Strengthening HIV/TB Laboratory Quality Management Systems and Services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief

(CoAg #: 1U2GGH001307)

Evaluation Report

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

List of Acronyms

ACILT	African center for integrated Laboratory Training
APR	Annual Performance Report
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CLE	Continuous Laboratory Education
CoAg	Cooperative Agreement
CPUT	Cape Peninsula University of Technology
DSD	Direct Service Delivery
EHLS	Eswatini Health Laboratory Services
EQA	External Quality Assurance
GKOE	Government of the Kingdom of Eswatini
HSS	Health Systems Strengthening
ICAP	ICAP at Columbia University
IP	Implementing Partner
IQC	Internal Quality Control
KII	Key informant interviews
LIS	Laboratory Information System
LQMS	Laboratory Quality Management System
LST	Laboratory Systems Technologies
MDC	Medical and Dental Council
MER	Monitoring, Evaluation and Reporting Indicator Reference
MLS	Medical Laboratory Sciences
MOEPD	Ministry of Economic Planning and Development
MOH	Ministry of Health
MOHA	Ministry of Home Affairs
MSF	Médecins Sans Frontières
NERCHA	National Emergency Council on HIV/AIDS
NTRL	National TB Referral Laboratory
NRL	National Reference Laboratory
PEPFAR	President's Emergency Plan for AIDS Relief
PHP	Public Health Practice
POC	Point of Care
QMS	Quality Management System
SANU	Southern-African Nazarene University
SADCAS	Southern African Development Community Accreditation Service
SID	Strategic Information Department
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SNAP	Eswatini National HIV/AIDS Program
SOP	Standard Operation Procedures
SCU	Swaziland Christian University
TA	Technical Assistance
TOR	Terms of Reference
TWG	Technical Working Group
URC	University Research Center
USG	United States Government

Executive Summary

Background: The goal of this evaluation was to assess the implementation processes and achievements of the "*Strengthening HIV/TB Laboratory Quality Management Systems and Services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief*" project. The award focused on strengthening laboratory capacity within Eswatini through enhancing lab human resources, strengthening quality management systems, improving access to testing, strengthening equipment and supplies management, improving laboratory information systems and improvement and expansion of viral load testing networks. The assessment looked at the extent to which objectives and activities have been completed and whether implementation resulted in the intended outcomes. The evaluation assessed the sustainability of capacities built during the award period and identify areas where additional work may be needed to help inform future implementation strategies.

Methodology: A mixed-methods approach was used that included both qualitative and quantitative methodologies. Data was collected from key informant interviews and laboratory walk-throughs in addition to the following data sources; 1) performance indicators and program data collected and routinely reported to CDC, 2) results from monthly laboratory reports, and 3) routinely collected data available to beneficiary units. Primary data collection for this mixed-methods evaluation was completed in January 2020. Key Informant Interviews KII were transcribed, reviewed, and cross-checked against findings from desk review and review of program/indicator data. Results from KIIs were triangulated with other data sources and performance indicator data from program administrative records to evaluate the level of success in implementing planned program elements and to assess outcomes associated with the program. Evaluation findings were used to assess stakeholder engagement during the implementation of the program, the extent to which planned activities were implemented, as well as effectiveness and sustainability of the program in building laboratory capacity.

Findings: Support for the development of accreditation licensing guidelines, laboratory trainings, and Medical Laboratory Sciences (MLS) curriculum development helped enhance laboratory human resource capacity, however efforts to support recruitment of program graduates into the workplace during later years may have been hampered at least in part due to a government hiring freeze. Quality management systems in general were also improved through expanded implementation of the Strengthening Laboratory Management Towards Accreditation/Stepwise Laboratory Improvement Process Towards Accreditation (SLMTA/SLIPTA) program, SLMTA trainings, and embedded mentorship. While these activities contributed to the accreditation of two main labs in 2019, a number of laboratories enrolled in the program displayed limited improvement in SLIPTA ratings over the course of the award. Access to testing, particularly viral load (VL) testing, was improved and expanded through support activities conducted under the award. Enhancements to the sample transport system, decentralization of lab services, expanded Laboratory Information System (LIS) capacity, and strengthening of the equipment and supplies management system has helped build core capacity and strengthen the lab: clinic interface.

Conclusions and Actionable Items: In coordination with the Eswatini government and the CDC Eswatini office, ICAP provided technical support leading to initial enhancements in laboratory capacity, quality, and system strengthening in Eswatini. At the time of the evaluation, the majority of workplan activities were completed or scheduled for completion by the end of the award period, activity completion rates were as follows; 78% [Objective 1], 89% [Objective 2], 100% [Objective 3], 83% [Objective 4], 79% [Objective 5], and 93% [Objective 6]. While the work completed over the course of the award helped provide a solid foundation, sustainability of capacity building efforts remains a challenge in the absence of external funding. Actionable items include finalization of the National Laboratory Strategic Plan, strategic planning to address budget/funding gaps and prioritize quality improvement activities, and additional review of disaggregated output variables such as

equipment downtime, specimen rejection rates, reagent stockouts and their relationship with testing performance to further identify specific areas and labs to focus and target improvement efforts.

1.0 Program Background

The Kingdom of Eswatini with the support of the President's Emergency Fund for AIDS Relief (PEPFAR), the Centers for Disease Control and Prevention (CDC), and other implementing partners (IPs), has made great progress towards achieving HIV epidemic control and meeting the UNAIDS 95-95-95 goals. As laboratories play a key role achieving these goals, the Government of the Kingdom of Eswatini (GKOE) and PEPFAR/CDC identified the importance of strengthening laboratory quality management systems (QMS) and services across the tiered network as a key priority. Enhanced lab capacity is also needed to support evidence-based decision-making by governmental and nongovernmental stakeholders addressing the control of HIV, TB, and associated conditions.

To address these needs and to help build sustainable laboratory capacity within Eswatini, ICAP at Columbia University, entered into a 5 year agreement entitled 'GH15-1581-*Strengthening HIV/TB Laboratory Quality Management Systems and Services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief*', herein referred to as 'Lab Co-Ag'. During the project period, ICAP worked in coordination with the GKOE and CDC to strengthen laboratory capacity within Eswatini through support for the following 6 strategic objectives:

1) **Enhance lab human resources** through strengthening pre-service education, in-service training, and professional licensing and accreditation to increase lab human resource capacity and competency
2) **Strengthen quality management systems (QMS)** by increasing lab accreditation through implementation of national lab strategic plan, QMS, and accreditation processes across the tiered lab network
3) **Improve access to testing** by strengthening lab networks through standardization and decentralization of lab services and improvement of sample transport system
4) **Strengthen equipment and supplies management** to ensure uninterrupted quality lab testing services through the development and implementation of robust systems for equipment and supply chain management
5) **Improve laboratory information systems (LIS)** through strengthening of data management capacity and increased connectivity across the tiered network by developing and implementing a sustainable LIS that interfaces with existing Health Management Information System (HMIS)
6) **Expand viral load testing networks** *(updated from original objective which was to Expand Lab Research Capacity)*

2.0 Evaluation Purpose and Objectives

2.1 Evaluation Objectives: The purpose of this evaluation was to assess the implementation processes and achievements of the "*Strengthening HIV/TB Laboratory Quality Management Systems and Services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief*" project, including the extent to which interventions were delivered and received (dose), implemented as designed (fidelity), and available and accessed by the intended beneficiaries (reach). As described in the evaluation protocol, the evaluation was also intended to highlight successful strategies and areas where additional work is needed to guide future implementation strategies. The primary objectives of the evaluation include the following:

1) To assess the extent to which laboratory human resource capacity has improved through training, mentorship and certification.

2) To assess the extent to which laboratories improved implementation of quality management system towards accreditation.
3) To measure the extent of decentralization of laboratory services and improvement of sample referral on the tiered laboratory network.
4) To assess the extent to which facilities have systems for laboratory equipment preventive maintenance and updated maintenance records.
5) To assess the extent to which the number of laboratories and mini-labs that have LIS connection has been increased.
6) To determine the extent of increase of access to viral load testing services to the health facilities in the network.

2.2 Evaluation Questions: To evaluate the program, the evaluation team conducted both a process and outcome evaluation. The *process* evaluation aimed to assess the relative successes and challenges in the *implementation* of program and included the questions below:

1) To what extent have the planned program activities been implemented?
2) To what extent did decentralization (of VL Labs, HIV, CD4 and TB POC) improve access to quality laboratory services?
3) To what extent has ICAP supported laboratories and mini-labs with LIS connection to improve workflow optimization and result turnaround times?

The *outcome* evaluation aimed to assess the *effectiveness* of the program in improving laboratory capacity in Eswatini and included the following questions:

1) How well have laboratories in Eswatini achieved national accreditation and licensing standards?
2) To what extent has access to viral load testing to all patients including pediatric and breastfeeding women viral load testing been improved in the country and how often is viral testing data being used for program monitoring by MOH?

This report describes the extent to which program activities were implemented and the effect of implementation on the overall accessibility and quality of laboratory services supported under the Lab Co-Ag. The report presents key findings and conclusions in addition to identifying key challenges and successes of the program that may help inform future implementation objectives to further strengthen laboratory quality management systems in Eswatini.

3.0 Evaluation Design

This evaluation was designed and conducted in line with the CDC's framework for program evaluation in public health. A mixed-methods approach was used that included both qualitative and quantitative methodologies. Data from key informant interviews and laboratory walk-throughs were triangulated with other data sources including 1) performance indicators and program data collected and routinely reported to CDC, 2) results from monthly laboratory reports, and 3) routinely collected data available to beneficiary units.

3.1 Stakeholder Engagement

Governmental and non-government stakeholders (people who had directly been involved with the planning and implementing of program) included GKOE officials, ICAP project officers, and CDC staff. Stakeholders were engaged in the different planning stages of the program, including prioritizing what to evaluate, budgeting and funding decisions, identification of the evaluation questions, and dissemination and use of findings and recommendations. Stakeholders were engaged multiple times throughout the evaluation design, implementation, and data collection. Key stakeholders from MOH were sensitized on the need to conduct a program evaluation and were listed on the evaluation protocol to highlight their institutional affiliations, roles, and responsibilities.

Conference calls between the ICAP Evaluation Team, the CDC Atlanta Evaluation Team and the sponsor (CDC Eswatini) provided an opportunity to discuss and refine the design of the evaluation and outline the scope of work for the Evaluation Team. Information from these discussions was used to develop an implementation manual and supporting materials.

3.2 Ethical Considerations and Assurances

Evaluations should be conducted in a manner that is respectful to and protects human rights, privacy, and confidentiality and maintains the dignity of participants and other stakeholders. The Columbia University Institutional Review Board (CUIRB) and the Eswatini National Health Research Review Board (NHRRB) reviewed and approved the evaluation protocol entitled '*Evaluation of the Program to Strengthen HIV/TB Laboratory Quality Management Systems and Services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief (PEPFAR).'* The protocol was also reviewed in accordance with CDC human research protection procedures and was determined to be nonresearch, program evaluation. Protocol submission and approval dates are shown in Table 1:

Table 1: IRB Submission and Approval Dates

IRB/Ethic Review	Protocol Submission Date	Protocol Approval Date
CUIRB	June 13, 2019	August 2, 2019
NHRRB	June 3, 2019	September 3, 2019
CDC	May 8, 2018	August 28, 2019

All Evaluation Team members completed the Collaborative Institutional Training Initiative Social and Behavioral Research training before starting the evaluation. This training covers Good Clinical Practices in reference to research protocol, recruitment and retention, informed consent communication, confidentiality and privacy, participant safety and adverse event reporting, quality control and assurance, and research misconduct. Evaluation team members from CDC are staff members from the Monitoring Evaluation and Data Analysis Branch and have experience conducting quantitative and qualitative assessments under protocol in alignment with the PEPFAR Evaluation Standards of Practice. Evaluation team members have been trained on patient data confidentiality and security guidelines and have signed a conflict of interest statement per protocol requirements [*Protocol Appx 3*].

Informed consent was obtained from all KII participants using the approved consent form [*Protocol Appx 1*]). As part of the consent process, participants were informed that their participation in the interview was voluntary, and they were free to stop participation at any time without penalty or loss of benefits. All individual-level information reported has been de-identified to protect participant confidentiality.

4.0 Methodology

The evaluation consisted of the following components: 1) key informant interviews, 2) laboratory walkthroughs and assessments, 3) desk review of key project documents, and 4) analysis of relevant program data.

4.1 Key Informant Interviews (KIIs)

KII participants were selected by purposive sampling to represent stakeholders with a high-level understanding of laboratory quality management systems (LQMS) issues across the key areas intended to benefit from ICAP support. Specific KII participants were selected by members of the protocol team based on their expert knowledge of the program activities and expected outcomes and scheduled for interviews by the ICAP evaluation coordinator. Permission from the supervisors was obtained prior to scheduling appointments to conduct private

interviews with relevant staff. The selected participants included relevant staff from the organizations listed in Table 2 that aligns the KII participants with protocol objectives below:

1) To assess the extent to which laboratory human resource capacity has improved through training, mentorship, and certification.
2) To assess the extent to which laboratories improved implementation of quality management system towards accreditation.
3) To measure the extent of decentralization of laboratory services and improvement of sample referral on the tiered laboratory network.
4) To assess the extent to which facilities have systems for laboratory equipment preventive maintenance and updated maintenance records.
5) To assess the extent to which the number of laboratories and mini-labs that have LIS connection has been increased
6) To determine the extent of increase of access to viral load testing services to the health facilities in the network.

Table 2: Alignment of Key Informant Interviews and Evaluation Objectives

		Objectives					
#	**Organization**	1	2	3	4	5	**6**
1	ICAP Eswatini	x	x	x	x	x	x
2	ICAP Eswatini				x	x	x
3	ICAP Eswatini	x	x	x	x	x	x
4	CDC Eswatini	x	x	x	x	x	x
5	Eswatini Health Laboratory Services (EHLS)	x	x	x	x	x	x
6	Eswatini Health Laboratory Services (EHLS)		x	x	x		
7	Eswatini National AIDS Program (SNAP)		x	x			
8	University Research Centre (URC)		x	x			x
9	National Emergency Response Council on HIV and AIDS (NERCHA)	x		x	x		x
10	AIDS Free		x	x	x		x
11	Medical and Dental Council (MDC)	x					
12	Southern-African Nazarene University (SANU)	x					
13	Clinton Health Access Initiative (CHAI)		x	x	x		x
14	National TB Reference Lab (NTRL)		x	x	x	x	
15	National Molecular Reference Lab (NMRL)		x	x	x	x	x
16	National TB Hospital		x	x	x	x	x
17	Lubombo Referral Hospital		x	x	x	x	x
18	Nhlangano Health Centre		x	x	x	x	x
19	RFM Raleigh Fitkin Memorial Hospital		x	x	x		
20	Ministry of Health (MOH)		x	x			x

Twenty KIIs were completed over a four-week period in 2019. CDC Atlanta Evaluation Team members served as primary interviewers and ICAP Evaluation Team members served as secondary interviewers, note-takers, and provided additional probing questions when necessary. Individual interviews were conducted in a private room, and a unique identifier was assigned to each participant that was used to code all information collected during the interview to ensure confidentiality. Prior to conducting the interview, informed consent was obtained from the participant using the approved consent form *[Protocol Appendix 1].* To facilitate data collection and reduce inter-interviewer variability, a tailored job aid *w*as developed based on the protocol and aligned with the KII guide

[Protocol Appx F]. Interviewers used the job aid in conjunction with the KII guide to conduct the interview, collect notes, and capture information on the completeness of specific activities. A summary table was used to consolidate observations from the Evaluation Team members who participated in the interviews and aligned the observations with relevant sections from the KII guide. All interviews were audio-recorded, transcribed by an ICAP staff member, and underwent a quality assurance process initiated by the ICAP Evaluation Lead.

4.2 Observation of Laboratory Workflow Process [Laboratory Walk-throughs]

To gain a better understanding of laboratory workflow, six ICAP supported laboratories representing all 4 regions within Eswatini were purposively selected for observation of workflow processes and included the following:

1. Lubombo Referral Hospital [Lubombo]
2. Nhlangano Health Centre [Shiselweni]
3. National TB Reference Laboratory [Hhohho]
4. Raleigh Fitkin Memorial Hospital [Manzini]
5. National TB Hospital (Manzini)
6. National Reference Molecular Laboratory [Hhohbo]

Evaluators visited the laboratories (including mini-labs) and observed workflow processes to assess the laboratory's conformity to regulated standards of practice. Pre-analytical, analytical, and post analytical stages of the workflow processes were assessed and findings documented using a data collection tool *[Protocol Appx G].*

4.3 Desk Review

To provide an orientation to the program, the evaluators reviewed background documentation about the program and ICAP Project Officers were also asked to provide a brief overview presentation of the program. Available documentation for each program area supported by the CoAg was reviewed by the evaluation team. A list of reviewed materials and data sources is included in *Appendix 1*. Findings from the desk review were triangulated with key informant responses and review of performance indicators to assess completeness of activities and whether key program objectives and outcomes were met over the award period.

4.4 Review of Program Data

Secondary data review was conducted on project records and data derived from 74 laboratories (22 major laboratories, 52 mini-labs) and 288 clinics. Data from both Monitoring and Evaluation Reports (MER) and non-MER performance indicators were collected [*Protocol Appx C and D*] and reviewed. Laboratory data statistics were aggregated across all laboratories from routine data collected between October 2016 (month 1) to September 2019 (month 48); therefore, each datapoint represents multiple labs. The data was collected using excel-based templates and the following variables were assessed:

1) *Testing Cascade Performance:* Analysis was performed to determine if 95% of samples were processed from cascade Step 1 through Step 4 where Step 1= Number of tests requested, Step 2 =Number of samples received, Step 3=Number of processed samples, and Step 4= Number of results returned.

2) *Turn-around time (TAT):* Median and expected TAT (time from sample collection to results returned) were compared to the laboratory data. Expected TAT was based on laboratory outputs in Eswatini.
    - VL: optimal TAT <= 2 weeks.
    - GeneXpert TAT = 2 days
    - TB Culture Positive TAT= 21 days
    - TB Culture Negative TAT= 42 days
    - CD4 test TAT= 3 days

3) Trends in Testing Volume

5.0 Data Collection, Management, and Analysis

5.1 Data Collection Tools

Data collection tools [*Protocol Appx C, D, G*] were adapted to aid in capturing data to verify results against proposed indicators and targets. Data collection included the following categories:

- Performance indicators, targets and results routinely reported to CDC
- Data from baseline assessments and follow-up assessments conducted under SLIPTA
- Routinely collected data available to beneficiary units
- Training reports and relevant HR records

5.2 Data Management

Data and documents for the desk review were stored in encrypted files on a desktop computer in a locked room, with access given to relevant evaluation team members. Electronic data and desk review documents that did not contain personal identifiable information (PII) were shared between ICAP and CDC Atlanta team members through a secure email provider. Data from KIIs was collated from interview summary sheets and transcripts. The audio files for transcription were housed on encrypted password protected computers. Once the interviews were transcribed and the transcriptions have undergone a quality assurance process, audio recordings were destroyed. The finalized transcriptions will be kept in a secure location at ICAP. Paper-based records will be maintained for not more than 5 years to permit evaluators to review and audit the data. ICAP in Eswatini is the custodian of the qualitative data that will be collected in KII. These data will be kept as per ICAP's disposition plan at the end of the donor-funded program. The MOH is the custodian of routine program data. Data collected through MOH and other beneficiary units remain the property of the GKOE departments.

5.3 Data Analysis

Data analysis was conducted in alignment with data analysis plan outlined in the protocol. Information from secondary data review, key informant interviews and observation of workflow processes was triangulated to assess the extent to which planned project activities have been implemented and whether key program objectives and outcomes were achieved. For quantitative program data, regression analyses were used to assess trends in the laboratory statistics data. We used linear regression analysis to examine changes over time in the number of samples processed, examining the residuals of the models to ensure that the normality assumption was not violated. Linear regression coefficients represented the average increase in the number of samples processed per month. F-tests were used to test for significance of the linear trend, with $p<.05$ as the cutoff for statistical significance.

6.0 Key Evaluation Observations and Findings

6.1 Observations and Outputs from Co-Ag Evaluation Objectives

This section of the report provides an overview of the key observations and program outputs for the six Co-Ag objectives reviewed in the evaluation. Data sources used in this analysis included review of routine program data, desk review materials (*Appendix 1*), key information interview findings and transcripts, and results for the laboratory workflow walk through exercise. Findings from KII and review of desk review materials related to completeness of activities are provided in table form *Appendix 2* and summarized in Section 6.2.

Objective 1: Enhance Lab Human Resources

The program narrative outlined four main areas of concern in this area; 1) lab human resources were not sufficient to meet demands, 2) academic opportunities for students was limited, 3) licensure standards for professionals were needed, and 4) continuing professional development (CPD) and additional in-service training was needed. In Dec 2015, a summary report that assessed the status of registration and license renewal of laboratory professional in Eswatini was drafted that provides a good baseline measurement for comparison purposes. The baseline report indicates that there were a total of 2441 health care workers registered in Eswatini including the following registered laboratory professionals: 69 Medical laboratory technologists, 19 medical laboratory scientist, 33 Medical laboratory technicians, and 3 medical assistants. The report indicated that phlebotomists were not registered, and no clear guidance existed for how laboratory professionals are registered. To bolster the number of laboratory professionals, two universities (Southern African Nazarene University and Swaziland Christian University) had just started offering programs in the field of Medical Laboratory Science, however there was no continuous professional development or system in place and an HR database was only partially completed and had no IT support.

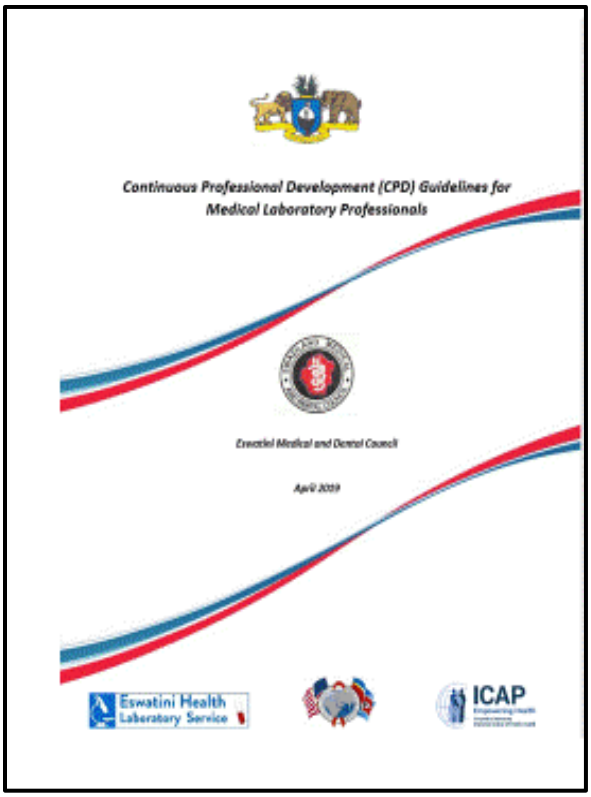
Objective 1 of the Co-Ag was therefore aimed at providing support for strengthening pre-service education, in-service training, and professional licensing and accreditation to increase lab human resource capacity and competency. The main subobjectives supported by ICAP under the award included:

1) Providing TA to the Medical and Dental council to develop a strategy for accrediting and licensing lab professional, including continuing professional development requirements
2) Providing TA to Southern African Nazarene University (SANU) to support lab pre-service training program
3) Providing TA on curriculum development to all tertiary education institutions providing laboratory pre-service training (SANU)
4) Providing TA to Eswatini Health Laboratory Services (EHLS) to implement laboratory pre-service practical training (e.g., internship),
5) Providing scholarships to support four MOH employees who are in the middle of the 4-year laboratory technology course at SANU
6) Working with all appropriate government bodies (e.g. MOH, Ministry of Public Service (MOPS), and Ministry of Finance (MOF)) to support recruitment of MLS graduates.

In addition to document review, seven key informants provided feedback on this objective.

Subobjective 1.1

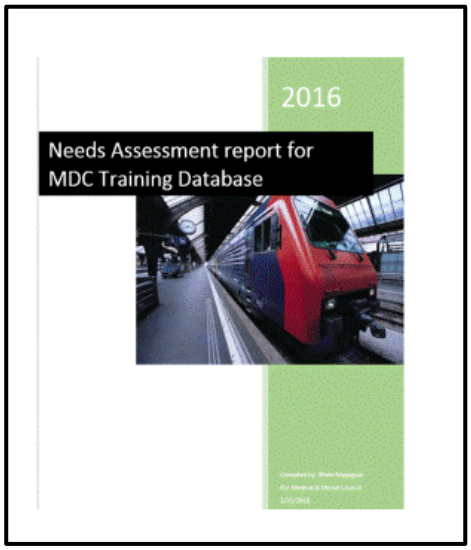
Medical and Dental Council (MDC) Accreditation and Licensing Guidelines and SOPS: The Lab Co-Ag supported the development of accreditation and licensing guidelines and SOPs. The finalized continuing professional development (CPD) guidelines (April 2019) were submitted to the MDC registrar for commissioning and approval was secured (*see figure*). The thirty-six page guidelines define CPD as 'the continuous updating of professional knowledge and the improvement of professional competence throughout a person's working life; a commitment to be a professional; keeping up to date and continuously seeking to improve' and covers the roles responsibilities of different stakeholder, CPD standards for laboratory professions, scope and types of CPD programs, CPD course accreditation information, requirement for lab professionals, application procedures for licensure renewal, audit appeals procedures and monitoring and evaluation framework.

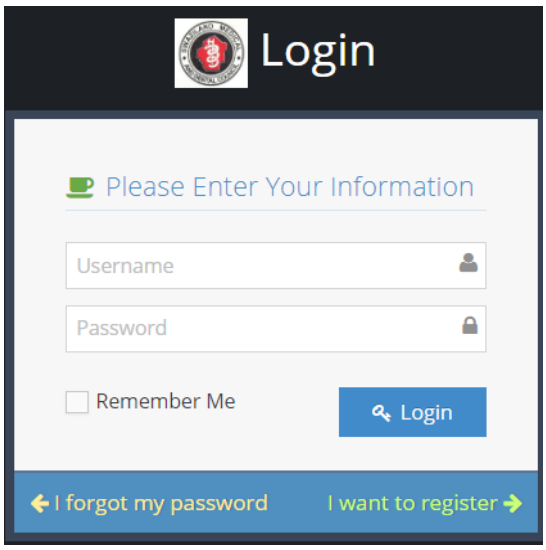


EHLS staff attending continuous education: A review of training records over the award period included 149 trainings or seminars held on laboratory processes, laboratory quality management systems, health systems strengthening, and HIV Care & Treatment (3845 participants attended these trainings, note that this may reflect the same individual attending multiple trainings). Funding was also provided for continuous laboratory education for EHLS participants (13 staff members) to attend the following African center for integrated Laboratory Training (ACILT) courses conducted in Johannesburg, Republic of South Africa:

- Strengthening Laboratory Biosafety and Biosecurity training (3 staff, July 20-25,2015)
- TB Culture and Identification Training (2 staff, Aug 30 to Sept 11, 2015)
- Drug Susceptibility Testing course (1 staff, Nov 2-13, 2015)
- Practical Course for Mycobacterium TB Susceptibility Testing (1 staff, Feb 5-26, 2016)
- Strengthening Laboratory Management Towards Accreditation (SLMTA) training of trainer (TOT) workshop (3 staff, Feb 28-Mar 12, 2016)
- Roche CAP/CTM96 operation training (4 staff, May 30-June 30, 2016)
- SLMTA 2 workshop (2 staff, Feb 5-11, 2017)

MDC Human Resource (HR) Database: Documenting and tracking of laboratory staffing and certification is a natural follow-on to building and enhancing human resource (HR) capacity to support laboratory testing and requires easy access to staffing and certification information. Tracking capacity to document trainings and licensing was provided through support for the development and installation of an HR MDC Training database. Prior to development of the database a Needs Assessment report (see desk review materials) for the MDC Training Database was conducted in 2016 to inform development of the HR training database, and in FY2018, the database was installed, and old data migrated. All registered medical staff can be listed and viewed in the database and includes demographic, educational, professional (employment), CPD acquisition and Licensure. The system also captures CPD activities and events. As of May 2020, there were 3544 health care workers registered in the system.





Subobjective 1.2

Pre-service training and Deployment of Instructors to SANU: The primary outputs for this activity was a strategic plan for laboratory pre-service training as well as an exit plan for PEPFAR support. Targets included hiring of at least 3 full-time SANU faculty members and SANU capacitated to sustain lab pre-service training without PEPFAR support. According to the Annual Performance Report (APR, August 2015), ICAP entered into a sub-agreement with SANU to increase lab human resource capacity through pre-service training programs and enhanced preceptorship and internship. ICAP facilitated advertising and conducting interviews for potential lecturers (APR16), however all initial employment offers were refused as SANU did not enter into salary negotiations with the candidates. After additional negotiations between ICAP and SANU, agreement was reached to allow ICAP to hire and second the lecturers to SANU. Per the APR17 report, three lecturers were successfully hired under the project to support the MLS, however SANU delayed the recruitment of the other two lecturers, ultimately leading to only one lecturer being employed. Due to a budget deficit encountered during the program year, support for this element was dropped after consultation with CDC.

SANU's internship program provides work-based experience in learner year 3 in the clinical referral labs and regional hospital laboratory. A SANU Clinical Laboratory Placement Handbook provides guidance for the student intern. ICAP's APR17 achievements note re-employment of 3 retired lab personnel by the government to support the preceptorship program and procurement of a vehicle to enable regular site visit to monitor progress of students during their internships at different laboratories.

Subobjective 1.3

Medical Laboratory Science (MLS) Curriculum

A standardized training curriculum is needed to ensure quality and consistency. One of the Lab CoAg supported activities undertaken between FY16-FY18 involved providing support for the review of the pre-service training curriculum (MLS) and updating of the TB/HIV diagnostics and processes sections. KII feedback indicated that the course outlines were updated (BSc Medical Laboratory Science Syllabi) and approved by SANU. A workshop was held that provided technical insight and ensured appropriate integration of the TB/HIV quality management system into the curriculum.

Subobjective 1.4-1.6

Internships, Scholarship support for MoH employees, and Recruitment of MLS graduates

Scholarship support was provided through the Lab CoAg for 4 MOH employees who were enrolled in a 4-year laboratory technology course at SANU; of the four staff, 3 completed the training and graduated in FY18 award period (one student passed away). KII participants reported that 67 people graduated from the laboratory technology course (MLS) at SANU. Based on KII feedback, all graduates from the first year of the program were already earmarked for jobs by the time they graduated, over half of the graduates from the second cohort are also employed, however the third cohort has seen significantly less employment. As another KI noted, while the MOH provides a recommendation letter for all graduated interns; the current problem is not lack of jobs, but rather the government hiring freeze resulting in huge demand for lab technologists with little money to hire them.

Objective 2: Strengthen Quality Management System

The program narrative indicates that despite implementation of quality assurance programs and EQA at upper level facilities, gaps exist in the effectiveness of the programs and additional support is needed to help laboratories develop a more comprehensive approach to QMS to support accreditation.

Evaluation Objective 2 was therefore aimed at increasing accreditation of labs through development and implementation of a national laboratory strategic plan, QMS, and accreditation processes. The main areas supported included:

1) Providing TA and, as necessary, Direct Service Delivery (DSD) to increase the number of hospital and health center labs participating in the Strengthening Laboratory Management Towards Accreditation (SLMTA) program/Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), including public, mission, and industry facilities

2) Providing TA and, as necessary, DSD to EHLS to establish International Organization for Standardization (ISO) system for all smaller health facilities not enrolled in SLMTA (e.g. mini labs and other health facilities providing any point of care testing (POCs))

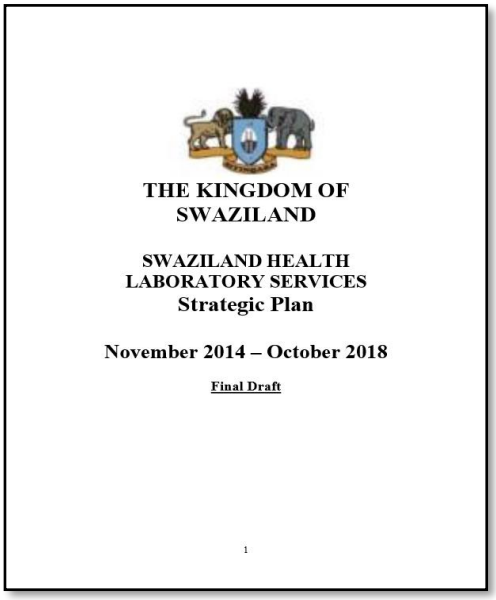
3) Providing TA and, as necessary, DSD to EHLS to implement quality management systems at all facilities (e.g., clinics, health centers), including public, industry, and mission facilities not participating in SLMTA (e.g., clinics, health centers).

Sixteen KIIs provided feedback on this objective. In addition to document review, data from the Lab PT indicator were used to assess EQA participation and pass rates and laboratory walk-through/mini-assessment of six laboratories provided a snapshot view of pre-analytical, analytical, and post-analytical testing phases.

Subobjective 2.1

Scale up of quality assured HIV rapid testing Services: The project aimed to expand the quality assurance activities to all point of care HIV testing in the country by enrolling old and newly opened sites into a proficiency testing program. As of 30 October 2019, there were 387 point of care sites providing HIV testing and counselling that are supported under this project. These point of care sites exist under the following categories: 116 sites from major laboratories, 136 sites from clinics, 67 testing points from clinics with mini laboratories and 68 community-based facility outreach sites. Additionally, the project supports the implementation of HIV rapid test proficiency testing in 387 point of care testing sites where 183 of these are found within the PEPFAR supported laboratories and the remaining 204 are found in other clinics and community outreach sites.

National Laboratory Strategic Plan: Information gathered through KII and desk review materials indicated that while significant effort was put into planning and drafting of the laboratory strategic plan, at the time of this evaluation the plan was drafted but not yet fully approved. Additional probes during key informant interviews provided insights into the decision to delay release to ensure that the laboratory plan was in alignment with the overarching 5-year National Strategic Plan that was still in development. As this report was being prepared, the evaluation team was informed that this strategic plan was drafted with the previous CoAg and was submitted to MOH officials for approval. However, due to changes in cabinet membership, the strategy could not get approved. Therefore, ICAP continued working by developing annual plans jointly with the EHLS over the years. The second National Lab strategic plan 2019-2023 was in the planning stage and one brainstorming workshop was conducted in August 2019. However, this effort was put on hold due to competing priorities.



THE KINGDOM OF SWAZILAND

SWAZILAND HEALTH LABORATORY SERVICES
Strategic Plan

November 2014 – October 2018

Final Draft

1

Strengthening Laboratory Management Toward Accreditation (SLMTA) / Stepwise Laboratory Improvement Process Toward Accreditation (SLIPTA): The SLMTA program was launched in 2009 and is a structured quality improvement program that is designed to achieve immediate, measurable improvement in laboratories. To date, the SLMTA program has been implemented in 1368 laboratories in 55 countries (slmta.org). The program consists of training and mentoring curriculum composed of a series of short training courses, assessments, and quality improvement projects. A standardized checklist and 5-star scoring system is used to assess compliance with ISO 15189 requirements aimed at helping prepare laboratories for accreditation [*Appendix 3*]

In 2010 Eswatini began implementing the program through the enrollment of Mbabane Hospital Lab, the National TB Reference Lab, Pathology Lab, and the National Molecular Reference Lab. In 2014, the country reported training 20 technologists and mentors on SLMTA. In 2015, the Lab Co-Ag project began supporting efforts to improved laboratory services in the Kingdom of Eswatini.

Enrolment and Training: The Lab Co-Ag provided technical assistance to increase the number of hospital and health center labs participating in the SLMTA /SLIPTA. To help strengthen quality management systems across laboratories in Eswatini, the Lab Co-Ag supported the expanded roll-out of SLMTA/SLIPTA programs in 22 main labs. The program used an iterative process in which laboratories were enrolled over time. Based on a review of training records, 7 SLMTA trainings were conducted with 188 total participants.

Table 3: Enrollment of Main Labs in SLMTA

#	Name of Lab	Location (City)	SLMTA Enrollment (YR)
1	Baylor Centre of Excellence	Mbabane	Dec-14
2	Dvokolwako health center	Dvokolwako	Dec-15
3	Mbabane Central Lab	Mbabane	Nov-10
4	Mbabane Hospital	Mbabane	Nov-10
5	National TB Reference Lab	Mbabane	Nov-10
6	Emkhuzweni Health Centre	Emkuzweni	Dec-15
7	National Molecular Reference Lab	Mbabane	Nov-10
8	Piggs Peak Hospital	Piggs Peak	Jul-12
9	Anatomical pathology lab	Mbabane	Nov-10
10	Good Shepherd Hospital	Siteki	Dec-14
11	Lubombo Referal Hospital	Siteki	Dec-15
12	Siphofaneni Clinic	Sipofaneni	Jul-12
13	Sithobela Health Centre	Sithobela	Dec-14
14	Lamvelase AHF	Manzini	Dec-15
15	Mankayane Hospital	Mankayane	Jul-12
16	Matsapha comperhensive Health care (AHF)	Matsapha	Dec-14
17	National TB Hospital	Manzini	Jul-12
18	Phocweni Military Clinic	Matsapha	Dec-14
19	RFM Hospital/PHU	Manzini	Jul-12
20	Hlatikulu Hopsital	Hlathikhulu	Jul-12
21	Matsanjeni Health Center	Matsanjeni	Jul-12
22	Nhlangano Health Center	Nhlangano	Jul-12

Baseline Audits: Baseline audits were conducted in 2015 using the SLIPTA audit tool. Of the 20 laboratories assessed, 63% received zero stars, 26% had 1 star, and 11% scored 2 stars. Table 4 shows the SLIPTA scoring ranges for assignment of Stars. While some sites made improvements in scoring each year, some laboratories experienced a decrease in their star rating/scores in later years compared to previous years. Specifically, RFM and the TB Hospital achieved 3 stars in 2018 and only 1 star in their 2019 SLIPTA audits. As part of the laboratory walk-through, the RFM noted that they had been unable to participate in some PT programs due to funding shortages as the hospital could not continue to partly finance the PT program as it has been used to.

Table 4: Range of percentage scores based on stars

Number of Stars	Minimum Score	Maximum Score
0	0%	54%
1	55%	64%
2	65%	74%
3	75%	84%
4	85%	94%
5	95%	100%

Table 5: 2015-2019 Results of SLIPTA Audits (Stars based on percentage scores)

Facility	2015	2017	2018	2019	2015-2019 Change
AHF	0	0	0	1	0 to 1
Baylor	1	0	1	2	1 to 2
Central Lab	1	1	2	2	1 to 2
Dvokolwako	0	1	2	1	0 to 1
Emkhuzweni	0	0	0	0	0 to 0
Good Shepard	1	0	1	1	1 to 1
Hlathikhulu	0	0	0	0	0 to 0
Lubombo Hospital	0	0	0	1	0 to 1
Mankayane	0	0	1	0	0 to 0
Matsanjeni	0	0	0	0	0 to 0
Matsapha MSF	0	0	0	0	0 to 0
Mbabane_MGH	0	0	1	2	0 to 2
Nhlangano Main lab	2	0	1	1	2 to 1
NMRL	0	2	3	Accredited	0 to Accredited
NTRL	2	1	3	Accredited	2 to Accredited
Pathology *	2	1	0	0	2 to 0
Phocweni	0	0	1	1	0 to 1
Piggs Peak	0	0	0	0	0 to 0
RFM	1	1	3	1	1 to 1
Siphofaneni	0	0	2	0	0 to 0
Sithobela	0	0	0	0	0 to 0
TB Hospital	1	1	3	1	1 to 1

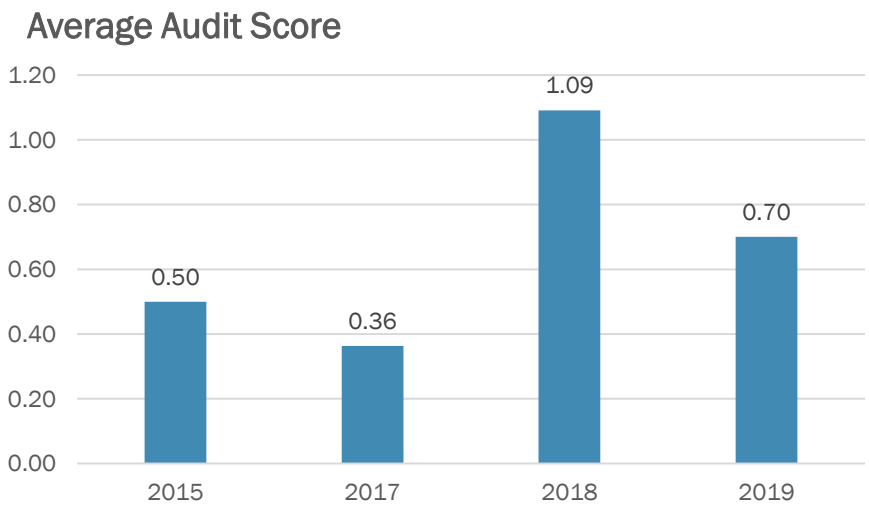
**Laboratory was in the program in Year 1 and 5; support was dropped in years 2-4.*

Changes in Star Ratings:

Of the 22 laboratories that were assessed each year, 2 laboratories achieved accreditation (green), 7 laboratories increased their star rating by 1 star over the project period (yellow), 11 laboratories did not show an increase in star rating between 2015 and 2019 (orange), and 2 laboratories experienced a decrease in star rating over this time period (red). Note that one of the labs (Pathology) was dropped per CDC guidance at the end of year 1 and supported was only reinstated at year 5. Of the 11 labs that did not show an overall increase 4 labs showed an increase in star rating for 2018, however the improved score was not sustained in 2019 assessment.

Figure 1 below shows the average number of stars achieved by lab in each audit year. While 2018's average score is significantly higher than 2019, two labs were accredited in 2019 and thus did not receive a score, lowering the 2019 average. Excluding those two labs from the analysis, the mean score in 2018 was 0.9 (still higher than 2017's average).

Figure 1: Average SLIPTA Audit Score



Dimensions of Lab Quality: The SLIPTA audit measures twelve different dimensions of lab quality, changes in Star rating are therefore based on overall performance in the different areas measured by SLIPTA. As part of the evaluation we looked at the performance in different dimensions over the course of the award. The three highest scoring dimensions across all fiscal years were facilities and safety (range: 66% - 75%), information management (67% - 86%), and purchasing and inventory (42% - 55%). The lowest scoring dimensions were management reviews, evaluations and audits, and non-conformities identification and corrective action. Two scores decreased between 2015 and 2019: evaluations and audits (-4%) and non-conformities identification and corrective action (-2%). The largest increases were seen in information management (+17%) and client management (+16%). Almost all scores decreased between 2018 and 2019 except for purchasing and inventory which did not increase or decrease between 2018 and 2019.

Mentorship Program: As part of the program, a structured laboratory mentorship program was implemented where mentors were embedded for a 3-month period per facility to provide onsite mentoring and build CQI capacity. A model framework document describing the framework was developed by EHLS and ICAP in 2015. The framework describes roles and responsibilities, methodologies (baseline audit using WHO SLIPTA checklist, mentorship, review meetings, supportive supervision, and auditing progress), mentoring tools, baseline and target audit scores, in addition to a mentorship schedule.

Annual SLIPTA audit and Improvement on LQMS: Following the baseline audit and mentorship program, enrolled facilities gradually improved the implementation of LQMS overtime. Annual SLIPTA audits were conducted. The number of laboratories with a minimum of one-star SLIPTA score was seven at baseline in December 2015 but reached to thirteen laboratories by August 2019.

Accreditation: Two laboratories, NMRL and NTRL, achieved 3 Stars in August 2018 and continued through the SLMTA/SLIPTA program and achieved ISO15189:2012 accreditation from SADCAS in August 2019.

Laboratory Walk-throughs: As part of the evaluation, six laboratories were selected and an abbreviated assessment was conducted to review pre-analytical, analytical, and post-analytical procedures. Appendix G was used to collect information on the performance of the laboratories in each of these areas. Note that the scoring in the original tool is incorrect (total score was indicated as 80 points, however the actual total points is 66, therefore the percentage scores were based on 66 total points). The scoring scale was assigned by the protocol investigators; in comparison to the SLIPTA checklist this was a very abbreviated assessment were the scores largely reflected availability and completeness of SOPS.

Table 6: Scores from Laboratory Walk-Through Assessments

Phase	Review Category	Points	National TB Lab	Lubombo	NMRL	NTRL	Nhlangano	RFM
	2019 Star		1	1	A*	A*	1	1
Pre-Analytic	1. Test ordering	10	8	6	7.5	8	8	7
	2. Sample collection	6	6	6	6	6	6	6
	3. Sample transport	6	6	6	6	6	6	6
	4. Sample Receipt and Processing	10	10	8	10	10	9	10
Analytic	5. Examination	16	16	16	16	16	15	16
	6 Result Review and Follow-up	8	8	8	8	8	8	5
Post-Analytic	7: Interpretation	10	10	10	10	9	10	10
	Total	66	64	60	63.5	63	61	61
	Percentage	100%	97%	91%	96%	97%	92%	92%

**A= Accredited, Scoring: >90%=Excellent (Dark Green), 76-90% = Very Good (Light Green), 61-75% =Good (Yellow), 50-60% = Satisfactory (Orange), <50% = Poor (Red)*

In general, there was good evidence in all the laboratories of the existence and use of standardized laboratory procedures and implementation of quality assurance/quality control procedures. We noted some issue with completeness of the Test Ordering forms (missing patient ID numbers) and for some procedures some details around sample collection, specimen types were captured in different source documents. Run charts and PT results were in general available, however for one lab (RFM), no EQA had been done due to funding restrictions. The walk-throughs provided an opportunity to see the impact of efforts to strengthen VL capacity, LIS, and improve quality management systems through the CoAg.

***Laboratory Proficiency Testing*:** Proficiency testing is a key element of laboratory quality management systems helping to ensure the competency of laboratory staff to conduct specific tests and thus the reliability of laboratory testing results. As part of the assessment, data for the laboratory indicator Lab_PT was collected using *Protocol Appendix C* for fiscal years covered by the award. The indicator reports on the a number of laboratories performing the different tests (HIV Serology, CD4, HIV VL, EID, AFB, TB culture, TB GeneXpert) and of those, the number that are participating in a PT program and number of labs that achieved passing criteria on the PT panels. This is of interest as laboratory proficiency testing is a critical component of external quality assurance and an integral part of quality management systems. Data collected on proficiency testing by year is summarized in *Appendix 4*. In brief, the number of laboratories reporting against this indicator increased from 60 to 74 over the course of the award. The number of laboratories conducting TB culture and EID testing did not increase significantly over the review period whereas the number of laboratories conducting HIV serology test, CD4, and viral load testing did increase. With these increases, there was a concurrent increase in the number of labs participating in PT programs. Laboratory PT results were in general within acceptable ranges, however the percentage of laboratories achieving acceptable passing results for CD4 was lower than expected and improvement was not observed over the review period.

ISO standards for Mini-labs

In 2016, ICAP provide support to develop a framework for supportive supervision and mentorship of Mini-Labs. As described in the framework document, mini-labs are manned by trained phlebotomists who are responsible for collection and preparation of samples either for referral or testing on site. The test menu for mini-labs includes pregnancy test, CD4 POC, Hgb POC, HIV test, syphilis tests, POC glucose, urine biochemistry and malaria. Some mini-labs also added TB diagnostic testing using Gene Xpert. The framework describes roles and responsibilities, methodology including a baseline audit, in addition to supportive supervision and mentorship. Mentors were recruited and embedded in 21 laboratories and other mentors supported mini-labs with a structured supportive supervision and mentorship approach. A stepwise tool was developed to assist with mentorship visits on mini-labs and the quality improvement projects were undertaken to implement change in response to issues identified. Six ISO trainings [81 total participants] were conducted and 60 mini-labs enrolled between 2015-2017. An additional 395 clinics were enrolled in the HTS/RT proficiency testing program.

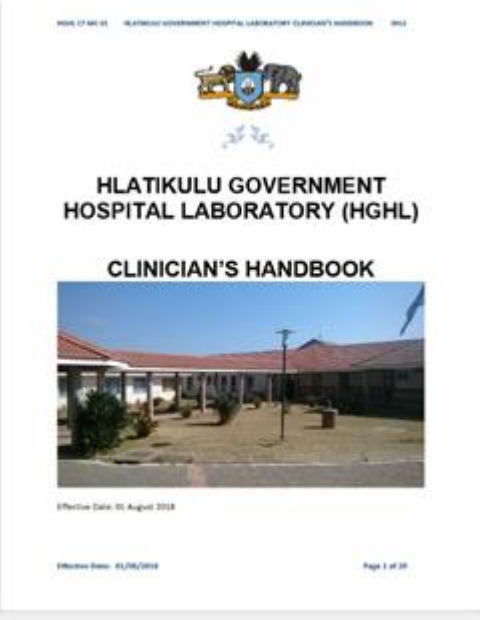
Objective 3: Improve Access to Testing

This objective aimed to strengthen lab networks through standardization and decentralization of lab services and improvement in the sample transport system. The main areas supported included:1) Providing TA to EHLS to develop and implement a lab handbook based on services identified in the Eswatini MOH Essential Health Care Package and 2) Implement national referral test menu via a sample transport system that is sustainably operated by the MOH and is consistent with national lab handbook.

In section 3.3 we also reviewed other factors contributing to access to testing including staff training, testing turn-around times, and testing volumes. Laboratory walk-throughs, document review and feedback from 17 key informant interviews were used as data sources for this section.

Subobjective 3.1

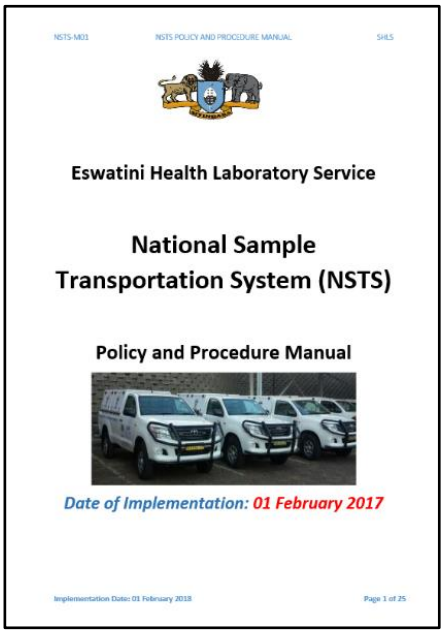
Laboratory Handbook: The Lab CoAg provided technical assistance for the development and implementation of a laboratory handbook. The laboratory handbooks provide standardized information to the clinicians and other clinic and laboratory staff the availability of specific tests (testing menu), specimen collection, storage, and transport, and other relevant testing information that is customized for individual facilities. KII's noted that the laboratory handbook was a critical piece in the process of keeping clinicians informed as to what testing is currently available and how to appropriately order and collect specimens for testing. We also found the handbooks to be readily available and in use at the site when conducting the lab walk-throughs.


HLATIKULU GOVERNMENT HOSPITAL LABORATORY (HGHL)

CLINICIAN'S HANDBOOK

Subobjective 3.2

Sample Transport System: ICAP provided support for the design and implementation of national referral test menu via a sample transport system. As part of the laboratory walk-throughs, the evaluation team was able to access and review specimen referral SOPs/forms and specimen transport procedures. A specimen referral manual [NSTS Policy and Procedure Manual dated February1st 2017] was also developed as part of this objective and *Appendix 5* depicts the workflow and pick-up times for laboratories in the network. ICAP also provided support to fill transportation gaps through hiring of rental cars for specimen transport and providing fuel coupons to NSTS (APR17). Additionally, ICAP procured and transferred four customized vans with refrigeration capacity over to NSTS.


NSTS-M01 NSTS POLICY AND PROCEDURE MANUAL SHLS

Eswatini Health Laboratory Service

National Sample Transportation System (NSTS)

Policy and Procedure Manual

Date of Implementation: 01 February 2017

Implementation Date: 01 February 2018 Page 1 of 25

3.3 Other factors contributing to testing access:

Staff Training: In addition to ensuring sample collection and transport are streamlined and efficient, increased access to high quality testing is also dependent on a laboratory having enough trained staff to conduct the tests and ensuring that testing quality is maintained through refresher trainings and ongoing proficiency testing. As noted in Section 1 above, the Lab CoAg provided support for ~150 trainings and webinars. Examples of training that help to build HIV, TB, and CD4 testing capacity include, but were not limited to the following:

HIV Tests

- EID and Viral Load trainings (2 people, 2-week training and 10 people, 5 days)
- HIV Drug Resistance (2 people, 5 days)
- QMS including viral load roll-out for phlebotomist (30 people, 4 days)
- DBS viral load sample collection, preparation, handling and transportation (191 people)
- Training on HIV rapid testing (61 people)

Tuberculosis

- TB Culture and Drug Sensitivity: (5 people, NICD -National institute of Communicable Diseases)
- TB susceptibility (2 people, 2 weeks)
- GeneXpert: (27 lab professionals, 5-day training with FIND)
- GeneXpert: Super User training (15 people)

CD4:

- Refresher training on CD4 testing and equipment maintenance (20 people, 5 days),

Laboratory Turn-Around Times: In addition to the number of specimens a laboratory can routinely test (testing volume) , the turn-around time from sample collection to return of results is also an important indicator of testing accessibility as long turnaround times limit clinicians' access to results and may negatively impact patient outcomes. For this analysis, reported turn-around times (monthly laboratory reports) were compared with recommended TATs to assess the laboratories capacity. While various factors can influence TAT, long turn-around times may be indicative of unoptimized workflow, equipment down-time, and/or commodities stock-outs; management of laboratory workflow and procurement is a key component of good laboratory quality management systems. The data presented below represents median TATs for the four assay types for the time period between FY2016 and FY2019 spanned by the Lab Co-Ag award. The TATs are aggregated across all the laboratory facilities on a monthly basis resulting in 48 individual timepoints during the study period. Each TAT value represents the aggregate number across all facilities for the month. Due to data aggregation, we were unable to correlate TATs with potential causes such as stock-outs to specific laboratories that may have impacted turn-around time. Trend plots for TATs are captured in *Appendix 6*.

Table 7: Comparison of Expected vs Actual Turn-Around Times

Test Type	Expected TAT (days)	Median TAT (days)	Minimum TAT (days)	Maximum TAT (days)	# Timepoints exceeding expected TAT
GeneXpert	2	1.3	1	18	9
TB Culture Positive	21	29.5	15	49	45
TB Culture Negative	42	48.5	46	71	48
CD4	3	2.28	1.1	6.5	4
Viral Load	14	10.2	2.9	30.9	13

Testing Volume as a Measure of Testing Access: To more closely assess improvement in access to testing, the evaluators reviewed routine program data to ascertain testing volumes for laboratory tests in four areas: CD4, HIV Viral Load, GeneXpert [TB], and TB Culture. Minimum, median, and maximum monthly testing volumes were calculated over the award period from fiscal year 16 through fiscal year 19 and are shown in Table 3 below.

Table 8: CD4, TB, and HIV VL Testing Volumes for Award Period FY16-FY19

Test	Minimum	Median	Max
CD4	4538	10970	17622
VL	1350	13355	21452
GeneXpert	1236	2483	4673
TB culture	32	847	1147

Trends in testing volume were also assessed for the four laboratory tests (*Appendix 7*) and summarized below:

CD4: The number of CD4 tests processed declined steadily from FY2016 to FY2019 (in 2016 the country started implementing test and treat approach), with a slight increase in FY2019. The decrease in the number of CD4 tests was statistically significant ($P<0.01$) with the monthly testing volume decreasing by 84 tests on average per each monthly increase in time. Over the course of the award, PEPFAR guidance has advocated for increased use of viral load testing for patient monitoring resulting in a shift from CD4 testing to VL testing that may in part account for the observed decrease in CD4 tests.

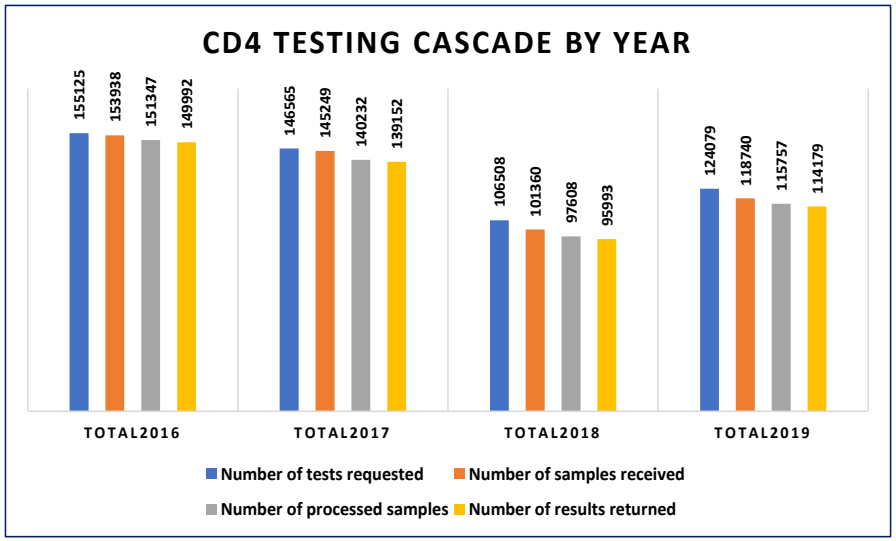
HIV Viral load: There was a notable increase in the number of VL tests conducted from FY16 to FY19. This increase was statistically significant (P<0.001) with the monthly testing volume increasing by 347 tests on average per each monthly increase in time and likely reflects the decentralization of HIV viral testing through creation of new viral load testing laboratories.

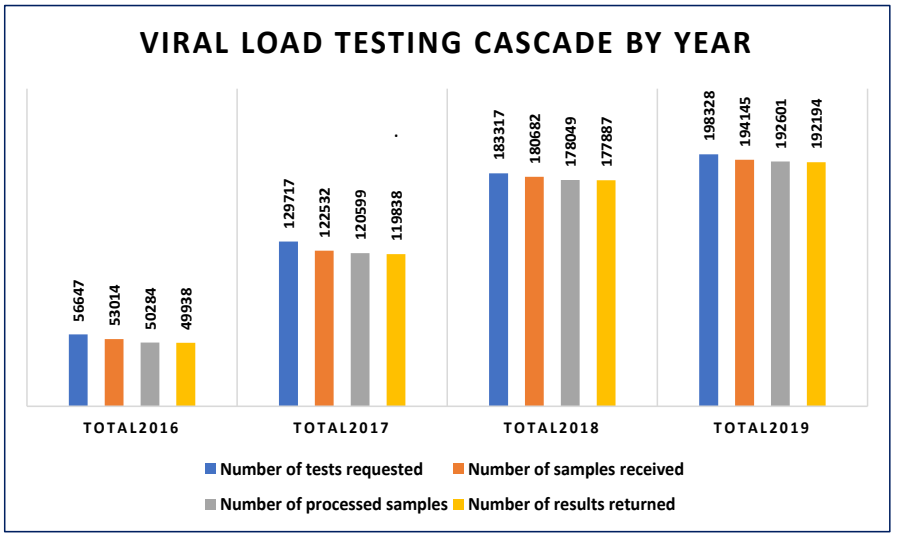
Tuberculosis Testing: testing trends were reviewed for two different types of TB tests; near point of care testing using GeneXpert and the laboratory-based TB culture assays. Of note TB testing appears to have decreased over the award period as is reflected by testing volumes for both assays.

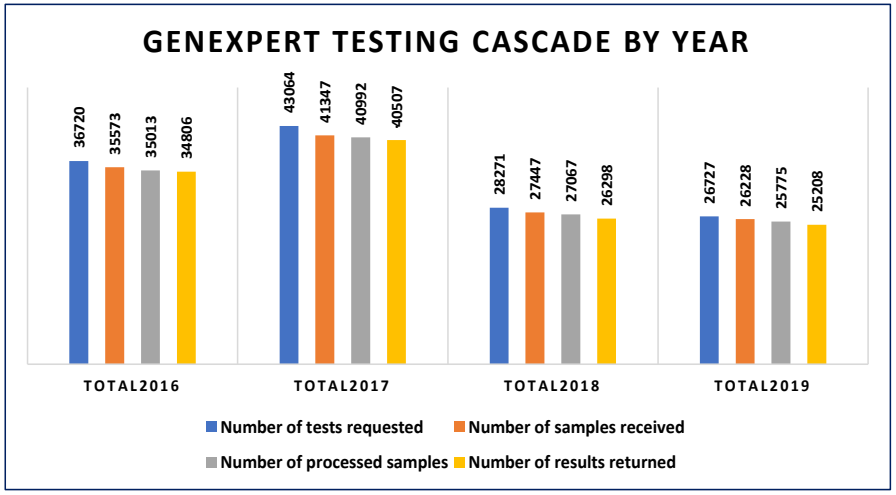
GeneXpert [TB Point of Care test]: There was a gradual decrease in the number of GeneXpert tests conducted from FY16 to FY19. This decrease was statistically significant (P<0.01) with the monthly testing volume decreasing by 23 tests on average per each monthly increase in time.

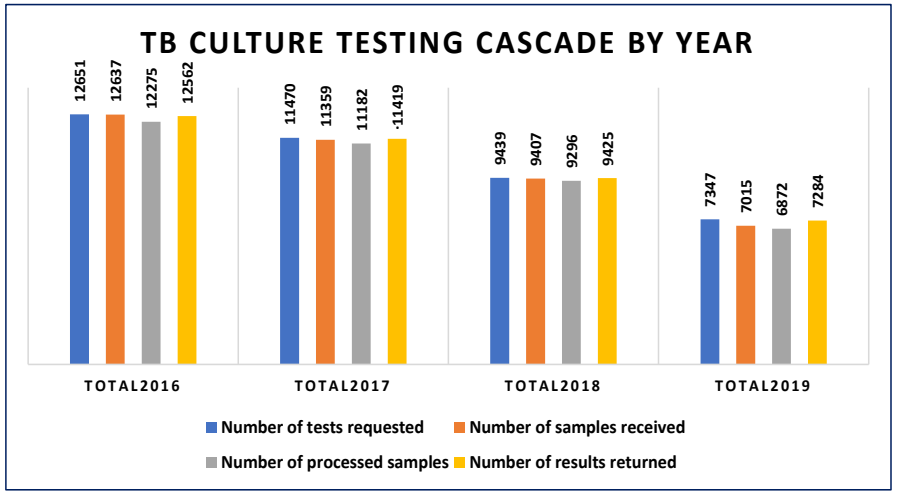
Testing Cascade: As shown in Figure 2 below, CD4 testing, GeneXpert and TB cultures tests had a downward trend in the number of tests conducted over the course of the award. In contrast, viral load testing increased steadily from FY16 through FY19. For all 4 tests, across the testing cascade, 95% of samples transitioned through the steps. However, for both viral load tests and TB culture, the proportion of samples processed was at or exceeded 100%. This is most likely due to the aggregation of data across labs (i.e. each monthly data represents multiple labs) so the true cascade performance of the individual labs is masked. Additional cascade performance data is displayed in *Appendix 8*.

Figure 2: Testing Cascades





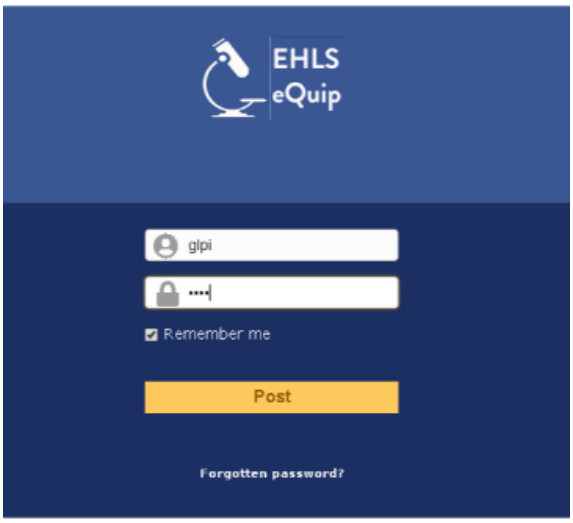




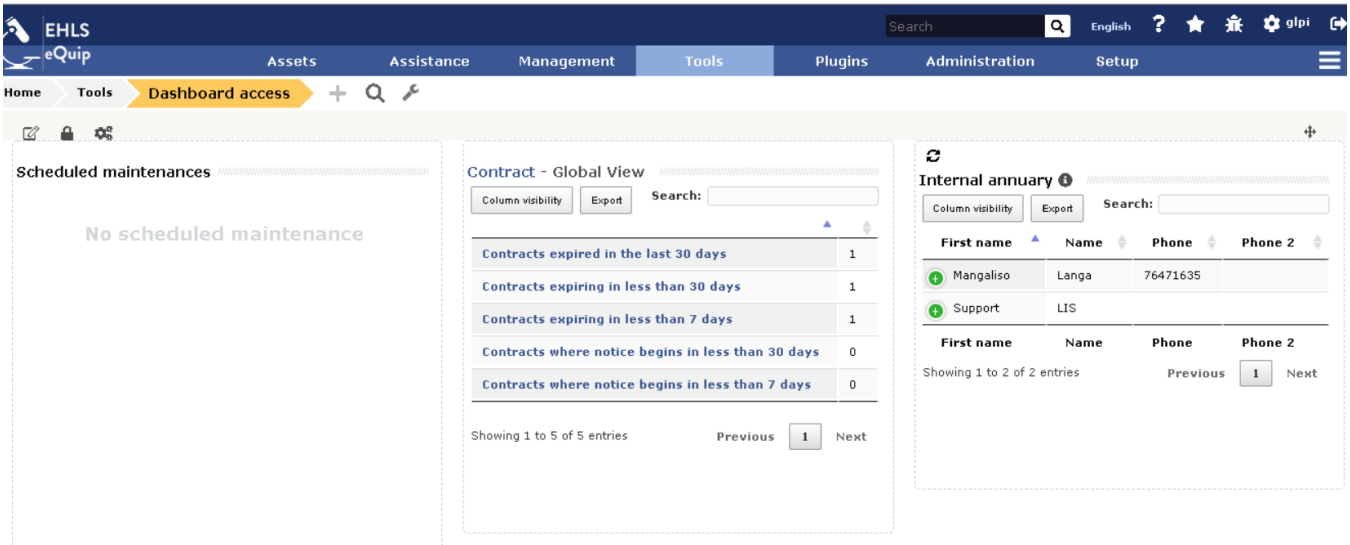
Objective 4: Strengthen Equipment and Supplies Management

Objective 4 included the development and implementation of robust systems for equipment and supply chain management. The main activities in this area involved the provision of TA to Biomedical Services and EHLS to develop and implement sustainable strategies for establishing equipment standards, maintenance plans, as well as appropriate supply plans that support implementation of the handbook. In addition to site visits and document review, 15 key informants provided insights on this objective.

Equipment Inventory and Management: At the beginning of the award ICAP supported the development of an equipment inventory list by EHLS in 59 laboratories that documented the equipment category, number of labs with equipment, and the total number of each type (APR16). To streamline the process, the equipment inventory system is being transitioned to an electronic database system



eQuip: To further advance efforts to maintain an accurate and up to date equipment inventory, the Lab Co-Ag provided support for development of a PC-based database (eQuip) for equipment management that included platform types, distributions and maintenance history. eQuip is an open source database which was developed and tailor-made to suit the needs of EHLS. At the time of the review, the database resided on the IT Office Desktop, managed by the LIS team. The database is password protected and will be manned by the Principal Technologist (Equipment Focal Person). eQUIP is currently running on a LAN private IP address with an end plan of commissioning the database to the EHLS website.



A member of the evaluation team was able to visit the main laboratory in November 2019 to access and view the EHLS eQuip database and meet with the LIS Manager and LIS Coordinator. At the time of the visit, only 14 out of the 22 main labs had submitted their equipment inventory lists. The LIS Coordinator conducted site visits to get updated equipment lists but still no updated records were received. Communication with vendor is facilitated through the database, when fully operational, the EHLS (facilities) will be able to send comments about equipment directly to the vendor by creating a ticket on the database. The ticket will generate a real-time email direct to the vendor and follow up will be done telephonically and feedback updated onsite as the vendor attends to the equipment. Observations during laboratory walk-throughs, review of available documentation, and KII interviews, confirmed that information on equipment types and maintenance is collected and maintained in the database and that equipment maintenance and service information was being submitted annually.

Guidelines and SOPs: ICAP support for the areas below was provided in the form of technical assistance to Biomedical Services and EHLS to develop and implement strategies for establishing equipment standards, maintenance plans, as well as appropriate supply chain plans. As such, we have focused on the outputs (SOPs, and guidance documents), recognizing that these are collaborative activities with ICAP providing support to EHLS to generate the documents and process.

Equipment verification and maintenance standards and validation process for new equipment and tests: Based on desk review of example SOPs, Swaziland Health Laboratory Services SOPs for equipment verification and maintenance were available for Method/Equipment Verification (no year), POC HIV VL and EID testing verification (no year), FACSCalibur verification (no year) VL quantification on Cobas (2017), Beckman Coulter (2016), GeneXpert (2017). Key informants also reference the laboratory equipment management guidelines from 2017. Of note, while a percentage of the reviewed SOPs had well developed methods sections, several did not list an effective date, so it was unclear whether these were fully implemented or still in draft stage. As part of the laboratory walk-through conducted at 6 of the main laboratories, SOPS for equipment maintenance and supply planning (stockouts of consumables) were reviewed and available at all 6 visited facilities [*Appendix G, Section 5*]. SOPs viewed on site in general were in alignment with national SOPs. The evaluation team was also able to view equipment maintenance logbooks onsite during the walkthroughs. Feedback from key informant interviews indicated that while the situation has improved, implementation is incomplete with only about 50% of the facilities having preventative maintenance plans in place. Vendors are in many cases providing services contracts on larger instruments.

Supply Chain Management System (SCMS) and Inventory control: At the onset of the program, lab quality management system training materials were reviewed and as part of the mentorship program, support was provided to facilities in inventory management tracking and procedures (APR15 and 16). The APR17 report indicated that ICAP provided emergency replenishment of critical lab supplies and to strengthen the inventory system, ICAP developed and distributed to the lab mentors, the NSTS manager and NSTS drivers to monitor and capture information on stock-outs. As part of the desk review, six SOPs with an effective date of Aug 2017 were shared and reviewed as part of the desk review materials as example of SOPs covering different components of supply chain management including; a) selection and evaluation of supplies, b) ordering, receipt, inspection and storage of lab reagents, c) Disposal of damaged and expired products, and d) inventory control system. Excel-based tracking sheets ('Noisemakers Report' examples from 2016, 2017, 2018) documenting inventory tracking and reporting for warehouse stocks were also reviewed. The reports include current stock as well as forecasting components that flag issues with forward month coverage (several forecasts indicate potential for stock outs in multiple areas). For inventory control and consumption data, KII's described the use of stock cards, LMIS form,

and order and reporting form that is sent monthly to Central stores with KII's also indicating that consumption data and supply chain management lagging behind other areas. KII's referenced a supply chain TWG and training on lab forecasting and a training by CDC expert on supply chain and procurement of lab commodities.

Objective 5: Improve Laboratory Information System (LIS)

Objective 5 was focused on strengthening data management capacity and increasing connectivity across the network through implementing a sustainable LIS that interfaces with existing HMIS. Main areas supported included: 1) Facilitating the roll-out of a cost-effective LIS coordinated with HMIS and blood safety information system that is sustainable without PEPFAR support and 2) Strengthening the functionality & networking of laboratories with the LIS.

Laboratory Information System Roll-out: Under this objective, the main tasks were to develop the platform, identify new sites for LIS installation, procure hardware, provide troubleshooting support to sites, and conduct LIS trainings. The Swaziland MoH LIS project was initiated by APHL in conjunction with Swaziland MOH. ICAP took over the further roll-out of DISA*LAB from Feb 2017. Information derived from an August 2016 report indicated that the DISA*LAB Laboratory Information System (LIS) had been installed in 4 phases at 13 sites (LIS Site Visit Report, Aug 2016, M Langa and T Zanamwe). This baseline assessment served to document the current status of the LIS at each of the sites and provided recommendations for staff training, system upgrades, and equipment needs. As part of phase 5, ICAP was appointed to install DISA*LAB at an additional 4 labs bringing the total to 17. Challenges were however noted in APR17 with sustaining the LIS due to limited government funding and competing priorities and the need to expand to all 60 labs in the country. To move forward with additional installations, Laboratory System Technologies (Pty) Ltd (LST) was selected as the vendor to deliver, install, conduct training (5 day) and provide site support services for phase 5 of the project. DISA*LAB requires an initial license fee and then an annual renewal fee each year thereafter.

As part of the laboratory walk-through the evaluation team was able to view both the DISA*LAB system and how it is being used by both laboratories and clinics. The system has also been deployed to mini-labs. Feedback from key information participants and laboratory/clinic staff indicates that the system functions well and provides a useful interface for test ordering and timely return of results to the clinics.

LIS Functionality and Networking: The Lab Co-Ag also aimed to strengthen the functionality and networking of laboratories with the LIS. Key activities include implementing DISA LINK (a module of DISA*LAB) to facilitate efficient transfer of information, providing technical assistance and support for trouble-shooting LIS issues, training new users, conducting situational analysis to assess needs for hardware replacement/procurement and financial support of software licenses. Information derived from review of program documents and key information interviews indicated that these activities were completed, and technical support provided in a consistent and productive manner.

Objective 6: Improve and Expand Viral Load Testing Networks

Objective 6 was focused on increasing access to viral load testing. The main areas supported included: 1) Support for the roll-out of routine viral load monitoring, 2) Improving decision making through enhanced information management system, 3) Optimize VL laboratory test workflow & efficiency at NMRL and Satellite molecular labs of Lubombo and Manzini.

Strengthen the roll-out of viral load testing: Key activities completed under the award included providing training on viral load sample collection, processing and referral, procurement of additional equipment, hiring and training personnel on viral load testing, and strengthening the transport system. Over the award period, two new molecular laboratories for viral load testing were renovated and brought online including procurement of equipment and hiring of staff. As part of the laboratory walk-throughs, the evaluation team visited the 4 viral load laboratories, one of which is ISO15189 accredited. Technical support for the set up new viral load equipment was conducted by the vendor and additional support was provided through the CDC's International Laboratory Branch within the Division of Global HIV and TB (DGHT). These efforts resulted in a significant increase in testing capacity; with the average number of viral load tests increasing each FY from 4417 (FY16) to 10211 (FY17) to 15056 (FY18) to 16178 (FY19).

VL Data use: The Lab Co-Ag supported the development of a VL eTool Dashboard (*Appendix 9*) and all VL labs were submitting weekly data, however at the time of the evaluation, the Dashboard had not yet been released. Findings from discussions with laboratory staff during the laboratory walk-throughs indicated that data was being collected and reviewed on a weekly schedule and that there were processes in place to actively identify and flag high viral load results and alert the clinic to enable recall of the patient for rapid follow-up. The effort to establish interface between LIS and CMIS to improve VL data use was also supported through this Co-Ag.

6.2 Limitations

Several factors limited the analysis and reporting

- Laboratory data was shared as aggregate data and not available at the laboratory/facility level. Analysis could only be performed at the aggregate level therefore other trends and performance at the facility level could be masked in the aggregate results
- Data dis-aggregations were not available for laboratory statistics, including disaggregated results for subpopulations identified in outcome evaluation question 2
- Challenges with interpretation of report data on aggregate equipment downtime. Data values should be less than 30 days as this represents the numbers of days that equipment are down during the month. Values exceed 30 days and therefore may represent more than one equipment being down or more than one month.
- Appendix G point assignments were incorrectly labeled resulting in a lower total score (66 vs 80) for calculating final percentages. It is also unclear how the weighting of individual assessed elements and assignment of qualitative scoring (Excellent, Very Good, Good, Satisfactory, and Poor) was derived.
- Evaluation team staff availability was limited during report development due to COVID-19 deployments.

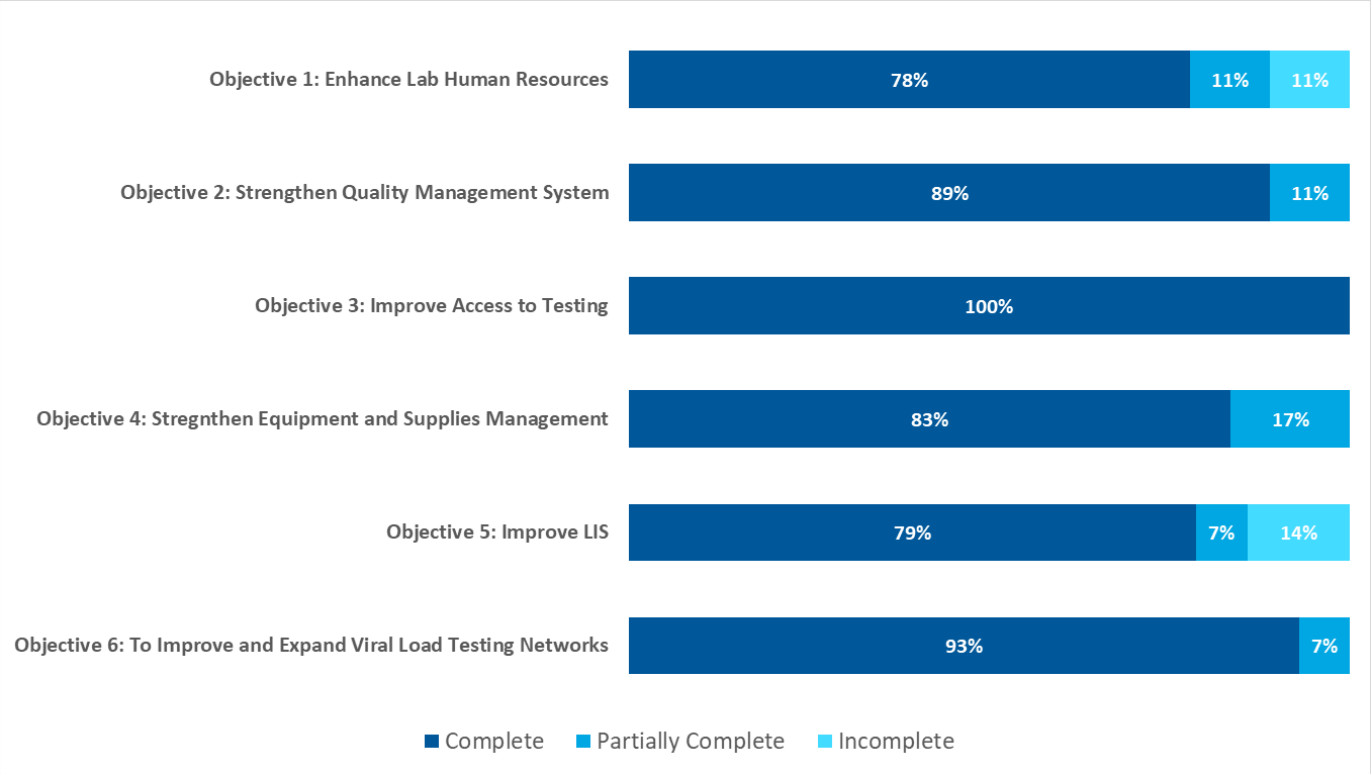
7.0 Conclusions and Potential Actionable Items

Evaluation conclusions related to completeness of implementation, capacity building and achievement of key outcomes are described in this section of the report. This section also reflects on stakeholder satisfaction with how the program was implemented (collaboration) and sustainability of the approach and achievements of the program.

7.1 Completeness of Program Activities

The process evaluation sought to assess the relative successes and challenges in implementation of program. The first process evaluation question [*Process Evaluation Question 1*] looked at the extent to which planned program activities had been implemented. To address this question, we reviewed findings from KII and cross-checked with program documents as part of the desk review to document the status (complete, partial, incomplete) of key activities under each sub-objective (*Appendix 2*). The percentages of activities completed under each objective are displayed in Figure 3 below. They were calculated by dividing the number of activities that fell in each status category (complete, partial, incomplete) by the total number of activities in that specific objective. In general, very few activities scored as incomplete with the majority of activities under each of the objectives have either been completed or are in progress and scheduled for completion by the end of the award period.

Figure 3: Overall Status of Planned Activities



7.2 Capacity Building

Capacity building efforts supported under the Lab-CoAg focused on strengthening different components of the laboratory system and in general resulted in expanded capacity in the areas described below.

7.2.1 Successes

1) *Laboratory workforce development:* Core components that contributed to building this capacity included support for the enhancement of the MLS curriculum for pre-service training, establishment of CPD Guidelines and participation in in-service trainings, and the MDC HR database to monitor lab staffing and certification. Through the support from the Lab-CoAg laboratory professionals had greater access to in-service trainings that served to enhance both the staff's knowledge base and competency in conducting HIV, TB, and CD4 testing. Key informants indicated that the support provided through the Lab Co-Ag helped provide the necessary training and made it easier to recruit and deploy laboratory staff.

2) *Laboratory quality management systems:* Establishing a culture of continuous quality improvement occurs over time and requires sustained monitoring and feedback to achieve and maintain high laboratory quality standards. The SLMTA program supported through the award is designed to build capacity in a stepwise fashion to support laboratory accreditation. While achieving accreditation may be the end goal and an important milestone for individual laboratories, building capacity and ensuring quality of the overall laboratory program is also vital as it serves to improve patient outcomes through the availability of timely and accurate laboratory results. Through implementation of SLMTA/SLIPTA, ISO standards for mini-labs, and the laboratory mentorship program the Lab Co-Ag was able to support quality improvement efforts as evidenced by an increased number of labs participating in PT programs as well as significant improvements in audit scores for several labs over different years of the award, and ISO15189 accreditation of 2 main laboratories (NMRL and NTRL).

3) *Access to Testing:* Making testing more accessible requires a number of capacities including building a knowledge base and understanding of the types of tests available, specimen collection methods, and a robust specimen transport network to ensure samples are shipped and results returned (turn-around time) in a timely fashion. The development of the Laboratory Handbook, enhancements to the sample transport network, and specialized training contributed to building testing capacity. Specimen transport systems and LIS also contribute to achieving acceptable laboratory TATs.

4) *Equipment and Supplies Management:* Progress was made in establishing a routine method for equipment inventory using the eQuip system and also in the development of inventory tools and procedures. The ICAP team was also instrumental in identifying critical gaps and providing support to bridge government funding gaps.

5) *Laboratory information systems:* The ICAP team took the lead in the roll-out and support for DISA*Lab, expansion of the system has helped to strengthen data management and increase connectivity within the network. From observation of the use of the system in the laboratories, DISA appears to be working well and supports more rapid test ordering and return of results.

6) *Expansion of viral load testing networks:* Support for expansion from two to four viral load laboratories resulted in a significant increase in viral load testing capacity. While not fully implemented at the time of the onsite assessment, the VL eTool, shows promise as a means to improve VL data use and to flag and track high viral load results. The latter is extremely important to the country's ability to achieve the 95% viral load suppression rates needed for epidemic control.

7.2.2 Challenges: While the program was able to make great progress and build capacity in key areas, several challenges were identified as part of the evaluation:

1) *Objective 1:* While ICAP was able to successfully recruit and hire 3 lecturers, challenges with coordination of hiring of the staff directly at SANU resulted in the ICAP needing to hire and then second the staff to the university. Consequently, only one instructor was successfully deployed to the SANU medical laboratory school and KII's reported that the mechanism used for the deployment was costly and may have also resulted in salary disparity between what the ICAP supported faculty member and other faculty (lower paid). This subsequently led to challenges with absorbing the faculty member into the SANU's budget due to the higher payscale. KII's noted that ICAP met monthly with SANU to try and understand and address the challenges and also noted that high turn-over among professors is a significant problem in general.

2) *Objective 2:* ICAP provided support for development of the National Laboratory Strategic Plan, however at the time of the onsite assessment, the plan had not yet been finalized or disseminated. This is based on decision to delay release to ensure that the laboratory plan was in alignment with the overarching MOH 5-year National Strategic Plan that was still in development. While the desire to align the plans is understandable, this has resulted in a significant delay in release of the plans which may now require additional updating due to the time lag.

3) *Objective 2:* With regards to the SLMTA program, some laboratories show only limited improvement in scores. Maintaining capacity and quality also proved challenging for a subset of laboratories assessed as a review of the data showed several labs that regressed in their star rating over the period of the award. As part of the laboratory workflow walk-through we were able to observe operating procedures and documentation and in general noted that SOPs were in place and appeared to be consistent across sites, we did however note some challenges in maintaining EQA programs due to funding issues which raised some concerns about the sustainability of the program longer term.

4) *Objective 4:* While solid progress has been made supporting the development of the equipment management platform (eQuip), several challenges were noted: 1) *coverage of the database*- only 14 out of 22 labs have submitted information, 2) *data completeness*-lack of complete information (date equipment procured, cost, source of funds, service contract) provided from all main labs to update the database which limits the utility of the database, and 3) *accessibility*-inadequate clearance of some lab staff which limits their ability to share updated inventory lists.

5) *Objective 4:* Based on review of the SOPs provided, it was unclear at times what the effective date of implementation was for some of the procedures and whether all tests and equipment was covered. This is related to a more general observation where we observed during the lab walk-through that in some cases SOP were available, however the effective dates and training status was not always clear.

6) *Objective 6:* The VL eTool Dashboard, while a useful tool to promote data use, at the time of the evaluation, several of the labs that submit data were unable to access the dashboard so were unaware of its content.

7) *General:* Governmental funding gaps also created implementation challenges for several activities.

7.3 Process Evaluation Questions 2 and 3

Evaluation question 2 and 3 ask 'to what extent has access to quality laboratory services (VL Labs, HIV, CD4 and TB POC) and ICAP support for LIS connection improve workflow optimization and result turn-around times. Access to quality laboratory services is inter-related with the findings and challenges identified under Objective 3 and 6. As was noted earlier in the report, access to VL testing significantly increased over the course of the award due to decentralization of viral load testing. TATs for all tests were in general in alignment with national standards. Distribution of viral load testing results through the DISA system provides for more rapid access to results for clinicians enabling improved patient management and more rapid recall of patients with high viral loads.

7.4 Evaluation Outcomes

We next reviewed and analyzed the results from the different methodologies used in the evaluation to assess how program activities contributed to specific outcomes identified in the evaluation program.

Outcome Evaluation Question 1 looked at how well laboratories in Eswatini achieved national accreditation and licensing standards. This question is directly linked and addressed in the findings related to Objective 2 which had a long-term outcome of improving the quality of lab services at all levels of public, mission, and industry-managed health facilities in the country. In general, the activities supported by the CoAg contributed to increases in licensing standards and national accreditation with two laboratories achieving accreditation over the course of the award and several labs displaying improvements in SLIPTA scores. Additional effort is however needed to drive quality improvement a number of laboratories that either had very low scores and/or showed limited improvement in overall star ratings over time.

Outcome Evaluation Question 2 asked to what extent has access to viral load testing to all patients including pediatric and breastfeeding women viral load testing been improved in the country and how often viral testing data being is used for program monitoring by MOH. Key findings for this question are reviewed under Objective 3 and Objective 6 above. In brief, the program supported decentralization of viral load testing through the addition of two new viral load testing laboratories. Testing volumes increased while turn-around times and specimen rejection rates decreased reflecting good scaling of testing while retaining specimen collection and testing quality. The laboratory testing data accessible to the evaluators did not provide disaggregated data for different population types, so we were unable to access the specific effect on pediatric and breastfeeding women.

7.5 Satisfaction, Sustainability, and Stakeholder Engagement

Key informants in general responded favorably to questions surrounding how satisfied they were with the implementation of program activities. Participants noted that they found QMS to be a strength and that it has resulted in change in understanding of quality that has helped improved services. KI's also expressed satisfaction with the embedded mentorship program.

Multiple KI's expressed concerns over the sustainability of the program as the lab structure depends on external funding, particularly in human resource.

Responses to engagement of KI's by the partner varied with some individuals indicating they had little engagement or their engagement was primarily through the embedded mentors. Differences in level of engagement may be also reflective of the KI's position and duties.

7.6 Actionable Items

Recognizing that this is an end-term evaluation, the report provides short-list of actionable items to consider that may inform future implementation strategies.

- *Finalization of 5-year National Laboratory Strategic Plan:* Ensure key strategies and approaches are documented and in alignment with future implementation plans through finalization of a current 5-year strategic plan

- *Budget and funding gaps:* While this may be unavoidable, programs should maintain an awareness of potential budgetary gaps that may negatively impact program performance and where possible take proactive steps to mitigate. There were several instances noted in the program where the partner was able to proactively address critical gaps through monitoring and awareness of the issue.

- *Engagement of stakeholders:* Several instances were noted during the evaluation where staff contributing to dashboards (eVL Dashboard) or databases (eQuip) had limited knowledge or engagement as the project developed other than being asked to contribute data. Stakeholders having a more complete understanding and awareness may provide additional insights into the design and use of the tool.

- *Standard Operating Procedures:* Development of SOPs is a key step in routinizing a procedure or process to achieve standardization and harmonization of approaches particularly for laboratory programs. While in most SOPs we observed contained effective dates, adherence to version control procedures and documentation of training on the SOP will help ensure that all staff are trained and operating under the same procedure.

- *Robust Data Analyses:* To further understand how strengthening HIV /TB Laboratory Quality Management Systems and Services has improved the performance of the laboratories and other facilities, additional analyses examining trends in output variables such as equipment downtime, specimen rejection rates, reagent stockouts and their relationship with testing performance e.g. TAT. To facilitate this analysis, laboratory data should be collected at the facility level and not aggregated across laboratories to better understand the performance of individual labs or groups of laboratories with similar characteristics.

8.0 Dissemination Plan and Use of Data

The evaluation report was shared with the CDC Eswatini and ICAP Eswatini offices throughout the drafting process. The final report will also be shared with key stakeholders and will be made publicly available on CDC Stacks within 90 days of completion. CDC Eswatini will use the preliminary findings to inform partner management and to plan for future programming. ICAP Eswatini will utilize this report, in addition to a dissemination meeting, to improve their activities and resolve some of the outstanding activities that have yet to be completed.

9.0 Evaluation Budget and Timeline

CoAg funds totaling $2400 were requested for the evaluation. Upon completion of the evaluation, the total cost of the evaluation was estimated to be $2534 from the CoAg funding. CDC HQ evaluation staff salaries and travel costs to conduct the evaluation was provided in kind from CDC DGHT HQ. Please contact the DGHT intramural financial unit for further information. The Gantt chart below highlights the key activities and timeline for this evaluation.

Table 9: Project Workplan

Activities	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July
Project Team Calls											
Desk Review											
In-Country Evaluation											
Transcription											
Qualitative Analysis											
Quantitative Analysis											
Report Writing											
Report Finalization and Clearance											
Report Dissemination											

10.0 Appendices

Table 10: Appendices

Appx #	Appx Title	Description	Attachment
Protocol Appx I	KII Informed Consent form	Informed consent for key informant interviews	Appendix I Informed Consent F
Protocol Appx K	Conflict of Interest Form	Evaluator conflict of interested form	Appendix K Conflict of Interest Form.pdf
Protocol Appendix C	Protocol Appx C: MER Indicator Table	Data Collection Tool	Appendix C MER Indicators.pdf
Protocol Appendix D	Protocol Appx D: Non-MER Indicator Table	Data Collection Tool	Appendix D Non-MER Indicators
Protocol Appendix F	Protocol Appx F: Key Informant Interview Guide	Data Collection Tool	Appendix F Key informant interview
Protocol Appendix G	Protocol Appx G: Data collection tool for observation of workflow processes	Data Collection Tool	Appendix G Data collection tool for o

Appendix 1	Appendix 1: List of Desk Review Materials	Listing of documents reviewed as part of desk review	Appendix 1_List of Desk Review Materi
Appendix 2	Appendix 2: Summary Activity Completeness Tables	Completeness status summary tables for all objectives	Appendix 2_Summary Activity (
Appendix 3	Appendix 3: SLIPTA Star Scoring	Overview of SLIPTA scoring system	Appendix 3_SLIPTA Star scoring_July 20
Appendix 4	Appendix 4: Lab Indicator Results	MER & non-MER Lab results for FY16-FY19	Appendix 4_Lab PT Results.docx
Appendix 5	Appendix 5: NSTS Routes	Specimen pick times, routes for lab network	Appendix 5_ NSTS Routes.docx
Appendix 6	Appendix 6: Trends in TAT	Trend plots for TAT	Appendix 6_Trends in Turn Around Time
Appendix 7	Appendix 7: Trends in Testing Volumes	Trend plots for testing volumes	Appendix 7_Trends in Testing volumes.c
Appendix 8	Appendix 8: Clinical Cascade Table	Additional cascade data	Appendix 8_Clinical Cascade tables.docx
Appendix 9	Appendix 9: EHLS Viral Load Dashboard	Description and screenshot of viral load dashboard	Appendix 9_EHLS Viral Load Dashboar

11.0 References

Please see Appendix 1, list of Desk Review materials.