

CONTINUOUS QUALITY IMPROVEMENT APPROACHES FOR ACCURATE, RELIABLE TEST RESULTS

OVERVIEW

Investment in laboratories is an investment in health. Strong national public health laboratories are essential for responding effectively to HIV, tuberculosis (TB), and other diseases. Quality laboratory services are crucial at every step in responding to epidemics, from accurate testing to effective treatment, care, and monitoring of disease and prevention of new infections.

Continuous quality improvement (CQI) is central to expanding diagnostics, quality assurance, and quality improvement processes for HIV and TB diagnostic tests. CQI for HIV and TB diagnostics is focused on increasing access to quality HIV testing, including early infant diagnosis (EID), increasing rapid diagnosis of HIV, detecting TB and drug resistance, and rapidly scaling up viral load (VL) testing to monitor people living with HIV on antiretroviral treatment.

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 Tuberculosis program to effectively reach UNAIDS' global targets to control the HIV epidemic, the World Health Organization's "End TB Strategy," and the Stop TB Partnership's "Global Plan to End TB" targets. A key component of CDC's strategic approach to HIV and TB epidemic control is to develop and strengthen partner countries' capacity for robust laboratory and point of care testing CQI processes.

CDC'S ROLE

Laboratories are at the core of any country's ability to prevent, identify, and respond to HIV, TB, and other diseases. CDC works side-by-side with ministries of health (MOHs) and other in-country partners to strengthen laboratory systems and networks in over 50 countries hard hit by HIV and TB epidemics. CDC supports training and mentoring, laboratory systems strengthening and capacity-building, and the development of laboratory infrastructure to help countries respond to current and emerging epidemics. This assistance helps transform the landscape of HIV and TB testing and diagnosis worldwide. CDC's response to these types of domestic and international public health threats keeps America safe and secure.

ACCOMPLISHMENTS / RESULTS

Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA)

Beginning in 2009, CDC helped develop two complementary programs that empower laboratories to pursue accreditation to international standards: Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). SLMTA is a mentoring and training program that promotes immediate and measurable quality improvement using existing resources. SLIPTA is a measuring tool that was developed together with the WHO Regional Office for Africa. It serves as a blueprint to quantify stepwise improvement through SLMTA and related programs. More than 1,100 laboratories worldwide have been supported by these complementary programs and 65 participating laboratories have been accredited to international standards.

After five years of implementation experience, CDC conducted an in-depth analysis of SLIPTA audit scores to better understand the key barriers to laboratories achieving accreditation. Based on these findings, SLMTA 2.0 was designed to address the remaining challenges. The course was piloted in September 2016 with 27 participants from 12 countries.

In 2019, SLMTA is launching a revised curriculum that will address challenges and combine elements of SLMTA 1.0 and 2.0. This curriculum is aimed at teaching a process-based approach to designing a cost-effective Quality Management System (QMS) that meets ISO 15189 requirements.

HIV Rapid Test-Continuous Quality Improvement (RT-CQI)

With increased demand and decentralization of HIV rapid testing at thousands of PEPFAR-supported testing sites, ensuring testing is conducted by trained non-laboratory personnel with demonstrated proficiency to perform testing remains a challenge. To combat this, CDC and WHO have developed and implemented a multi-pronged approach to ensure the quality of testing at HIV rapid testing sites and certification of testing staff. RT-CQI is a comprehensive package of quality assurance and improvement activities initially piloted by seven PEPFAR-supported countries and adopted as a continuum of integrated planned activities that supports and promotes accurate rapid HIV testing. Now implemented in most PEPFAR-supported countries, this unique program includes:

- Guidelines and policies on quality assurance and improvement of rapid HIV testing,
- A certification program for testers and sites using innovative tools and approaches,
- Scaling up proficiency testing programs,
- Improving uptake of the standardized HIV testing logbook, and
- Strengthening capacity to assure the quality of rapid HIV test kits.

RT-CQI increases the implementation of best practices at the site level. This program was rolled out in seven countries in sub-Saharan Africa, covering 1,400 rapid testing sites with demonstrated improvements of testing sites using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist. As a result of the RT-CQI rollout, several countries have developed an aggressive scale-up plan and resources have been allocated to local implementing partners. For example, Malawi achieved a 60 percent increase in the number of sites eligible for national certification after 15 months of RT-CQI implementation. CDC is currently evaluating the impact of this program on HIV misdiagnoses. The program has been integrated into the PEPFAR country planning guidance and PEPFAR-supported countries are now implementing this key initiative. CDC is actively engaged in the technology transfer, training and implementation of these tools in PEPFAR-supported countries in collaboration with partners, MOHs, and in-country CDC colleagues to strengthen country capacity and ownership.

Similar to laboratory processes requiring ongoing supervision and monitoring, RT-CQI is a critical component of HIV testing services due to large number of sites and testers, turnover among testers, variable training and competencies, lack of adherence to standard operating procedures, and periodic lot failures of rapid test kits. For testing sites enrolled in the proficiency testing, RT-CQI has helped increase their performance by 63 percent after four proficiency testing (PT) rounds. In Malawi, Q-Corps volunteers addressed logistical challenges in RT-CQI, which resulted in a 38 percent reduction in the turnaround time for returning proficiency testing results to the national reference laboratory. This also resulted in 90 percent of the sites receiving their proficiency testing scores and corrective actions within six weeks of testing instead of several months.

Improving the Efficiency and Quality of Tuberculosis Diagnostic Services

In 2017, there were an estimated 10 million new cases of TB, 9 percent of these cases were among people living with HIV, of whom 300,000 died from TB. Prompt TB screening and testing of HIV-positive patients is essential, as they are 20 to 30 times more likely to develop active TB than those without HIV. Knowledge of TB status is essential for initiation of TB preventive therapy or disease treatment.

To improve access to, and efficiency and quality of TB diagnostic services, CDC supports the establishment and expansion of CQI for TB diagnostic networks. CDC works with MOHs and partner organizations to develop practical guidance on TB laboratory mentorship and CQI implementation to improve quality management practices and optimize resource utilization. CDC, Foundation for Innovative New Diagnostics (FIND), and the African Society for Laboratory Medicine (ASLM) developed a practical guide to implementing a quality assurance system for Xpert MTB/RIF testing that aids countries to assess and strengthen national Xpert MTB/RIF rapid diagnostic and drug susceptibility testing networks. Currently being demonstrated in field settings, the guide is slated for release in early 2019. CDC is also implementing and evaluating a CDC/American Society for Microbiology (ASM) Mentor4TB Program in select countries that provides TB laboratories with a long-term, structured mentorship framework for human resource and quality management capacity building.

Based on the success of the two CDC-led PEPFAR CQI flagship programs for clinical and medical laboratories, SLMTA and SLIPTA, CDC has adapted this approach for TB laboratories. This program has been rolled out in China and is being expanded to additional countries.

External Quality Assessment Programs

As part of CDC's commitment to quality assurance for HIV molecular testing, such as EID and VL, CDC has developed PT programs using novel dried specimens. To ensure sustainable and accurate test results, more than 170 laboratories from over 60 countries participate in CDC's quality assurance programs. The program has expanded to include regional external quality assessment providers in South Africa and Senegal. CDC developed a web-based PT system to streamline data management to improve efficiencies and monitor laboratory testing performance. CDC is actively transferring these technologies to regional PT providers to facilitate country ownership and sustainability.

Laboratory African Regional Collaborative (LARC)

Quality laboratory systems, driven by a trained, competent workforce, are critical to HIV diagnostics by increasing access to quality HIV testing. Breakdowns in the clinical cascade pose challenges in the ordering, collection, testing and reporting of patient samples/test results and their use in patient management. To address these challenges, LARC, an innovative solution to strengthen the laboratory-clinical interface, was developed. Launched in February 2016, this learning collaborative uses a proven CQI methodology to diagnose and rectify health systems bottlenecks and improve laboratory and clinical workforce collaboration to ensure that VL tests are ordered, collected, tested, and reported, and that the results are used to inform patient management.

This novel initiative was launched in six countries to address the low rates of VL testing, reporting, and use for patient management. Within a year of training, countries made measurable improvements in their health systems projects. For example, in enrolled clinics in Kenya, before the implementation of LARC, only three percent of VL results could be found in patients' charts. After implementation, this increased to nearly 80 percent. CDC is currently finalizing a training and mentorship package to facilitate further scale up of this program and expansion into TB diagnostic and treatment services.