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INFECTIOUS DISEASE DETECTION AND SURVEILLANCE PROJECT

Annual Report, Fiscal Year 2022
Tuberculosis Supplement



Photo by IDDS.

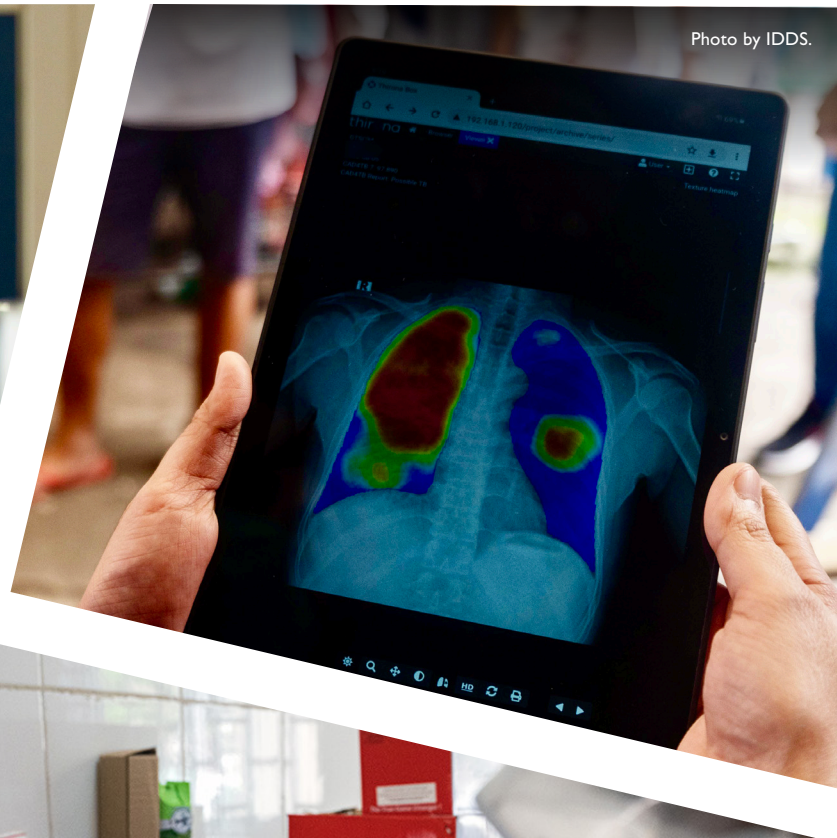


Photo by IDDS.



Photo by Cindy Liu for IDDS.

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INTRODUCTION

ABOUT IDDS

Established in May 2018, the Infectious Disease Detection and Surveillance (IDDS) project is a six-year initiative that operates in low- and middle-income countries where there are significant gaps in health systems’ ability to detect, track, and rapidly respond to infectious diseases and drug-resistant infections that pose a major threat to public health and global health security. The project focuses on developing the capacity of—and access to—diagnostic networks that provide accurate, timely results to tests for infectious diseases—and to effectively communicate those results to health care providers, public health officials, and other key decisionmakers.

IDDS is a \$135 million project that can take in funds from multiple sources and pivot quickly as countries’ needs change. In fiscal year (FY) 2022, \$49.15 million was allocated to tuberculosis (TB) activities—funds from the United States Agency for International Development (USAID) in Washington, DC, USAID missions, and the President’s Emergency Plan for AIDS Relief.

ICF leads IDDS with a consortium of organizations: FHI 360, PATH, Abt Associates, the African Society for Laboratory Medicine, the Association of Public Health Laboratories, Gryphon Scientific, the Mérieux Foundation, and Metabiota.

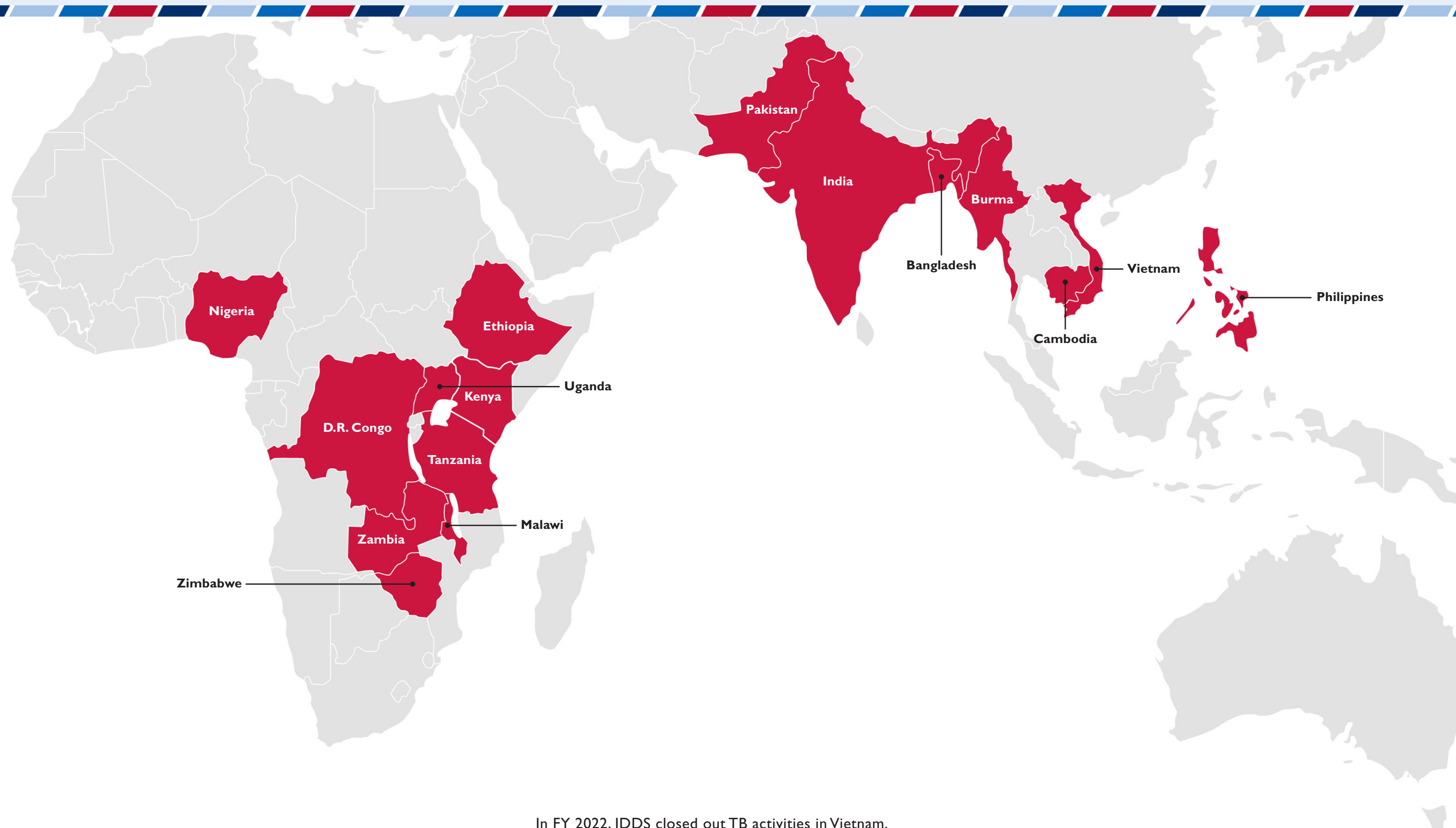


WHY TB

IDDS prioritizes diagnostic testing for diseases and drug-resistant pathogens that have the potential to spread quickly, devastate public health, and disrupt economies. Tuberculosis is a focus for USAID as it remains one of the world’s leading infectious disease killers. Globally, TB continues to kill more people each year than HIV and malaria combined, and it is among the top 10 causes of death in Africa and Asia. Drug-resistant forms of TB, which include multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), are a major public health challenge because they are more deadly, and more difficult and expensive to diagnose and treat.

USAID INFECTIOUS DISEASE DETECTION AND SURVEILLANCE (IDDS) PROJECT

Tuberculosis Activities, FY 2022



In FY 2022, IDDS closed out TB activities in Vietnam.

IDDS BY THE NUMBERS
 FY 2022

2,201

People trained to improve
 laboratory capacity

26

Multi-sectoral data sharing
 meetings supported

350+

Laboratories with improved
 diagnostic capacity

63

SOPs, plans, and
 guidelines developed



Truenat training in Zimbabwe. Photo by IDDS.

DELIVERING RESULTS

INFORMING DECISIONS

Analyzing networks and forecasting needs

Why it matters: Around the world, far too many people lack access to laboratory tests, either because the diagnostic services are unavailable or because their location is not well aligned with where patients live or seek health care. Poor infrastructure for transporting specimens for testing and a lack of laboratory equipment are compounded by weak supply chains for the materials that are needed to perform the tests. Designing better diagnostic networks requires analysis of the existing testing capacity, gaps, and opportunities for improvement—and we are delivering this information across the countries where we work so that decisionmakers can optimize the placement of new instruments and services to best reach the patients who urgently need them. The ability to provide treatment and health care services based on laboratory test results depends on these efforts to inform expansion of laboratory services.

Following guidance from the World Health Organization (WHO), countries are expanding use of rapid molecular tests for the initial TB diagnosis, instead of smear microscopy. Countries need to understand their current supply of rapid tests and where that testing capacity will have the greatest benefits for patients—and IDDS equips them with this knowledge. We implemented laboratory network spatial analysis (LNSA)—a methodology that combines geospatial analysis with population and disease data—to determine current capacity and identify areas in greatest need of access to rapid molecular diagnostics. During FY 2022, we supported these analyses to inform placement of instruments in **Burma**, the **Democratic Republic of the Congo (DRC)**, **Ethiopia**, **Kenya**, **Malawi**, the **Philippines**, **Tanzania**, and **Zambia**, and began planning for analyses in **Uganda** and **Zimbabwe**. Our findings are already informing decisions to expand access to testing. For instance, in **Burma**, our LNSA identified 12 sites where new GeneXpert® (GX) instruments will be added to improve diagnostic network coverage, including in the private sector.

We adapted the TB-NET Tool (a scoring system to review TB diagnostic networks against 10 core competencies) and integrated pediatric and drug-resistant TB (DR-TB) checklists to allow the TB diagnostic network assessment (DNA) to assess more of the diagnostic network and implemented IDDS' flagship DNA in **Ethiopia** using these tools. We also worked with stakeholders in **Malawi** and **Cambodia** to support a self-assessment of their diagnostic networks, an important step to understanding diagnostic network strengthening needs in these countries.

Generating data to inform policies and plans

Why it matters: Beyond our efforts to assess national capacity for diagnosing diseases, we are working to build the evidence base for national efforts to modernize disease detection through regulations and strategic planning. This involves gathering data from community and regional sources, cleaning and analyzing data, and reporting data into national health information systems to enable national monitoring of disease trends and drug resistance, which informs program planning and strategic decisions.

In **India**, we convened more than 70 stakeholders for cross-sectoral meetings to review and update the country's National Action Plan (NAP) for antimicrobial resistance (AMR). Our technical and managerial support in organizing the national experts' consultation for the human health component of the NAP-AMR process resulted in strategic inputs collated for development of the NAP-AMR 2.0, including its draft operational plan and monitoring and evaluation framework for the strategic priorities.

Sharing our knowledge

Why it matters: IDDS is committed to deploying its expertise and research capabilities to further scientific knowledge and understanding of infectious disease prevention and control. Building on our 4 years of experience supporting more than 20 countries, IDDS thought leaders contributed to webinars, academic conferences, scientific papers, and public health communications, further sharing our experience across countries and regions.

Four IDDS country teams from **Bangladesh**, **India**, **Vietnam**, and **Zimbabwe** presented five posters and one satellite session at the 52nd Annual Union World Conference on Lung Health in October 2021. We also continued our contributions to furthering TB research, with the development of TB research protocols across seven countries: **Bangladesh**, **Burma**, **Cambodia**, **India**, **Tanzania**, **Vietnam**, and **Zimbabwe**. We held two webinars covering the topics of [diagnosing TB in children](#) and performing [geospatial analysis](#) to improve access to TB diagnostics. The webinars drew hundreds of attendees during their live broadcast, and hundreds more have viewed them through our [YouTube channel](#). We have also published videos developed by the IDDS team in **Burma** on use of the GX platform and taking digital chest X-rays (CXRs) on the IDDS YouTube channel and translated them into English and French for sharing globally.

We participated in global health days and events such as the Step Up to End TB Summit 2022 on World TB Day in **India** to showcase contributions to the National Tuberculosis Elimination Program (NTEP) along with a wide range of national and international stakeholders.

OPTIMIZING RESOURCES

Fostering local partnerships

Why it matters: Together with our local partners in each country, we have a shared responsibility to determine how to sustain IDDS’ results. As we reflect on four years of implementation and impact, we look to the future and consider how IDDS has built the capacity of local governments and organizations (public, private, and civil society) to continue to improve disease detection systems. One key area is forecasting costs so that existing financing and new investments may be utilized—across sectors and partnerships—to continue improvements to diagnostic networks.

Through a participatory approach in **Bangladesh**, we supported the National Tuberculosis Control Program (NTP) to complete costing of the TB Laboratory Strategic Plan (2021–2025), a milestone that will enable NTP to plan for resource mobilization and implementation. We also worked with NTP to shift routine diagnostic activities from the National TB Reference Laboratory (NTRL) to the regional level, helping decentralize these services and expand access. We supported a similar laboratory strategic plan in **Zimbabwe**, and we facilitated a TB diagnostic working group in **Tanzania**—efforts that will ensure local leadership of improvements to TB diagnostic networks in these countries. Our work to connect global suppliers of TB diagnostics and connectivity, like Cepheid, Molbio Diagnostics, and SystemOne, with local distribution and equipment maintenance partners built bridges to ensure that TB diagnostic solutions are not only introduced effectively, but also locally managed and maintained.

Working across sectors

Why it matters: Problems like TB morbidity and mortality are multi-factorial, requiring large-scale solutions. They require that stakeholders from different academic disciplines and across the public, private, and civil society sectors align their efforts in pursuit of a shared goal. By breaking down silos and incentivizing cooperation, our work to foster multi-sectoral collaboration offers potential gains in efficiency, new opportunities to take pilots to scale, and deeper engagement of end users in the solutions that aim to benefit them.

In **India**, we launched the “One-Stop TB/DR-TB Diagnostic Solution model” in Hisar district of Haryana state to engage private laboratories in the TB diagnostic network. The new model is generating evidence that private sector laboratories are able to reduce turnaround times for TB test results and improve the rate of drug susceptibility testing (DST), which is expected to improve the rate of patients that initiate the correct treatment regimen.

In **Burma**, we secured a commitment from a private hospital association to transport specimens through the private sector, which is essential to strengthen coverage of the private sector diagnostic network. After the specimen referral system (SRS) is implemented, the new organizational linkages are likely to improve equity, quality, and timeliness of diagnosis for patients with DR-TB. In addition, we provided private sector hospitals in Burma with new tools that will improve capacity to quickly and accurately detect TB infections, including rapid molecular tests and software for computer-aided detection (CAD) of TB that uses artificial intelligence (AI) to read X-rays. In **Zimbabwe**, we provided financial and technical support to develop the government-led TB-HIV Public Private-Partnership framework. This framework outlines cross-sectoral strategies for formulating policies, strategies, and agreements for collaborating toward achieving universal access to TB-HIV prevention, diagnostics, treatment, and care services.



Truenat training in Zimbabwe. Photo by IDDS.

EXPANDING ACCESS

Strengthening laboratory systems to decentralize access to diagnostic services

Why it matters: Laboratory-confirmed diagnoses allow health care providers to rapidly employ the most effective treatment methods, which stop the disease from spreading and save lives.

In **Bangladesh, Burma, DRC, Malawi, Mozambique, and Vietnam**, we improved diagnosis of childhood TB by implementing stool specimen collection and processing—an important method for identifying children with TB, because most young children are unable to produce sputum specimens. We implemented standard operating procedures (SOPs) and trained laboratory workers to use the simple one-step process for stool specimen processing with GX instruments.

Improving specimen referral systems

Why it matters: In many countries, specimens with time-limited viability must be transported from remote areas to central laboratories for testing, and the systems for delivering the specimens are fractured or pose biosafety and biosecurity risks. Moreover, many SRSs need to be updated and adjusted to incorporate new capacity for decentralized testing. Improving the efficiency and effectiveness of specimen transport systems accelerates referral of confirmed cases to treatment, prevents resources from being wasted when specimen integrity is compromised during delivery, and reduces biosecurity risks.

In **Bangladesh**, we participated in a workshop to update the SOPs for the SRS. In **Burma**, we developed software architecture for an innovative web-based SRS mobile application, which was shared with WHO to ensure its interoperability with other applications and with private sector TB service providers to enhance utilization and sustainability of the initiative.

As part of our new “one-stop” model launched in Hisar district in **India**, we re-evaluated the SRS routes that had been developed with Google Maps and designated X-ray facilities as potential specimen collection sites. This will ensure more comprehensive TB screening and streamline the SRS to improve patients’ experience of diagnostic care.

Deploying new tools

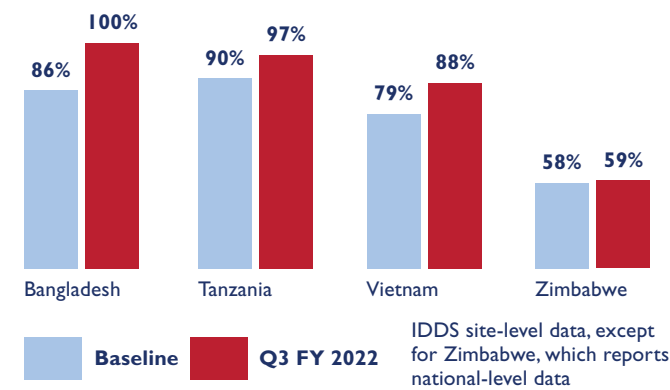
Why it matters: Recent innovations in diagnostics and digital health technologies offer significant advantages, such as faster turnaround time for test results and suitability for use in remote areas without access to stable power. Countries with a high burden of TB need access to these new tools—and critically, training on how to use and maintain them—so that they can improve patient outcomes and save lives.

In line with WHO’s recommendation that molecular testing replace smear microscopy for the initial diagnosis of TB, we supported the introduction of Truenat® technology (278 instruments have been installed across 9 countries) and trained 625 laboratory technicians and NTP staff to use it in **Bangladesh, Cambodia, DRC, Kenya, Nigeria, the Philippines, Uganda, Vietnam, and Zimbabwe**. This is part of the introducing New Tools Project (iNTP), a collaboration between USAID and the Stop TB Partnership. We trained Truenat “super-users”: end users who receive extra Truenat training to become experts who can pass on their knowledge and troubleshooting skills to others. During a pilot in **Zimbabwe** in early 2022, we trained 15 participants through technical and hands-on sessions, identifying lessons to inform rollout to other countries. After seeing the benefits in **Zimbabwe**, we rolled out the Truenat super-user training to five additional countries: **Bangladesh, Cambodia, DRC, Kenya, and Uganda**. A total of 98 super-users have been trained by the project.

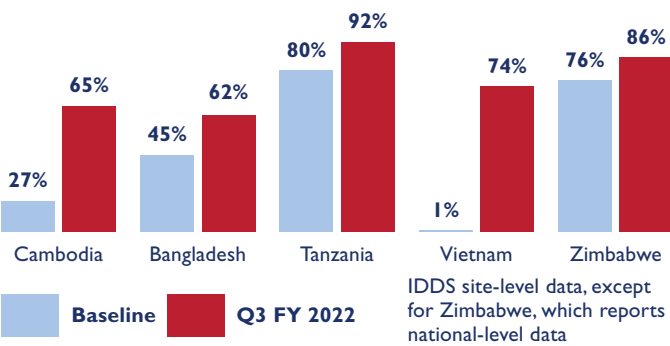
CXRs remain a key tool for diagnosing TB, and we are expanding access by rolling out ultra-portable machines that can take CXRs outside of typical X-ray rooms, as well as CAD-AI software for reading X-ray results. Our training on ultra-portable X-ray machines in **Cambodia, DRC, Nigeria, Uganda, and Vietnam** resulted in 154 people newly trained to screen patients for pulmonary TB, and we monitored 4 provinces in **Vietnam** that received CAD-AI software to observe the medical examinations and ensure the quality of AI-assisted diagnosis.

Through the deployment of new tools and optimizing the diagnostic network, IDDS helped increase the percent of presumptive TB patients tested with a WHO-recommended rapid diagnostic test (RDT) and TB cases that are bacteriologically confirmed.

Percent of new and relapsed bacteriologically-confirmed pulmonary TB cases



Percent of presumptive TB patients tested with a WHO-recommended RDT



IMPROVING QUALITY

Updating government guidelines and procedures to conform to international standards

Why it matters: In 2018, the United Nations High-Level Meeting on TB set ambitious global goals for improving TB diagnosis and care, including targets to treat 40 million people with TB and 3.5 million children with TB by 2022. We are contributing to these targets through our work to update TB strategic plans and SOPs.

Across our portfolio of TB countries, we assisted national TB programs in updating strategic plans and SOPs to improve the quality of TB testing. For example, in **Tanzania**, we finalized an operational plan for the TB laboratory network that will enable the zonal laboratories to expand their accredited scope of work to include culture and line probe assay (LPA) tests, enhancing the overall quality and capacity of TB testing in accordance with the goals and targets of the National TB Strategic Plan. In **Zimbabwe**, our national TB testing manual improved access to SOPs for TB testing throughout all levels of the laboratory network. Our work

to develop SOPs in **Bangladesh** for LPA, culture, DST, and GX testing of extra-pulmonary TB (EPTB) contributed to standardizing diagnostic tests across the network while improving quality of tests. And in **Malawi** and **Zimbabwe**, we revised each country's algorithm for diagnosing TB. Malawi's revised algorithm is now being used to inform revision of national guidelines, ensuring that our efforts to improve detection of DR-TB are integrated into the national diagnostic network. This will enable the country to test for isoniazid and fluoroquinolone resistance and expand DR-TB testing in the country to allow detection of patients with pre-extensively drug-resistant TB.

Empowering networks through quality management

Why it matters: As the technology at a laboratory improves and the services it provides expand, it is vital to closely monitor the quality of its testing services to ensure the accuracy and timeliness of results and improve clinicians' and patients' confidence in utilizing newer laboratory diagnostics and services. Quality management systems (QMSs) establish and control work processes to ensure consistent and accurate laboratory results, while laboratory accreditation independently verifies results and ensures they conform to national and international standards. We also work to flag underperforming laboratories and identify paths for corrective action and quality improvement.

We are building capacity for accurate diagnosis of TB through our work to expand external quality assessment (EQA) in **Bangladesh**, **Tanzania**, and **Vietnam**. We subcontracted with the Bangladesh Rural Advancement Committee and the Damien Foundation to select 80 GX sites for EQA activities and adapted and translated the GX EQA SOPs to the local context.

We also supported quality control and EQA in all countries where we provided new Truenat technology and training. To achieve quality control for Truenat testing, we worked with SmartSpot Quality, an established *Mycobacterium tuberculosis* (MTB) EQA provider in Africa, to develop EQA training materials, and provided EQA panels to six countries: **Bangladesh**, **Cambodia**, **DRC**, **Kenya**, **Uganda**, and **Zimbabwe**. Early results from **Zimbabwe** already demonstrate the impact, with 16 of the 20 laboratories (80 percent) successfully reporting EQA results in the first cycle, and half achieving perfect (100 percent) or acceptable (>91 percent) scores.

In **India**, we introduced a revised supervisory, monitoring, and evaluation package that the Central TB Division (CTD) will use to supervise every level of the diagnostic network and developed a grading tool that CTD will use to rank the national reference laboratories (NRLs) and intermediate reference laboratories and provide feedback

on performance and opportunities for quality improvement. In **Pakistan**, we are supporting one national and three regional TB reference laboratories to move toward receiving accreditation for diagnostic services. We are doing this through weekly training sessions on 12 essential QMS topics, and by reviewing, revising, and adapting essential documents such as technical and management SOPs, a quality manual, a biosafety manual, and a client handbook that are required for accreditation.

Launching digital solutions

Why it matters: Public health officials and other decisionmakers need real-time information from modern, digital reporting systems that can connect to diagnostic equipment, aggregate information from many sources, and automate data synthesis and visualization. Digital solutions for diagnostic connectivity and disease reporting provide opportunities for monitoring laboratory performance, identifying and containing outbreaks, managing inventory to forecast supply needs, and improving network efficiency across sectors.

In **Mozambique**, **Tanzania**, and **Zimbabwe**, we installed and configured an upgraded platform (Aspect) to provide connectivity between newer technologies such as Truenat and existing reporting systems so that real-time TB results reporting can be used for patient management and TB program improvement. The new connectivity solution allows monitoring of indicators such as drug-resistant infections, so that the program can reduce the spread of resistant TB strains. We also signed a blanket purchase agreement with SystemOne (Aspect's manufacturer) to deploy the platform to additional countries in FY 2023 and review the usage and design of dashboards for collection and review of and response to TB diagnostic data.

In **Cambodia**, we developed and implemented an SMS notification system called DataToCare (DTC). We trained laboratory technicians across 20 GX sites to use DTC to remotely monitor performance of GX utilization and cartridge stock, so that supplies can be reallocated to avoid shortages and prevent waste.

COMMUNICATING OUR IMPACT

We increased the visibility of the project and expanded its reach through a variety of communications channels. During FY 2022, we published blogs on BMJ Global Health, Agrilinks, and New Security Beat, among others.

In March 2022, we created a [LinkedIn page](#), which had 684 followers at the end of the fiscal year. We increased our followers on [Twitter](#) from fewer than 50 to 184.

Our followers on Twitter and LinkedIn include global health stakeholders encompassing government agencies, multilateral institutions, non-governmental organizations, USAID projects, academia, and private sector entities. Our posts on LinkedIn and Twitter regularly receive hundreds of views and are shared widely.

Our [YouTube channel](#) has 118 subscribers. The three videos of the [webinar series](#) we began during FY 2022 received 640 views. IDDS News, our quarterly e-newsletter, has nearly 300 subscribers.



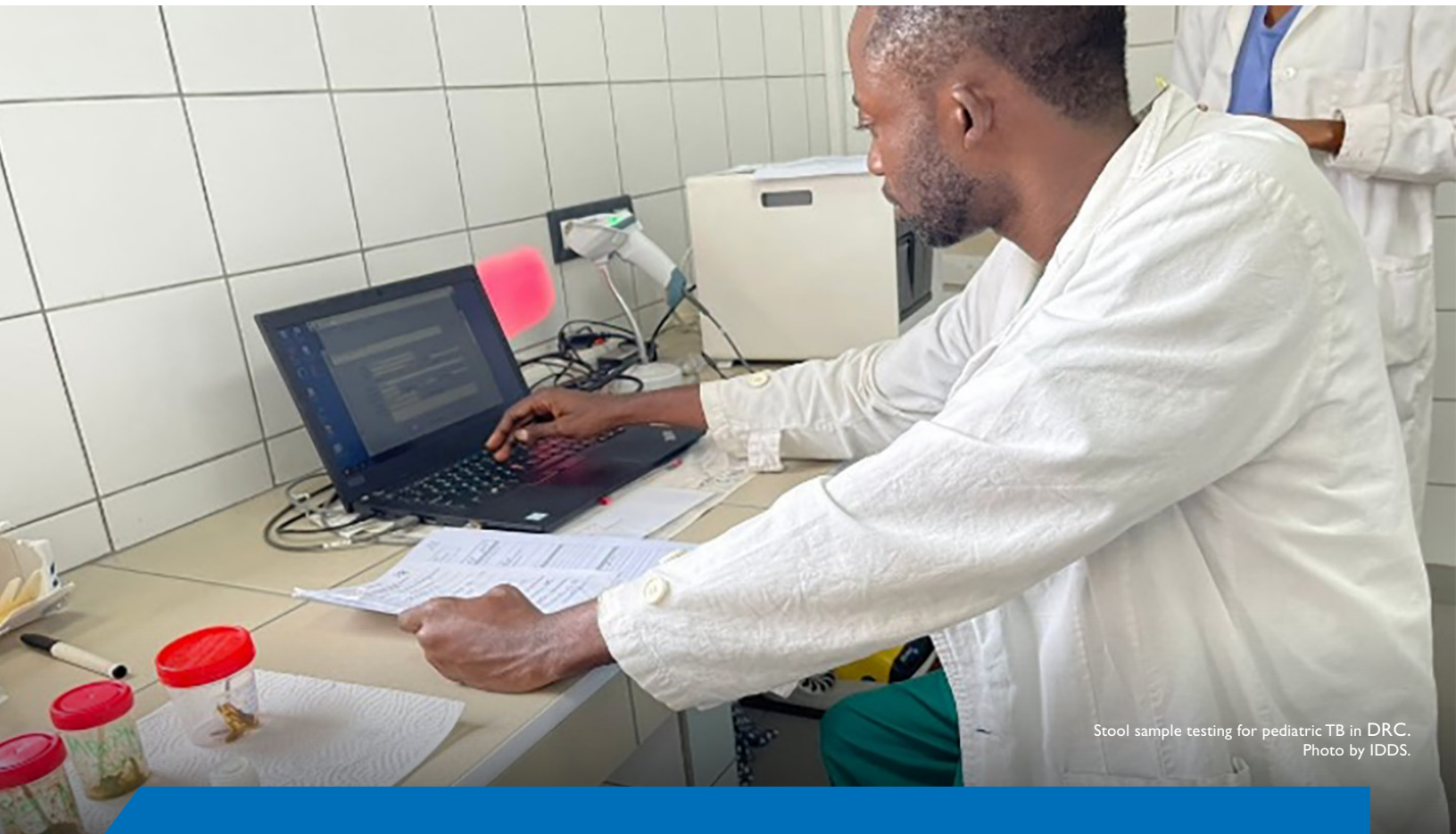
Project outputs related to strengthening TB diagnostic networks for FY 2022 and the countries that contributed to these outputs.

TB: Gaps in diagnostic networks identified and essential components supported													
	TOTAL	New Diagnostic Tools	Pediatric TB Testing	Other Testing Skills and Procedures	Equipment Maintenance	QMS	Diagnostic Connectivity Solutions	Biosafety	TB DNA	Laboratory Diagnostic Data Analyses	Private Sector Engagement	Specimen Referral	Other Diagnostic Network Topics
People trained	2,201	1,028	162	28	32	296	369	97	63	0	0	0	126
SOPs, plans, and guidelines developed or revised	63	5	3	22	11	3	0	18	0	0	0	0	1
TWG* meetings held	26	8	2	1	0	1	0	0	0	0	0	2	12
Supervisory visits conducted	294	92	0	7	0	80	80	0	0	0	4	0	31
Pilots conducted	6	2	2	0	0	1	1	0	0	0	0	0	0
Assessment reports completed	21	5	0	2	1	0	0	0	2	4	1	0	6
People mentored	28	0	0	28	0	0	0	0	0	0	0	0	0
Countries†													
Bangladesh		●		●	●			●					●
Burma		●		●									●
Cambodia		●	●				●					●	●
Core TB‡									●	●			●
DRC				●	●			●					●
India		●		●		●					●		●
Malawi			●									●	
Pakistan				●		●							
Tanzania				●		●							●
Vietnam		●	●			●			●				
Zimbabwe		●		●		●	●	●					●

*TWG=technical working group.
†Countries listed are those that contributed to specific outputs in FY 2022.
‡Activities implemented with funding from USAID in Washington, DC. These activities took place in Bangladesh, Burma, Cambodia, DRC, Ethiopia, India, Kenya, Malawi, Nigeria, Pakistan, the Philippines, Tanzania, Uganda, Vietnam, Zambia, and Zimbabwe. [For more information, please see the Core TB highlights on page 37.](#)

PEDIATRIC TB: A NEW POTENTIALLY LIFESAVING TESTING TECHNIQUE

Tuberculosis (TB) kills thousands of children every year in the Democratic Republic of the Congo (DRC), and yet many cases are being missed: 15,660 cases in children in 2020 were not diagnosed in the country, according to the World Health Organization (WHO). WHO estimates that children should represent up to 20 percent of cases in a high-burden TB country like DRC, but currently children make up only 11 percent of diagnosed patients.



Stool sample testing for pediatric TB in DRC.
Photo by IDDS.

“We saw an opportunity to identify pulmonary TB in a highly vulnerable and too-often ignored population and wanted to prove that we could find TB in children using an easy to collect and process specimen. Testing stool requires no invasive procedures or specialized equipment.”

—Moe Moore, TB strategic lead for IDDS

Access to TB testing is one problem in high-burden TB countries (see [Bringing TB Testing to Patients](#)) and another is the method of testing. Patients are expected to cough up sputum (not saliva from the mouth, sputum comes from the respiratory tract), something that young children especially find very difficult to do. Because of this, TB diagnosis in children relies heavily on clinical diagnosis without bacteriological confirmation, leading to delayed or missed diagnoses or even overdiagnosis.

However, when children with pulmonary TB cough and swallow their sputum, the genetic material of TB bacteria survives the digestive process and can be detected in stool samples. The collection of a stool sample is not invasive and can be easily collected at a clinic or in the home. In April 2022, WHO endorsed stool samples as an alternative specimen for pulmonary TB diagnosis in children (when the TB bacteria affects the lungs, it is known as pulmonary TB, and when the infection is outside the lungs—which is less common—it is called extrapulmonary TB).

USAID’s [Infectious Disease Detection and Surveillance \(IDDS\) project](#) saw an opportunity to radically improve the process of TB diagnosis in children. IDDS, together with the host national TB control programs (NTPs), launched pilots to assess the feasibility and potential of using stool samples for pediatric pulmonary TB diagnosis in DRC in July 2022 and an earlier pilot in Vietnam, which started in June 2020.

During the pilot in DRC from July to September 2022, 601 stool samples from children presumed to have TB were tested with the new stool sample method, resulting in 90 positive results (15 percent), including patients with drug-resistant TB.

As part of the IDDS assessment of the pilot, staff carried out appraisal interviews, and community beneficiaries and clinicians said that “stool testing saves our children.” They stressed how much relief this technique brings to parents who have a child with presumed TB. This bacteriologically confirmed diagnosis can be obtained simply and leads to fast and correct treatment. Health care workers trained by IDDS appreciated the new technique and recognized that it is as simple and easy as sputum analysis. Samples can be collected in a health care facility or at a child’s home and processed by any laboratory technician familiar with the GeneXpert® instrument.

The director of DRC’s NTP, Professor Michel Kaswa Kayomo, said, “I’m very satisfied with the pilot phasis of the introduction of stool Xpert study for pediatric TB diagnosis.” The NTP is now planning to scale up and integrate the technique into the routine of TB diagnostics across DRC.

In Vietnam, with IDDS support, stool-based testing accounted for 37 percent of all pediatric TB diagnosis testing in 2021, and over 2022, IDDS continued supporting Vietnam’s NTP to strengthen stool testing to diagnose TB in children in five provinces. The NTP has recommended continuing to carry out stool-based diagnostic tests for TB in children, with priority given to children under five.

Next, IDDS will expand access to stool testing in Malawi. The project recently trained 114 laboratory technicians on the simple one-step process for stool testing and obtained approval from the National Health Research Committee for a study protocol to assess the impact of introducing stool-based GeneXpert MTB/rifampicin (RIF) Ultra as an alternative diagnostic across nine study sites. In Zimbabwe, stool-based testing will be paired with TB preventive therapies for children in contact with persons with TB. In households with a person with active TB, all children will be screened for TB using stool-based testing; children who test positive for TB will be enrolled in the appropriate regimen, and children who test negative will be given preventive therapies, ensuring that children receive the right treatment. Children living with HIV will also be screened for TB through stool-based testing.

PRIVATE SECTOR PARTNERSHIP: A NEW ALLY EXPANDS TB TESTING AND PIONEERS A ONE-STOP SOLUTION

India struggles with the world’s highest burden of tuberculosis (TB), and expanding access to testing is vital to countering the spread of the disease, including drug-resistant strains. India’s National Tuberculosis Elimination Program (NTEP) has made progress in providing a complete diagnostic assessment of potential TB patients through more than 80 public sector laboratories for the detection of drug-resistant TB (DR-TB). Despite these efforts, nearly 50 percent ([Government of India TB Report, 2020](#)) of estimated multidrug-resistant TB patients remain undiagnosed in India.

In addition to a shortage of TB testing in India, there is a delay in starting appropriate TB treatment for patients, and some patients require a revision in treatment regimens after they have started. The testing process demands multiple journeys by patients (e.g., visits to doctors, trips to specimen collection centers), leading to delays and sometimes requiring hospital admissions and the loss of income.



Thyrocare runner carrying sputum specimens in a biological sample bag. Photo by IDDS.

Recognizing that testing is needed to serve people more effectively, NTEP began to explore partnership options with private laboratories. Inspired by this creative approach, USAID’s [Infectious Disease Detection and Surveillance \(IDDS\) project](#) came up with the idea of the “One-Stop TB/DR-TB Diagnostic Solution” model: engaging private diagnostic laboratories for quality-assured diagnosis. The new model is intended to provide complete diagnostic assessment of identified presumptive TB patients and diagnosed TB patients, enabling swift initiation of correct treatment regimens for drug-sensitive TB and DR-TB strains. “Why do patients need to move between sites to be screened? This doesn’t happen for other diseases, so why not also replicate this model for TB?” said Dr. Umesh Alavadi, a USAID project management specialist in the Division of Tuberculosis and Infectious Diseases.

IDDS launched the one-stop model in Hisar district of Haryana state on May 14, 2022, together with the state TB officer and Central TB Division, which is part of the Ministry of Health and Family Welfare. Hisar district is a prime candidate for improving access to TB diagnostic services because most patients have to travel an average distance of 10–15 kilometers (6–9 miles) from a partially functioning or non-functioning designated microscopy center, the most peripheral type of laboratory (serving around 100,000 people), to a facility TB unit or district TB center that offers diagnostic services, including drug resistance testing. Patient dissatisfaction and diagnostic delays were all too common given these challenges.

In 2021, 76 percent of the TB diagnoses in Hisar district used sputum microscopy, and 24 percent used much faster molecular tests like GeneXpert® or Truenat®. Testing for drug-resistant patterns among TB patients was not conducted at the state reference laboratory of Haryana over the last year due to operational reasons, hampering DR-TB case detection.

An NTEP-certified private sector laboratory, Thyrocare Technologies, was contracted to expand the TB diagnostic care in Hisar, with the aim of providing end-to-end services: from one-time specimen collection to delivering the test results within the stipulated turnaround times (GeneXpert: 2–4 days, direct line probe assay: 3–6 days, liquid culture and drug susceptibility testing: 27–53 days).

Under the new model, the entire Hisar district is covered, including rural and urban areas. Both public and private clinics screen the presumptive TB patient, refer them to specimen collection points, and enter patient details in NTEP’s patient management system, called Ni-kshay. Chest X-ray services are offered to potential patients through facilities engaged locally by the private laboratory. Reports are communicated to the patient, program staff, and the referring physician. Patients’ test results are also entered into in the Ni-kshay web portal within the stipulated turnaround time. The model provides specimen transportation services, so that patients do not have to travel to distant testing laboratories. Specimens are collected from the public and private health facilities by private “laboratory runners” using a defined route map. These specimens are then transported in cool chain from the point of collection to Thyrocare’s facility in Gurugram, Haryana, adjoining New Delhi, for testing with GeneXpert. Specimens that test positive on GeneXpert, including specimens to be tested for DR-TB, are flown to Thyrocare’s main laboratory outside Mumbai for full drug susceptibility testing. Test reports are sent to program staff, the referring physician, and updated in the Ni-kshay portal within the stipulated turnaround times. The diagnosed TB patient is then guided by NTEP supervisory staff to the referring physician to begin the appropriate treatment.

A senior TB laboratory supervisor who has been working in the Hisar District TB Center since 2004 explained how the new model is working: “Initially, GeneXpert test reports were received and communicated to the patient in 5–15 days on average, and for sequential testing, the samples of only severely ill patients were sent to a private lab in Delhi. We were receiving the results of first-line line probe assay test[ing] in around 2–3 months. This is taking only 4–5 days through implementation of this model. We are highly thankful to the IDDS team and the district efforts for this noble and humanitarian work.”

Thanks to the new model, the proportion of TB diagnoses that have been confirmed with a laboratory test (for more accurate diagnosis) has risen from 44 percent in 2021 to 84 percent in August 2022. Hisar now ranks second for universal drug susceptibility testing (for the detection of rifampicin resistance) in Haryana state, up from tenth prior to the implementation of the new model.

The new model demonstrates the role that private sector laboratories can play in TB diagnostics to help promptly initiate the appropriate treatment for TB patients. The potential benefits of—and learnings from—the new model include improved feasibility, impact, and cost savings—not only for India, but also for other countries facing similar challenges in expanding TB diagnostic services.

“The work in Hisar has the potential to change Hisar, India, and even the world.”

—Dr. Rajesh Raju, state TB officer in Haryana

BRINGING TB TESTING TO PATIENTS

“The [Truelab] machine is a very easy machine to use,” said Clement Mapuranga, a laboratory microscopist at Madziwa Clinic in Zimbabwe. “Even a novice microscopist can be taught how to use it without any difficulties.” USAID’s [Infectious Disease Detection and Surveillance \(IDDS\) project](#) introduced the Truenat® chip-based test (run on the Truelab® device) at the clinic in May 2022, where it is bringing accurate and fast testing for tuberculosis (TB) to this rural area of northern Zimbabwe.

“Most patients are flocking to this place because of the introduction of this [Truelab] machine.”

—Clement Mapuranga, a laboratory microscopist at Madziwa Clinic in Zimbabwe



Truenat training in Cambodia.
Photo by Cindy Liu for IDDS.

Zimbabwe suffers from one of the world’s highest burdens of TB, with 193 people per 100,000 infected in 2020, according to the World Health Organization. But testing for TB by Truenat rose 24 percent between January and September 2022 across the 20 sites where IDDS installed the technology. To end the TB epidemic, not only in Zimbabwe but also other high-burden countries, it is vital to make reliable testing easily accessible for those at risk.

“As a resource-limited country, we are very much excited that this technology can be spread down to the lower level, to the community level,” said Tanaka Sakubani, national TB laboratories coordinator, Zimbabwe Ministry of Health and Child Care. “Our patients and population also benefit from this great intervention of TB diagnostics.”

In addition to piloting the Truenat rollout in Zimbabwe, IDDS is launching the Truenat technology and training laboratory technicians to use it in Bangladesh, Cambodia, the Democratic Republic of the Congo (DRC), India, Kenya, Nigeria, the Philippines, Uganda, and Vietnam. This is part of the introducing New Tools Project (iNTP), a collaboration between USAID and the Stop TB Partnership. TB is the world’s largest killer infectious disease after COVID-19, and iNTP aims to greatly reduce its impact in high-burden countries by making fast, accurate testing available at local clinics to increase detection and treatment.

“To defeat TB, we need accessible diagnosis,” said Dr. Lucica Ditiu, Stop TB Partnership executive director. “In resource-challenged countries, we can’t expect people to travel long distances for a TB test when they have other vulnerabilities and their symptoms may be a cough and fever, and we know the challenges faced in specimen referral. Therefore, people turn to their local clinics, which is where we are bringing Truenat.”

Truenat and the Truelab platform, which were developed in India by Molbio Diagnostics, are well suited to small, community clinics. Truelab machines are portable, have back-up battery power, and can be used at temperatures of up to 40° Celsius/104° Fahrenheit. “With rapid molecular diagnostics like Truenat accessible in the neighborhood, you are not only getting people tested and treated early, but you are reducing community infection with early diagnosis and with fewer people remaining untreated for TB,” said Dr. Suvanand Sahu, Stop TB Partnership deputy executive director.

It is not enough to simply deliver the technology and expect that laboratories and health care workers will be able to use it to improve TB testing in their communities. Even with initial training and remote technical support, Truenat users can still face problems that range from unknown error messages to maintenance and repairs. Recognizing these obstacles, IDDS came up with the idea of training Truenat “super-users”: end users who receive extra Truenat training to become experts who can pass on their troubleshooting skills to others.

During a pilot in Zimbabwe in early 2022, IDDS trained 15 participants through technical and hands-on sessions, identifying lessons to inform rollout to other countries.

After seeing the benefits in Zimbabwe, IDDS rolled out the Truenat super-user training to four more countries between April and June 2022: Cambodia, DRC, Kenya, and Uganda, and to Bangladesh over April to September 2022.

During the training in DRC, the super-users were taught how to assist Truenat end users in the field when faced with common technical problems during installation or other issues. After the training, the super-users began providing local support to Truenat end users in their home provinces, including participating in an external quality assessment. “We are in the process of adopting this new Truelab machine, to overcome the difficulties encountered here in the city of Mbuji-Mayi with recurring failures of existing machines,” said super-user Alphonse Lufulwabo, head of the provincial TB laboratory in Mbuji-Mayi, Kasai-Oriental province, DRC. “This training as a super-user will greatly help us to support the sites and solve the challenges encountered in the field.”

IDDS will train super-users in three other countries later in 2022–2023: Vietnam, Nigeria, and the Philippines. In Cambodia, IDDS will repackaging Truenat training materials, including job aids.

“We have served so many patients since the day we received the machine. They are having their treatment right now and most of them have recovered.”

—Peter Chipaka, a laboratory microscopist at Madziwa Clinic in Zimbabwe



Truenat technology delivery in the Philippines.
Photo by IDDS.

BANGLADESH

Context

In Bangladesh, IDDS seeks to strengthen the TB diagnostic network and systems, establish a functional network of GX instruments, and introduce new technologies and tools to improve TB diagnosis.

“This training will usher in a new era for NTP to boost early detection of TB at the remote areas of the country.”

—Dr. Md. Khurshid Alam, line director of the National TB Control Program, speaking at a three-day training of trainers for Truenat implementation

Annual Highlights

Diagnostic

- IDDS increased access to TB diagnostics in remote areas by introducing Truenat technology at 21 of 38 selected peripheral microscopy laboratories, training 12 mentors (5 female) to train others to use the new technology, and directly training 41 medical technologists (11 female) who will use Truenat. In the first two months (August and September 2022) after introducing Truenat, 307 TB cases, including 2 RIF-resistant cases, were detected by testing 4,304 presumptive TB patients. Truenat will empower these sites to increase TB case detection and inform the next phase of expansion of the new technology.
- IDDS built capacity for regulating the TB diagnostic network by providing technical support to develop a costed national TB Laboratory Strategic Plan (2021–2025) through a participatory process involving senior NTP and other TB implementing partner staff. The plan will empower NTP to mobilize domestic and global resources to implement the laboratory strategy in alignment with its mission to end TB.
- IDDS improved diagnostic coverage by expanding LPA and EPTB testing to three regional laboratories (Shyamoli, Khulna, and Rajshahi). To standardize diagnostic testing and improve quality across the laboratory network, IDDS trained 65 (24 female) microbiologists on SOPs that are being finalized for LPA, liquid culture, DST, GX testing of EPTB specimens, and stool testing for detection of TB among children.

Challenges

- Shortages of laboratory supplies (reagents for LPA and liquid culture) and delays in obtaining customs clearance (for these supplies as well as GX EQA panels for 80 GX sites) affected diagnostic performance and delayed IDDS’ activities. IDDS requested an expedited process for the laboratory supplies and reached an agreement with the Vietnam NRL to provide new GX panels for 50 GX sites, and NTP also received new funds for processing future customs clearances.
- Activities were delayed because of changes in NTP decisions, but IDDS met with NTP to expedite decisions and adapt activities. For example, after a procedural delay by NTP slowed the delivery of Truenat equipment to supported sites, IDDS received NTP approval for site refurbishments to take place during the period of delay.

PARTNERS AND COLLABORATORS

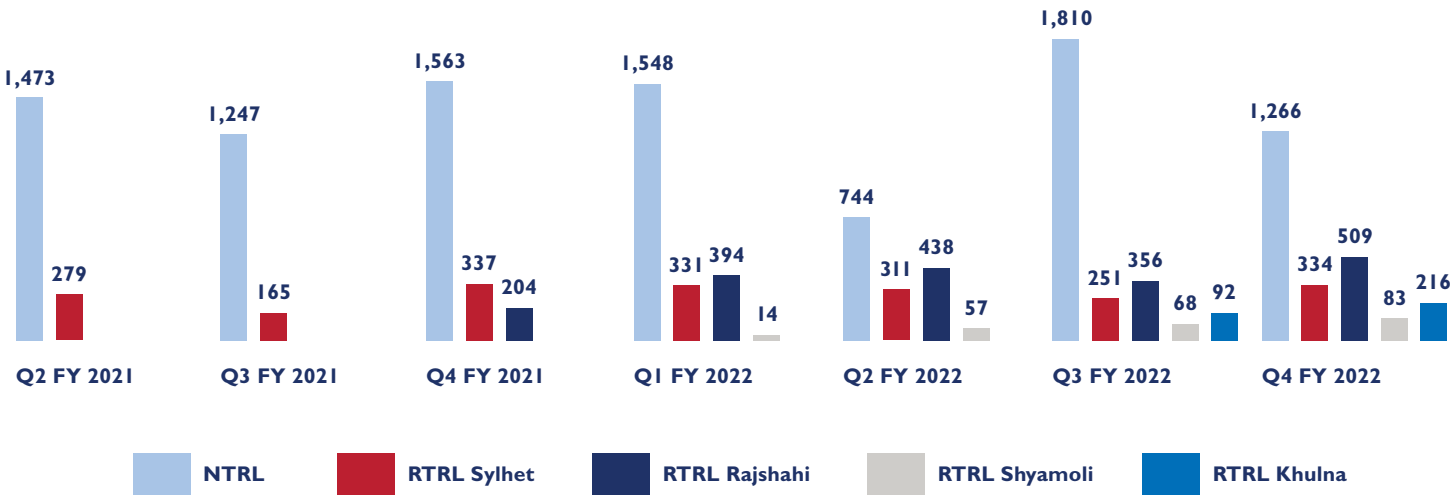
- Ministry of Health and Family Welfare
- Bangladesh Rural Advancement Committee
- Damien Foundation
- Institute of Epidemiology, Disease Control, and Research
- National Tuberculosis Control Program

What We Learned

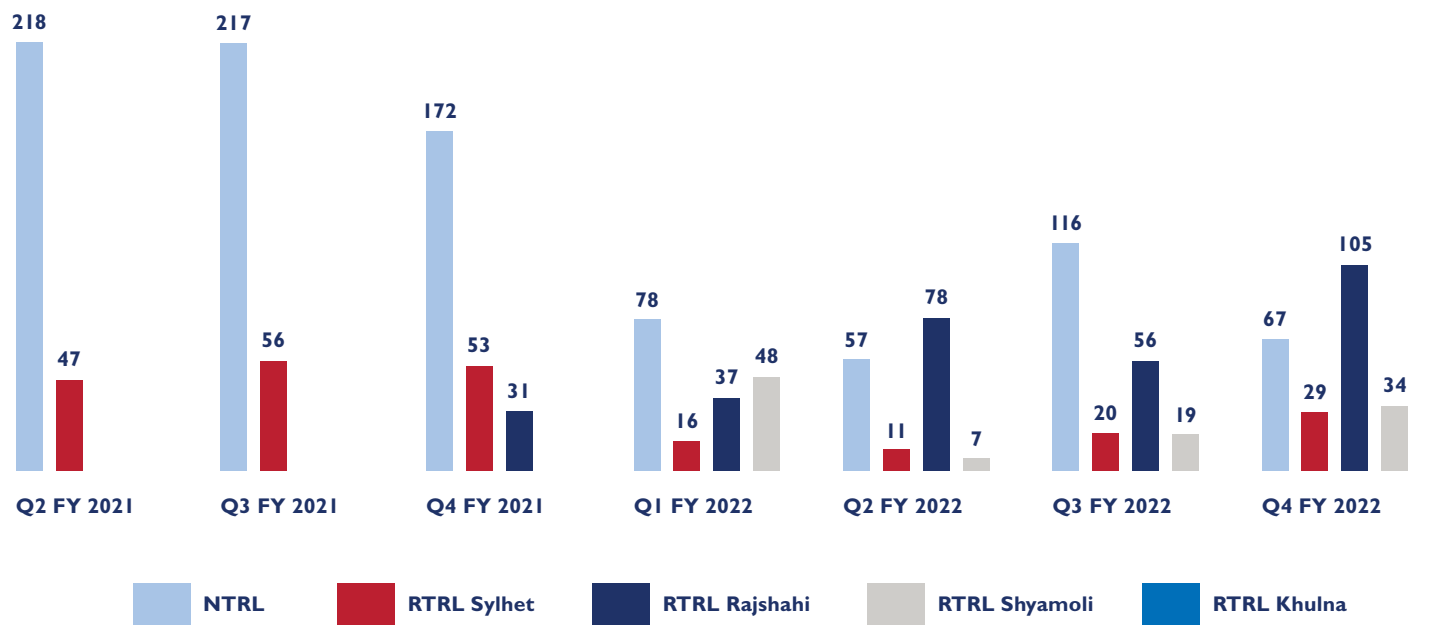
- “Early wins” and proof of impact are often needed to achieve NTP buy-in of project activities. NTP’s initial guardedness about Truenat implementation, for instance, has now shifted to enthusiasm: NTP recently decided to procure about 150 instruments to continue expanding access to molecular TB at the peripheral level.
- Quality improvement involves many moving pieces that need to be coordinated simultaneously: a timely supply of reagents, close monitoring and supervision, data collection and analysis, and provision of feedback all inform improvements in the field.
- Customs clearance by NTP is a challenging process. To prevent delays, IDDS staff must ensure accuracy of all information mentioned in relevant shipping documents and involve NTP staff at every step.

Outcome Data

Bangladesh: Number of Culture, Phenotypic DST Tests Performed at IDDS Sites



Bangladesh: Number of RIF-resistant Patients Tested by Second-line LPA at IDDS Sites

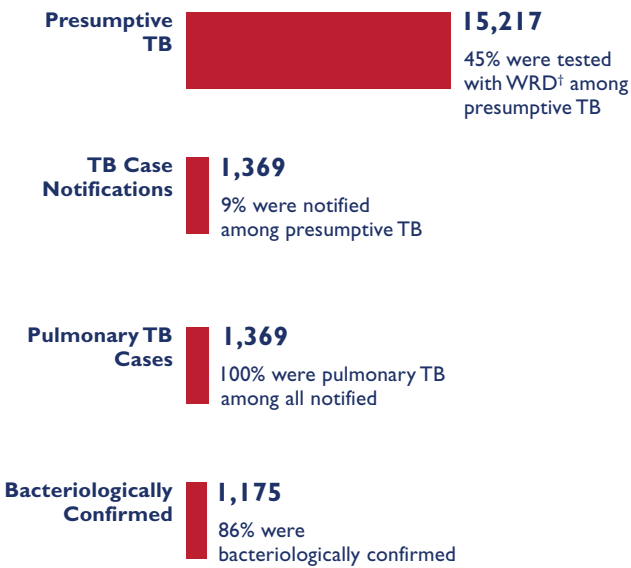


The culture and LPA capacity built by IDDS at regional TB reference laboratories (RTRLs) has resulted in increased testing over time at these sites and a reduced testing volume at NTRL.

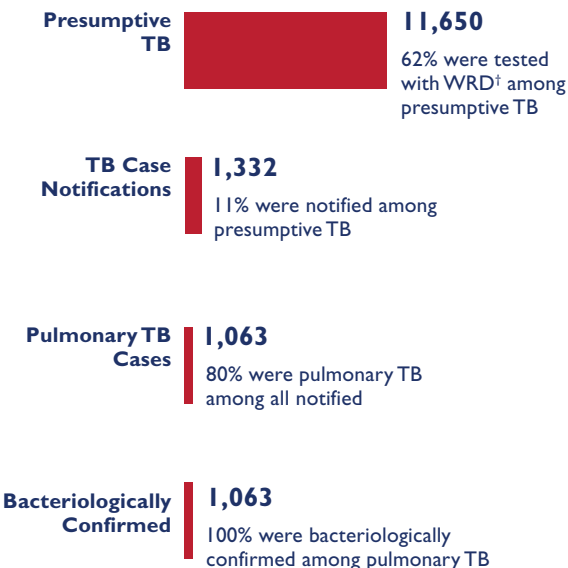
Outcome Data

Outcome data are provided through Q3 FY 2022.

Bangladesh Diagnostic Cascade: IDDS Site-level* Data, Baseline (Q1 FY 2020)



Bangladesh Diagnostic Cascade: IDDS Site-level* Data, Q3 FY 2022



*Bangladesh IDDS sites: One national and four regional laboratories.
[†]WRD: WHO-recommended RDTs.

IDDS’ interventions contributed to an increase in testing with WHO-recommended rapid diagnostics in IDDS-supported laboratories in Bangladesh from 45 percent at the baseline to 62 percent during the third quarter (Q3) of FY 2022. There was also an increase in bacteriological confirmation from 86 percent at the baseline to 100 percent. The decrease in pulmonary TB cases from 100 percent at the baseline to 80 percent can be attributed to the increase in detection of EPTB cases in Q3 FY 2022, which is one of the objectives of the IDDS TB program in Bangladesh.

Output Data



New diagnostic tool - Truenat (53)
Pediatric TB (37)
TB testing (28)
Equipment maintenance (28)
TB diagnostic connectivity solutions (30)
EQA for GX (15)
TB training for TB and leprosy control assistants (20)



TB testing (4)
GX assessment (8)
Reporting system (3)



Strengthening laboratory network (2)
Other (1)



Laboratory upgrade feasibility (1)
Site readiness for Truenat (3)
Equipment installation (1)



Context

IDDS provides technical assistance to expand access to rapid, reliable, safe, and integrated molecular diagnostics for TB to all persons who access the diagnostic network in Burma. IDDS focuses on increasing detection of TB and DR-TB through expanded and strengthened diagnostic services, microbiological confirmation, and engagement of the private sector.

“We found that by expanding 12 GeneXpert machines in the existing diagnostic network, 10 percent more of the population will be covered within 5-kilometer distance from the nearest facility.”

—IDDS program specialist Soe Htut Aung, explaining the results of the LNSA in Burma during an IDDS webinar

Annual Highlights

Diagnostic

- To improve quality diagnosis and management of TB across population segments, IDDS led planning for the establishment of the private-sector diagnostic network, which will use WHO-recommended RDTs.
- IDDS laid the groundwork for more timely TB diagnosis by analyzing sustainable options for strengthening the specimen transport mechanism (including in the private sector), advancing progress toward an adequate, reliable, and faster transport system.
- IDDS expanded clinician and patient access to TB diagnostics by providing ultra-portable X-ray, CAD-AI, and Truenat technology to partner organizations, including in the private sector.
- IDDS built capacity for CXR screening in the private sector by developing a training curriculum, materials, and practical training videos in Burmese and English, which were used to train 39 participants (10 female) from 10 organizations and 5 private hospitals.

PARTNERS AND COLLABORATORS

- Ministry of Health
- National Tuberculosis Program
- National Tuberculosis Reference Laboratory
- Myanmar Private Hospital Association

Challenges

- Implementation of some activities was delayed due to strict rules and coordination policies imposed at the central level. Comprehensive support from the technical and program backstop is needed to ensure quality and sustainability of continued technical assistance for essential TB diagnostic services.
- Unpredictable changes in policy and programmatic limitations affected the development and approval of implementation plans by NTP, NTRL, and partner organizations. IDDS is ensuring that approvals from NTP are received and that foreign currency transactions for procurements are secured through licensed banks to enable project implementation.
- The coup d’état of February 1, 2021, quickly shut down all access to government facilities and staff, and most TB services and Internet communications were severely restricted. IDDS staff continue to work from home, and the project is working with the USAID mission to propose a work plan revision that reflects a meaningful and sustainable avenue for private sector engagement in TB diagnosis.
- The lack of a central coordinating mechanism for TB activities and regular disruption of communication channels are significant barriers. Persistent challenges in coordinating with NTP, NTRL, and even among TB implementing partners have delayed IDDS activities, but IDDS has worked tirelessly with USAID, partners, and a newly hired coordination consultant to mediate, revise activities as necessary, and ensure progress and sustainability.

What We Learned

- Creative solutions are the antidote to unpredictable political changes that can disrupt project implementation. IDDS kept project activities on track despite the nationwide political, organizational, and governmental changes and challenges, thanks to continued collaboration with technical and implementing partners. For instance, the creation of a joint support diagnostic group engages implementing partners to fill the gap left by the country’s central coordinating mechanism in strengthening diagnostic services.

- The diagnostic technologies and laboratory training video clips for TB diagnosis—developed by IDDS to replace the hands-on-training of laboratory technicians—helped maintain the quality of TB diagnosis during COVID-19 restrictions.
- During the political crisis, the capacity of the public sector (the major player in TB services in Burma) was disrupted. This points to the need to build the capacity of the private sector to ensure continuity of TB diagnostic services, even during unpredictable and highly volatile political contexts.

- Lack of a local Molbio service engineer delayed troubleshooting and Truenat instrument repair, interrupting TB diagnostic testing services. The availability of newly trained super-users is expected to help mitigate this issue.

What We Learned

- Close coordination with CENAT is critical to ensure buy-in for introducing new and innovative technologies for TB case finding and management and to avoid lengthy delays in initiating activity implementation.

Output Data



TB diagnostic connectivity solution (243)
New diagnostic tool - Truenat (168)



TB diagnostic connectivity solution (1)
New diagnostic tool - Truenat (1)



New diagnostic tool - Truenat (56)
TB diagnostic connectivity solution (10)



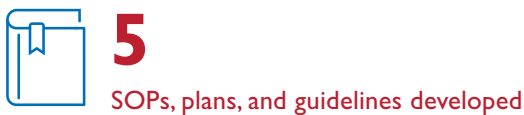
TB testing - TB and diabetes bidirectional screening



Output Data



Chest X-ray procedures (39)
Biosafety (42)



New diagnostic tool - Truenat and CAD (2)
Biosafety (1)
DR-TB testing (1)
Logistics management information system (1)



CAMBODIA

Context

IDDS is supporting the National Center for Tuberculosis and Leprosy Control (CENAT) to expand and improve the quality of the TB diagnostic network in line with national priorities. IDDS is also working with CENAT and the Community Mobilization Initiatives to End Tuberculosis (COMMIT) project in 10 underserved operational districts to develop, implement, and expand TB interventions.

“The X-ray machines we hand over today will help find missing TB cases in the community and will improve health for the most vulnerable Cambodians.”

—Erin Nicholson, USAID Cambodia’s acting mission director

Annual Highlights

Diagnostic

- To expand access to rapid TB diagnosis, IDDS equipped 15 sites with Truenat technology and trained 21

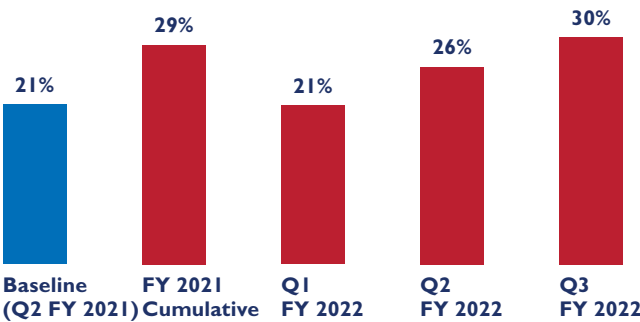
super-users (3 female) and 77 end users (9 female) on the new technology. IDDS also conducted a joint supportive supervision visit with CENAT and COMMIT to ensure proficiency at 14 health centers that are implementing Truenat for TB and DR-TB detection.

- To improve detection of TB among children, IDDS, in collaboration with CENAT, customized the Simple One-step Process for Stool Testing method, algorithm, and implementation plan for pediatric TB diagnosis using GX Ultra.
- To build capacity for national monitoring, IDDS, in collaboration with CENAT, provided training and technical support to expand DTC connectivity to 20 GX sites, reducing the turnaround time for TB diagnostic results from 7 days to 24 hours at supported sites. In Cambodia, 30 of 88 GX sites (34 percent) have now been connected to DTC. IDDS conducted training on the proper use of DTC for 225 data managers (36 female) from CENAT, IDDS staff, COMMIT staff, and all laboratory technicians in the supported operational districts. IDDS also identified 18 DTC super-users (1 female) from CENAT, IDDS, and COMMIT and trained them on the use of DTC, software installation, troubleshooting, and how to conduct further training for the end users as necessary.

Challenges

- Truenat procurement and implementation were delayed due to the product registration status in Cambodia.

Cambodia: Percent of Notified TB Cases Tested Using Molecular Technology, IDDS Sites*



*IDDS sites include 19 laboratories in 10 districts.

PARTNERS AND COLLABORATORS

- Ministry of Health
- Community Mobilization Initiatives to End Tuberculosis
- Global Fund to Fight AIDS, Tuberculosis and Malaria
- National Center for Tuberculosis and Leprosy Control
- National Tuberculosis Reference Laboratory



Context

In DRC, IDDS is supporting NTP and NTRL in collaboration with the Global Fund to Fight AIDS, Tuberculosis and Malaria and other TB implementing partners. IDDS helps NTP and NTRL mitigate the impact of COVID-19 on TB services by focusing on multi-disease testing platforms. IDDS activities focus on upgrading the DRC NTRL, improving service delivery in three TB reference laboratories, and improving TB diagnostic services at provincial TB reference laboratories.

“We are in the process of adapting this new Truenat machine, to overcome the difficulties encountered here in the city of Mbuji-Mayi with recurring failures of existing machines. This training as a super-user will greatly help us to support the sites and solve the challenges encountered on the field.”

—Alphonse Lufulwabo, IDDS-trained Truenat super-user

Annual Highlights

Diagnostic

- IDDS built the rapid molecular diagnostic capacity of the TB laboratory network by introducing Truenat in 38 sites across 4 provinces of the country. This has improved TB case detection in many Truenat sites, especially in Mbuji-Mayi.
- IDDS informed mobilization of national resources and guidance by providing a consultant to lead the development of the new Strategic Plan for the National Tuberculosis Reference Laboratory (2023–2026).
- To improve quality and standardized practices across the TB laboratory network, IDDS supported the development or revision of 28 SOPs, plans, and guidelines to build capacity of NTRL staff to process and test specimens and interpret test results.
- IDDS conducted assessments of the Kisangani and Lubumbashi provincial laboratories to identify activities that will strengthen their capacities to be able to perform DST, reducing the burden on NTRL and decentralizing testing nationally.

Challenges

- IDDS planned to purchase some small materials and to repair the biosafety cabinet (BSC) at Kisangani Provincial Laboratory, but an assessment conducted jointly with NTP found that the BSC needed to instead be replaced. IDDS therefore revised the procurement plan to integrate the purchase of a new BSC.
- In Q4, NTP organized major activities, including internal review, annual review, and external review, with all TB partners and stakeholders. This agenda conflict resulted in a delay in the implementation of IDDS activities.

What We Learned

- Creating new opportunities for communications is key to success. The Truenat super-users’ WhatsApp group created by IDDS proved to be a very useful monitoring tool for field actors. Through this platform, users can share information, discuss issues, and find solutions to challenges related to Truenat implementation.

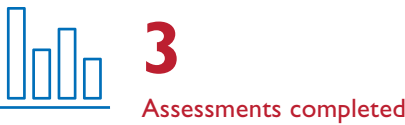
PARTNERS AND COLLABORATORS

- Ministry of Public Health
- National Biomedical Research Institute
- National Tuberculosis Program

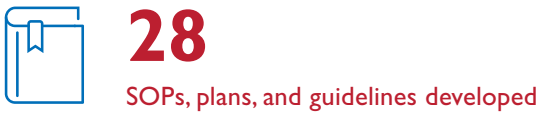
Output Data



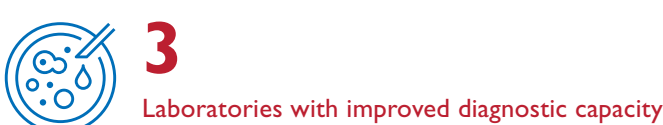
Equipment maintenance (4)
Logistics management information system (20)
Biosafety (36)



TB testing (2)
NTRL power assessment (1)



Equipment maintenance (11)
Biosafety and biosecurity (17)



Practical session during the Truenat training at the Provincial Laboratory of Mbuji-Mayi (Kasaï Oriental) in DRC. Photo by IDDS.

INDIA

Context

In India, IDDS works to strengthen strategic public sector TB laboratories and engage private sector laboratories to improve TB diagnosis and care. IDDS collects evidence on the feasibility and impact of new TB diagnostics and supports laboratory networks in detecting and preventing the spread of AMR.

“The work in Hisar has the potential to change Hisar, India, and even the world.”

—Dr. Rajesh Raju, state TB officer in Haryana, speaking about the potential impact of private sector engagement in IDDS’ new one-stop model for diagnosis of TB

Annual Highlights

Diagnostic

- IDDS improved the quality of the TB diagnostic network by revising and introducing a supervisory, monitoring, and evaluation package for NRLs and intermediate reference laboratories and developing a grading tool to rank TB laboratories according to their performance in delivering key services. With inputs from NRLs and CTD’s laboratory unit, IDDS also developed a biosafety manual and an associated monitoring mechanism.
- IDDS increased TB case notification and provided patients with faster access to their laboratory results by engaging a private sector laboratory in Hisar district of Haryana state to demonstrate the feasibility of a new “one-stop” model. By reducing turnaround times and improving the DST rate, the new model is expected to improve the rate of patients who initiate the correct treatment regimen.
- To generate evidence supporting the effective utilization of Truenat at NTEP sites, IDDS, in partnership with the National Institute for Research in Tuberculosis, conducted a study of the root causes of Truenat “invalid/ indeterminate” rates. IDDS also established the proof of concept of using Trueprep-extracted DNA for LPA testing.
- To advance the national effort to contain the spread of AMR, IDDS provided technical and managerial support in organizing expert inputs to the National Action Plan on AMR for 2022–2026.

PARTNERS AND COLLABORATORS

- Ministry of Health and Family Welfare
- Intermediate reference laboratories
- IQVIA through USAID iDEFEAT TB
- Haryana State Tuberculosis Cell
- Hisar District Tuberculosis Center
- National Institute for Research in Tuberculosis
- National reference laboratories
- National Tuberculosis Elimination Program
- Thyrocare Technologies Limited

Challenges

- Ministry staff are challenged by commitments to other projects, so IDDS has devoted extra time to following up and closely coordinating to advance project activities. sustainability of continued technical assistance for essential TB diagnostic services.

What We Learned

- Active involvement and support from district stakeholders (chief medical officer, district TB officer, medical officer TB control, and other NTEP staff) have helped in gaining ownership and leadership of the one-stop TB diagnostic model in Hisar district.
- The runner mechanism for specimen collection and effective channels of communication between the public and private facilities contributed to a more effective TB diagnostic care cascade. This was a groundbreaking approach to obtaining specimens from remote areas without delays. For district stakeholders, this is a vital learning opportunity to expand this model to other districts and states.
- The involvement of block coordinators from the community enhances the rapport building and engagement for the smooth implementation of the one-stop model.
- To ensure the data quality and validity of the tests offered by the private laboratory engaged in the one-stop model, digital and in-person monitoring is necessary to ensure that data were uniform across levels.

Output Data



QMS (131)
New diagnostic tools - Truenat (16)



QMS

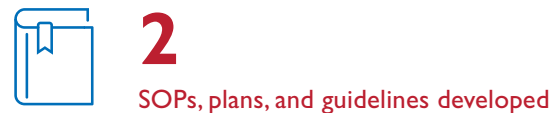


Testing skills and procedures (3)
New diagnostic tools - Truenat (11)
Private sector engagement (4)
QMS (1)
Implementation of NTEP policies (4)
Certification-TB free status (6)

*Private sector laboratory supported in Hisar to provide TB services as part of the national TB network.



QMS (1)
New diagnostic tools (1)



QMS



Private sector engagement (1)
New diagnostic tools - Truenat and other (2)



IDDS team supervising the training of laboratory technicians in Chennai, India. Photo by IDDS.

MALAWI

Context

IDDS is working in Malawi to expand and improve the TB diagnostic network and introduce new diagnostic technologies and approaches, such as digital X-ray and stool testing for diagnosis of childhood TB.

Annual Highlights

Diagnostic

- IDDS improved capacity for detecting DR-TB by conducting a workshop to review and revise Malawi’s diagnostic algorithm. Seventeen participants (two female) from the National TB and Leprosy Elimination Program (NTLEP), NTRL, and TB Local Organization Network (LON) partners gathered in Lilongwe and updated the algorithm, which is now being used to inform revision of national-level guidelines that incorporate use of new diagnostic technologies.
- IDDS hosted a DNA self-assessment process workshop in Lilongwe, during which the project trained 24 participants (6 female) who then conducted the self-assessment. Self-assessment participants included representatives from NTLEP and NTRL, two district-level health workers and one community-level health worker, TB laboratory supervisors, and other implementing partners.
- To improve access to TB screening, IDDS concluded the bidding process for a contractor to complete X-ray room refurbishments at Ekwendeni Hospital. IDDS procured an X-ray machine, which arrived in the country in the last week of September 2022 and will be transported to Ekwendeni Hospital upon clearing customs.



IDDS visit to Ekwendeni Mission Hospital in Malawi. Photo by IDDS.

Challenges

- Fuel shortages interrupted the project team’s ability to collect baseline data from supported sites. By the end of the fiscal year, IDDS had collected data from 65 percent of the 54 supported sites and will complete the remainder of baseline data collection during future routine data collection efforts.

What We Learned

- Close collaboration with NTLEP and other implementing partners is key for sustainability and effective implementation. For pediatric TB activities, IDDS worked with NTLEP to deliver stool-based pediatric TB detection training, which included site assessments and briefing of research committees at nine sites. IDDS is also working with the USAID-funded partners TB LON 1 and TB LON 2 for all planning and implementation, which has helped address identified bottlenecks.

PARTNERS AND COLLABORATORS

- National Tuberculosis Program
- National Tuberculosis Reference Laboratory
- Tuberculosis Local Organization Networks

Output Data



Pediatric TB



Pediatric TB



Pediatric TB

NIGERIA

Context

In Nigeria, IDDS is working to expand access to quality and timely TB diagnosis through introduction of new rapid molecular diagnostics and digital X-ray. IDDS is also building capacity to detect DR-TB.

“Ensuring TB diagnostic access to the hard-to-reach rural communities will be key in finding missing TB cases in Nigeria. The addition of Truenat to the TB diagnostic menu in the country is helping to address this key barrier to TB case finding.”

—Dr. Bethrand Odume, executive director of KNCV Nigeria

Annual Highlights

Diagnostic

- IDDS expanded access to rapid molecular TB diagnostics in partnership with the KNCV TB Foundation and the Institute of Human Virology, Nigeria, by installing 38 Truenat instruments and co-hosting training of 39 trainers (11 female) who will transfer knowledge to end users and troubleshoot issues with Truenat instruments. IDDS also co-hosted direct training (cluster format) to 75 Truenat end users (30 female) and 28 state laboratory and implementing partner staff (8 female).
- IDDS tracked challenges with Truenat equipment and provided mentoring and supervisory visits throughout the year.

Challenges

- Truenat end users faced difficulty in adhering to guidance and SOPs on quality control immediately after installation, but this issue was addressed by supervisory visits.
- The Truenat platform is not yet incorporated into the EQA program, limiting the ability to identify issues with underperforming sites.

PARTNERS AND COLLABORATORS

- Institute of Human Virology, Nigeria
- KNCV Tuberculosis Foundation
- Stop TB Partnership

What We Learned

- Engagement of community gatekeepers and facility management greatly improved Truenat ownership and acceptability.
- Understaffed sites need ad hoc staff support to ensure continuous operation of Truenat.
- To improve quality and sustain performance across sites, incentives (non-financial and logistics support) are needed for private facilities and volunteers.

PAKISTAN

Context

IDDS is strengthening Pakistan’s TB diagnostic network to better detect cases of pulmonary TB and identify DR-TB. To mobilize resources and improve quality across the network, IDDS is supporting a DNA and an LNSA, developing a five-year roadmap, and working to support laboratories to obtain ISO accreditation.

Annual Highlights

Diagnostic

- To improve quality across the diagnostic network, IDDS reviewed and revised 17 QMS documents, including technical and management SOPs, quality and biosafety manuals, and client handbooks.
- IDDS provided weekly training for one NRL and three provincial reference laboratories that are working toward accreditation. Fifty people have been trained through the QMS trainings.
- To strengthen sentinel surveillance of TB and DR-TB across the country, IDDS developed a draft protocol for a drug resistance survey and a protocol for sentinel surveillance at six pilot sites in the provinces.

What We Learned

- NTRL and the management staff of Pakistan have shown leadership qualities by being engaged in every activity, from documentation to QMS training. This buy-in is critical for the success of project activities.



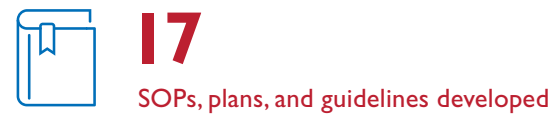
PARTNERS AND COLLABORATORS

- National Tuberculosis Reference Laboratory
- Provincial reference laboratories
- Supranational Reference Laboratory in Milan

Output Data



QMS



Testing skills and procedures

TANZANIA

Context

In partnership with national programs and academic collaborators, IDDS is working to achieve universal access to TB diagnostic services in Tanzania by strengthening zonal and regional TB diagnostic capacity and building the capacity of four zonal laboratories, the Central TB Reference Laboratory, and their respective catchment areas.

“Hosting the GxAlert server locally will keep us more informed and improve technical troubleshooting and maintenance of the server.”

—Collins Minja, information and communications technology officer at Tanzania National TB and Leprosy Program

Annual Highlights

Diagnostic

- To enhance the overall quality and capacity of TB testing, IDDS supported the dissemination of a TB DNA report and TB laboratory operational plan. The operationalization of the plan will enable the zonal laboratories to expand their scope of accredited services to include culture and LPA tests.
- IDDS is improving real-time TB results reporting and data use for patient management and TB program improvement. IDDS contributed to the installation and configuration of a GxAlert server/Aspect platform for TB diagnostic connectivity with the new TB diagnostic technologies in the country’s TB diagnostic network.

Challenges

- After experiencing delays in planned activities, IDDS focused on technical review and submission of FY 2021 deliverables and continued to engage stakeholders to align and coordinate the planned activities with government priorities and avoid duplication of efforts.

What We Learned

- Digital applications improve data quality and use.
- Engagement of stakeholders prior to implementation of planned activities ensures that work is streamlined and aligned with national priorities and avoids duplication of efforts.
- The monthly reviews of functionality, access, and utilization of TB molecular platforms led by IDDS were helpful in identifying implementation challenges. These challenges were discussed during TWG meetings, and corrective measures were identified.

PARTNERS AND COLLABORATORS

- Ministry of Health
- Baylor University
- Global Fund to Fight AIDS, Tuberculosis and Malaria
- National Tuberculosis and Leprosy Program
- Tanzania Health Promotion Support
- USAID Comprehensive Client-Centered Health Program

Output Data



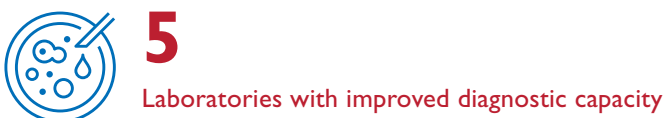
QMS



Testing skills and procedures

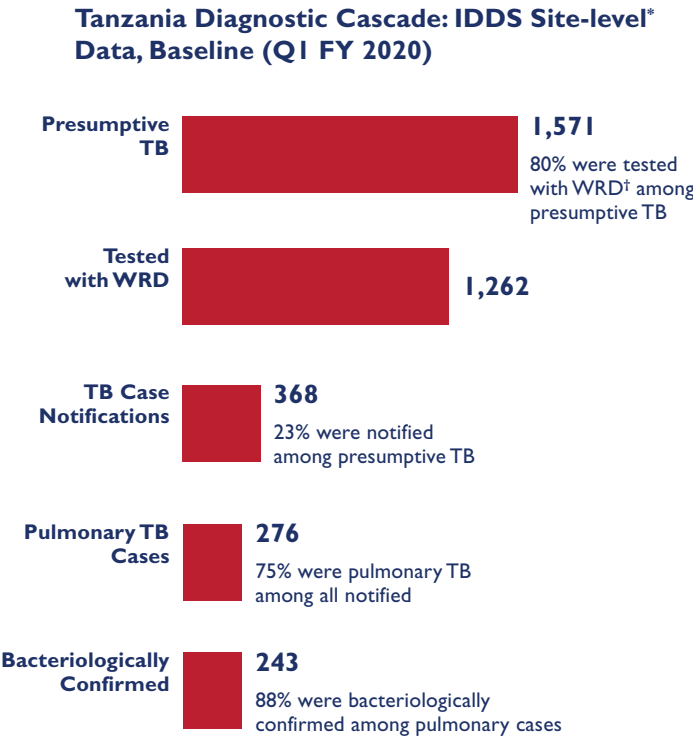


TB diagnostic network



Outcome Data

Outcome data are provided through Q3 FY 2022.



*Tanzania IDDS sites: five diagnostic sites (four zonal reference laboratories and one national reference laboratory).
†WRD:WHO-recommended RDTs.

IDDS interventions in supported laboratories in Tanzania contributed to increased testing with WHO-recommended RDTs from 80 percent at the baseline (Q1 FY 2020) to 92 percent in Q3 FY 2022. Bacteriological confirmations also increased from 88 percent at the baseline to 97 percent during Q3.



VIETNAM

Context

In Vietnam, IDDS strengthened the TB diagnostic laboratory network and surveillance and reporting systems in line with the National Strategic Plan. TB activities in Vietnam closed out at the end of the fiscal year.

“Previously, it was very difficult to collect sputum or gastric aspirate in small children, and it could only be performed at the hospital. However, now it is easy to collect stool samples from children of any age at home—and the children do not need to go to the hospital.”

—Dr. Nguyen Thi Tham, a laboratory technician from Nghe An Hospital

Annual Highlights

Diagnostic

- To improve detection of TB cases among children, especially those who are under five years of age and have difficulty producing sputum for TB testing, IDDS supported implementation of stool GX testing for pediatric TB patients in 13 laboratories in 5 provinces.
- In collaboration with the Stop TB Partnership, IDDS increased capacity for TB screening by providing training and implementing ultra-portable X-ray with CAD-AI software at 10 sites. These sites are now able to use ultra-portable X-ray with CAD-AI software for TB case finding.
- IDDS completed a study on trace results analysis and developed recommended updates to the diagnostic algorithm that account for GX trace results.
- To improve capacity for detecting DR-TB, IDDS finalized the landscape assessment report for next-generation sequencing application for DR-TB surveillance.
- IDDS increased the coverage and capacity of the diagnostic system for bacteriological confirmation of TB through the rollout of Truenat technology to 28 sites. These sites are now capable of using Truenat to diagnose TB and detect RIF-resistant TB.

PARTNERS AND COLLABORATORS

- National Institute of Hygiene and Epidemiology
- National Tuberculosis Program
- Pasteur Institute (Nha Trang and Ho Chi Minh City)

Challenges

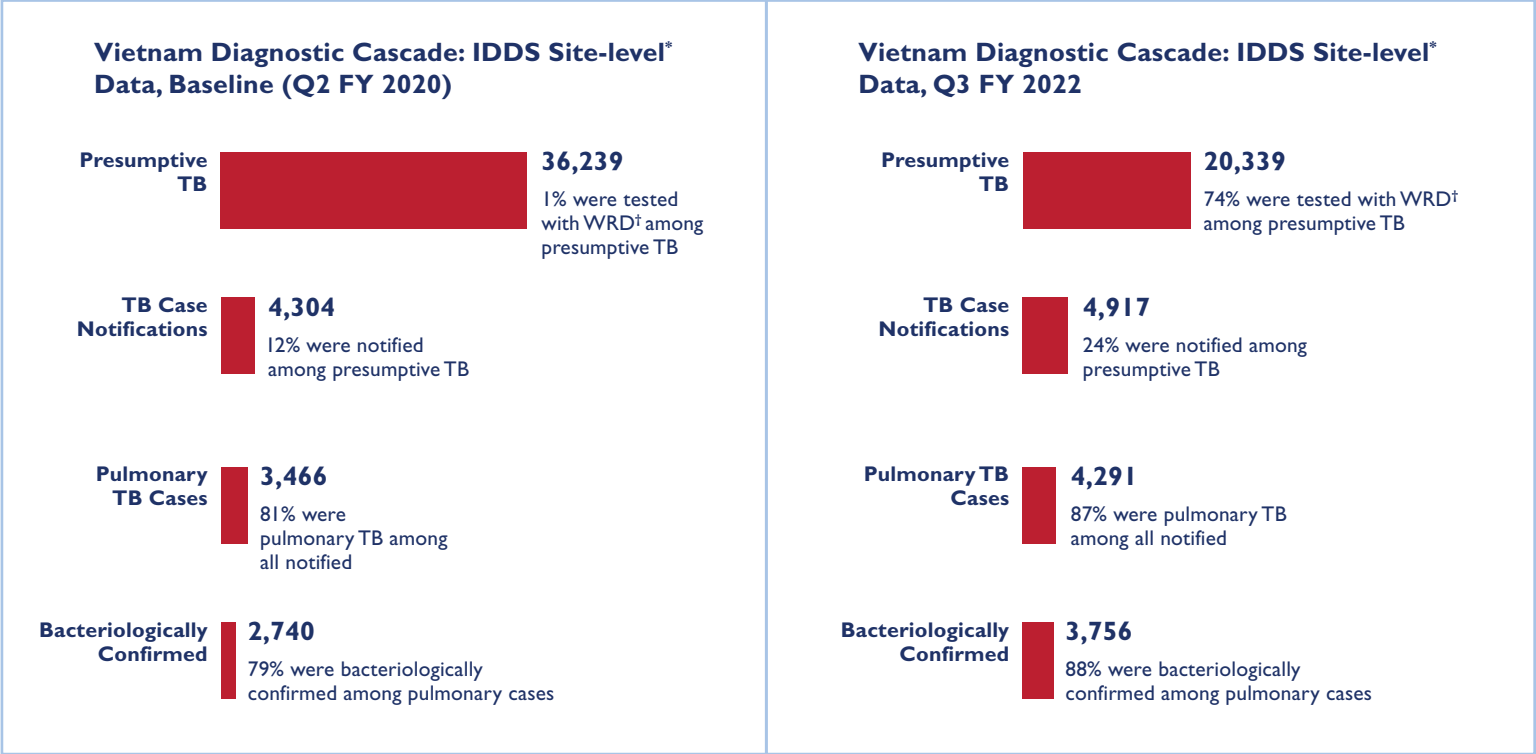
- Delayed responses from NTP due to heavy workload and staffing challenges slowed progress. IDDS followed up with NTP to expedite timelines as much as possible.
- NTP did not renew the contract with SystemOne, the vendor designated to support the implementation of the specimen referral network, delaying its launch. IDDS and NTP discussed the implementation of the SRS with TekMax, a company that agreed to support the specimen referral network by providing their specimen management software (TB Trans).
- The slow approval process for the Truenat instruments delayed implementation in some districts.

What We Learned

- Implementation timelines need to account for the long approval process for importing diagnostic equipment and other commodities to Vietnam.
- Project closeout planning should account for established service contracts and monitoring and evaluation data collection to ensure an efficient transition process.

Outcome data

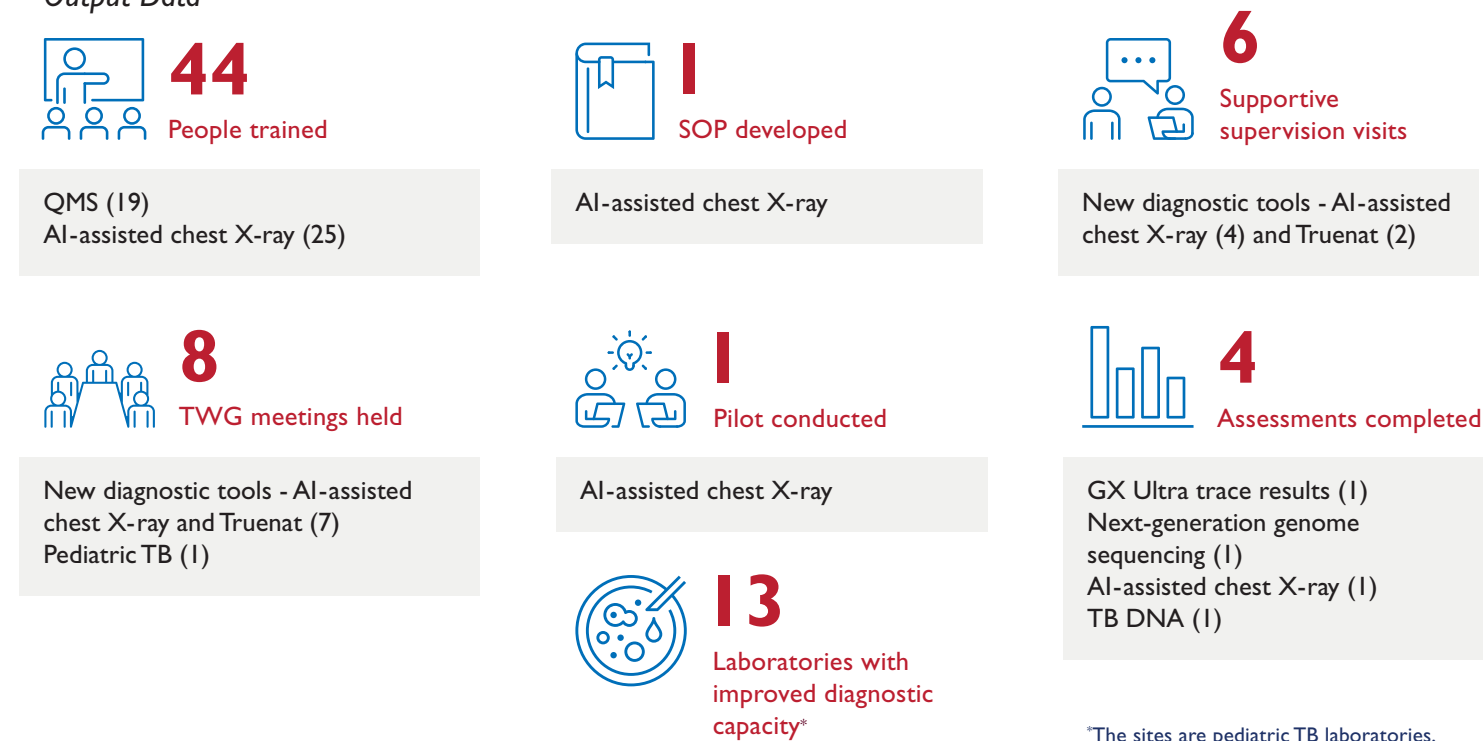
Outcome data are provided through Q3 FY 2022.



*IDDS-supported sites in Vietnam are laboratories from seven provinces.
†WRD: WHO-recommended RDTs.

IDDS interventions in Vietnam contributed to improvement in the rate of testing with WHO-recommended RDTs in IDDS-supported provinces from only 1 percent at the baseline (Q2 FY 2020) to 74 percent in Q3 FY 2022, thereby increasing bacteriological confirmation from 79 percent to 88 percent during the same period.

Output Data



*The sites are pediatric TB laboratories.

ZIMBABWE

Context

IDDS is supporting strengthening of the Zimbabwe national TB diagnostic network to be accessible, accurate, adaptable, timely, and integrated for TB and multidrug-resistant TB diagnosis.

“[Truenat] is saving lives and it has made an impact in terms of TB diagnosis so that TB treatment is offered earlier.”

—Tanaka Sakubani, national tuberculosis laboratories coordinator, Zimbabwe Ministry of Health and Child Care

Annual Highlights

Diagnostic

- To improve quality across the diagnostic network, IDDS supported the development of the National TB Testing Manual, which contains SOPs for TB testing to be accessed and used by laboratories at all levels of the diagnostic network.
- To mobilize resources for improving access to TB diagnostic services, IDDS supported the revision of the TB-HIV Public-Private Partnership Framework (2022–2025).
- IDDS contributed to expanded diagnostic services through its capacity building activities at Bulawayo NTRL, which was recommended for international accreditation by the Southern African Development Community Accreditation Services.
- To expand access to rapid molecular diagnostics, IDDS supported the introduction of 20 Truenat instruments and trained, through Core TB funds, a cadre of 22 (7 female) national and district-level TB molecular diagnostic subject matter experts (super-users) to provide ongoing supervision and mentorship to the laboratories.
- IDDS laid the groundwork for advancing understanding of technical issues by enrolling 40 participants in the GX MTB/RIF Ultra “Trace Call” study across five sites. The study will inform development of a revised diagnostic network algorithm that accounts for TB trace results.

Challenges

- Differences in reporting timelines by NTP and the IDDS Monitoring, Evaluation, and Learning team necessitated additional efforts to align and verify data.

PARTNERS AND COLLABORATORS

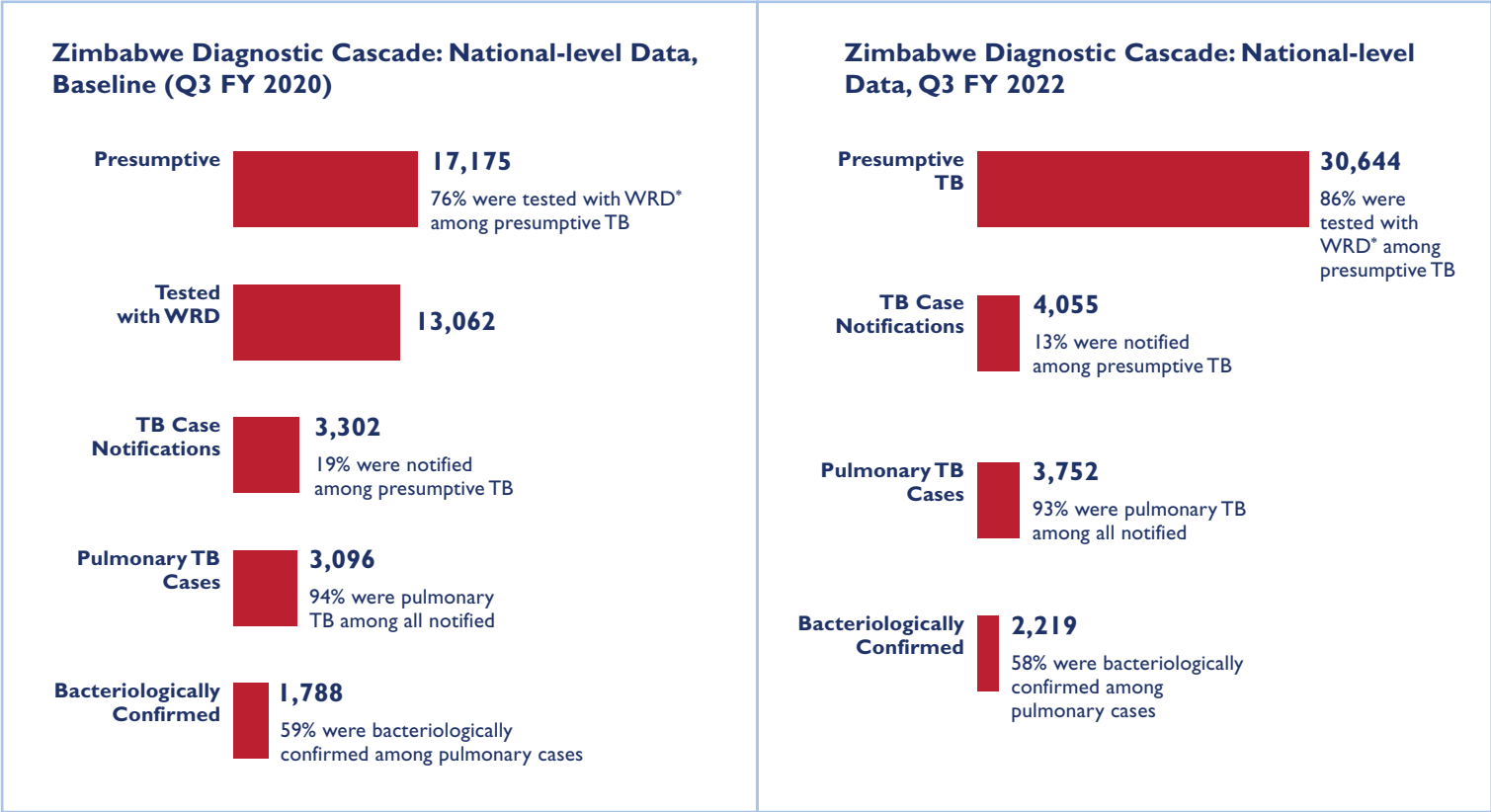
- Ministry of Health and Child Care
- Biomedical Research and Training Institute
- Chemonics
- Clinical and Laboratory Standards Institute
- Clinton Health Access Initiative
- Elizabeth Glaser Pediatric AIDS Foundation
- Jointed Hands Welfare Organization
- National Tuberculosis Control Program
- The Union Zimbabwe Trust
- USAID Tuberculosis Implementation Framework Agreement
- U.S. Centers for Disease Control and Prevention
- World Health Organization
- Zimbabwe National Quality Assurance Program

What We Learned

- Collaborating with the Ministry of Health and Child Care for development of work plans has reduced duplication of TB activities.
- Engaging with USAID implementing partners can build additional support (including financial support) for TB activities.

Outcome Data

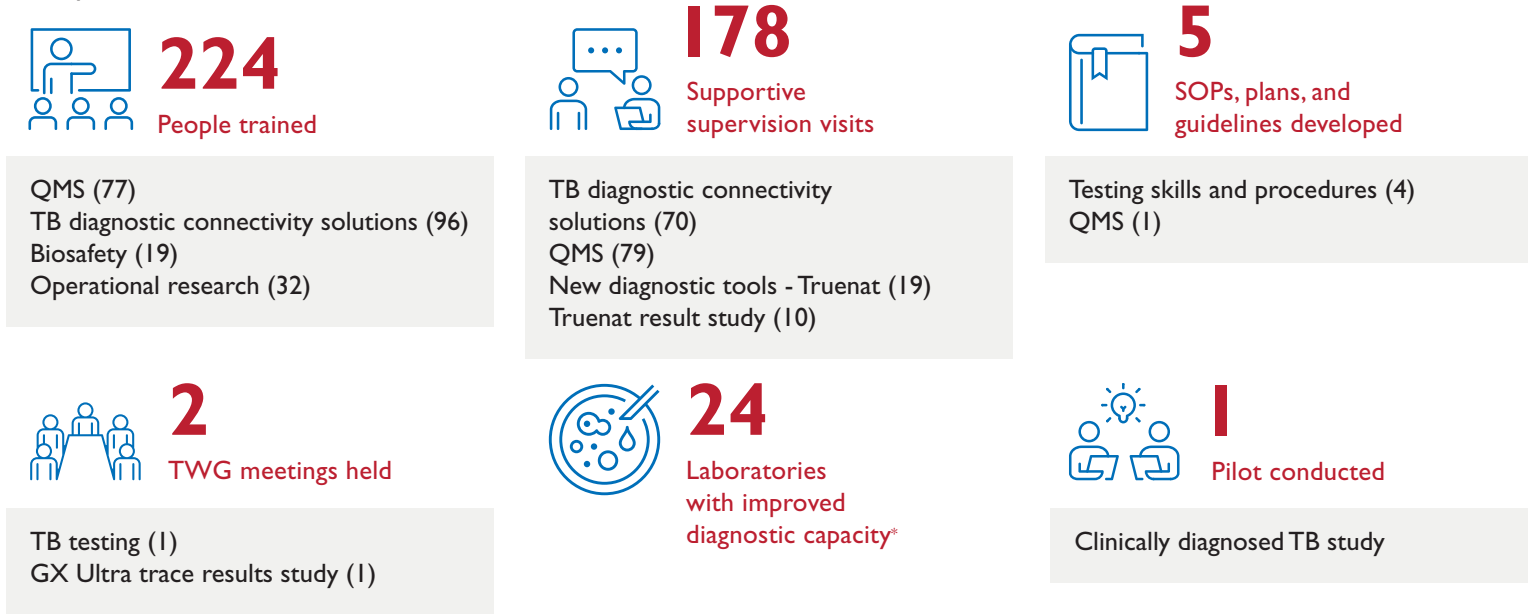
Outcome data are provided through Q3 FY 2022.



*WRD:WHO-recommended RDTs.

The proportion of presumptive TB cases tested with WHO-recommended RDTs increased from 76 percent at the baseline (Q3 FY 2020) to 86 percent in Q3 FY 2022. During the same period, there were increases in the number of TB case notifications from 3,302 to 4,055; in pulmonary TB cases from 3,096 to 3,752; and in bacteriologically confirmed cases from 1,788 to 2,219.

Output Data



Challenges

- In Vietnam, NTP has not yet approved Truenat sites to begin project implementation. Four EQA panels that had already been shipped by SmartSpot have not been distributed due to delayed approval. IDDS redistributed the four panels to TekMax to be used for super-user training and paused the shipment of the remaining 34 panels until NTP approval is obtained.
- The Philippines implemented Truenat testing but did not implement EQA testing right away, because partners wanted to train super-users first and later distribute the EQA panels during supervisory site visits. After IDDS educated partners about the importance of conducting EQA shortly after installation, the program agreed to receive all 3 cycles of EQA panels for 22 sites and will conduct 1 cycle per month during October to December 2022.
- In Cambodia, activities to improve detection of DR-TB have progressed slowly, but IDDS has hired a diagnostic specialist in the country to support both DR-TB and field-funded activities, which should expedite progress.

What We Learned

- Providing virtual training to end users and group managers and in-person training to super-users has improved Truenat EQA reporting rates.
- Collecting data on errors and failures of the Truenat instruments in the field is valuable to better understand challenges and work with stakeholders to develop solutions to reduce recurrences.
- Including all stakeholders at the start of an activity and ensuring their buy-in can delay implementation (as was observed in Pakistan for DR-TB activities), but it remains valuable in the long term because once activities begin, they move much more quickly since stakeholders have reached consensus.

ABBREVIATIONS

AI	artificial intelligence	RDT	rapid diagnostic test
AMR	antimicrobial resistance	RIF	rifampicin
CAD	computer-aided detection	SOP	standard operating procedure
COMMIT	Community Mobilization Initiatives to End Tuberculosis	SRS	specimen referral system
COVID-19	coronavirus disease 2019	TB	tuberculosis
CTD	Central Tuberculosis Division	TWG	technical working group
CXR	chest X-ray	USAID	United States Agency for International Development
DNA	diagnostic network assessment	WHO	World Health Organization
DR	drug-resistant	WRD	WHO-recommended rapid diagnostic test
DRC	Democratic Republic of the Congo		
DST	drug susceptibility testing		
DTC	DataToCare		
EPTB	extra-pulmonary tuberculosis		
EQA	external quality assessment		
FY	fiscal year		
GX	GeneXpert		
IDDS	Infectious Disease Detection and Surveillance		
INTP	introducing New Tools Project		
LNSA	laboratory network spatial analysis		
LON	local organization network		
LPA	line probe assay		
MTB	<i>Mycobacterium tuberculosis</i>		
NAP	national action plan		
NRL	National Reference Laboratory		
NTEP	National Tuberculosis Elimination Program		
NTLEP	National Tuberculosis and Leprosy Elimination Program		
NTP	National Tuberculosis Program		
NTRL	National Tuberculosis Reference Laboratory		
QMS	quality management system		

Output Data

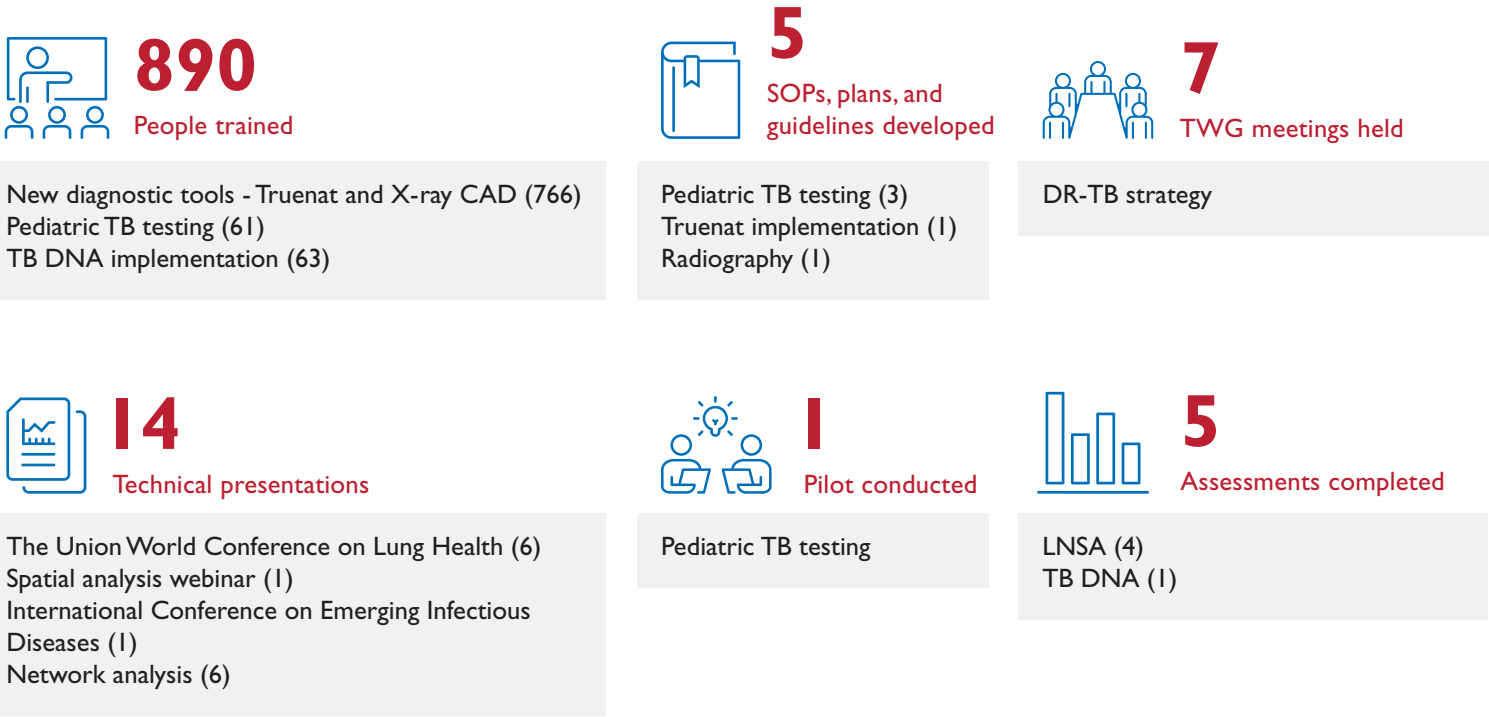




Photo by Cindy Liu for IDDS.



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