





Progress Report

October 2010 – September 2013

Building Global Capacity for Diagnostic Testing of Tuberculosis, Malaria, and HIV through Laboratory Strengthening and Integration of Services under the President's Emergency Plan for AIDS Relief (PEPFAR)

FIND
foundation
for innovative new diagnostics

Contents

Our vision is of a world where everyone has equitable and timely access to high quality and affordable diagnosis.

Our mission is to drive the development and early implementation of innovative diagnostic tests that have a high impact on patient care and disease control in low-resource settings.

Foreword

In 2013, FIND and partners mark ten years of developing new diagnostic tools and supporting their implementation in resource-constrained settings. Significant progress has been made during the past decade, and FIND is proud of the contribution it has made alongside its global partners. Through FIND's TB programme alone, six new technologies have been developed and introduced for diagnosis of TB and rapid detection of drug resistance. Recent estimates suggest that scale up of these new TB diagnostic tools may save 300 000 lives per year. FIND's malaria, sleeping sickness and neglected diseases programmes have likewise notable achievements, including a multi-partner malaria programme focused on quality assurance of malaria rapid diagnostic tests, development of an improved and safe blood transfer device, and development of the first ever rapid test for sleeping sickness.

Despite progress, implementing and integrating new diagnostic technologies can only be successful in a well-functioning laboratory system. FIND recognizes that laboratory services in resource-limited settings are known to face many challenges. To address this need, FIND's delivery programme has been guiding countries in strengthening laboratory capacity. With the aim of accelerating the rational adoption of new tools, ensuring increased and improved patient access to diagnosis and treatment using the new technologies, FIND works through its extensive network of laboratory and health systems professionals to deliver country level support through long-term in-country engagements. Across the globe, FIND has a team of over 60 professionals working with more than 200 partners in 61 countries. FIND's work in laboratory strengthening is guided by promoting local ownership, working in partnership under the leadership of the Ministry of Health, and developing locally appropriate solutions based on international best practices.

In September 2010, the Centers for Disease Control and Prevention (CDC) awarded FIND a five year cooperative agreement to build global capacity for diagnostic testing of tuberculosis (TB), malaria and HIV through laboratory strengthening and integration of services under the President's Emergency Plan for AIDS Relief (PEPFAR II). In this report we present the activities conducted to date under this Cooperative Agreement within countries in Africa, Asia and the Caribbean. This report documents key achievements of the first three years of the programme (October 2010 – September 2013). We look forward to building on the gains made in the first three years and to expanding our scope of work to include the Rapid HIV testing Quality Improvement Initiative in the remaining two years of the programme.

C Boehme

Dr. Catharina Boehme
CEO, FIND

Background

HIV/AIDS, tuberculosis (TB) and malaria remain the leading causes of morbidity and mortality in the developing world, accounting for about 5 million deaths every year. It is estimated that globally, 34 million people were living with HIV in 2011, of which 3.3 million were children. In 2011, 2.5 million people were newly infected and 1.7 million people died of AIDS. There was an estimated 8.7 million new cases of TB in 2011 (13% co-infected with HIV) and 1.4 million TB deaths. An estimated 1 million deaths occurred among HIV-negative individuals and 430 000 among HIV-positive people. Multidrug-resistant TB remains a threat to successful TB control, with an increasing number of cases being notified in the 27 high MDR-TB burden countries, and almost 60 000 cases notified in 2011. The actual number of MDR-TB cases is estimated by WHO to be perhaps five times this number[1]. For malaria, there was an estimated 219 million cases and 660 000 deaths in 2010.

"… implementing and integrating new diagnostic technologies can only be successful in a well-functioning laboratory system."

Despite encouraging progress made towards Millennium Development Goal targets, the burden of these diseases remains extremely high. Furthermore, the African region lags behind other regions in its progress towards the MDG targets, despite the overall global achievements.

Since 2010, major advances have been made in rolling out the implementation of Xpert MTB/RIF, a rapid molecular test for TB and drug resistance. More than 4 million test cartridges have been procured and testing has been implemented in 95 of 145 countries eligible for FIND-negotiated pricing[2]. However, drug susceptibility testing coverage remains low overall and scale up of testing as well as ensuring linkage to appropriate treatment remain challenging in many settings.

Well functioning laboratory services are critical in improving the diagnosis and management of the TB and HIV epidemics. Laboratory systems face many challenges in resource-limited settings. In recent years, there has been an increased focus on improving the quality of laboratory services. Donors such as PEPFAR, the Global Fund, and other funding and technical agencies have increased resources dedicated to strengthening health systems. This drive has focused to implementation of improved diagnostic technologies aimed at improved monitoring of the status of HIV-infected patients, diagnosis of TB and drug resistance, and parasite-based diagnosis of malaria.

The Maputo Declaration of 2008 recognized the importance of an integrated laboratory network to meet these diagnostic needs and calls on governments to develop national laboratory policies and strategic plans to serve as the foundation for an integrated laboratory network. The Global Plan to Stop TB 2011 – 2015 further emphasizes the importance of TB laboratory capacity strengthening, and includes an ambitious target of more than 50% of national reference laboratories implementing a quality management system (QMS) according to international standards by 2015.

"… substantial support for laboratory strengthening has had fundamentally positive effects for the response to HIV and has been leveraged to improve the functioning of entire health systems."

[Institute of Medicine, 2013][3]

Programme overview

The FIND-CDC Cooperative Agreement Programme, Building Global Capacity for Diagnostic Testing of Tuberculosis, Malaria, and HIV through Laboratory Strengthening and Integration of Services, falls under the President's Emergency Plan for AIDS Relief (PEPFAR II) programme, which called for immediate, comprehensive and evidence-based action to turn the tide of global HIV/AIDS. The 2008 PEPFAR Reauthorization Bill (2009 to 2013) focused on transitioning PEPFAR from an emergency approach to HIV/AIDS to a focus on sustainability, including health system strengthening and partnership building[4], and it is within this context that this project operates. As highlighted in the PEPFAR Blueprint[5], one of the key actions required to impact the HIV/AIDS epidemic is expanding access to interventions to improve the early diagnosis and treatment of TB among people living with HIV.

FIND is contributing to the development of strong and well-functioning laboratories able to offer quality services, and increasing access to new diagnostic tests.

1. Guide countries in developing national plans for new diagnostic tools
2. Accompany countries through early implementation of new diagnostic tools
3. Develop comprehensive approaches to improve quality

FIND's work is guided by the following principles:

Promote local ownership and leadership by Ministries of Health

Collaborate with local, regional and international implementing and funding partners in the best interest of the countries

Create unique and comprehensive solutions based on the country context and anchored in international standards and best practices

Share field-tested tools and best practices

Programme areas

Guide countries in developing national plans for new diagnostic tools

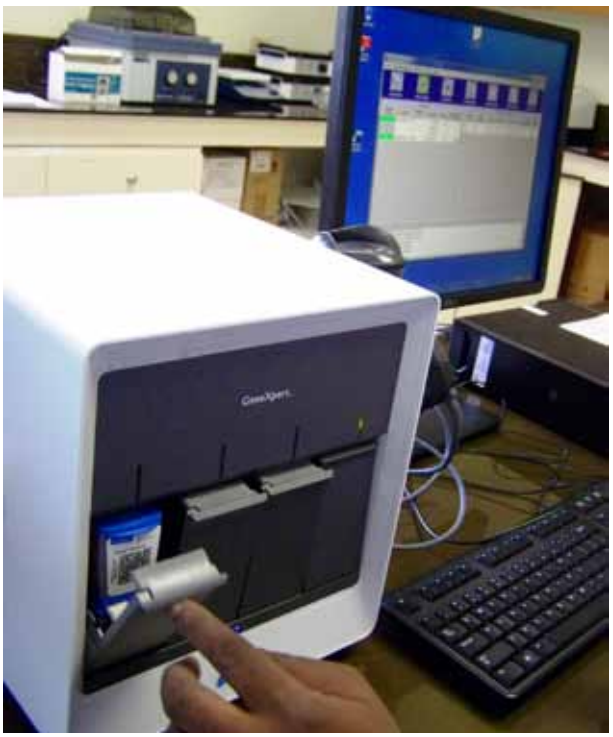
What We Do

1. Provide guidance and advice to Ministries of Health (MOH) in developing evidence-based implementation plans for new TB diagnostics, in alignment with national laboratory and disease-specific strategic plans
2. Assist countries in the development of their national diagnostic algorithms based on WHO recommendations
3. Conduct and mentor personnel in the analysis of epidemiological data to inform algorithm and phased roll out plans
4. Work with local and international implementing and funding partners to achieve a harmonized approach in support of the national laboratory strategy
5. Assess the readiness of laboratories for new diagnostics implementation

Why We Do It

It is critical that new diagnostics implementation plans are rooted within the context of national laboratory and disease-specific strategic plans. FIND assists countries to develop implementation plans to integrate new tools and approaches into their existing laboratory network based on WHO and other international guidelines and best practices.

Accompany countries through early implementation of new diagnostic tools



What We Do

1. Develop and customize training materials, practical tools and job aids to support deployment of new technologies
2. Train country staff and conduct user proficiency testing
3. Evaluate programme during early implementation
4. Mentor and support local programme coordinators, in-country trainers, and advanced users

Why We Do It

Implementation of new technologies requires substantial changes in laboratory, clinical and programmatic aspects. A coordinated approach to addressing these issues will enable effective introduction and maximum patient impact to be achieved. "Learning by doing" using long-term in-country mentorship is the most effective way to build sustainable capacity beyond the life of this project.

Develop comprehensive approaches to improve quality

1. Quality Management Systems

What We Do

1. Train country personnel using the Strengthening Laboratory Management Towards Accreditation (SLMTA) approach to facilitate and advance laboratories progress towards national or international laboratory accreditation
2. Develop and implement TB-specific Quality Management Systems training
3. Mentor country personnel and conduct follow-up visits to ensure and verify implementation of quality improvements and progress towards accreditation

Why We Do It

Working towards laboratory accreditation is a challenging process requiring long-term commitment and support. FIND is implementing the SLMTA programme (developed by CDC and partners), a structured and highly task-based programme which incorporates training workshops, improvement projects and follow-up visits - see "Changing the culture of laboratory quality. Implementing the SLMTA Programme (FOGELA) in Dominican Republic." FIND has also developed a TB-specific programme based on SLMTA to harness the advantages of this innovative training approach incorporating technical guidance and best practices for TB - see "Aligning for Accreditation. Tailoring Laboratory Quality Management Systems Strengthening to TB Laboratories."

2. Quality Assurance

What We Do

Quality assurance (QA) comprises many activities and processes aimed at ensuring the quality of diagnostic test results. This includes use of quality controls, adopting routine data collection and monitoring and evaluating trends in performance indicators, as well as external quality assurance (EQA). FIND develops and supports the distribution of EQA samples, develops and pilots field-tested best practices in quality assurance, develops tools and provides training and support for implementation of data management solutions.

Why We Do It

QA is a fundamental component in ensuring the quality of laboratory testing. However, in many settings despite well established international guidelines, QA is poorly and inconsistently implemented. Challenges include organization of laboratory site visits, feedback of recommendations to laboratories, as well as data management associated with these tasks. We use innovative implementation models, develop simple field-tested guidance and tools and electronic data management systems to improve implementation of QA programmes.

Programme in a nutshell

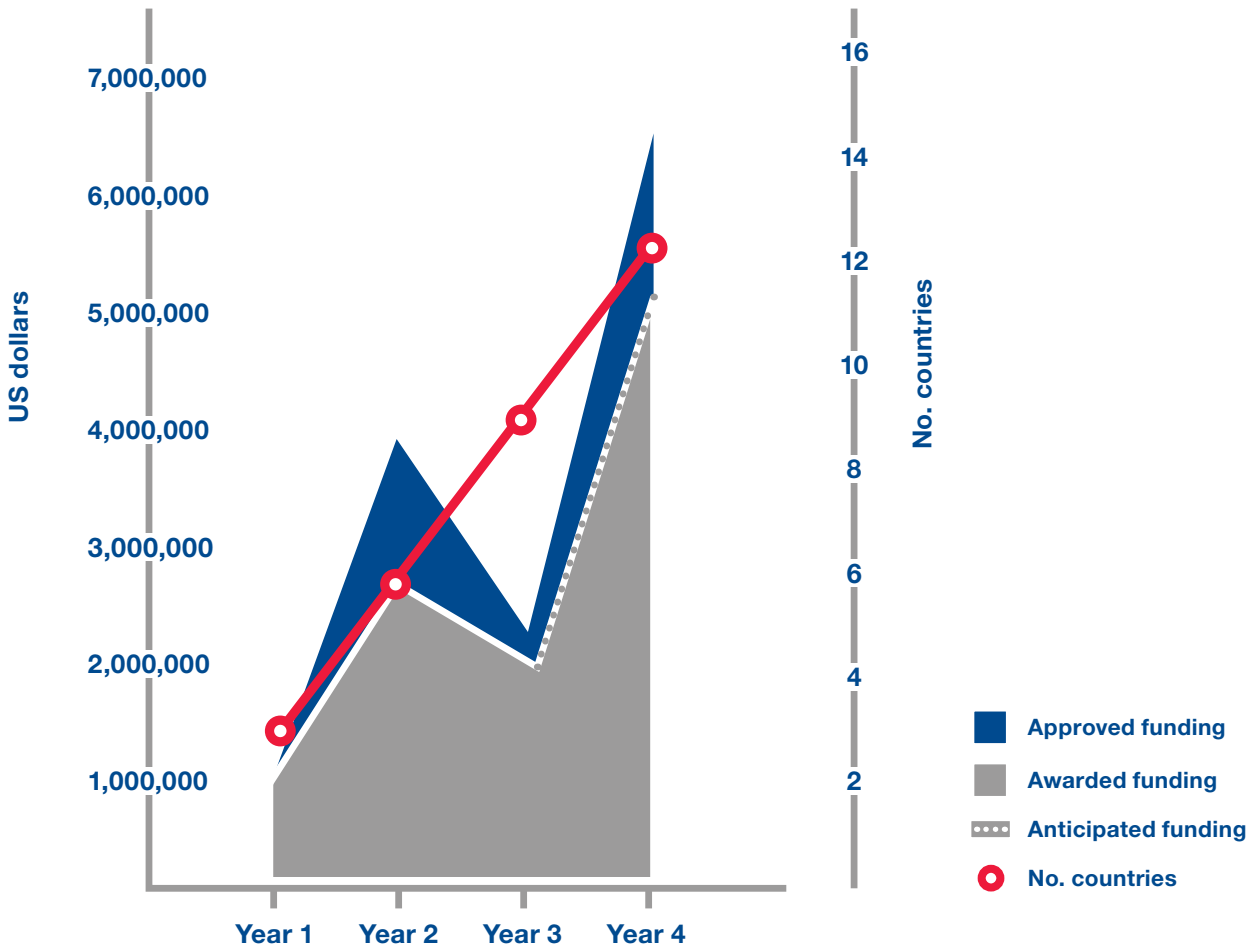


Figure 1a. FIND-CDC Cooperative Agreement: funding from Year 1 to 4

Approved funding amount and actual funding awarded may differ due to timing of approval and award processes, or limited funds awarded to the CDC country offices.

12 countries

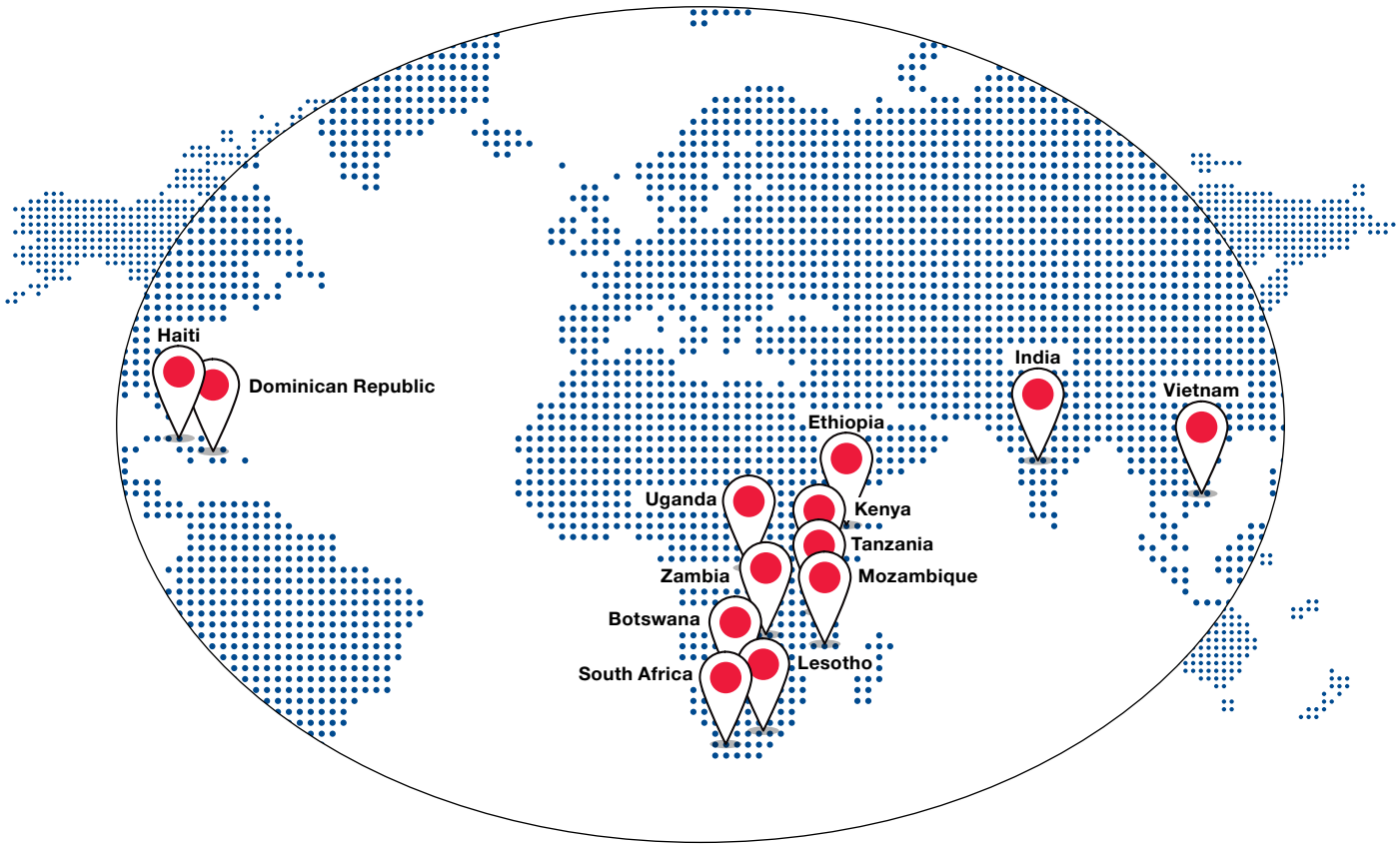
Working with over 260 laboratories

Close to 2000 laboratory and health workers trained

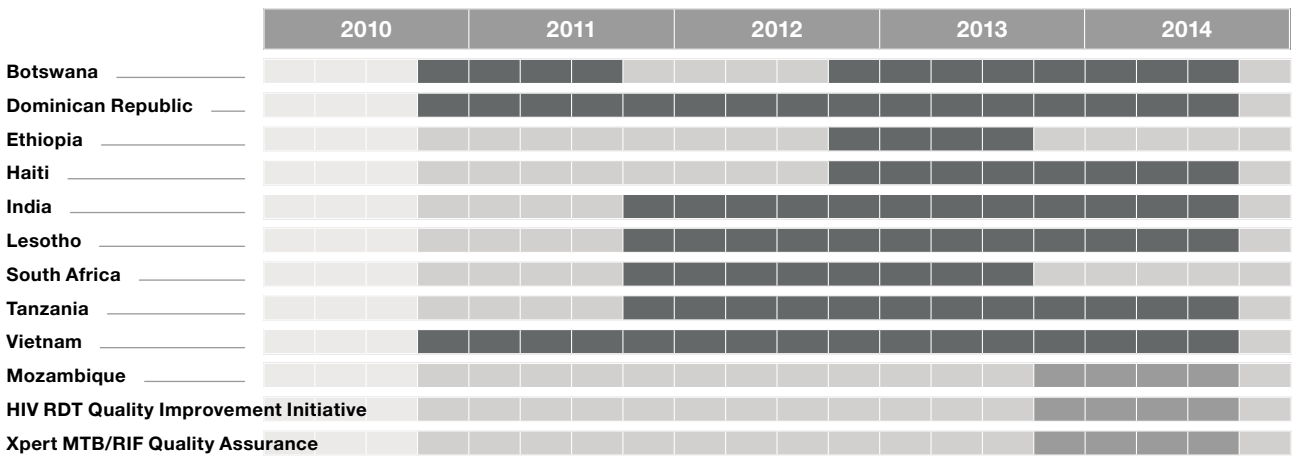
Extended in-country engagement and mentorship

Figure 2. Range of trainings conducted in new diagnostics, quality management systems, quality assurance and laboratory capacity strengthening. *SLIPTA: Stepwise Laboratory Improvement Process Towards Accreditation (WHO-AFRO); SLMTA/FOGELA: Stepwise Laboratory Management Towards Accreditation / (FOGELA is Spanish translation of SLMTA)*

Timeline & achievements



Timeline



2010

• Cooperative agreement awarded
• YEAR 1 activities start in Botswana, Dominican Republic (DR), Vietnam

2011

• SLMTA/FOGELA programme starts in DR

• HIV Rapid Test Quality Assurance activities start in DR

• First SLMTA/FOGELA workshop in Spanish in DR

• YEAR 2 activities start in India, Lesotho, South Africa, Tanzania
• First TB Laboratory Management Training in Vietnam

2012

• Biosafety & Equipment Maintenance Training in DR for 20 hospitals

• Xpert implementation starts at 2 hospital labs in Tanzania

• Coordination of TB culture & LPA training at International Centre of Excellence for Lab Training (ICELT), Bangalore, India
• Support for TB laboratory strengthening in 18 labs in South India

• YEAR 3 activities start in Ethiopia, Haiti and restart in Botswana
• FIND's comprehensive Xpert MTB/RIF training package introduced
• Xpert EQA proficiency panel evaluation study conducted, South Africa

2013

• Biosafety cabinet certification with mentoring of MOH bioengineers in DR

• TB SLMTA Training Pilot in Cape Town, SA
• TB and Blood Bank programme starts in DR
• FIND's comprehensive Xpert training package available in French

• FIND supports first Latin American regional Training of Trainers for SLMTA/FOGELA
• Rosa Hazim, FIND consultant, becomes first SLMTA Master Trainer in Latin American region
• First Xpert training in Haiti

• YEAR 4 funding awarded
• HIV RDT validation study completed in DR
• TB SLMTA First African regional Training of Trainers, Lesotho

2014

• HIV RDT Quality Improvement Initiative due to start
• Xpert MTB/RIF Quality Assurance Project due to start

Botswana

Know your data, know your programme

Population[6]	2 004 000	
Gross national income (GNI) per capita, 2012	$7430	UPPER MIDDLE INCOME
HIV prevalence among adults aged 15-49 years[7]	23.4%	HIGH HIV
TB incidence, per 100, 000 population[8]	408	HIGH TB
HIV prevalence in incident TB cases	64%[9]	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	1.6%; 12%	HIGH MDR-TB

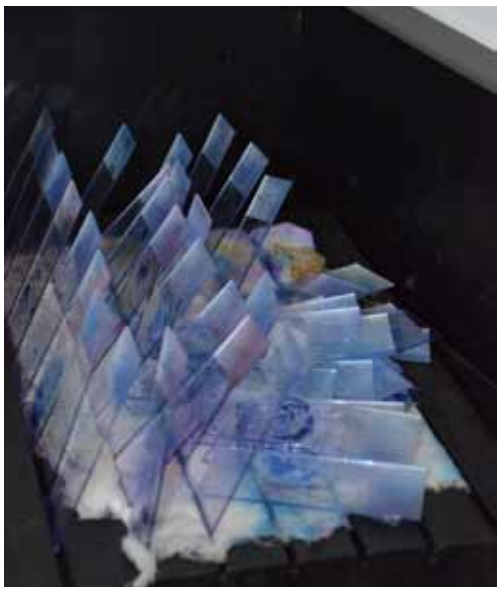
Timeline

Partners

Ministry of Health, Botswana
Centers for Disease Control and Prevention, Botswana
Global Implementation Solutions (GIS)

Activities

Botswana has one of the most developed public health systems in Africa, which is built on a strong health infrastructure. However, the country is experiencing one of the most severe HIV/AIDS epidemics in the world, and this has placed severe strain on the system, both from a human resource and infrastructure perspective. Botswana's national health system priorities and strategies are articulated in the Second HIV/AIDS National Strategic Framework, and laboratory-specific strategies and goals are defined in the National Laboratory Strategic Plan. Botswana has made notable achievements in the past several years including high coverage of its anti-retroviral programme, Prevention of Mother to Child Transmission (PMTCT) and improvement in laboratory quality systems, including attainment of international accreditation by several laboratories.



FIND, together with partner GIS, has been working with the Ministry of Health in the implementation of strategic goals and objectives in the Botswana National Laboratory Strategic Plan related to Monitoring and Evaluation (M&E). This has included support to MOH in establishment of a Monitoring and Evaluation Unit and building the capacity of the Chief of Service, M&E staff and laboratory managers. Capacity building has been achieved by a combination of in-country and remote mentoring approaches.

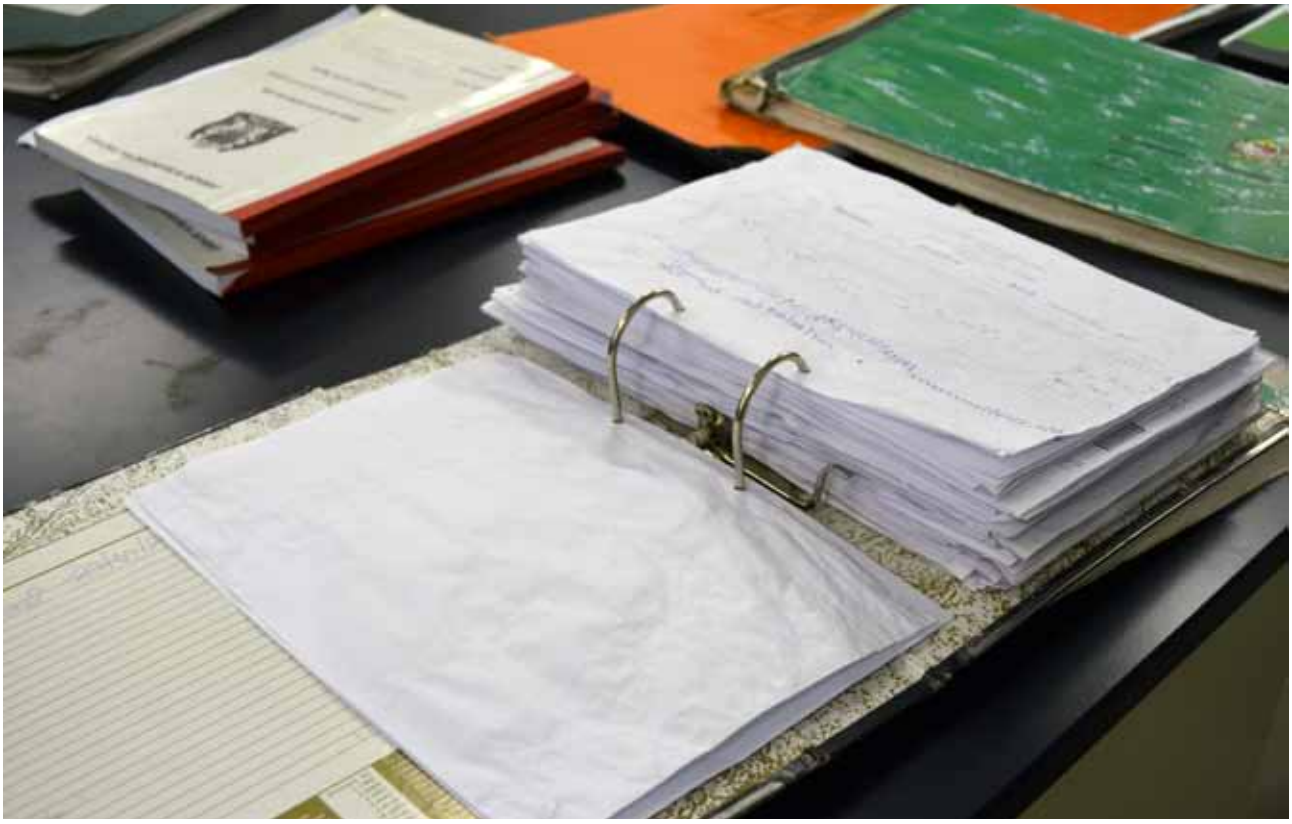
Key Achievements

Laboratory Quality Management Systems

- Countrywide laboratory assessment to determine readiness for laboratory M&E indicators
- Stakeholders' meeting to introduce M&E concepts, establishment of M&E framework and develop core laboratory M&E indicators
- Conducted M&E concepts training for 38 supervisors and staff
- Developed and provided training for data collection system for laboratory indicators and designed and implemented a database for national data collection
- Approved key indicator summary with data collection sources and defined responsibilities for data collection
- Remote mentoring support to key M&E staff on an ongoing basis

Impact

Routine monitoring and evaluation of laboratory indicators are essential for tracking performance and efficiency, and for evidence-based planning of resource allocation and service delivery.



Dominican Republic

Building regional excellence in laboratory quality management

Population	10 280 000	
Gross national income (GNI) per capita, 2012	$5470	UPPER MIDDLE INCOME
HIV prevalence among adults aged 15-49 years	0.7%	HIGH HIV
TB incidence, per 100, 000 population	62	HIGH TB
HIV prevalence in incident TB cases	26%[10]	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	6.6%; 20%	HIGH MDR-TB

Timeline

Partners

Ministry of Health, Dominican Republic
Centers for Disease Control and Prevention, Dominican Republic
Global Implementation Solutions (GIS), Chicago, USA
Alliance Biosciences, Richmond, VA, USA
Eagleson Institute, Sanford, ME, USA
Lucerae Consulting (Pty) Ltd., Johannesburg, South Africa
Integrated Quality Laboratory Systems (IQLS), Lyon, France

Activities

The Dominican Republic occupies two-thirds of the Island of Hispaniola, which it shares with the Republic of Haiti. Although the Dominican Republic has experienced substantial economic growth over the past decades, this has led to high income disparity among the population. Despite an extensive health systems infrastructure, providing equitable access to high quality care remains a challenge, and the country notably suffers from a high level of maternal and infant mortality.

The Dominican Republic National Health Plan (2006-15) outlines strategies and goals for health system reform and is built upon the attainment of the Millennium Development Goals (MDGs) in HIV/AIDS, maternal and child health and TB, and aims to provide improved access to quality health services for at risk and vulnerable populations.

Among many important national policies and guidelines aimed at steering the health system reform process, a National Quality Assurance Policy was launched in October 2011. This policy focuses on achievement of improved healthcare quality, which is seen as a major challenge for the Dominican Health System.

FIND's work in Dominican Republic has focused primarily on implementing laboratory quality management systems in the country. At the outset, this prioritized laboratories in hospitals with large maternal and child health programmes. Later, our support extended to implementing quality management systems in TB laboratories and blood bank services.

FIND's activities in the country have been led by a strong local team of highly experienced laboratory professionals working as SLMTA trainers and mentors, in close collaboration with the CDC Dominican Republic laboratory advisor and SLMTA trainer.

FIND's activities in Dominican Republic are as follows:

- Implementation of the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme in Spanish (FOGELA)
- Technical assistance to LNSPDD (Laboratorio Nacional de Salud Publica Dr. Defillo) to build capacity for quality evaluation and performance comparison of HIV rapid diagnostic tests (RDTs)
  - o Validation study of HIV RDTs completed and national External Quality Assessment (EQA) programme to be introduced
- Training on laboratory safety, waste management, and equipment maintenance
  - o Ongoing support for biosafety cabinet maintenance and calibration, including training and mentoring two Ministry of Health bioengineers towards the US National Science Foundation (NSF) examination and certification
- Support to the Tuberculosis Laboratory Network in strengthening quality management systems in the national TB reference laboratory and selected peripheral laboratories
- Support blood bank service in implementation of quality management system
- Technical assistance for the Epidemiology Laboratory Network

Key Achievements

Laboratory Quality Management Systems

- Sixteen laboratories are participating in the SLMTA/FOGELA programme; eight laboratories have completed the programme (Groups A and B): three of these laboratories achieved three or four stars (Figure 1)
- Eight laboratories continue SLMTA/FOGELA programme and will complete in Year 4
- Measurable improvement in laboratory quality systems; positive attitude and behavior change of lab staff
- Ongoing mentoring and on-site support given for continued progress in quality improvement projects for all 16 laboratories using detailed and structured approach to gap analysis and continuous quality improvement (Figure 2)
- Together with CDC and partners, FIND conducted the first SLMTA Training of Trainers (TOT) in Spanish in August 2013
- FIND consultant, Rosa Hazim, became the first Spanish-speaking SLMTA Master Trainer in the region
- Quality Manuals for Blood Banks have been developed and Quality Management Systems training for eight blood bank centres in Santo Domingo are ongoing, to be completed in 2014

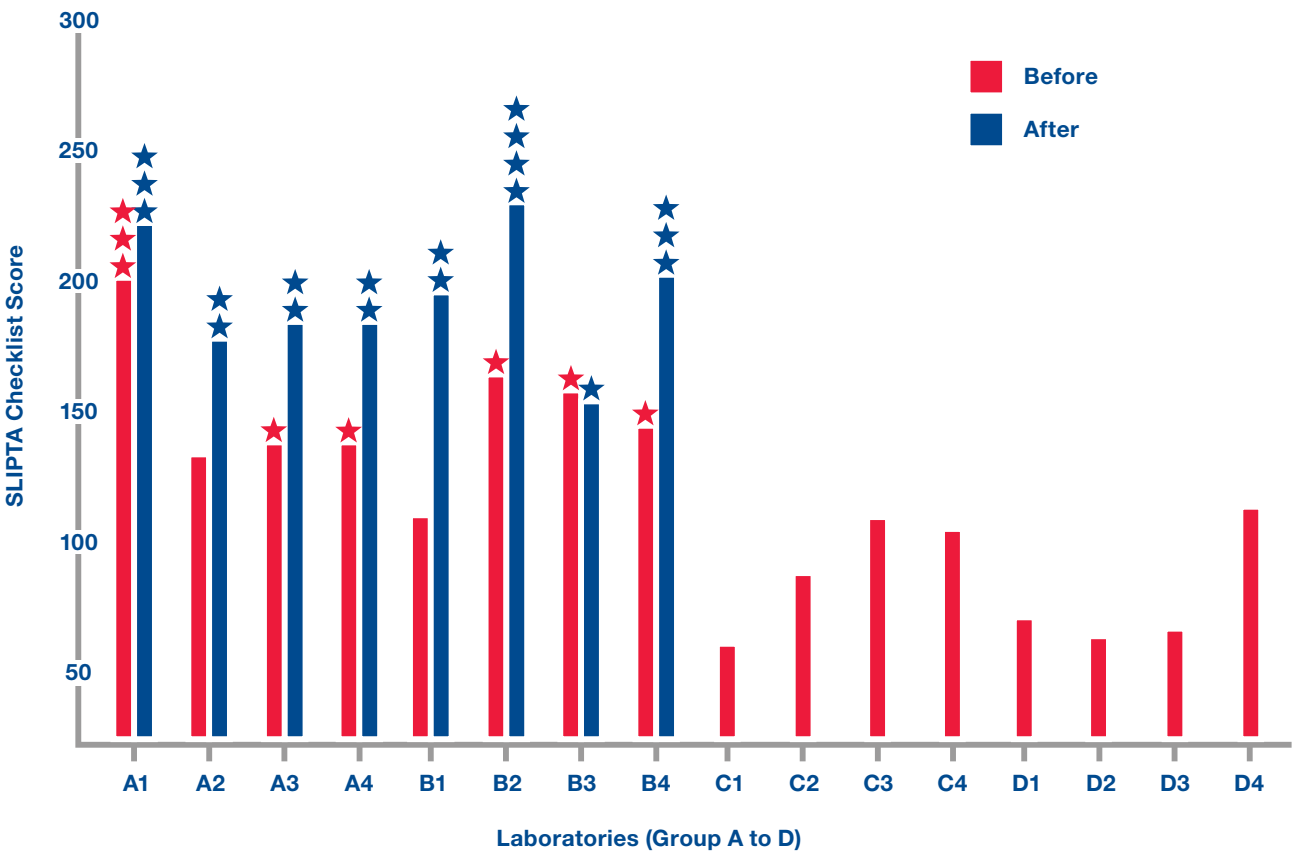


Figure 1. Measurable improvement in laboratory quality systems: SLIPTA checklist scores for Group A and B laboratories before and after SLMTA/FOGELA. SLIPTA: Stepwise Laboratory Improvement Process Towards Accreditation (WHO-AFRO) ; SLMTA/FOGELA: Stepwise Laboratory Management Towards Accreditation / (Spanish translation)

Diagnostics Quality Assurance

- Validation and EQA laboratory for HIV RDTs established at LNSPDD
- Development and implementation of an HIV RDT quality assurance database for data capture and generation of automated reports for validation study
- CAP proficiency testing implemented in LNSPDD for HIV testing

Laboratory Capacity Strengthening

- Two MOH bioengineers are in the process of receiving training and mentoring to become the first fully qualified biosafety cabinet certifiers in the country
- 7 Biosafety cabinets were certified by qualified US certifier and trainer during in-country mentoring of MOH bioengineers and the trainees have subsequently tested a further 16 cabinets as part of their training
- Training in equipment maintenance and biosafety was conducted; equipment and supplies for maintenance and calibration were procured
- Support for laboratory infrastructure was provided, including procurement of equipment

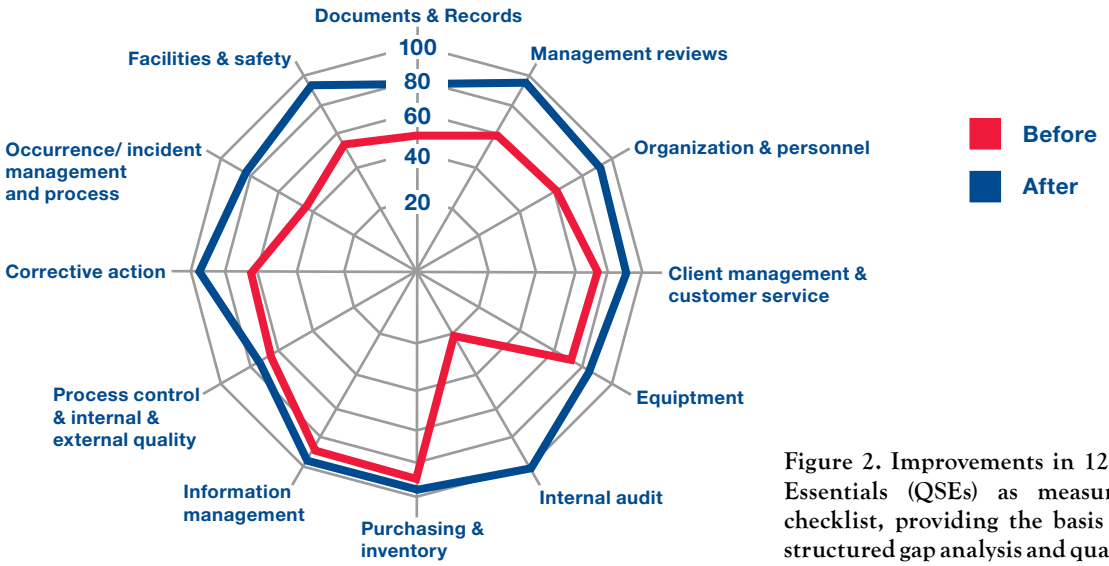


Figure 2. Improvements in 12 Quality Systems Essentials (QSEs) as measured by SLIPTA checklist, providing the basis for detailed and structured gap analysis and quality improvement

Impact

This programme is building a strong culture of quality among laboratories in the country. Improved services and stronger relationships with clinicians and hospital management are leading to improved patient care. Building on the gains already achieved, local laboratory quality champions will continue to drive progress towards laboratory accreditation in the coming years, to deliver more equitable access to high quality care across the country.

Changing the culture of laboratory quality

Implementing the SLMTA Programme (FOGELA) in Dominican Republic

A Leading Light - Rosa Hazim
FIND Dominican Republic laboratory consultant and first Spanish speaking SLMTA Master Trainer

Q & A

Q: Tell me about yourself

A: I am a "bio-analyst" (name for Clinical Laboratory professional in Dominican Republic), working for over 30 years in the field. Currently, I am finishing a speciality in Administration and Quality Management in Laboratories and have worked with FIND since February 2011. God has blessed me with two wonderful daughters and a beautiful grandson. I have been always surrounded by amazing people from whom I have learned all I know and who I am.

Q: When and how was your first contact with SLMTA?

A: That was some time ago, when I participated in the SLMTA Training of Trainers (TOT) in Johannesburg in 2011, with my colleagues and friends Aleida Landestoy (FIND DR Project Manager) and Annie Malla (Laboratory Specialist CDC DR).

Q: What is the difference between SLMTA and other QMS training programs?

A: SLMTA is a training and mentorship programme for achieving results that can be measured and reached in the short term in laboratories with limited resources. It includes a framework composed of 66 tasks and routine management items describing what a laboratory manager needs to do, over 45 "learn by doing" activities and more than 100 tools and job-aids to help accomplish the tasks. All the contents are linked to a checklist to help assess the progress made.

The program is conducted through a set of three workshops whose aim is to transform knowledge into behavioural changes and laboratory practices. During each workshop, improvement projects are developed. Furthermore, follow-up visits are conducted on a regular basis to assess the training results, monitor improvement projects and to follow up on specific issues within each lab.

I truly believe that SLMTA is a powerful tool to implement a Quality Management System in the labs in a step-wise approach. The main differences with traditional QMS training programs are that SLMTA is standardized not only in how to conduct the training but also in the long term follow-up and mentorship of the participating laboratories. Furthermore, results can be measured and so the trainees have a real motivation to reach the stars awards throughout!

Q: How was the process to become a SLMTA Master Trainer?

A: Soon after we returned from the TOT in 2011, my colleagues and I started to implement the workshops here in Dominican Republic in 16 clinical laboratories selected by the Ministry of Public Health. Later in September 2012, I participated as a trainer in the PROMELA program in Peru (Military Laboratory Improvement Program in Latin America), organized by the US Naval Medical Research Unit, where I facilitated 3 "Express" SLMTA workshops, along with the other trainers.

Finally, in July 2013, I was invited to participate in the first SLMTA TOT training in Spanish held in Dominican Republic as a Master Trainer candidate. At the end of the workshop, I was very honoured to be recommended as a Master trainer.

Q: How has SLMTA changed the way laboratories in the DR work?

A: The main change is in the approach and behaviour of the laboratory staff towards a "quality culture". Now I can see that this understanding and incorporation of QMS principles is part of their routine work.

Q: Which are the main challenges of introducing SLMTA in the DR?

A: One of the biggest challenges I see is the lack of staff dedicated to work on QMS within the laboratories in the country. Low salaries and short working hours (4-6 hours per day) in the public sector are a limiting factor. Furthermore, there is always resistance to change among some of the laboratory staff. However, slowly but steadily they have understood the impact and more importantly experienced the benefits of the SLMTA approach.

“The main differences with traditional QMS training programs are that SLMTA is standardized not only in how to conduct the training but also in the long term follow-up and mentorship.”

[Rosa Hazim, SLMTA Master Trainer, FIND, Dominican Republic]

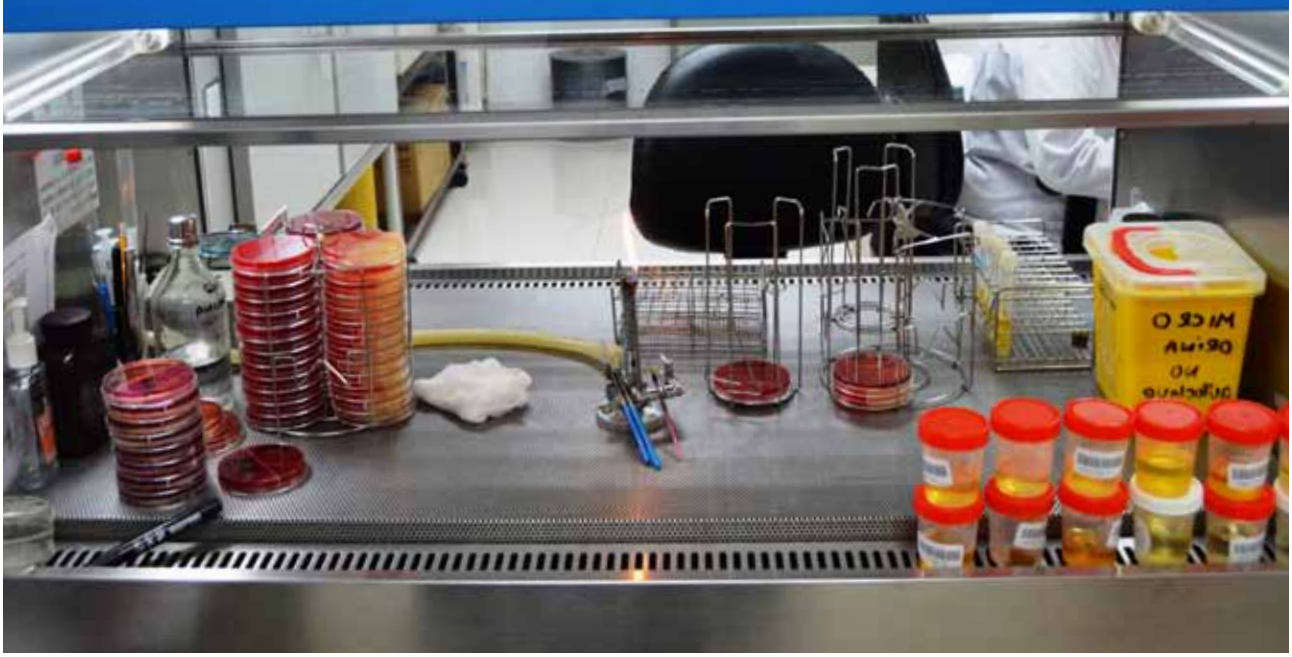
Stars in the Caribbean - Hospital Materno Infantil San Lorenzo de Los Mina

Hospital Materno Infantil San Lorenzo de Los Mina is situated in the southern region of Dominican Republic, the most secluded region which lags behind the rest of the country in terms of economic development. During the baseline lab assessment, the lowest scores were found in this area and the SLMTA trainers prepared themselves for challenges ahead. However, due to the hard work and dedication of the laboratory staff, and with support from the FIND team during workshops, mentoring and follow up visits, results in this region were very good - with three out of the four laboratories in the region showing the fastest improvement in scores among all sixteen laboratories participating in SLMTA. This is a testament to the fact that SLMTA equips people with the skills to become their own agents of positive change, even in conditions with limited resources.

Such was the change at Los Mina laboratory that lab technicians in a neighbouring hospital heard of their achievements since participating in the FOGELA programme. Following an invitation to Los Mina staff to present their experience, the two laboratories formed a strong relationship, with Los Mina providing mentorship and support to the other laboratory to implement its own improvement programme. SLMTA/FOGELA is truly growing!

"... results can be measured and so the trainees have a real motivation to reach the stars."

[Rosa Hazim, SLMTA Master Trainer, FIND, Dominican Republic]



Ethiopia

Improved data, improved impact

Population	84 734 000	
Gross national income (GNI) per capita, 2012	$410	LOW INCOME
HIV prevalence among adults aged 15-49 years	1.4%	HIGH HIV
TB incidence, per 100, 000 population	258	HIGH TB
HIV prevalence in incident TB cases	17%	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	1.6%; 12%	HIGH MDR-TB

Timeline

Partners

Ethiopian Health and Nutrition Research Institute (EHNRI)
Centers for Disease Control and Prevention, Ethiopia
Integrated Quality Laboratory Systems (IQLS)

Activities

Ethiopia has almost 2,000 laboratories performing TB smear microscopy, which remains the primary diagnostic tool for TB in the country. External quality assurance is fundamental in ensuring the quality of testing. Slides from peripheral laboratories are re-checked at a higher level laboratory. Timely re-examination of slides, feedback of result to laboratories, and implementation of corrective actions are challenging and a large amount of data handling is associated with all these steps. Although an EQA programme existed in the country prior to the project, the programme relied on paper-based recording and reporting, leading to potential errors, delay in feedback of results and implementation of corrective actions. FIND, with partner IQLS, has trained laboratory personnel in use of a newly developed electronic EQA database system (www.slide2check.net). The system allows easy data management, monitoring and automated reporting of all EQA activities, thus saving laboratory personnel time and improving the programme effectiveness. This enhanced data management system is an important step towards improving feedback to laboratories participating in the programme, thus supporting their continued improvement in quality of laboratory testing.

Key Achievements

- 7 laboratory personnel trained in TB quality assurance electronic data management system
- System to be piloted in one re-checking laboratory in Bahir Dar region, responsible for supervising 4 peripheral laboratories; results of early implementation will be available in 2014

Impact

Improved data management supports quality improvement of the TB laboratory network, bringing more accurate diagnosis to TB patients.

Haiti

Rebuilding a stronger TB laboratory network

Population	10 170 000	
Gross national income (GNI) per capita, 2012	$760	LOW INCOME
HIV prevalence among adults aged 15-49 years	2.1%	HIGH HIV
TB incidence, per 100, 000 population	213	HIGH TB
HIV prevalence in incident TB cases	19%[11]	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	2.2%; 14%	HIGH MDR-TB

Timeline

Partners

Laboratoire National de Santé Publique (LNSP), Ministry of Health
Centers for Disease Control and Prevention, Haiti
Integrated Quality Laboratory Systems (IQLS)

Activities

Even prior to the earthquake in January 2010, the Haitian health system faced serious challenges. Haiti had the highest HIV/AIDS incidence outside Africa, high maternal and infant mortality and low rates of childhood immunisation. More than three years since the earthquake, which killed 200,000 Haitians, displaced millions of people and decimated the health system infrastructure and the cholera epidemic which followed, severe challenges remain and Haiti continues to suffer from inadequate sanitation systems, poor nutrition, inadequate health services and poor transport infrastructure. However encouraging signs of progress are being seen.

FIND initially started work in Haiti in late 2010 to support rebuilding of TB diagnostic services, and this PEPFAR-supported project began at the end of 2012.

FIND's activities in Haiti are as follows:

- Support the implementation of the Xpert MTB/RIF for rapid diagnosis of TB and detection of drug resistance
- Improve quality assurance of TB microscopy by implementation of an electronic TB smear microscopy EQA management system for blinded slide rechecking
- Support LNSP and two regional laboratories to establish quality assurance system for TB microscopy and Xpert MTB/RIF

Key Achievements

Diagnostics implementation

- Conducted 7 site assessments for Xpert MTB/RIF implementation
- Conducted a 5-day comprehensive Training of Trainers workshop for Xpert implementation for 7 participants
- Provided assistance for installation and start of Xpert MTB/RIF testing at LNSP; other sites to start in fourth quarter 2013
- Participated in Xpert MTB/RIF strategic planning with LNSP and other partners
- Developed an Xpert MTB/RIF implementation and monitoring and evaluation framework

Quality Assurance

- Conducted training for 6 participants in electronic EQA database at LNSP
- Conducted laboratory assessments and provided assistance to start implementation of blinded slide re-checking at 11 sites (to be increased to 30 sites by end of 2013)
- Proficiency testing panels supplied by CDC were implemented in 6 Xpert MTB/RIF testing sites

Impact

Access to rapid TB diagnostics nearer to the point of care, as well as improvement in the quality of diagnosis using existing technologies, will lead to better diagnosis and care for patients.

India

Contributing to large-scale TB laboratory capacity strengthening

Population	1 237 000 000	
Gross national income (GNI) per capita, 2012	$1530	LOW MIDDLE INCOME
HIV prevalence among adults aged 15-49 years	0.3%	
TB incidence, per 100, 000 population	176	HIGH TB
HIV prevalence in incident TB cases	5%[12]	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	2.2%; 15%	HIGH MDR-TB

Timeline

2010	2011	2012	2013

Partners

Revised National Tuberculosis Control Programme, India
International Centre of Excellence for Laboratory Training (ICELT), National Tuberculosis Institute, Bangalore
Centers for Disease Control and Prevention, India
Expand-TB Programme (WHO/GLI, GDF, FIND)
World Health Organization (WHO)
Clinton Health Access Initiative (CHAI)
PATH

Activities

The Revised National Tuberculosis Control Programme (RNTCP) has embarked on an ambitious expansion of the Programmatic Management of Drug-Resistant TB (PMDT). FIND is proud to be supporting RNTCP to strengthen laboratory capacity and introduce new tools for the diagnosis of TB and MDR-TB in the country in parallel with expansion of the treatment and care of MDR-TB patients. The work supported by the Cooperative Agreement has been complementary to other FIND India activities which are supported by Global Fund and the Expand-TB programme.

Through this programme, FIND has supported the coordination of TB laboratory training at the International Center of Excellence for Laboratory Training (ICELT). ICELT was established at the National Tuberculosis Institute, Bangalore by Expand-TB in 2010. The funding was provided by WHO Global Laboratory Initiative with OGAC financial support. The mission of ICELT is *"To support the scaling up of laboratory capacity building in India and Asia by providing hand-on training courses in the diagnosis and monitoring of major infectious diseases such as TB, HIV/AIDS and Malaria."*

Since 2011, ICELT has supported the rapidly growing demand for a well-trained, competent, and motivated laboratory workforce through specially designed hands-on practical courses for senior and mid-level line mangers, and front line laboratory staff of RNTCP.

Training courses conducted include:

1. Hands-on training in molecular line probe assay (LPA) for the rapid detection of TB and drug resistant TB (5-day training);

2. Hands-on training in liquid culture growth detection, identification and susceptibility testing of TB (10-day training);

3. Biosafety in TB Laboratory (5-day training);

4. Hands-on training on Xpert MTB/RIF (1-day training)

FIND has also provided coordination for laboratory infrastructure upgrades, and provided training and support towards introduction of new diagnostic tools in 17 laboratories: 8 in Southern India and 9 in Northern India.

Key Achievements

- Seventeen laboratories were assisted to upgrade infrastructure, procure and install equipment and reagents, undergo training and complete proficiency testing prior to routine implementation of liquid culture and/or molecular line probe assay
  - 13 laboratories have routinely implemented liquid culture and molecular line probe assay
  - Four additional laboratories routinely implemented molecular line probe assay only
- A total of 14 training courses were conducted at ICELT with support from FIND-CDC (8 liquid culture and DST, 5 line probe assay, 1 Xpert MTB/RIF)
- 17, 430 liquid cultures were performed since routine implementation in 2012, of which 1, 637 were TB positive
- 32, 783 line probe assays were performed since routine implementation in 2012, from which 4, 276 MDR-TB cases have been detected

Impact

Strengthening of TB laboratory capacity and introducing new rapid TB diagnostics ensures more patients across the country can access high quality diagnosis and treatment by RNTCP, improving the health outcomes for themselves, their families and communities. More than 4, 000 MDR-TB cases have been identified thus far using new tools introduced with support from this programme.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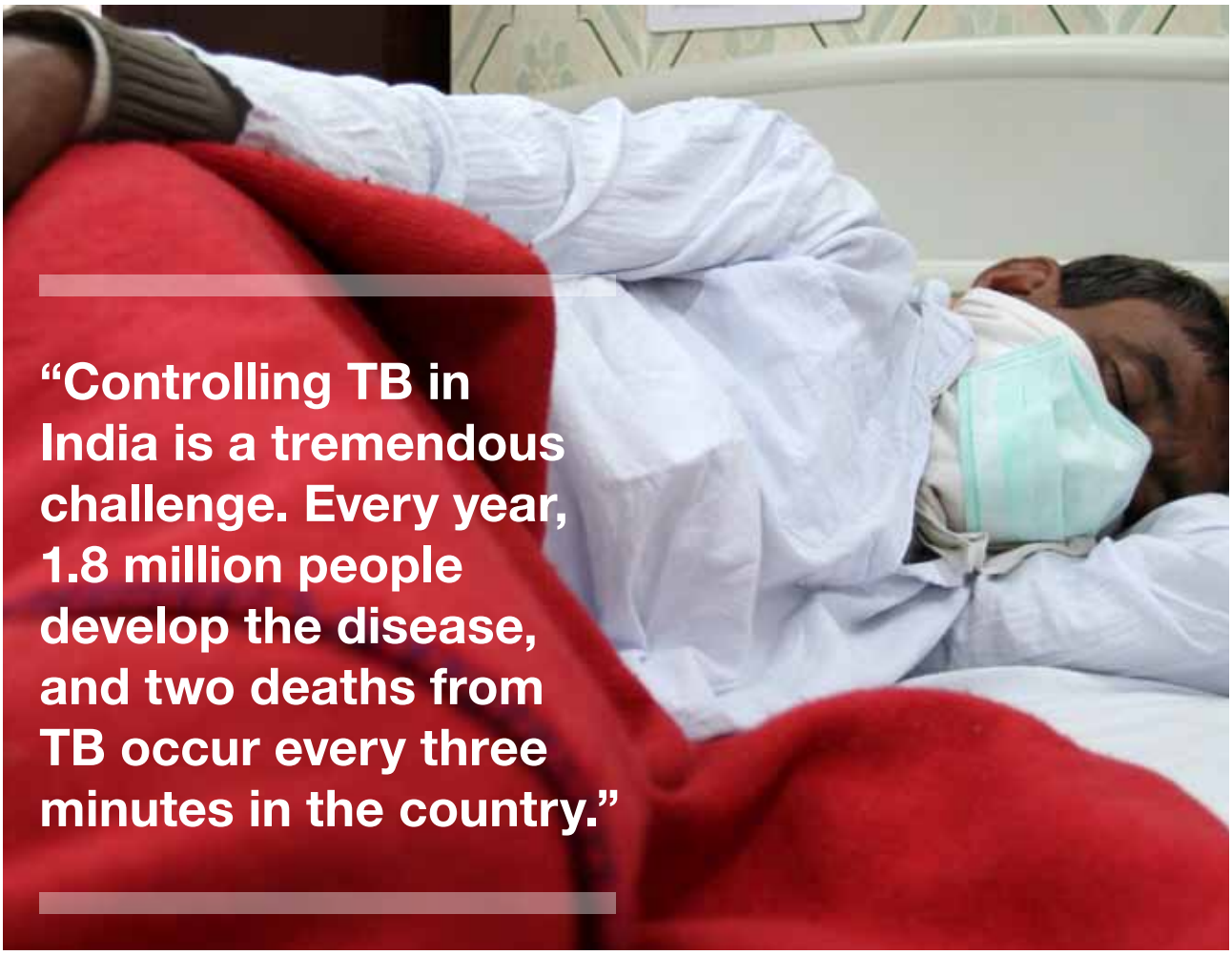
MDR-TB CLINIC
2

Strong partnerships essential to large-scale TB laboratory strengthening

Strengthening TB and MDR-TB diagnostic capacity in India



Controlling TB in India is a tremendous challenge. Every year, 1.8 million people develop the disease, and two deaths from TB occur every three minutes in the country[13].

The Revised National Tuberculosis Control Programme was established as a national programme in 1997, and during its first phase the programme's focus was on ensuring expansion of quality DOTS services to the entire country, which was achieved in 2006. As well as consolidating achievements during the first phase, the second phase of the RNTCP aims to address TB-HIV, MDR-TB and other challenges, by scaling up TB-HIV joint activities, DOTS-Plus, and other approaches.

Battling TB on this scale requires ambitious targets, strong leadership, and solid partnerships between government, funding and technical agencies. FIND India is proud to be working with RNTCP and partners to build capacity for the diagnosis of TB and MDR-TB, through establishment of 40 laboratories capable of performing liquid culture and/or molecular line probe assay for rapid detection of multidrug-resistant TB.

One such laboratory is the Intermediate Reference Laboratory, Chennai, Tamilnadu. The Programme for the Management of Drug Resistant TB started in Tamilnadu in 2008, and the entire state was covered by the end of 2011. However, initially the laboratory relied on solid culture and drug susceptibility testing (DST) to diagnose and follow up MDR-TB patients. This method is slow, taking many weeks for a result. FIND, through the Expand-TB project, together with CDC support under this programme, supported the upgrade of the IRL Chennai, equipment and reagent procurement (Expand-TB) and training, leading to the introduction of molecular line probe assay in September 2012, covering 9 districts. Since that time, the laboratory has tested close to 2, 000 patients and been able to rapidly diagnose 230 cases of MDR-TB. With ongoing support, a BSL-3 laboratory has been established and introduction of liquid culture and DST is expected shortly.

The upgrade of laboratories across the country has led to a rapidly growing demand for a well-trained, competent, and motivated laboratory workforce. The International Centre of Excellence in Laboratory Training at the National Tuberculosis Institute in Bangalore has met this need through specially designed hands-on practical courses for senior and mid-level line mangers, and front line laboratory staff of RNTCP.

Dr. Pradyot Prakash is Assistant Professor in the Department of Microbiology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, which is responsible for the diagnosis of TB and MDR-TB cases in Eastern Uttar Pradesh region. Dr. Pradyot was selected to attend training for TB LPA at ICELT in August 2013. Although having previous experience working in PCR, Dr. Pradyot did not have experience working in a biosafety level 3 laboratory or practical knowledge of molecular line probe assays. After undergoing training at ICELT Dr. Pradyot felt *"... confident of inducting good laboratory practice" at Intermediate Reference Laboratory, IMS, BHU, Varanasi where I have to train laboratory technicians. Now I know how to execute LPA in diagnosis of MDR-TB both directly from clinical samples as well as TB culture isolates in just 2 working days."*

Lesotho

Strengthening TB diagnosis using old and new techniques

Population	2 052 000	
Gross national income (GNI) per capita, 2012	$1380	LOW MIDDLE INCOME
HIV prevalence among adults aged 15-49 years	23.3%	HIGH HIV
TB incidence, per 100, 000 population	630	HIGH TB
HIV prevalence in incident TB cases	76%[14]	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	0.91%; 5.7%	HIGH MDR-TB

Timeline

Partners

Ministry of Health, Lesotho
Centers for Disease Control and Prevention, Lesotho
Integrated Quality Laboratory Systems (IQLS)

Activities

Lesotho has the world's second highest incidence of TB and HIV-associated TB, making TB a public health emergency for the country. More than half the population lives below the poverty line. Despite being a small country, more than 80% of Lesotho is remote and mountainous, making delivery of health services challenging.

Lesotho has a laboratory network which includes 17 TB microscopy centres at district hospitals and sub-district level. Until recently, smear microscopy was the only TB diagnostic available outside the Central TB Reference Laboratory in the capital. The Ministry of Health, with support from partners is introducing Xpert MTB/RIF at the district hospital level for the diagnosis of MDR-TB and HIV-associated TB. However, TB smear microscopy remains the primary diagnostic test for many patients and maintaining and improving the quality of testing is essential to a strong TB laboratory network.

FIND's activities in Lesotho are as follows:

- Support the implementation of the Xpert MTB/RIF for rapid diagnosis of TB and detection of drug resistance
- Implement a molecular External Quality Assurance programme for TB
- Implement an electronic TB smear microscopy EQA management and monitoring system for blinded rechecking

Activities in year 4 and 5 will focus on strengthening the routine monitoring and evaluation, conducting competency assessment of Xpert MTB/RIF users and providing refresher training where needed, and building a sustainable system for equipment maintenance and quality assurance.

Key activities:

- Participated in national stakeholder meeting to determine the in-country use and target patient population, and to develop a diagnostic algorithm for testing with Xpert MTB/RIF with representatives of the Ministry of Health (MOH), CDC Lesotho and partners
- National TB diagnostic algorithm was approved by MOH
- Site readiness assessments were conducted for 5 sites
- On-site trainings for Xpert MTB/RIF were conducted in a total of 9 laboratories
- As part of the maintenance programme, 10 remote calibration kits were procured to ensure GeneXpert equipment warranty
- Trained 7 laboratory staff from MOH and Central TB Reference Laboratory in electronic database for microscopy EQA data management

Impact

Developing a strong quality-assured system for both smear microscopy and Xpert MTB/RIF will contribute towards rapid and accurate diagnosis for all patients with TB, and enable rapid treatment initiation for drug resistant and susceptible TB patients.

Changing lives – the human face of improving TB diagnostics

Meet Lebohang*, a 33 year old man from Maseru, Lesotho, who, along with many of his countrymen, has been a migrant worker at the mines in South Africa for many years. He stopped working in June 2013 due to illness and has been living with his parents since then. When he became ill, he initially sought the help of traditional healers, and only later went to a health clinic once his symptoms became very severe. By this time he was suffering from cough, extreme fatigue, painful joints and bones and had multiple abscesses.

At the clinic he was counseled and tested for HIV and the clinic nurse suggested that he should be tested for TB as well. Lebohang had no idea that he may be suffering from TB as he had not had TB in the past. He was given sputum containers and the nurse explained to him how to collect sputum samples and he was referred to the laboratory. The samples were tested using GeneXpert and smear microscopy and the results were issued the same day. The GeneXpert test showed the presence of drug resistant TB in the sputum, and the clinic was able to refer the patient the same day to the MDR-TB hospital.

Lebohang was advised to come to the next outpatient clinic at the MDR-TB hospital a few days later where he was admitted and put on treatment the same day. Because of GeneXpert, the diagnosis of TB and drug resistance can be done much faster than was previously possible, allowing patients to be started on treatment quickly.

The family is excited that their son was diagnosed and put on treatment on time and they are very supportive. Lebohang comments that it is thanks to GeneXpert that he was put on appropriate medication promptly. He thinks that the treatment is working because most of the symptoms have disappeared and he is feeling much better. He believes that the laboratory and hospital are working hand in hand to offer a quality service. However, he thinks that the community should be educated as there are people out there who still consult traditional healers like he did.

*A fictional name has been used to protect patient confidentiality. Lebohang means "Thankful" in the Sesotho language.

“Lebohang comments that it is thanks to GeneXpert that he was put on appropriate medication promptly.”

Comprehensive training and accompanying countries through early implementation

Leveraging FIND's unique expertise to support Xpert MTB/RIF

FIND co-developed the Xpert MTB/RIF test (with Cepheid and the University of Medicine and Dentistry of New Jersey) for rapid detection and drug resistance testing of TB, and led the evaluation and multi-country demonstration studies which led to WHO endorsement of the technology. This test was endorsed for use in HIV-associated pulmonary TB and patients at risk for multidrug-resistant TB in 2010[15]. Recent WHO guidelines published in 2013 extended the recommendations to extra-pulmonary TB[16]. Based on our unique expertise, FIND is providing training and technical assistance to the Ministries of Health in a number of countries implementing Xpert MTB/RIF, namely Haiti, Lesotho, Tanzania and Vietnam.

Providing technical training to laboratory workers to perform Xpert MTB/RIF is necessary but insufficient. Our experience has shown that a number of broader aspects are critical to successful implementation of the technology, including specimen collection and referral, recording and reporting, quality assurance, monitoring and evaluation, troubleshooting, and training of clinicians.

Therefore, FIND has developed a comprehensive 5-day Xpert MTB/RIF training programme. This training has thus far been rolled out in several countries, including Haiti, Tanzania and Lesotho. FIND's training programme, together with materials developed by other partners, is

"Evidence on "where" to locate Xpert® MTB/RIF … and "whom" to test … is growing, allowing rational and sustainable roll-out of the technology even in resource-constrained settings."

[Weyer, 2013][17]

being reviewed and harmonized by the Global Laboratory Initiative (GLI), and an approved GLI training package will be available by the end of 2013.

FIND has also developed an online Xpert MTB/RIF clinicians training programme together with NHLS (South Africa), to accommodate their need for wide-scale training of clinicians to accompany the extensive roll out of the test in the country.

In addition to training, FIND accompanies countries through the early implementation of Xpert MTB/RIF by means of long-term country engagement with Ministries of Health. We work together on phase implementation, help to develop comprehensive approaches to strengthen laboratory quality assurance and quality management systems and support country level adoption in a holistic fashion.

FIND is contributing to a growing body of evidence around best practices for Xpert MTB/RIF implementation, including placement of instruments, patient populations, training, practical and operational factors.

South Africa

A bold solution for a dual epidemic

Population	51 190 000	
Gross national income (GNI) per capita, 2012	$7610	UPPER MIDDLE INCOME
HIV prevalence among adults aged 15-49 years	17.3%	HIGH HIV
TB incidence, per 100, 000 population	1003	HIGH TB
HIV prevalence in incident TB cases	65%	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	1.8%; 6.7%	HIGH MDR-TB

Timeline

Partners

National Priority Programme, National Health Laboratory Services (NHLS), Johannesburg, South Africa
Department of Molecular Medicine and Haematology, University of the Witwatersrand, Johannesburg, South Africa
National Department of Health, Pretoria, South Africa (NDoH)
Centers for Disease Control and Prevention, South Africa
Global Laboratory Initiative (GLI), Geneva, Switzerland
Vircell SL, Santa Fe, Spain
Novasano Health and Science Inc., New York, USA

Activities

South Africa has the largest HIV epidemic in the world with about 5.7 million people living with HIV. It ranks third highest in terms of TB burden, and has high levels of MDR-TB. High rates of TB-HIV co-infection exist and make diagnosis and care of patients more challenging.

The National Health Laboratory Service (NHLS) is responsible for providing laboratory services to the national and provincial health departments and serves over 80% of the population through a national network of more than 260 laboratories. Given the scale of the TB and HIV epidemics in the country, the National Department of Health took the bold decision to rapidly scale-up of Xpert MTB/RIF as a replacement for smear microscopy as the primary TB diagnostic tool in an attempt to turn the tide of the epidemics. The National Priority Programme (NPP) of the NHLS has spear-headed this large scale implementation. South Africa is leading the way in terms of Xpert MTB/RIF implementation and accounts for more than half the global procurement of GeneXpert instruments and cartridges to date.

FIND has worked with the NPP of NHLS and the Department of Molecular Medicine and Haematology, University of the Witwatersrand to support the national roll-out of the Xpert MTB/RIF assay, in the areas of quality assurance and training.

FIND's activities in South Africa are as follows:

To develop and implement an External Quality Assurance scheme for Xpert MTB/RIF

- Development of a computer-based system to manage Xpert MTB/RIF EQA
- Updating and developing job aids and Standard Operational Procedures (SOP) for rapid molecular TB EQA testing
- Development of cell-based molecular controls for Xpert MTB/RIF EQA
- Feasibility study of five proficiency panels for Xpert MTB/RIF EQA

To assist with training of clinicians for national roll-out of Xpert MTB/RIF

- Development of standard operating procedures, revise training materials and develop job aids
- Conduct training of nurses, doctors and programme officers for Xpert MTB/RIF roll-out, in coordination with national and provincial departments of health
- Development of an online training programme for Xpert MTB/RIF clinical training

Key Achievements

Diagnostics Implementation

- A revised Xpert MTB/RIF clinical training package, including facilitators guide, job aids and standard operating procedures was developed and approved by NDoH
- 25 Xpert MTB/RIF clinical training sessions conducted (20 for nurses and operations managers; 5 for doctors) and a total of 1, 320 healthcare workers trained
    - 1, 151 nurses and 76 operations managers were trained in conjunction with NDoH in Tshwane, Ekurhuleni, Mpumulanga, Northwest Province, Limpopo and northern KwaZulu Natal
    - 92 doctors (and 1 laboratory manager) were trained in Nelspruit Hospital and referral clinics, Tembisa Hospital, Tambo Memorial Hospital, Witbank Hospital, and Kalafong Hospital

Quality Assurance

- Development of a computer-based system to manage Xpert MTB/RIF EQA. Roll out of Xpert® on a nationwide scale, as well as addressing the need for results reporting, instrument maintenance and support and EQA requires the capacity to manage large amounts of data. A web-based database was initially established by NHLS/Wits (www.tbgxmonitor.com), for initial GeneXpert instrument verification. In collaboration with FIND/CDC this functionality of the platform has been expanded to allow for the management of a national Xpert MTB/RIF EQA program. The upgraded system has been deployed in over 95 Xpert testing sites.
- Molecular controls for Xpert MTB/RIF EQA were developed by FIND with partner, Vircell. A panel of these controls were included in the multi-centre evaluation and found to perform satisfactorily.
- Feasibility study of five proficiency panels for Xpert MTB/RIF EQA was conducted by FIND, NHLS/Wits, CDC and GLI in 11 Xpert testing facilities. All panels had similar performance characteristics. A manuscript was submitted for publication, entitled "A multi-centre feasibility study to assess External Quality Assessment panels for Xpert® MTB/RIF assay in South Africa." NHLS/Wits have taken a decision to use their own in-house dried culture spots (DCS) for EQA in South Africa. Other options are being pursued for possible use in other countries.

Impact

Roll out of a new technology on this scale requires a strong focus on quality to ensure cost-effective and efficient implementation. Training of clinicians in addition to laboratory personnel is critical to ensure that this large scale implementation delivers the maximum patient impact and contributes towards tackling the TB/HIV epidemics. Roll out of a new technology on this scale requires a strong focus on quality to ensure cost-effective and efficient implementation. Training of clinicians in addition to laboratory personnel is critical to ensure that this large scale implementation delivers the maximum patient impact and contributes towards tacking the TB/HIV epidemics.

Tanzania

Supporting early adoption of Xpert MTB/RIF

Population	47 780 000	
Gross national income (GNI) per capita, 2012	$570	LOW INCOME
HIV prevalence among adults aged 15-49 years	5.8%	HIGH HIV
TB incidence, per 100, 000 population	165	HIGH TB
HIV prevalence in incident TB cases	39%	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	1.1%; 0%	

Timeline

Partners

National TB and Leprosy Programme, Ministry of Health and Social Welfare (MOHSW), Tanzania
Centers for Disease Control and Prevention, Tanzania
PATH

Activities

Tanzania is one of the poorest countries in the world. HIV/AIDS, malaria and TB continue to be major public health challenges and the leading causes of morbidity and mortality in the country. Despite having developed an extensive health system infrastructure, there remain many challenges in delivering good quality services, notably a severe shortage of skilled health workers. The MOHSW is responsible for the provision of diagnostic services in collaboration with faith-based organizations, private-for-profit and NGOs. A National Laboratory Strategic Plan (2009 – 2015) was developed to give direction to the strengthening of laboratory services, and some encouraging improvements in laboratory services have been achieved in recent years.

Tanzania is one of the early adopters of the Xpert MTB/RIF assay, with among the highest number of Xpert MTB/RIF cartridges ordered to date[19]. However, many partners have been involved in the implementation, and national coordination of the roll out is needed.

FIND's work in Tanzania is focused on the following:

- Implement and pilot the use of Xpert MTB/RIF at two district hospital laboratories to provide evidence to inform development of national algorithm and implementation plan
- Provide assistance for development of the national TB diagnostic algorithm and Xpert implementation plan
- Support the Central Tuberculosis Reference Laboratory and provide mentoring for analysis of routine data from Xpert implementing sites for programmatic management
- Provide assistance and mentoring of local staff to implement a routine monitoring and evaluation (M&E) programme for Xpert MTB/RIF, including performance indicators and data for procurement planning
- Provide assistance and mentoring of local staff to implement a programme of regular calibration, maintenance and servicing of instruments to ensure a cost-efficient and uninterrupted service

Key Achievements

Diagnostics Implementation

- Xpert MTB/RIF implemented at two district hospitals: Temeke Hospital, Dar Es Salaam, and Iringa Hospital since April and August 2012, respectively
- Training of 7 staff (laboratory and clinical) conducted per site
- 3 GeneXpert instruments procured (2 at Temeke Hospital, 1 at Iringa Hospital)
- 9, 000 Xpert MTB/RIF cartridges procured for routine testing of HIV-associated and MDR-TB
- Report prepared on performance of Xpert MTB/RIF at the two sites

Quality Assurance

- Laboratory staff completed proficiency tests prior to routine implementation and instruments were verified using GLI validation panels
- Regular supervision visits to both sites were undertaken by Central TB Laboratory staff, using standardized monitoring checklist
- Extensive on-site supervision and assessment visits were conducted at a total of 13 Xpert sites, including data collection, implementation questionnaire and calibration of instruments
    - Data used for gap analysis and planning of M&E and maintenance programme development

Impact

Strengthening the coordination of the Xpert MTB/RIF testing network and implementing routine systems for M&E and other quality assurance activities will improve the efficiency, cost-effectiveness and quality of testing, bringing greater benefits to patients.

Ensuring quality-assured TB diagnostic testing

A comprehensive approach to Xpert MTB/RIF quality assurance

Quality assurance is a fundamental component in ensuring the quality of laboratory testing. However, in many settings despite well established international guidelines, QA is poorly and inconsistently implemented. Challenges include organization of site visits, feedback of recommendations to laboratories and support for quality improvement, as well as data management associated with these tasks. New technologies are not introduced into a vacuum, and quality assurance of new technologies must be integrated into existing systems in order to be done.

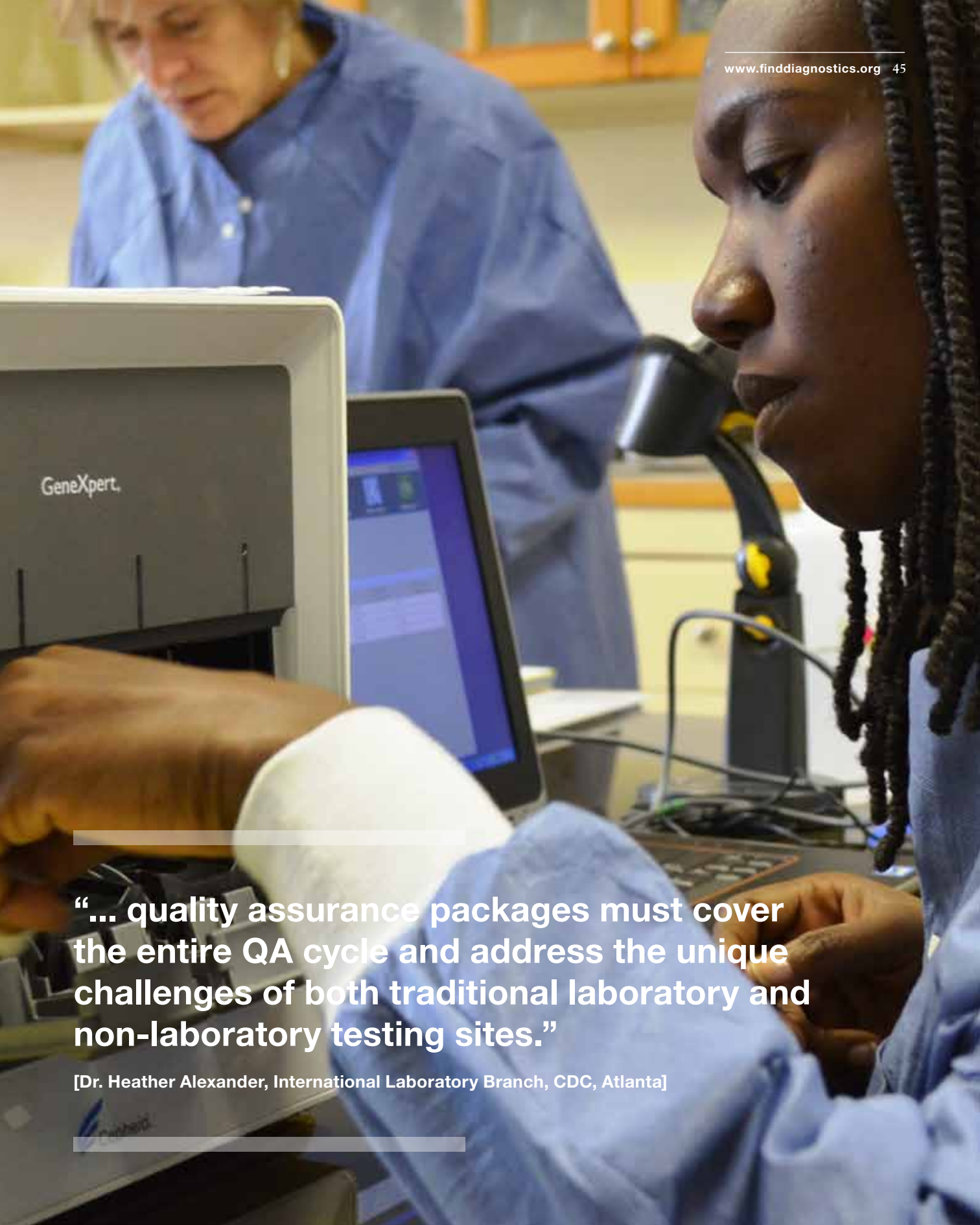
FIND has developed and is implementing standardized data collection tools for routine monitoring of Xpert indicators, and standardized checklists for on-site monitoring. Work is continuing to develop and field test guidelines and tools to improve routine Xpert quality assurance at country level. The most critical factor is finding innovative ways to ensure prompt and relevant feedback and assistance to laboratories to enable them to implement corrective measures.

The rapid scale-up of Xpert MTB/RIF in both laboratory and clinic settings should be coupled with appropriate measures to ensure the provision of accurate and timely test results. Working in close collaboration with the International Laboratory Branch at CDC, FIND is supporting a comprehensive approach to Xpert MTB/RIF quality assurance that incorporates standardized and systematic implementation of instrument verification; training and competency assessment; and routine monitoring of performance indicators, proficiency testing, and on-site supervisory visits.

Proficiency testing (PT) is one of the key components of a quality assurance scheme. Currently there is no international PT scheme for Xpert MTB/RIF. Based on CDC's expertise and experience in developing dried tube spots for rapid HIV proficiency testing, the TB team of the International Laboratory Branch at CDC Atlanta, headed by Dr. Heather Alexander, is taking the lead in developing and distributing an Xpert MTB/RIF PT panel. FIND is working to support piloting of this programme in a number of countries, including Tanzania, Lesotho and Vietnam. In addition, FIND is working with other partners, including CDC, to evaluate other alternatives for Xpert MTB/RIF PT, and more information on these activities is provided in the South Africa country report.

However, proficiency testing is but one component of a comprehensive quality assurance programme, and must be linked to routine monitoring of performance indicators, as well as regular on-site supervision visits by experienced laboratory staff, in order to be effective.

"… EQA is not meaningful if data are not collected and analyzed in a timely manner and sites are not provided feedback." **[Parekh, 2010][20]**



“... quality assurance packages must cover the entire QA cycle and address the unique challenges of both traditional laboratory and non-laboratory testing sites.”

[Dr. Heather Alexander, International Laboratory Branch, CDC, Atlanta]

Vietnam

Strengthening lab systems for effective adoption of new tools

Population	88 780 000	
Gross national income (GNI) per capita, 2012	$1400	LOW MIDDLE INCOME
HIV prevalence among adults aged 15-49 years	0.5%	HIGH HIV
TB incidence, per 100, 000 population	147	HIGH TB
HIV prevalence in incident TB cases	7%	
Estimated multidrug resistance (MDR-TB) prevalence (new and previously treated TB cases)	2.7%; 19%	HIGH MDR-TB

Timeline

Partners

Ministry of Health, Vietnam
LIFEGAP Vietnam
Centers for Disease Control and Prevention, Vietnam
Integrated Quality Laboratory Systems (IQLS)
Expand TB Programme

Activities

Every year in Vietnam approximately 150,000 people get TB, including up to 5,000 people with drug-resistant TB. HIV/AIDS in Vietnam to date has been concentrated among high risk populations, such as injecting drug users, and the HIV-TB co-infection rate is quite low at present in the general population. Vietnam's National Tuberculosis Programme has made strides towards addressing the TB and MDR-TB challenges. The laboratory network has also shown encouraging progress, with much evidence of the priority being placed on quality improvement initiatives and working towards accreditation, along with a number of partners.

FIND's activities in Vietnam have focused on strengthening the quality management system of TB diagnostics, both traditional (microscopy) and more advanced technologies (culture/DST and molecular testing). We have supported laboratories in improving quality systems, thereby preparing them for future accreditation, as well as developing, customizing and supporting implementation of electronic tools aimed at simplifying and improving management of quality systems and external quality assurance-related data.

"Every year in Vietnam approximately 150,000 people get TB, including up to 5,000 people with drug-resistant TB."

FIND has conducted the following activities:

- TB Laboratory Management Training to national and regional TB laboratories
- Strengthening TB Microscopy External Quality Assurance by introduction of an electronic database for blinded slide re-checking
- Introduction of an electronic TB-specific Laboratory Information Management System (LIMS)
- Provide assistance for the introduction of EQA panel testing for Xpert MTB/RIF
- Support of EXPAND-TB project implementing new TB diagnostics in Vietnam at 4 laboratories

Key Achievements

Diagnostics Implementation

- Liquid culture (2 labs), molecular line probe assay (2 labs) and Xpert MTB/RIF (4 labs) were introduced (together with **EXPAND-TB** programme), at National Reference Laboratory - National Lung Hospital, DaNang Lung Hospital, Pham Ngoc Thach Hospital, Ho Chi Minh City and Hanoi Lung Hospital
- A total of 559 LPA tests, 6, 074 liquid culture tests, and 842 Xpert MTB/RIF tests have been conducted for suspected MDR TB patients and treatment monitoring

Quality Assurance

- Electronic slide re-checking database has been implemented in 3 laboratories. Re-checking of more than 5000 slides from 49 peripheral labs has been completed. For more details see: **"From paper-based to e-data. Introducing electronic TB laboratory data management in Vietnam."**
- Xpert MTB/RIF proficiency testing was introduced at 22 laboratories in September 2013

Quality Management Systems

- A comprehensive **TB Laboratory Management Training** was developed and conducted by FIND in collaboration with CDC-Vietnam, LIFE-GAP Vietnam and IQLS. The training included participants from the National Reference Laboratory- National Lung Hospital and six regional reference laboratories, Hanoi Lung Hospital, National Lung Hospital K71, National Lung Hospital K74, Da Nang Lung and Respiratory Diseases Hospital, Can Tho Lung and Respiratory Diseases Hospital, Pham Ngoc Thach Hospital.
- Training was conducted in two parts (November 2011 and March 2012), with ongoing mentorship and on-site visits between the two workshops. Training included good management practices, workflow, TB biosafety, equipment maintenance, quality assurance, stock management, documentation, human resources.
- Measurable improvements were evident in all participating laboratories, and two laboratories have subsequently been accredited according to ISO 15189.

Impact

Significant improvements in TB laboratory quality management systems have been achieved, which are essential for the successful implementation of new technologies aimed at improving TB and MDR-TB diagnosis and care.

From paper-based to e-data

Introducing electronic TB laboratory data management in Vietnam

Vietnam is taking full advantage of modern electronic data management systems to improve its TB laboratory services and ultimately to bring benefits to the patients it serves.

Vietnam has an extensive TB laboratory network consisting of close to 900 laboratories performing smear microscopy. External quality assurance is fundamental in ensuring the quality of testing. Slides from peripheral laboratories are re-checked at a higher level laboratory. Timely re-examination of slides, feedback of results to laboratories, and implementation of corrective actions are challenging and a large amount of data handling is associated with all these steps. Vietnam's EQA programme has, until now, relied on paper-based recording and reporting.

Working with NTP, CDC Vietnam, and partner IQLS, we implemented TB Companion®, a modular electronic database for EQA programme management. It can provide rapid reporting, easy online data management, and has a single web database for an entire country, even where several regional rechecking centres are involved in the programme. TB Slide2Check®, the slide re-checking module of TBCompanion, was first implemented at Pham Ngoc Thach Hospital in August 2012 and then expanded to 2 more laboratories, Hanoi Lung Hospital and Danang Hospital for TB and Lung Diseases in March 2013. To date, the 3 laboratories have completed re-checking for 49 peripheral labs with a total of over 5,000 slides being re-checked using the system. The results show 99.62% concordance between the initial diagnostic results and the re-checked result. All three laboratories plan to continue use of the system, and FIND plans to support NTP in expansion to further laboratories in the coming year. Dr. Dang Thi Minh Ha, Deputy Lab Manager, Pham Ngoc Thach Hospital, Hoch Minh City, Hanoi, commented that *"If this software is implemented for NTP (National Tuberculosis Programme) it will help to endorse the results more rapid, confidential and generates the results more swiftly."*

Dr. Bao Thuyet, Lab Manager, Danang Hospital for TB and Lung Diseases, expressed the advantages of the system as *"... truthfulness, objectiveness, rapidness, avoidance of errors and mistakes ... it helps EQA activity gain better quality to support NTP."*

A second electronic data management system recently introduced in Vietnam is TBeLog® (IQLS), a simple and easy to use TB-specific Laboratory Information Management System (LIMS). This application can greatly reduce paperwork and workload, and simplify tracking and archiving of patient and sample information. The system enables easy analysis of TB patient data, laboratory performance indicators and reporting to the national program.

TBeLog® is currently being implemented in two laboratories, National Lung Hospital and Pham Ngoc Thach Hospital, which covers approximately 70% of TB patients in the country. TBeLog® was translated into Vietnamese and modifications to suit local requirements were made after initial piloting to facilitate its adoption.

Dr. Nguyen Van Hung, Head of NTP Lab Group, Head of National Reference Laboratory. National Lung Hospital, Hanoi, Vietnam.

"Accessing data more quickly which can help us to save time of lab operators and reduce workload of lab users. TBeLog allows analysis of TB patient data, quality indicators for laboratory and more useful for the national health program."

[Dr. Nguyen Van Hung, Head of NTP Lab Group, Head of National Reference Laboratory. National Lung Hospital, Hanoi, Vietnam.]

Aligning for accreditation

Tailoring Laboratory Quality Management Systems Strengthening to TB Laboratories

New diagnostic technologies can only be successfully implemented within a well-functioning laboratory system. FIND has used its considerable experience in implementing new TB diagnostics and building laboratory capacity in many diverse resource-limited settings as well as our success in implementing SLMTA (Strengthening Laboratory Management Towards Accreditation), to develop a unique approach to TB Laboratory Quality Management Systems strengthening. This approach is based on harnessing and aligning components of internationally recognized tools and established best practices to bring a specific focus on the needs of TB laboratories working towards accreditation.

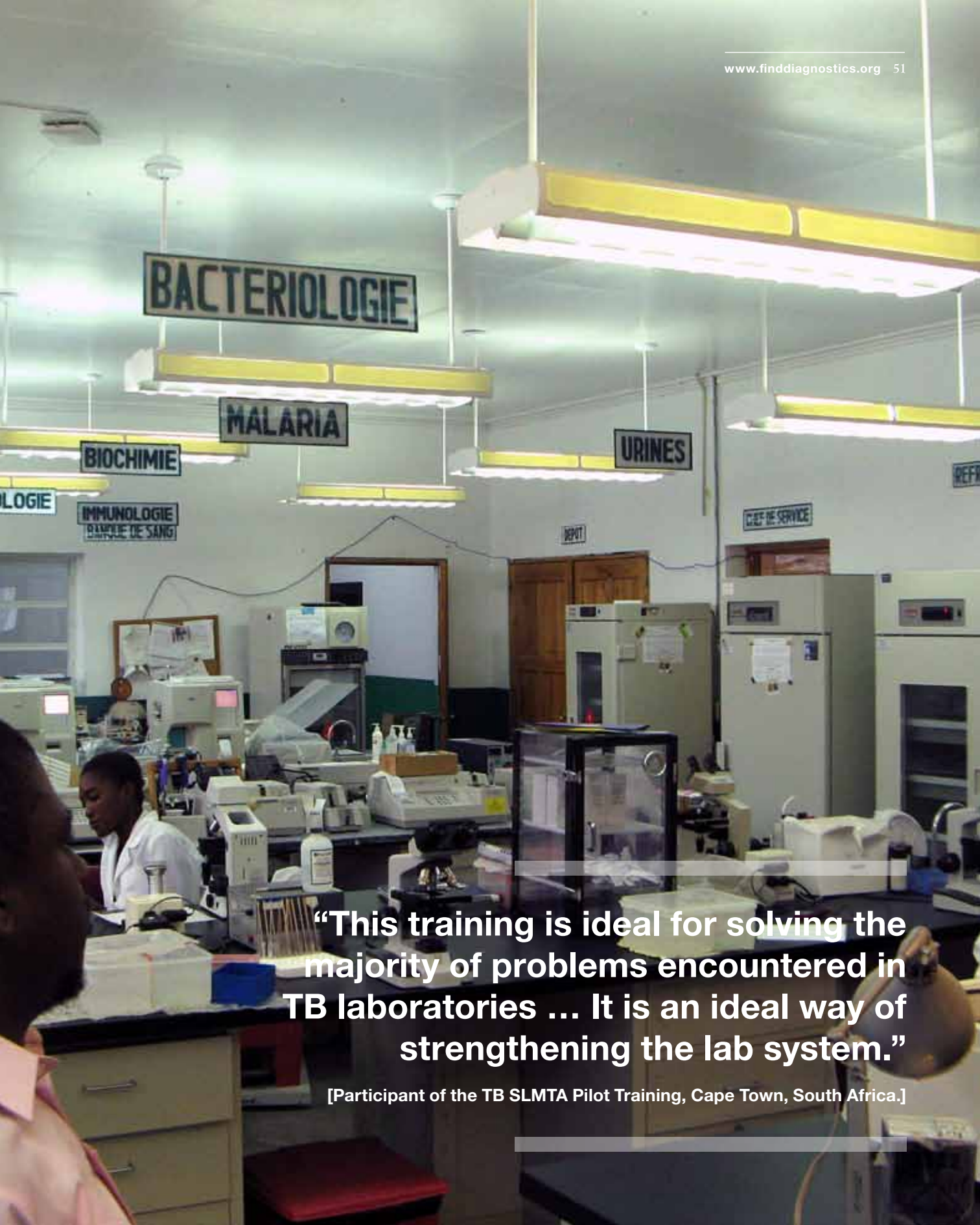
Key features of FIND's approach:

- Uses the task-based and highly interactive SLMTA-based training model
- Incorporates detailed TB technical guidance into a general quality systems approach
- Uses a modified WHO-AFRO SLIPTA checklist to measure baseline and track progress – allowing SLIPTA scoring and comparison of progress with non-TB laboratories
- Incorporates Global Laboratory Initiative (GLI) technical guidance for TB laboratories
- A highly structured approach with quality improvement projects, directly linked to ISO 15189 standard requirements
- Uses the best of internationally recognized tools to offer a tailored approach to TB laboratory strengthening

FIND has developed a TB SLMTA Training Programme – a modified version of the SLMTA programme, which includes TB specific modules and guidance (safety, sputum collection and transport) with TB specific activities, examples and tools, but following the successful SLMTA format and interactive, task-based teaching approach. FIND has also developed a TB Laboratory Quality Management Towards Accreditation Harmonised checklist – incorporating GLI TB specific checklist components into the SLIPTA checklist.

Development of FIND's approach was undertaken with a team of FIND staff and laboratory consultants in many varied settings, allowing us to incorporate a substantial body of practical experience. The TB SLMTA training was initially piloted in Cape Town, South Africa in April 2013, and the first African regional Training of Trainers took place in Lesotho in November 2013, funded by Expand TB and DFID and included participants from Tanzania, Lesotho, Rwanda, Cameroon, Kenya.

"… learning by doing, intense but rewarding, and certainly worth the investment in terms of time and effort." **[Feedback from participants of the TB SLMTA Pilot Training, Cape Town, South Africa.]**



"This training is ideal for solving the majority of problems encountered in TB laboratories … It is an ideal way of strengthening the lab system."

[Participant of the TB SLMTA Pilot Training, Cape Town, South Africa.]

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Christiane Elfman, Administrative Assistant (formerly)
Christophe Broggi, Chief Financial Officer
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Josefina Pimentel, Dominican Republic (formerly)
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Pamela Nabeta, Dominican Republic
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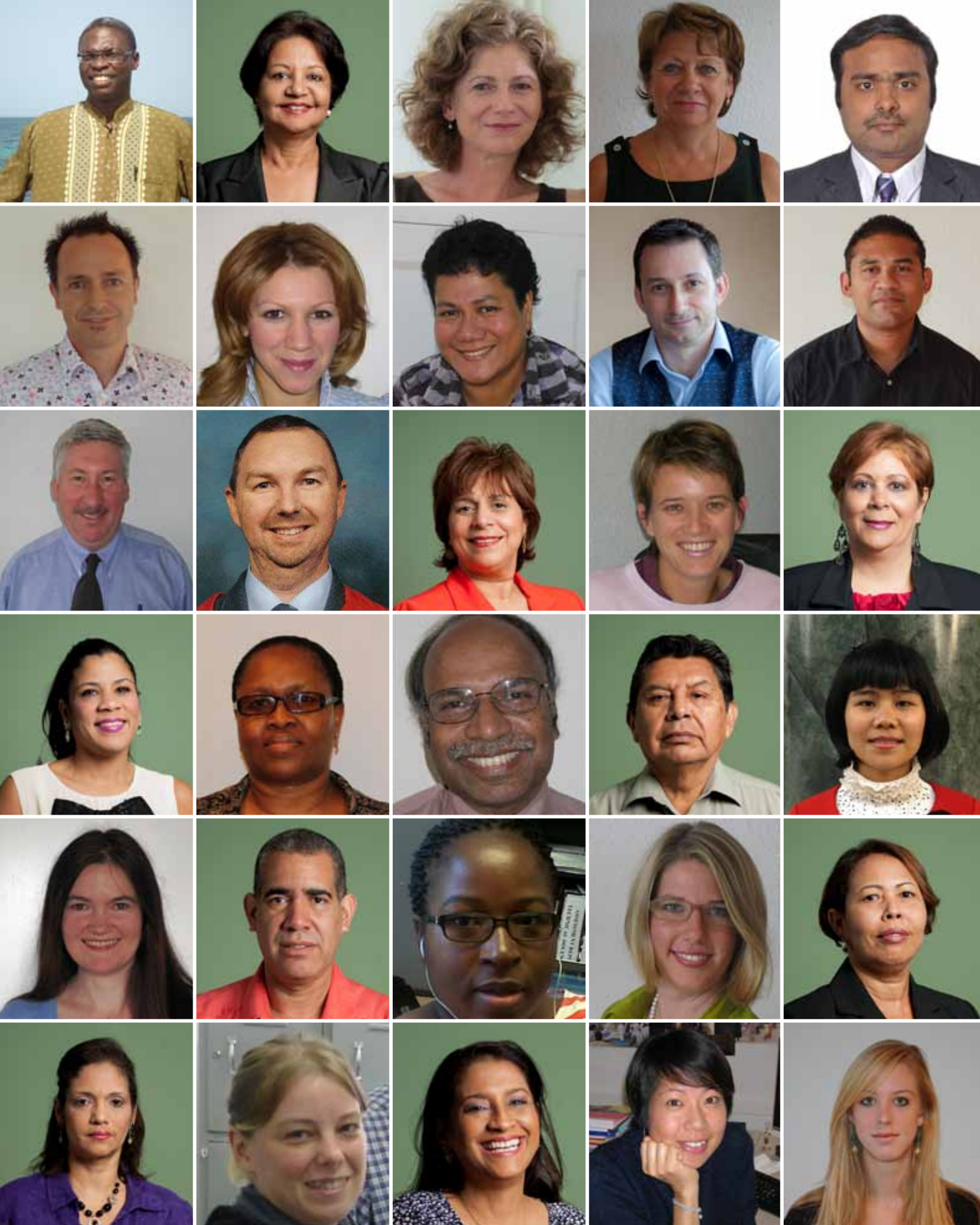
Partnering for better diagnosis for all



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www.finddiagnostics.org

Avenue de Budé 16 • 1202 Geneva • Switzerland • Tel.: +41 (0)22 710 05 90 • Fax: +41 (0)22 710 05 99