



FIND INDIA ACTIVITY REPORT 2014



Because diagnosis matters

2014 FOCUS

- > **GENERATING**
evidence to guide scale-up
- > **DRIVING**
results through partnership
- > **EXTENDING**
diagnosis to more children
- > **STRENGTHENING**
capacity to reach the hardest to reach

226,674

*patients tested using newer diagnostic technologies across
FIND India-supported laboratories*

19,266

*DR-TB cases detected with FIND India's support along with
other partners – taking the cumulative total to:*

63,579 DR-TB cases detected from 2010 – 2014

6 LPA laboratories established, taking the 2010-2014 cumulative total to **41**

6 national training sessions conducted

36 onsite training sessions conducted

228 laboratory staff trained in newer TB diagnostics

FIND INDIA – PRIORITIZING TB DIAGNOSIS



Dr. C.N. Paramasivan
Head, FIND India and South-East Asia

Tuberculosis (TB) remains a major global health problem, with India reporting over a quarter of the global total. In India, more than 810,000 new TB cases go undiagnosed annually, which is a substantial proportion of the world's undiagnosed 3 million TB cases each year.

It has been a pivotal year for FIND India in extending our scope to reduce the TB burden across the country. We have seen significant increases in people reached, testing over 230,000 patients across FIND-supported laboratories, using a range of newer diagnostic technologies. This represents a 30% increase from 2013.

2014 has brought with it many challenges in the battle to control this disease, but we have also made great progress towards achieving our core aim – quality, timely and accessible diagnostic solutions.

A rapidly emerging global health threat of major concern in our field is antimicrobial resistance in the form of multidrug-resistant TB (MDR-TB) and extensively drug-resistant (XDR)-TB. This obstacle

is further intensifying the TB problem in India and, if not managed efficiently, will undermine global efforts and progress in TB control. Perhaps the most significant strategy to stem the tide of antimicrobial resistance is the effective engagement of India's extensive and highly fragmented private sector, which manages a substantial proportion of all TB patients, to complement public sector activities under the country's Revised National TB Control Programme.

Generating robust evidence to guide future scale-up

One of our major achievements this year has been our ability to confirm, through a large-scale study, that the use of the diagnostic test Xpert MTB/RIF significantly increases the number of TB cases detected and notified. These results underscore the potential for the test to revolutionize TB case detection in high-burden, decentralized, low-resource settings. We also found a five-fold increase in MDR-TB case notification. So health

care providers can now not only diagnose TB in less than two hours, they can also determine whether the patient has a form of TB that is resistant to the drug rifampicin. Our robust data in this area facilitated the development of workable policy guidelines by the TB control programme of India in the scale-up of testing with newer technologies.

Extending reach to more children

2014 also marked a milestone of great importance to our work – a FIND-initiated project using Xpert MTB/RIF exclusively for children and infants for the first time in India. TB is particularly difficult to diagnose in infants and children, which is why we are encouraged by the results. Our lab teams in four major sites across the country surpassed the targets in terms of the number of children with suspected TB tested. We saw a significant increase in detection rates compared with the use of smear microscopy. What does this mean for childhood TB? The ability to detect childhood TB with pulmonary and extra pulmonary manifestations with greater levels of accuracy, speed and reach is one of the top challenges identified in the roadmap for childhood TB, which sets the goal of achieving zero deaths for children. Here at FIND India we are pleased to be part of this critical global challenge.

Driving results through partnership

Thanks to the sustained support of EXPAND-TB, almost 20,000 MDR-TB cases were detected in India in 2014. As the main implementing partner of EXPAND-TB, we are encouraged with the significant scale-up of capacity to detect drug resistance.

The theme for World TB Day 2014 was “Reach the 3 Million”, with a particular emphasis on those who

are struggling with complex drug-resistant forms of the disease. Through the EXPAND-TB partnership, our work this year with WHO, USAID, CDC, UNION, PATH and others has enabled us to accelerate uptake and establish the know-how needed for correct use of TB technologies, playing an important role in this global fight.

Strengthening capacity & capabilities on the ground

Establishment of new laboratories and quality assurance across all sites, particularly in remote regions, are two key areas we have focused on to maximise the impact of diagnostic tools. There has also been a marked increase in the services offered at these labs, which has strengthened capabilities on the ground.

Ensuring we have highly skilled and well-trained staff across all labs in the country, our training activities continue to be of paramount importance. This year we concentrated on enabling and mobilizing laboratory staff primarily in the areas of analytical and quality assurance skills.

Looking forward

Looking forward, we are excited about the coming year where our priorities will focus on innovative interventions. These will include:

A connected diagnostics initiative – We will be placing a high priority on ensuring that tests are compatible with eHealth solutions and accompanied by supporting IT connectivity tools for safe, efficient and appropriate collection, storage and transmission of valuable diagnostic data. Connected diagnostics will strengthen rapid linkage of diagnosis to treatment and further care. The potential impact of this approach also reaches

beyond the care of the individual patient to include device management and health surveillance systems.

Laboratory Information Management Systems

– We will provide structured mentoring and training for laboratory quality control, focusing on sample tracking and electronic data exchange, particularly at peripheral sites. This will be linked to a nationally recognized software programme called NIKSHAY, which aims to establish real time reporting, recording and monitoring of TB patients.

Private-public partnerships – There is now greater and more diverse private sector engagement in diagnostics. In the coming year, FIND India will build bridges between partners to create efficient

partnerships in implementing new, quality-assured TB diagnostics in line with the public sector.

Transmission modelling – In the coming year, we will work with partners to assess the impact of diagnostics in reducing ongoing TB transmission, including MDR-TB.

Closing the gap on TB in India is a formidable task. Based on our performance in 2014, we are confident we are on track in making a substantial contribution and demonstrating the impact of diagnostics in TB control and patient health. With support from our partners, we will continue to participate fully in global TB control efforts, ensuring that India is equipped with the right tools and infrastructure to take on the challenge.



BUILDING A SOLID FOUNDATION FOR TACKLING CHILDHOOD TB

Childhood TB in the global spotlight

Globally, childhood TB accounts for approximately 10% of all TB cases. Childhood TB is an important cause of illness and death in children in many TB-endemic countries, and recent breakthroughs in diagnosis and treatment have put the childhood TB epidemic in the global spotlight.

TB is particularly difficult to diagnose accurately in infants and children for they often cannot expectorate the sputum sample needed for analysis. The diagnosis is also complicated because the bacteria can mimic many other common childhood diseases.

India carries the highest global burden for childhood TB. Going forward, diagnostic and treatment speed and accuracy is vital.

“Though there are no precise figures, at ICMR [India Council of Medical Research], there are 85,000 kids who are brought in with TB every year. We strongly suspect that the number of children who have TB and MDR-TB is twice as much as the current numbers suggest.”

Dr Soumya Swaminathan,
Director of National Institute for Research in TB (NIRT)

Partners:

- FIND India
- Revised National TB Control Programme (RNTCP) of India
- National Institute for Research in Tuberculosis (NIRT), India
- Funded by the United States Agency for International Development (USAID) and CDC Cooperative Agreement

FIND India played an important role in tackling childhood TB by spearheading a pilot project to chart a future course that will accelerate access to quality TB diagnosis for children across India. Launched in April 2014, the project covered four cities in India – Hyderabad, Chennai, Kolkata and New Delhi – and aimed to assess the feasibility of Xpert MTB/RIF testing for children under routine

programme conditions. The test also determines if the child has developed resistance to rifampicin, one of the first-line drugs used in TB treatment.

The first routine initiative of its kind, the project evaluated Xpert’s performance, monitored turnaround time for specimen transportation, tested and reported results, and assessed the diagnostic

yield on different types of specimens (sputum and non-sputum).

One of the key interventions under the project was intensified advocacy efforts for a public-private mix of individuals and organizations focused on paediatric health to ensure better uptake of services in all sectors. Efforts to roll out better quality diagnostic services were achieved under the project by reaching out to prominent health experts in the public and private sectors, policy makers and leaders from faith-based organizations, paediatric and corporate hospitals, medical colleges and large numbers of private paediatricians.

While making strides, we must capitalize on this experience and take forward advocacy efforts to ensure further roll-out. Replication of this model to other major cities to address the various challenges in paediatric diagnosis needs to be a priority.

In summary, this project:

- Conducted a robust pilot of a potential future model for scale-up

- Established high-throughput Xpert labs in each of four major cities, covering a total population of 14.3 million
- Conducted 45 stakeholder awareness and advocacy meetings
- Tested 9,300 children with TB symptoms, from birth to 14 years of age, free of charge
- Included testing on non-sputum samples in 49% of tests (first time the test has been extended to non-sputum specimens)
- Detected both pulmonary and extra-pulmonary manifestations
- Resulted in a three-fold increase in detection of cases over the less sensitive smear microscopy
- Found rifampicin resistance in about 10 % of bacteriologically confirmed TB cases, across all age groups
- Provided rapid door-to-door service to health providers – most specimens were transported, tested and results communicated on the same day via SMS or email to the paediatrician
- Linked all diagnosed TB cases to treatment free of charge in the public sector under the Revised National TB Control Programme or, in cases where patients' families opted for private care, to appropriate treatment in the private sector



PILOT PROJECT DEMONSTRATES LIFE-SAVING RESULTS



Three-year old Rehman is on the road to recovery from MDR-TB thanks to rapid and accurate TB test results that led to the right treatment in sufficient time to battle this potentially deadly disease. The boy, now happily back at home with his family in Mustafabad on the outskirts of Central Delhi, may have had a different outcome if not for the coordinated efforts of India's strengthened approach to detecting and notifying TB and MDR-TB, including in young children.

After a 10-day period of coughing and fever, Rehman's parents first took their little boy to see a local private doctor who prescribed medicinal syrup. Rehman took the syrup for approximately two months but showed no signs of improvement. Rehman's parents then took him to the paediatric department in nearby Kasturba Hospital where he received a blood, urine and tuberculin skin test – all of which revealed no significant findings. A further chest x-ray revealed miliary TB. To confirm this diagnosis, and in a coordinated effort to pinpoint Rehman's exact condition and treatment plan, the team at Kasturba Hospital took a gastric sample for analysis at the New Delhi TB Centre, one of the four centres across the country taking part in FIND India's Childhood TB pilot project. Gastric sampling is one testing method recommended for young children because it is difficult for them to expectorate a sputum sample.

Rehman's sample tested negative on direct smear examination, but when tested using Xpert MTB/RIF it was positive for TB and for rifampicin resistance. The speed and accuracy of the diagnosis were critical for

rapidly initiating Rehman on the correct treatment for his drug-resistant TB.

The results were sent to the treating doctor at Kasturba Hospital on the same day that Rehman was tested.

Rehman was put on a category IV treatment regimen consisting of intensive and continuation phases. He spent one month in hospital and after showing signs of improvement, he returned home to continue his treatment at a local treatment centre near Mustafabad. This centre works with patients to ensure they complete therapy to cure, and to prevent ongoing transmission of MDR-TB in the community.

Rehman is no longer showing any symptoms but will continue with the treatment as long as required to ensure a complete cure. All services extended to Rehman and his family were provided free of charge as part of the country's national TB control programme.

Among notified cases, 26,000 people died from MDR-TB in India in 2013. The success of Rehman's case can be attributed to accurate and reliable drug susceptibility testing, quick turnaround times and efficient communication between medical teams, effective treatment regimens and support in the community to ensure complete treatment. With prompt and appropriate diagnosis, treatment and care, MDR-TB can be cured.



> In 2014, a total of 226,674 patients were tested using newer diagnostic technologies across FIND India-supported laboratories.

GENERATING ROBUST EVIDENCE TO GUIDE FUTURE SCALE-UP

Reaching remote locations

Reaching, diagnosing and notifying TB cases in a country as diverse as India is a challenge. Physical access is a difficult task in densely populated urban areas, and this is compounded when faced with the difficulties of distance, rough terrain and sparse populations. The population of India is 68% rural. Some of the highest rates of TB in the country have been reported among remote tribal communities, and the health status of these marginalised groups is in need of targeted attention.

Closing the gap on missed cases

According to WHO's Global Tuberculosis Report 2014, India tops the list of the world's missed TB cases with 24% of the global total, and this number is growing every year. "Missed" is the gap between the estimated number of people who became ill with TB in a year and the number of people who were notified to national TB programmes. Some of the barriers to TB case notification include:

- weaknesses in recording and reporting within the public health system
- poor linkages with private practitioners, hospitals and labs
- mandatory case notification not enforced
- lack of adequate training

Partners:

- FIND India
- World Health Organization
- Government of India's Central TB Division
- Funding support from USAID

Use of Xpert MTB/RIF in decentralized public health settings and its effect on pulmonary TB and MDR-TB case finding in India

Innovative solutions are needed to address the challenges of reaching remote locations, engaging the private sector, tackling drug-resistant TB and closing the gap on missed cases. Through a

large-scale study, FIND India focused substantial attention this year on confronting these challenges. The study shows that the use of Xpert MTB/RIF as the initial test for TB in public health facilities in India significantly increases the number of TB cases detected and notified.

Over 100,000 patients took part in the study in 18 geographically and demographically diverse TB programme sites across India, including eight rural

sites and four sites in sparsely populated and hard-to-access tribal areas. Results showed an increase in case notification rates of all bacteriologically confirmed TB by 39% and a five-fold increase in rifampicin drug-resistant TB (DR-TB) case notification.

The study aimed to assess, under routine programme conditions, the impact of Xpert MTB/RIF for its ability to reduce detection time, replace current smear microscopy test methods and deliver additional data on drug sensitivity.

Current test methods are too complex for routine, widespread implementation in India. The study underscores the potential for the use of Xpert MTB/RIF to transform TB case detection in high-burden, decentralized, low-resource settings.

The study is also the first large-scale attempt to offer universal drug susceptibility testing (DST) to all suspected TB cases in the public sector in India and demonstrates the potential impact of this strategy to detect drug-resistant and multidrug-resistant TB cases.

With this test, health care providers can diagnose TB in less than two hours and at the same time determine whether the patient has a form of TB that is resistant to the commonly used TB drug rifampicin.

The robust data from this study facilitated the development of workable policy guidelines by the TB control programme of India in the scale-up of testing with newer technologies. The study represents a milestone for TB diagnosis and care in India and, with further scale-up, has the potential to have a global impact, considering the size of the country's TB burden.



STRENGTHENING DIAGNOSTIC CAPACITY & CAPABILITIES ON THE GROUND

Battling TB on such a large scale requires solid partnerships between government, funding and technical agencies. FIND India is proud to be working with partners to build capacity across the regions. First and foremost, implementing and integrating new diagnostic technologies can only be successful in a well-functioning laboratory system with a trained workforce of health professionals.

FIND India has strengthened laboratories across the country by taking part in a massive expansion of laboratory services, now providing more than 300 FIND laboratory staff. The year saw the establishment of six more line probe assay (LPA) labs (now a total of 41) and seven more liquid culture labs (now a total of 30). This initiative is supported by The Global Fund to Fight AIDS, Tuberculosis and Malaria and works in partnership with the Revised National Tuberculosis Control Programme (RNTCP) in India.

EXPAND-TB

The EXPAND-TB (Expanding Access to New Diagnostics for TB) project is a collaboration between the World Health Organization (WHO), the Global Laboratory Initiative (GLI), FIND and the Stop TB Partnership Global Drug Facility (GDF), funded by UNITAID.

EXPAND-TB was set up to accelerate access to rapid diagnostics for patients at risk of MDR-TB in 27 countries. India is now on track to reach the 2015 targets for reductions in TB prevalence and mortality. Based on data from the latest WHO Global TB report, 75% of all MDR-TB cases reported in 2014 in India were diagnosed in laboratories supported by EXPAND-TB. The aim of the project is to diagnose more than 100,000 patients with DR-TB by the end of 2015.

“The EXPAND-TB project is critical for scaling up the capacity to detect TB drug resistance. It has also laid the groundwork for rapid uptake and proper use of future diagnostic innovations that are urgently needed to effectively fight TB and drug resistance. Continued commitment from the global health community in support of new tools, especially point-of-care diagnostics, should remain a high priority.”

Dr Catharina Boehme,
FIND's Chief Executive Officer on World TB Day, 2014

“We need to ensure that diagnostics are accessible and closer to people. This project is a successful multi-partner strategic approach where diagnosis, treatment capacity and medicines supply have been linked together, showing the path for a stronger fight against MDR-TB”

Dr Joel Keravec,
Global Drug Facility Special Advisor

Triyambakesh Mohanty

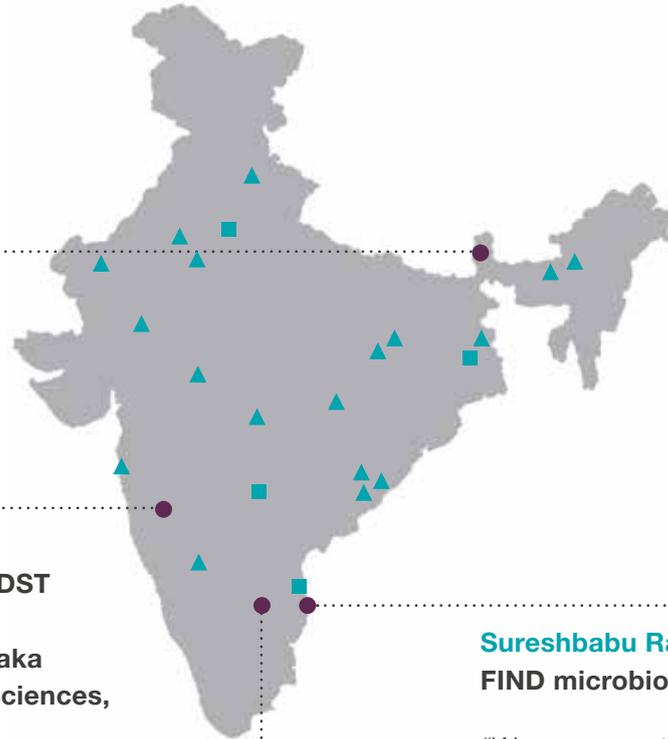
FIND microbiologist, C&DST Laboratory, Siliguro, North Bengal Medical College

“This year, I’ve received further training and I’m able to work confidently with the newer TB diagnostic tests. This has enabled me to contribute towards early and improved detection compared with the conventional techniques I’ve used in the past.”

Dr. C.N. Paramasivan

Head, FIND India and South-East Asia

“The four-site childhood TB study tested 9,300 children with TB symptoms from birth to 14, and more than 99% of the suspects received valid results.”



M. K. Anand

Technical Officer, C&DST Laboratory, Dept. of Microbiology, Karnataka Institute of Medical Sciences, Hubli, Karnataka

“It is encouraging to see more people from rural and remote places benefitting from newer diagnostic techniques.”

Sureshbabu Ramalingam

FIND microbiologist, IRL Chennai

“We are currently processing around 1,000 specimens per month, and with the latest rapid technology we are diagnosing more DR-TB patients than ever before.”

Dr. C.N. Paramasivan

Head, FIND India and South-East Asia

“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 (ICELT) at the National Tuberculosis Institute in Bangalore has met this need through specially designed hands-on practical courses for senior and mid-level line managers, and front line laboratory staff of RNTCP. This year, FIND India has supported the second-line DST training at ICELT, keeping in line with the country’s plan for a universal DST facility for TB and DR-TB.”

Dr. Neeraj Raizada

Medical Officer, FIND India

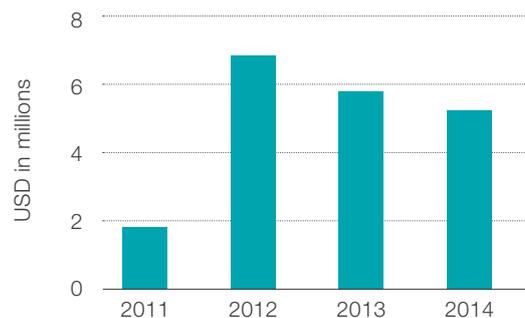
“Over 100,000 patients took part in the study in 18 geographically and demographically diverse TB programme sites across India, including eight rural sites and four sites in sparsely populated and hard-to-access tribal areas.”

2014 KEY FINANCIAL INFORMATION

Expenditure 2011-2014

	2011	2012	2013	2014
INR in lakhs	869	3,364	3,236	3,179
USD in thousands	1,826	6,789	5,752	5,202

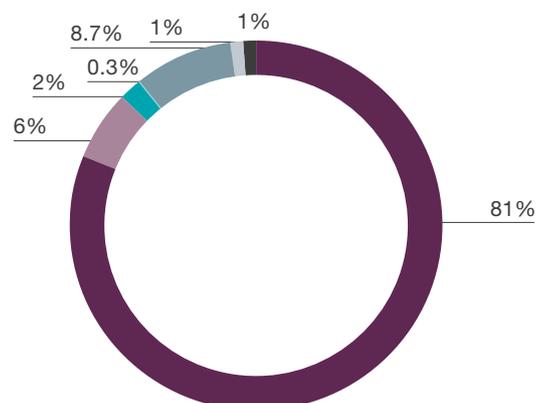
Expenditure includes activities conducted in India, funded by FIND India and FIND headquarters in Geneva.



Expenditure 2014

	INR in lakhs	USD in thousands
■ Building laboratory capacity [The Global Fund]	2,554	4,179
■ Demonstration of feasibility of Xpert use in India [USAID-PATH]	195	318
■ Demonstration of feasibility of Xpert use in India [WHO]	65	106
■ Demonstration of feasibility of Xpert use in India [TB Challenge Via Union]	9	15
■ Improving access to MDR-TB diagnostics [EXPAND-TB-UNITAID]	278	455
■ Lab strengthening & quality assurance for diagnostics [CDC]	36	60
■ Indirect expenditure	42	69
Total	3,179	5,202

Expenditure includes activities conducted in India, funded by FIND India and FIND headquarters in Geneva.





**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



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