FIND INDIA

2015 ACTIVITY REPORT

FIND

Because diagnosis matters

2015 FOCUS

> *PARTNERING*
to increase TB case detection

> *STRENGTHENING*
India's laboratory capacity for diagnosing TB and DR-TB

> *REACHING*
the hard-to-diagnose, including children, with accurate diagnostics

> *COLLECTING*
evidence on new diagnostic technologies to inform policy and scale-up

2015 RESULTS

313,270 patients tested using newer diagnostic technologies across FIND-supported laboratories

21,646 multidrug-resistant TB cases diagnosed in 2015 through the EXPAND-TB project and…

81,162 cases detected from 2010-2015

302 laboratory personnel trained in new technologies for the diagnosis of drug-resistant TB

47 on-site training sessions conducted for laboratory personnel

LEADERSHIP MESSAGE

Dr. Sanjay Sarin

Head of FIND India

The past year has been one of change. One of the most marked was the departure of my predecessor, Dr Paramasivan, whose role I assumed in December of 2015 after he retired as the Head of FIND India. Dr Paramasivan, a dedicated and inspired leader, left me with a strong foundation upon which FIND India can continue to work to promote India's capacity to diagnose tuberculosis and drug resistance, and to strengthen India's contributions to research on diagnostic technologies and implementation strategies. I am honoured to have been given the opportunity to lead the FIND India office and am committed to continuing the fight against tuberculosis, in India and across the globe.

In addition to the leadership transition, 2015 marked the end of EXPAND-TB, an important five-year project funded by UNITAID, as well as the conclusion of complementary projects supported by the Global Fund. Through this work, FIND India in partnership with Revised National Tuberculosis Control Program (RNTCP) made significant progress in laboratory capacity building and implementation of tuberculosis diagnostics. In doing so, we increased access to multidrug-resistant tuberculosis testing, markedly improving case detection and reporting in target areas. We also learned important lessons and collected critical evidence that, taken together, will inform programme scale-up and policy-making.

As the world collectively pushes harder to end TB and recognizes the critical role of rapid and accurate TB diagnosis, we look forward to sharing the expertise and insights we have gained through these projects. We will be continuing our efforts in laboratory strengthening and expanding access to high-quality TB diagnosis through a new multi-year agreement with the Central Tuberculosis Division of the Indian Ministry of Health and Family Welfare, supported by the Global Fund. I am particularly excited about continuing our paediatric work. Our novel approach to the challenge of diagnosing tuberculosis in children has been a remarkable success and we are keen to continue to refine and magnify the reach of this initiative.

I am happy to report that FIND India has new legal status. We are now registered as a non-profit Section 8 company, which will allow us to broaden our activities and our commitment to promoting TB diagnosis in India.

As you read the report below, I hope you are as impressed with the year's outcomes as I am.

- Dr. Sanjay Sarin

PARTNERING TO TRANSFORM DIAGNOSIS OF MULTIDRUG-RESISTANT TB

From 2010 to 2015, FIND was the technical and implementing partner of India's Revised National TB Control Programme (RNTCP) for the nationwide laboratory network for drug-resistant TB diagnostic services. This initiative began in 2010 as part of the EXPAND-TB project with funding from UNITAID and was complemented with funding from the Global Fund.

The EXPAND TB project supported key diagnostic technology equipment, test kits, consumables and national trainings. The Global Fund provided the funds for laboratory infrastructure upgrades, equipment for enhancing diagnostic capacity, additional human resources in labs, on-site training, equipment maintenance and regional programme reviews.

The two projects have radically changed the MDR-TB diagnostic landscape for the RNTCP's Programme for the Management of Drug-resistant TB in India. From 2010 to 2015, the projects aided in setting up 46 labs with the line probe assay, 40 labs with liquid culture and 38 with GeneXpert. In addition to on-site training, two major national-level trainings were held on TB lab biosafety and TB lab management (see text boxes). Global Fund provided resources for the personnel that support day-to-day functioning of an additional 300 laboratories, including microbiologists, technical officers, lab technicians and data entry operators.

In 2015, a total of 313,270 people were tested for TB and 21,646 MDR-TB cases were diagnosed. From 2010-2015, a total of 81,162 MDR-TB cases were detected in these newly high-capacity labs.

NATIONAL-LEVEL TRAININGS

TB LABORATORY MANAGEMENT TRAINING

Managing a TB culture and drug susceptibility testing (C&DST) laboratory is a complex art, combining a thorough understanding of day-to-day operations with knowledge and experience in tackling the challenges of quality assurance, laboratory maintenance, biosafety, and the management of stock, samples, workflows, human resources and diagnostic data.

Covering all of these topics, a major TB laboratory management training was held in Hyderabad in December 2015. It was attended by microbiologists and technical officers nominated by the Central TB Division (CTD) from some 45 TB C&DST labs across the country. The training was facilitated by faculty from FIND, national reference laboratories, SHARE and senior faculty from TB C&DST sites in the country under the leadership of Dr C.N. Paramasivan.

TB LABORATORY BIOSAFETY TRAINING

The safe operation of diagnostic TB laboratories requires the implementation of modern biological safety (biosafety) standards. These standards are designed to protect laboratory personnel from infection in the lab as well as the environment outside the lab. A training on TB laboratory biosafety was held at the National Tuberculosis Institute in Bangalore in November 2015. This training was organized by the Central TB Division (CTD) with support from FIND. Microbiologists from 30 culture and drug susceptibility testing (C&DST) labs across the country participated.

The training included the specifics of biosafety in a TB lab, a risk-based grading system, lab design and maintenance, biosafety equipment for the lab as well as personal protective equipment, biohazardous waste management, safe transport and handling of biological samples, biosafety monitoring and surveillance, and the safety requirements of the Government of India's National Accreditation Board for Testing and Calibration Laboratories training was co-facilitated by personnel from the U.S. Centers of Disease Control & Prevention (Atlanta), FIND, and national reference and TB C&DST labs around the country.

"The value of laboratory trainings cannot be overstated. Only with capacity building of this nature will India have the ability to bring the TB epidemic under control."

- Dr Sanjay Sarin, Head of FIND India

EXPAND-TB

The EXPAND-TB (Expanding Access to New Diagnostics for TB) project began in 2009 to accelerate access to new, rapid diagnostic tests for patients with multidrug-resistant tuberculosis (MDR-TB) in 27 countries that represent 40% of the global MDR-TB burden. The project aimed to close the serious gap in case detection by building sustainable MDR-TB diagnostic capacity and integrating the new testing technologies into national TB programmes. Funded by UNITAID, this unique initiative was a collaboration between the World Health Organization (WHO), the Stop TB Partnership's Global Laboratory Initiative and Global Drug Facility, and FIND.

In India, the project started in 2010 and concluded at the end of 2015. During that time, the project built sustainable capacity to diagnose MDR-TB across the country with the newest rapid diagnostic technologies endorsed by WHO, including liquid culture and drug susceptibility testing, rapid speciation, line probe assay and Xpert MTB/RIF. The new diagnostic technologies were integrated into the national TB control programme and implemented in quality-assured laboratories by newly trained and monitored staff.

Drawing on its expertise in implementing laboratory services within the context of national TB control strategies, FIND worked with India's Revised National TB Control Programme in three phases: laboratory preparedness, technology transfer, and routine testing and monitoring. FIND was responsible for project management, including support for procurement and logistics, and provided training, expertise and tools to support the introduction and optimal use of the new TB tests.

FIND organized an end-of-project symposium in September 2015 attended by 123 delegates from India's Central TB Division, partner organizations, national and intermediate reference labs, and culture and drug susceptibility testing labs. Attendees assessed the results of their work to scale up MDR-TB diagnostic capacity, shared their experiences in quality assurance and maintaining an uninterrupted supply chain of essential equipment and lab commodities, and reviewed the transition plan for carrying the work forward with Global Fund and other partner support.

INTERNATIONAL CENTRE FOR EXCELLENCE IN LABORATORY TRAINING

To build the necessary additional capacity required to increase access to the diagnosis of TB and other major communicable diseases, FIND in collaboration with RNTCP established an International Centre for Excellence in Laboratory Training (ICELT) at the National Tuberculosis Institute (NTI) in Bangalore, which began operating in 2011.

ICELT provides national-level and on-site trainings for the implementation of new TB diagnostic technologies, including liquid culture and drug susceptibility testing, line probe assay and GeneXpert MTB/RIF. ICELT supported the following TB laboratory capacity-building activities in 2015:

- **NATIONAL-LEVEL TRAININGS**
  Revised training materials and facilitated TB lab biosafety training in Bangalore for 31 lab technicians in November 2015, and conducted TB lab management training in Hyderabad for 58 lab technicians in December 2015. One GeneXpert training for 22 laboratory staff was conducted in Delhi in March 2015.

- **TECHNICAL ASSISTANCE AT NATIONAL TUBERCULOSIS INSTITUTE**
  Provided faculty for lab trainings, including co-facilitation of two rounds of Central TB Division-led, comprehensive and integrated training on all TB diagnostics in June and August 2015 for 16 trainees and co-facilitated a five-day training on light-emitting diode fluorescence microscopy for 9 trainees in October 2015 in Bangalore.

- **ORGANIZATION OF WORKSHOPS**
  Supported a national workshop on second-line drug susceptibility training and evidence collection on drug-resistant TB for 20 lab technicians in September 2015, and reviewed the implementation plan for a study on the use of the line probe assay to assess drug resistance to second-line TB treatment.

- **ON-SITE TRAININGS**
  Facilitated 10 on-site trainings on new TB diagnostics in labs across India for 72 lab technicians.

- **PARTICIPATION IN MONITORING ACTIVITIES**
  Participated in Central Internal Evaluation of Andhra Pradesh in January 2015 and the Joint Monitoring Mission to review programme implementation and laboratories in Andhra Pradesh and Telangana in April 2015.

- **ASSESSMENT VISITS FOR COMMISSIONING OF THE LABS**
  Supported assessment visits for commissioning of the TB containment labs in Hyderabad and Vishakhapatnam and the cartridge-based nucleic acid amplification (CBNAAT) testing sites in Vijayanagaram and Warangal.

- **SUPPORT TO THE NATIONAL TUBERCULOSIS INSTITUTE**
  Provided ICELT lab premises for Programmatic Management of Drug-resistant TB lab activities when needed.

ROUTINE ON-SITE TRAINING IN NEW TB DIAGNOSTIC TECHNOLOGIES

FIND India routinely organizes on-site trainings in new diagnostic technologies, based on needs identified by the Central TB Division and national reference laboratories. Trainings are held for the staff of new laboratories and for the newly recruited or untrained staff of existing laboratories. Trainings are normally co-facilitated by the regional microbiologist or a senior microbiologist from a reputable lab, and a local facilitator who has been previously trained at the national level.

In 2015, FIND trained 302 laboratory staff at 47 labs as part of this programme to ensure that sites providing TB diagnosis have adequately trained staff. This work was funded by the Global Fund.

Area	Number of onsite trainings	Number of trainees
Line probe assay	13	83
Liquid culture and drug susceptibility training	26	159
Cartridge-based nucleic acid amplification test	08	60
Total	47	302

ACCELERATING ACCESS TO TB DIAGNOSIS & CARE FOR PAEDIATRIC PATIENTS

Paediatric TB accounts for some 10-15% of all TB cases around the world and is one of the top 10 causes of childhood mortality. However, paediatric TB is difficult to diagnose because infants and children are not able to produce the sputum sample required for testing, and the sensitivity of smear microscopy for the diagnosis of paediatric TB remains low. TB can also mimic many other common childhood diseases, including pneumonia, other respiratory infections and malnutrition.

In India, childhood TB is estimated to be about 10.2% of the total adult incidence. Recent studies have shown higher levels of drug-resistant TB than previously thought in India. The sensitivity of smear microscopy for the diagnosis of childhood TB remains low and the diagnosis of childhood TB in India continues to be based on clinical criteria, which has the potential for both under- and over-diagnosis. The WHO-endorsed Xpert MTB/RIF is a highly sensitive and specific diagnostic tool with a quick turn-around time and good results with regard to paediatric TB diagnosis. WHO has recommended that Xpert be used instead of conventional microscopy and culture as the initial diagnostic test in all children suspected of having TB.

In consultation with the Revised National TB Control Programme (RNTCP) of India and with funding support from USAID and the U.S. Centers for Disease Control and Prevention, FIND began implementing a new paediatric initiative in 2014 for the diagnosis of TB in children in Chennai, Delhi, Hyderabad and Kolkata, using Xpert MTB/RIF. This pilot project represented the first time in India that Xpert was being offered as the up-front test to diagnose TB in children. In 2015, FIND extended the project to five additional cities: Nagpur, Vizag, Surat, Lucknow and Agra.

The project was implemented in the public sector and also in the private health-care sector, where many patients seek medical care. A high-throughput Xpert lab was established in each of the four cities at RNTCP sites, and public and private health care facilities were provided with workshops to sensitize them to paediatric TB and ensure that children were referred for testing. Upfront Xpert-based diagnosis was offered to all children showing symptoms of pulmonary and extra-pulmonary TB from linked facilities, free of charge. Rapid specimen transportation and a reporting mechanism using email and SMS was established for same-day transportation and results reporting.

KEY PROJECT ACHIEVEMENTS IN 2015

- 17,870 suspected paediatric TB cases were tested using a high-sensitivity cartridge-based nucleic acid amplification test.
- More than 8 workshops, continued medical education sessions for clinicians and advocacy meetings were held across 4 project sites, reaching 487 providers and facilities.
- More than 1,434 TB cases were detected on Xpert, of which over 132 (9.2%) were diagnosed as MDR-TB.
- Of the total diagnosed TB cases, 87.3% are accessing treatment.

LOOKING AHEAD

...there are several important projects planned for the coming years. At the foundation of all projects is FIND India's commitment to continuing as a trusted partner of the disease control programmes of the Government of India, to build and sustain laboratory capacity in India. FIND will continue to support the Central TB Division to integrate new diagnostic technologies into the country's labs to increase the detection of TB and drug-resistant TB.

The UNITAID-funded EXPAND TB project and important complementary support from the Global Fund resulted in the establishment of a strong network of 46 TB culture and drug susceptibility labs throughout India and an increase in the detection of drug-resistant TB. FIND India looks forward to providing ongoing support to sustain these labs and to further augmenting India's lab capacity with the addition of 15 more liquid culture labs, all planned under a new grant through the Global Fund's new funding model.

In addition, over the next two years, FIND will support the Central TB Division to establish two genome sequencing facilities and support the accreditation of India's TB culture and drug susceptibility labs through the Government of India's National Accreditation Board for Testing and Calibration Laboratories.

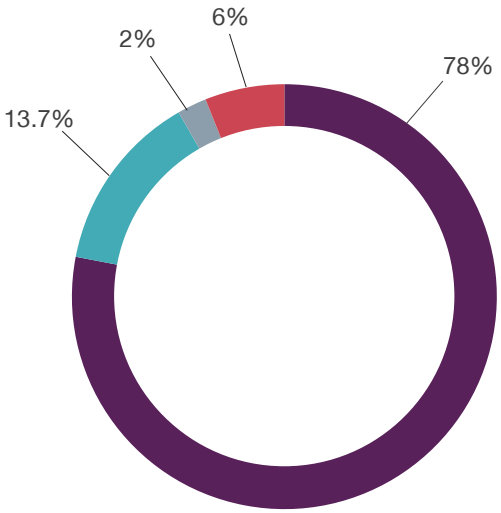
Also with Global Fund support, FIND and the RNTCP are implementing a study to validate a new test for drug resistant TB at five sites.

Expanding upon work in TB, FIND India is planning to support the assessment and use of hepatitis C diagnostics in the country's pilot screen-and treat-programs.

2015 KEY FINANCIAL INFORMATION

Expenditure 2015

	INR in lackhs	USD in thousands
Building laboratory capacity [The Global Fund]	2520	3923
Improving access to MDR-TB diagnostics [EXPAND-TB-UNITAID]	443	689
TB Challenge via Union	195	304
Indirect expenditure	72	113
Total	3203	5028



Expenditure 2012-2015

	2012	2013	2014	2015
INR in lackhs	3364	3236	3,79	3230
USD in thousands	6789	5752	5202	5028

ABOUT FIND

FIND was founded in 2003 to bridge existing development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector, and the in vitro diagnostics industry. Today, FIND is a leading partner across the value chain of diagnostics development and delivery. We have programmes in Tuberculosis and Acute Febrile Respiratory Infections, Malaria and Acute Febrile Syndrome, Hepatitis C, and Neglected Tropical Diseases. We also have mini-portfolios in areas affecting reproductive and child health: HIV; sexually transmitted infections; and infections and nutritional deficiencies in children under five years old. At FIND, we envision a world where diagnostics guide the way to health for all people. We aim to turn complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives. To do this we focus on four strategic goals throughout all the disease areas in which we work:

Catalyse development:

Identify needed diagnostic solutions and remove barriers to their development.

Guide use & policy:

Lead products through the clinical trials pathway to global policy on use and market entry.

Accelerate access:

Support uptake and appropriate use of diagnostics to achieve health impact.

Shape the agenda:

Improve understanding of the value of diagnostics and strengthen commitment to their funding and use.

FIND's Vision

A world where diagnosis guides the way to health for all people

FIND's Mission

Turning complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives

FIND India

Flat No. 6-14, 9th Floor, Vijaya Building,
17 Barakhamba Road,
New Delhi 110001
India

Tel: +91 (11) 40419500 - Fax: +91 (11) 40419577