

FIND INDIA

2016 ACTIVITY REPORT



2016 FOCUS

PARTNERING

to increase TB case detection

REACHING

the hard-to-diagnose, including children, with accurate diagnostics

EXPANDING

our focus to diagnose and treat hepatitis C

STRENGTHENING

India's laboratory capacity for diagnosing TB and DR-TB

COLLECTING

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

2016 RESULTS

254,223 patients tested for TB and drug-resistant TB using newer diagnostic technologies across FIND-supported laboratories

35,627 presumptive paediatric TB cases tested

14,692 cases of multidrug-resistant TB detected at FIND supported sites, more than 1/3 of all cases detected in India

2,512 paediatric TB cases diagnosed, of which 225 were Rif resistant

53 continuing medical education (CME) sessions on managing paediatric TB conducted for a total of 2,739 healthcare providers

16 on-site training sessions conducted for laboratory personnel

LEADERSHIP MESSAGE



Dr Sanjay Sarin
Head of FIND India

2016 was a year of new beginnings for FIND India

In my first full year as the Head of FIND India, I was inspired by the dedication of our team and our partners in the fight against tuberculosis, hepatitis C (HCV) and other diseases.

In 2016, we renewed our commitment to support national and local efforts to build ever greater capacity for TB diagnosis, and to fight antimicrobial resistance by ensuring better, more rapid diagnosis of drug-resistant TB. Through our collaboration with the Global Fund in their new funding model, we will be able to scale up our activities in building TB laboratory capacity and implementing high-quality diagnostics by developing an additional 15 liquid culture and DST labs, introducing second line LPA testing and developing genome sequencing capabilities within the Revised National Tuberculosis Control Programme (RNTCP).

We continue to ensure uninterrupted service delivery through the existing network of 46 RNTCP laboratories, on-site training and maintenance of laboratory equipment. We also continue to successfully scale up our paediatric TB initiative by expanding access to more than 35,000 presumptive paediatric TB patients and, more importantly, have developed an operational service delivery model for replication within programme settings.

In 2016, FIND signed a new agreement with Unitaid to unlock the hepatitis C diagnosis and treatment market in India, a country with more than 7.5 million HCV infected individuals. As part of this project, we aim to bring new and simpler HCV tests to the market, establish innovative models for screening and treatment in HIV/HCV co-infected patients and increase the affordability of HCV testing. I am excited that the project will contribute to policy change at global and national levels, and help pave the way for a public health approach to HCV, integrated into HIV programmes, to maximize cost-efficiency.

Let me take this opportunity to thank you – our partners, donors and staff – for your unshakeable resolve to ensure that every patient has access to life-saving diagnostics. Our work would not be possible without your support and collaboration.

In this activity report, you will find some highlights of FIND's innovative work in India. I am proud to share with you what we achieved with our partners during this year!



ACCELERATING ACCESS TO QUALITY TB DIAGNOSIS AND CARE FOR PAEDIATRIC PATIENTS

Childhood tuberculosis (TB) is difficult to detect. Children often have trouble producing sputum, which is required for most TB tests. TB also causes symptoms that are similar to many common childhood diseases, including pneumonia and other respiratory infections.

The existence of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) is well documented in the paediatric age group. However, it is difficult to estimate how many children are infected – partly due to the diagnostic challenges and also because children are not included in most drug resistance surveys. Globally, children make up 10% of all TB cases,

and the proportion of children among new TB patients reported in India was 6% in 2016.^{1,2} Cases of drug-resistant TB are also on the rise among children.

Since 2014, FIND has been partnering with the Revised National TB Control Programme of India (RNTCP) to put into place a novel paediatric initiative for the diagnosis of TB in children in four cities: Delhi, Kolkata, Chennai, and Hyderabad. The project, funded by USAID and the U.S. Centers for Disease Control and Prevention (CDC), uses WHO-endorsed Xpert MTB/RIF (Cepheid Inc.), known in India as cartridge-based nucleic acid amplification test (CBNAAT). This test responds to the challenges of diagnosing paediatric TB, namely the inability of children to produce sputum and the low sensitivity of smear microscopy in paediatric TB diagnosis. CBNAAT is a highly sensitive and specific diagnostic tool with a quick turn-around time and reliable results. WHO has recommended that CBNAAT be used instead of conventional microscopy and culture as the initial diagnostic test for all children presumed to have TB.

Following the success of the project, five additional cities were added in 2016 under Challenge TB, with funding from USAID: Vizag, Guwahati, Surat, Bangalore and Nagpur. In 2017, the project will be expanded to include the city of Indore.

The project has been ground-breaking on many fronts. For the first time, CBNAAT was offered as an upfront and free-of-charge diagnostic test for all children with symptoms of pulmonary and extra-pulmonary TB who were referred from participating facilities. In addition, the project marked the first time that a large proportion of extra-pulmonary specimens were routinely tested. Rapid specimen transport and a reporting mechanism using e-mail and SMS were also established, and more than 90% of healthcare providers received their patients' test results in less than 24 hours.

In order to reach the highest number of paediatric TB patients, FIND aims to build diagnostic capacity in both the public and private sectors in the target cities. A total of 4,953 providers were contacted, and 957 of these became linked to the RNTCP to receive training for initiating patients on appropriate treatment regimens. Of the engaged providers, approximately 59% were from the private sector. Additionally, 53 workshops and continued medical education (CME) sessions on managing paediatric TB were conducted by FIND across nine project sites, reaching 2,739 providers.

LOOKING AHEAD

Given the success of this pilot project, FIND is now working to ensure sustainability. While the project continues to expand to new sites, ownership and management of the project has been transferred to the Government of India at established sites. FIND is working with project sites to ensure a smooth transition of current activities, responsibilities and logistics to the RNTCP, which will be finalized by the end of 2018.

FIND is in the process of analysing the data from the project and publishing the findings. We will also work to broaden the scope of CME to include other aspects of the clinical management of paediatric TB, including specimen collection and treatment regimens.

Key project achievements in 2016

- 957 providers engaged, of which 59% were from the private sector
- 35,627 suspected paediatric TB cases were tested using a high-sensitivity cartridge-based nucleic acid amplification test
- More than 2,500 TB cases were detected on CBNAAT, of which over 9% were diagnosed as MDR-TB
- 91.8% of specimen results were reported within 24 hours of receiving samples, thus facilitating early access to treatment
- 86% of the total patients diagnosed with TB were able to access treatment

1. World Health Organization. 2017. Bending the curve - ending TB: Annual report 2017. World Health Organization, Geneva, Switzerland. Available at: <http://apps.who.int/iris/bitstream/10665/254762/1/978929022584-eng.pdf>

2. Central TB Division, Directorate General of Health Services. 2017. TB India 2017 Revised National TB Control Programme annual status report. Directorate General of Health Services, New Delhi, India. Available at: <http://tbcindia.gov.in/WriteReadData/TB%20India%202017.pdf>

PROVIDING UNIVERSAL ACCESS TO DRUG-RESISTANT TB (DR-TB) CONTROL SERVICES & STRENGTHENING CIVIL SOCIETY ENGAGEMENT IN TB CARE & CONTROL

In 2016, FIND began scaling up its support of India's 46 TB culture and drug-susceptibility testing laboratories. This Global Fund-financed work will continue through 2017 and enables FIND to build lab capacity within the RNTCP for high quality, rapid diagnosis of patients suspected to have TB or DR TB. This partnership builds on FIND's long-term commitment to support the Government of India's efforts in TB control, specifically through the introduction of innovative diagnostic technologies in national reference laboratories and intermediate reference laboratories.

Also in 2016, FIND-supported sites performed a total of 254,223 TB tests and diagnosed 14,692 cases of MDR-TB, more than 1/3 of all 42,106 MDR-TB cases reported in India. One key area of work in 2016 was to strengthen maintenance and inventory management in India's TB laboratories to ensure reliable and uninterrupted service delivery. FIND also negotiated comprehensive contracts for the annual maintenance of equipment and the provision of spare parts for 52 laboratories certified for culture and DST and/or line probe assay (LPA).

FIND worked with the RNTCP to update the 2008 technical specifications for equipment and laboratory consumables for intermediate reference laboratories and microscopy centres and developed additional, detailed technical specifications for TB Containment facilities, which included technical specifications for 49 types of equipment and 219 consumables.

Alongside this, FIND began upgrading 15 laboratories with TB containment infrastructure to enable liquid culture and drug susceptibility testing (LC-DST). This involves conducting needs assessments of each site in conjunction with the Central TB Division (CTD), National Reference Laboratory (NRL) and state teams. This included creating detailed lab layouts, listing additional equipment requirements and developing action plans for service delivery.

FIND is working to enhance quality management systems in 15 TB LC-DST laboratories, selected jointly with the CTD. FIND organized a meeting with participants to address challenges from a quality management systems (QMS) perspective and assisted the sites in developing plans to bridge the identified gaps. To execute this, FIND created a checklist which will be used for site assessments and to identify gaps in quality management going forward. Preparatory support was also provided to seven of the 15 facilities that are applying for accreditation through the National Accreditation Board for Testing and Calibration Laboratories, which regulates ISO 15189 certifications in India.

Technical capacity building for personnel from the State and National laboratories was carried out in collaboration with the CTD and NRL to perform high quality TB and MDR-TB testing. In the past two years alone, 63 trainings have been conducted, with a total of 407 laboratory personnel trained. These sessions included trainings for CBNAAT use, LC-DST and LPA.

Under this project, FIND is supporting the development of six genome sequencing facilities, which will be used for surveillance purposes and for mapping epidemiological patterns of TB strains prevalent in the country.

LOOKING AHEAD

FIND will co-facilitate an ‘Internal Auditors and Quality Management Systems’ training for 31 participants from the TB LC-DST laboratories, with the intention of further institutionalizing QMS practices.

FIND will also continue upgrading the 15 selected sites for LC-DST and six of these will be equipped to become regional storage facilities. Six genome sequencing sites are expected to be up and running by the end of 2017, and seven TB LC-DST labs will have submitted their application for ISO 15189 accreditation with the support of FIND.

In addition, FIND is developing a laboratory information management system (LIMS) software to facilitate the recording and reporting of TB/DR-TB cases. This will complement and connect with Nikshay, India’s online case-based reporting system. The LIMS developed by FIND will help strengthen the internal processes within labs to increase efficiency and reduce the time spent on data analysis and monitoring the flow of samples. The LIMS will be

implemented in more than 60 TB LC-DST labs in 2017 and is expected to be used for all future TB LC-DST labs providing services within the RNTCP.

FIND will provide the initial technology, expertise and training needed to connect the existing 629 CBNAAT devices in the public sector (and all other new machines to be installed under RNTCP), as well as the support and maintenance for a period of 12 months. After this time, the Ministry of Health is expected to take full ownership of the project with the support of USAID.

Going forward, the RNTCP’s action plan includes active case finding within key populations, especially those susceptible to contracting TB. With the support of the Global Fund, FIND will procure more than 40 fabricated mobile vans and equip them with CBNAAT machines to enable the CTD to carry out active case finding drives.

	Number of tests performed in 2016	Number of MDR-TB cases diagnosed in 2016
Line probe assay	102,313	12,441
Liquid culture	133,103	NA
Liquid culture and DST	18,807	2,251
Total	254,223	14,692*

* Number of MDR-TB cases detected at FIND-supported sites. A total of 42,106 MDR-TB cases were reported in India in 2016 overall.

ENABLING RAPID DRUG SUSCEPTIBILITY TESTING

Under the Global Fund grant, FIND India and the RNTCP undertook a study to validate the use of molecular diagnostic platform GenoType MTBDRs® (Hain Lifescience) to detect resistance to second-line TB drugs. The DNA-based test uses LPA to rapidly identify genetic mutations in MDR-TB strains that are resistant to fluoroquinolones and injectable second-line TB drugs.

In 2016, a total of 1,257 DNA samples from DR-TB cases at five sites were analyzed with both LPA and LC-DST. Results from 1,166 samples were included in the study.

LOOKING AHEAD

Preliminary results are promising and the data from the study in India is expected to be published in 2017. After reviewing the interim results of the study, as well as WHO recommendations,³ the RNTCP plans to include second-line LPA with LC-DST in their diagnostic algorithm for drug-resistant TB.



3. World Health Organization. 2016. The use of molecular line probe assays in the detection of resistance to second-line anti-tuberculosis drugs. World Health Organization, Geneva, Switzerland. Available at: <http://www.who.int/tb/publications/policy-guidance-molecular-line/en/>

ENSURING HIGH QUALITY MOLECULAR TB TESTING

In India, CBNAAT has proven to be an effective tool in providing high quality and decentralized molecular testing for TB. Currently, 628+ laboratories are using CBNAAT in the public sector and 200 in the private sector, with more than 500 sites added in 2016 alone. At this scale, machine maintenance is an essential part of continued accurate diagnosis.

External quality assurance (EQA) is an important process that can help identify problems with devices early and give healthcare providers the support they need to correct the issues promptly. Proficiency testing is an important component of EQA and guarantees accurate and reproducible results. These measures ensure that high quality testing can be carried out efficiently and without interruption.

In 2016, the Central TB Division (CTD) organized a workshop with FIND India, the CDC and SHARE India to discuss the development and scale-up of EQA mechanisms for CBNAAT in the public sector. A key outcome of this meeting was the initiation of proficiency panel production. Two microbiologists (one from FIND, the other from the National Tuberculosis Institute (NTI)) were trained at International Laboratory Branch of CDC in Atlanta in manufacturing proficiency testing panels for CBNAAT using dried tube specimen technology. After the training, the microbiologists started manufacturing panels at NTI, providing support to enhance CBNAAT EQA.

LOOKING AHEAD

In-country capacity for manufacturing panels will be further strengthened by training additional staff members at NTI Bangalore with help of the International Laboratory Branch of CDC. Under the guidance of the CDC, NTI and FIND, a phased implementation of the CBNAAT EQA is planned for 2017.

Through the TB REACH partnership, to address the EQA for CBNAAT in the private sector, FIND is developing a comprehensive set of quality assurance tools for CBNAAT machines. The package will build local capacity for CBNAAT proficiency test panel production and programme implementation that can be scaled up in laboratories across all sectors (including the private sector) by the RNTCP.

FIND will provide a structured approach to quality assurance, including standardized assessments, on-site mentoring and monitoring of quality indicators. The package will be free of charge and customizable, and will be piloted in 20 private sector labs to guide the national scale-up of EQA in India.

UNLOCKING THE HEPATITIS C DIAGNOSTICS & TREATMENT MARKET IN INDIA



FIND is the lead partner on a multi-year, six-country hepatitis C (HCV) project funded by Unitaid to build an efficient and sustainable public health response to HCV. The goal of the project is to contribute to WHO 2030 targets for HCV: a 90% reduction in incidence, a 65% reduction in mortality and 80% of patients receiving treatment. The key outcome of the project will be a change in normative guidelines and national policies that are conducive to scaling up HCV management globally.

India is a country with a substantial HCV burden, with an estimated 7.5 million people infected with the disease. HCV disproportionately affects vulnerable or socially marginalized populations, including HIV and TB infected patients and people who inject drugs. While most HCV cases in India are mono-infected, approximately 13% of the 2.1 million people living with HIV are also infected with HCV. HCV is now seen as one of the most critical public health problems facing the HIV community today because co-infected patients suffer the highest morbidity and mortality from rapidly progressing liver scarring.

In India, the project aims to implement innovative models for the screening and treatment of HIV/HCV co-infected and other high-risk patients, initially using existing diagnostic platforms and direct acting antivirals (DAA), and introducing other technologies as they become available.

Through this project, FIND will provide healthcare stakeholders with the evidence they need to develop and implement a national, sustainable HCV policy.

In 2016, FIND began establishing relationships with key national stakeholders in HCV care, including the National AIDS Control Organization, the National Disease Control Programme, the Institute of Liver and Biliary Sciences and the Indian National Association for Study of the Liver. Going forward, FIND will also partner with state governments in Manipur, New Delhi, Punjab and Uttar Pradesh, as well as civil society organizations, for the implementation of project related activities.

FIND India also contributed to national and regional level meetings on viral hepatitis to further broaden the understanding around challenges and opportunities for HCV diagnostics and treatment. To this end, the Ministry of Health and Family Welfare under the Government of India and the Institute of Biliary Sciences endorsed the Unitaid project through letters of support.

LOOKING AHEAD

The Unitaid-funded project officially launches in India in late 2017, and 394,000 patients are expected to be screened for HCV over the course of the project, with targets of 105,000 cases confirmed and 23,000 people receiving DAA treatment.

Because diagnosis matters



SWASTH BHARAT: Better outcomes through better diagnosis

In April 2016, FIND held its first stakeholder meeting in India to bring together key actors from the public, private and non-profit healthcare sectors to focus on the advancement of medical diagnostic tests in India. Entitled *Swasth Bharat: Better outcomes through better diagnosis*, the forum provided a platform for experts with diverse health backgrounds to share insights on tackling some of the most pressing healthcare challenges facing India today.

Panel highlights included the role of public-private partnerships in supporting research and development to drive access to diagnostics for tuberculosis and HCV, and the growing threat of antimicrobial resistance. Participants also discussed the urgent need to accelerate the development, evaluation and roll-out of new, high quality and cost-effective diagnostic tests, particularly in light of India's infectious disease burden. The need for innovative diagnostic solutions for TB and HCV was also highlighted, particularly for point-of-care tests that could be used in even the most remote parts of the country.

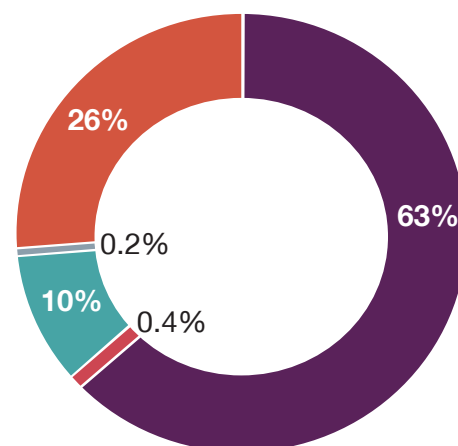
The event also marked the formal announcement of a partnership between FIND and the Indian pharmaceutical company Cipla to make HCV care more available and affordable. FIND's collaboration with the CDC to strengthen TB laboratories in India was also announced.

FIND received wide media coverage for the diagnostics forum, including a three-part blog series for Huffington Post India by Dr Sanjay Sarin, the Head of FIND India, as well as an online interview series for ETHealthworld with FIND Board Chairman Mark Kessel, FIND CEO Dr Catharina Boehme, FIND Chief Medical Officer Dr Bill Rodriguez and Unitaied Executive Director Lelio Marmora.

2016 FINANCIAL FIGURES

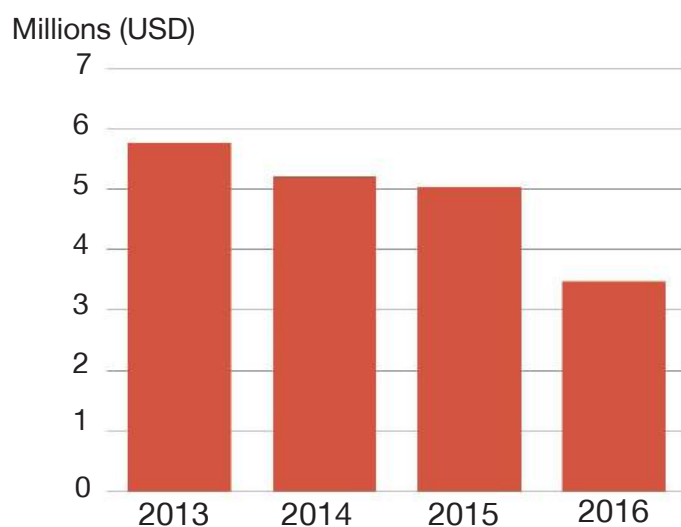
Expenditure 2016

	INR in lakhs	USD in thousands
■ Building laboratory capacity (The Global Fund)	1,484	2,199
■ Improving access to MDR-TB diagnostics (EXPAND-TB-Unitaid)	10	14
■ Indirect expenditure	230	341
■ Lab strengthening & QA for diagnostics (CDC)	4	6
■ TB Challenge via The Union	615	911
	2,343	3,472



Total expenditure

	2013	2014	2015	2016
INR in lakhs	3,236	3,179	3,230	2,343
USD in thousands	5,752	5,202	5,028	3,472



FIND INDIA: LOOKING AHEAD

FIND India is carving a niche as the partner of choice to deliver innovative diagnostic solutions that meet the healthcare challenges facing India today, while anticipating future needs. Our team of experts, with rich experience in handling complex projects—both in the public and private sectors—is working to expand TB diagnostic capacity in the country and is preparing for newer challenges like HCV.

Efficient management of our programmes requires the support of the finance, human resources, procurement, logistics, and administrative teams, which will all contribute to the many important projects planned for the coming years. FIND India is committed to continuing as a trusted partner of the government of India, building up and sustaining laboratory capacity in the country and supporting portfolio growth in the region.



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ABOUT FIND

FIND was founded in 2003 to bridge gaps for essential diagnostics by initiating and coordinating research and development 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, Malaria, Fever-AMR-Outbreaks, Hepatitis C, and Neglected Tropical Diseases, including sleeping sickness, leishmaniasis, Buruli ulcer and Chagas disease. We also have mini-portfolios in areas affecting reproductive and child health: HIV, sexually transmitted infections, and infections and nutritional deficiencies in young children.

Our Vision:

We envision a world where diagnostics guide the way to health for all people.

Our Mission:

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:

- **Catalyse development:** Identify needed diagnostic solutions and remove barriers to their development
- **Accelerate access:** Support the uptake and appropriate use of diagnostics to achieve health impact
- **Guide use & policy:** Lead products through the clinical trials pathway to global policy on use and market entry
- **Shape the agenda:** Improve understanding of the value of diagnostics and strengthen commitment to their funding and use

OUR PARTNERS



FIND



Because diagnosis matters



SWASTH BHARA

Better outcomes
through better diagnosis

14th April 2016

Shangri-La Hotel, New Delhi

