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Bangladesh Rolls Out New TB Testing Technology

Bangladesh suffers from one of the world's highest burdens of tuberculosis (TB) with some 44,000 people estimated to have died from the disease in 2020. The World Health Organization also estimates that in 2020 almost 130,000 TB cases went undiagnosed in Bangladesh, and the missing cases mean that tens of thousands of people are still potentially spreading the disease in their communities. To reach these missing cases it is important to bring testing for TB as close to potential cases as possible.

To reach patients, health care workers need portable testing technologies that can operate in hot, humid conditions without a permanent external power supply. These are the conditions in community health centers where people will most likely seek relief from coughs or fevers, or other potential symptoms for TB. The Truenat test will accurately and rapidly diagnose TB and drug-resistant TB in these challenging conditions. The Truenat test is run on a system that is portable, can operate on its own battery power, and does not need to operate in an airconditioned building.

Truenat is a chip-based, rapid molecular test (it identifies the DNA of the pathogen, the disease-causing organism) and was endorsed by the World Health Organization in 2020. The introduction of the Truenat technology is a milestone for the Bangladesh National TB Control Program (NTP) in its fight to end TB. USAID's Infectious Disease Detection and Surveillance (IDDS) project is providing support for rolling out Truenat to 38 sites across the country.

As part of this rollout, IDDS and NTP organized a three-day training-of-trainers event on April 25–27, 2022. These trainers will, in turn, train 40 technicians who will be using Truenat at the new sites, teaching them how to process and test specimens using Truenat. In addition, the trainers will support NTP in the implementation, monitoring, and supervision of the Truenat rollout. Dr. Md. Khurshid Alam, NTP line director, inaugurated the training and said, "This training will usher in a new era for NTP to boost early detection of TB at the remote areas of the country." He also thanked IDDS for extending its support in organizing the training.

The training sessions included presentations and discussion of the advantages of the Truenat technology in the country context, including its potential contributions to increasing the detection of drug-sensitive and drug-resistant TB cases in remote and hard-to-reach areas. The modular training sessions covered various technical areas, including specimen collection, processing, and testing; results interpretation; recording and reporting; quality assurance and biosafety; procurement planning for supply and store management; and monitoring and evaluation. Hands-on practical sessions on specimen processing and testing, preventive maintenance of the equipment, and other topics reinforced the learning.

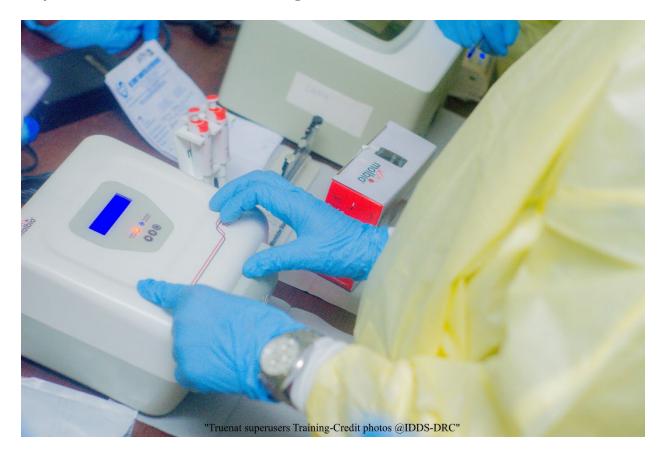
Twelve participants (five of which were female), including microbiologists and supervisory staff from NTP, national and regional TB reference laboratories, and non-governmental implementing partners (including BRAC and Damien Foundation) completed the training. Experts from IDDS, NTP, and Bio-Trade International, the local service provider for Truenat, facilitated the training sessions. The participants spoke highly of the effectiveness of this training in building their skills and confidence to serve as future trainers. Dr. Afzalur Rahman, program manager of NTP, thanked IDDS for supporting this training and predicted that Truenat will be an effective tool for early detection of TB.



Participants testing TB specimens by Truenat. Photo by IDDS



Trainers of Truenat pose to celebrate training completion. Photo by IDDS



Super Users Overcome Challenges to Truenat Rollout in the DRC

The Democratic Republic of the Congo (DRC) is among the 10 countries with the highest burden of tuberculosis (TB) in the world. The World Health Organization also estimates that some 85,000 cases of TB went undiagnosed in the country during 2020, meaning that tens of thousands of people were potentially spreading the disease in their communities. The DRC also has high rates of people diagnosed with both TB and HIV and with drug-resistant TB. Rapid, accurate testing for TB, as close to communities as possible, is the key to reducing these rates.

Molecular testing is a vital tool in boosting TB diagnostics. It works by identifying the DNA of the pathogen, the disease-causing organism. The DRC does not have enough of these molecular diagnostic tools for the rapid diagnosis of TB, and the tools that it does have need controlled laboratory temperatures and a constant external power supply—conditions that often prevent these devices from being located in regions where TB testing is needed in the DRC.

Truenat rapid molecular testing can withstand high temperatures and uses a system that runs up to eight hours on its own power supply. It was developed by Molbio Diagnostics in India, which shares challenging conditions similar to the DRC, and was endorsed by the World Health Organization in 2020. USAID's Infectious Disease Detection and Surveillance (IDDS) project is supporting the introduction of Truenat in the DRC in partnership with the United Nation's Stop TB Partnership and USAID's Introducing New Tools project. IDDS supported the introduction of 38 machines for Truenat in four DRC provinces: Kinshasa (10 machines), Kasai-Oriental (7 machines), Lualaba (11 machines) and Haut-Katanga (10 machines). IDDS conducted training for these site providers in April 2022.

After the initial training of the Truenat end users and the installation of the machines in April 2022, difficulties began to emerge. Users were receiving error messages when installing cartridges, the machines were not recognizing printers, the time and date would be wrong, and internal tubes were clogging. IDDS created a WhatsApp group for sharing experiences and challenges encountered in using the new tool.

Molbio trainers joined the WhatsApp group to provide remote support and technical guidance to solve some issues, but in-person support was still needed. Two machines from Lubumbashi had been sent to Kinshasa to be repaired, despite the risk that the transporting the machine might cause.

IDDS hit upon 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. In collaboration with Molbio, IDDS supported the training of 11 super users in Kinshasa from May 30 to June 3, 2022, focusing on maintenance and technical support for Truenat end users. During the training, the super users were taught how to assist the Truenat end users in the field when faced with one of the frequent errors or other difficulties. 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.

One super user, biologist Alphonse Lufulwabo head of the provincial TB laboratory in Mbuji-Mayi, Kasai-Oriental Province, supported the sites to submit the results of the external quality assessment.

"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," said Lufulwabo.

The province of Kasai-Oriental with its 19 Health Zones and 121 centers for diagnosis and treatment of TB had only 10 existing molecular machines, some of which have module failures causing TB diagnosis delay. Kasai-Oriental is a "hot spot" province with a high number of drug-resistant TB patients diagnosed each year.

Lufulwabo is responsible for the provincial TB laboratory in Mbuji-Mayi. He has more than 15 years of experience in TB diagnosis and manages the TB diagnostic network with 121 centers for diagnosis and treatment of TB. Truenat has been introduced in seven sites in his province. After his training as a super user, he participated in the first round of the external quality assessment for the 38 Truenat sites.

All seven of the sites in Lufulwabo's province took part in the external quality assessment. Lufulwabo also guided sites in other provinces through their participation in external quality assessment via the WhatsApp group. Sites experiencing internet difficulties had to send their results to the super users of their respective provinces who then submitted their results.

WhatsApp audio messages were recorded in French, demonstrating the technique of participation in external quality assessment. Results were then transmitted by WhatsApp to the super users of the respective provinces for submission. With the combination of these two approaches, the DRC achieved strong participation in the first round of external quality assessment, with 37 out of 38 sites completing the assessment.



Biologist Alphonse Lufulwabo using Truenat in Mbuji-Mayi Provincial Laboratory. Photo by IDDS

IDDS Finalizes Supervisory Package for Monitoring TB Laboratories in India

USAID's Infectious Disease Detection and Surveillance (IDDS) project is supporting India's Central Tuberculosis Division (CTD) to design an integrated and comprehensive supervision, monitoring, and evaluation (SME) framework for all laboratories that perform tuberculosis (TB) diagnostics across the country. The checklists used for supervision and monitoring of the laboratory network were developed in 2005 and focus only on the quality assurance (QA) for sputum smear microscopy (identifying dye-stained TB bacteria in patient specimens under a microscope). With advances in diagnostic tools across the medical industry in recent years, such as molecular testing devices that examine DNA to identify microorganisms, there was a need to update the existing SME framework.

The revised SME framework is based on India's National Strategic Plan for Tuberculosis Elimination 2017–2025. The updates reflect newer TB and drug-resistant (DR)-TB technologies, as well as other national policies on TB laboratories and diagnostics that serve as a reference for all National Reference Laboratories (NRLs) and Intermediate Reference Laboratories (IRLs). Effective and stringent supportive supervision by national and intermediate laboratories is the key to improving TB diagnostics in smaller regional and local facilities.

IDDS revised the existing supervisory checklists and reporting formats in September 2021 to cover quality system essentials and all diagnostic technologies in the National Tuberculosis Elimination Program process. The new SME framework includes:

- Checklists to guide comprehensive supervision by NRLs of IRLs and by IRLs of districts
- Template documents to capture feedback and highlight key issues identified during onsite evaluation visits
- Formats for periodic reporting of activities to higher levels (NRL to CTD, IRL to states and NRLs)
- Follow-up strategy for corrective actions.

The new supervisory package was piloted at four IRLs and their related districts in collaboration with their NRLs from October to January 2022 (IRL Pune and IRL Bangalore in collaboration with NRL-National Tuberculosis Institute Bangalore; IRL Puducherry, TB C-DST laboratory Madurai in collaboration with National Institute for Research in Tuberculosis, Chennai; and IRL Delhi in collaboration with National Institute of TB and Respiratory Diseases, Delhi).

On April 20, 2022, IDDS organized a meeting with CTD, the Ministry of Health and Family Welfare, and the NRLs involved in the piloting, to share lessons learned and feedback from the process and to finalize the package for full-scale implementation. Laboratory managers and microbiologists from all NRLs attended the meeting. On May 18, 2022, the revised supervisory package was shared with all NRLs, IRLs, and TB C-DST laboratories by CTD. Next, IDDS will

support the implementation of this package in 15 target IRLs (for the first phase), in coordination with their NRLs.



Dr. Jyoti Kayesth, senior diagnostic advisor, IDDS India, giving an overview of the revised supervisory package on April 20, 2022 in New Delhi. Photo by IDDS

IDDS Launches Pilot "One-stop" Model to Improve TB Diagnostic Services in India

About half a million people died from tuberculosis (TB) in India in 2020, one-third of the global total at a time when TB deaths rose for the first time in more than a decade. During the COVID-19 pandemic, <u>India faced one of the largest gaps between</u> the number of people estimated to have fallen ill with TB and the number who have been newly diagnosed and reported, revealing the strain on the public health system as well as new obstacles for TB patients seeking care. Access to diagnostic services (tests that can lead to a TB diagnosis) remains a critical gap, because patients who are never accurately diagnosed are also left untreated and can potentially infect others.

India's National Tuberculosis Elimination Program (NTEP) aims to eliminate TB in India by 2025. The COVID-19 pandemic has undermined the country's progress, but India remains committed to the target. To meet the elimination goal, USAID's Infectious Disease Detection and Surveillance (IDDS) project supports NTEP to improve access to diagnostic services in India.

In May 2022, IDDS, NTEP, and other partners launched a patient-centric model that engages private laboratories to provide TB diagnostic services, which have historically been available only in the public sector. Patients are often "lost to follow-up" between their initial health-seeking behavior and receipt of follow-up tests and a confirmed diagnosis due to long delays. By consolidating services such as X-ray screening, rapid molecular testing, and universal drug susceptibility testing under a single provider, the new "one-stop TB/drug-resistant (DR)-TB diagnostic model" aims to eliminate delays in diagnosis to ensure that patients who are sick with TB receive accurate, timely, and quality-assured diagnoses to obtain potentially life-saving treatment. During the pilot in Hisar district of the state of Haryana, IDDS is collaborating with public sector partners and a private laboratory (Thyrocare Technologies Ltd.) to ensure the program complies with NTEP policy, including meeting requirements that specify how quickly test results must be returned to clinics and patients.

The pilot requires significant buy-in from partners across sectors because it links diagnostic services in the private sector with public sector reporting and monitoring and the financial support of non-governmental partners. To bring these stakeholders together, a launch event was held on May 14, 2022, in collaboration with the Hisar NTEP team. It attracted nearly 250 delegates from various organizations, including government agencies at local, state, and national levels.

The director general of health services of Haryana, Dr. Veena Singh, opened the event with special guests Dr. Priyanka Soni (deputy commissioner of Hisar) and Dr. Rajendra P. Joshi (deputy director general of the Central TB Division at the Ministry of Health and Family Welfare). Dr. Singh emphasized that the state of Haryana is committed to extending all necessary support for the successful implementation of the model and exploring the possibility of incorporating the learnings into similar models in other districts.

Following the keynote, a panel discussion was moderated by Dr. Umesh Alavadi, USAID India on "TB Diagnostic Care Cascade in NTEP – Success, Challenges, and Solutions." Panelists shared their experiences about sustaining and financing the NTEP diagnostic services in public sector, practices in the private sector, patient perspectives and consequences of the delay in TB diagnosis, learnings from the COVID-19 pandemic which can be implemented in NTEP, and the significance of private laboratory engagement in strengthening NTEP's diagnostic network.

Clinicians, medical officers, and key National Health Mission district staff attended the event to learn more about the pilot program and how they can support patient access. Other partners including USAID, World Health Organization consultants, iDEFEAT TB, IQVIA, the U.S. Centers for Disease Control and Prevention, Solidarity and Action Against the HIV Infection in India, the Joint Effort for Elimination of Tuberculosis, and World Vision India also participated in the launch event. Finally, private sector representatives from the Indian Medical Association in Hisar, Thyrocare Technologies Ltd. (the laboratory involved in implementing the new program), and local health care providers attended the event to offer their perspectives and support.

This cross-sector participation is vital for the success of the project in contributing to the mission to end TB, and the impact could be far-reaching beyond TB infection and treatment. The state of Haryana expressed its faith that the "one-stop TB/DR-TB diagnostic model" will help the state to better engage private laboratories in implementing similar models across disease control programs as well as in general health care services.

"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?" asked Dr. Umesh Alavadi, a USAID project management specialist in the Division of Tuberculosis & Infectious Diseases. "It's very exciting." According to other speakers at the event, the new model will address these challenges in specimen transportation and completion of tests, as per the diagnostic algorithm.

It is systems-level interventions like these that set the stage for public health success at scale. In 2021, India's public health sector <u>conducted almost 12.5 million TB tests across all laboratory tiers</u>. In addition to co-locating services through the new model, improvements in supervision and monitoring from higher-level tiers and improving the quality of the testing throughout the network will help to close the gap in access to diagnostic services and linkages to care.

"Elimination of TB may yet require innovation in the type of diagnostics that are provided at the point of care," says Moe Moore, IDDS' TB strategic lead. "But functional and efficient diagnostic systems and continuous quality improvement are foundational to the rapid diffusion of new technologies once they become available."

Over the coming months, IDDS will monitor the implementation of the "one-stop TB/DR-TB diagnostic model" to understand the feasibility of the program design and demonstrate its impact on TB diagnostics. The evaluation of the new model will include a cost assessment to understand potential efficiencies at scale. The evaluation will also assess turnaround times for test results to understand if the private laboratory can provide improvements over the baseline. "The work in Hisar has the potential to change Hisar, India, and even the world," says Dr. Rajesh Raju, state TB officer in Haryana.



Dr. Veena Singh, director general of health services, Haryana (center, right), Dr. Priyanka Soni, district commissioner, Hisar (center, left), and dignitaries from USAID India, State and District NHM, State and District NTEP, State and District IMA, MAMC Agroha, IDDS and other key stakeholders inaugurating the launch event in Hisar district on May 14, 2022. Photos by IDDS

IDDS Convenes Experts to Draft National Action Plan on Antimicrobial Resistance for the Human Health Sector

Antimicrobial resistance (AMR) occurs when bacteria, viruses, and other parasites mutate and no longer respond to antibiotic medicines, making infections more difficult to treat and increasing the risk of disease transmission, illness, and death. It's an urgent issue that threatens a century of progress in public health and stymies achievement of the United Nations' Sustainable Development Goals. A <u>recent analysis in The Lancet</u> estimated global deaths from antibiotic-resistant bacterial infections at 1.3 million in 2019.

As India's existing National Action Plan (NAP) on AMR (2017–2021) concludes, the country's National Center for Disease Control, the nodal agency for AMR under its Ministry of Health and Family Welfare (MoHFW), other Government of India agencies, and World Health Organization (WHO) with USAID's Infectious Diseases Detection and Surveillance (IDDS) project's support, planned a series of cross-sector meetings to understand the status of implementation of NAP–AMR, including its achievements, gaps, challenges, and lessons learned.

The first consultation meeting of the experts from the human health sector was organized in New Delhi on June 22–23, 2022. The goal of the meeting was the creation of an updated NAP–AMR for the human health sector. More than 70 professionals from across the nation attended the meeting, which brought together experts from the human health sector and other sectors and disciplines such as food safety and animal health, the environment, program managers (of national health programs and state AMR action plans), clinicians, microbiologists, public health professionals, health administrators, researchers, academics, and international development partners.

Among the key dignitaries were:

- Dr. Atul Goel, Director General of Health Services, MoHFW
- Dr. Sujeet Kumar Singh, Director, NCDC
- Dr. Reuben Swamickan and Dr. Umesh Alavadi, USAID India
- Dr. Payden, Deputy Representative, WHO India
- Dr. Daniel VenderEnde, U.S. Centers for Disease Control and Prevention
- Dr. Suresh Mohammed, World Bank

• Dr. Vikas Aggarwal, Fleming Fund



Dignitaries and experts in the National Consultation for National Action Plan on AMR for Human Health component on June 22– 23, 2022, in New Delhi. Photo by IDDS

Dr Rueben Swamickan, USAID India, speaking at the consultation meeting on June 22–23, 2022, New Delhi. Photo by IDDS

The experts from the states of Kerela, Delhi, and Madhya Pradesh also gave an overview of the development and achievements of their respective state action plans on AMR. Dr. Aravind R, assistant professor and head of the Department of Infectious Diseases at Government Medical College Thiruvananthapuram, briefed the gathering about activities completed under the state action plan to spread awareness about AMR among students, farmers, and civil society.

For example, these stakeholders established the first antibiotic stewardship hub in the country (outside of the health system), which is run on a hub and spoke model. Dr. Ravindra Aggarwal, additional director and chief coordinator of AMR at Lok Nayak Hospital highlighted that the state action plan has been successful in bringing together stakeholders representing different sectors and that various governance mechanisms are in place. Dr. Deepti Chaurasia, professor and head of the Department of Microbiology at Gandhi Medical College, presented the achievements made so far and challenges they faced during formulation and execution of their state action plan.

Intensive group work by experts involved identification of gaps and challenges left over from the previous plan. Gaps included lack of involvement of NGOs, AMR surveillance data mainly from tertiary care hospitals, incomplete implementation of infection prevention and control practices by many health care facilities, indiscriminate sale of antibiotics, unauthorized access and use of antimicrobials, and inadequate dedicated funding from national and state budgets.

A small group met to consolidate the inputs received from experts on June 24, 2022. The strategic inputs were collated for development of NAP–AMR 2.0, including its draft operational plan and monitoring and evaluation framework for the strategic priorities. This will pave the way to publish the new NAP–AMR (2022–2026).

The final action plan will incorporate the lessons learned from implementation of NAP-AMR (2017-2021); a SWOT analysis of various sectors in mitigating AMR in India; and a practical and realistic structure and operations of the national action plan for the next five years.

Established in May 2018, USAID's Infectious Disease Detection and Surveillance (IDDS) project is a five-year, \$120 million initiative that 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.

IDDS Trains Staff on PREDICT Laboratory Protocol in Indonesia

To increase the capacity to detect emerging zoonotic diseases (those that can spread from animals to humans) Infectious Disease Detection and Surveillance (IDDS) project, in collaboration with the Directorate of Surveillance and Health Quarantine, Indonesia Ministry of Health (MoH), and Eijkman Molecular Biology Research Center, conducted training on the PREDICT laboratory protocol in February and March 2022.



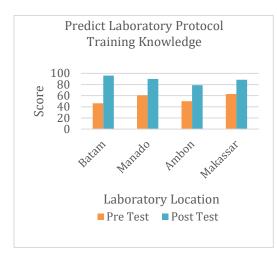
Laboratory officer in Batam in practicing RNA extraction. Photo by IDDS

PREDICT is a project of USAID's Emerging Pandemic Threats (EPT) program, initiated in 2009 to strengthen global capacity for detection and discovery of zoonotic viruses with pandemic potential. The project has developed basic laboratory procedures and provided training to more than 2,500 staff in developing countries. "The training is very valuable, impactful, and responded to our needs," said Salli Hattu, laboratory officer in Ambon, Indonesia.

The training was conducted at four public health laboratories in Batam, Ambon, Makassar, and Manado, Indonesia. A total of 23 people were trained. The training successfully increased the participants' knowledge (see graph below). The goal is to replicate this training in other Indonesian laboratories.

Following the recent trainings, the four laboratories are expected to be able to detect new pathogens (the microorganisms that can cause disease) and emerging infectious diseases and to carry out virus detection and characterization using the PREDICT protocol so that it complements the existing surveillance system for the following priority pathogen groups: influenza, filovirus, coronavirus, paramyxovirus, flavivirus, and hantavirus.

IDDS supported the Eijkman Molecular Biology Research Center in developing the curriculum for this training, which was certified by the Agency for Development and Empowerment Human Resources of Health (BPPSDMK), MoH.



Improving Laboratory Testing Quality in Liberia



Trainee SLIPTA auditors during the training session in Ganta. Photo by IDDS

As the technology at a laboratory improves and the services it provides expands, it is vital to closely monitor the quality of its testing services. The World Health Organization's Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist is an important tool to both monitor and improve the quality of laboratory services, and it was specifically developed for laboratories in Africa, like those in Liberia, as they take on a larger role in the detection of dangerous infectious diseases.

In Liberia, the National Diagnostic Division (NDD) of the Ministry of Health is building a national quality management system (QMS), which will support national and regional laboratories across the country. This is being done with financial and logistical support from USAID's Infectious Disease Detection and Surveillance (IDDS) project.

IDDS, together with NDD and the National Public Health Reference Laboratory (NPHRL), organized the training of in-country (internal) SLIPTA auditors who will play a vital role in evaluating the progress of QMS implementation and ensuring compliance at national and subnational levels. The training was conducted at Ganta United Methodist Hospital in Ganta, Nimba county, June 13–17, 2022, and involved classroom-based teaching and practical sessions.

The training used the One Health approach. The One Health approach brings together the human and animal sectors for a coordinated response to outbreaks of infectious diseases. IDDS collaborated with the Food and Agriculture Organization of the United Nations (FAO) in Liberia to organize the training. Seven laboratory specialists were trained, with IDDS supporting five participants from the human health laboratories and FAO supporting two participants from the National Veterinary Laboratory. The facilitators were NDD and NPHRL laboratory specialists who are also auditors certified by the African Society for Laboratory Medicine (ASLM).

Using the One Health approach is key to improving Liberia's Joint External Evaluation (JEE) score measuring the quality of the national laboratory system. The JEE is the World Health Organization's method of assessing a country's capacity to prevent, detect, and rapidly respond to public health risks in both the human and animal health systems.

The trainees were divided into two groups to conduct mock QMS audits. One group audited Ganta United Methodist Hospital Laboratory and the other group audited the E&J Medical Center Laboratory in Ganta, both under the supervision of the two ASLM-certified auditors. The two groups prepared their reports and presented their audit findings to the team on June 17, 2022.

"This team has been empowered to provide real-time support for QMS implementation in Liberia," said Prince Gbondin, a quality manager with NDD. "This is truly a way of strengthening our laboratory system as we know that without accurate monitoring of progress by people who understand the SLIPTA checklist we would not be able to fully address the gaps in our system. IDDS is helping in building our capacity as local teams as well as ensuring our ownership of the systems being strengthened by creating learning opportunities for us so that we can continue improving quality of laboratory services in Liberia."

The trainees will be certified as Liberia's internal auditors after successfully conducting two SLIPTA audits under the supervision of the ASLM-certified auditors. Once the auditors are certified, Liberia will be able to provide timely QMS audits for its 15 counties and address QMS implementation gaps, strengthening quality of laboratory services as evidenced by the submission of quality-assured data to the WHO Global Antimicrobial Resistance Surveillance System in 2021.



Mark Seesay, Ministry of Health ASLM-certified auditor during a training session. Photo by IDDS



Discussions during the SLIPTA training at Ganta United Methodist Hospital, Liberia. Photo by IDDS



Participants of the SLIPTA auditor training. Photo by IDDS

IDDS Equips Mali for COVID-19 Genomic Sequencing



The INSP general director advisor (left) receiving a sample of the supplies from the senior advisor, global health security, USAID Mali. Photo by IDDS

Genomic sequencing is an important tool in combating pathogens, the organisms that can cause diseases. Scientists use genomic sequencing and surveillance to identify variants in a virus and to detect trends to inform important public health decisions. New variants can emerge anywhere—for example, the Omicron variant of COVID-19 was identified in South Africa. USAID recognizes that global heath security is only as strong as the weakest link in the global surveillance chain. This is why USAID's Infectious Disease Detection and Surveillance (IDDS) project works to equips lower-income countries to quickly detect, track, and respond to infectious disease threats.

In Mali, IDDS is supporting the fight against COVID-19. IDDS' donation of laboratory supplies and equipment in June 2022 will enable the country to start genomic sequencing and provide vital information about the COVID-19 variants currently present in Mali as well as those which have circulated since the outbreak began in March 2020.

"These commodities will be very useful for the government of Mali and our different partners to follow the disease genomic trend in the country and make better decisions for diseasefighting measures," said Etienne Coulibaly, director advisor with Mali's National Institute of Public Health (INSP).

The supplies and equipment, including 2,000 test kits, were officially handed over to INSP on June 6, 2022, by the Global Health Security Agenda's senior advisor at USAID in Mali, Dr. Mounkaila A. Billo.

Boosting Bacteriology Capacity in Senegal

In Senegal, USAID's Infectious Disease Detection and Surveillance (IDDS) project has made significant progress toward upgrading key laboratories to develop and strengthen their bacteriology capacity. Bacteriology is vital for the laboratory diagnosis of infectious diseases, and for detection of antimicrobial resistance (AMR): the analysis of bacteria and other microorganisms to test their resistance to certain drugs.

Since 2019, IDDS has provided technical assistance to seven priority regional laboratories (Roi Baudouin de Guédiawaye, El hadji Abdou Aziz Sy Dabakh de Tivaouane, Magatte Lô de Linguère, Ndamatou de Touba, Kaffrine, Richard-Toll, and Sédhiou) to develop or improve their bacteriology capacity. The laboratories were either not performing bacteriology tests or were performing the tests without any standardized procedures. Standard operating procedures (SOPs) are crucial to maintaining the consistency, accuracy, quality of laboratory work.

In 2021, IDDS supported Senegal's Ministry of Health Directorate of Laboratories to create 54 SOPs for performing antimicrobial susceptibility testing (AST) and shared them with the seven laboratories. AST is the process for checking a specific specimen for AMR.

In 2022, two regional laboratories were added to those supported by IDDS: Social and Hygiene Institute of Medina and Mbour Health Center. The two newly enrolled laboratories received training in a three-day workshop on June 22–24, 2022, held in the National Public Health Laboratory in Dakar. The goal was to adapt the previously approved SOPs based on how the new laboratories are performing AST and align them with national guidelines. The workshop was facilitated by the Directorate of Laboratories representatives and technicians from two of the seven laboratories that were initially enrolled in the IDDS initiative to improve bacteriology testing. These sessions provided an opportunity for the new laboratories to share evidence-based experiences about the effectiveness of the SOPs. During working group sessions, discussions focused on gaps noted in the AST process in the different laboratories and corrective actions were provided by the facilitators.

The workshop allowed the two newly enrolled laboratories to have 54 SOPs adapted for their routine bacteriology testing. Standardization of AST in these laboratories will improve the reliability and accuracy of their test results and improve the quality of the AMR data entered into the District Health Information Software 2 online platform for health data. Improved quality will also reinforce the trust of clinicians in laboratory results, enabling better patient care.

One trainee from Mbour Health Center said: "IDDS' support is really appreciated because we did not have any SOPs for bacteriology testing, and further these SOPs will greatly promote the improvement of our quality management system where SOPs are a requirement for any testing process accomplished in the laboratory."

IDDS will continue to work with the nine laboratories to help them achieve the requirements for quality and competence in medical laboratories set by the International Organization for Standardization (ISO 15189:2012).



Working group from the Medina Health Center. From left to right: Dr. Mouhamadou Sakho, manager of Tivaouane laboratory and facilitator of this session; Adjaroutou Diop, IDDS diagnostics specialist; Ndeye Ngone Fall, lab technician; Dr. Roughyatou Ka, microbiologist and facilitator of this session, Seynabou Kounta, laboratory technician; and Amath Diouf, laboratory technician. Photo by IDDS



Working group from Mbour Health Center. From left to right: Mansour Wane, laboratory technician; Khadija Datt, Directorate of Laboratories representative; Dr. Mohamadou Drame, laboratory manager; Dr. Mame Diarra Bao, IDDS team lead; and Aissata Tall, laboratory technician. Photo by IDDS

IDDS Supports Statistical Process Control Training for Laboratory Staff in Uganda

Laboratories are our key defense against outbreaks of infectious diseases with their capacity to test for dangerous pathogens, the microorganisms that can cause diseases. But the testing of specimens involves complex procedures such as clinical analysis and microbiological investigation. These procedures take place under varying conditions, such as temperature and humidity, and staff use various equipment. Quality control is vital to ensure the precision and accuracy of test results. Laboratories are required to implement quality management systems (QMSs) in alignment with standards for the competence, impartiality, and consistent operation of laboratories. One of the most important aspects of a QMS involves controlling laboratory processes to ensure validity of their test results.

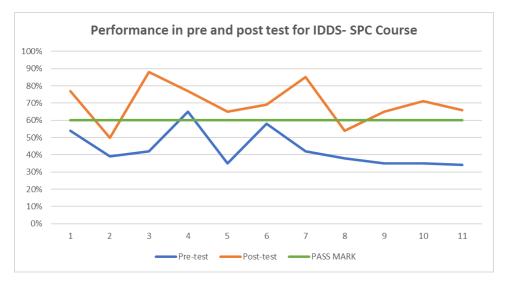
Laboratories validate their test results using a variety of equipment. This equipment must conform to the specifications of the manufacturer, and laboratories must keep records of manufacturer-specified parameters. The laboratory further ensures the reliability of the test results by conducting and practicing quality control methods such as running an external quality assessment (EQA) of specimens, conducting proficiency testing, and running inter- and intra-laboratory comparisons of test results. The EQA results are monitored and verified to identify trends and ensure the laboratory conforms to a set of rules that measures whether any discrepancies were likely to occur through random variation, or whether there may be a problem with the measurement system. If a problem is identified, the laboratory takes steps to address it through a corrective action-preventive action process, which helps to identify the root of the problem and ensure that it does not happen again.

For the laboratory to fully apply EQA results and other data, staff need to understand the different statistical techniques that can inform their decisions. This is done through a process called statistical process control (SPC), which is defined as the use of statistical techniques to control a process or production method. SPC tools and procedures can help laboratories to monitor process behavior, discover issues in internal systems, and find solutions for production issues.

SPC Knowledge Improved

Participant scores increased from an average of 45% on the pre-test to an average of 70% on the post-test, with 9 of 11 participants receiving a passing score of 60% or more on the post-test.

USAID's Infectious Disease Detection and Surveillance (IDDS) project collaborated with the Bio Risk Management Department of the Ugandan Ministry of Health; National Livestock Resources Research Institute (NaLIRRI); Ministry of Agriculture, Animal Industry and Fisheries (MAAIF); National Animal Disease Diagnostics and Epidemiology Center (NADDEC); and the Uganda Wildlife Authority (UWA) to conduct SPC training of quality managers. Laboratory quality managers participated from the four IDDS-supported Regional Animal Disease Diagnostics and Epidemiological Centers, NaLIRRI, NADDEC, and UWA, as part of the mandatory training required to fulfill requirements for laboratory operations. The training was conducted on April 11–15, 2022, and pre- and post-training test results indicated a significant increase in participants' knowledge of SPC (see below).



The training targeted veterinary laboratory personnel from selected veterinary laboratory facilities across the country. The 11 participants were from the facilities of Gulu (1), Moroto (1), Mbale (1), Mbarara (1), NADDEC (3), UWA Queen Elizabeth Veterinary laboratory (1), and NaLIRRI (3).

Recognizing the impact that method/equipment verification and validation can have on the accuracy of the test results, the quality manager at NADDEC, Gladys Nakanjako Kigunddu said, "This training was a timely intervention to bridge the knowledge gap in areas of method verification, validation, and measurement uncertainty."

SPC should be one of the major technical areas in laboratory operations employed by every laboratory staff during their day-to-day implementation of their duties. A robust understanding of SPC can really help to make informed decisions regarding the quality of services offered, and to quickly identify any problems in laboratory processes so that corrective actions can be taken. While laboratories strive to reduce errors and improve accuracy of their test results, quality is best improved by having systems in place that are well understood by managers, such as SPC.



A facilitator oversees participant "teach back" sessions during the SPC training. Photo by IDDS



The facilitators, participants, and IDDS staff after the SPC training. Photo by IDDS

Harnessing the Power of Animal Health Data to Detect Outbreaks in Uganda

Zoonotic diseases can jump from animals to humans when a person handles or is bitten by a sick animal, eats its meat, or encounters the bodily fluids of a sick animal (for example, blood, feces, respiratory droplets, or saliva). Once ill, the infected person can spread the zoonotic disease with frightening speed. To detect and prevent zoonotic diseases, there must be a coordinated effort among human, animal, and environmental health professionals across all levels of a health system—an approach called One Health.

Uganda's One Health strategy for a multisector fight against zoonotic diseases has yet to be fully implemented. In particular, the World Health Organization identified capacity gaps in use of data identified in the animal sector during its 2017 Joint External Evaluation of International Health Regulations (IHR) capacities. This evaluation assesses the performance of countries in emergency preparedness, providing benchmarks which, if achieved and sustained, indicate an optimal level of readiness to prevent, detect, and respond to threats such as infectious disease outbreaks.

Uganda's animal health sector lacks optimal capacity to detect and respond to zoonotic diseases and alert human health and environmental health officials of potential outbreaks. For the past two and a half years, USAID's Infectious Disease Detection and Surveillance (IDDS) project has worked to build capacity in Uganda's animal health sector to better detect, report, and respond to zoonotic diseases.

Most recently, IDDS established a team of trainers and conducted a training of trainers (ToT) workshop on the topic of data analysis in the animal health sector. The ToT was conducted on May 23–27, 2022 in Jinja, using training materials that were developed by the National Animal Disease Diagnostics and Epidemiology Center (NADDEC) with support from IDDS in fiscal year 2021. The ToT built national-level capacity in the animal health sector to conduct advanced epidemiological and statistical analyses and laid a firm foundation for achieving the World Health Organization's IHR benchmark 9.3, on systematic analysis of surveillance data for action. The IDDS ToT addressed these IHR requirements:

- Establishing a dedicated team for data analysis, risk assessment, and reporting at national and intermediate levels.
- Developing a mechanism and training staff to share data with other tools that are used at regional or international levels.

While closing the training workshop, Dr. Robert Mwebe, head of the epidemiology unit at NADDEC, said, "I would like to thank IDDS for demystifying mapping. The days of all departments lining up at Esther's desk [NADDEC data entrant's desk] to have maps drawn now lie behind us."

The ToT established a pool of national trainers who will continue to develop the data analysis skills of other ministry and district veterinary staff. For example, trainees have already begun to

transfer data analysis and mapping skills to 15 district veterinary staff in the districts of Gulu, Mbale, Mbarara, and Moroto in training held in Jinja on June 13–17, 2022.



Jonathan Ejoku, IDDS consultant, facilitates training of trainers in data analysis. Photo by IDDS



Jonathan Ejoku, IDDS consultant, addresses the participants during the training of trainers in data analysis. Photo by IDDS

Established in May 2018, USAID's Infectious Disease Detection and Surveillance (IDDS) project is a five-year, \$120 million initiative that 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.

Strengthening Quality TB Testing Through On-site Mentorship

Some 29,000 people were diagnosed with tuberculosis (TB) in Zimbabwe in 2020, and most of these were in Harare Province (the capital region). This high rate of cases in Harare was confirmed by a TB diagnostic network assessment—a complete analysis of the country's TB diagnostic network and system—carried out by USAID's Infectious Disease Detection and Surveillance (IDDS) project from December 2019 to February 2020.

The assessment found out that a wide network of both public- and private-sector TB laboratories were making TB diagnoses. While the public-sector laboratories received routine supervision from City of Harare Beatrice Road Infectious Disease Hospital (BRIDH) Laboratory and training materials in the form of processes, registers, guidelines, and standard operating procedures, the private sector lacked this support. The private-sector facilities were facing challenges in accessing the latest guidelines and program materials, as well as training and mentorship opportunities.

It was clear to Zimbabwe's National TB Control Program (NTP) that there was very uneven quality in TB testing and action was needed to raise standards for all. To better understand gaps and opportunities for improvement, IDDS supported a baseline assessment of 25 public, private, and nonprofit laboratories in Harare together with NTP and BRIDH, carried out in March 2022. The baseline assessment used the national TB diagnostic checklist that had previously been developed by IDDS. The assessment found:

- A lack of standard operating procedures and job aids
- Poor documentation practices
- Failure to monitor quality indicators
- Training, competency, and staff records were not available
- Lack of standardized tools and registers at private laboratories
- A shortage of biosafety equipment and materials



IDDS, NTP, and BRIDH staff conducting baseline assessment interviews. Photo by IDDS

USAID Infectious Disease Detection and Surveillance (IDDS) FY 2022 Quarterly Report April–June 2022 To address these issues and improve quality, IDDS enrolled the 25 laboratories in a training and mentorship program, which includes:

- Quarterly supportive supervision visits by IDDS, NTP, and BRIDH
- Every quarter, three days of classroom training workshops to address the issues identified during the quarterly supportive supervision visits
- Twelve-week, on-site mentorship sessions to enable participants to translate the knowledge gained into practice. Mentorship sessions are facilitated by IDDS technical experts (see Figure 1 below).

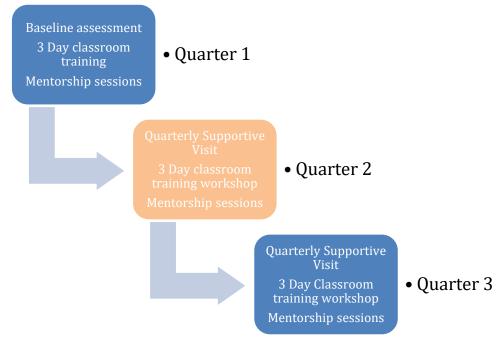


Figure 1: Training and mentorship cycle of Harare laboratories

The Zimbabwe national TB laboratories coordinator, Tanaka Sakubani, appreciated the blended capacity building model being supported by IDDS. "This model avails an opportunity for TB laboratory professionals to translate the theoretical principles learned during the classroom sessions into practice during the on-site mentorship sessions. We expect the laboratories to establish a culture of quality in TB diagnostic activities."

IDDS provided financial and technical support for the first classroom training workshop, which took place April 12–13, 2022. Participants from the 25 laboratories were trained on developing documents and records, defining and monitoring quality TB diagnostic indicators, and process improvement and safe work practices in the TB laboratory.

IDDS then began conducting the first cycle of on-site mentorship sessions in May 2022 for the 25 laboratories. IDDS also shared stationery and printing materials to ensure that laboratory staff can develop and print documents and records.

Also, to formalize standardized support to all the laboratories in Harare, IDDS supported NTP and the city government of Harare to develop the Harare Quality Improvement Framework document in January 2022. The document provides guidance on the key areas that need to be addressed to improve the quality of TB testing.



A laboratory technician undergoing competency assessment. Photo by IDDS

Preventing the Next Pandemic: Scaling Laboratory Operations in Developing Countries

(As published in New Security Beat, July 8, 2022)

In 1976, a Belgian Catholic mission and hospital in what is now the Democratic Republic of the Congo (DRC) was stricken with a mysterious illness that caused fever-like symptoms. Most of the patients who contracted the illness died. A young microbiologist named Jean-Jacques Muyembe Tamfum was called to the mission, where he extracted blood samples from those who had fallen ill. The DRC did not have a functional research laboratory at the time, so Muyembe had to send his samples to Belgium for analysis. The results that came back revealed that they contained a new deadly virus: what the world came to know as Ebola, named after a river near the mission.

The virus that was novel almost fifty years ago is now recurrent—and intensifying in its occurrences. Today, the DRC is <u>facing its sixth Ebola outbreak</u> in <u>the last four years</u>. While risk of transmission remains high (due to "spillover" that occurs when the virus jumps from animals to humans), the labors of Professor Muyembe have ensured that the country is now better equipped to contain the spread of not only Ebola, but also other emerging infectious diseases.

At a recent <u>symposium</u> hosted by the George Washington University <u>Milken Institute</u> School of Public Health and the <u>Mérieux Foundation</u> USA, Muyembe shared the story of his life's work. It is a journey that not only led to his discovery of an antiviral Ebola treatment, but also a quest to equip the National Institute of Biomedical Research (<u>INRB</u>) that he directs in the DRC.

"For more than four decades since its discovery in 1976, [Ebola had] no treatment or vaccine," said <u>Professor Muyembe</u> in his keynote address. "Today, thanks to international collaboration, Ebola virus disease is preventable and curable."

Investing in Laboratory Capacity

In her remarks at the symposium, Dr. Rebecca Katz, director of Georgetown's Center for Global Health Science and Security, observed that international collaboration is more than just one-off funding for laboratory equipment and staff. It takes a strong partnership to find the "right balance between what the needs are, as defined by the country, and then being able to match that to both national-level investments as well as global investments."

That's where the <u>Infectious Disease Detection and Surveillance (IDDS) project</u>, funded by the U.S. Agency for International Development (USAID), comes in. The project's impact goes far beyond Ebola and the DRC, aiming to strengthen countries' laboratories and health systems to quickly detect, track, and respond to infectious disease threats. The project has already supported more than 100 laboratories to improve testing and trained 2,000 people on disease surveillance. On a broader front, the IDDS project also has spearheaded 31 national strategies and plans to accomplish this work.

Muyembe's nation has remained on the front lines of these larger efforts. During the Ebola outbreak of 2018–2020, USAID and the Mérieux Foundation funded and supported the

Rodolphe Mérieux Laboratory at INRB Goma to address lack of testing and surveillance capacity in the eastern territory of the DRC. When COVID-19 arrived, the lab became the main testing center in eastern DRC and the base for outbreak control in that region.

"The response to the new emerging infections all depends on labs being able to get the diagnosis right and then being able to scale up diagnostic testing efforts in the community," <u>explained Dr. Tom Inglesby</u>, director of the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health, to the audience at the Milken symposium. "We need to identify cases quickly, which means not only diagnosing those who are initially present, but also going out and doing active surveillance in the community to quickly seek out new cases. We need diagnostic tests that are widely available, not only in reference labs."

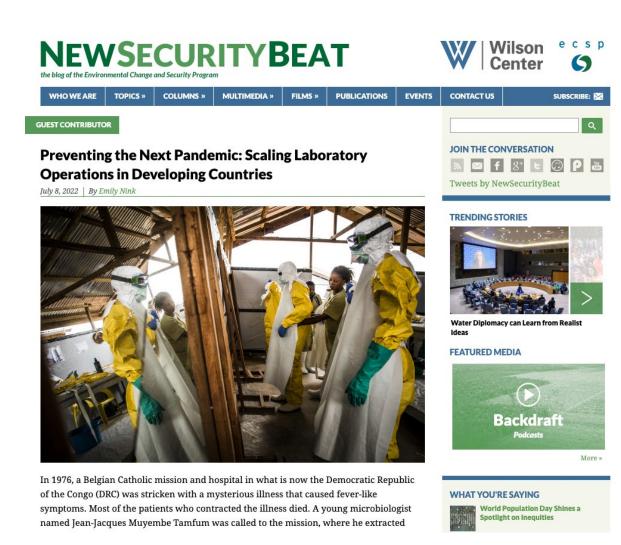
Seeking Skilled Collaborators

In the DRC and nearly two dozen other countries, IDDS is working to decentralize laboratory services and make these tests more widely available. One of the major challenges is retaining skilled laboratory workers.

Significant investments are required to sustain the efforts to train health workers, ensure compliance with national and international guidelines, and accredit programs and laboratories. But when these initiatives are led by local experts and supported by international aid, they work.

"From 1998 to 2003, I was the only PhD at the INRB," noted Muyembe. "Today, I am surrounded by a team of PhD collaborators. Most of these PhDs were trained abroad, but they all decided to come back and work at the INRB because we have developed research infrastructure at the INRB."

Further substantial investments will be needed to replicate Muyembe's success in the DRC and stop infectious diseases at their source. "There's never been sufficient funding," said Dr. Katz. "There is not currently sufficient funding—and we need a lot more money to be able to build sufficient capacity to be able to prevent, detect, and respond to public health emergencies."



Pandemic Prevention Hinges on Linking Animal and Human Health: A Look at Uganda

(As published in AgriLinks, July 13, 2022)

A chicken is sick in Uganda. Left unaddressed, it could affect us all. A USAID project is working to prevent infectious disease outbreaks in Uganda by improving the ability to detect and respond to zoonotic diseases in the animal health sector.

Zoonotic Diseases: A Global Threat

A livestock farmer in Uganda notices one of his chickens is sick. Later the chicken dies, but the farmer is not alarmed because the rest of the flock appears healthy. He takes the flock to market, unwittingly exposing vendors and shoppers, some of whom fall ill. The shoppers return home to their villages and spread the illness to their families and neighbors. One neighbor has a family member visiting from another country. The visitor becomes ill but needs to return home. At the airport, the visitor exposes travelers from other countries all over the world to the illness. The illness spreads. Suddenly, a single chicken in Uganda has infected enough people to lead to a worldwide pandemic.

This hypothetical example is not implausible. Chickens and many other animals are carriers of zoonoses (zoonotic diseases), which are caused by pathogens such as viruses and bacteria that can infect both humans and animals. These diseases can jump from animals to humans through "spillover events" when humans come into close contact with wild or domesticated animals. In recent years, global headlines have featured zoonotic diseases such as COVID-19, Ebola virus disease, avian influenza (bird flu), monkeypox, and Zika virus disease. Three out of every four new, emerging or reemerging infectious diseases in people come from animals. On World Zoonoses Day, July 6, we recognize that human and animal health are inextricably linked.

To prevent a sick chicken from perpetuating an outbreak among humans, there must be a coordinated effort between human, animal (livestock and wildlife), and environmental professionals across all levels and sectors of a health system—an approach called <u>One</u> <u>Health</u>. Uganda's One Health strategy to fight zoonotic diseases is complex and involves an integrated, multisectoral approach. Due to its complexity, implementation and coordination across sectors require additional support to optimize the country's ability to detect and respond to zoonotic diseases. For the past two and a half years, USAID's <u>Infectious Disease</u> <u>Detection and Surveillance (IDDS) project</u> has focused its efforts to build capacity in the animal health sector to better detect, report, and respond to zoonotic diseases.

Accelerating Disease Detection

The first step to preventing the theoretical outbreak described above is to submit a specimen (such as a blood sample) from the sick chicken to an animal health laboratory for analysis. The laboratory can test the specimen for infectious bacteria or viruses and return the results to a local veterinarian. The veterinarian can provide the livestock farmer with an accurate diagnosis, and the farmer can take quick action to resolve the issue.

Prior to IDDS's support, most animal specimens in Uganda were sent to a central laboratory for testing. This system experienced significant delays in specimen transport to the laboratory, low test request volumes and limited laboratory staff. These factors resulted in veterinarians and farmers having to wait for test results, thus delaying detection and outbreak response. To reduce turnaround times, IDDS focused on empowering regional laboratory staff to conduct testing at their facilities, which are located closer to potential disease hotspots where humans have close contact with animals. IDDS developed a toolkit for national trainers to use in mentoring regional laboratory staff on how to properly conduct diagnostic tests for zoonotic diseases. The project then trained a group of twelve national mentors who have been mentoring staff at four regional laboratories.

At the conclusion of the mentorship program, the regional laboratories will qualify for accreditation, indicating that the laboratories' tests are conducted according to international standards and the results are accurate and reliable. For the communities served by these regional laboratories, this means that livestock owners, such as the hypothetical chicken farmer, will be able to test sick animals, quickly receive accurate results and, when necessary, take actions to prevent zoonotic diseases from spreading to humans. After observing quality improvements IDDS made at one of the regional laboratories, U.S. Ambassador to Uganda Natalie Brown commented, "We commend all the partners who have dedicated their time and resources to improving and monitoring the status of animal health. This is very important to both families and communities in which they live as it prevents future pandemics."

Coordinating Outbreak Response

If a positive laboratory test leads to timely and accurate diagnosis of a sick chicken by a local veterinary health official, public health authorities can take action to alert the vendors and shoppers who were exposed at the market by the rest of the chickens. Veterinary health officials rely on aggregate testing data to determine the scale of an outbreak (how many animals are sick and where). Reports of positive cases are sent from regional testing sites to national authorities for monitoring and surveillance. In Uganda, data were compiled manually—a time-consuming, inefficient process that was prone to errors. IDDS developed an electronic data entry tool for four regional pilot sites that is easier to use and prevents mistakes. At the national level, the new tool helps officials to aggregate and analyze data, making it easier to spot outbreaks and mobilize resources.

To contain an identified outbreak, human and animal health officials must coordinate their response across national and local governments (vertical coordination) and across sectors (horizontal coordination). At the national level, IDDS worked with the National One Health Platform to develop a national strategy and plan for implementing a One Health approach to zoonotic disease surveillance. Musa Sekamatte, the national One Health coordinator said, "With this implementation plan in place, we can now move the One Health concept from national level meetings to actual One Health practice at a community level."

To support collaboration and implementation of a One Health approach at the community level, IDDS assembled and trained District One Health Teams (DOHTs) in Mbale and Kazo districts, which have experienced several outbreaks of zoonotic disease in the last five years. Prior to the launch of the DOHTs, many of the human health officials had never spoken to

veterinary officials in the districts. Now, the DOHTs meet monthly to share data and strategize to prepare for a future outbreak. When there is an active outbreak, the DOHTs meet weekly to share new developments, coordinate their response, and prevent the outbreak from spreading.

Though zoonotic diseases can be challenging to address, there are opportunities to intervene before local outbreaks become global pandemics. To contain outbreaks, the human and animal health sectors must be able to work together, and act quickly based on the available evidence across all levels of government. If we employ a holistic One Health approach, we need not wait until the next catastrophe—or even the next local outbreak—to act. There are actions we can take now to prevent spillover events from animals to humans and ensure that when the next spillover event occurs, public health officials are ready to sound the alarm, isolate sick animals and humans to minimize the threat, and save lives.



Veterinary officials demonstrate how a blood specimen is collected from a cow in a rural Ugandan district. Photo Credit: IDDS