Annex B. Success Stories, FY 2023 Q4

Contents

Decentralization for Universal Access to Quality Tuberculosis Testing

In Bangladesh, a strategic goal of USAID's Infectious Disease Detection and Surveillance (IDDS) project was to decentralize tuberculosis (TB) diagnostic capacity. IDDS focused on drug susceptibility testing (DST) as well as on culture (used to confirm an initial test) to identify drug-resistant TB, across the laboratory network at both the national and regional levels).

IDDS support for TB diagnostics was vital for ensuring timely and universal access to rapid and accurate testing of all forms of TB, including drug resistance, and for achieving the national goal of ending the TB epidemic by 2030.

Decentralized Capacity of TB Diagnostics

At the start of the IDDS project in 2020, only the National TB Reference Laboratory (NTRL) in the capital, Dhaka, was able to perform solid and liquid culture, DST, and line probe assay for second-line drugs. The four regional TB reference laboratories (RTRLs) were nominally functional at sub-standard facilities that lacked biosafety systems, critical TB equipment, and trained staff. During its four-year lifetime, and with the first year devoted to COVID-19 response, IDDS brought about dramatic changes in decentralizing the network and diagnostic capacity. With IDDS support, the network has been transformed, with five RTRLs, including the newly established Shyamoli RTRL in Dhaka, upgraded with standard biosafety systems and equipment for performing liquid culture and DST. Four of these RTRLs are now fully functional in liquid culture and DST, and the fifth RTRL in Chattogram will soon be in operation. IDDS also supported the development of standard operating procedures and trained all staff on culture and DST, line probe assay, testing extrapulmonary TB (EPTB), and stool specimen testing

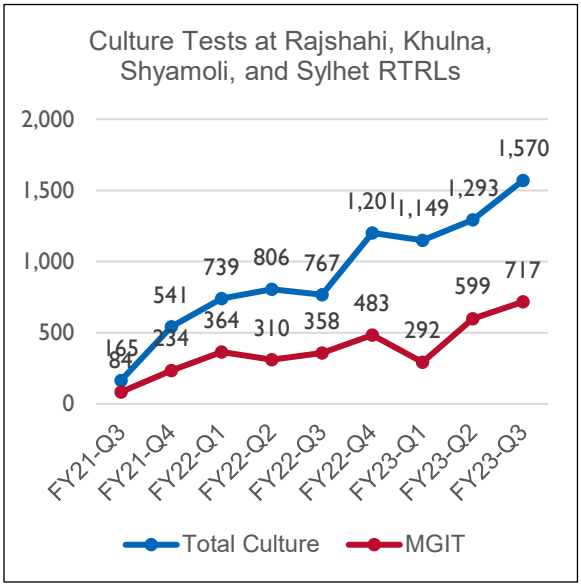
Upgraded Rajshahi RTRL. Photo by IDDS

DST training at the NTRL, May 22-25, 2022. Photo by IDDS

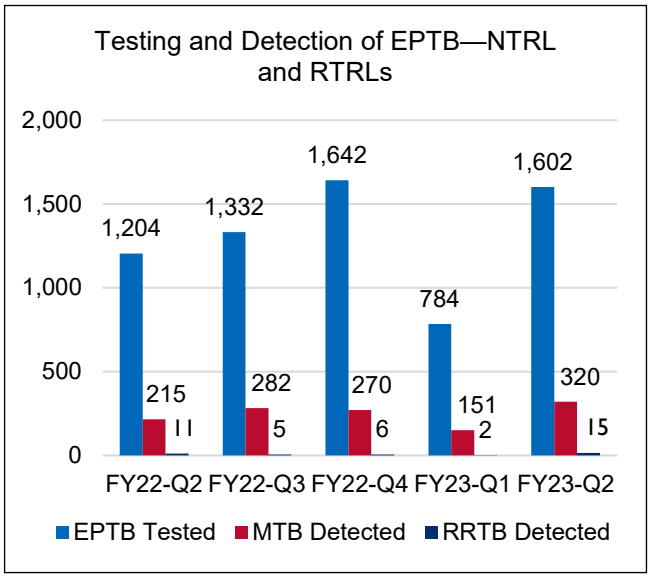
for childhood TB. The combined capacity of these RTRLs is now sufficient for meeting the total estimated needs for first- and second-line DST for all patients, greatly strengthening Bangladesh's efforts to fight drug-resistant strains of TB.

Results of IDDS Support

The RTRLs started to perform culture at different dates, depending on facility readiness. Rajshahi, Khulna, and Sylhet RTRLs provide both solid and liquid (MGIT) culture services, and Shyamoli RTRL only provides liquid culture services. The graph shows the trend in uptake of total culture services, including liquid culture, at the four RTRLs. Over the three-year period, the total number of solid and liquid culture performed at the RTRLs increased (as shown right). The project intended to transition the network solely to performing liquid culture because it reduces test time to 7–21 days, compared with the 8 weeks taken by solid medium. However, IDDS was unable to fully achieve this because transporting fresh samples, which is needed for liquid culture, from peripheral areas (outlying areas) was a challenging task. Performance was also affected at different times due to shortages or stockouts of reagents.



Introduction of standardized testing and detection of EPTB with GeneXpert® through the RTRLs is also a success for IDDS. Between FY 2022 Q2 and FY 2023 Q2, testing of EPTB at the RTRLs increased by 33 percent, resulting in increased detection of EPTB. IDDS has shown that RTRLs have great potential for increasing detection of EPTB, provided that they receive a timely supply of test kits and periodic networking and advocacy meetings with the clinicians to promote their support for collection and referral of specimens.



Conclusion

The decentralization of diagnostic capacity through divisional-level reference laboratories has boosted the early detection and effective management of TB patients. Most important are the benefits to patients as the laboratories reduce delays in response by

referral services, enabling patients to begin treatment quickly and more easily following their diagnosis, and improving treatment outcome. The way forward is to strengthen the specimen collection and transportation system linking the peripheral laboratories and communities for improved access of the TB services at the RTRLs.

USAID's Infectious Disease Detection and Surveillance (IDDS) project operates in more than 20 countries in Africa and Asia 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.

Truenat Shows Great Potential for Rapid Detection of Tuberculosis Cases at the Peripheral Level in Bangladesh

Context

Bangladesh is one of the highest burden tuberculosis (TB) countries in the world. Despite remarkable progress, challenges remain to detect the estimated 18 percent of TB cases that go undiagnosed and 66 percent of the drug-resistant TB (DR-TB) cases that go undiagnosed (Global TB Report 2022). Without a diagnosis, these patients are not treated and continue to spread the infection in their communities.

Eighty percent of TB cases in the country are bacteriologically confirmed (meaning that a laboratory test was conducted to confirm the initial diagnosis). Only 24 percent of tests were carried out with rapid molecular diagnostics, despite World Health Organization recommendations on the use of rapid molecular tests as the initial test. Even though the use of GeneXpert® (rapid molecular testing technology) has expanded across the country, most of the presumptive cases are initially tested by smear microscopy, which is the older, standard method and is less sensitive than rapid molecular testing and cannot test for drug resistance. As a result, health care facilities at the peripheral level (outlying areas) are missing the early detection of large numbers of positive cases.

Medical technologist processing specimen for Truenat testing. Photo by IDDS

Hands-on Truenat testing by trainees. Photo by IDDS

To move the fight to end TB forward, USAID's and Stop TB Partnership's introducing New Tools Project (iNTP) provided the National TB Program (NTP) with 38 Truenat® Duo systems and reagents for rapid detection of TB and drug resistance in peripheral health care facilities. USAID's Infectious Disease Detection and Surveillance (IDDS) project, with NTP, BRAC, and the Damien Foundation, completed the first phase of the Truenat introduction from August 2022 to May 2023.

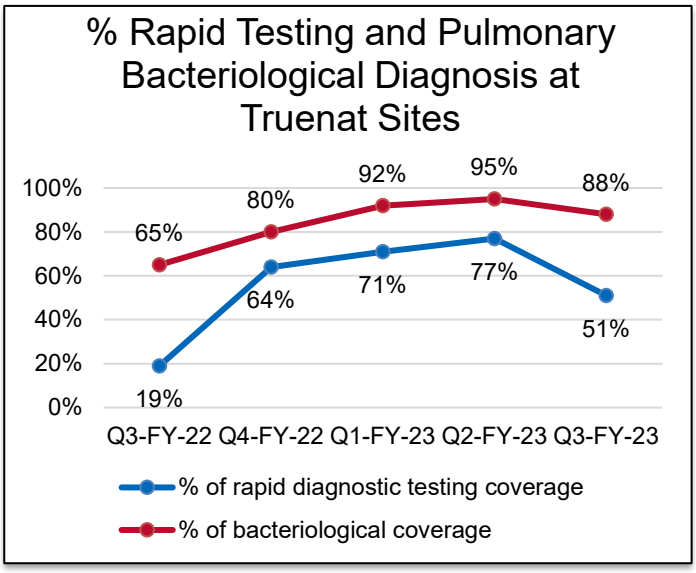
Setting the Stage for Truenat

Paving the way for the rollout, IDDS customized training materials, recording and reporting templates, job aids, and other tools. Following the equipping of Truenat trainers from NTP and partners, basic training was conducted for medical technologists and supervisory staff from all 38 health care facilities on the technical and programmatic components. In sync with the completion of facility readiness after necessary refurbishment, the local agent for Molbio Diagnostics, the manufacturer of Truenat, visited the sites and installed the instruments. A monitoring and supervision plan was developed with a tailored checklist for supportive supervision of Truenat testing at the facilities.

Implementation Results

Between August 2022 and May 2023, a total of 62,155 tests were carried out using Truenat on specimens from 59,008 people with signs and symptoms of TB. This resulted in the detection of TB in 4,446 individuals (7.5 percent), including rifampicin-resistant TB in 58 individuals (1.3 percent).

Truenat introduction started in August 2022. By September 2022, 22 sites became functional, and by October 2023, all 38 sites had started to provide Truenat services. The data show a steady increase in the proportion of rapid testing, from 65 percent to 95 percent, and in bacteriological coverage, from 19 percent to 77 percent between FY 2022 Q3 and FY 2023 Q2. The expiry of Truenat test kits on May 26, 2023, which led to the suspension of the Truenat operation for two months, explains the reason for the decline in coverage for FY 2023 Q3. The overall positivity rate (the percentage of positive tests) for Truenat has been 7.5 percent, compared to 3.2 percent for microscopy in the rollout sites. In other words, the increased coverage of rapid diagnosis resulted in early detection of a large number of TB cases that would have remained undiagnosed with microscopy.



The country has set ambitious targets for 75 percent reduction of TB related deaths and 50 percent reduction in TB incidence rate compared to 2015 by 2025. Achieving these targets requires universal access to rapid molecular diagnostic technologies to accurately detect TB and

DR-TB, while reducing delays in detection and treatment, which is critical for interrupting transmission of the disease.

Way Forward

The achievements of IDDS's Truenat rollout demonstrate its great potential for boosting the detection of TB, including DR-TB cases, and its functionality at rural and outlying health care facilities. The clear evidence of the successful rollout was the basis for NTP to procure an additional 112 Truenat systems with funding from the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The expanded coverage of Truenat is likely to make dramatic progress in increasing the detection of TB in Bangladesh and halting its transmission in the community, saving many lives.

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IDDS Prepares Local Airlines to Safely Handle and Transport Biological Specimens in the Democratic Republic of the Congo

The epidemiological profile of the Democratic Republic of the Congo (DRC) is characterized by the re-emergence of significant outbreaks such as Ebola, plague, cholera, bacterial and viral meningitis, bacillary dysentery, poliomyelitis, and measles. These outbreaks occur particularly in the eastern region of DRC, where the security situation and recurrent armed conflicts constitute a major challenge for transporting biological specimens from remote sites to testing laboratories.

Additional challenges include poor road conditions, the size of the country and its limited resources, inaccessibility of certain areas, and the lack of involvement of private airlines in transporting biological specimens during outbreaks.

To address the challenge of safely moving specimens during outbreaks and pandemics, USAID's Infectious Disease Detection and Surveillance (IDDS) project worked with the Ministry of Public Health (MoH) to raise awareness and involve local airlines in outbreak response support efforts specifically related to the transport of biological specimens.

IDDS and the MoH Directorate of Laboratory Services (DLS) developed a contact list of airlines operating in the country, mainly in the eastern region, including the United Nations Humanitarian Air Service and other local airlines, to facilitate discussions with each of them.

One-on-one discussions with representatives from these companies demonstrated their willingness and confirmed their interest in adding this service to their portfolios. However, the company representatives also identified the need to strengthen the capacity of their staff in the safe handling and transport of biological specimens.

In response to this need, IDDS and MoH/DLS designed and conducted an online training session on the safe transport of biological specimens. The training included topics such as the categorization of biological materials and principles of triple packaging, among others. The online training format was designed to accommodate all participants attending from various provinces (Ituri, Maniema, South Kivu, North Kivu, and Kinshasa). In total, 20 participants (3 female) from the United Nations Humanitarian Air Service and local airlines successfully completed the training.

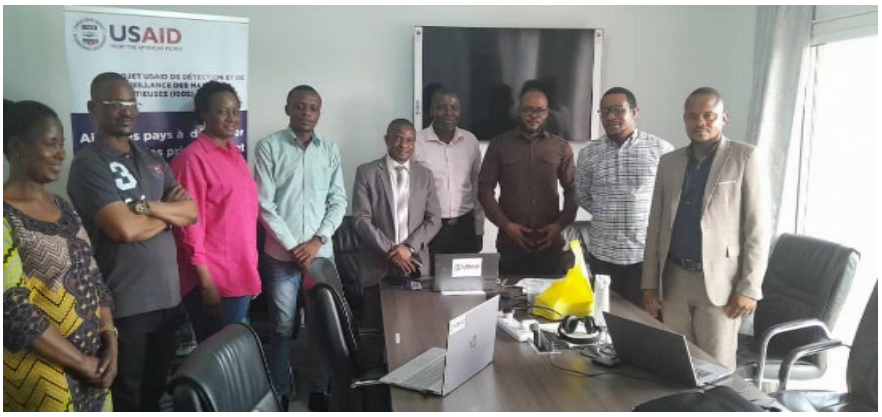
The training session considerably increased the participants' knowledge of safe handling and transporting biological specimens, as evidenced by the marked increased in post-test scores (from the average score of 70 percent at the pre-test to 90 percent at the post-test). The participants also expressed their willingness and determination to contribute both individually and on behalf of their respective organizations in the response efforts to safely transport biological specimens during future outbreaks in DRC.

“For me, as a trainer for the staff of the African Airline (CAA), the largest airline operating throughout the DRC, the training for local airlines on the safe handling and transport of biological products was very timely and useful because it allowed me to acquire new knowledge and abilities, especially concerning triple-packing," said Junior, CAA ground operations training officer. “I have already integrated this knowledge into the training curriculum that I am currently conducting for CAA staff and our services are expected to improve accordingly.”

The collaboration between IDDS, MoH, and local airline companies will gradually help resolve the challenges related to transporting specimens during potential outbreaks. This will significantly increase the timeliness of outbreak detection, reduce the testing turnaround time, and facilitate evidence-based decisions for outbreak response and control and real-time surveillance, for the benefit of the affected communities.

The following recommendations have been formulated for the MoH to consider:

- Maintain an open line of communications with the airlines, ensuring that they are promptly informed and ready to participate in the response to outbreaks,
- Continue building the airlines’ capacity through practical, in-person follow-up training on triple packaging and use of personal protective equipment.
- Conduct dangerous goods certification training approved by the International Air Transport Association.



IDDS and DLS training facilitators. Photo by IDDS

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IDDS Supports Country Self-Evaluation and Implementation of the Core Capacities of the International Health Regulations in Ethiopia

Viruses, bacteria, and other pathogens that cause disease can easily pass international borders undetected, and outbreaks can spread across the globe very rapidly. First adopted by the World Health Organization in 1969, the goal of the International Health Regulations (IHR) is to prevent, protect against, control, and provide a public health response to the international spread of diseases. The revised IHR (2005) require that all states parties (member nations) develop core public health capacities related to the ability to detect, assess, notify, and report public health risks and public health emergencies of international concern.

There is also a need for countries to know how well the IHR are being implemented, and that is where the Joint External Evaluation (JEE) comes in. The JEE is a voluntary multisectoral IHR capacity assessment developed by the World Health Organization. The JEE combines self-evaluation, peer review, and other external evaluations involving a combination of domestic and independent experts. The evaluation covers 19 technical areas crucial for sufficiently and effectively implementing the IHR.

Ethiopia conducted its first JEE to assess IHR core capacities in 2016 and launched the National Action Plan for Health Security (NAPHS) in 2019 to respond to the JEE findings. Recently, the Government of Ethiopia elected to conduct the second round of JEE self-evaluations to assess the current IHR capacities and further expand the NAPHS to address capacity building in all IHR technical areas.

The Ethiopian Public Health Institute (EPHI) of the Ministry of Health (MoH), in collaboration with partners, including USAID's Infectious Diseases Detection and Surveillance (IDDS) project, conducted two rounds of JEE Self-Evaluation Validation Workshops. The first workshop was conducted on May 29–May 31, 2023, in Hawassa, to discuss the JEE tools and procedures. Participants were divided into six groups, each covering designated IHR core capacities based on their experiences and project support areas. The IDDS team lead in Ethiopia actively participated and provided valuable inputs on the three thematic IHR core capacities: antimicrobial resistance (AMR) surveillance, zoonotic disease, and food safety.

To further refine the draft of the country JEE self-evaluation documents and group assessment and to validate the assessment reports, EPHI, in collaboration with partner organizations, conducted a follow-up JEE validation workshop on July 11–14, 2023. The IDDS team, including an IDDS senior diagnostic specialist, participated in the validation workshop, and the Ethiopia USAID mission health programs director and the USAID mission global health security advisor also attended the meeting. The health programs director delivered closing remarks. The IDDS team lead, who is a member of the country JEE evaluation planning core group, and the IDDS

senior diagnostic specialist were part of the technical team that reviewed AMR surveillance and national laboratory capacity.

In addition to the active technical support for the JEE self-evaluation, IDDS financially supported the JEE evaluation by covering ground transport for the government participants of the validation workshop, which was highly appreciated by the Ethiopian MoH.

IDDS's support to EPHI and the MoH in the JEE Self-Evaluation Validation Workshops built on the project's contributions to and active engagement in addressing the IHR (2005) AMR surveillance and national laboratory system capacities in Ethiopia. By identifying gaps and priority intervention areas, IDDS's contributions will outlive the project period, because they will also be included in the second NAPHS, to be developed over multiple years after the JEE report is complete.

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IDDS Successfully Introduced PCR Testing for COVID-19 Detection in Madagascar's Boeny Region

In December 2019, the world witnessed the emergence of COVID-19, with the first reported case in China. Several months later, Madagascar faced the arrival of the virus, with the first case confirmed on March 19, 2020. This diagnosis stemmed from a specimen collected from an individual returning from Europe, who was in isolation at the time, just before the Malagasy government initiated a lockdown.

At that time, the sole facility equipped to process specimens and detect the virus was the National Reference Center for Influenza within the Virology Unit at Institut Pasteur in the capital city, Antananarivo.

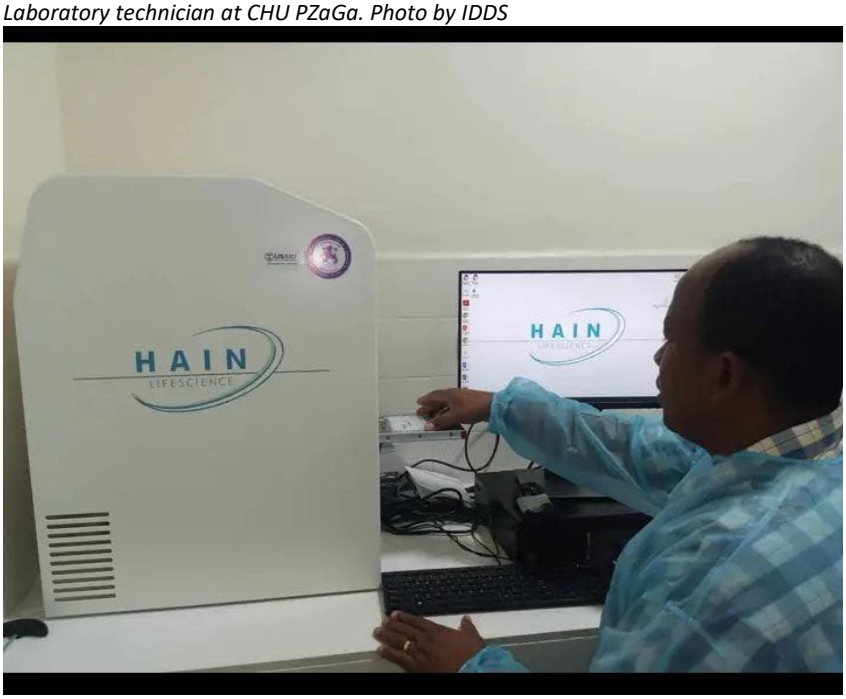
The rapid spread of COVID-19 affected not only the capital, but also the regions across the country, especially those with high levels of person-to-person and goods exchange with Antananarivo, like Boeny region in northwest Madagascar. Public health care facilities faced a flood of cases, and there was an absence of public laboratories equipped for COVID-19 detection across all regions of Madagascar. Also, given the novelty of this disease, health care personnel lacked comprehensive knowledge and training for its diagnosis.

In 2021, USAID's Infectious Disease Detection and Surveillance (IDDS) project started work to enhance the laboratory capabilities of CHU PZaGa Hospital, located in Androva Mahajanga in the Boeny region, for COVID-19 detection.

The laboratory infrastructure received a significant upgrade, primarily focusing on facilities for polymerase chain reaction (PCR) testing, resulting in the creation of three essential rooms: one for DNA extraction from specimens, another for master mix preparation, and a third for DNA amplification (which included gel electrophoresis for conventional PCR and visualization for quantitative PCR).

To ensure the effective operation of these facilities, IDDS trained three laboratory technicians and one biologist in specimen packaging and COVID-19 PCR procedures. Also, to streamline the testing process, a nucleic acid extraction automation (GenoXtract®) and a thermocycler (FluoroCycler® XT real-time PCR cycler) were provided, along with the necessary reagents and consumables required for COVID-19 detection.

Laboratory technician at CHU PZaGa. Photo by IDDS



Biologist at CHU PZaGa. Photo by IDDS

CHU PZaGa, which had received support for its bacteriology diagnostic capabilities long before the pandemic, is now equipped to conduct COVID-19 testing. This transformation led to a remarkable reduction in turnaround times, with results becoming available in less than 24 hours compared with the previous 3 to 90 days prior to the support provided by IDDS. This accelerated access to results greatly improved patient care management, allowing for prompt and appropriate treatment of confirmed COVID-19 cases and accelerated contact tracing for improved disease surveillance and control. ''The presence of this PCR platform has increased the esteem and confidence of the population of the Boeny region for the laboratory and for the

PZaGa University Hospital. We have noted the increase in demand for paraclinical assessment since the arrival of this PCR platform in our laboratory,'' said Dr. Rivo Rakotomalala, biologist at CHU PZaGa Laboratory.

Between September and November 2021, a total of 147 COVID-19 tests were conducted, and a laboratory-based surveillance system was established for CHU PZaGa to monitor tests of ships' crews arriving in Boeny from the Comoros Islands. The experience shows the critical importance of public laboratories in resource-constrained countries like Madagascar, both during normal times and in the face of epidemics and pandemics.

Now that COVID-19 cases have declined, the upgraded PCR platform at CHU PZaGa can be used to diagnose other infectious diseases that remain prevalent in the region, demonstrating the enduring value of the support provided by IDDS.

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IDDS Supports Universal Access to TB and DR-TB Diagnosis Through Supporting the Introduction of Truenat Technology in Tanzania

Tanzania is among the pioneer countries adopting early implementation of Truenat® technology for the detection of tuberculosis (TB) and drug-resistant TB (DR-TB). The Truenat test is a near point-of-care test that rapidly detects TB bacteria as well as resistance to rifampicin, a frontline TB drug. Some of the strengths of Truenat technology are its portability and flexibility. It can be used in almost any setting, making it suitable for local health care clinics with limited resources. This helps improve access to high-quality molecular diagnostics for rural patients. Criteria for placement of this technology were predetermined based on the TB diagnostic network structure to increase access to the testing.

USAID's Infectious Disease Detection and Surveillance (IDDS) project spearheaded the introduction of Truenat technology by supporting Tanzania's Ministry of Health and the National TB and Leprosy program to review guidelines, an algorithm, and training materials for Truenat's rollout. On November 28–December 6, 2022, IDDS organized a training of Truenat super-users. These are experienced national and regional-level laboratory staff who receive extra training to pass on their expertise to others by providing help with troubleshooting, supportive supervision, and mentorship to end users.

IDDS provided logistic support for super-users to conduct readiness assessments for the selected Truenat sites. The super-users provided logistic and technical support to train Truenat end users, and, in collaboration with local Molbio Diagnostics (the manufacturer of Truenat) representatives, they supported the installation of 30 Truenat instruments in 30 facilities across 24 regions in Tanzania between May and July 2023. The super-users continue to provide technical support and troubleshooting support to Truenat users at the 30 facilities.

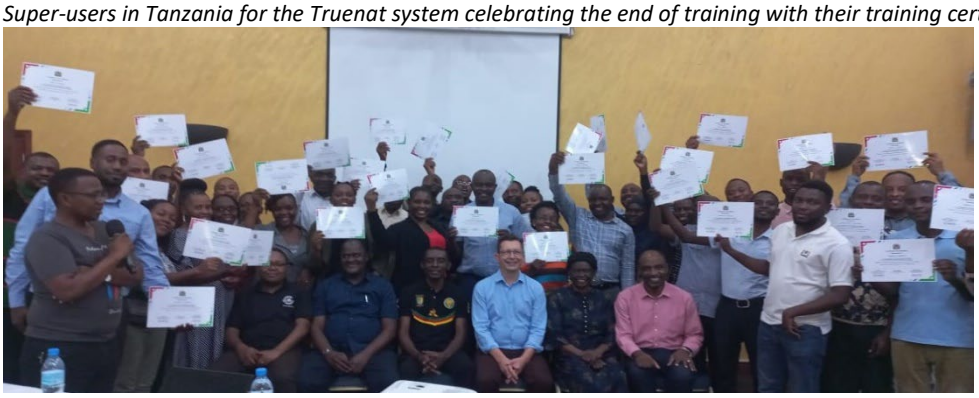
Between May and September 2023, Tanzania performed more than 1,800 TB tests using Truenat instruments. Out of 1,800 tested, 109 had TB, with 7 having TB resistant to rifampicin.

The National TB and Leprosy Program has greatly appreciated the collaboration and support provided by IDDS. ''We greatly appreciate the huge efforts and costs incurred by the IDDS project to support all processes in the roadmap toward adopting Truenat technology in Tanzania," said Edgar Luhanga, a TB laboratory diagnostic network coordinator for the national program. "We invite other implementing partners to take the responsibility to maintain and monitor functionality of the installed Truenat machines. This being the initial experience of technology implementation, we are planning to collaborate with the IDDS project to evaluate

the performance of the technology and document best practices to inform strategic scale-up of the technology in Tanzania,'' Luhanga said, during a multi-partner monthly Truenat implementation updates meeting.

''We have had a great cooperation from the IDDS project, and they made our work easy, we collaborated with IDDS during the super-users and end users training as well as during the machines installation and on-site training," said Miku Mfuru, a Molbio technical support specialist in Tanzania. "Molbio is committed to keep collaborating with IDDS and other stakeholders in maintaining the optimal functionality of Truenat machines and making it a friendly technology to consumers.''

Super-users in Tanzania for the Truenat system celebrating the end of training with their training certificates. Photo by IDDS



Practical sessions during the Truenat training in Tanzania. Photo by IDDS

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Sustaining the Laboratory Supply Chain for AMR Surveillance in Tanzania: Benjamin Mkapa Hospital

Laboratory capacity to detect and report data on antimicrobial resistance (AMR) plays a key role in countries' efforts to curb drug-resistant infections. However, most hospitals in low-resource settings are faced with a shortage of essential materials for AMR testing and reporting. A robust supply chain system for reagents and other testing materials is essential for a laboratory system to perform diagnostics, including AMR detection.

Even though the Tanzania essential commodities list includes many microbiology commodities to support the isolation and characterization of infectious organisms, local health officials had identified issues that affect microbiology testing in general and in particular antimicrobial susceptibility testing. During initial visits to the laboratory facilities, USAID's Infectious Disease Detection and Surveillance (IDDS) project noted problems, including the lack of a comprehensive AMR microbiology commodities strategy that ensures that essential diagnostic commodities (culture media, antimicrobial susceptibility disks, fermentation sugars, transport media, etc.) are selected based on quality criteria and are available in adequate quantities at the relevant diagnostic facilities that support AMR surveillance. IDDS also noted insufficient budget for AMR microbiology commodities, lack of a national forecasting team to quantify and cost microbiology AMR commodity needs, weak skills for local forecasting and ordering using the electronic logistics management information system, inadequate information technology infrastructure, and weak inventory management systems for AMR testing in some diagnostic facilities.

To improve the ability to perform AMR testing in Tanzania, IDDS worked closely with national partners. IDDS supported activities to strengthen the diagnostics supply chain and help ensure that diagnostic facilities supporting AMR surveillance sites can reliably perform AMR testing and prevent downtime or the reduction in the rate of testing that occurs when laboratories lack necessary consumables and reagents.

In July 2023, IDDS procured and distributed microbiology commodities to three laboratories at Temeke, Morogoro, and Maweni Regional Hospitals to meet short-term needs for AMR testing. The government was then expected to provide the budget to address long-term needs and sustain the efforts.

In August 2023, Benjamin Mkapa Hospital, one of the IDDS-supported AMR testing sites, procured sufficient AMR commodities for continuous testing through internal funding. This achievement sets an example for other AMR testing sites.

Fred Francis, the laboratory manager at Benjamin Mkapa Hospital, attributed the prioritization of essential laboratory commodities by the hospital's management as a significant factor that facilitated the allocation of local funds for the procurement of the necessary laboratory AMR commodities. He also highlighted the role of feedback received regarding IDDS's work on AMR

within the hospital. This feedback, in conjunction with the collaborative efforts of other global health partners, evidently underscored for the hospital management the critical importance of AMR detection and surveillance, as well as the added value of bolstering laboratory testing capabilities.

IDDS remains committed to advocating for the allocation of local funds for the procurement of these basic commodities in the other IDDS-supported facilities.

Mr. Benjamin Kipilipili, laboratory scientist and laboratory storekeeper at Benjamin Mkapa Hospital, verifying stock status of petri dishes at the hospital main store (left) and ready-to-use culture media at the laboratory (right). Photo by IDDS

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Two IDDS-supported Laboratories in Uganda Submit Accreditation Applications to South African National Accreditation Scheme

Official accreditation by an internationally recognized standards organization is viewed as a guarantee of competence and quality for a medical laboratory. The process of accreditation begins with the laboratory submitting its documents for its established quality management system, which is a system of the laboratory processes, procedures, and responsibilities for achieving quality results. An accrediting body reviews these documents as part of the laboratory's initial application.

USAID's Infectious Disease Detection and Surveillance (IDDS) project has supported two animal health laboratories in Uganda—the Mbale Veterinary and Diagnostics Laboratory and the Uganda Wildlife Authority Diagnostics and Research Laboratory—to achieve accreditation during the third on-site mentorship cycle conducted on August 13–25, 2023.

These two laboratories have submitted applications to the South African National Accreditation Scheme (SANAS). SANAS is a member of the International Accreditation Forum and can issue accreditation for ISO 17025, a standard for testing and calibration laboratories.

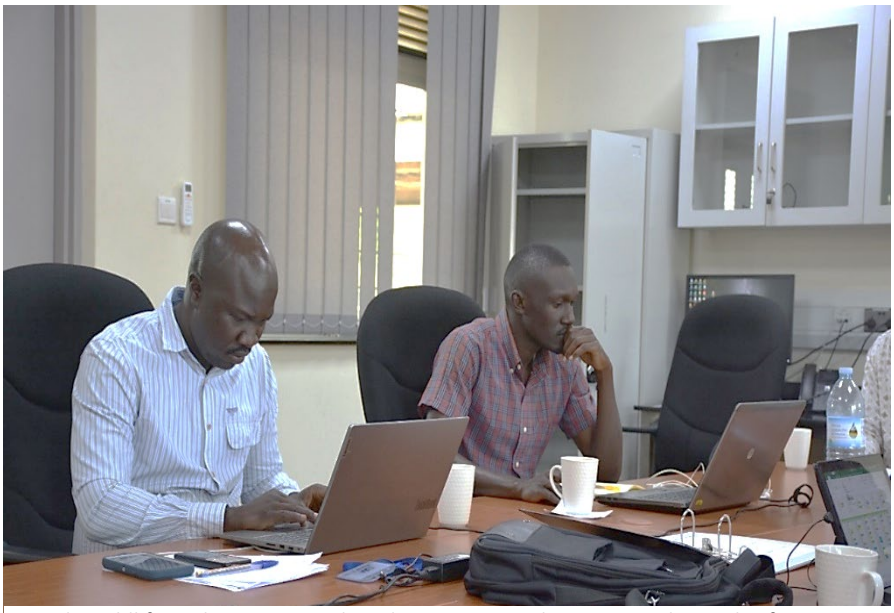
This application process involved several steps, including baseline audits and two mentorship cycles, and these efforts supported the laboratories in developing and aligning documents to ISO standard 17025:2017. The documents that were submitted to the accrediting body during the third cycle included:

- Completed application form
- Pre-completed SANAS assessment forms
- Quality management system documents and policy manuals
- Verification reports for all scope tests
- Measurement uncertainty reports
- Organizational structures (both the laboratory and its legal entity)
- Equipment and method procedures
- Proficiency testing plan
- Floor plan and evacuation plan
- Calibration, internal quality control, and competence assessment plans
- Staff appointment letters, job descriptions, and curricula vitae

After editorial review of these documents, they were uploaded onto a SANAS website portal, and accepted for consideration.

"I am overjoyed by this great milestone, all our work and efforts are starting to yield the desired effect, I thank you IDDS for making this possible, the next few months we will be able to realize our dream of accreditation to the tickborne identification tests and the Brucella screening tests

that will greatly improve our diagnosis and treatment of these diseases, which are predominant in our catchment area," said Moses Okotel, the laboratory quality manager at the Uganda Wildlife Authority Research and Diagnostics Laboratory.



Uganda Wildlife Authority Research and Diagnostics Laboratory quality and safety managers completing SANAS application forms. Photo by IDDS

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Engaging the Private Sector to Improve Tuberculosis Diagnostics and Treatment

(This article was first published on ICF.com.)

Bold strategies are needed to address the growing numbers of tuberculosis (TB) and drug-resistant TB (DR-TB) cases globally. Cases of tuberculosis, a major cause of illness and death worldwide, have increased following the lingering impact of the COVID-19 pandemic on health systems. Many people around the world—especially in low- and middle-income countries (LMICs) that bear the highest burden of TB—continue to lack access to diagnostic tools and services, and delays in testing and initiation of appropriate treatment have dire consequences on health outcomes.

The End TB Strategy

Many countries have recognized the impact TB can have on their health systems and have adopted the End TB Strategy, which is the World Health Organization's (WHO) roadmap to eliminating the disease by 2035. Operationalizing the strategy has meant introducing and expanding use of WHO-recommended rapid diagnostic tests that detect both *Mycobacterium tuberculosis* (the bacterium that causes TB) and drug resistance to the first-line and second-line drugs used to treat the disease. However, competing health service priorities and limited resources mean that governments must look beyond public sector-provided diagnostic services to private sector-supplied testing services.

Currently, 50% to 70% of patients in LMICs first seek care in the private sector. In India and Pakistan, which account for more than a quarter of all global TB cases, engagement of private sector laboratories will enable national TB programs to reach new patients and utilize additional resources. Tapping into the existing infrastructure and resources private sector laboratories possess provides greater availability of resources for TB control efforts and improved potential for financial sustainability. In recognition of the important role the private sector can play to support the End TB Strategy, in 2022 the WHO released guidance for national TB programs to engage with both the public and private sectors in TB prevention and treatment. Depending on the context, this may necessitate finding innovative new partnership models that align incentives in mutually beneficial ways, to ensure that patients are the ultimate beneficiaries with higher quality, but lower cost, testing services that lead to accurate treatment regimens.

IDDS's pilot initiatives

Approaches to engage private sector laboratories were conceptualized and piloted through USAID's Infectious Disease Detection and Surveillance (IDDS) project, led by ICF. In India's Hisar district in the northern state of Haryana, home to some 2 million people, IDDS worked with the national TB program to engage a private laboratory to support timely TB testing for patients served by community-level health facilities. As part of the activity, IDDS identified and integrated 44 private facilities into the newly developed "one-stop" TB testing model, bolstering the diagnostic network.

I was fortunate to be in India as part of the planning meetings between national and state governments and the private sector. The excitement was immense, with the chief medical officer for Hisar noting, "The work in Hisar has the potential to change Hisar, India, and even the world." Another stakeholder wondered, "Why do patients need to move between sites to be screened; this doesn't happen for other activities, so why not also replicate this for TB?"

Preliminary results show that the new model increased access to rapid TB tests (specifically, rapid molecular testing) from 26% to 63% and drastically reduced the waiting period for patients to receive their test results.

Similarly, in Pakistan, 70% of people with TB seek care from the private sector, which encompasses more than 70,000 separate providers. This provides the national TB program with an immense challenge: how to gather TB testing data from private laboratories to support national resource allocation and planning and ensure that patients served by private providers are linked to accurate treatments. As it stands, Pakistan has the fifth highest TB burden in the world and the fourth highest DR-TB burden. IDDS has supported diagnostic network assessments in more than 10 countries, including Pakistan, gathering information, and collating recommendations on where and how to engage private sector laboratories in support of TB control efforts.

Choosing a private sector partnership

As countries consider partnership models with the private sector to improve TB diagnostics and linkages to treatment, key considerations include:

- **How can private sector laboratories procure the diagnostic instruments and supplies needed for TB testing?** National TB programs have a role to play in facilitating access to costly diagnostic instruments and supplies such as GeneXpert® instruments, line probe assay, culture or drug susceptibility testing platforms, and associated consumables. By pooling procurement across public and private facilities, it may be possible to reduce or waive testing costs to patients. Market-based approaches have also been used in India through the Initiative for Promoting Affordable and Quality TB Tests and in the Philippines through a private sector diagnostics consortium. In both cases, diagnostic developers, suppliers, distributors, and private sector entities work together to ensure mutually beneficial outcomes that also provide subsidized testing costs to patients.
- **How can TB specimens be collected, transported, and referred to laboratories for testing?** India's Hisar district model engaged a private laboratory to conduct these activities, while in other cases, the specimens collected at private facilities may be transported to and tested in public reference laboratories. For the latter, ensuring that feedback loops exist to report test results back to providers promptly is important for initiating treatment.
- **How can private sector facilities and laboratories report results to national and international surveillance systems?** Reporting TB test results to clinicians and patients allows timely and accurate treatment, but it is also important to report them to

national and international disease surveillance systems, ideally, directly from diagnostic instruments. This allows decision makers to observe hot spots and other epidemiological trends and effectively target education and outreach programs, promote timely testing, allocate financial and other resources to support TB control efforts, and provide the national TB program with greater oversight into the varying quality of diagnostic services across private laboratories—a challenge that must also be overcome to ensure TB patient outcomes improve over time.

Potential replicable success

The global push for universal health coverage has brought greater focus on health service integration across diseases to maximize existing, limited resources. Greater engagement and networking with the private sector provide a path for national TB programs to expand access to diagnostic resources, while governments gain access to information on the epidemiology of the TB and DR-TB epidemic in their own countries as patient TB disease profiles are aggregated through connected national health information systems.

Ultimately there is potential to improve health outcomes and reduce costs along the entire diagnostic cascade, from referring patients or samples for testing to linking laboratory results with service providers and patients with accurate treatment regimens. The success of the IDDS-supported "one-stop" Hisar model pilot shows the feasibility of expanding the pilot to other parts of India, while providing an approach that other countries can replicate.

USAID's Infectious Disease Detection and Surveillance (IDDS) project operates in more than 20 countries in Africa and Asia 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.

Working Together to Stop Infectious Disease Outbreaks

(This article was first published on ICF.com.)

In low- and middle-income countries, patients with frightening fever symptoms may never find out what caused them to get sick, even if they receive care from a doctor who is able to manage their symptoms. By one estimate, up to 40% of fevers in Africa are never diagnosed or attributed to a specific illness. By failing to properly diagnose these "fevers of unknown origin," we not only fail to initiate appropriate treatment regimens, but also miss opportunities to contain outbreaks of dangerous infectious diseases that could be spreading within the community and then beyond.

This was not the case recently in Equatorial Guinea, where laboratories in neighboring Cameroon were able to quickly confirm that patients were suffering from Marburg disease, a highly contagious illness from a virus spread by bats that causes death in up to 88% of patients who get sick. Laboratory confirmation was a critical aspect of confirming the outbreak, because the disease caused by the Marburg virus is difficult for doctors to distinguish from other hemorrhagic fevers like Ebola.

Even so, "while the [Ministry of Health in Equatorial Guinea] has done a great job tracking cases, I think we would be foolish to assume that no cases have gone undetected," said Nancy Sullivan, director of Boston University's National Emerging Infectious Diseases Laboratories, at an emergency meeting convened by the World Health Organization.

Community health workers as the first line of defense

In Mali, when community health worker Djenebou Kola Cisse noticed a yellow tint in a young mother's eyes, she suspected the woman had yellow fever, a dangerous disease that can be spread quickly by mosquitos. Cisse is one of 72 community health workers who were trained in Mali's Kadiolo health district to recognize signs of yellow fever and other deadly infectious diseases by USAID's Infectious Disease Detection and Surveillance (IDDS) project (ICF leads a consortium of partners to implement IDDS). The project works to improve disease detection and surveillance systems in more than 20 countries across Africa and Asia, including by implementing community-based surveillance, an approach that depends on frontline workers like Cisse who are also community members.

"With the training received on community-based surveillance and the communication tools, I can conduct sensitization sessions in my community on diseases and events under surveillance so I can detect and report suspected cases to my supervisors," explains Yacouba Kone, another community health worker in the town of Niamala in southern Mali who was trained by IDDS. Kone used his new skills to successfully detect a case of acute flaccid paralysis, a rare but serious disease that affects the nervous system and causes muscle weakness.

Community health workers like Cisse and Kone are well positioned to receive information through informal channels, rapidly refer potential cases to health centers for diagnosis and

treatment, and report findings to health officials for follow-up, typically by SMS message alerts. During a one-year period, Mali's newly trained workers issued 761 alerts of potential public health events to district officials. IDDS has also expanded community-based surveillance in Burkina Faso, Guinea, Senegal, and Vietnam.

Transporting dangerous materials

Whether a disease case is detected by a community health worker or in a more traditional setting by a health care provider, clinicians often need laboratory confirmation of their diagnoses. To receive an accurate test result, first they must transport the patient's specimen to a laboratory with the relevant testing capabilities, often located far away from a potential outbreak. "Effective referral systems are urgently needed to ensure that specimens reach the laboratory safely and within the timeframes where they remain viable for testing," said Ebi Bile, IDDS Guinea team lead. IDDS has worked to improve specimen transport systems in 12 countries across Africa and Asia.

In Mali, Cisse referred the above-mentioned young woman with yellow-tinted eyes to a local health center, where a blood specimen was collected and transported to the National Institute of Public Health in Bamako, some 300 miles away, or an 8-hour journey by road. After that, the specimen traveled by plane to the Pasteur Institute of Dakar in Senegal—another 870 miles away—which was able to confirm the diagnosis. In some cases, specimens must be transported by air freight from remote areas to central laboratories, or even shipped internationally so that reference laboratories can double-check the original results. No matter the route or mode of transport, special packaging materials and trained professionals are needed to prevent spills or leaks that might pose a biosafety risk, and to preserve the quality of the specimen.

At the laboratory bench

Once a specimen safely reaches the laboratory, it must be quickly and accurately tested, and the results need to be shared back to clinicians, patients, and public health authorities. While diagnostic capacity for infectious diseases—including yellow fever—has rapidly expanded in recent years across Africa, laboratories continue to face a myriad of challenges, including inadequate stockpiles of essential supplies, inability to maintain and repair diagnostic equipment, and lack of quality control. During the COVID-19 pandemic, an explosion of public interest in diagnostics brought stakeholders together in new ways to address these issues, with solutions ranging from data sharing to dual screening for multiple diseases at once.

IDDS has worked to improve testing capacity at regional laboratories in countries like Ethiopia, Kenya, and Liberia, to bring diagnostics closer to potential patients and to reduce specimen transfer times and distance. "Diagnostics [are] now seen as a core component in strengthening future pandemic preparedness," wrote global health experts Emma Hannay and Madhukar Pai. "While this is much-needed progress, it is critical to ensure that diagnostics are not just used during outbreaks."

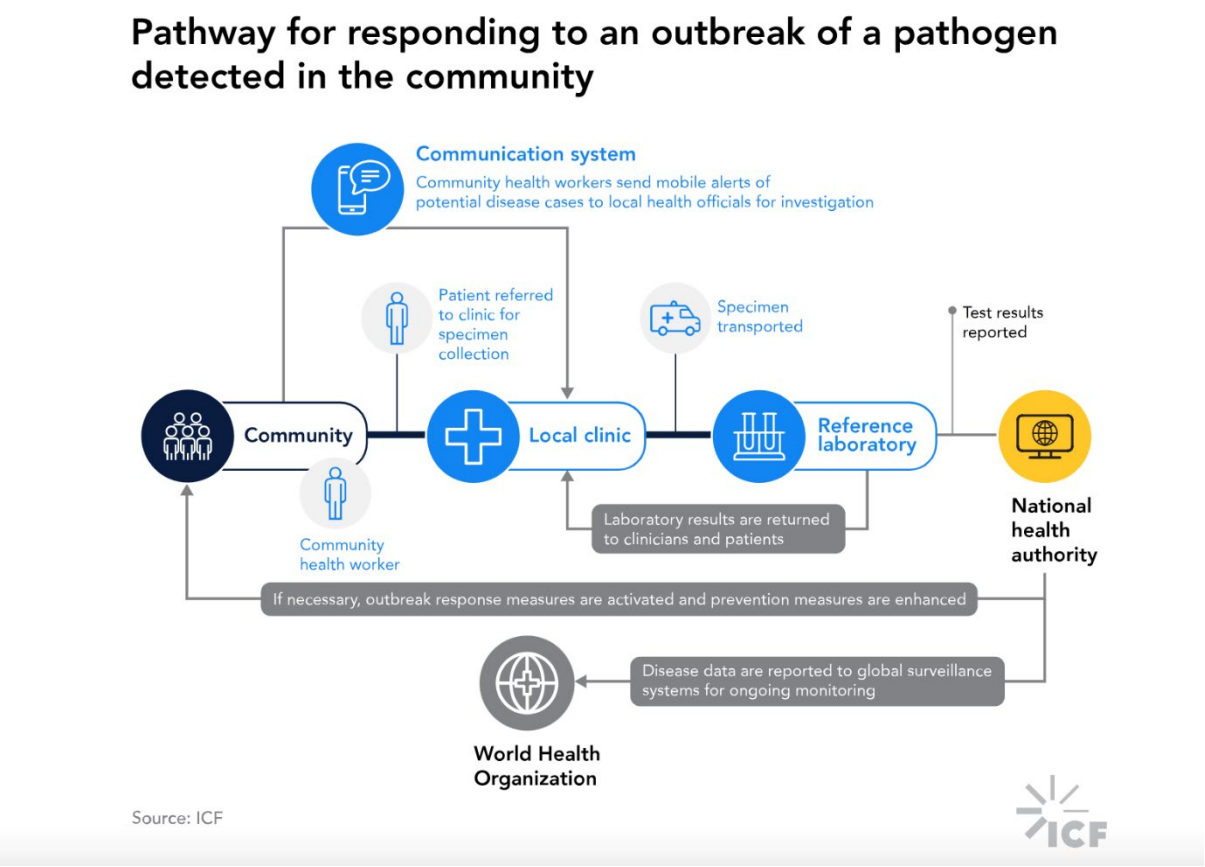
Delivering clear public health messaging

Engaging the community is key at all junctures of the "response pathway" but especially when sharing health information to drive behavior change. Public health messages must be culturally appropriate and delivered by trusted sources if community members are to take actions to stop the spread of the disease.

Cisse's decision to visit the young mother and refer her to the community health center meant that the woman received timely supportive care and did not develop severe yellow fever. Her diagnosis also prompted the Kadiolo health district to conduct community outreach about the disease and the importance of vaccination. Supported by IDDS and the district's World Health Organization advisor, this effort reached 920 people and likely saved many lives.

Going international

As witnessed during the COVID-19 pandemic, outbreaks can spread very quickly across international borders. The final key to effective outbreak response is for national health systems to also report into international databases, which allows policymakers at the local, national, and international levels to make informed decisions. One reporting system is GLASS, or the Global Antimicrobial Resistance and Use Surveillance System—the World Health Organization's database for tracking the drug-resistance of microbes that can cause serious diseases. It gives clinicians and health officials crucial information on matching the right drugs to infections, but GLASS is only as accurate as the information coming into the database. IDDS has equipped five national health systems, Cameroon, Ethiopia, Kenya, Liberia, and Tanzania, to report into GLASS. To prevent the next pandemic, additional investments in disease surveillance—and training on how to use existing systems more effectively—are urgently needed.



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Creating a Roadmap to Laboratory Sustainability in Liberia

(This article was first published on ICF.com.)

Liberia, located in West Africa, faced the brunt of the 2014-2016 Ebola virus disease outbreak, which killed 4,800 Liberians—more than any other country affected by it. One reason for this was that the outbreak followed on the heels of a 14-year period of civil war that crippled the national health system and left the country with only 50 doctors available to treat more than 4.3 million people.

Since 2016, the nation has made great strides in rebuilding its health system to become more resilient, regain community trust in public health authorities, and integrate its fragmented laboratory system. Still, poor coordination among laboratories, siloed programs that only address specific diseases, staff shortages, and dysfunctional supply chains for key commodities continue to undercut progress. Because laboratory services are not standardized across the country, procuring essential equipment is difficult and there are no service contracts in place to maintain and repair equipment, which causes frequent interruptions in diagnostic services.

Strengthening health systems

In 2020, USAID's Infectious Disease Detection and Surveillance (IDDS) project set out to strengthen the national laboratory system in Liberia, employing a model that involved renovation, equipment, technical assistance, and mentorship. The project started by tackling the problems at the county referral laboratory located at the G.W. Harley Hospital in Nimba County, which serves more than 200,000 people. In 2019, a laboratory assessment conducted by the Ministry of Health found that, because the hospital did not have sufficient space to accommodate basic laboratory equipment beyond microscopes, specimens had to be sent to the capital, Monrovia, for testing—about four and a half hours' driving distance.

Through meetings with the county health team and the hospital management, IDDS identified buildings that could be renovated to relocate and expand the laboratory. In 2021, IDDS completed the renovations to comply with biosafety standards and equipped the newly functional laboratory with key supplies including a biosafety cabinet, microscopes, incubators, freezers, and autoclaves.

Meanwhile, IDDS also furnished laboratories located in neighboring counties (Bong and Lofa) with essential equipment required for the detection of bacterial pathogens. With three county referral laboratories newly equipped to provide bacteriology services, IDDS began focusing on providing technical assistance to county laboratory staff to build their capacity for conducting bacteriology culture and antimicrobial susceptibility testing, which helps to identify drug-resistant pathogens.

Building laboratory capacity

Together with the National Diagnostics Division of the Ministry of Health, the IDDS project identified William Walker, a laboratory technician at Phebe Hospital in Bong County, as a mentor and national bacteriology trainer. After receiving training from IDDS in April 2021, Walker began his new role to provide on-site mentorship on a quarterly basis, during which he provides coaching and helps laboratory technicians process patient specimens. He also provides remote mentorship whenever it is needed. The results of Walker's training have been impressive—as of March 2023, staff from across the three sites had cultured 486 specimens.

In addition to bacteriology, other diagnostic services such as clinical chemistry and hematology are now available at all three laboratories. Now that the laboratory has ample space to fulfill growing testing demand, G.W. Harley Hospital has attracted other research projects to the site. For instance, the Acute Febrile Illness (AFI) Surveillance project was able to use the newly renovated space there to collect and store patient specimens from February 2021 to December 2022.

"The organization and space at the G.W. Harley Hospital laboratory greatly ensured the smooth operation of activities," said Elijah Paa Edu-Quansah, a project coordinator for the AFI Surveillance project. Edu-Quansah emphasized the availability of space for enrollment and laboratory materials in the storeroom, the designated freezer room that met quality standards for specimen storage, and the separate, comfortable waiting area for patients that ensured their movements did not interfere with laboratory procedures.

Clinicians are especially enthusiastic about the availability of bacteriology services because they can now make informed decisions before prescribing antibiotics. "I have been able to move knowledge into practice," said Dr. Siedoh Freeman, medical director of G.W. Harley Hospital. "In other places we don't have the opportunity of doing culture and sensitivity; we just use antibiotics as we think. But since I came to Nimba, at least I am able to benefit from doing culture and sensitivity for my patients. I am able to identify the right antibiotic for my patients and reduce [the length of their] hospital stay and the cost to the patient."

Expanding access to quality services

Most recently, Ganta Rehabilitation Hospital, located 37 kilometers (23 miles) from G.W. Harley Hospital, began referring specimens for culture to G.W. Harley as word continues to spread about the newly available services. Recognizing the positive effect of the IDDS model, the Ministry of Health has requested that the same process be applied to laboratories in other counties of Liberia. "IDDS has been instrumental in strengthening the laboratory system in Liberia," said Henry T. Kohar, director of the National Diagnostics Division (NDD) of the Ministry of Health. "IDDS worked closely with NDD and respected the decision of the NDD, [enabling] Liberia to have a laboratory built to international standards."

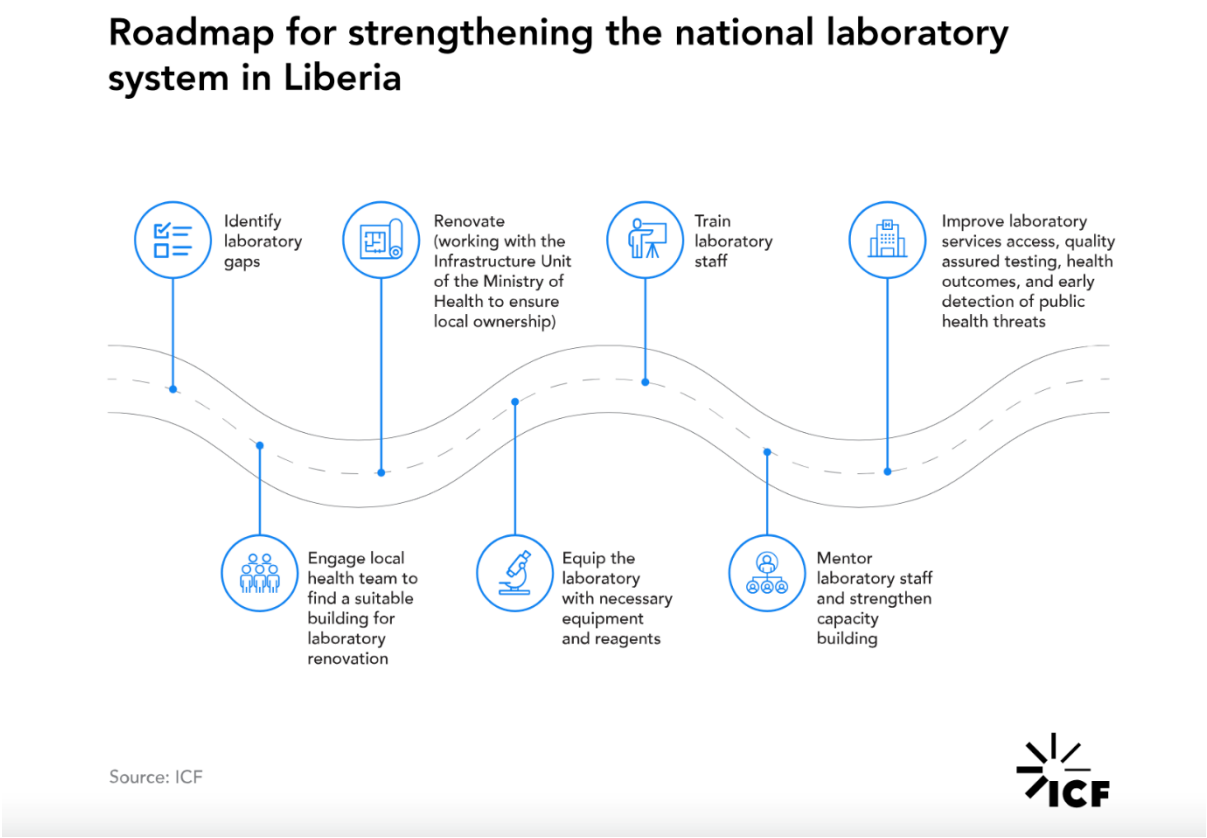
The model that IDDS has applied to G.W. Harley can be easily transferred to other counties in Liberia and to other low-resource countries. In fact, if countries want to see long-lasting impact, this is a good approach to ensure local ownership: It strengthens infrastructure by

renovating the physical building, addresses biosafety and biosecurity concerns, introduces and applies international standards, and procures standardized equipment in line with what the country needs. For sites that work with international donors, the next steps to ensuring local ownership are to train additional users on how to use the equipment and train the biomedical engineers on-site who will service and maintain the equipment.

Dr. Gorbee G. Logan, assistant minister of curative services at the Ministry of Health, visited G.W. Harley Hospital, praising the laboratory model for helping to "shift the microbiology dynamics of our country."

"Our expectation is that at least every hospital should have something like this as a start across the country," said Dr. Logan. "I'm so excited about this setup, especially the microbiology component, because over the years we have struggled as doctors in managing deadly wounds. If we have this laboratory in the 15 county hospitals, it is going to drastically reduce surgical wound infections and address the situation surrounding antimicrobial resistance."

To complete the model, the laboratory staff have been empowered to provide quality-assured laboratory services through the implementation of quality management systems that include laboratory commodity management and computer-based interoperable laboratory information systems utilization. If followed, this model will promote laboratory sustainability and produce quality-assured tests and results. Thanks to prompt laboratory results that inform clinical decisions, Liberia's health system is already well on its way to improving patient outcomes and reducing the burden of antimicrobial resistance.



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World Zoonoses Day: Five Strategies to Prevent Outbreaks and Safeguard Public Health

(This article was first published in Science Speaks.)

Zoonotic diseases continue to emerge rapidly, and efforts to contain them are critical for preventing pandemics and reducing their impact, as World Zoonoses Day, observed annually on July 6, reminds us.

Approximately 60% of emerging infectious diseases that are reported globally are zoonoses, and about 75% of newly emerging pathogens originate in animals, with the number rising yearly, according to the World Health Organization. There are more than 200 known types of zoonoses, including COVID-19.

After five years of work across more than 20 countries, USAID's Infectious Disease Detection and Surveillance (IDDS) project offers the following strategies and lessons learned on preventing and curbing disease outbreaks:

1. Utilize capacity gained during COVID-19 response

In early 2020, various entities joined forces to curtail the spread of SARS-CoV-2, the virus that causes COVID-19. IDDS rapidly mobilized resources, personnel and technical assistance in several countries to address immediate demands and identified critical gaps in resources and infrastructure. IDDS was already operational in these countries prior to the pandemic and was able to expand on existing interventions.

Lesson: Identify existing human resources, sites and essential supplies that can be prepositioned to launch a baseline response effort; expand from there with additional inputs to rapidly mobilize a response while optimizing available resources.

2. Expand access to diagnostic services

The ability to rapidly detect, confirm and report cases requires sufficient laboratory capacity at all levels of a health system. A competent laboratory workforce is critical for improving patient outcomes; and unfortunately, trained personnel are typically concentrated in urban centers. While there are benefits to consolidating services — cost savings, process efficiencies, qualified workforce and sufficient infrastructure — the need for broader access to services is urgent. IDDS is helping countries decentralize their diagnostic capacity while maintaining quality of service.

Besides COVID-19, other outbreaks of zoonoses have occurred over the past decade such as Ebola virus disease, Marburg virus disease, Lassa fever and mpox. In countries where decentralizing diagnostic capacity is not possible, IDDS has established specimen referral systems to transport patient samples. For example, IDDS worked in Guinea and Vietnam to ensure specimens were transported quickly and safely from minimally-equipped peripheral sites to a central testing facility to conduct confirmatory testing.

Lesson: Quality-assured, decentralized testing is critical to detecting cases at the source. Combined with a specimen referral system, case detection is greatly improved.

3. Engage the community for faster case detection

Detecting outbreaks at the source is a huge challenge for many resource-constrained countries. Empowering community members to identify and report potential cases fills health system gaps. In Mali, IDDS trained community health workers, who have successfully reported hundreds of potential cases. Building community capacity is critical for success; civil society brings high value to response efforts.

Lesson: Training and mobilizing community members to detect cases is a proven, cost-effective and sustainable public health investment.

4. Promote One Health

IDDS takes a One Health approach to strengthen countries' diagnostic networks. IDDS has integrated the human and animal health sectors via cross-sector training to encourage data sharing and interoperability of systems, development of multisectoral policies and implementation of resource-sharing solutions. These steps inform interventions to reduce morbidity and mortality, as evidenced by the implementation of the PREDICT laboratory protocol in Indonesia. In Liberia, IDDS worked with the Food and Agriculture Organization of the United Nations to strengthen the national quality management system. By integrating the human and animal health sectors, IDDS helped the government improve the country's Joint External Evaluation score.

Lesson: Sharing resources, costs and knowledge across sectors is critical to supporting ongoing, sustainable One Health strategies.

5. Align with national policies

USAID's push to empower local actors to lead their own development has been integral to supporting sustainable health systems strengthening. By developing policies with local entities that prioritize disease detection and prevention, IDDS is furthering the localization agenda. For example, IDDS facilitated the development of India's revised National Action Plan to Combat Antimicrobial Resistance by convening a meeting of experts from the food safety and human, animal, and environmental health sectors. To respond to mpox in Cameroon, IDDS worked with the government to train community surveillance officers and health care providers on case detection and collaborated with local stakeholders on developing the National Integrated Plan for the Control of Mpox in Cameroon, 2023–2027.

Lesson: Locally-led solutions are the most effective means to ensuring sustainability.

In the past two decades, there has been a clear shift in the public health sector toward recognizing the increasing risks posed by zoonoses; this has prompted a push toward more collective action. From establishing specimen referral systems and diagnostic services to training community health workers, IDDS endeavors to identify the systems-level challenges that affect laboratory networks and collaborate with local governments to develop cost-

effective solutions that will reduce the threat of zoonoses and contribute to better health for all.

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