

About FIND India

The Foundation for Innovative New Diagnostics (FIND) established its presence in India in 2007, following a memorandum of understanding with the Central TB Division (CTD), Ministry of Health and Family Welfare, to evaluate and introduce new, rapid, quality-assured tests for tuberculosis (TB) at affordable prices for the public health sector.

The data from these evaluation studies formed part of the body of evidence that ultimately enabled their endorsement by the World Health Organization (WHO). The data also informed India's Revised National TB Control Program (RNTCP), helping to formulate guidelines for the detection and management of drug-resistant TB with these new diagnostic technologies.

Today, FIND India's portfolio has expanded significantly. We have a team of over 500 people (including third-party associates) based in 5 states, working with our partners on multiple projects across 4 disease areas. Alongside a continued focus on TB diagnostics, we have expanded our scope and are now working on a range of technical and community-level interventions across the country in viral hepatitis, antimicrobial resistance (AMR), fevers and digital health. Current projects include expansion of India's TB laboratory capacity through establishment of 20 new culture and drug susceptibility testing (C&DST) sites for the RNTCP, implementation of the largest-ever pan-India private sector engagement project in TB, and a multi-year hepatitis C project aimed at providing policy makers with the necessary

evidence to develop and implement a sustainable national policy for hepatitis C care. In addition, we are collaborating with the Indian Council of Medical Research (ICMR) on an AMR Diagnostic Use Accelerator focused on evaluating the role of point-of-care diagnostics to combat AMR. We are also working with the National Institute of Malaria Research on the clinical evaluation of a new malaria-CRP rapid diagnostic test that we co-developed, which can indicate whether an infection is likely to be viral or bacterial, in the case of a negative malaria result.

FIND India programme highlights

Driving efforts to eliminate TB

TB continues to be a major public health challenge in India, which accounts for a quarter of the world's 10 million annual TB cases according to WHO. India has an ambitious target to eliminate TB by 2025 – a vision that is supported by the highest levels of government.

FIND is a key implementing partner of the Central TB Division (CTD), Ministry of Health & Family Welfare, Government of India, to strengthen and expand TB laboratory diagnostic capacity within the RNTCP. FIND has a comprehensive portfolio of projects to support the government's vision.

Introducing and evaluating new diagnostics since 2007

FIND India has been instrumental in the introduction of every TB diagnostic technology currently approved by WHO (liquid culture, line-probe assay, TB speciation assay, LED-FM and GeneXpert®) into India's national TB diagnostic algorithm. We are currently conducting validation studies for new technologies, including Truenat™.

Partnering to transform the diagnosis of multidrug-resistant TB (2010–ongoing)

From 2010 onwards, FIND has been a key technical and implementing partner for India's 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, complemented by funding from The Global Fund. The projects have radically changed the diagnostic landscape for the RNTCP's management of drug-resistant TB in India.

Through the ongoing and previous grants from The Global Fund, FIND India has supported the establishment of all 61 currently existing C&DST laboratories for the RNTCP, with 20 more planned under the ongoing grant. FIND has ensured sustained service delivery in the national programme's C&DST laboratories through management of laboratory reagent supplies, and maintenance of equipment. Since 2010:

- Approximately 1.3 million patients have been tested for TB and drug-resistant TB across FIND-supported laboratories
- More than 110,000 cases of multidrug-resistant TB have been detected
- More than 3100 personnel have been provided with onsite/national-level training on various laboratory techniques, diagnostic tools and quality assessment

To help establish uniformity across the RNTCP's laboratory network, minimize data-entry errors and automate notifications, we are rolling out Laboratory Information Management System (LIMS) software at all 61 C&DST laboratories across the RNTCP network and linking to RNTCP's web-portal for patient notification (called Nikshay/eNikshay).

Accelerating access to quality TB diagnosis and care for children (2014–2018)

Paediatric TB accounts for ~10% of all TB cases around the world and is one of the top 10 causes of childhood mortality. In India, childhood TB is estimated to be about 10.2% of the total adult incidence, and recent studies have shown higher levels of drug-resistant TB than previously thought. However, paediatric TB is difficult to diagnose.

In consultation with the RNTCP, and with funding support from the United States Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (US CDC) as part of a Challenge TB project, FIND implemented a novel paediatric TB initiative in April 2014 in four cities (Delhi, Kolkata, Chennai and Hyderabad), with scale-up to include five more Indian cities (Bangalore, Guwahati, Surat, Nagpur and Visakhapatnam) in 2016 and a tenth city (Indore) in mid-2017, using Xpert MTB/Rif. This pilot project demonstrated the use of Xpert MTB/Rif as the upfront test to diagnose TB in children for the first time in India.

Upfront Xpert MTB/Rif-based diagnosis was offered to all children with symptoms of pulmonary and extra-pulmonary TB from linked facilities, free of charge, through a hub-and-spoke model. Rapid specimen transport and a reporting mechanism using email and SMS were established. The activities at the initial four sites gained significant momentum during the project tenure, with an increasing number of providers engaged in each successive quarter. These sites were transitioned, in a phased manner, to the RNTCP by the end of March 2018.

The project provided a comprehensive diagnostic solution for paediatric TB in the intervention cities. This solution was optimized by additional high-throughput GeneXpert laboratories located within the public sector reference laboratories. Detailed mapping of potential referral institutions (both public and private) was conducted, followed by one-to-one meetings and Continuing Medical Education (CME) for these facilities/providers.

KEY RESULTS IN PAEDIATRIC TB



Overall, **94,415** children (<15 years of age) with suspected TB were tested using GeneXpert across the 10 project intervention cities



This resulted in diagnosis of **6270** TB cases (6.6% of tests were positive)



The project successfully engaged **1416** facilities/providers, 61% from the private sector, through sensitization meetings, CME sessions and outreach activities across the project cities



Creation of laboratory-based e-training packages for the Central TB Division (2017–2019)

Under the Challenge TB project supported by USAID, FIND developed a comprehensive set of e-training modules for four TB diagnostic technologies (sputum microscopy, CBNAAT testing, LPA and culture and DST [liquid and solid]) as well as for laboratory-related bio-safety practices. Over 12 hours of content was developed with the help of subject matter experts from NRLs (national reference laboratories), IRLs (intermediate reference laboratories) and relevant partners. This content, hosted on the WHO “e-swasthya gurukul” portal, in conjunction with other learning methods/material, will be used for induction trainings, routine competency assessments and provision for refresher trainings on various TB diagnostics technologies in use under the RNTCP.

GeneXpert®/Cartridge-Based Nucleic Acid Amplification Test (CBNAAT) EQA programme for public & private sector sites (2016–ongoing)

GeneXpert is a point-of-care molecular platform that has changed the landscape in TB diagnosis and drug-susceptibility testing: time taken to obtain a test result has been reduced from months to less than 2 hours. India’s National TB Programme over the last decade has expanded the number of the GeneXpert machines rapidly and currently has over 1200 laboratories with GeneXpert machines in the public sector providing diagnostic and follow-up services for complex drug resistant (DR) TB cases across the country. In order to deliver quality-assured service, it is critical that these laboratories have a strong Quality Management System (QMS).

In collaboration with the RNTCP, US CDC, WHO India and the National Tuberculosis Institute (NTI), we are implementing a comprehensive CBNAAT External Quality Assurance (EQA) programme for all CBNAAT sites across the country in a phased manner using CDC’s Dried Tube Specimen (DTS) technology. The project aims to build in-country capacity to manufacture proficiency-testing panels at NTI Bangalore. Microbiologists from FIND and NTI were trained in November 2016 by CDC’s International Laboratory Branch (ILB) at Atlanta, USA.

A similar project was undertaken with the Stop TB Partnership’s TB REACH focused on Xpert laboratories in the private sector from 2017 to 2018.



Building national capacity for diagnostic development and manufacturing (2018–ongoing)

Building national diagnostic capacity is a high priority. Truenat, a molecular technology to diagnose TB and test for resistance to rifampicin in under an hour, has been developed by Molbio Diagnostics Pvt Ltd, based in Goa, with development funded by Bigtec Labs, in Bengaluru. Truenat represents the most advanced “homegrown” TB diagnostic to date, created in India specifically to tackle the high TB burden in the country. The instrument is battery operated, making it portable as well as suitable for settings in which electrical power is unreliable.

FIND has conducted an initial evaluation on frozen samples at 9 sites in India, along with an operational feasibility study. Assessment of Truenat assays in settings of intended use is now ongoing across 4 countries, including India, to inform WHO policy recommendations.

Overall, the project demonstrated more than

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increase in the microbiological detection of paediatric TB through upfront use of GeneXpert



Of the total TB cases detected on GeneXpert, around

9%

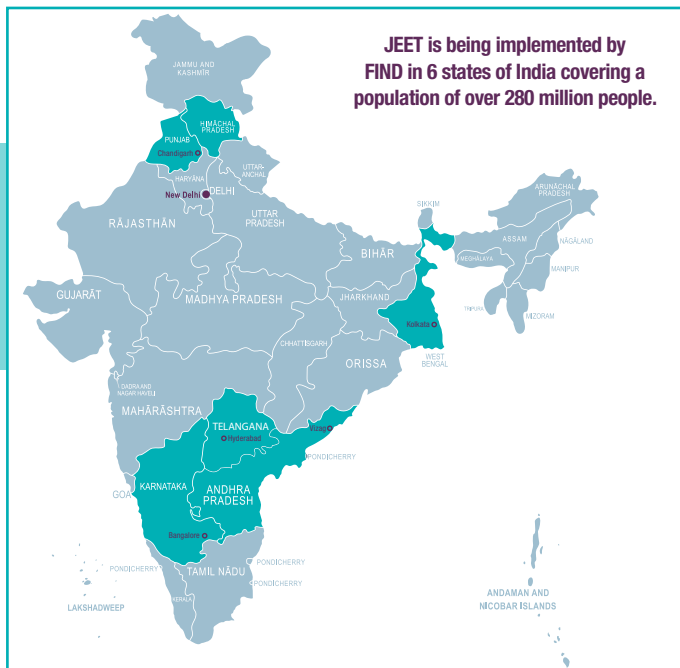
were diagnosed as rifampicin-resistant TB

The project facilitated prompt access to quality diagnostic services. Average turnaround time for GeneXpert testing was 1 day, including specimen collection, transportation, testing, and reporting



89%

of the children diagnosed with TB were linked to treatment



Hepatitis C elimination through access to diagnostics in India



The treatment landscape for hepatitis C is currently undergoing a dramatic transformation. Potent, well-tolerated, all-oral regimens achieve cure rates of more than 90% with 12 weeks of treatment. While large-scale manufacturing of new regimens has provided access to affordable treatments in countries like India, rapid, inexpensive and accurate diagnosis remains a critical bottleneck that must be addressed to eradicate hepatitis C. To address the gap in hepatitis C virus (HCV) diagnostics, FIND is the lead partner on a multi-year, four-country HCV project called Hepatitis C Elimination through Access to Diagnostics (HEAD-Start), funded by Unitaid to build an efficient and sustainable public health response to HCV.

HEAD-Start aims to improve diagnosis of HCV by making it more affordable and more widely available to those in need, with a focus on serving people co-infected with HIV. 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.

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 (DAAs) and then by introducing other technologies as they become available. Through this project, FIND India will provide healthcare stakeholders with the evidence they need to develop and implement a national, sustainable HCV policy.

Our work is supported by the government of Punjab, the government of NCT of Delhi, the Institute of Liver and Biliary Sciences (ILBS) and the YR Gaitonde Centre for AIDS Research and Education (YRG CARE). In India, we are currently implementing the project in 3 states (Delhi, Manipur and Punjab).

Joint Effort for Elimination of Tuberculosis (JEET) (2018–ongoing)

With an annual incidence of 2.8 million, India has the highest burden of TB globally. Studies have shown that nearly half of these patients seek care in the private sector and there are significant gaps across the patient care cascade in the private sector on account of under-reporting, diagnostic delays, and irrational and non-standardized regimens. India's National Strategic Plan (NSP) for TB elimination advocates the strategy of 'going where the patients go' and highlights the importance of engaging private sector to improve the standards of TB care. The key objective of this project is to set up effective and sustainable structures to strengthen existing systems and seamlessly extend quality TB care to patients seeking care in private sector.

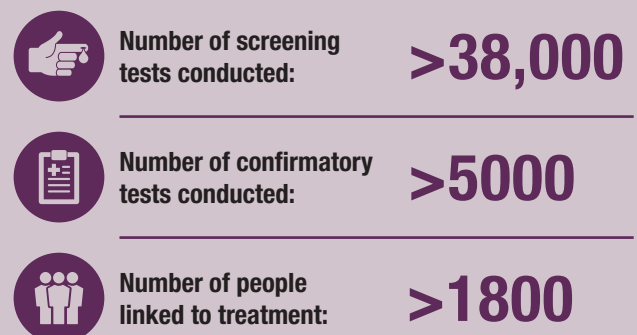
This project aims to partner with private sector physicians, laboratories and pharmacies in over 93 districts across various states of India to establish linkages that increase identification and notification of TB, and facilitate early treatment initiation and adherence support systems for improved treatment completion rates with mechanisms to reduce catastrophic costs to patients. The project will enable identification and notification of over 260,000 patients over the project period of 3 years, and ensure that over 70% of patients complete treatment.

This project is being implemented by FIND in 6 states of India covering a population of over 280 million people. To date, over 45,000 TB patients have been notified through JEET (April 2018 to March 2019).

Technical assistance for laboratory upgrades (2018–ongoing)

FIND is providing technical assistance to 6 states to build new TB C&DST laboratories where they currently don't exist. Being at the forefront of developing and maintaining a majority of the government-run C&DST laboratories, we are in a unique position to offer the required technical assistance. The activities are aimed to sustain laboratory upgrades and functioning, and increase testing capacity. The intervention will not only serve to offer on-ground technical assistance, but will also result in the development of a comprehensive guidance document for capacity building, long-term sustainability and knowledge transfer to the national programme. The project will also serve as a catalyst for domestic funding to grow the network of TB laboratories in the country.

KEY RESULTS IN HEPATITIS C



(Data collected from June 2018–June 2019)

Improving fever management and combatting antimicrobial resistance

AMR Dx Use Accelerator (2018–ongoing)

The AMR Diagnostic (Dx) Use Accelerator is a platform to evaluate a package of interventions and provide evidence to inform policy change that can positively impact AMR and contribute to universal health coverage (UHC).

The AMR Dx Use Accelerator will ultimately help to prepare for the introduction of new diagnostics and provide a safe environment for new antibiotics to enjoy a longer useful therapeutic lifespan. It complements R&D initiatives for both diagnostics and drugs from FIND, GARDP and CARB-X, by ensuring there is a robust downstream mechanism for driving uptake and implementation.

In the first instance we are focusing on interventions to improve management of patients presenting with fever, by providing and evaluating a “toolbox” that can help healthcare professionals provide more targeted treatments. By adopting available diagnostic tests and other diagnosis aids, and encouraging behaviour changes in outpatient clinics, we hope to rationalize the use of antibiotics.

To generate the data to support this toolbox, we are running two clinical trials in Africa, two in Asia, and one in India. The clinical trial in India is being conducted through a partnership with the ICMR. The University of Oxford is supporting us with grant management, and trial monitoring and evaluation. The WHO Special Programme for Research and Training in Tropical Diseases (TDR) is providing technical support, and collaborating with us on study design and implementation. These first-wave activities are supported by UK aid from the British people, and the Swiss Agency for Development and Cooperation (SDC).

Differentiating the causes of fever (2018–ongoing)

Fever is one of the most common symptoms of illness around the world, whether from bacterial, viral or other causes, with an estimated 5.1 billion fever episodes occurring in India every year. Due to the increased use of malaria rapid diagnostic tests, we know that less than half of presenting fevers in malaria-endemic countries are caused by malaria parasites. Global studies have shown that the causes of these fevers can be attributed to a small group of pathogens which cause a significant amount of morbidity and mortality in Asia, namely dengue, influenza, *Salmonella Typhi* (typhoid) and *Orientia tsutsugamushi*. However, accurately diagnosing the cause of fever remains difficult due to their similar clinical symptoms. In the absence of a confirmed diagnosis, patients are often prescribed broad-spectrum antibiotics, frequently an inappropriate treatment that contributes to AMR and leaves the patient at risk of death.

Currently, on a global front, FIND is working with partners to support the development of affordable and appropriate new tests that meet the needs of low- and middle-income countries (LMICs). These include a rapid triage test to distinguish between bacterial and non-bacterial infections, and rapid point-of-care tests to identify the most common infectious diseases that cause fever in different regions.

In collaboration with SD Biosensor, we have developed a new rapid diagnostic test (the STANDARD™ Q Malaria/CRP Duo Test) combining the detection of the pfHRP2 and panLDH antigens for diagnosis of malaria, and semi-quantitative detection of CRP (above levels of 20 mg/L) to provide an indication of potential bacterial infections. We are working with the National Institute of Malaria Research (NIMR) in New Delhi, India, to conduct a clinical evaluation of this rapid diagnostic test, to help guide a clinician's treatment decisions, and more particularly the use of antibiotics in malaria-negative febrile patients.

While development of these simple and affordable tests is a crucial step to ensure identification of fever-related ailments, we are planning to go beyond and explore interventions in community settings to ensure uptake of better diagnostics, superior clinical management, targeted treatment, lower out-of-pocket expenditure with reduced chances of mismanagement leading to drug resistance.





Our many partners include public, government donors, philanthropic organizations, commercial companies, academic and research institutions, international public health organizations (including non-governmental organizations and foundations), health ministries and disease control programmes.

FIND India is grateful for support received from donors, national reference laboratories and the Indian government. FIND India also appreciates the oversight and guidance provided by the National Health Mission (NHM) and the RNTCP in the implementation of our work.



FIND India

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About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations.

FIND is a WHO Collaborating Centre, with priorities clearly aligned with the global public health community. We turn complex diagnostic challenges into simple solutions through unique partnerships with the public, private and non-profit sectors.

Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs).

Since 2003, we have been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015.

FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control, and prevention.