INFECTIOUS DISEASE DETECTION AND SURVEILLANCE
TUBERCULOSIS FACT SHEET

Truenat introduction and training in Zimbabwe. Photo by IDDS.

IDDS Strengthens TB Diagnostics Through TB DNA

A TB diagnostic network is a collaborative group including all (public, private, non-governmental) laboratories and health facilities within a country, whose mission is to address individual patient care and public health needs from the peripheral to the national level.

The TB Diagnostic Network Assessment (DNA) is a country-driven process that assesses the functionality of the national TB diagnostic network and system. It aids in determining the system's capacity to meet the needs of the country's national TB strategic plan (NSP) for achieving the goals outlined in the End TB Strategy. The TB DNA:

• Reviews holistically the diagnostic network, current practices, and algorithms

• Identifies challenges that prevent the diagnostic network from performing efficiently and effectively

• Proposes evidence-based interventions to improve the overall ability of the diagnostic network to meet the goals and targets of the NSP

The Infectious Disease Detection and Surveillance (IDDS) project supports countries to detect priority diseases and antimicrobial resistance (AMR) through building countries' national capacities to improve diagnostic networks.

BACKGROUND

The United Nations High-Level Meeting on Tuberculosis, on September 26, 2018, was a landmark in the fight against tuberculosis (TB). Countries committed to diagnose and treat a cumulative number of 40 million people by 2022. Despite significant progress toward this goal, the COVID-19 pandemic has set back the fight against TB by several years, and the gaps identified in TB diagnostic services before the pandemic have now widened. The World Health Organization (WHO) estimates that 9.9 million people fell ill with TB and 1.5 million died from it in 2020, because of reduced access to TB diagnosis and treatment. This is the first time TB deaths have risen in more than a decade.

To get the correct treatment, a person with TB needs to get the right diagnosis. Of the 9.9 million people with TB in 2020, the WHO estimated that 4.1 million went undiagnosed or unreported, up from 2.9 million in 2019. Only 59 percent of the identified pulmonary TB cases were confirmed to have TB through bacteriological testing, and only 71 percent of persons with bacteriological confirmation were tested for drug resistance. Just one in three people with drug-resistant TB received necessary treatment in 2020 due to lack of diagnosis.

An estimated 1.1 million children fell ill with TB in 2020, and 63 percent of those were not reached with, or reported to have obtained, TB diagnosis and treatment. The proportion was even higher (72 percent) for children under five years. Poorer access to services means that children make up a disproportionate number of those who die from TB.

Comprehensive and holistic strategies to scale up TB diagnostic services across health sectors are needed now if the commitments made by governments in 2018 are to be met and TB control to be achieved.

TB-NET TOOL AND THE TB DIAGNOSTIC NETWORK ASSESSMENT

USAID has supported the development of the TB Diagnostic Network Assessment (DNA) process to evaluate the capacity and functionality of a country's diagnostic network. The process, endorsed by the Global Laboratory Initiative, was piloted in Nigeria and India and revised with input from key stakeholders. The revised version was applied in Uganda. IDDS is continuing to refine the TB NET Tool (the documents that guide the process) and is conducting a series of assessments in targeted countries to gauge how effective TB diagnostic networks are in these countries and make recommendations for strengthening them.

Figure 1. Using LNSA, the map shows priority locations for the placement of new GeneXpert machines for TB diagnosis.

IDDS further supports implementation of some of the recommendations from the DNA that will contribute to strengthening TB diagnostic networks while encouraging the national TB programs (NTPs) to galvanize support from other donors and implementing partners to address the outstanding gaps identified by the TB DNA. TB DNAs have been successfully conducted in Ethiopia, Tanzania, Vietnam, and Zimbabwe with IDDS support, and findings shared with the NTPs. IDDS is also planning TB DNAs in Burma, the Democratic Republic of the Congo (DRC), and Malawi. IDDS has translated the TB-NET tool into French, and prepared mobile-friendly versions and specialized content for pediatric TB and drug-resistant TB.

As part of the DNA process, IDDS conducts a laboratory network spatial analysis (LNSA). The LNSA provides data-informed recommendations to the NTP plans for expansion of testing capacity including placement of testing instruments, specimen referral networks, and overall diagnostic network design. USAID and IDDS have successfully supported LNSAs in Afghanistan, Bangladesh, Burma, the DRC, Kenya, Mozambique, Vietnam, Zambia, and Zimbabwe to utilize existing testing capacity and recommend allocation of new capacity based on their respective testing needs and anticipated expansion plans. By the end of 2022, IDDS will have completed LNSAs in Cambodia, Ethiopia, Malawi, the Philippines, Tanzania, and Uganda. IDDS has also revised the LNSA data protocols to incorporate collection and analysis for second-line drug susceptibility testing (culture and line probe assay) and developed a protocol for others to follow the methodology.
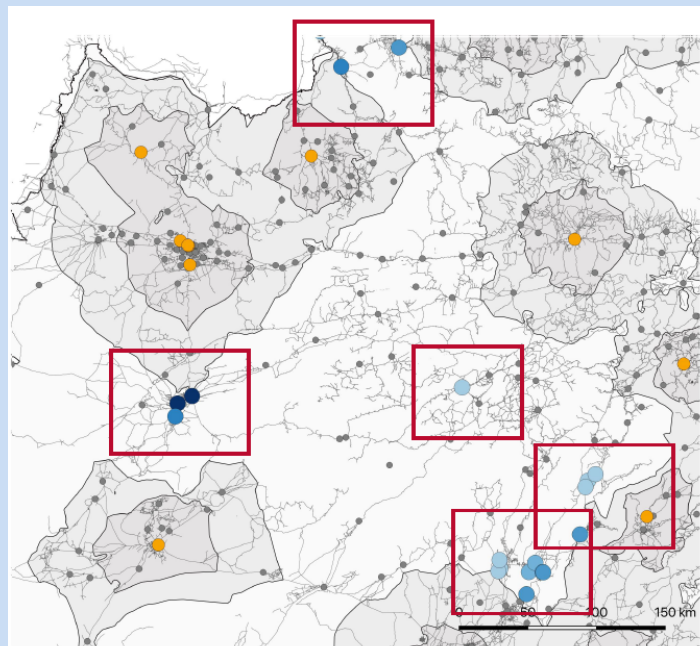
DESCRIPTION

USAID's IDDS project designs and implements comprehensive frameworks to improve TB diagnostics. It is a five-year project, awarded in May 2018 to ICF with sub-partners: FHI 360, PATH, Abt Associates, Metabiota, African Society for Laboratory Medicine, Gryphon Scientific, Association of Public Health Laboratories, and Mérieux Foundation. IDDS supports USAID's TB and Global Health Security strategies and portfolios, while encouraging integration or coordination across public health diseases and between the human and animal health sectors (One Health approach) where appropriate.

OBJECTIVES

The primary objective of IDDS is to strengthen detection and surveillance of priority diseases including TB. IDDS will implement USAID, U.S. Government, and global initiatives and strategies to reduce global health threats posed by infectious diseases, including TB and multidrug-resistant TB (MDR-TB), by focusing on strengthening disease detection networks.

IDDS helps targeted countries avert the spread of these diseases, prevent and mitigate outbreaks, and inform interventions to reduce associated mortality and morbidity. IDDS aims to improve access to accurate, timely, safe, reliable, and integrated TB diagnostic tests for all presumptive TB cases. USAID and IDDS work with countries' TB programs to develop and implement comprehensive national TB/MDR-TB laboratory strategic plans to improve diagnostic networks.

Truenat introduction and training in Zimbabwe. Photo by IDDS

IDDS training session in Vietnam. Photo by IDDS

STRATEGIC FOCUS AND APPROACHES

IMPROVING HEALTH SYSTEMS TO ADDRESS TB

IDDS focuses on improving diagnostic tools and technologies and scaling up TB detection and notification in countries, while strengthening the underlying health systems and supporting improvements in quality-based services. IDDS works closely with national TB programs (NTPs) and other health programs in Bangladesh, Burma, Cambodia, the Democratic Republic of the Congo, India, Malawi, Tanzania, Vietnam, and Zimbabwe to establish and strengthen integrated TB diagnostic networks. IDDS employs a technical approach that is based on a core principle: the need to implement a sustainable and patient-centered framework to improve access to accurate TB diagnostic technologies and equipment, based upon WHO and USAID recommendations. These technologies need to be adaptable, and results should be given in a timely manner to requesting facilities and clinicians, and meet the patients where they seek care.

TRUENAT

Since its endorsement by the WHO in 2020, Molbio Diagnostics's chip-based nucleic acid amplification test, Truenat, has faced slow adoption by high-burden TB countries. In collaboration with the United Nation's Stop TB Partnership, IDDS has developed training on Truenat for laboratory technicians. The first training sessions took place in Nigeria, DRC and Zimbabwe, and there are plans for Truenat introductory and training sessions in Bangladesh, Cambodia, Kenya, the Philippines, and Vietnam. IDDS also supports proficiency testing for technicians and mentoring to ensure testing is carried out appropriately and TB programs have confidence in the outcomes.

Truenat can be used at the point of care – it has eight hours of battery life and can withstand temperatures up to 40° Celsius – and can diagnose rifampicin resistance. Use of Truenat will enable countries to decentralize rapid molecular testing for TB. Truelab, the system which Truenat runs on, also can test for other pathogens including COVID-19 and HIV, making it a highly flexible option for laboratories.

IMPROVING RESPONSES TO TACKLE DRUG-RESISTANT TB

IDDS provides support to NTPs to strengthen their response to rifampicin-resistant TB (RR/MDR-TB) through improved case detection at TB diagnostic facilities. IDDS provides technical assistance to update TB diagnostic algorithms and share best practices in line with WHO's End-TB strategy and the U.S. Government's National Action Plan for MDR-TB. IDDS also supports the introduction and implementation of rapid molecular tests for TB and rifampicin resistance, including Truenat and GeneXpert, and the linking of these instruments to online platforms for rapid reporting and analysis. IDDS support the implementation of the Xpert MTB/XDR cartridge for detection of resistance to isoniazid and fluoroquinolones on the GeneXpert platform. As other new and innovative tools enter the market and receive endorsement from the WHO, Global Fund, USAID, and others, IDDS will review and stand ready to support evaluation for use by partner NTPs.

STRENGTHEN THE CAPACITY TO ANALYZE AND USE TB DATA

IDDS provides technical assistance to scale up integrated TB diagnostic data for accurate data capture from and incorporation into national notification systems. The Aspect and DataToCare platforms have tremendous potential to improve reporting speed and response when rapid diagnostic instruments are connected and the data collected are reviewed. These systems lead to increased reporting of TB indicators in real time, automated processes, and delivery of disease diagnostic data to national databases while also providing diagnostic confirmations to clinicians. Automated systems also provide laboratory directors with the ability to monitor stock, minimize errors, and reduce downtime for maintenance and repair.

IMPROVING DETECTION OF PEDIATRIC TB

IDDS supports the scale-up of child-friendly diagnostic techniques, specifically the use of stool as a testing medium for TB. Many children will swallow their sputum, and enough of the TB bacteria survives passage through the digestive tract to make testing stool as reliable as testing respiratory samples and less traumatic for the patients. This method will not eliminate the need for pediatricians to be trained in TB detection, but it will provide an excellent source of information to make a diagnosis.

IDDS aims to improve people's access to accurate, adaptable, reliable, safe, and timely TB tests and technologies.