testing
- Waste of scarce resources by repeat testing between facilities

Testing in rural settings

Dr. Lorna Madurai, Global Laboratories

The private sector testing caters for medically insured and cash paying patients. The medical aid schemes are controlled by the Board of Health Care Funders, there is a chronic management plan for HIV patients, but TB is not considered a chronic disease therefore treatment is based on existing benefits. This anomaly must be addressed and TB must be included in the Prescribed Minimum Benefits within medical aids. There is no problem of over-testing in the private sector as it is very well governed. However, cost remains a big issue. The links between private and public sector collaboration should be promoted. The private sector must implement the national guidelines.

Introducing new diagnostic technologies

Dr. Nazir Ismail, NICD – NTBRL

The presentation highlighted the gaps in TB diagnosis and linkage to care and the importance of early diagnosis using the new rapid diagnostic tests (Xpert MTB/RIF, LPA) based on the WHO Policy recommendations. He shared the NHLS experiences with the roll out of the liquid culture, LPA and Xpert. Some of the requirements include the development of an evidence based algorithm, adequate infrastructure, staff – TB technicians and equipment taking into consideration

the volume of tests to be conducted. There has been a 48% increase in the number of liquid cultures done since its introduction in 2007 and a 79% increase in first line DST by LPA since 2011. South Africa is leading globally in number of equipment and cartridges procured since the introduction of the Xpert MTB/RIF. The population coverage for Xpert is currently 84%. The NHLS is planning to introduce reflex testing (first and second line DST) for Rifampicin resistant TB.

Discussions and Comments

1. How are the algorithmMs. being utilized? The private laboratories algorithmMs. are determined by the costs; therefore expensive tests like GeneXpert cannot be used for screening. Since the private laboratories are constrained by the profit imperatives, greater efficiencies are needed to lower the costs of diagnosis. This can be addressed by getting buy in from the Medical schemes and lobbying the Department of Health to take the lead. It remains unclear how the reduction in costs in the private sector would change the overall role of the private sector in TB management and control. In the public sector there is non-compliance to the algorithm in that some doctors requested preferred tests instead of following the algorithm. The national target of time to treatment initiation for DS-TB is two days and for MDR-TB five days, is not realistic and needs to be reviewed. On the other hand the NHLS wants to program the diagnostic algorithm within their IT system to conduct reflex testing but the system is not conducive for this as the laboratory systems are interlinked making it difficult to track previous test results on a patient. There has to be an evaluation of the existing diagnostic algorithmMs. in order to determine which one is most efficient.
2. How to improve the efficacy of the diagnostic processes in both the public and private sectors? The private sector should be engaged in the development of the national diagnostic algorithmMs. from the onset. Ongoing training is required in both the private and public sectors. A combination of interventions is required to improve the efficacy of the diagnostic processes, these include: i) the laboratory information systems that are interfaced within the laboratory network, ii) implementation of the unique identifier and iii) improving communication between laboratory personnel and clinicians. The public sector can learn from the private sector on how to improve logistics and linkages. Ideally, all testing should be standardized across all sectors. All labs are accredited by South African National Accreditation System (SANAS); some labs do undergo assessments from organizations like Pharmaceutical Product Development (PPD) as per agreements with research partners.

Panel Discussion – Challenges in Implementing the Technologies

Panel Chair: Professor Maphoshane
Nchabeleng, MEDUNSA

Introduction

Professor Lesley Scott, NHLS/Wits University

Infection hotspots include mines, prisons and transport routes, and these need to be addressed specifically. There is an increase in smear negativity and HIV co-infected TB patients where diagnosis is made too late. Smear sensitivity drops 25-40% with HIV. Since March 2011 there has been phased implementation in the public sector and 2.3 million tests done. Training of 916 laboratory staff and 3500 health care workers was done and 100 centres are reporting via website developed with SAFAID. Remote calibration is also being used. Work has been done to improve assay version changes and stock outs. SMS printers have been installed 2096 SMS printers in clinics to improve TAT. The programme needs to be expanded to mines and correctional services, using experts as the frontline.

Current challenges include non-adherence to algorithms, and no confirmatory tests for resistance being done. Multiple tests are requested on a single form, so there is a need to simplify the algorithm. On level of placement in clinics, GeneXpert is 46% more expensive if placed in clinics, where 2.5 staff members are needed to get 15 patients from test to treatment in one clinic in one day. Future assay changes and stock outs are a concern.

Data volumes are in place and must now be linked to care, but how this will be done is not clear. Strengthening of health systems is urgently required. On the costs of the revised models, many peripheral costs related to GeneXpert have pushed up costs, where costs at the laboratory are 50% lower than POC costs. For example, if there are 100 TB suspects, 20 will be TB positive. GeneXpert will pick up 16 and miss 4. So 84 suspects must be investigated via culture to positively identify the 4 patients who were missed.

Paediatric performance shows that 67% of sputum specimens are below the required volume. The WHO in 2012 recommended use of GeneXpert. It is also useful

in reducing TTT where before GeneXpert use only 21% of patients were initiated within 5 days whereas since the use of GeneXpert 95% are initiated within 5 days.

Clinical challenges

Dr. Xavier Padanilam, Sizwe Hospital

The Sizwe Hospital is a dedicated MDR-TB facility. Experience indicates that a unique identifier is urgently required as many patients use different names, a range of tests is done in different hospitals, and the number of patients diagnosed in Gauteng with MDR-TB is higher because of the duplication of patients. The situation is exacerbated by migration in and out of Gauteng where there is a high level of inter-provincial movement. This leads to discrepancies in statistics and it is difficult to locate patients for treatment. Many patients also die because doctors make a diagnosis but do not refer to Sizwe for specialist treatment.

A key challenge is that laboratories do not report on mycobacterium TB and clinicians are then unable to make an informed decision. The laboratory should report fully and without omissions especially as regards mycobacterium TB since only then can the clinician provide an appropriate regimen.

GeneXpert is good when the smear is positive but when the smear is negative it is necessary to re-confirm the diagnosis. Smear negative culture takes 6-8 weeks, which means the patient could be on the wrong treatment for two months. In a hospital like Sizwe which does not have designated GeneXpert patients, this can lead to greater infection. Furthermore, GeneXpert is sometimes used on dead bacilli to assess progress of the disease but this is incorrect.

Reporting of mutational pattern for INH is needed that can guide clinicians, but most laboratories do not provide this essential information. Gauteng is the only province providing mutational information.

LPA for Second Line Drugs is not yet validated in terms of MDR-TB. If Second Line probes can be used then proper treatment can commence earlier rather than waiting for up to 8 weeks, and this can save a life.

New drugs should be tested as there are often very positive responses. Contamination and laboratory errors occur frequently, often after patients have been on a treatment, and these kinds of mistakes in the laboratory can impact on mortality. Significant morbidities can result from a wrong laboratory result.

Challenges related to reaching all levels of the Health System

Dr. Adeboyi Adelekan, CDC Laboratory Advisor

Having the required human capacity in place is key to ensuring Quality Assurance in delivery of health services. Even where a lot of training is done, people may still need to be mentored. Expensive equipment is in place and needs to be used appropriately and maintained adequately and this requires the required number of people to be properly trained. Calibration and periodic service of machinery is essential. However, the necessary technical expertise is not always available.

Supply chain management is important – consumables must be readily available and managed properly. For example, reagent must be carefully stored, and forecasts must be accurate to avoid stock outs. Biosafety level 3 is the minimum requirement, including temperature regulation.

Verification needs should be considered for a pilot study. What existing tests are being done and how are they linked to other networks? Draw on workflow analysis to optimize testing per site, and then scale up implementation. The strengthening of health systems overall is important – the best equipment will not work in a weak system, and it is recognized that the laboratories do not contribute to the delays, yet there are delays in getting results back to patients. The blockages need to be accurately identified.

Quality assessment checks should be in place when introducing new technologies. A comprehensive Quality Assurance plan will address the details of testing from the first collection of sputum to return of results. Linkages are essential, as well as compatibility with existing systems, so as to avoid data quality concerns. It is necessary, therefore, to ensure that facilities are connected via internet.

Having new technology that is being badly applied has a greater negative impact than not having it at all and it is important therefore to ensure that new technologies are integrated with the existing testing environment. Quality Assurance processes must ensure value for money.

Measuring the Challenges

Dr. Pren Naidoo, Desmond Tutu TB Centre, Stellenbosch University

First assess and measure the challenges and then decide on implementation. In assessing new molecular diagnostic tests, the focus should not be on individual tests but rather on the impact on diagnostic algorithms, and how to move from targeted algorithms to a universal algorithm.

A key question is whether there are more TB cases being diagnosed, in the context of the high level of resources that have been directed to improving TB identification. Over a period of 2.5 years, the total number of people tested in 5 sub-districts was tracked, both in targeted and universal algorithms. The results indicated that there had been no change in the number of individuals evaluated. There has therefore not been an increase in the TB yield in Cape Town. The number of MDR-TB cases diagnosed was 188 in 2010 and 196 in Quarter 2 in 2013. There was previously an effective algorithm for smear-negative TB. The median treatment commencement time of 43 days in the targeted algorithm has been reduced to 17 days median to treatment in the universal algorithm. Laboratory turnaround time in the targeted algorithm was 25 days to less than day in the universal algorithm – this indicates 80% improvement in laboratory and 20% improvement in the health facility. However, when comparing two sets of facilities going from targeted to universal algorithm there is little change.

There was an increase in cost of 120% for presumptive TB cases, from R1.7 million to R3.7 million. The only real benefit in Cape Town has been a reduction in delay for MDR-TB cases. Laboratory results are completed in one day yet it takes 17 days to get patients to treatment due to operational blockages. The factors contributing to delay are all under the sphere of control of facility managers. There is a concern regarding the degree of agency and level of autonomy afforded to patients, where the results could in fact be sent directly to the patient. The current system assumes patients coming to facilities but this remains slow. It may also not be realistic to attach 5-day targets to chest x-rays and blood tests

In addition to the use of GeneXpert, the DISA system has also reduced delays but human capacity continues to present challenges. There is a need to allocate resources to training and capacity building of frontline staff in order to strengthen the health systems.

Evaluating GeneXpert rollout – Challenges in implementing TB diagnostic technologies

Dr. Kerrigan McCarthy, Aurum Health

Both formal and informal roll-out needs to be evaluated. It is preferable to use the diagnostic modalities that are currently available as well as feasible, rather than being overly aspirational. A current study that will become available early in 2014 has shown that the effectiveness of any diagnostic is the function of test performance.

It is important to keep in mind that TB can manifest anywhere and not only in the lungs. Sputum tests are then irrelevant. The kind of test being requested needs to be assessed. Furthermore, where tests are done, the connection between the primary health care facility where the patient first arrived and the referring doctor is often lost, and this is an important connection that needs to be maintained. A PHC that has a doctor in place with access to chest x-rays could follow up on this algorithm. The other possible approach is to examine potential indicators of TB, drawing on a range of symptoms, and include the use of microscopy.

Operationalizing new diagnostics, it is suggested that targeted testing is preferable. One of the challenges is getting results back to patients quickly. This could be addressed at the time of enrolment by ensuring informed consent, take a cell number and stay in contact, and follow up over time, at 2 months and 10 months. This will help to keep the patient in the system. The best way to do this is via a high quality of human interaction, trust, respect and availability. Fieldworkers are encouraged to know the patients and build on the clinic connection. Patients need to be assisted to understand TB, patient agency and involvement. Health care workers need to empower patients at the time sputum is taken, not when results arrive. Pre-counselling testing is recommended.

Societal factors include migration which is the biggest source of loss to follow-up and this can be mitigated by understanding and identifying patient risk of migration when taking the sputum.

Diagnosis of TB in children

Dr. Ute Feucht, Tshwane District/University of Pretoria

Many children are being lost to treatment. The TB epidemic manifests differently in children and the main difference for children is that, like HIV, TB comes from adults, rather than being a childhood disease. There is high exposure to TB for children but not all children with TB will have HIV as well. In South Africa, TB is strongly linked to high levels of malnutrition. There is a risk of both over-treatment and under-treatment of children with TB.

Paucibacillary disease has an impact on diagnosis, and doctors often do not diagnose correctly. There is a high level of infection in children under 5 who should get prophylaxis, and who are under greater threat if they are malnourished or otherwise compromised.

There is an increase in neonatal disease and also of maternal HIV and TB in pregnancy – therefore pregnant women should be screened for TB.

Symptoms in children are often non-specific so scoring systems are useful in resource-constrained countries. Standardized clinical case definitions are vague and broad. TB diagnostics clarity must be improved at implementation level. The concepts of preventing TB and diagnosing and treating TB are often confused and must be clearly separated.

Greater clarity is needed on appropriate diagnostics, how they are used and at which level? For example, who will do an x-ray or read an x-ray? It has been proposed that screening be done by all HC facilities but at present children are not included. TB prophylaxis at facility level is not done, and there is a tendency to delay until children become ill and then go to hospital.

It can be difficult to get samples from children and so this is often overlooked. Furthermore, there are few guidelines on sample collection from children and these should be provided. The role of IMCI for HIV rollout must be refined for TB testing rollout with a focus on obtaining samples from children and renewing the focus on child health.

Discussion and Comments

1. Regarding Quality Assurance, was there a similar system for rollout of GeneXpert and what were the outcomes? How long does such a process take and what does it cost? Response: Some of the things were done. The EQA was in place at initiation of rollout and work was done on the algorithm at commencement. There had been a lot of preparatory work done but some things could not be anticipated, like stock-outs. It was hard to identify reasons for stock-outs but the lesson was that stock levels need to be measured more accurately. The audits showed that it was more cost-effective to keep certain functions in the laboratory rather than at POC.
2. The GeneXpert external quality assessment programme was in place before rollout including verification, so every item used in the field was tested to show fitness for purpose; this now forms ongoing quality assessment programmes via NHLS. Every instrument is linked to laboratory information systems, so results are reported in real time through a central data warehouse and then back to clinics and the SMS printers to speed up TAT. Remote calibration is in place to check every module and remote connectivity allows for a real-time process that shows when every module was tested. This is a web-based programme at 100 sites. Quality standards for GeneXpert have always been in place.
3. There was an expectation that there would be an increase in case identification with GeneXpert, but in fact there was not a big increase in case detection. On time to diagnosis, shortening of laboratory time has contributed to reducing clinical lead times. On time to detection, GeneXpert has reduced the clinical diagnosis lag which lacks specificity. It is accepted that patients are being put on the correct treatment which costs more than diagnosis does. Response: All laboratories provide confirmed diagnosis although there is a timing issue to some extent. In terms of yield, this is not based only on patients being put on treatment but also the laboratory diagnosis. There was an effective algorithm in place and Cape Town has a good health infrastructure and high adherence to the algorithm for smear negative cases. This reinforces the importance of effective training of staff on the frontline so that results get back to patients more quickly.
4. Cost effectiveness is an issue even where there is a broad approach to test suspects. How can a more targeted approach be found where there is an extensive array of facilities? Response: There is relative yield in different clinics. For example, one clinic might be low yield but testing a high number of people who were not symptomatic. It has been possible to show the linear proportion of yield based on the number of symptomatic people who are biologically plausible, but asymptomatic people may still have TB and pregnant women can be asymptomatic yet have culture-positive TB. This relates not only to cost effectiveness but also to how much TB can be prevented, and how health systems can positively impact on transmission by identifying more cases of TB, as that is where cost effectiveness is balanced against the importance of intervention as a public health issue. It is not possible because of cost to screen the entire population but those with symptoms of more than two weeks' duration must be properly screened. There are 400 000 cases annually of TB testing, with about 200 000 smear positive cases seen in primary health care clinics, and the other 200 000 seen in hospital and via pulmonary diagnosis. A quarter of these have had a diagnosis of TB outside of their presentation clinic. The algorithm was functioning, but many people find themselves diagnosed with TB due to the natural progression of the disease.
5. Sero-studies have been done on the costs of reducing TB from laboratory and clinic but it is unclear whether it addressed interventions from a rural and urban setting perspective since there will be major differences and benefits. For example, to what extent can one compare the Eastern Cape and Gauteng? In the Eastern Cape because of the great distances it would be particularly important to have results provided the same day. It is important to keep the patient at the centre.

Panel Discussion – Community, Patients, Civil Society: Linking Communities to Services

Introduction

Many people do not enjoy adequate access to health care, yet there are 4790 health facilities across the country, of which a small fraction provides initiation of MDR-TB. There is a decrease in incidents of regular TB cases, but the numbers of MDR-TB are growing, reaching around 15 000 in 2012. This is a serious challenge. Of all those TB tests done in labs, 20% fall through the cracks with regular TB and half of those with MDR-TB do not commence treatment. This means many highly infectious patients remain in families and in communities.

Regarding the interface between community and diagnostics, most TB patients are at the PHC facilities. The number of people being screened for TB is much lower than the number of individuals being offered HIV testing. There are ineffective referral mechanisms between HIV clinics and TB clinics, including in the large public hospitals, and little synergy between the different clinic or hospital services and people are reluctant to access these services. Areas to be addressed related to poor linkages to patient care, concerns about lack of data, and the need for an enabling policy.

In Gauteng, for example, the numbers come from different facilities and not only public health. Patients who are poly-resistant often remain unconfirmed to mono-resistance. This relates to the inaccuracy of data. Approximately 3 000 TB patients are treated in a three-month period so the way patients are recorded is important. The numbers appear to be constantly increasing. Many TB patients are not linked to care, and even with poor data recording, high numbers are being diagnosed and not getting into care. The issue of decentralization could be revisited. The most appropriate technology to map patients needs to be examined.

The interface between Community and Diagnostics

Dr. Ribka Berhanu, Right To Care/Helen Joseph Hospital

Clinical trial settings are very different from real world settings. Solid information about which service delivery models work or not in TB treatment is best collected in programmatic settings.

There are many NGOs working in this field and a lot of TB operational research is being undertaken.

Right to Care operating at the Helen Joseph Hospital in Gauteng tested GeneXpert rollout feasibility. Two full-time staff were appointed to run 15 tests per day. Tracking for results in the same day was often difficult, and the way the clinic flow worked made it hard to accommodate the same-day delivery model.

Research indicates that POC testing is likely to be more expensive. Decentralized MDR-TB management has been discussed with average length of stay being 105 days at a cost per patient of R17164 – 90% of cost is not the usual cost drivers, but the direct hospitalization costs such as building and staffing, and only 2% of cost is related to drugs and diagnostics. The Helen Joseph Hospital in partnership with the City of Johannesburg is examining cost and outcomes of decentralized MDR-TB management and also promoting linkages.

Piloting clinical care models is an important role for NGOs, especially in light of the increase in TB patient numbers. The referral system presents challenges since not all patients sent to a referring hospital actually arrive there and not all clinics are equipped to deal with TB.

The project works closely with microbiologists who track every culture result obtained in the Hospital, and also assists the City of Johannesburg to trace patients and assign a final outcome and linkage if any positive TB culture emerged.

There is a free electronic system pilot presently under way that has been internally developed as a clinical tool and should not be considered a replacement for EDR. Previously paper records were used – but the new systems allow for a better determination on patients including on referrals. The project is collaborating with Gauteng Provincial Health to expand the pilot. Most data is results data, information sent to the project and manual work, so there is a real need for an integrated electronic system.

NGOs provide a valuable link between academic, government, funder, and clinical interests, they have a greater capacity for innovation and flexibility, and they work at ideal sites and have better resources than government, and also have a strong Monitoring & Evaluation background to evaluate the work being done.

Early diagnosis of TB and MDR-TB in the community setting

Dr. Mokgadi Sinah Vlug, FPD

South Africa has not achieved its health targets and has to deal with a high burden of health costs. The TB epidemic is driven by multiple factors – a growing HIV epidemic, socioeconomic profile of very poor people, poor environmental conditions, and a dysfunctional health care system which is considered by many to present the greatest challenge. Further factors that exacerbate the situation are chronic illness and alcohol and substance abuse.

Diagnostic challenges include limited knowledge and training at community PHC level, especially with regard to staff having knowledge of policies and guidelines. Paediatric knowledge is identified as being particularly lacking.

There is poor management of smear negative patients, either not being put on treatment and no further investigation being done, or when referred up, they get lost in the system. Health care staff may exhibit stigma about TB and HIV, thereby marginalizing patients within the health system. There is a poor level of TB suspicion in non-HIV infected patients and in children, where patients are often treated for other illnesses but not for TB.

Community issues include a limited understanding of TB and how it is spread, not recognizing TB symptoms. In children, late presentation of patients and patients lost to care and being difficult to locate, poor follow-up and low level of compliance unless very ill.

System issues include infrastructure problems. In PHC facilities that are often badly designed, with inadequate resources, poor communications and data collection tools, transport challenges related to specimens, and poor TAT from laboratory to clinician to patient.

The health status of those working in the health sector is often overlooked, yet it also contributes to the TB & HIV burden, since they are often at higher risk. Health Care Workers themselves have died from TB and also infected others, yet employee wellness programmes do not speak to this situation. What is required is the re-education of communities, and HCP need to provide proper information to inform better decisions, strengthen health systems. and QIP implementation to ensure integrated high quality delivery.

Linking communities to services

Dr. Tony Moll, Philanjalo, Tugela Ferry

TB is preventable and curable, yet in South Africa in 2012, 344 000 patients were diagnosed with TB and 14 000 with MDR-TB. Treatment outcomes are being improved but the spread has not been reduced. TB is a communicable disease that has direct links to situations of poverty. The pool of untreated cases in communities is the driver of a serious epidemic.

HIV fuels the TB epidemic so a community-based must integrate TB and HIV. There are powerful TB prevention strategies including intensive Case Finding and infection control and this should be community-based.

Case studies show that in Sub-Saharan Africa, intensive Case Finding works well. This promotes an understanding of who to target and what yield to expect. For example, of 946 sputum samples, 37 would be TB-positive, of which 11 would be MDR-TB so overall it is necessary to screen 147 patients to find 1 TB case. Yield varies according to the population setting which is high in prisons, where only 38 were screened to find 1 case, and lower at taxi ranks, where 148 people were screened to find 1 case.

In health care settings 70% of TB cases were HIV positive but in communities over 90% of TB cases were HIV negative. Household contacts present a high yield group, where for every 13 index patients and every 61 household contacts screened, 1 MDR-TB case was identified.

At Tugela Ferry, 1211 adults started ARV and all were screened for TB – this indicated 345 new TB cases. There were 200 new cases identified in two years in health care settings. However, as a result of community interventions, there was a dramatic decrease in new infections. It is advisable to screen at community level and use the portable CD4 counter to stream patients into appropriate care.

Linking patients to treatment services

Marian Loveday, Medical Research Council

A 4-year study was done at decentralized MDR-TB sites with all 4 sites given the same guidelines and training. Yet outcomes were quite different. At the centralized site 54% and 58% achieved successful outcomes. At the four decentralized sites, successful outcomes were lower. The reasons for unsuccessful outcomes varied. This is similar to how GeneXpert has been implemented, with site variations. It is useful to understand therefore, that the rollout of a programme is done very differently at different sites. If a new programme can integrate into health systems that exist it

Panel Discussion – Key Players in Diagnostics: Researchers, Academics, Private Sector, Manufacturers, and Medical Schemes

Introduction to New Diagnostics

Professor Andrew Whitelaw

Progress is being made towards decentralized affordable field-friendly POC NAATs for TB, and some are well-suited for use in resource-limited settings. Antigen detection is used but sensitivity trends to be sub-optimal especially in patients with high CD4 counts. This means there is a “rule in rather than rule out” process which is not conducive to accurate screening. It can be used better in hospital settings.

For detection of resistance, the molecular approach is recommended with improvements already under way. In the diagnostic landscape of South Africa, GeneXpert remains the selected rapid diagnostic test. Second line assay works reasonably well as an add-on but cost and operational implications are not yet fully assessed.

Early phase technology includes volatile organic compounds, various NAATs including for DST, VOCs such as e-noses and rats and further equipment is under development. Biomarkers play a differentiation role but there are presently no commercial biomarkers available. Point Of Care tests should be 80% in smear negative results, with same-day results. There are various specimen types and simple minimal training is needed, but currently no test offers all of this.

It is important to demonstrate the impacts that a specific test has on burden of disease. Discussion is needed around WHO endorsement, when to adopt a specific test, how to choose for the settings, whether the test is a replacement or an add-on and how to use it. It is important to be able to measure impact, including cost effectiveness.

What is on the horizon for TB diagnostics, global and local?

Dr. Glaudina Loots, Department of Science and Technology

Rather than taking a clinician’s view, or a laboratory view, the patient should be at the centre. People who have used their last money on transport to reach a clinic are the clients who must have immediate care and quick results. The DACST has a health innovation unit that examines ways to support local research and development and innovation capacities. Areas of study include HIV, TB, malaria, diagnostics, treatment, building clinical capacity, and promoting local manufacturing.

The many stakeholders need to be brought together as Strategic Health Innovation Partnerships to promote synergies, and collegial work, drawing on international experiences. Collaborative research is a key component.

It is important to identify what is presently being done at universities that can be drawn on. South Africa is doing a lot of biomarker research because of easy access to clinical trial opportunities. An interesting project relates to rapid testing in 30 minutes, costing under \$4 and easy to administer. This is presently being validated. Links that will hold interest for corporates such as Novartis are being promoted and there have been a number of successes in a short period.

Mr. Peter Mehlape, BD Diagnostics

Regarding POC technologies, a recent survey was done on what patients and health care systems wanted in 23 African and Asian countries, in particular around TB and HIV. Whatever the test that must be done, patients want simple, easy, cheap tests and the health systems want tests that require limited infrastructure. In the past 5 years a CD4 POC product has been produced that can be used without a doctor and this is being expanded to TB POC products that will be accessible in the last mile of health care with limited infrastructure.

Capacity for POC technology has been built that is of world class standards and can be brought to developing countries in a viable way. The collaborative approach has worked well, and valuable experience has been shared. The CD4 POC products took some time to develop but provided valuable lessons going forward that will inform the TB POC product development. There is collaboration with the NHLS to bring in second line drugs.

Mr. David Hain, Hain Life Science

A comprehensive range of microbacterial test systems provide rapid and easy test options. South Africa is an important market and there is strong collaboration. An important test currently being marketed is for second line drugs – this was drawn from what was available at the time and it does exactly what is expected from the assay. The probe is very accurate and there is a new version of the Line Probe Assay (Version II). There are also tests for NTMs, which are important in South Africa.

New assays are under development – fluorescence-based multiplex – in a single tube that will be customer-friendly and go into laboratories easily. With the new drug regimes, there needs to be discussion around what drugs should be tested in the future. It is important to be aware that new resistant markers are emerging and design accordingly. Therefore vanguard studies are being done – an assay can be designed based on new technologies, but in designing such an assay it is important that the scientific community makes input on what is needed. Research must inform product development and public-private partnerships are useful in this regard.

Mr. Paul Steuperaert, Cepheid HBDC

This is a high growth company with innovative approaches. Future products include the 50-pack of GeneXpert which is much cheaper and easier to use and store. There is an extended warranty worldwide, on-site preventative maintenance, and simpler calibration. Web-based training for users is provided around the world and a user-friendly approach is promoted.

On rollout of national programmes, there has been expert MDR-TB provision in HBDC countries which includes installation and training. Accurate monitoring of system usage is important. User functionality support is available free to all users, and relates to any instrument sold. Going forward, simplified installation and settings with remote upgrade, and appending data to test results, as well as Excel export is possible. Administration will include external application interface, data share with other institutions, and assistance with system replacement or relocation. This is the future for defining molecular diagnostics—any test, any time, any sample, any place!

Discussions and Comments

1. A concern in South Africa is that we focus on training people who perform the different tests but health care workers also need to know when to request a test and why. How can a manufacturer contribute to guiding health care workers in knowing when to request a test? Response: Extensive training has already been done in South Africa that has been well received and there are monthly training updates as well as support platforms.
2. At hospital level, using GeneXpert has been challenging as modules start to fail over time, usually after the warranty has expired, and 30% of modules are replaced after 2-3 years of use. This has a serious impact on budget. What is intended for cost of maintenance and replacement of this equipment? Response: Module failure is an issue that must be avoided at all costs, and this is being addressed at the international level. In South Africa a new repair and calibration centre was established with new tests that are more rigorous, such as 17 hours of non-stop testing on a single module before it is validated. Expert calibration will improve performance. There is also remote calibration service. Current failure rate is 4% that is constantly being worked on. However, end users must also play a role in maintaining quality, especially in rural settings.
3. It is not only a question of training, but assessing the entire stakeholder chain and educating and informing all stakeholders, including funders and clinicians. They need to be included in processes at the outset to ensure their commitment to a new way of working. They need to buy into the new technology and see its value.

In summary, Dr. L Mvusi noted that the key outcomes that are expected from the Summit relate to examining the existing tests and the extent to which these are currently being optimized, and where there are gaps, there must be discussion as to how these can be addressed.

The health systems must be strengthened so as to improve diagnostics and early diagnosis and promote linkages to care and treatment, including a higher level of compliance with treatment.

Research gaps need to be identified and relationships with academia, and indeed with all stakeholders, strengthened.

It is clear that in introducing new tests, the implementation has not been consistent and there were unexpected challenges. There was a lack of commitment from provinces, districts, health care workers and the patients themselves that has impacted on outcomes. It is important that all stakeholders are equally informed and

The Role of TB Diagnostics in Reaching Zero TB Deaths

Dr. Sanni Babatunde, WHO

The World Health Organisation embraces a vision of a world free of TB and this is what we must all aspire to. The intention is that many of us will become unemployed in 2035 because we will have attained our goals!

What should we be targeting into the future? It is necessary to draw on the draft 2015 strategy which will be adopted in 2014. The target is fewer than 10 TB cases per 100 000 population for 2035—this provides a baseline figure. To achieve this will require innovative principles and thinking based on the three pillars of high quality integrated care and prevention; bold policies and supportive systems; and intensified research and innovation.

If the current trajectory can be optimized with the addition of social stability and other positive influencers, then there will be a decline of 10% a year, but even in this positive scenario the goals will not be achieved. There is a need to improve not only diagnostics but also the entire health systems continuum. Diagnostics is important but a comprehensive approach goes beyond that. The term Universal Health Coverage speaks to access, quality, and fullest possible access for patients. Social protection plays a key role and requires a comprehensive package that optimizes tools and promotes Universal Health Care, and this will contribute to a 10% decline in incidence. This requires innovative, strong health and surveillance systems that can be measured. New R&D outcomes are also an important factor.

On the role of TB diagnostics, the TB infection pool is 2 million people at present. It is important to prevent expansion of this number by early case detection and good TB management, including treatment. This is a key role for the health systems. Shorter duration of treatment will contribute to better treatment management. High specificity is needed and the necessary tools are available.

South Africa has good GeneXpert coverage which reduces TAT in laboratories, but this has not contributed to improved treatment initiation. Any patient benefit is unclear because while the laboratory processes are acceptable, the main opportunities for improvement are found in the space between the laboratory and the patient.

Technology endorsed by the WHO indicates a significant shift in the accessibility of a good TAT testing environment. It is important to keep in mind that TB is both pulmonary and extra-pulmonary and therefore the most appropriate test

is required to ensure accurate detection. An ongoing concern remains the delay in TAT with test results, and the higher level expertise required to analyse the tests and influence the outcomes. Public health diagnostic evaluation for TB also requires revised policy recommendations that are based on the use and outcomes of updated technology. A new focus is now possible on the diagnosis and treatment of adults and children, including presumptive MDR/HIV associated with TB.

The main recommendation is that GeneXpert should be used rather than traditional microscopy for initial testing. It is important to agree on the kind of diagnostic approach to be promoted in order to move towards zero incidence, and draw on the existing diagnostic tools to attain this. GeneXpert appears to be that option.

Discussions and Comments

1. The WHO figures seem to indicate a downward trend in TB infections but this is not the case, and there is definitely an upward trend. The WHO recommendations are good but an activist model is needed in South Africa.
2. GeneXpert is recommended in certain situations as first line instead of microscopy. Can molecular testing also be used as this is cheaper than GeneXpert? Response: Not all molecular testing is acceptable because the assessment is based on GeneXpert in comparison with the gold standard.
3. The WHO and NDOH finalized extensive reviews which covered all provinces and based on the findings it is possible to assess where diagnostics fits in. Response: With a review it will be seen that this linked up with what the WHO study indicates, that the burden is beyond the excerptor only and has to do with other components that were not reviewed. To attain the proper perspective there is a need to know what the current South African TB burden is. The WHO asserts that the basis for activation and arriving at this particular estimate is still not entirely clear and triangulation is needed to derive accurate meaning. For the health sector review, it will provide a picture of what the health sector can do to improve the TB situation based also on external factors.
4. There are two things relevant for the URC – the unique identifier and patients not returning for results. Data from NHLS showed 14 000 MDR-TB cases but these are not all patients so the challenge is to improve the process to quantify both testing and treatment. The other concern is that there are districts where one third of people with TB symptoms had a smear taken but did not come back for results yet these are infectious patients. This means there are 30-40% of tested patients who are infectious and we now cannot find them. Response: The NHLS in conjunction with the CPW is making a significant effort to address duplication in the absence of a unique identifier – although everyone agrees that a unique identifier is critically needed.

Group Work Reports

Group One: Introduction of new tests (liquid culture, LPA & GeneXpert)

Group proposals, Discussions and Comments

- The NHLS and the private laboratories should collaborate on data sharing and Quality Assurance.
- The current regulatory framework for laboratories is limited. Therefore there is a need for a statutory body for labs – that includes a multi-stakeholder expert group. For example there are certain tests that are too costly and should only be allowed in specific contexts. The NDOH does have recommendations regarding laboratories and prescribed tests but this is not statutory and not well enforced.
- The private sector should comply with the national TB diagnostic algorithms
 - However the private sector costs are too high, medical schemes are reluctant to pay for the test, and patients cannot afford to pay.
 - NDOH should engage private funders on cost reductions for GeneXpert tests.
- The NDOH should encourage operational research on newly introduced tests, in order to assess their impact on outcomes, patient delays in seeking care and the time to treatment initiation.
- A better tracking system should be implemented to prevent duplication. Explore use of a unique identifier (e.g. Identification number, thumb prints, etc.)
- Accelerate the implementation of a single request form which must be aligned with the algorithm and level of care. The form should integrate NDOH and NHLS requirements.
- The sample collection from patients and storage at facility level need to be improved.
- The NDOH must standardize practice as far as possible throughout provinces. For example, consider changing from collecting one specimen to two upfront, similar to the Western Cape approach, but this could be considered in a programme that has a good system of linkage to care.
 - There are two components to this discussion— one is the issue of the baseline smear in GeneXpert positive cases, and could that part of the algorithm be dropped? However, the smear result is still essential for contact investigation and bacteriological monitoring. The matter is presently

under review by the NDOH where case definition will be reviewed with regard to notification requirements.

- The NDOH must invest in improved IT systems to ensure that all facilities have a computer and internet to facilitate access to the results.
- There is a need to create a strong local evaluation system for new tests, which is inclusive of the private sector. Where appropriate, new tests can be endorsed and implemented locally without waiting for WHO approval.
- Develop linkages across the board, such as the South African Health Products Regulatory Authority (SAHPRA) for registration of new technologies, and the Office of Health Standards and Compliance which evaluate the quality elements.
- Leverage the power of the new diagnostics to improve the health system overall and strengthen linkages to care.

Recommendations

- Propose the development of a generic implementation framework within which the review and rollout of all new diagnostics is undertaken and this to be developed with the involvement of all stakeholders, for example, the private sector will contribute innovation and efficiencies.
- NDOH should consider establishing a voluntary regulatory body that will oversee development of the regulatory framework for all laboratories (private and public) based on international norms and standards.
- NDOH should consider appointing a national laboratory co-ordinator who will oversee liaison between DOH and public and private laboratories.

Group Two: Challenges in implementing the technologies

Group Discussions and Comments

- Adopt a standardized national referral form that will capture basic information to communicate to the hospital. This form would contain the following information: smear negative results, HIV status as well as chest x-rays for the facility to commence the correct treatment.
- Proper sputum collection, as well as transportation of specimens has proven to be a problem in the past.
- Encourage induction of sputum in children with TB.

- Collection of two specimens upfront saves a lot of time for MDR-TB confirmation
- The definition for turnaround time (TAT) was agreed upon as the time taken from sample collection to when the results reach the clinician again. The proposed targets for TAT were 5 days for drug susceptible TB and 10 days for drug resistance TB. The proposed TAT for culture is 6 – 8 weeks.
- Healthcare workers and laboratory staff need to be trained on the diagnostic algorithm.
 - Training sessions with healthcare workers on the pre-analytical process is important.
 - There is a gap in training of clinicians
 - There should be follow up support and mentoring after training
- A unique identifier should be used for patients to avoid duplication of tests.
- There should be an effort to strengthen ward-based outreach teams.

Recommendations

- NHLS needs to process sputum samples over weekends, instead of only processing samples received on a Friday on the next Monday.
- The processes that were followed when implementing new tests should be reviewed in order to establish what has been done, identify gaps and then develop a framework / strategy to address the gaps.
- There should be an effort to strengthen ward based outreach teams.
- Develop systems to monitor turnaround times.

Group Three: Community, patients, civil society: Linking communities to services

Group Discussions and Comments

- Training of community health workers and communities is important
 - Treatment adherence counselling
- Social mobilization
 - Use community dialogues to address stigma, discrimination and Xenophobia
- Clarify the role of stakeholders such as faith based organisations (pastors preaching healing and to stop medication) and ward councillors.
- There must be coherent messages communicated to avoid confusion.

- Strengthen public/private partnerships within communities.
- Right to care is not sufficiently prioritized.
- Ward based Outreach Teams. – but this had little impact on the TB programme.
- Managing the influx of migrant patients from outside South Africa seeking treatment for MDR-TB remains a challenge.
- Guidelines must be revised to include the role of clinics and home based carers in the decentralization of MDR-TB management.
- Train professional nurses on the IMCI strategy to improve TB diagnosis in children under 5.

Recommendations

- Strengthen the functionality of clinic committees and hospital boards
- Screening at community level must target high risk groups
- Explore options to improve access to testing at community level
- Strengthen linkage to care
- Develop tools for monitoring community TB care

Group Four: Key players in Diagnostics: Researchers, Academics, Private Sector, Manufacturers, Medical Schemes

Group Discussions and Comments

- The private sector focuses on cost issues – but this is correct because when on medical aid patients must have access to the best tests – those with TB must be diagnosed and managed creatively under medical aids.
- In house tests must go through robust evaluation, and there must be regulated standards to evaluate against.
- No government body evaluating technology/tests. Although tests done internationally, local studies are wanted. European manufacturers use European and American standards for thorough evaluation and products then carry CE mark. Need to know where local tests are required to take place.
- Currently manufacturers have education and training teams for all levels of medical personnel in laboratory and health facilities. They are willing to provide training at no cost but have to be requested to do so. Coordinated approach should include all manufacturers to share knowledge.

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- Currently NHLS makes decisions on placement of new tests, with very little consultation, especially with provincial departments on what equipment is placed where.

Recommendations

- Consultation with district and provinces on closing the gap between diagnostics and implementation
- Strong national leadership is essential to drive the process of adoption and implementation of new technologies equitably across all provinces.
- Training of health care workers should be centrally organized and coordinated, driven by the DOH with the support of the private sector.
- All academic and research institutions should be involved in pre- and post-marketing research for new tests.
- Create a national repository of data including publications on basic research.
- Set priorities for operational research to evaluate the implementation of new tests
- Develop a framework/guidelines for registration procedures of new technologies.
- Establish a national body to review new tests/ technology

Recommendations

The report, recommendations and presentations will be shared electronically.

Next Steps:

1. Report to the quarterly meeting with all provinces and partners on 27 and 28 November and present findings and also circulate within NDOH. Follow up on tasks on what to operationalize from this meeting.
2. The expectation is to provide an implementation plan, talk about progress, and evaluate new evidence that might have become available.
3. A recommendation is that there must be a national task team that will advise how best to introduce these tests. Also request approval within the Department for appointment of such a team and contact individuals regarding terms of reference of this team and circulate for input and suggest candidates.
4. It is hoped that the team will be representative but not overly large.
5. It is suggested that another meeting of this nature be convened a year from now – we need to assess if this is too soon or not soon enough. General agreement was that the meeting would be useful with an expanded agenda that has feedback from the field.
6. We are committing to the TB programme in that next week provinces will already take up some of the points raised here – this forms part of health systems strengthening to be incorporated into coming year plans.
7. When we meet again we must have clear guidelines about what we will need to do and how to assess our progress. Outline the recommendations from this meeting and those organizations or people would have to say what they have done and share the challenges and learnings. We need to have begun to implement recommendations.
8. Timeline for all the suggested work – report for inputs by 1st week December to circulate for comment from participants. Friday 13th December to provide feedback to Convenors who will then consolidate for early in 2014.

Closure

The Summit shared a high level of technical expertise in a short time and the exceptional quality of all inputs into this important area of work is acknowledged. TB Diagnostics have long experienced challenges and the opportunity to host such a Summit and include a wide range of stakeholders is very welcome. It is hoped that the recommendations and inputs from this meeting will also contribute to the guidelines that are presently in development.

Presentations can be accessed via the following link:
<http://tbsouthafrica.org/node/267>

National Summit on TB Diagnostics: AGENDA

DAY 1 (18 November 2013)

Program Directors: Dr. Lindiwe Mvusi & Dr. Refiloe Matji

TIME	ACTIVITY	PRESENTER
08:30 – 09:00	Registration	
09:00 – 10:00	Welcome and Introductions	Session chair: Mr. David Mametja (DOH)
	USAID Support	Ms. Catherine Brokenshire-Scott (USAID)
	TB Diagnostics, Global context	Dr. Refiloe Matji (URC)
	<ul style="list-style-type: none"> NDOH priorities and challenges on TB diagnostics in South Africa Objectives of the summit 	Dr. Yogan Pillay (DOH)
10:00 – 10:15	TEA BREAK	
10:15 – 11:40	Panel Discussion Session I: Introduction of new tests (liquid culture, LPA & GeneXpert)	Panel Chair: Dr. Giorgio Roscigno
	Session introduction	
	<ul style="list-style-type: none"> What are the key issues in TB diagnosis? How were the currently available tests in SA introduced? What was the rationale? What lessons have been learnt? How are the algorithms being used? What is the role of private sector? 	Panel Members: <ul style="list-style-type: none"> Prof. Koleka Mlisana (UKZN/NHLS) Dr. Jan van Rooyen (Ampath) Dr. Peter Cole (Lancet), Dr. Lorna Madurai (Global Labs) Dr. Suleiman Hajee (Toga Labs) Dr. Nazir Ismail (NICD)
11:40 – 13:00	Panel Discussion Session II: Challenges in implementing the technologies	Panel Chair: Prof. Maphoshane Nchabeleng (MEDUNSA)
	Session introduction	Prof. Wendy Stevens (NHLS/WITS)
	Challenges related to reaching all levels of the Health System? <ul style="list-style-type: none"> Quality Assurance challenges Clinical challenges Operational challenges Diagnosis of TB in children 	Panel Members: <ul style="list-style-type: none"> Dr. Adeboyi Adelekan (CDC) Dr. Xavier Padanilam (Sizwe Hospital) Dr. Pren Naidoo (DTTC) Dr. Kerrigan McCarthy (Aurum) Dr. Ute Feucht (Tshwane District/UP)
13:00 – 13:45	LUNCH	
13:45 – 15:05	Panel Discussion Session III: Community, patients, Civil Society Linking communities to services	Panel Chair: Mr. David Mametja (DOH)
	Session introduction	Dr. Norbert Ndjeka (DOH)
	<ul style="list-style-type: none"> Interface between community and Diagnostics Access to TB Screening and HIV testing Early Diagnosis of TB and MDr. TB Linking patients to treatment services 	Panel Members: <ul style="list-style-type: none"> Dr. Rebecca Berhanu (Right to Care) Dr. Sinah Vlug (FPD) Dr. Tony Moll (Philanjalo) Marian Loveday (MRC)
15:05 – 15:20	TEA BREAK	

TIME	ACTIVITY	PRESENTER
15:20 – 16:40	Panel Discussion Session IV: Key players in Diagnostics Researchers, Academics, Private Sector, Manufacturers, Medical Schemes	Panel Chair: Dr. Refiloe Matji (USAID TB Program, URC)
	Session introduction	Prof. Andrew Whitelaw
	<ul style="list-style-type: none"> What is on the horizon for TB diagnostics- globally and in South Africa? What are the roles of the public, private and the research sectors? What do we need? 	Panel members: <ul style="list-style-type: none"> Dr. Giorgio Roscigno Ms. Glaudina Loots (DST) Mr. Peter Mehlape (BD Diagnostics) Mr. David Hain (Hain Lifescience), Mr. Paul Steuperaert (Cepheid) (Roche, TBC)
16:40 – 17:00	What role will TB diagnostics play in getting to Zero TB Deaths?	Dr. Sanni Babatunde (WHO)
17:00-17:10	Closing Remarks	Chairperson- David Mametja
18:30-20:00	DINNER	

DAY 2 (19 November 2013)

Program Directors: Dr. Lindiwe Mvusi & Dr. Refiloe Matji

TIME	ACTIVITY	PRESENTER
08:30 – 09:00	Recap Day 1	Chairperson
09:00 – 09:20	Working Group (WG) Instructions	Facilitator (TBC)
09:20 – 10:00	Group Work	Group Facilitators
10:00 – 10:15	TEA / COFFEE BREAK	
10:15 – 12:00	Group Work continuation	Group Facilitators
12:00:13:30	Feedback presentations	
	WG 1	Group representative
	WG 2	Group representative
	WG 3	Group representative
	WG4	Group representative
13:30 – 14:30	LUNCH BREAK	
14:30-15:30	Feedback Presentations continued	
15:30–16:30	Way Forward	Chairperson
16:30 – 17:00	Closure and Departure	David Mametja (DOH)

List of Participants

Name	Organization
Ms. Dakhile Ndiwalane	URC
Dr. Dawie Theron	PDOH
Mr. David Hain	Hain Lifescience
Mr. David Mametja	NDOH
Mr. Detlef Siewert	BD Diagnostics
Dr. Dimakatso Moloji	PDOH
Dr. Donna Jacobs	URC
Ms. Duduzile Mbambo	PDOH
Mr. Banele Dlamini	URC
Ms. Smita Kumar	USAID
Mr. Elvis Ngobeni	PDOH
Ms. Evelyn Mhlope	URC
Dr. Frederick Balagadde	K-RITH
Dr. Giorgio Roscigno	NEXT
Ms. Claudina Loots	DST
Dr. Harold Hlophe	PDOH
Dr. Faizan Ismail	NHLS
Mr. Iain Sharp-Paul	Cepheid
Dr. Keshree Pillay	Lancet
Prof. Koleka Mlisana	NHLS
Dr. Kerrigan McCarthy	Aurum
Dr. Kgomotso Vilakazi	NDOH
Mr. Dirk Smit	Hain Lifescience
Dr. Leigh Berrie	NHLS
Ms. Lerato Legoabe	URC
Ms. Lessie Mnisi	USAID
Dr. Limenako Matsoso	URC
Dr. Lindiwe Mvusi	NDOH
Dr. Lorna Madurai	Global Laboratories
Mr. Sebaka Molapo	NHLS
Prof. Maphoshane Nchabeleng	Medunsa
Ms. Marian Loveday	MRC
Prof. Mark Nicol	NHLS
Dr. Martie van der Walt	MRC

Name	Organization
Ms. Maswikana Sithole	URC
Mr. Mokete Phungwayo	NDOH
Dr. Mpho Ratshikana-Moloko	URC
Dr. Muhammad Osman	City of Cape Town
Mr. Musawenkosi Simelane	URC
Dr. Sibongile Mahlangu	NHLS
Mr. Marlon Burgess	MDG
Mr. Sicelo Dlamini	NDOH
Mr. Garvon Molefe	NDOH
Ms. Eva Kobola	PDOH
Mr. Masala Silinda	NDOH
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Mr. Neil Barker	Cepheid
Ms. Nellie Gqwaru	USAID
Dr. Nesri Padayatchi	CAPRISA
Ms. Nicole van der Westhuizen	PDOH
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Ms. Nonkululeko Nkomo	URC
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Dr. Mokgadi Sinah-Vlug	FPD

Name	Organization
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Ms. Patricia Ntsele	NDOH
Mr. Raymond Mabope	NDOH
Dr. Rebecca Berhanu	Right to Care
Dr. Refiloe Matji	URC
Prof. Rob Warren	University of Stellenbosch
Dr. Robert Makombe	URC
Dr. Sanni Babatunde	WHO
Mr. Simphiwe Mayaphi	URC
Dr. Suleiman Hajee	Toga
Ms. Sineli Shabalala	NDOH
Ms. Thandeka Dayimani	URC
Mr. Thulani Mbatha	URC
Dr. Tiyani Mabunda	PDOH
Dr. Tony Moll	Church of Scotland Hospital (COSH)
Ms. Tumi Mbengo	URC
Ms. Ursula de Kok	BD Diagnostics
Prof. Wendy Steven	NHLS
Prof. Wesley Scott	Wits University
Dr. Xavier Padalimum	NDOH
Mr. Zanoxolo Mbundu	Hain Lifescience
Dr. Varough Deyde	CDC
Dr. Beki Magazi	University of Pretoria (UP)
Dr. Ute Feucht	UP/DOH Tshwane
Dr. Francesco Balletti	Italian Cooperation
Mr. Thulani Tukulu	Faranani Healthcare
Ms. Georgina Wessie	URC
Ms. Fikile Dlongolo	URC
Dr. Adeboye Adelekan	CDC
Ms. Alvera Swartz	PDOH
Dr. Andrew Shija	MP NDOH
Prof. Andrew Whitelaw	NHLS
Prof. Anne Grobler	NWU
Ms. Catherine Brokeshire-Scott	USAID
Ms. Cindy Dladla	URC
Dr. Claudio Marra	URC
Ms. Elizabeth Matsepe	FPD



USAID TB PROGRAM SOUTH AFRICA: DR-TB TECHNICAL BRIEF

Background

Drug resistant tuberculosis (DR TB) is a global public health crisis that threatens to undermine TB control efforts in many countries. South Africa currently has the fifth highest burden of multidrug resistant TB (MDR TB) and in the world, with 15,400 diagnosed cases in 2012. Approximately 10% of these MDR TB cases were reported to have extensively drug resistant TB (XDR TB).¹ As part of its National Strategic Plan on HIV, STIs, and TB (2012 – 2016), the Government of South Africa is committed to the prevention of DR TB through improvement in identifying and curing drug-susceptible TB, and early detection and effective treatment of all MDR/XDR TB cases. Since 2009, the USAID TB Program South Africa has been supporting the National Department of Health in combating DR TB in the country through expanding access to diagnostics, improving programmatic management of MDR TB at the community level, and increasing provider capacity at all levels to implement DR TB programs.

Improving Management of DR TB

The traditional model of care for MDR TB involves hospitalizing MDR TB patients during the intensive phase of their treatment (6–8 months) to ensure proper administration and adherence to treatment and to limit transmission. However, this model often results in bed shortages; delays in treatment initiation for MDR TB patients; a high likelihood of transmission of MDR/XDR TB at health facilities; and lack of social support for patients, who are isolated from their families during treatment and who may face financial burdens due to the lengthy hospital stays.

To address these challenges, South Africa is increasingly moving toward community-based programmatic management of DR TB (cPMDT), which is designed to allow patients to receive DR TB treatment in their own community.

Countering the threat of MDR TB

Multi-drug resistant tuberculosis (MDR TB) is defined as TB that is resistant to at least isoniazid and rifampicin, the two most potent TB drugs. These drugs are used to treat all persons with TB disease. South Africa has also experienced ongoing intermittent cases of extensively drug resistant TB (XDR TB), MDR TB that is resistant to these drugs as well as several second-line drugs normally used.

Drug resistance to anti-TB drugs can develop as a result of health systems gaps which limit patients' or providers' ability to properly access, manage, or adherence to standard (first line) treatment for drug susceptible cases. Increasingly, primary infections are occurring among those exposed to someone with MDR TB.

The USAID TB Program South Africa has helped expand cPMDT by working with districts and MDR TB treatment sites to develop and operationalize cPMDT programs. This includes conducting situational analyses in prospective sites, identifying the gaps that would hinder implementation and the resources that would fill them, the mapping of MDR TB patients to inform planning, building the capacity of nurses and other health care workers to provide MDR TB treatment, and developing tools to monitor and evaluate cPMDT programs. Through its small grants program, TB Program South Africa is supporting four local NGOs in three provinces to expand cPMDT programs. At the community level, mobile injection teams comprised of nurses have been developed to conduct daily home visits to MDR TB patients to give second-line TB drugs by injection and observe doses of oral TB medications and ARVs. After introduction of cPMDT, a large number of DR TB patients are now being discharged after a short stay in hospital.

¹ World Health Organization (WHO). Global Tuberculosis Report, 2013. http://www.who.int/tb/publications/global_report/en/

Community-Based Care for MDR TB Patients

TB Program South Africa continues to advocate for and assist districts and communities to adopt community-based management of MDR TB patients, which has been shown to:

- Improve treatment compliance through individualized patient care and counseling
- Allow patients to receive sustained family and community support
- Reduce hospital acquired infections
- Reduce high hospital caseloads and delays in treatment initiation, and reduce inpatient costs

Increasing Capacity to Implement DR TB Programs

TB Program South Africa is working to increase the capacity of health care providers at all levels of the health system to effectively address DR TB. The project provides policy support and advocacy for the development and expansion of national plans to increase availability of MDR TB services, and has provided expert assistance to train physicians in each of the nine province in the clinical management of DR TB, in coordination with the International Union Against TB and Lung Disease (IUATLD) and other groups. This cadre of DR TB trainers will

continue to provide regular training to ensure compliance with international standards and national guidelines.

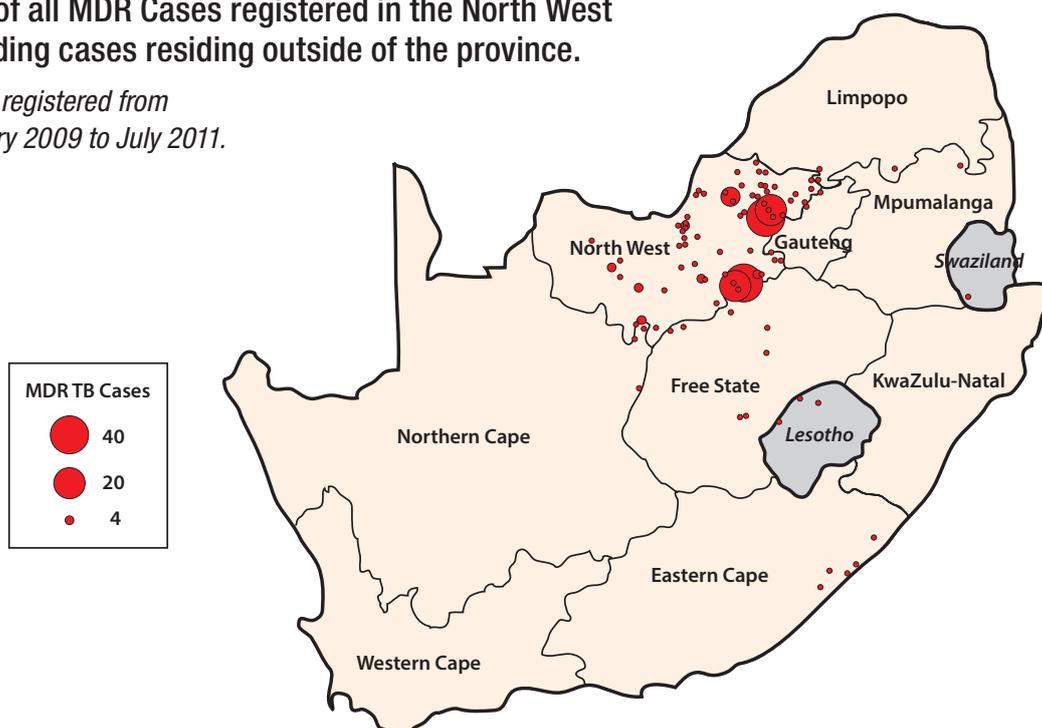
In, 2011 TB Program South Africa conducted a DR TB household mapping designed to identify “hot spot areas” of MDR TB burden and to inform community interventions based on case loads. Through use of smart phones and geomapping technologies, locations and distributions of patients in the community are able to be mapped, allowing program managers to identify hotspots and monitor treatment progress. This system is also being used to better identify, map and plan services for vulnerable communities, such as miners.

The project is also collaborating with district health offices to ensure that resources for DR TB are effectively mobilized and integrated into existing TB programs at the facility level. These activities include:

- Monitoring implementation of district TB plans and identifying areas for follow up support;
- Emphasizing the importance of community management of DR TB and the role of district TB managers/DR TB units in supporting cPMDT roll out;
- Providing monitoring tools (both paper-based and electronic) to improve DOT worker performance;
- Advocating immediate tracing and screening of all household contacts of index cases to promptly identify active TB disease – including among children;
- Emphasizing the importance of accurate, detailed previous TB treatment history reports in identifying retreatment cases;

Map of all MDR Cases registered in the North West including cases residing outside of the province.

Cases registered from January 2009 to July 2011.



-
- Ensuring strict compliance with TB patient management guidelines;
 - Ensuring early identification and tracking of patients lost to follow up;
 - Conducting infection control assessments and educating families of index cases on TB and DR TB control.

Innovating to meet the challenge of DR TB

The USAID TB Program South Africa is driven by the idea that South Africa is equipped to be an incubator for best practices in health system development and that it has the human and material resources to drive change and lead the Southern African region in the development of solutions to critical challenges like DR TB, which pose enormous threats to the country's health and social development. Drawing on the cutting-edge expertise of TB program's staff, URC is working to promote additional strategies to close the gaps in MDR TB services by:

- Supporting the introduction of new drugs and shorter treatment regimens (bedaquiline and 9-month regimen);
- Introducing new cadres of health providers to increase access to treatment (exploring systems for nurse-led MDR TB treatment);

MDR TB in Children

Approximately 15–20% of South Africa's TB cases occur in children. TB Program South Africa developed a tool to assess the status of pediatric TB and MDR TB case detection and management in selected health facilities. The assessment revealed weak child contact tracing and evaluation systems. Strengthening these systems to identify MDR TB in children is an essential component of the DR TB response.

Further study is needed to quantify the burden of MDR TB in children and to develop dosing and treatment regimens for them.

- Connecting health and strategic technology solutions to support contact tracing, patient tracking and case management; and
- Developing systems to increase palliative care services for patients who cannot be cured.



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**TUBERCULOSIS
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USAID TB PROGRAM SOUTH AFRICA: TB/HIV TECHNICAL BRIEF

Background

One of the main factors behind the high rates of tuberculosis (TB) in South Africa is the HIV epidemic. TB is the leading cause of death among people living with HIV/AIDS (PLHIV) and is easily spread among people whose immune systems are suppressed by the AIDS virus. HIV-positive TB patients also have worse treatment outcomes than HIV-negative TB patients. In South Africa, approximately two-thirds (65%) of TB patients are HIV positive. The USAID-funded TB Program South Africa (2009-2014) is supporting the South Africa National Department of Health (DOH) to provide comprehensive, decentralized, and high quality TB/HIV services at the community and facility levels. The project is working with partners to integrate TB and HIV services by introducing strategies to increase HIV testing for TB patients and TB screening for people living with HIV, building referral networks to TB treatment from HIV entry points and vice versa, and streamlining systems to allow co-infected patients to access coordinated care.

Decreasing the Burden of HIV in TB Patients

The TB Program South Africa is working to ensure that all TB patients are provided with HIV counseling and testing (HCT). From 2010 - 2013, HIV testing among TB patients has increased from 75.9% to 90%.

In 2012, South Africa adopted the World Health Organization (WHO) recommendation that all HIV positive TB patients be initiated on antiretroviral therapy (ART), regardless of their CD4 counts. From 2012 – 2013, ART uptake among HIV positive TB patients increased from 43% to 62%. Over the same period, uptake of cotrimoxazole preventive therapy (CPT), which can extend and improve the quality of life for PLHIV by reducing the risk of opportunistic infections that can affect their weakened immune systems, has also increased—from 71.6% to 81.2%.

Benefits of TB/HIV integrated services

For patients:

- More convenient—one stop service
- Improved access to prevention, diagnosis, and treatment services
- Fewer drop outs and loss to follow up
- Improved adherence and outcome of treatment

For health systems:

- More efficient, effective use of resources
- Increased competency of health care workers
- Joint management and a team-based approach can improve quality of both TB and HIV services

Decreasing the Burden of TB in HIV Patients

The TB Program South Africa is also promoting HIV care as an entry point for TB screening and referral. In 2013, 97.5% of HIV clients were offered symptomatic screening for TB. Isoniazid preventive therapy (IPT), which reduces the risk of TB infection in PLHIV, was provided to 130,578 clients who were found not to have HIV. This increased from 101,991 HIV clients initiated on IPT in 2012.

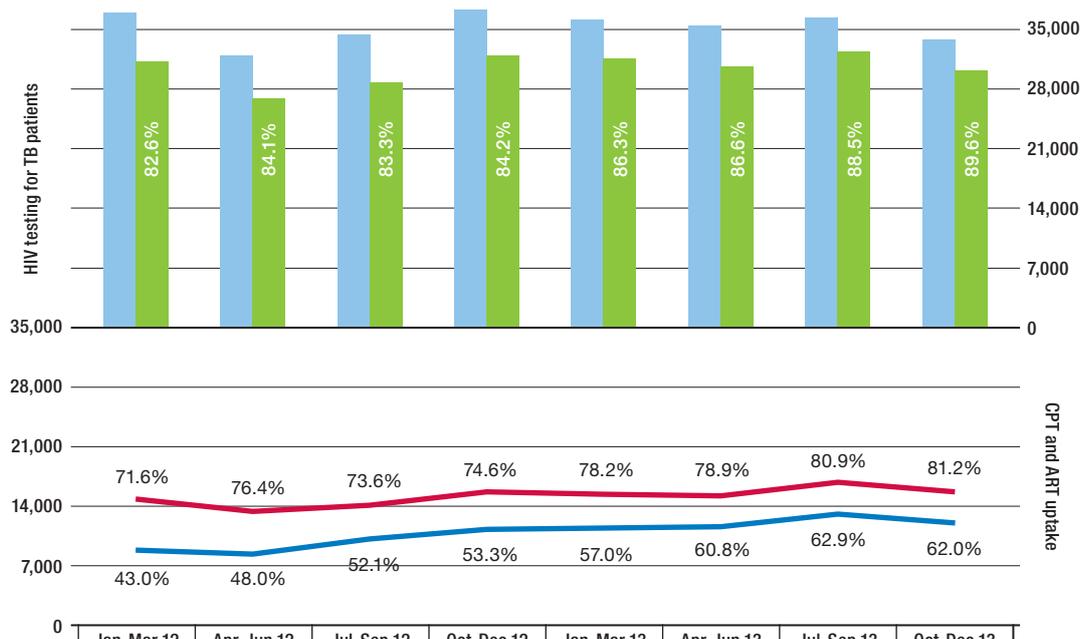
Expanding Access to TB Diagnosis for PLHIV

To ensure prompt and accurate diagnosis of TB in PLHIV, the project has also worked with the National Department of Health to introduce and scale up use of GeneXpert – a rapid testing machine that can diagnose TB in less than two hours and has the potential to greatly reduce the delay between sputum sample collection and treatment initiation for TB patients. South Africa now has 289 GeneXpert machines placed throughout the country (the project itself initiated the purchase and placement of 11 GeneXpert machines in project-supported districts). Since 2011, 3.2 million TB tests have been conducted and nearly 400,000 cases of TB have been diagnosed thanks to GeneXpert.

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Figure 1: HIV testing among TB patients; CPT and ART uptake for co-infected patients



	Jan-Mar 12	Apr-Jun 12	Jul-Sep 12	Oct-Dec 12	Jan-Mar 13	Apr-Jun 13	Jul-Sep 13	Oct-Dec 13
TB Cases Registered	37819	31980	34503	37913	36405	35292	36789	33655
TB pts with known HIV status	31221	26911	28737	31909	31435	30567	32540	30159
Co-infected on CPT	14850	13396	14226	15795	15620	15453	16815	15720
Co-infected on ART	8921	8415	10081	11286	11375	11913	13088	12017
TB pts co-infected with HIV	20737	17541	19341	21183	19966	19596	20796	19367

Source: Electronic TB Register (ETR.Net)

Building the Capacity of Health Workers to Deliver TB/HIV Services

Since 2009, the TB Program South Africa has provided training to health care workers on a collaborative approach to TB/HIV with emphasis on the WHO Three I's strategy – intensified case finding, IPT provision, and infection control for TB. In 2013, the TB Program South Africa provided training to 2,124 health care workers on TB/HIV co-infection and ongoing mentoring and coaching to facility staff in project-supported districts to encourage them to use TB as an entry point for the provision of HIV services. The project has also designated “champion facilities” to serve as a model for integrated TB/HIV care. In Q4/2013, eight of the eleven champion facilities in Amathole district of Eastern Cape achieved 100% CPT uptake and 100% ART uptake.

Also in 2013, the TB Program South Africa partnered with the International Union Against TB and Lung Disease (IUATLD) to train 22 managers from the Department of Correctional Services on the management of TB, HIV, and STIs in prisons.

The TB Program South Africa is also working to expand ART provision to TB/HIV co-infected patients through scale up nurse-initiated and managed ART (NIMART). By building the capacity of nurses at TB clinics and primary health care centers to administer ART, NIMART reduces delays in patient care by eliminating the need for TB

Scaling Up the Three I's for TB/HIV

Through training of health care workers and ongoing mentoring at the facility level, the TB Program South Africa is helping to promote:

- **Intensified Case Finding (ICF)** – screening of all people living with HIV for TB to determine if they are co-infected.
- **Isoniazid Preventive Therapy (IPT)** – giving IPT to all people living with HIV to prevent future TB infection.
- **Infection Control for TB (IC)** – ensuring TB does not spread to people living with HIV through improved IC practices at health facilities.

patients to visit a second site and see a second provider (usually a doctor) to begin ART. At NIMART sites, co-infected patients can gain access to more comprehensive and coordinated care.

Development of TB/HIV policies and guidelines

Since 2009, the TB Program South Africa has worked closely with the National Department of Health to develop and revise a number of guidelines and treatment protocols to promote TB/HIV integration. These include:



USAID TB Program South Africa staff with other walkers during the TB Walk for Humanity procession from SABC studios to Park Station in central Johannesburg.



School children participate in a Kick TB activity for World TB Day 2013.

- Revising the ART treatment guidelines to include prioritization of ARVs for TB/HIV co-infected patients and MDR/XDR TB patients;
- Revising the HCT guidelines to promote TB screening for all those tested for HIV;
- Developing and rolling out of guidelines on infection control and provision of IPT;
- Developing the diagnostic algorithm for GeneXpert to promote more rapid diagnosis and correct treatment initiation for TB patients;

Providing Support to National TB/HIV Joint Review

In 2013, the National Department of Health commissioned a Joint Review of HIV, TB, and PMTCT Programs in South Africa. The purpose of this independent review was to assess performance of the programs and provide recommendations to improve the delivery and impact of HIV, TB, and PMTCT services. The TB Program South Africa participated in the planning and development of this review, and was represented on the review steering committee. The results of this review, released in April 2014, will guide policy formulation and inform future interventions related to TB and HIV services in South Africa.

Strengthening the community-based response to TB/HIV

For more than a decade, South Africa's community and faith-based organizations have been at the forefront of the fight against HIV/AIDS in the country. The TB Program South Africa is working to expand on this legacy by

building the capacity of these groups to respond to the dual threats of TB/HIV in their communities. Since 2009, the TB Program South Africa has provided 85 grants to 70 community organizations in all nine provinces. These organizations provide a range of TB/HIV services to unreached and underserved populations, including helping patients stay on treatment through direct observation of treatment (DOT), tracing of TB patients lost to follow up and household contacts, reducing stigma and encouraging people to seek testing and treatment early, and increasing involvement of vulnerable populations such as youth and prisoners. From 2012-2013, these grantees reached more than 228,923 community members with TB and TB/HIV messages.

Increasing awareness of and demand for TB/HIV services

To raise community awareness of TB/HIV and encourage more people to get testing and treatment, the TB Program South Africa is actively engaged in advocacy, communication, and social mobilization (ACSM) activities at the national, provincial, and community levels. In 2011, the project launched a mass media campaign called **"We Beat TB!"** with a key campaign message that *TB is curable, even if you have HIV.*

The project has also used the Kick TB campaign model to engage young football fans in health and wellness activities related to TB and HIV. To date, Kick TB has reached 108,941 learners, who were asked to take the **zero challenge** – *"are dlale"* or *"let's play is safe for zero new HIV and TB infections."*



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USAID TB PROGRAM SOUTH AFRICA: TB DIAGNOSTICS TECHNICAL BRIEF

Lack of diagnostic capacity has been a significant barrier in preventing an effective response to the tuberculosis (TB) epidemic worldwide. According to the World Health Organization (WHO)'s Global Tuberculosis Report 2012, "a high-quality laboratory system that uses modern diagnostics is a prerequisite for early, rapid and accurate detection of TB". Inadequacies in laboratory capacity in many low and middle income countries have been cited as part of the reason why only 66% of the estimated 8.7 million TB cases in 2011 were diagnosed and notified by national TB control programs. South Africa has nearly half a million incident cases of TB each year, as well as high burdens of multidrug-resistant TB (MDR-TB) and TB/HIV co-infection. Funded by the United States Agency for International Development (USAID), the TB Program South Africa (2009–2014) is supporting the South Africa National Department of Health to expand access to rapid, high-quality diagnostics so that TB patients are initiated on treatment sooner, raising their chance of being cured and reducing their chance of spreading TB to others.

Mapping and Identifying Gaps in Laboratory Systems

The USAID TB Program South Africa undertook a desk survey in 2010 to identify preliminary challenges with the country's laboratory system. Identified challenges included prolonged sputum turn-around time, problems in cold chain maintenance during the transportation of specimens and insufficient access to laboratories by the clinics and screening sites. The next year, in partnership with the National Health Laboratory Service, the program mapped all the TB microscopy diagnostic centers in the country to determine the coverage of TB laboratory services. The program also developed a facility diagnostic information collection (FDIC) tool and a laboratory diagnostic information collection tool (LDIC) to collect information on bacteriological diagnosis of TB and document whether appropriate procedures were in place. Using these tools, the program can investigate

Rapid Assessment

In 2011, the TB Program South Africa used the FDIC and LDIC tools to conduct a rapid appraisal of 22 facilities in Mafikeng district and 10 facilities in Ventersdorp district of Northwest Province in response to the poor performance of the province's TB program. The assessment revealed a lack of TB registers in some facilities and poor recording and updating of results in others. These results informed the development of tailored interventions to help the facilities address their diagnostic challenges.

laboratory challenges, share the findings with facility and district staff, develop interventions, and monitor progress through follow-up site visits.

Roll Out of GeneXpert Rapid TB Testing

Early diagnosis is essential to achieving significant reductions in death and disability as a result of TB and HIV. One of the key objectives of TB Program South Africa is to foster early diagnosis through expanded access to new and effective diagnostic technologies.

In December 2010, WHO endorsed Xpert MTB/RIF (GeneXpert), a rapid testing machine that can simultaneously diagnose TB and detect resistance to rifampicin, one of the most important anti-TB drugs, in less than 24 hours - and has the potential to greatly reduce the delay between sputum sample collection and treatment initiation for patients with suspected MDR TB. This test can also diagnose up to 72% of smear negative pulmonary TB. In an effort to improve the diagnostic capacity for drug susceptible and drug resistant TB, South Africa was among the first countries to adopt and implement GeneXpert as a replacement of smear microscopy for all people presenting with TB symptoms. The TB Program South Africa partnered

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closely with the National Department of Health to facilitate GeneXpert roll out beginning in March 2011. Thanks to strong government investment, South Africa now has 289 GeneXpert machines placed throughout the country (the project itself initiated the purchase and placement of 11 GeneXpert machines in project-supported districts). Since 2011, 3.2 million TB tests have been conducted and nearly 400,000 cases of TB have been diagnosed thanks to GeneXpert. The number of MDR-TB (RIF-resistant) cases identified has risen from 2,467 in 2011 to 13,817 in 2013.

Capacity Building of Laboratory and Clinical Staff

The TB Program South Africa worked with the Department of Health to develop and incorporate a diagnostic algorithm for GeneXpert into the National TB Treatment Guidelines. Previously, patients with suspected DR TB had to wait for confirmation of drug-susceptibility testing before starting on second-line treatment, and new and treatment TB cases were treated using separate diagnostic algorithms. Now, health care workers are able to treat all TB suspects using one revised algorithm. Through a lab-based training program, the TB Program South Africa has trained 916 technical and 3968 clinical staff on the use of the GeneXpert machines. The project is continuing to monitor GeneXpert roll out, working with districts and laboratories to improve compliance with the diagnostic algorithm and ensure accurate reporting. Adherence to the algorithm is continuing to improve over time.

National TB Diagnostics Summit

On November 18-19, 2013, the project facilitated a National TB Diagnostics Summit, which brought together key stakeholders to review and discuss the state of TB diagnostics in South Africa and to create a roadmap for improving laboratory diagnosis of TB throughout the country. A total of 100 local and international participants



Participants at the National TB Diagnostics Summit in November 2013

attended, including representatives from the National Department of Health, the Department of Science and Technology, USAID, public and private laboratory service providers, diagnostic product manufacturers, funders, academics and researchers, and implementing partners.

Key recommendations resulting from the summit include:

1. Develop of a generic national implementation framework for review and roll out of new diagnostic tests;
2. Establish of a multi-stakeholder national task team of experts to provide ongoing guidance on the introduction of new tests/diagnostic procedures;
3. Host of annual meetings to follow up on implementation.

The USAID TB Program South Africa is continuing to work with the National Department of Health and other partners throughout South Africa to ensure that scale-up of more sensitive diagnostic tests is accompanied by wider health systems strengthening efforts, so that increased diagnostic capacity increases TB treatment initiation and decreases mortality among TB patients.

Key Topics of the National TB Diagnostics Summit

Introduction of new tests

- How were currently available tests introduced in SA (culture, LPA, GXP)?
- What was the rationale?
- What lessons have been learnt?
- How are the algorithms being used?
- What is the role of private sector?

Linking communities to services

- Interface between community and Diagnostics
- Access to TB Screening and HIV testing
- Early Diagnosis of TB and MDR TB
- Linking patients to treatment services

Challenges in implementing the technologies

- Challenges related to reaching all levels of the Health System?
 - QA challenges
 - Clinical challenges
 - Operational challenges
- Diagnosis of TB in children

Key role players in diagnostics

- What is on the horizon for TB diagnostics- globally and in South Africa?
- What are the roles of the public, private and the research sectors?



USAID TB PROGRAM SOUTH AFRICA: PROJECT OVERVIEW

Introduction

Globally, more than nine million people become ill with tuberculosis (TB) each year, and more than 1.5 million die of the disease. South Africa is classified by WHO as a high burden TB, HIV and multi-drug resistant TB (MDR-TB) country. The country has the world's third highest TB burden, with nearly half a million incident cases each year (or approximately one out of every 100 South Africans). Two-thirds (65%) of tested TB patients are found to be HIV positive and South Africa has some of the highest incidence of MDR-TB and extremely-drug resistant TB (XDR-TB) in the world. The USAID-funded TB Program South Africa is a 5-year project (2009-2014) implemented by University Research Co., LLC (URC). This project builds on the successes of the USAID-funded TASC II TB Project (2004–2009), also implemented by URC.

Program Goals and Objectives

The USAID TB Program South Africa supports the National Department of Health in improving early case detection, increasing access to diagnostics, ensuring treatment support for patients on TB treatment and ensuring that there is provision of appropriate and timely HIV care for TB patients and ART treatment for all TB/HIV co-infected patients. The USAID TB Program develops multi-level support, working closely with the National TB Control Programme (NTP) to build national support by mobilizing resources and creating a conducive environment for expansion of TB services, as well as with provincial and district health departments to support the collaborative development of need-based strategies to combat TB, TB/HIV and drug resistant (DR) TB, and with communities to create appropriate social mobilization and service delivery models for rapid expansion of directly observed treatment short-course (DOTS) in the country.

Expected results from this program include:

- A national TB treatment success rate of 80%;
- Improved capacity to plan and implement TB DOTS at community, facility, district, municipality, provincial and national levels;



USAID TB Program South Africa staff with other walkers during the TB Walk for Humanity procession from SABC studios to Park Station in central Johannesburg.

- Improved surveillance system resulting in early detection of TB cases, MDR TB cases, co-infected patients for ART as well as to prevent treatment defaulters and reduce mortality.
- Improved understanding and support among the general population regarding TB and TB/HIV signs, symptoms, referral, and treatment.

Geographic Coverage

The project works nationwide, providing support to all nine provinces, and 22 of 52 (42%) districts across the country, particularly those with the highest burden of TB, as illustrated on the map in Figure 1.

Key Implementation Strategies

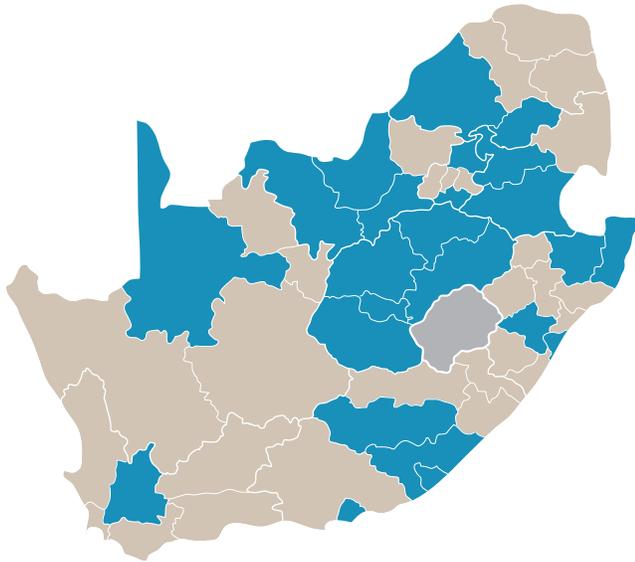
Support for the implementation of the Stop TB Strategy:

TB Program South Africa is assisting the National Department of Health to implement and actualize the six components of the

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Figure 1. USAID TB Program allocated districts by province



Stop TB strategy, which include 1) pursuing high-quality DOTS expansion and enhancement; 2) addressing TB/HIV, MDR-TB, and the needs of poor and vulnerable populations; 3) contributing to health systems strengthening based on primary health care; 4) engaging all care providers; 5) empowering people with TB, and communities through partnerships; and 6) enabling and promoting research.

Patient-centered care: TB Program South Africa works to improve the content of care, through development of and training on evidenced-based guidelines and treatment protocols; the process of care, through quality improvement strategies designed to increase the efficiency and effectiveness of systems; and the context of care, through support for community-based social support and counseling services.

Decentralized treatment: TB Program South Africa promotes a shift away from clinically-focused, hospital-based TB treatment toward programmatic management and community-based care for TB and MDR TB patients. This model reduce hospital caseloads and delays in treatment initiation, reduced inpatient costs, and allows patients to receive sustained family and community support during their treatment.

Focus Areas

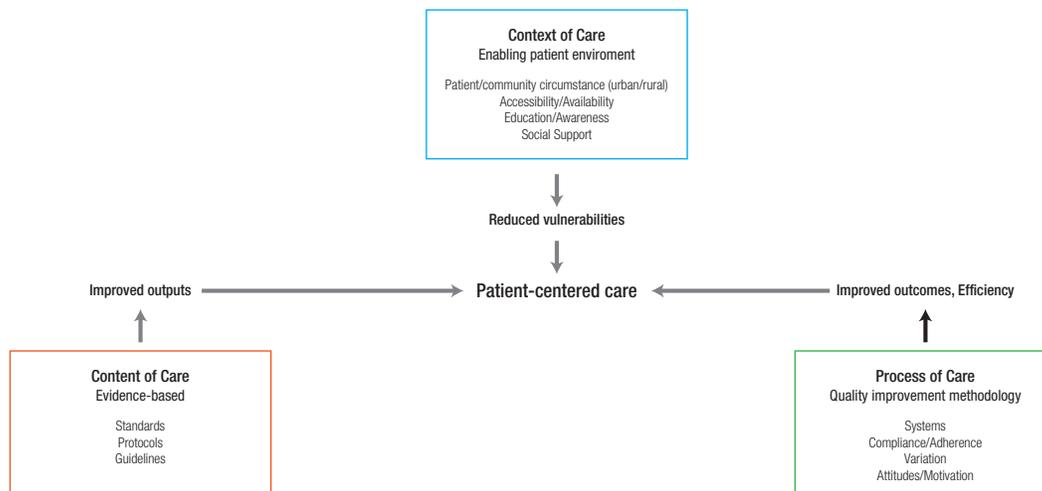
Improving the Quality of TB Services

- Working with the National Department of Health, provinces, districts, and other stakeholders to develop and implement strategic interventions that address the threats of TB, TB/HIV, and DR-TB;
- Jointly reviewing and update clinical and programmatic guidelines for TB, TB/HIV, and drug-resistant TB;
- Reviewing laboratory systems at all levels of intervention, by conducting needs assessments, mapping TB microscopy diagnostic centers countrywide, and addressing laboratory challenges;
- Continuing efforts to strengthen the six components of the expanded STOP TB strategy;
- Conducting operational research on programmatic aspects of the project jointly with institutional partners.

Increasing the Availability of TB Services

- Providing need-based training and mentoring for managers and health care staff at all levels of the system on basic TB management; TB/HIV, including the national 5 I's (intensified case finding, isoniazid preventive therapy, infection control, and integration and initiation of antiretroviral therapy, or ART); programmatic and clinical management of DR-TB;

Figure 2. Improvement Strategies for Expanding Quality TB Services



laboratory diagnosis of TB and DR-TB; and advocacy, communication, and social mobilization (ACSM).

- Introducing quality improvement methods to facilitate implementation of TB/HIV health care services from provincial to facility levels as per WHO recommendations and through innovative models.
- Assisting provinces, districts, and community partners in implementing the national strategy for decentralization of DR-TB management.
- Expanding the available DOTS system in high burdened rural, urban and peri-urban communities through community-based active case finding strategies.

Increasing Demand for TB Treatment

- Promoting and participating in the implementation of the national ACSM policy through national events (i.e., World AIDS and TB days, TV and radio public service announcements), local activities (e.g., community dialogues, Kick TB campaign), and distribution of materials (e.g., pamphlets, posters, lap desks with TB messages for school children).
- Disbursing grants to and building the capacity of nongovernmental and community/faith-based organizations to expand community-based TB, TB/HIV, and MDR-TB and XDR-TB TB management.

Improving Management of TB Support Systems

- Conducting data verification exercises and ongoing interaction with relevant counterparts.
- Jointly analyzing reports and linking them to facility case management.
- Strengthening facility-based TB information systems through regular data quality audits.
- Improving supportive supervision and surveillance through trainings.
- Strengthening linkages between health facilities and laboratory networks.

Testing and Scaling up New Approaches for Expanding DOTS Coverage

- Supporting the expansion of TB diagnostics, particularly rapid molecular testing methods (GeneXpert MTB/Rif® - GeneXpert).
- Identifying and supporting TB and TB/HIV public-private mix strategies and interventions.
- Disseminating the use of geographic information system technologies to map laboratories, health facilities, treatment supporters and households for better TB control including DR TB.

Key Achievements

DOTS

- From October 2009 - April 2014, TB Program South Africa has trained 17,755 health care workers on various components of TB management.
- In FY2013, the treatment success rate was 78.8% among new sputum smear positive TB cases.

Case Identification

- Through active case finding, TB Program South Africa is helping the National Department of Health more accurately quantify and address South Africa's TB burden. The total number of TB cases reported has declined from 42,887 in FY2010/Q1 to 35,294 in FY2014/Q1.

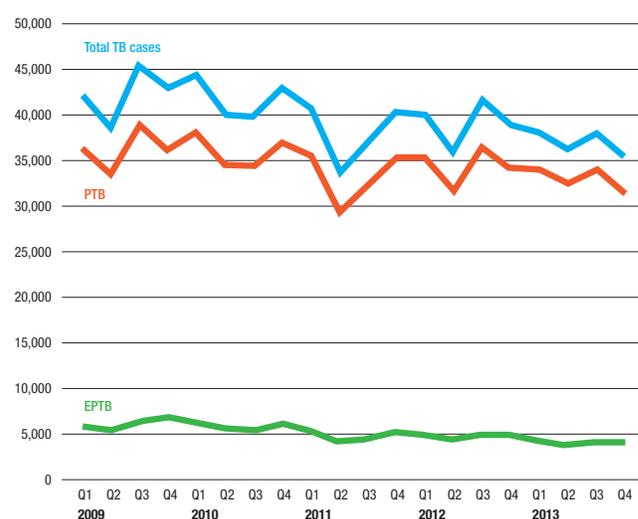
Development of TB Policies, Tools, and Training Materials

- TB Program South Africa has assisted the Department of Health in making a number of improvements to national TB policies and guidelines to improve access to and use of health services. These materials include: GeneXpert Training Manual, Clinical DR-Training Manual, a TB screening tool for use by traditional health practitioners, and a paediatric TB screening tool to identify TB in children and guidelines for the management of TB, HIV and STIs in correctional facilities.

Diagnostics

- TB Program South Africa has been instrumental in assisting the Department of Health in introducing GeneXpert as a first line TB diagnostic and achieving 100% coverage countrywide. The project is continuing

Figure 3. Total TB Cases in all Project-Supported Districts, Jan 2009 – Dec 2013



Data source: Electronic TB Register (ETR.Net)



Participants at the National TB Diagnostics Summit in November 2013

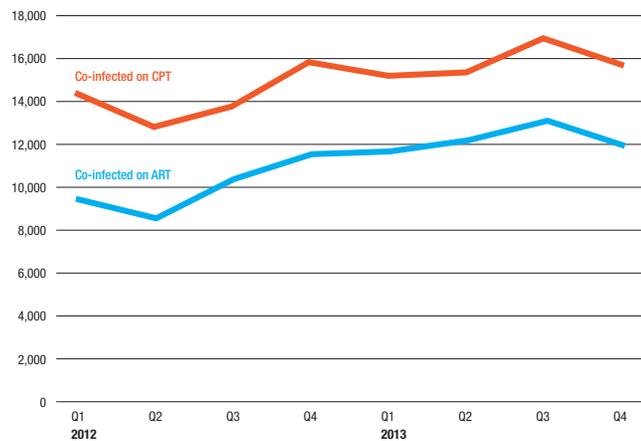
to monitor and improve implementation, including follow up of GeneXpert tested and diagnosed patients. From February 2012 - November 2013, 1122 health care workers were trained on GeneXpert.

- On November 18-19, 2013, the project facilitated a National TB Diagnostics Summit, which brought together key stakeholders to review and discuss the state of TB diagnostics in South Africa and to create a roadmap for improving laboratory diagnosis of TB throughout the country.

TB/HIV

- HIV counselling and testing uptake for TB patients reached 90% in FY14Q1, increasing from 83% in Q2/2012. Similar upward trends are seen for the provision of co-trimoxazole preventive therapy (CPT) to HIV-infected TB patients, as well as ART initiation.

Figure 4. HIV testing among TB patients; CPT and ART uptake for co-infected patients



Data source: Electronic TB Register (ETR.Net)

Public-Private Mix (PPM)

- TB Program South Africa is working to expand private sector participation in TB service delivery by engaging employers, private practitioners, and traditional healers in TB care and control.
- The project is actively engaging with the mining sector, particularly in Limpopo and Gauteng Provinces to facilitate community-based TB awareness and treatment services for mining communities and to assist in the development and expansion of TB workplace programs.

ACSM

- To heighten awareness on TB and TB/HIV, TB Program South Africa uses media as an integral part of its strategic communication framework. The project has developed public service announcements (PSAs) on cough etiquette and TB in children to encourage TB care and control. Broadcast in conjunction with World AIDS Day and World TB Day, these PSAs have reached millions.



TB in Children PSA

MDR-TB Management

- TB Program South Africa is supporting the decentralization of MDR/XDR TB patient care and support. In 2010, only 22 MDR-TB specialized hospitals were functional, resulting in long waiting periods for MDR-TB patients requiring treatment initiation. Following the roll-out of the decentralized MDR-TB management program, the number of MDR-TB sites more than doubled to 45 by 2013.

Small Grants

- Since 2009, TB Program South Africa has provided 85 grants to 69 non-governmental organizations (NGOs) in all nine provinces of South Africa. Additional NGOs are in the process of still being funded. Both the number of awards and the impact of grantee activities have expanded over time.
- From 2012 –2013, 228,923 community members were reached by TB/HIV messages through grantee activities. Grantees screened 129,345 individuals for TB, and 5,860 patients were registered under the DOT program and provided treatment support.
- So far in 2014, grantees have been making an impact in looking after MDR-TB and XDR-TB patients, addressing high loss-to-follow-up rates by tracing treatment interrupters, and scaling up awareness of TB in children.



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**TUBERCULOSIS
PROGRAM
SOUTH AFRICA**

THE USAID TB PROGRAM'S ROLE IN THE FIGHT AGAINST TB IN THE MINING SECTOR

TB is a major occupational disease for the mining sector. The South African mining industry is currently estimated to include more than 500,000 workers and in the gold mines of South Africa, the incidence of TB is estimated to be three times higher than the national average. Among the factors contributing to the higher rates of TB among miners include exposure to silica dust, the prevalences of HIV/AIDS, and the generally poor communal living conditions in the mine residences and in the settlements developing around mining sites. Two years of efforts by a trio of health ministers from South Africa, Swaziland and Lesotho has culminated in a pledge by Southern African heads of state to fight this epidemic in the South African mining industry. The Declaration on TB in the Mining Sector, a legal instrument, was signed by 15 heads of state at the Summit Meeting of the Southern African Development Community (SADC) in August 2012.

The declaration is a call to action for all stakeholders, including national, provincial, and district governments, mining companies, development partners, and civil society organizations to build new partnerships that yield collective impact in the fight against TB. Following the declaration, a new emphasis has emerged on identifying effective means for implementing the policy objectives in a practical way in collaboration with private and public multi-sector partners. University Research Co., LLC (URC) through the USAID TB Program South Africa has been working to provide robust technical assistance to the Department of Health (DOH), National TB Control Programme (NTCP) in response to the high prevalence of TB in the mining sector.

The USAID TB Program South Africa is using one of the World Health Organization (WHO) Stop TB strategies of engaging the business sector through a Public-Private Mix (PPM) approach. PPM promotes new approaches



Workers at Medupi Power Station in Waterberg District receive TB screening, HIV counseling and testing, and information on TB/HIV during a USAID TB Program South Africa-led active case finding campaign in May 2014.

Two years of efforts by a trio of health ministers from South Africa, Swaziland and Lesotho has culminated in a pledge by Southern African heads of state to fight the TB epidemic in the South African mining industry.

and partnerships for the delivery of TB care and control by engaging all health care providers, especially within the business sector.

The mining sector is supported through the principals of the Tripartite Stakeholders including the Department of Mineral Resources, DOH, the Department of Labour and the South African National Aids Council, and the Chamber of Mines. The USAID TB Program South Africa works with the DOH to provide technical support to the Tripartite Stakeholders by supporting DOH in ensuring

JUNE 2014

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Supporting the NTCP's strategy for increasing TB services for miners

Increasing TB and HIV awareness in peri-mine communities through social mobilization and awareness raising activities is a key objective of the NTCP's strategy for increasing TB services for miners. The USAID TB Program South Africa is working in Sekhukhune and Waterberg Districts, which are two of the six districts identified by the NTCP for immediate support due to the number of mines and the large number of perimining communities. As part of the TB Program's PPM interventions, the USAID TB Program applied its advocacy, communication and social mobilization (ACSM) approach to partner with the Provincial Department of Health, Waterberg District Health, Eskom Health Team and local partners working on HIV/AIDS programs to lead a one week active TB case finding campaign to Eskom's Medupi power station located in Lephalale in the Limpopo Province. The power station, when

completed, will be the fourth largest coal plant in the southern hemisphere, and will be the biggest dry-cooled power station in the world. At present there are 13,000 contract workers in Medupi.

The intended outcome of this one week campaign was to address access to TB prevention, diagnosis, and treatment in Waterberg District, which has a concentration of mines. The activities in Medupi included TB symptomatic screening, HIV testing and counselling, providing of information, education and communication (IEC) materials. Through this campaign, 3324 mine employees received TB screening, 422 sputum samples were collected, and 4 TB cases were diagnosed and referred for treatment. In addition, 1834 employees were tested for HIV, and 134 individuals testing HIV positive were referred for treatment.

that the TB services provided in the mines conform to international standards for TB care and the NTCP guidelines.

The USAID TB Program's support for improving TB services within the mining community and strengthening TB management in the mining companies. The technical assistance provided by the TB Program focuses on developing lasting multi-sectoral partnerships geared around the following activities:

- Advocacy and consensus building among mine operators, mine health services, mine laborer's representatives, and local ministry departments on practical steps to implement the objectives within the declaration

- Development of service linkages between TB and other health and social support agencies working with miners and mining communities
- Assistance to develop and expand TB workplace programs in key mines
- Identification of priority areas for further operational research and policy development

The USAID TB Project's approach has emphasized developing programs and TB service linkages within mines in Limpopo and Gauteng provinces, and has facilitated coordination with local community based TB awareness and treatment services able to work with the mining communities in Limpopo, Gauteng, and North West provinces.



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TUBERCULOSIS
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Strengthening Systems and Empowering Communities to **Fight TB**

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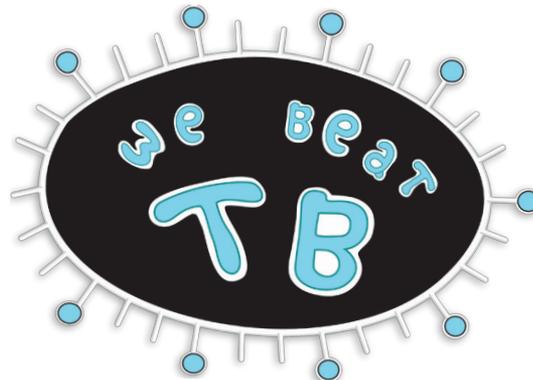


1 Background

Globally, more than 9 million people become ill with tuberculosis (TB) each year, and more than 1.5 million die of it. South Africa is classified by the World Health Organization as a high-burden TB, HIV and multi-drug resistant TB (MDR-TB) country. It has the world's third highest TB burden, with nearly half a million cases each year. Two-thirds (65%) of tested TB patients are found to be HIV positive, and South Africa has some of the world's highest incidence of MDR-TB and extremely drug-resistant TB (XDR-TB).

2 Introduction to TB Program South Africa

The United States Agency for International Development (USAID) funds TB Program South Africa, a 5-year project (2009–2014) implemented by University Research Co., LLC (URC). The project builds on the successes of the USAID-funded TASC II TB Project (2004–2009), also implemented by URC. The project works closely with the National Department of Health (DOH) and other stakeholders to support South Africa's health sector reform through the expansion of quality and accessible TB services. It also works with provincial and district health departments in the development, implementation and evaluation of needs-based strategies to combat TB, TB/HIV and drug-resistant TB and to promote best infection control practices. The project is also helping communities create appropriate advocacy, social mobilization and health systems strengthening and innovate service delivery models for the rapid expansion of Directly Observed Treatment Short course (DOTS) to control TB.



“...helping communities create appropriate advocacy, social mobilization, and health systems strengthening and innovate service delivery models for the rapid expansion of DOTS for the control of TB.”

3 Introduction to the Small Grants Program

As a component of the project, URC supports community-based organizations to increase the demand for and availability of TB, TB/HIV and MDR-TB services in partnership with the Department of Health, South African National TB Control Programme, local agencies and district health managers. Their work also includes the integration of appropriate advocacy, communication and social mobilization (ACSM) that extend to community dialogues and the use of mass media to help people recognize the symptoms of TB and HIV, test early, adhere to treatment and take infection prevention and control measures.

Since 2009, the project has provided 85 grants to 67 non-governmental organizations (NGOs) in all nine provinces in South Africa. The project is currently on its 4th wave of funding, and more grantees are being added all the time. Grants are initially awarded for a 12-month period.

Wave 1 (2009–2010): 16 grants

Wave 2 (2010–2012): 17 grants

Wave 4 (2012–2013): 18 grants

Wave 5 (2013–2014): 34 grants

The NGOs have carried out a range of activities in their communities, including:

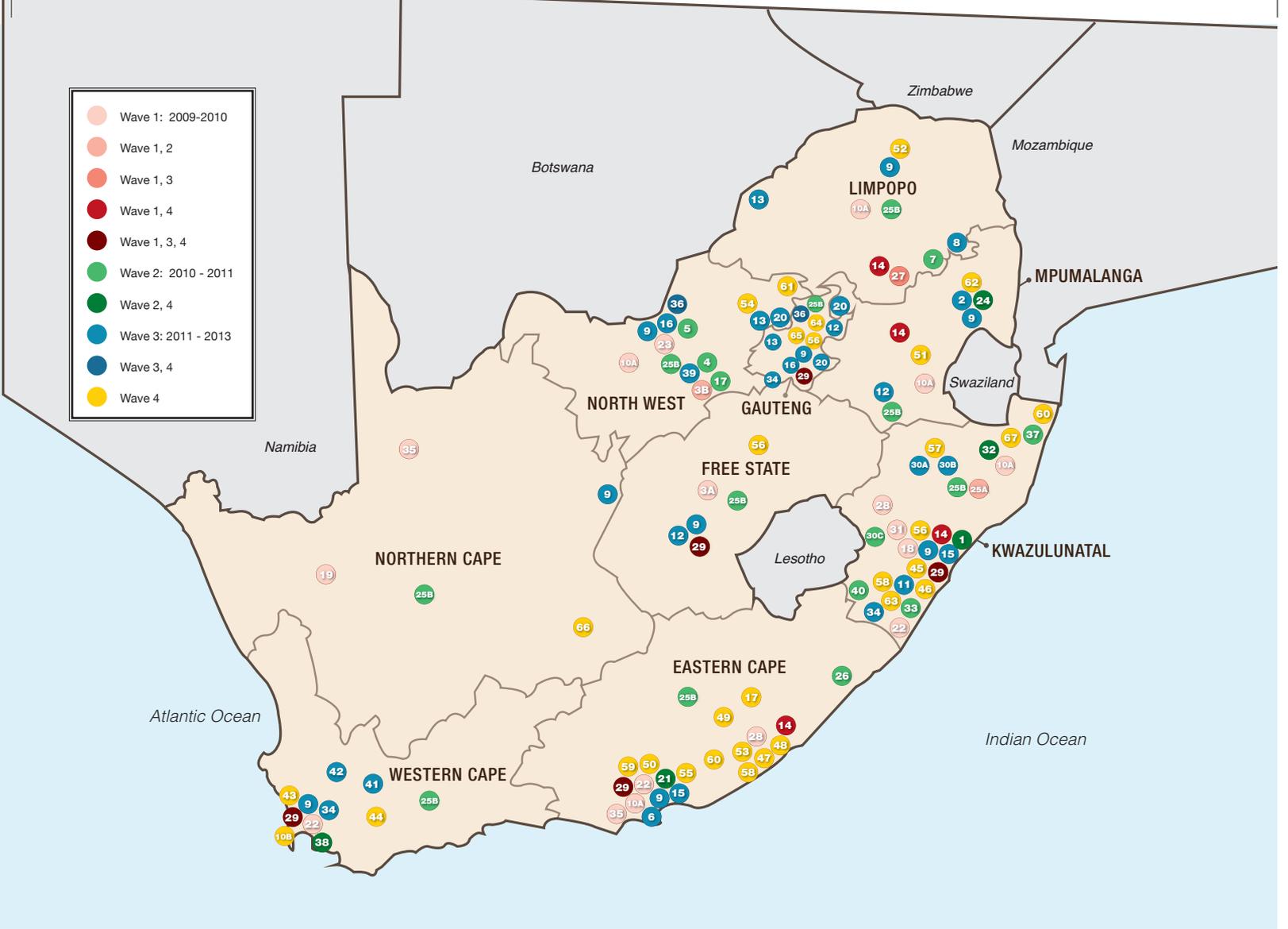
- Identifying presumptive TB cases through active case finding and referring them to health facilities for screening, diagnostics and treatment;
- Tracing TB patients lost to follow up and household contacts;
- Creating community support to help patients stay on treatment through DOT;
- Reducing stigma and encouraging people to seek testing and treatment early;
- Strengthening local advocacy, communication and social mobilization on TB and HIV;
- Strengthening services for people co-infected with TB/HIV;
- Increasing the involvement of vulnerable populations and groups—such as youth, workers and prisoners—often left out of traditional TB control strategies;
- Promoting public-private partnerships for TB.

Grants are given to local community- and faith-based organizations, as well as larger NGOs with a proven track record or interest in the area of TB and HIV management. Through the grants program, these organizations have been able to provide TB education, screening and treatment services to formerly unreached or underserved populations.

Many grantees have pioneered innovative models of service delivery and community outreach, such as injection teams for MDR-TB patients and door-to-door TB and HIV screening, which can serve as models for other organizations working to combat TB and TB/HIV throughout the country, particularly among vulnerable and hard-to-reach populations.



Since 2009, the program has provided 85 grants to 67 NGOs in all nine provinces of South Africa.



Name of Grantees

1	Amakhumbuzo Community Development and Health Care Center	23	Perinatal HIV Research Unit	45	Durban Chamber Foundation
2	Arthur Seat Home Based Care	24	Phaphamani Home Based Care	46	Durban University of Technology
3A	Aurum Institute 3-I's	25A	Philanjalo ICF	47	Eastern Cape Gender and Development Program
3B	Aurum Institute DCF	25B	Philanjalo (MDR)	48	Gwebindlala HIV/AIDS Organization
4	Baptist Body or Christ Ministry Orphan and HIV/AIDS Care	26	Quakeni Empowerment Centre	49	HIV/AIDS Prevention Group
5	Bright Future HBC	27	Reach for Life	50	Human Sciences Research Council (HSRC)
6	Catholic Diocese of PE	28	SA Catholic Bishops Conference	51	Isiphephelo Home Based Care Centre
7	Centre for Positive Care	29	SACTWU	52	Lehlabile Development Project
8	Community Responsiveness Program	30A	SAMRC/GenExpert	53	Letsema Circle Trust
9	DENOSA	30B	SAMRC/MDR	54	Maboloka HIV/AIDS Awareness Organization
10A	Desmond Tutu TB Centre (DTTC)	30C	SAMRC/OVSA	55	Mfesane
10B	Desmond Tutu TB Centre (DTTC) - Kid Care	31	Siyaphila Youth Support Services	56	South African Business Coalition on HIV and AIDS (SABCOHA)
11	Eyaluth Development Unit	32	Siyathuthuka Women's Group	57	Siloah Lutheran Hospital
12	Footballers for Life	33	Siyazama Youth Development Centre	58	Siyakhana Health Trust
13	Get Down Productions	34	Sustainable Livelihoods Foundation	59	St. Francis Hospice
14	Humana People to People	35	TB HIV Care Association	60	TEBA Development
15	Impangle Projects	36	Thabo Mwale TB Foundation	61	Winterveldt HIV/AIDS Project
16	Killer Disease Targeter	37	Tholulwazi Usivikele	62	Wisani Community Project
17	Mamosa Home Based Care	38	Touching Nations	63	Bhambayi Settlement Project
18	Medical Care Development International	39	Tshepang Caregivers Project	64	University of Pretoria
19	Namakwa Development Foundation	40	Turn Table Trust	65	Rophe Community Services
20	Nkathalo Wellness Program	41	Wagon of Hope	66	Ethembeni (Place of Hope) Community Centre
21	Octavovect Association	42	Witzenberg Community Care	67	Mpilonhle
22	Operation Hunger	43	At Heart		
		44	Breede River Hospice		

4 The TB Program South Africa Small Grants Capacity Building Model

While the primary goal of the small grants program is to provide TB services to people, the program has also acted as a capacity-building mechanism for local NGOs, helping them build their technical, financial and management systems. It also helps them establish and cultivate collaborative partnerships with the DOH to sustain and expand the provision of services after the grant ends. TB Program South Africa hosts an orientation workshop for incoming grantees and conducts site visits to monitor progress and address challenges. Over the course of the grant cycle, the project trains grantees on topics such as administrative and financial management, monitoring and evaluation, and TB diagnosis and treatment. The project also developed a series of on-line training courses, where grantees can go to refresh their basic understanding of TB and get help managing their TB/HIV projects.

NGO Technical and Monitoring Responsibilities v3 (01:53 / 05:52) | ATTACHMENTS

USAID TUBERCULOSIS PROGRAM SOUTH AFRICA

Outline Thumbnails Notes Search

1. NGO Technical and Monitoring Responsibilities
2. Two Lessons
3. Lesson One Overview of Technical Activity Framework
 4. Introduction
 5. Activity Reporting Requirements
 6. Knowledge Check 1 Overview of technical
 7. Instructions for the Knowledge Check
 8. Knowledge Ck 1
 9. Knowledge Check is Complete
10. Lesson Two Workplans, Monitoring and Evaluation
 11. How to Write the Finalized Workplan
 12. How to Write the Finalized Workplan (continued)
 13. How to Write the Finalized Workplan (continued)
 14. Template for Workplan
 15. How Do I Write Workplan Objectives?
 16. How Do I Write Workplan Objectives? (continued)
 17. Examples of S.M.A.R.T. Objectives
 18. Workplan Example
 19. Purposes of Monitoring and Evaluation
 20. Purposes of Monitoring and Evaluation (continued)
 21. What Is an Indicator?
 22. Why Are Indicators Important?
 23. Indicators Are Not
 24. Types of Indicators
 25. How to Develop the Finalized Indicator List

Workplan Example

Activities	Time lines												Benchmarks	Responsible person
	O	N	D	J	F	M	A	M	J	J	A	S		
Objective 1: To increase case detection of TB patients in project areas by 06/2012														
1. Screen TB suspects using symptomatic screening	x	x	x	x	x	x	x	x	x	x	x	x	1000 TB suspects screened	Nurse
2. Refer TB suspects to clinic for sputum smear	x	x	x	x	x	x	x	x	x	x	x	x	200 TB suspects referred	Nurse
Objective 2: To increase education of community members on TB/HIV in project areas by 06/2012														
1. Conduct training of caregivers	x												1 training conducted	Nurses
2. Conduct door-to-door campaigns		x		x			x					x	4 door-to-door campaigns conducted	Nurses and caregivers

articulate POWERED PRESENTATION | SLIDE 18 OF 49 | CLICK NEXT TO ADVANCE | 00:06 / 00:06

Sample slide from TB Program South Africa Online Training Course



5 Grantee Spotlights

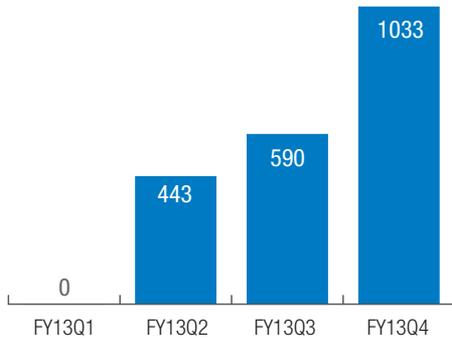
5.1 Footballers for Life: Addressing TB among Prisoners

Prisoners and former prisoners worldwide are at a higher risk of TB than the general population. Overcrowding, poor ventilation and nutrition, limited health services, and lack of proper referral and follow-up upon release can fuel TB transmission, putting other prisoners, prison staff and families and communities of released prisoners at risk.

Footballers for Life (F4L) is committed to addressing the challenge of TB in prisons through the motivating and engaging medium of football (a.k.a. "soccer"). F4L uses retired professional football players who are trained in life skills and wellness to work with communities to share their knowledge and experience. The players, known as Wellness Coaches, help create and promote sustainable behavior changes that help prevent TB and HIV. In a country such as South Africa where "football rules," these retired players have a unique ability to influence and impact behavior change that other health promotion workers lack.

For the past four years, F4L has worked in prisons in Gauteng and Free State Provinces, promoting healthy behaviors among inmate populations. In 2013, F4L received funding through the USAID

F4L: Number of suspects screened for TB in 2013



TB Program South Africa small grants program to conduct TB/HIV and life skills education sessions and TB/HIV advocacy events at correctional facilities, improve TB case detection for inmates and establish functional and effective TB/HIV support groups in correctional facilities.

With training and technical support from the USAID TB Program South Africa, F4L was able to:

- Reached 4963 inmates and 2282 Department of Correctional Services Officials (wardens) with TB and HIV awareness campaign messages.
- Trained 1561 inmate peer educators on life skills. These graduated “Assistant Coaches” are now able to engage fellow inmates on TB, HIV/AIDS, and other health issues.

- Established 10 inmate-led DOT groups, which assisted in screening 2066 inmates, identifying 498 patients with presumptive TB, and referring 393 TB patients for HIV counseling and testing.
- Assisted in the development of integrated TB and HIV/AIDS guidelines for the Department of Correctional Services.

For more information, please visit:
www.footballers4life.co.za.

5.2 Nkathalo Wellness: Addressing TB among Mining Communities

Numbering more than 500,000, mine workers in South Africa have some of the world’s highest rates of TB. Recent research estimates that 3% to 7% of miners are becoming ill with the disease each year. Most South African miners are migrants from neighboring countries (Lesotho, Mozambique, and Swaziland), causing a huge risk of cross-border spread: Each migrant worker who returns home with TB spreads the disease to an estimated 10–15 people in his community.¹ Mine workers are exposed to a multitude of factors that compound their risk of TB infection: their working conditions (prolonged exposure to silica dust, poor ventilation, exposure to occupational

¹ STOP TB Partnership Declaration on Tuberculosis in the Mining Sector.

Success Story: Door-to-Door Community Drives

To increase TB and MDR-TB case detection in the communities of Bapong, Modderspruit, Wonderkop, and Majakaneng, Nkathalo conducted 12 door-to-door community drives. During this drives, volunteers from neighboring communities joined Nkathalo wellness teams to provide TB and HIV awareness information. As a result, 8087 people were screened for TB, 5711 sputum smears were collected and sent to the lab for testing, and 150 cases of TB were diagnosed.

injuries); socio-economic factors (migrant status, cramped and unsanitary living conditions, lack of knowledge of the health system and their rights to access to care); and their disease burden (co-exposure to HIV, silicosis, or both).

In North West Province, Nkathalo Wellness is working to combat TB among four communities of miners (Wonderkop, Majakaneng, Bapong and Modderspruit) who work in the Lonmin Platinum Mines. Nkathalo is filling a critical gap in the availability of services for mining communities by making screening and treatment more available for miners' families.

Many mine employees reside in neighboring communities, so the risk of spreading TB was high.

In 2013, Nkathalo, with help from USAID TB Program South Africa, worked to bridge this gap by expanding services to communities of mine workers and increasing active contact tracing. Specifically, Nkathalo worked to: 1) intensify TB case finding and reporting; 2) improve TB treatment compliance; 3) increase uptake of isoniazid preventive therapy (IPT) to reduce TB transmission among people living with HIV; and 4) expanding HIV counseling and testing in the community.

For more information, please visit:
www.nkathalo.co.za.

5.3 Mpilonhle: Addressing TB in Schools

The Umkhanyakude District is not only the poorest and most rural district in KwaZulu Natal Province and in South Africa overall, it also has one of the highest HIV infection rates in the world. Adolescents here have almost a 50% chance of contracting HIV during their lifetime and eventually dying from the disease: 15% of female high school students are infected with HIV by the time they graduate, and 25% will become pregnant.² Along with HIV come very high rates of TB infection, including MDR-TB.

Mpilonhle has been operating a school health program since 2007: It uses schools as a base for providing services to youth and the community. This program cooperates with the South African Departments of Health, Education, and Social Development, and Mpilonhle relies on government teams where possible to deliver services directly.

Mpilonhle received a grant in November 2013 from the USAID TB Program South Africa to expand its school health program to another 10 secondary schools and 10 higher primary schools.

To work with the schools, Mpilonhle deploys mobile health units comprising a pair of identical but mirrored trailers with fold-out screens and an

² <http://www.mpilonhle.org/hiv-and-disease>



With support from the TB program South Africa in 2014, Mpilonhle will reach:

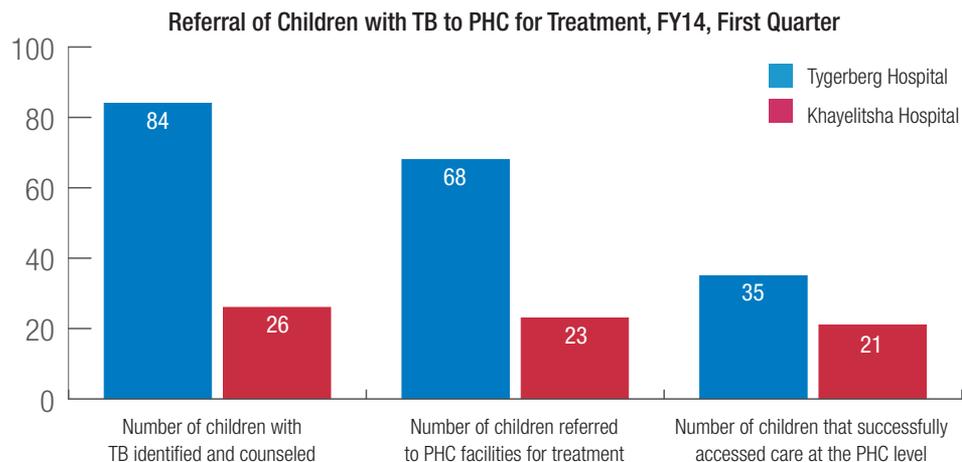
- 7,000** learners screened for TB
- 300-500** learners screened for TB
- 700** students referred to clinics for follow-up and treatment
- 10,000** learners reached through health education sessions
- 20,000** community members reached through take-home TB informational materials
- 20** school-based community information sessions

awning that forms a “teaching space” between the parked trailers. Each trailer has two counseling rooms and three storage lockers. The project places eight mobile units at a time at each school site for 1–2 weeks. Each mobile unit is staffed by eight counselors: seven to perform health screenings and one to conduct TB and health education sessions. A professional nurse is on-site to see anyone who screens positive for TB or HIV and coordinate their care at the nearest clinic.

For more information, please visit:
<http://www.mpilonhle.org>.

5.4 Desmond Tutu TB Centre: Addressing TB in Children

Approximately 15–20% of TB cases in South Africa occur among children.³ Of the country’s 390,069 confirmed TB cases in 2011, 47,571 (12%) were among children under 15, making TB among the top five underlying causes of morbidity and mortality in children there. Identifying and diagnosing TB and MDR-TB remains difficult in children, whose symptoms may be non-specific. Furthermore, routine diagnostic tests for TB are not child friendly: It is difficult to collect sputum specimens from infants and young children. The lab tests that are used to find TB in sputum are less likely to generate a positive result in children (as children are more likely to have TB disease caused by a smaller number of bacteria).



To combat TB in children, the Desmond Tutu TB Centre at Stellenbosch University, with support from USAID TB Program South Africa, received a grant in 2013 to implement and assess the operational feasibility and usefulness of a package of health systems strengthening interventions called **Kid-Care** to improve routine pediatric TB care in the Khayelitsha sub-district, an impoverished community in Cape Town. The components of *Kid-Care* include strengthening 1) TB prevention (using multiple strategies to increase awareness, uptake and adherence to IPT for child TB contacts, 2) provider knowledge (increase the knowledge of pediatric TB among health care workers by different training models) and 3) TB

care (ensuring continuity of care between hospital and community clinics for children with hospital-diagnosed TB).

As of December 31, 2013, the centre had given 64 facility-based health talks, reaching 2,498 patients with messages on preventing TB in children. Fourteen health care workers had completed additional training on the diagnosis and management of pediatric TB: nine through a traditional didactic model and five via a self-learning module. To improve TB care among children diagnosed with TB, the centre worked with

³ <http://www.hindawi.com/journals/jtm/2012/818219/#B6>



Tygerberg and Khayelitsha Hospitals to provide inpatient counselling and then refer these children to receive outpatient care at the primary health care (PHC) level.

For more information, please visit:
www.sun.ac.za/tb.

5.5 Philanjalo:

Addressing MDR-TB through Decentralized Community Management Nationwide

South Africa has the fifth highest burden of MDR-TB globally. The number of MDR-TB cases has been increasing since 2004, with 15,419 confirmed cases in 2012. Philanjalo, an NGO based in the Tugela Ferry region of Kwa-Zulu Natal, was among the first to recognize the emerging MDR-TB epidemic. In 2007, with support from various

partners and the DOH, Philanjalo established one of Africa's first community-based MDR-TB management programs. This care model helps patients complete their treatment and reduce overcrowding in hospitals. It involves establishing mobile teams of nurses who conduct daily home visits to give second-line TB drugs by injection to patients and observe doses of oral TB medications and antiretrovirals (ARVs).

From March 2011–April 2013, Philanjalo used a grant from TB Program South Africa to begin scaling-up its model in eight provinces (Eastern Cape, Free State, Gauteng, KwaZulu Natal, Limpopo, Mpumalanga, Northern Cape and North West). Philanjalo provided targeted support to the 14 districts to assess their capacity to roll out the community-based MDR-TB management program. This involved conducting situational analyses of all sites by looking at what resources, infrastructure and TB services were in place and what could be done to improve them.

Philanjalo facilitated 14 provincial and 22 district advocacy and capacity-building workshops on comprehensive community-based MDR-TB management, training 539 provincial, district and sub-district managers. Philanjalo also worked to improve the skills of nurses, TB assistants and other health workers to carry out community-based management of MDR-TB. Philanjalo developed training material and tools and helped to train 634 health workers.

Brainstorming sessions during a situational analysis survey in Ehlanzeni District, Mpumalanga Province.



Participants attend an MDR-TB training workshop at Manguzi Hospital, uMkhanyakude.



After two years of support, districts were in different stages of decentralization, but progress was seen throughout the country. More than 2,000 MDR-TB patients were receiving follow-up in the community during injection and continuation phases, with uThungulu and Zululand districts in KwaZulu Natal recording the largest number of clients followed and injection team members trained.

For more information, please visit:
<http://www.philanjalo.org.za/>.

5.6 Octavovect Association: Addressing Loss to Follow-up

Getting TB patients to complete their full course of treatment is critical to both ensuring their cure and preventing the spread of MDR-TB. However, loss to follow-up can be common, particularly among mobile populations and those without sufficient social support to endure the lengthy treatment regimens. Since 2005, the Octavovect Association has been working in Nelson Mandela Bay Municipality in Eastern Cape to ensure follow-up for children on ARVs and TB patients so that they remain on treatment. With support from TB Program South Africa, Octavovect partnered with 18 primary health care facilities in three sub-districts to support their TB outreach efforts, providing DOT support as well tracing contacts and finding those lost to follow-up.

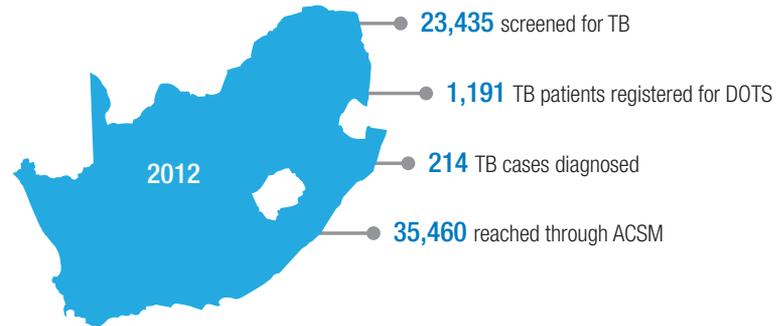
Octavovect developed a TB defaulter register, where their DOT supporters recorded a client's treatment history, whether the client relocated to another clinic, was lost to follow-up, died or went to prison. It also recorded the type of TB they had (normal, XDR, MDR, co-infection) and whether they were on ARVs. The contact register included information on each client's contacts: relationship, age, gender, number of TB symptoms, sputum collected and method of diagnosis. The daily patient treatment register provided information on diagnosis, treatment start dates, sputum results, list of drugs and presence of a home vegetable garden. Octavovect was able to use these data to help the PHC clinics update their own registers, relieving overburdened clinic nurses.

Through the USAID TB Program South Africa grant, from November 2011–November 2012:

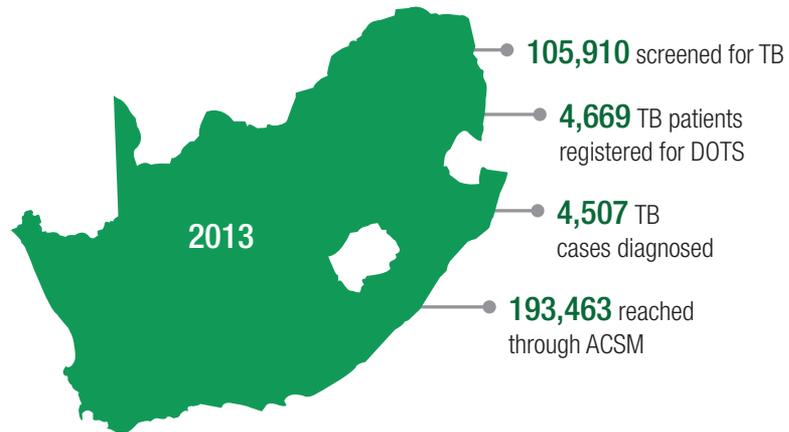
- 7,960 clients who had been lost to follow-up were traced and put back on treatment (2,352 of these were primary loss-to-follow-up cases).
- Contacts of 2,174 index patients were traced, resulting in the diagnosis of TB in 63 children.

“ Octavovect partnered with 18 primary health care facilities in three sub-districts to support their TB outreach efforts...

USAID TB Program South Africa Impact Over Time



To date, USAID TB Program South Africa has awarded 85 grants to 69 NGOs in all nine provinces of South Africa. Both the number of awards and the impact of grantee activities have expanded over time. So far in 2014, grantees are hard at work improving care for MDR TB and XDR TB patients, addressing high loss-to-follow-up rates by tracing treatment interrupters, and scaling up awareness of TB in children.



For more information, please visit: <http://tbsouthafrica.org> or <http://www.unc-chs.com/>.

MAY 2014

www.tbsouthafrica.org

