

ESTABLISHING SYSTEMS AND IMPROVING EFFICIENCIES FOR ENHANCING EQUITABLE ACCESS TO TESTING SERVICES AND UPTAKE OF TEST RESULTS

OVERVIEW

Reliable laboratory systems are critical to the delivery of quality healthcare services. Establishing and improving laboratory networks and systems for HIV and tuberculosis (TB) provides platforms that enable countries to better respond to other diseases. The sustainability of these systems is key to ensuring constant readiness of laboratory diagnostics services, surveillance, and outbreak investigations.

The U.S. Centers for Disease Control and Prevention (CDC) provides technical expertise to priority countries supported by U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and CDC's Global TB program to effectively reach UNAIDS' global targets to control the HIV epidemic, the World Health Organization's (WHO) "End TB Strategy," and the Stop TB Partnership's "Global Plan to End TB" targets. CDC's strategic approach to HIV and TB epidemic control is to develop and strengthen existing laboratory capacities, improve efficiencies, and strengthen a country's capacity for robust health services delivery.

HIV VIRAL LOAD TESTING

As more people are identified as HIV-positive and are placed on lifelong antiretroviral treatment (ART), there is an urgent need to monitor patients' treatment response. Viral Load (VL) testing measures the amount of HIV virus in the blood and can be used to monitor the effectiveness of treatment. To support HIV patient management and viral suppression, CDC establishes and improves the efficiency of systems for VL testing and uptake of test results. Scale-up activities include:

Strategic Planning: CDC efforts include convening regional workshops for joint ministry of health (MoH), stakeholder data review, knowledge-sharing, work plan development, supporting development of policy documents, country strategic plans, implementation, and monitoring and evaluation tools. CDC conducts laboratory instrument mapping and tiered laboratory network optimization and systems to increase access and reduce test result turnaround times (TAT).

Tools: CDC co-developed and deployed both the 1) VL Toolkit that covers clinician and laboratory training, specimen referral, costing, forecasting, and monitoring and evaluation, and 2) VL Scorecard and Quarterly Monitoring Tool to identify gaps and monitor improvements within the HIV VL and EID cascades.

Testing and QA: CDC evaluates new VL tests (including POC assays as part of the WHO pre-qualification process), has developed use of dried tube specimens (DTS) and dried blood spot (DBS) technologies for VL testing, and is conducting implementation studies on quality assurance (QA) activities to enable accurate and reliable testing in decentralized settings.

Technical Assistance: CDC supports countries with 1) hands-on technical training, 2) workflow optimization for plasma and DBS testing, and 3) development and implementation of sustainable strategies to reduce VL sample backlogs and turnaround time from sample collection to result delivery.

Partnerships: CDC collaborates with the U.S. Agency for International Development, Unitaid, WHO, the African Society for Laboratory Medicine, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, Médecins Sans Frontières, the Clinton Health Access Initiative, and other partners to support MoHs to scale up VL and with manufacturers to optimize platform procurement and maintenance. These efforts and activities contribute to effective virologic monitoring for patients on ART, informed adherence counseling and treatment changes for patients failing treatment, and improved efficiencies throughout the entire clinical and treatment spectrum.

QUALITY MANAGEMENT SYSTEMS AND BIOSAFETY

External accreditation is a tool to catalyze the full implementation of laboratory quality management systems (QMS). CDC has been a College of American Pathologists-accredited laboratory since 2007 and also achieved ISO 17025 accreditation in 2017. Building upon its hands-on experience in implementing QMS to support safe and efficient laboratory services, CDC provides technical assistance to MOHs as they pursue continuous quality improvement (CQI) programs consistent with recognized quality standards. To date, CDC has assisted more than 14 laboratories globally to attain internationally-recognized laboratory accreditation to ISO standards. CDC plans to obtain ISO 17043 external accreditation as a proficiency testing (PT) provider by 2020 for four PT programs (TB rapid molecular diagnostics, HIV VL, HIV EID, and HIV serology).

Biosafety in POC and laboratory settings is essential, not only for accurate diagnosis of patients, but to safeguard laboratorians, providers, and other workers against potential infectious exposures in healthcare and laboratory facilities. It is important that the necessary safety measures are in place to ensure that hazardous material and potentially dangerous pathogens are safely handled, stored, and disposed of. CDC provides biosafety technical assistance to evaluate laboratory and healthcare facilities on safe practices, procedures, and systems, and provides biosafety training and mentoring to laboratory and healthcare professionals. CDC is enhancing critical and sustainable biosafety and biosecurity practices through key biosafety initiatives in PEPFAR-supported countries, including training for laboratory and non-laboratory personnel, VL waste management, and the establishment of a regional biosafety cabinet certification training program in Tanzania for biomedical engineers and biosafety professionals.

EXTERNAL QUALITY ASSESSMENT

CDC has adapted DTS technology, built upon HIV rapid test DTS methodology, for VL and TB testing external quality assessment (EQA) activities and rolled out this technology widely in PEPFAR-supported countries. Proficiency testing (PT) is one of the key EQA elements in ensuring the quality of laboratory testing but enrollment in such programs can be quite costly and logistically challenging, due to cold chain transportation requirements and liquid handling precautions. DTS panels, however, are stable at ambient temperature and contain dried, non-liquid samples that do not require special shipping and, thus, have lower shipping costs. DTS can be used for training, PT, quality control, and competency assessments, thus providing an avenue for laboratories and POC testing sites in PEPFAR-supported countries to monitor and evaluate their VL, HIV rapid test and TB testing service quality.

Data indicate that laboratories participating in EQA programs for longer periods of time achieve overall higher performance scores, which may translate into better and more accurate HIV diagnosis, VL monitoring, or TB detection and, as a result, improved treatment and patient outcomes. CDC is directly supporting EQA for over 3 million VL tests/year. The CDC VL DTS PT increased by nearly eight times from 2010-2017 and is currently serving 248 laboratories in 53 countries. CDC has also developed and provides DTS-based EQA material for the rapid, near-POC Xpert MTB/RIF assay to over 940 sites in 24 countries and is actively transferring the Xpert MTB/RIF PT program to partner countries in a stepwise and supported manner.

CDC is also adapting this DTS technology for POC EID quality assurance. As new POC technologies are scaled and placed in more decentralized settings, parallel quality assurance tools will be essential to ensure the accuracy of testing. With DTS used to assess the quality of conventional VL and rapid HIV diagnostic testing, DTS for POC EID aims to mimic patient specimens and the workflow closely, allowing for assessment of operator proficiency and certification of testing sites.

PUBLIC PRIVATE PARTNERSHIPS

CDC's decades-long partnerships enable us to accelerate progress toward controlling the HIV epidemic and toward finding, treating, and curing TB. Recognizing that laboratories face challenges globally to keep pace with the rapid expansion of care and treatment activities, PEPFAR and CDC have built strategic public-private partnerships for laboratory strengthening with three private companies that support global HIV goals in sub-Saharan Africa and Asia. Combining resources from the private and public sectors help promote long-lasting impact of a country's response to the HIV epidemic in the areas of quality improvement, accreditation, sample referral and training programs. These partnerships include: Labs for Life with Becton Dickinson, Stronger Together with Siemens Healthineers, and the Roche Diagnostics-PEPFAR public-private partnership.