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SUPPORTING ACCREDITATION TO STRENGTHEN DIAGNOSTICS IN AFRICAN HEALTH SYSTEMS



USAID's Infectious Disease Detection and Surveillance (IDDS) project improves the detection of diseases of public health importance and identification of antimicrobial resistance (AMR) in priority pathogens under Global Health Security (GHS) through an accessible, accurate, adaptable, timely, and integrated diagnostic network system. IDDS also improves the quality of real-time surveillance systems for priority zoonotic diseases.

At every level of the health care system, clinical laboratories form the foundation of evidence-based patient treatment and care, and are a fundamental component of disease surveillance, diagnosis, and monitoring. Laboratory diagnostics influence over 75 percent of hospital health care decisions and represents about 5 percent of total health care costs.¹ A key priority in laboratory medicine is the improvement of quality management systems for patient safety. Laboratory efforts to improve quality aim to reduce diagnostic errors in all the three testing phases (pre analytical, analytical, and post analytical phases), to decrease turnaround time (TAT) with traceability of all laboratory procedures, and to assure the safety of patients and staff alike.

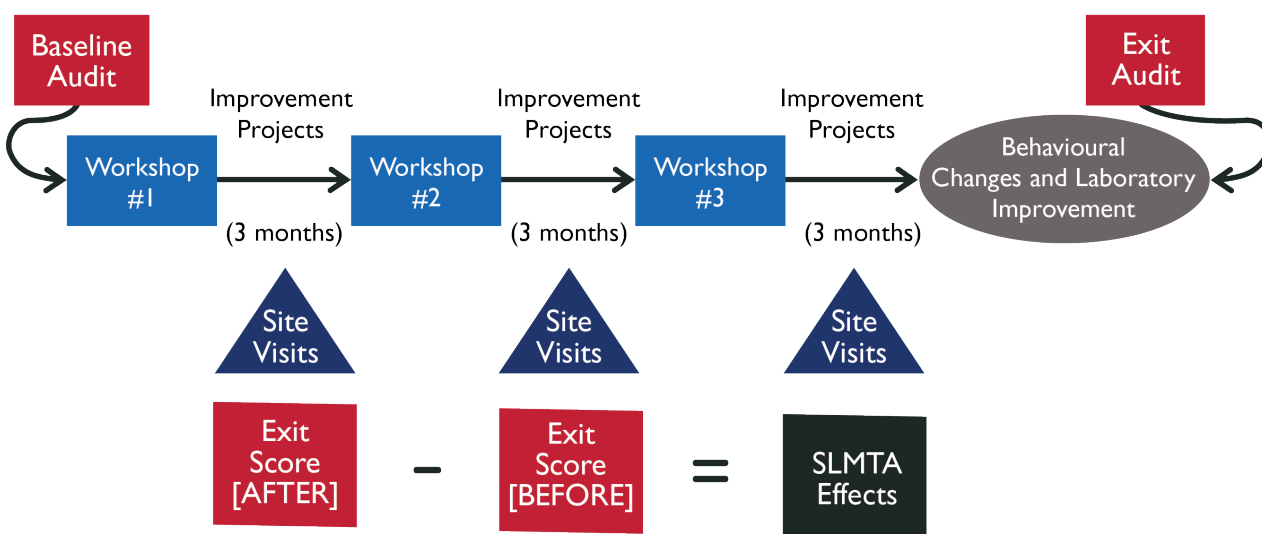
It is important to ensure laboratories' users safety through implementation of regulations based on accreditation, certification, quality monitoring, patients' rights, standard operating procedures (SOPs), and standards of health care quality. Accreditation is a procedure by which an independent and authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Conventionally, the accreditation process consists of multiple steps.

IDDS is working to support strengthening of quality laboratory services at central and sub-central levels. Beginning with the national or central level to ensure that quality diagnostics are provided and incorporating regional and district level laboratories into training and mentorship activities promotes a whole-of-system approach to quality improvement. With decentralized laboratory systems, timely and accurate diagnoses are provided to physicians and patients, services are more widely accessible, and patient outcomes are improved.

IDDS supports quality management systems (QMS) at both national and sub-national levels in Liberia, Kenya, Mali, Senegal, and Uganda. Liberia, Mali, and Senegal have chosen to concentrate on higher-level laboratories and then expand to lower-level facilities, cascading through the laboratory hierarchy one level at a time.

¹ The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care, 2005 AdvaMed, The Levine Group

The establishment of a formalized system to improve public clinical laboratories across Africa evolved to recognize the vital importance of laboratories in public health surveillance as part of the framework for the World Health Organization Regional Headquarters for Africa's (WHO-AFRO) Integrated Disease Surveillance and Response (IDSR) strategies. To promote this goal, the WHO-AFRO Strengthening Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) was established in 2011.²³⁴ SLIPTA is a framework designed to guide public health laboratories towards achieving baseline standards outlined in the ISO 15189 standard. Additionally, Strengthening Laboratory Management Toward Accreditation (SLMTA) is a training and mentoring program that has been developed to effect immediate reasonable improvement in laboratories in resource-limited settings using their existing resources. The program uses a stepwise process and clearly defined goals to evaluate the quality of service and competence of laboratories. Together, the SLIPTA framework and the SLMTA tool are comprehensive resources that prepare laboratories for international accreditation. The figure below illustrates a typical SLMTA process map.



SLMTA, Strengthening Laboratory Management Toward Accreditation.

Source: Katy Yao and al, Afr J Lab Med. 2014; 3(2): 194. Published online 2014 Sep 16. doi: 10.4102/ajlm. v3i2.194

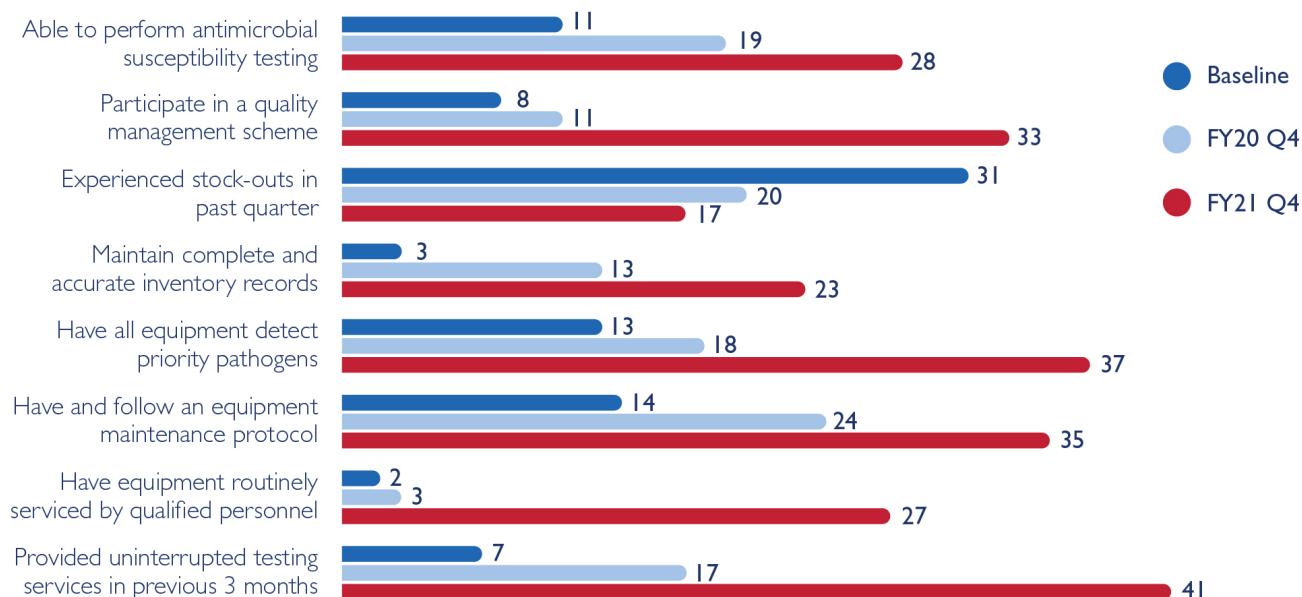
The inspiration for national standards in laboratory management are International Organization for Standardization (ISO) documents (ISO 9001, ISO 17025, ISO 15189, and Good Clinical Laboratory Practice [GCLP]). ISO 15189 and GCLP strive for the highest possible quality service: a rapid, reliable and reproducible test report. The first step of QMS in laboratories is establishment of internal quality control (IQC) and external quality assurance (EQA) educational activities, which are the core points in all accreditations systems. IDDS tracks the critical elements of laboratory performance and functionality in alignment with the ISO 15189: 2012 standard. Implementation of a quality management system, routine equipment maintenance, and ongoing inventory management are essential for laboratories to provide high-quality testing services at all levels of the laboratory network. The figure below shows IDDS's positive impact over the course of one year in many areas that contribute to ISO 15189:2012 accreditation:

² World Health Organization Regional Office for Africa. Laboratory accreditation checklist. Brazzaville: WHO-AFRO; 2009.

³ World Health Organization Regional Office for Africa. WHO guide for the stepwise laboratory improvement process towards accreditation in the African Region (SLIPTA). Brazzaville: WHO-AFRO; 2015 [cited 2019 March 06]. Available from: <http://www.afro.who.int/en/who-guide-for-the-stepwise-laboratoryimprovement-process-towards-accreditation-in-the-african-region-withchecklist.html>.

⁴ Gershy-Damet G-M, Rotz P, Cross D, et al. The World Health Organization African Region laboratory accreditation process. Am J Clin Pathol. 2010;134(3):393-400. <https://doi.org/10.1309/AJCPTUUC2V1WJQBM>.

Improved GHS laboratory capacity: Number of IDDS-supported laboratories meeting specific performance criteria



Liberia Experience

The National Diagnostic Division of the Ministry of Health of Liberia, in collaboration with laboratory system strengthening partners, led efforts to implement laboratory QMS taking into consideration the challenge of delivering reliable laboratory results in both clinical and public health laboratories across the country. To prepare laboratories for ISO 15189 accreditation, Liberia adopted SLIPTA in February 2017. Laboratory supervisors of hospital facilities from 15 counties were enrolled in the cohort of trainees. Six internal auditors were identified from a total of 30 participants and trained by the African Society for Laboratory Medicine (ASLM). Eight county hospital laboratories and two regional hospital laboratories were enrolled in the initial audit process. Implementation started in June 2019 and follows the SLMTA training program as outlined in the SLMTA figure above.

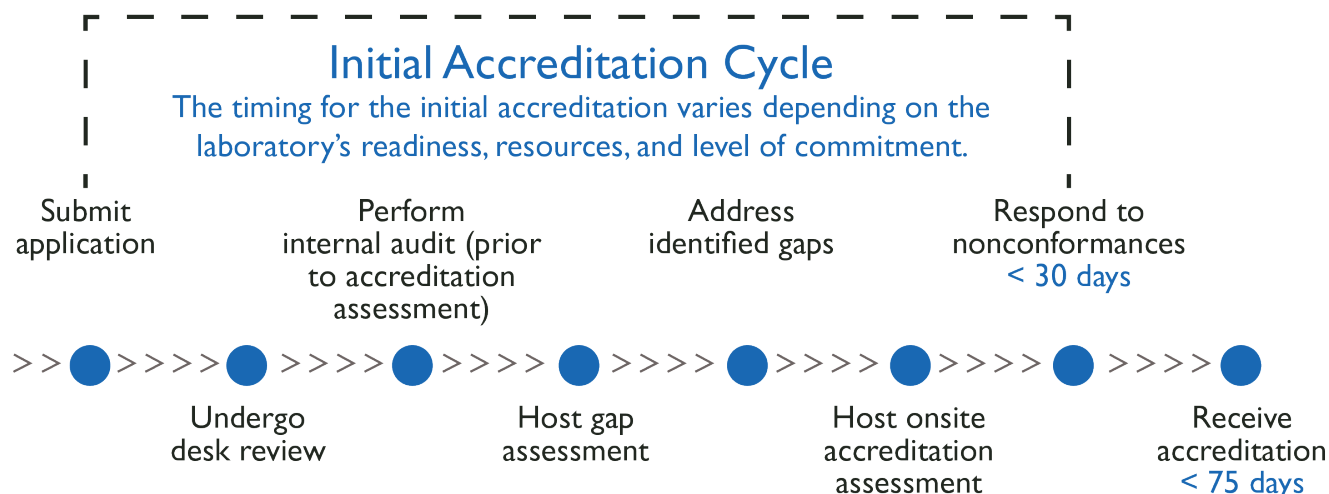
With IDDS support, 21 laboratory professionals were trained as SLMTA mentors from the district and county hospital laboratories in the three counties. After the training, the three county hospitals and six district hospitals in the project-supported counties were enrolled in the SLMTA-based QMS. The engaged hospitals selected various improvement projects that addressed stockouts, test statistics, TAT, EQA results, specimens rejected, customer satisfaction, and service interruptions due to staffing issues. IDDS Liberia developed QMS SOPs, a laboratory quality management plan and an integrated EQA plan to ensure sustainable QMS implementation. This initiative will prepare laboratories for ISO 15189 accreditation using a stepwise approach.

The accreditation process has benefits for laboratories such as:

- standardization of all processes,
- responsibility of each member of team,
- personal policy,
- demonstrability of results,
- systematic evaluation of suppliers,
- prestigious,
- and better communication with partners.

Accreditation improves the processes in laboratories, increasing the quality in all areas.

Accreditation Process



The laboratory accreditation process⁵. Mali is at stage three “perform internal audit” (March 2022)

Senegal Experience

Senegal's government adopted the ISO 15189 standard to manage the quality of medical biology laboratories. The Ministry of Health, through the Directorate of Laboratories, requested that IDDS support activities to improve the quality of service at seven clinical laboratories, five university hospital laboratories (4 of these in Fann Hospital, and 1 in Albert Royer National Children's Hospital) and two level I public hospitals (Guediawaye and Tivaoune). IDDS support included an audit, training and mentorship based on the WHO-AFRO SLIPTA tool. The seven medical biology laboratories were audited between November 2019 and February 2020 and provided ISO 15189 training. IDDS then provided technical assistance to the Directorate of Laboratories to develop laboratory-specific quality improvement plans (IPs). To implement the IPs, IDDS also provided onsite coaching and remote mentorship to strengthen towards ISO 15189 accreditation for quality testing services. For instance, a highlight of key achievements of this activity at the seven laboratories were: a) availability and utilization of equipment maintenance policies; b) provision of uninterrupted testing services; c) availability of adequate commodity management system (thus no stock outs); and d) 100 percent of specimens received being tested within specified timeframes.

Mali Experience

Per the Government of Mali's request, IDDS supported the accreditation process at the INSP (National Institute of Public Health) and Ségou regional hospital laboratory. The international laboratory accreditation process is a long journey, and the laboratory sector of Mali has taken the critical steps to initiate the process. IDDS has supported the two laboratory sites through a preliminary audit, led the development of an improvement plan based on the gaps, provided training on the ISO 15189, developed reference documents including a quality manual and SOPs, and provided post-training supportive follow-up visits.

⁵ College of American Pathologists: <https://www.cap.org/laboratory-improvement/accreditation/cap-15189-accreditation-program/cap-15189-accreditation-process>

Uganda Experience

In Uganda, IDDS has supported eight regional animal disease diagnostic and epidemiology centers (RADDECs) to strengthen towards ISO 17025 accreditation. To achieve this, IDDS supported development of a standardized QMS mentorship kit based on ISO 17025 and collaborated with key stakeholders to identify 12 suitable candidates that were trained as QMS trainer of trainers (TOTs) in March 2021. IDDS has been assisting these TOTs to conduct structured onsite and remote training, mentorship, audits, and improvement projects to four government prioritized RADDECs (Guru, Mbalala, Mbale, and Moroto) towards ISO 17025 accreditation.

Kenya Experience

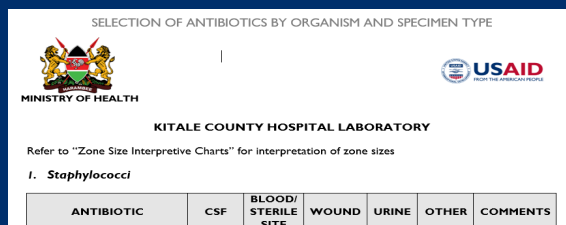
In Kenya, IDDS has supported three human health facilities (Bungoma, Malindi, and Murang'a) to include their bacteriology tests as part of their ISO 15189 accreditation scope. Specifically, IDDS has supported the three facilities to:

a) develop required SOPs,



MINISTRY OF HEALTH
NATIONAL PUBLIC HEALTH LABORATORY SERVICES
NATIONAL MICROBIOLOGY REFERENCE LABORATORY - NAIROBI, KENYA
STANDARD OPERATING PROCEDURE

TITLE / DESCRIPTION: ISOLATION AND IDENTIFICATION OF SALMONELLA SPP		SOP NUMBER: MIC-ED-08	
SPP		VERSION NUMBER: 0.0	
APPLIES TO:	HEADRESPONSIBLE PERSON:	EFFECTIVE DATE:	PAGE 1 OF 9



SELECTION OF ANTIBIOTICS BY ORGANISM AND SPECIMEN TYPE

MINISTRY OF HEALTH

KITALE COUNTY HOSPITAL LABORATORY

Refer to "Zone Size Interpretive Charts" for interpretation of zone sizes

1. *Staphylococci*

ANTIBIOTIC	CSF	BLOOD/ STERILE SITE	WOUND	URINE	OTHER	COMMENTS
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b) develop required forms to operationalize the SOPs,

c) provide essential supplies and equipment needed for bacteriology testing, including standard organisms, such as the American Type Collection Cultures (ATCC) necessary for internal quality control of antibiotics discs and reagents,

d) track the implementation of the quality improvement action plans,

e) provide on-bench mentorship to improve the personnel technical skills and strengthening of quality assurance practices.

As a result of this, Bungoma, Malindi, and Murang'a were assessed by Kenya Accreditation Service (KENAS) in 2020 (Bungoma) and 2021 respectively and their bacteriology tests are now accredited. Additionally, strengthening of quality laboratory services in all the five IDDS-supported facilities has resulted with cumulative workload increment from 50% (2019) to 79% (2021), which can be attributed to improved clinical trust leading to demand creation.

Do the right things right, describe how you do it, do the things as you describe and evaluate everything.