Supporting HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under PEPFAR

Annual Performance Report for cooperative agreement number

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African Field Epidemiology Network (AFENET) and do not necessarily reflect the views of CDC or of the United States Government.

Acronyms

AFENET	African Field Epidemiology Network
AIC	African Inland Church
CD4	Cluster of Differentiation 4
CDC	Centers for Disease Control and Prevention
DBS	Dry Blood Spot
DH	District Hospital
DNA	Deoxyribose Nucleic Acid
DTS	Dried Tube Specimen
ECHO	Extension of Community Health Outcomes
EID	Early Infant Diagnosis
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
FELTP	Field Epidemiology and Laboratory Training Programme
HEID	Health Center IV
HIV	Human Immunodeficiency Virus
MoH	Ministry of Health
NHRL	National HIV Reference Laboratory
PEPFAR	President's Emergency Plan For AIDS Relief
PMTCT	Prevention of Mother To Child Transmission
PT	Proficiency Testing
QMS	Quality Management System
RTCQI	HIV Rapid Test Continuous Quality Improvement
SLMTA	Strengthening Laboratory Management Toward Accreditation
SLIPTA	Stepwise Laboratory (Quality) Improvement Process Towards Accreditation
UVRI	Uganda Virus Research Institute

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Executive Summary

The African Field Epidemiology Network (AFENET) through its AFENET-Lab initiative received funding from the Centers for Disease Control and Prevention (CDC) in March 2018 to support HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under PEPFAR. From October 2019 to September 2020, AFENET has implemented a number of laboratory-strengthening activities in selected African countries, Four Caribbean region countries and Dominican Republic in collaboration with Centers for Disease Control and Prevention (CDC) and National Ministries of Health. Laboratory strengthening activities implemented include:

1. Laboratory Partnerships to Support the Diagnosis, Treatment and Management of PLHIV and TB through development of an electronic tracking tool for ancillary equipment.
2. Provide Technical support in the Caribbean region to strengthen laboratories in four countries, Guyana, Jamaica, Barbados and Trinidad and Tobago. Areas of focus include; viral load (VL) scale-up; training in waste management and purchase of consumables; support the expansion of LIS Jamaica; provide VL diagnostics support through quality Improvement activities for HIV Rapid Test Quality Improvement Initiative (RTQII) and quality systems strengthening
3. To provide Technical Assistance (TA) to the PEPFAR supported sites to achieve the 3rd 90 of the cascade and support the implementation of Recency Testing in 23 PEPFAR-supported sites, to enhance and guide HIV index testing activities.
4. Support strengthening of laboratory Management Towards Accreditation
5. Support Quality Improvement activities for HIV Rapid Test Quality Improvement Initiative (RTQII)
6. Facilitating implementation of continuous quality improvement initiatives for TB diagnostics.
7. Facilitating Project ECHO sessions to ensure the Quality of Rapid Test and other Point of Care Diagnostics in Uganda, Malawi and Tanzania

This report describes activities carried out under this program for the period October 2019 to April 2020. AFENET registered several achievements under the various funded scopes of work as highlighted in the scope specific report.

Reports are presented by region, scope of work, highlighting activities, achievements, challenges encountered, solutions, best practices, lessons learned and recommendations.

SECTION I: CURRENT BUDGET PERIOD PROGRESS

Caribbean region

AFENET through funding from CDC provided technical assistance to four countries, Guyana, Jamaica, Barbados and Trinidad and Tobago. Activities were aimed at building laboratory capacity in PEPFAR-supported sites in the region. The main areas of focus for this period-included building laboratory capacity for viral load (VL) scale-up, technical assistance to Viral Load test sites, training in waste management and purchase of consumables. The program continued to address challenges with access to VL results and supported expansion of LIS in selected sites in the Jamaica.

Additionally, the Laboratory Strengthening Program (LSP) provided VL diagnostics support through quality Improvement activities through HIV Rapid Test Quality Improvement Initiative (RTQII) and quality systems strengthening to reference laboratories as they work towards accreditation. The following report outlines a summary of achievements and activities conducted from October 2019 to April 2020.

Planned activities:

1. Recruitment of staff to oversee implementation of all planned activities (One Regional Technical coordinator, HIV Viral load network coordinator, Laboratory Information systems manager, Quality management systems mentor and technical mentor)
2. Support implementation of Quality management systems and accreditation of selected laboratories in Jamaica, Barbados, Trinidad and Guyana

3. Support HIV Viral Load scale up efforts through conducting assessments using the CDC VL scorecard, procurement of HIV VL testing consumables, development of an HIV Viral load dashboard.
4. Support HIV rapid testing continuous quality improvement initiatives and External Quality assurance.
5. Support HIV Drug resistance activities and surveillance in Jamaica and Barbados.
6. Facilitate implementation of HIV Recency testing in Jamaica, Guyana, Barbados, and Trinidad.
7. Facilitate expansion of the Laboratory Information Management System to more laboratories in Jamaica.

LABORATORY INFORMATION SYSTEM EXPANSION

One of the goals of the PEPFAR program for the reporting period was to increase access to Viral Load test results in Jamaica and plans were developed for the expansion of the laboratory information system to the Western Regional Health Authority (WRHA) of the island. There was a request to switch to Bika Open Source system from DISA LAB. This system is more affordable and is able to integrate with equipment. The LIS implementation plans in Jamaica were updated to collaborate with the LIS implementation team in Trinidad, to gain expertise and capabilities to implement the system in PEPFAR sites in Jamaica. By the end of March 2020, a Consultant was recruited and plans are underway to develop the work plan and implementation of the project.

VIRAL LOAD SCALE-UP

Viral Load strengthening activities were conducted in Guyana and Jamaica. The Viral Load Network Coordinator (VLC) visited sites in Jamaica and conducted assessments on the Viral Load network. Deficiencies identified were documented and trainings performed in some of the sites. These training covered sample preparation, use of centrifuge and conducted competency evaluation in specimen preparation techniques. HIV Viral load testing supplies were procured for testing sites and these included cryo- vials, blood collection and safety supplies.

Appendix 2a outlines achievements accomplished during this period and recommendations to mitigate the challenges. However, the key achievements are listed below.

Key Achievements

1. Assessed CD4 and VL sample management. This was conducted at four (4) sites; Comprehensive Health Centre (CHC), CHARES, Kingston Public Hospital (KPH) and Mandeville Comprehensive Clinic.
2. Procedures were developed and drafted for procurement and inventory management and shared with Mandeville Comprehensive Clinic.
3. Training on specimen preparation and inventory

- Conducted refresher training on plasma preparation with one staff at CHARES.
- Prepared training/presentation on safety and waste management. The training addressed the increase in the volume of waste in the laboratory due in part to the scale-up of VL and EID testing.
- Trained three persons at the Mandeville Comprehensive Clinic on procurement and inventory management. The training was to address the challenge of stock out of items previously experienced at the health facility.

4. Data Collection using the VL scorecard and QMT tool

- Used the CDC VL scorecard QMT to collect data on VL and EID testing at the NPHL, Jamaica and Mandeville Comprehensive Clinic for the period October to December 2019. The data provided VL suppression rates for each site and was useful in identifying gaps at the testing site such as samples rejection rates and machine downtime.
- Collected data on CD4, VL and EID testing at the NPHRL, Guyana for the year 2019. The data outlined the number of tests for the year, percentage VL suppressions by sites, positive EIDs, sample rejection rates and reason and challenges with equipment downtime and reagent stock outs.
- Distributed supplies to support VL plasma preparation to NPHL Jamaica and May Pen Health Centre: These included; 1500 cryo vials, 1 centrifuge, 4 sharps containers, and 500 transfer pipettes.

Challenges

The main challenges to conducting the activities throughout the period were: Unavailability of staff at the sites and Confirmation of COVID-19 cases in Jamaica and Guyana.

Laboratory Accreditation and LQMS-SIP Assessments

St. Ann's Bay Hospital Laboratory (SAB) and Trinidad Public Health Laboratory (TPHL) were scheduled to undergo an accreditation assessment by the Jamaica National Agency for Accreditation (JANAAC) in March 2020. However, all these assessments were rescheduled due the current COVID 19 pandemic. The new schedules are as shown below in Table 2.

Table 2: Planned Accreditation and LQMS-SIP Assessment Schedule

Assessment	Laboratory	New Date
Accreditation Assessment by JANAAC	St. Ann's Bay Hospital Laboratory (SAB)	TBD
	Trinidad Public Health Laboratory (TPHL)	June 8, 2020

External Quality Assurance (EQA)

The contract for proficiency tests (external quality assurance) was finalized with One World Accuracy (OWA). Panels were procured for seven countries in the region, Bahamas, Barbados, Trinidad and Tobago, Jamaica, Antigua, St. Lucia and Dominica. The first set of panels for 2020 was distributed to the regional sites. However, discrepancies were noted in two countries. In Barbados, two panels were received with the contents leaked out. The incident was reported to One World Accuracy (OWA) and the necessary adjustments were made. In addition, one site in Jamaica did not receive one of the panels that was anticipated. This is being investigated. Additional panels were approved for the Trinidad Public Health Laboratory in a needs assessment meeting with the team. A quote was requested from OWA and this is pending. Results from these panels will be reported in Quarter 3 report.

Mentorship activities in Jamaica, Trinidad and Guyana

Mentorship support was provided to six laboratories in Trinidad, Jamaica and Guyana during which the laboratories were evaluated cyclically and the findings used to guide subsequent mentorship activities. The Mentors supported each laboratory's efforts to close gaps identified in the LQMS-SIP reports. Site visits were cancelled in March 2020 due the COVID-19 pandemic. Table 3 below lists the travel performed by the Technical Mentor during this year.

Table 3: Cancelled Mentorship Travel

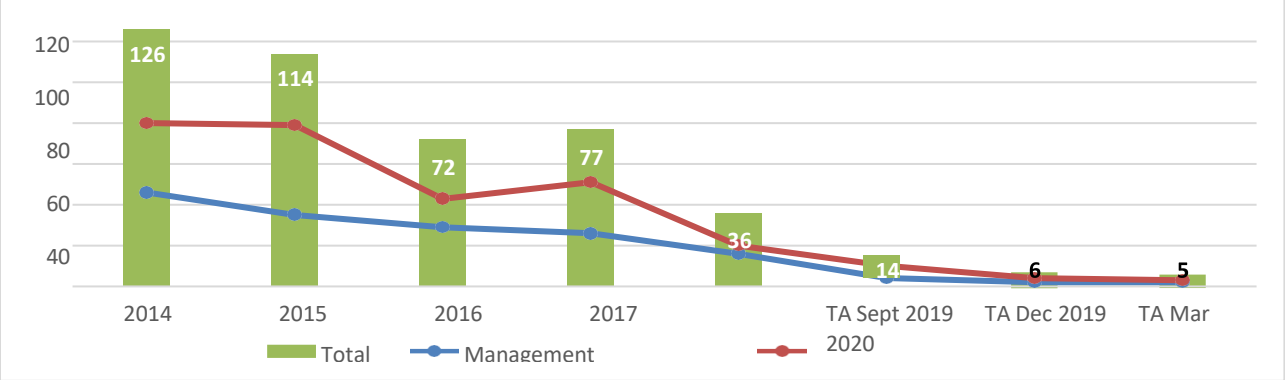
Month	Travel From	Travel To	Departure Date	Mentor
March	Jamaica	Guyana	March 1 - 6, 2020	Kerine Hay
March	Jamaica	Jamaica (SAB)	March 11 - 15, 2020	Kerine Hay
March	Jamaica	Jamaica (CRH)	March 17 - 21, 2020	Kerine Hay
March	Jamaica	Trinidad and Tobago	March 22 - 27	Janet Neil

JAMAICA

Mentorship St. Ann's Bay Hospital Laboratory (SAB)

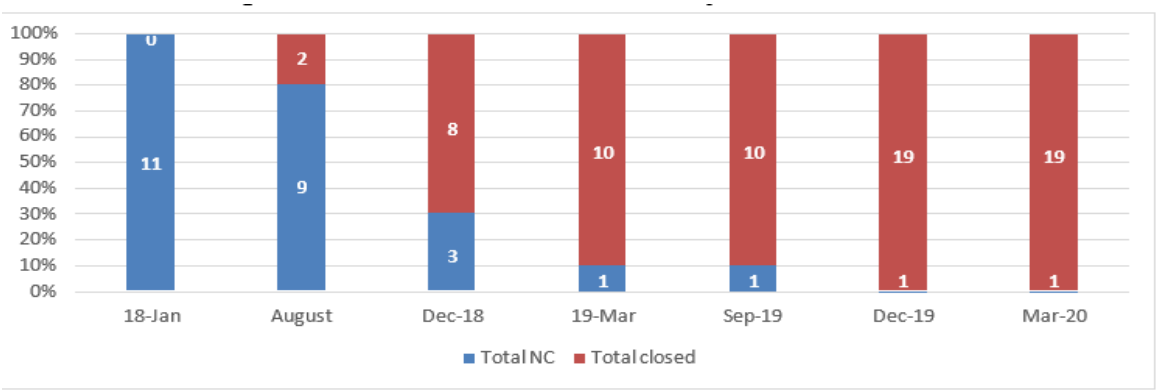
The St. Ann's Bay Hospital has been a part of the PEPFAR mentorship program since 2013 and has made significant progress since their initiation to the Laboratory Strengthening program. The goals outlined for this site have successfully been addressed. The nonconformities reduced from 36 nonconformities in 2019 to five (5) in March 2020. This stems from two (2) management and three (3) technical nonconformities. The number of nonconformities closed has decreased significantly with mentorship activities as illustrated in Figure 1.

Figure 1: St. Ann's Bay Hospital Laboratory LQMS-SIP Quality Improvement Trends



The laboratory continues to display competency in several areas, while a few still need mentorship support. The closure of nonconformities has slowed as the team tries to address the nonconformities that require significant investment of resources. The nonconformity closure trend is illustrated in Figure 2.

Figure 2: Status of the SABHL Safety Nonconformities



Resources have been made available to address the structural upgrade of the laboratory and this is scheduled to commence in quarter three. A comprehensive list of the goals and accomplishments is outlined in **Appendix 3**.

Key Achievements

1. Training: Staff document training and sensitization are complete for 3/5 departments (Haematology, Chemistry and Specimen reception)
2. Installation of records: a) Corrective action reports installed (JANAAC document review CA log, CA Logs for assessments and safety), b) Internal audits completed and report prepared, c) Risk assessments reviewed and updated. d) User feedback reports reviewed and finalized, and e) Master list of management documents was updated.
3. Safety Improvement initiatives implemented: a) A safety report was developed and submitted to the team for recording. b) Safety devices and documents were installed. c) Disaster plan for the laboratory updated and reviewed with In-Lab Quality Manager. d) First Aid Safety training was conducted (in-house) and e) The Management review meeting was conducted on February 17, 2020 and many of the activities are actively being addressed and await management approval. Additional staff hired to work in key sites of the hospital.

Best Practices

The utilization of detailed action plans that are specific for team members has proven to be very effective for SAB team. The action plans are updated to show accomplishments for the prior periods.

Challenges

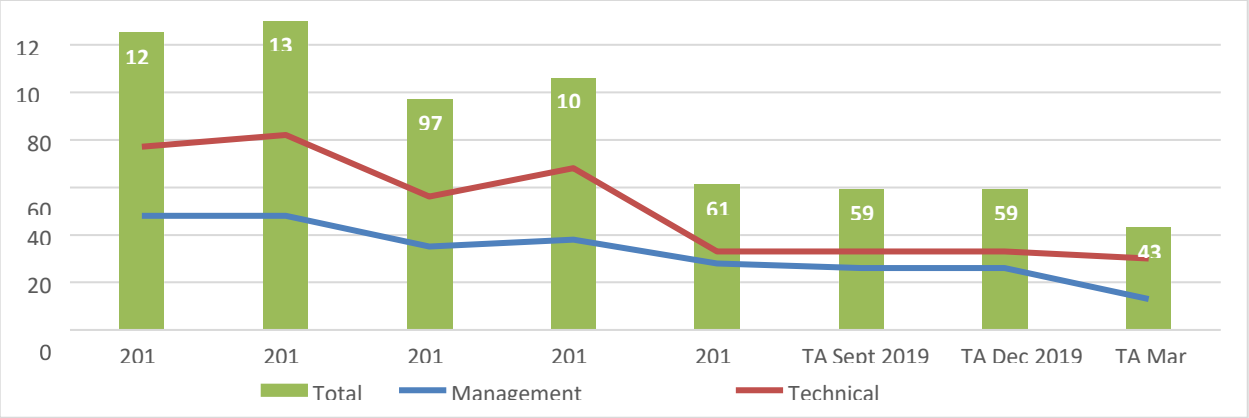
The corrective action process still requires close monitoring. The laboratory is consistently documenting nonconformities, but not diligent in recording corrective actions taken. The management of SAB is slow in addressing the needs of the laboratory. In addition, the low staffing does not allow for an efficient testing system and affect the quality activities required for the lab.

Mentorship at Cornwall Regional Hospital Laboratory (CRHL)

Three mentorship visits were conducted during the reporting period, Mentors worked with staff to address their nonconformities within the departments and with the Quality and Safety officers.

A number of procedures and documents were reviewed and drafted during this period; they are listed in **Appendix 1**. The safety manual was reviewed and records to address the safety requirement are now in use. The risk assessments are 75% complete and patient surveys were distributed. In addition, competencies for routines were completed for most departments and plans are in place for competencies for emergency personnel. Training was conducted to develop two inventory documents and specimen labelling procedures, verification records were implemented for thermometers and pipettes as well. The nonconformities and closures noted are illustrated below in Figure 3 and the goals archived are outlined in Appendix 4.

Figure 3: CRHL Laboratory LQMS-SIP Quality Improvement Trends



Key Achievements

a. Training

- Presentation on the LQMS SIP results was performed in a quality meeting with twenty-one (21) staff.
- Seven staff (7) participated in training exercise for two Inventory procedures (Inventory Management and Reagent Use and Maintenance). Three (3) staff were trained in Specimen Labelling Requirements.

b. Installation of Records

- Eight (8) procedures were reviewed: Hematology (5) and the Quality Manager (3) and Chemistry (2).
- Installation of all records of pipettes and thermometers verification for 2019; Completed patient survey report (clinician data still outstanding) and review of referral laboratories.
- Quality reports of activities to close nonconformities were prepared and submitted to the team after each visit.

c. Competency

Chemistry competency for routine staff is complete (6/6) 100% and competency for emergency staff is 54% complete (7/13). In Hematology 55% (5/9) of competencies drafted for routine staff.

Best Practices/Recommendations

The use of the ISO 15189 and 15190 standard when working with the laboratory has contributed to the increased understanding and competence of personnel that is now being seen. The laboratory-led internal audit exercise demonstrates this.

Challenges

Management support at CRH team needs strengthening. The lab has not implemented a management review meeting and they have limited quality meetings.

TRINIDAD

Trinidad Public Health Laboratory

All the management activities planned for this period were addressed out of which three were closed; these include the Staff and User Feedback, Risk Assessments, and Corrective actions process. The other areas of quality indicator report, risk assessments and internal audits were partially (50%) addressed. This resulted in six (6) management nonconformities being closed as illustrated in Figure 4. Progress was made towards completion of planned technical activities with the exception of the management review meeting.

In the technical area, nine (9) of the ten (10) outstanding NCs were closed. This represents 37 of the 38 NCs cited in the 2019 LQMS-SIP assessment closed for the technical requirements. All the technical activities were successfully addressed except the completion of the personnel records. The Safety nonconformity trends are illustrated in Figure 5. Additionally, all NCs for the JANAAC Document review are now closed. The seven open NCs from the review were closed in the second quarter. The laboratory also worked to implement the BIKA Senaite LIS and this was partially completed at the end of this period. **Appendix 5** outlines the goals achieved and the challenges experience in more detail.

Figure 4: TPHL Laboratory LQMS-SIP Quality Improvement Trends

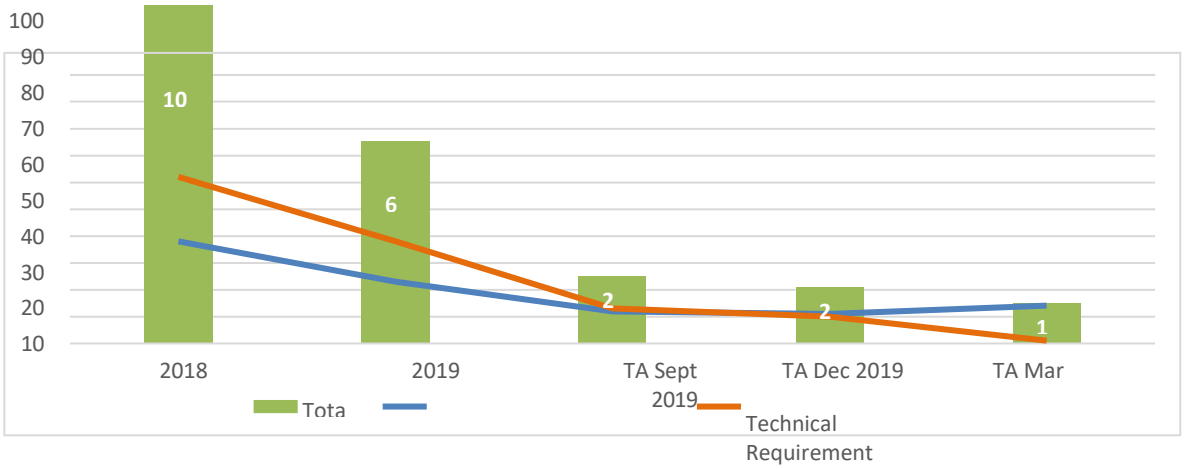
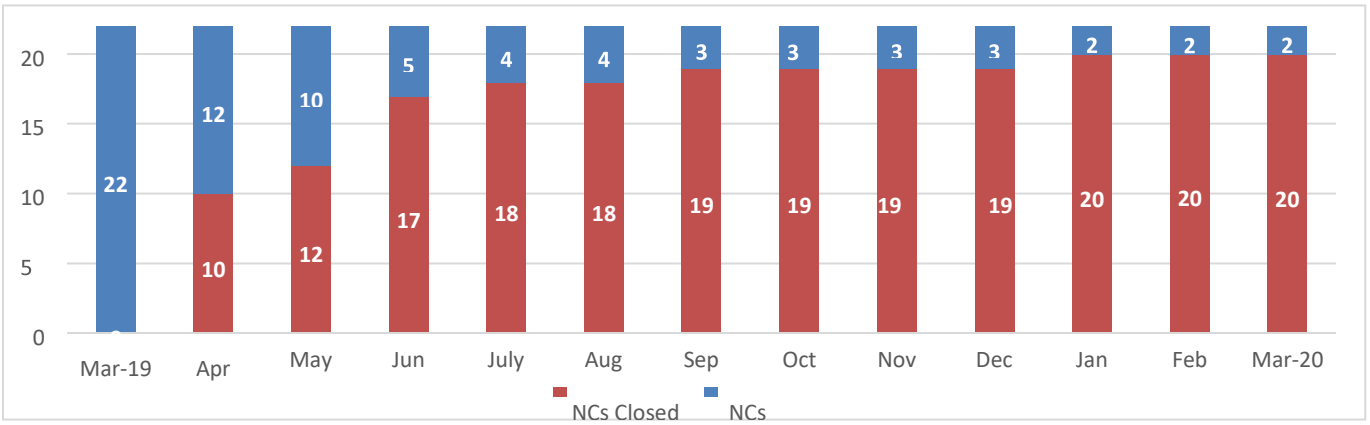


Figure 5: Status of the TPHL Safety Nonconformities



Pipette calibration services was provided and the CDC team is working with the MOHW to support Test supplies in HIV and Bacteriology to expedite closure of the JANAAC nonconformities. In order to bolster the QMS system, binders to organize their documents, a laptop and external storage device are to be procured for the site.

Key Achievements

1. Nine of the 10 outstanding technical NCs were closed. This means that 37 of the 38 NCs cited were closed for the technical requirements.
2. One NC was closed, resulting in 20 of 22 safety NCs closed.

3. Expired fire extinguishers were replaced.
4. All NCs closed from Document review. The seven remaining NCs were closed the second quarter.
5. Partial implementation of the Senaite LIS.

Challenges

1. Personal issues within the quality team have resulted in delays in the completion of activities. To try to address this, more than one (1) person was assigned to work on a task at any time. Smaller teamwork consisted of at least one (1) member of staff who previously demonstrated commitment to the process despite the challenging circumstances.
2. Stock-out of reagent, which has affected the testing of HIV.

Best Practices/Recommendations

Providing assistance with creating reports has helped TPHL laboratory towards the closure of some of the existing gaps. TPHL uses a team approach to all management and safety-related activities. The team continues to be informed and included in electronic mail correspondence, but targeted support will continue to be given to those persons that demonstrate the commitment to completion of activities

Port Of Spain General Laboratory (POS)

The activities with this laboratory are slow and not as productive as desired. In the past seven (7) month period, nonconformities were not addressed. However, for the management requirement, the internal audits for 2019, referral laboratory and supplier evaluations were completed. The management review meeting was not accomplished as planned. As a result, the laboratory was able to close seventeen (17) of the thirty-two (32) gaps identified in the management requirement in the LQMS-SIP assessment (see Figure 6) and a detailed outline is provided in **Appendix 6.**

For the technical requirement, focus was directed to activities in the chemistry and microbiology departments. The Manager indicated that laboratory staff shortage, shortfall in supplies and demands to address other activities are hindrances to addressing the quality and safety task. An internal audit was conducted in the

Microbiology Department and two nonconformities were closed. There were no improvements in the safety objectives during this period as illustrated in Figure 7.

Figure 6: POS Laboratory LQMS-SIP Quality Improvement Trends.

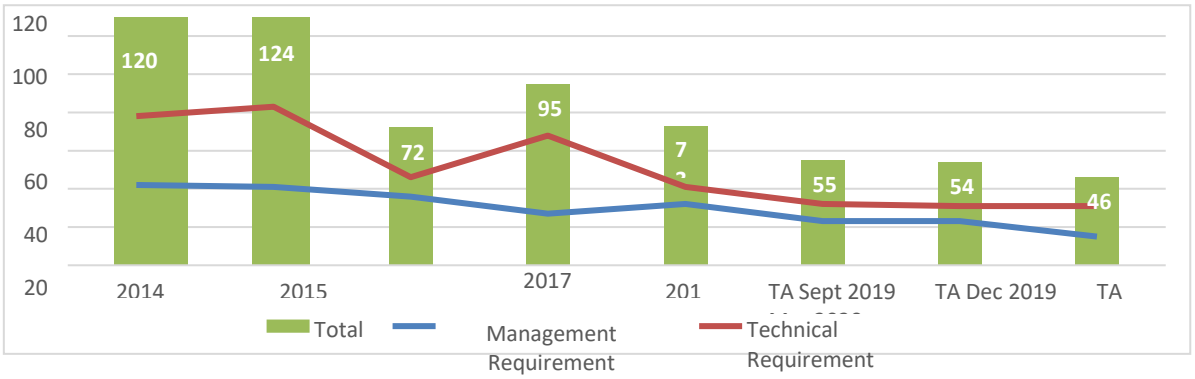
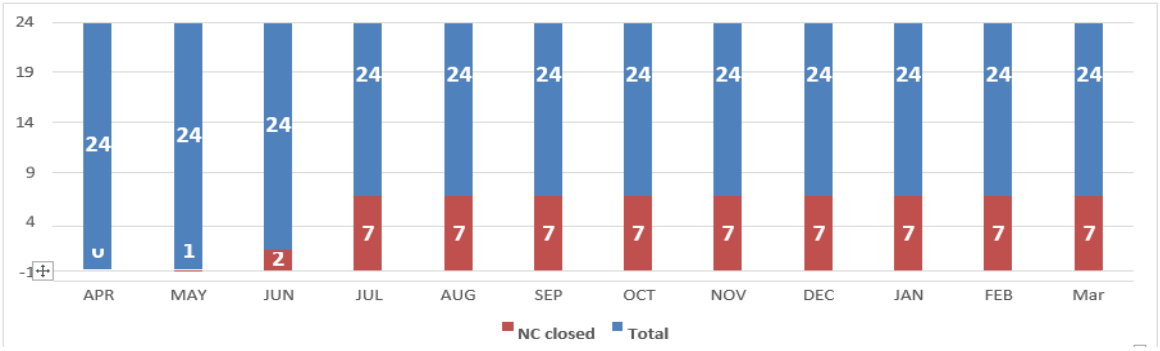


Figure 7: Status of the POS Safety Nonconformities



Challenges

1. There is no person assigned as Quality Manager and there is a lack of commitment to address the quality and safety initiatives. There are no QMS meetings in place despite a framework and schedule for the hosting of meetings. Therefore, dissemination of information to the departments does not occur on a regular basis.
2. The Laboratory staff are currently operating with half the staff complement. In March 2020, a positive case of COVID-19 was confirmed at the health facility. This resulted in the quarantining of the staff from Microbiology, Immunology and the Lab Manager.

GUYANA

Mentorship at National Public Health Regional Laboratory (NPHRL)

Scheduling and monitoring of activities with NPHRL has been challenging and there has been little progress over the year and no achievement was realized in the second quarter (Figures 8 and 9). The lab team at NPHRL requested that the quarterly visit be suspended and scheduled for March- April 2020 but this was disrupted by the COVID crisis. Figure 8 shows the status of progress at this lab.

The AFENET team will keep engaging with NPHRL lab management team to ensure that all gaps are closed out and reported in quarter three report.

Figure 8: NPHRL Laboratory LQMS-SIP Quality Improvement Trends

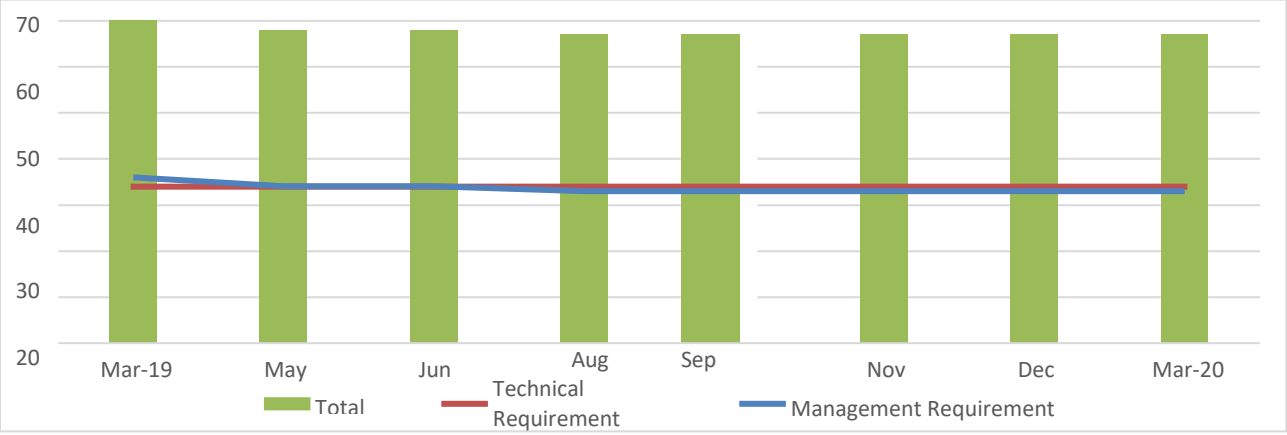
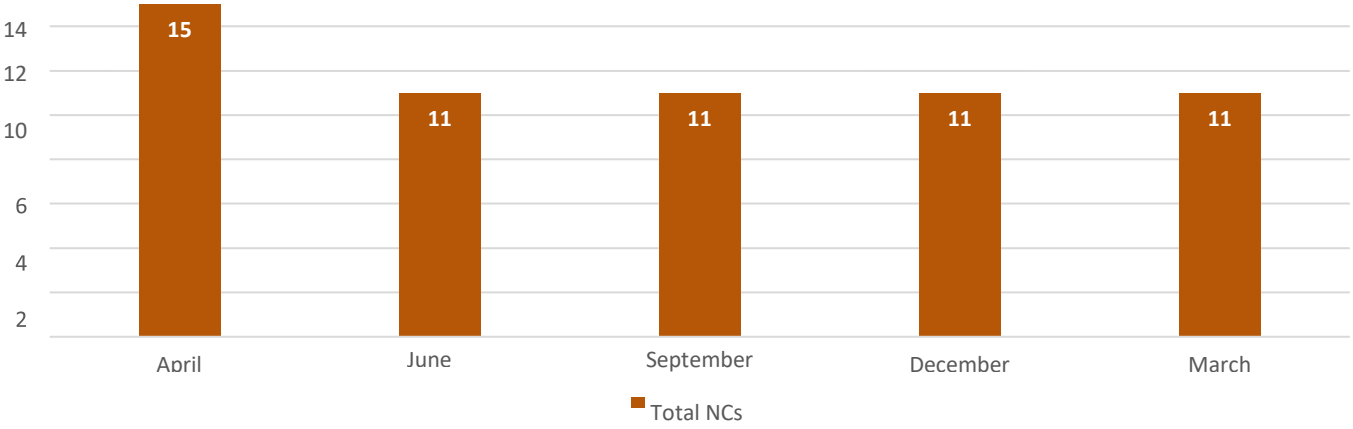


Figure 9: Status of the NPHRL Safety Nonconformities



Best Practices/Recommendations

The laboratory should be required to demonstrate some tangible sign of commitment to the process so that resources are utilized.

Challenges

The most significant challenge is the lack of communication and coordination between the management and the staff of the laboratory, which has greatly affected the rate at which documents are shared for review and closing out of non-conformities. Currently the Quality Manager has been relieved from her duties and there is no staff member assigned to assume this role.

Contractual activities through GLESSN

AFENET engaged the services of GLESSN to implement LQMS SIP assessments and RTQII strengthening activities to ensure increased access to high quality laboratory services, which efficiently support the HIV care and treatment programs in Jamaica, Trinidad and Tobago, Barbados and Guyana. AFENET and GLESSN agreed to a contract in February 2020. The main goal of this partnership is to achieve epidemic control while reinforcing sustainability and country ownership through:

1. Development and implementation of appropriate Quality Management Systems and International laboratory standards in supported laboratories to achieve accreditation.
2. Increased capacity of laboratories to provide timely and reliable results to ensure appropriate clinical decision making and improved treatment and care of patients infected with HIV and opportunistic infections.

a) LQMS SIP assessments

Assessments were organized and confirmed to be conducted in four (4) laboratories, one in each of the following countries; Trinidad & Tobago, Guyana, Barbados and Jamaica. Due to the different border restrictions and country guidelines, the visits had to be rescheduled. New dates have been set for the month of May 2020; however, these are to be confirmed pending the prevailing conditions at that time. See table 4 below:

Table 4: Rescheduled LQMSIP assessments

Previous Dates	Laboratory	New dates
March 16th to 17th, 2020	Port Of Spain General Hospital, Trinidad	TBD
March 23th to 24th, 2020	National Public Health Reference Laboratory, Guyana	TBD
March 26th to 27th, 2020	Best Dos Santos Public Health Reference lab, Barbados	TBD
March 30th to 31st, 2020	Cornwall Regional Hospital Laboratory, Jamaica	TBD

b) Laboratory consumables equipment and supplies

Through GLESSN, procurement of supplies and equipment calibration support was provided to different laboratories in Jamaica, Guyana, Trinidad and Tobago as shown in tale 5 below:

Table 5: List of Activities Performed by GLESSN

Activities	Comments
Support purchase of General Lab Supplies	The items to be procured for Port of Spain and Trinidad Public Health Laboratory were identified and submitted to GLESSN. Rapid Test Kits were procured for Guyana.
Support Equipment Calibration Services	Calibration services were initiated in Jamaica and Trinidad. During this period, Balance and Pipette calibration services were procured for Trinidad and arrangements are in place to complete activities in Jamaica.

c) RTQII Activities

Despite challenges experienced in getting the sites to agree to visits especially in Jamaica and Trinidad & Tobago, the Q Corps in Jamaica and Guyana were able to continue their on-site visits to the testing sites as a part of routine activities. The Q Corp in Trinidad contacted the sites remotely. Specific challenges encountered were:

RTQII Guyana

1) Testing personnel in most sites were not documenting testing quality elements accurately in the logbook

2) EQA and Quality Control testing was not accurately recorded and reviewed in the logbook.
3) Absence of country guidelines at testing sites.
4) No process for an alternative HIV testing algorithm

RTQII Jamaica

1) The Quality Assurance Coordinator at the National Public Health Laboratory/Reference Lab needs to be included in the implementing of standardized training curriculum and to be more involved to streamline competency at all sites and give closer monitoring to the CHARES site.
2) There is a lack of standardized training and the absence of competency records
3) All testing personnel need to complete an HIV testing refresher course
4) Absence of a system for certification and recertification
5) Need for HIV RTQII Program support and HIV Rapid Test Training and Refresher course
6) Need for standardization of the Rapid Testing algorithms used at all testing sites.

d) ePT Programme

The ePT consultant conducted two training sessions with PT administrators. One session was conducted on 31 January 2020 with the administrators from Trinidad and Tobago. A second session was held on 5 February with Administrators from Jamaica, Barbados, Guyana and Trinidad & Tobago. The sessions covered an explanation of ePT, advantages for the participants and steps for submitting PT results

Equipment Maintenance

Under this scope of work, the following activities were planned to be implemented in collaboration with respective Ministries of Health, Pan African Consortium (PAC) and local implementing partners:

1. Engage a consultant in partnership with PAC to develop an electronic tool for monitoring and tracking of equipment maintenance and calibration of ancillary equipment in viral load laboratories in Nigeria, Cameroon, and other PEPFAR-supported countries
2. Operationalize the equipment maintenance and calibration electronic monitoring tool in selected countries

3. Provide training and capacity building of laboratorians on the use of the etool
4. Coordinate with partners to update and collate data from equipment assessments for incorporation into the electronic tool

Achievements:

1. Scope of work for the consultant was developed. A consultant was recruited under PAC to develop the electronic tool for monitoring and tracking of maintenance and calibration of ancillary equipment in viral load laboratories. AFENET will support the operationalization of this electronic tool once the consultant has finalized its development.
2. Weekly conference calls and team of Information technology experts was set up to work with the consultant in the development of the electronic equipment maintenance tool. A team of Information Technology officers were part of these conference calls and made contributions to guide its development.

Challenges

1. Long approval processes in accessing previous data that had been collected in Nigeria and Cameroon have greatly affected the timelines of finalizing the electronic data tool. This has also affected the timelines for AFENET to begin its operationalization.

TB Diagnostic Test Continuous Quality Improvement (CQI)

Under this scope, the following activities were planned to be implemented:

1. Extend the Electronic Proficiency Testing (ePT) system for evaluating the quality of testing for tuberculosis using GeneXpert diagnostic instruments.
2. Use of an electronic meeting and tele-mentoring platform (ECHO) to rapidly, efficiently and economically improve the interface between HIV treatment clinics and tuberculosis diagnostic laboratories

Achievements

1) Electronic Proficiency Testing (ePT) system for evaluating the quality of testing for tuberculosis using GeneXpert diagnostic instruments.

AFENET was able to continue supporting System one to; a) maintain and update the electronic Performance Evaluation Platform for GeneXpert MTB/RIF Sample Processing and b)Addition of Cepheid Ultra, General Maintenance & Enhancements to Existing Performance Evaluation Platform The ePT plaform is for evaluating the quality of testing for tuberculosis using GeneXpert diagnostic instruments.

SystemOne was engaged by AFENET to complete and make upgrades to the electronic Proficiency Testing (ePT) system for evaluating the quality of testing for tuberculosis using GeneXpert diagnostic instruments. This platform allows participants to submit their results from performance evaluation panels sent to them by CDC in Atlanta.

Delivery progress

I. Genexpert ultra submissions

Changes to the web platform, Android and iOS mobile app are complete and running in the live ePT environment. Users can toggle between GeneXpert MTB/RIF and GeneXpert Ultra assays on their submission for which automatically changes labels and MTB Detected options.

Participant summary reports contain two separate sections so that submissions between MTB/RIF tests and MTB/RIF Ultra tests can be evaluated individually.

II. General system maintenance and web hosting

Several user interface enhancements and security changes have been requested during the course of this project, namely:

- Default response date should be set to current date in submission edit screen: **Compete**
- Actual date that the panel was submitted should be recorded and included in panel export report: **Compete**
- Ensuring consistency of the order of samples in each submission across the application: **Compete**
- Supervisor review filed to be made mandatory for submissions: **Compete**
- XMPEP reports should include a list of participants that submitted incorrect results as well as an extract of the full data export for easier referencing. **In Progress**

III. 2019-A Panel

A panel was sent to 958 participants in December 2019. The deadline for submission on the 2019-A panel was 14 February 2020.

- 765 participants indicated that they received the panel and
- 906 participants submitted a response to the panel (94.57% response rate)
- 588 participants scored higher than 80%

IV. XMPEP indicators reports

The following XMPEP Indicators reports for ePT Administrators were requested; these have been built, and separated into MTB/RIF submissions and MTB/Rif Ultra submissions.

- Longitudinal analysis of site's performance over time
- Participants that scored less than 100% but passed, Participants that failed
- Corrective action report

V. Bulk update of participant &PECC details

It was requested that PECC and participant profile data be editable through bulk update by uploading an excel spreadsheet template. After several discussions on how participant data should be updated and toggled between active and inactive states, the following was decided;

- Participants that exist on the system but not in the upload will remain untouched.
- A flagging field to activate/disable a participant will be included in the upload template.
- PECC profiles will be uploaded as a separate template.
- When enrolling an entire country into a panel, inactive participants will be omitted.

This feature development is complete and is currently in testing.

2) TB ECHO-CLICQ

The ultimate goal of this ECHO-CLICQ project is to make HIV clinic and TB laboratory interfaces as efficient and productive as possible. The objective for use of ECHO in the project is Facilitate the expansion of CLICQ to a larger number of clinic-lab sites in a sustainable manner at a lower cost.

A Stepwise Cohort Model will be utilized in implementation of this project; DICE assessments will be performed at 10 sites, 5 serve control sites (only receive DiCE assessment results), the remaining 5 receive DiCE assessment results and participate CLiCQ! training and ECHO sessions

- At the conclusion of the project, all 10 sites are to be evaluated (to isolate impact of the full CLiCQ! /ECHO project vs DiCE assessment alone.
- The control arm then participates fully in the second round of CLiCQ!/ECHO

Achievements:

1) Finalized selection of the host country (Uganda). The host country was selected based on the need (high HIV and TB burden), availability of PEPFAR MER data (expected TB cases versus number in treatment) and Capacity (existing PEPFAR and AFENET support)

Challenges:

1) There have been delays in approving the scope of work for this mechanism and this has greatly implementation of activities as earlier planned.

Strengthening Laboratory Management Towards Accreditation

Before SLMTA was launched, no government clinical laboratory in sub-Saharan Africa (SSA) outside of South Africa was accredited to international standards. In ten years, SLMTA has helped more than 107 medical laboratories in SSA achieve accreditation to ISO15189 out of which 82% are government owned. SLMTA TOT remains an important tool to build capacity and expertise for implementing QMS, particularly for laboratories rated at 0-1 SLIPTA stars. AFENET has been supporting implementation of SLMTA since 2010.

During this budget year, AFENET was to support implementation of three regional SLMTA trainings and these include: SLMTA 1 Training of Trainers Workshop; SLMTA 3: Illuminating the Path to ISO 15189 Accreditation and Statistical Quality Control and Method Validation

Achievements:

a) Developed and finalized terms of reference, contracts for the training facilitators. Currently the facilitators are updating and developing training aides and other materials that needed during the trainings.
b) Finalized application and payment for Continuous Professional Development Points (CPD) for SLMTA trainings
c) Set up ZOOM online account for SLMTA meetings

Dominican Republic

AFENET with funding from CDC- Dominican Republic office supported several laboratory-strengthening initiatives in the Dominican Republic under the following objectives:

1. Technical Assistance (TA) to the 76 accredited Integrated HIV Care Sites in addition to the primary care centers providing HIV services under PEPFAR, to achieve the 3rd 90 of the cascade:.
    a. Provide ongoing training to health care workers (HCWs) and clinic staff to increase the prescription of viral load tests to HIV patients on Anti-Retroviral Treatment (ART).
    b. Streamline the process of delivering viral load test results to the HIV clinics and registering them in the corresponding information systems.
    c. In conjunction with community level clinical teams from COIN, HS3 and PSI, follow-up on patients that have not received a viral load test, and had them tested
    d. Develop and strengthen the viral load sample collection process in the community and their transport to testing laboratories.
2. Provide TA to the 3 laboratories that process viral load samples in the country (National Reference Lab Dr. Defillo,Gurabo and Provenir) to ensure timely and reliable results.
    a. To provide TA and support implementation of Recency Testing in 23 PEPFAR supported sites, to enhance and lead the HIV index testing approach:
    b. Development and submission of HIV recency testing protocol.
    c. Procure 8,000 Recency tests, to be purchased in quarterly increments according to the demand.
    d. Monitor Recency test results and their timely reporting by a custom indicator.

Achievements:

Objective One: To provide Technical Assistance (TA) to the 76 accredited Integrated HIV Care Sites in addition to the primary care center providing HIV services under PEPFAR, to achieve the 3rd 90 of the cascade

1) Recruitment of Technical Assistants

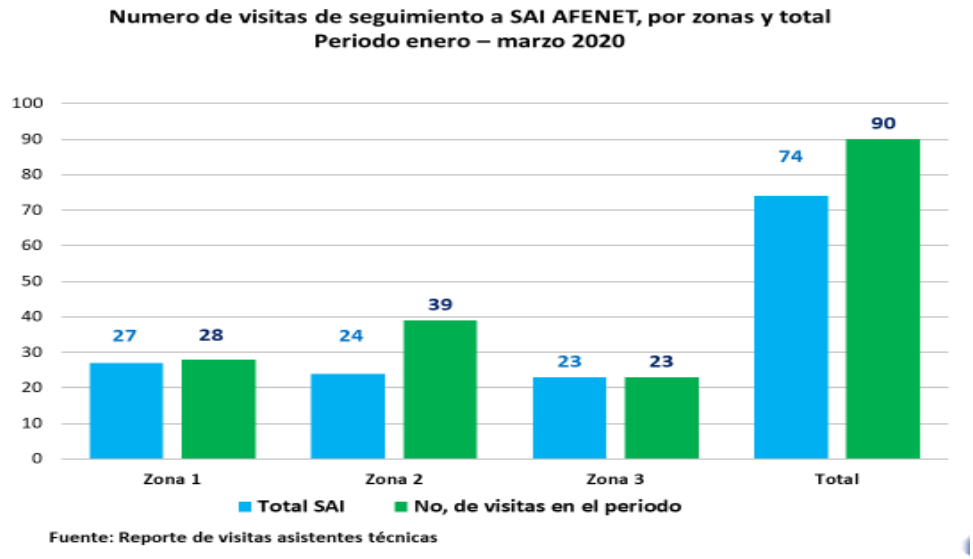
Four Laboratory technical assistants were recruited to support 74 Integrated HIV Care Sites throughout the Dominican Republic using the VL checklist for laboratory and HIV clinical services. Three of these technical assistants are based in Santo Domingo and the third is based in Santiago. Another three additional staff (Program Manager, Administrator and Monitoring and Evaluation officer) were recruited during this period.

2) Evaluated the VL Certification list.

AFENET Technical mentors concluded site evaluations in the 74 Integrated HIV Care Sites using "HIV VL Checklist." During this reporting period, mentors' visited HIV Care sites in Zone1 (has 27 SAIs), Zone 2 (has 24 SAIs) and Zone 3 (has 23 SAIs). A total of 90 visits were conducted in this period and the following were achieved

- Delivered technical assessment reports and supported the development of an action plan based on gaps identified. The reports were delivered to Hospital Maternal Infant San Lorenzo de Los Minas, Evangelina Rodríguez-Pro Familia Clinic and Casa Rosada
- Reviewed guidelines, patient records and documentation to ensure alignment with SOP's.
- Reconciled patient status and viral load testing documents in the FAPPS system vs physical files.

Figure 10: Number of visits conducted for each of the three zones



3) Monitoring of viral load suppression nationwide joining with National Health Services /MoH

- At the end of February 2020, 19 SAIs in Zones 1, 2 and 3 had recorded viral suppression of 80% and above, out of which two SAIs (Esperanza Y Caridad) had achieved 90% viral load suppression.
- Draft service agreement between AFENET and SNS has been developed and is currently being reviewed by the National Health Services /MoH team for finalization. 11 laboratory coordinators, 8 health technicians and 3 Digitators will be recruited to support training of health workers and to strengthen collection of viral load samples in the community.

4) Provide TA to the viral load laboratories to guarantee the quality in the processing of the samples and to ensure timely and reliable results.

- AFENET has recruited a Technical assistant to provide technical assistance to 4 laboratories processing viral load samples in the country (National Reference Laboratory Dr. Defillo, Gurabo, Porvenir and Centro Sanitario) to guarantee the quality of the processing of the samples and to ensure timely and reliable results.

Objective 2: To provide TA and support the implementation of Recency Testing in 23 PEPFAR-supported sites, to enhance and guide HIV index testing activities.

During this reporting period, AFENET has been able to develop a draft HIV Recency testing protocol that is currently under review by CDC Dominican Republic team, the final protocol is expected to be ready by June 2020.

Challenges:

1) Most health facilities are only open for limited Hours (morning hours) which restricts the number of health facilities that can be visited at any given time.
2) COVID 19 pandemic led to cancellation of all planned site evaluations in quarter 3 and follow up visits that had been planned from March 2020.

Recommendations / Best Practices

Activities in the month of April 2020 were interrupted on a global scale by the COVID 19 pandemic and the AFENET DR team has responded by adapting new methods of communication and document sharing to continue providing TA. Each technical staff member has virtual meetings with health facility staff to deliver some of the planned trainings.

Angola

During this reporting period, PEPFAR Angola shifted its focus to support key and priority populations in four provinces outside Luanda (Benguela, Lunda-Sul, Huambo and Cunene). Technical support was provided by AFENET technical mentors in 18 health facilities located in these four PEPFAR priority provinces in Angola. The main objective of this TA was to support viral load scale up through building capacity for viral load (VL) testing, creating a sample transport system and maximizing the national HIV laboratory's use of existing testing platforms. Additionally the project provided mentorship support to all the 18 health facilities to strengthen health care workforce capacity.

For this reporting period, the following specific objectives are presented per scope:

A. SCOPE: RTQI

- Ensure the quality of POC testing
- Improve the quality of HIV-RT

B. SCOPE: HIV-Viral Load/Early Infant Diagnosis (HIV VL/EID)

- Increase access to VL Testing
- Ensure the quality of VL quantification in reference laboratories
- Laboratory M&E
- Assist the implementation of the VLSM at Reference laboratories in Luanda and Benguela

C. SCOPE: Continuous Quality Improvement (CQI/SIMS)

- Perform on site assessment using a tool to evaluate the progress of the implementation of the activities in the four PEPFAR supported provinces.
- Implementation of a QMS at Heath facilities according to the SIMS tool.

Achievements and challenges

1) SCOPE: RTQI

The activities and achievements to develop HIV rapid testing guidelines were:

- Mapping of testers and counselors from Huambo and Cunene health facilities.

  The process of Mapping of HIV rapid testing Sites and Testers/Counselors started after the HIV-RT-Quality Certification training in Lunda-Sul and Benguela in January and ended in February 2020. AFENET developed the assessment tools and Provincial Mentors carried out the mapping process in each of the four PEPFAR priority provinces. Database was developed using the data collected to indicate the total number of counselors and testers in each health facility, total number of counselors and testers with proof of training and those that reported being trained.

- Development of HIV-RT- Quality Certification Training package :

  AFENET technical mentors through adapting WHO-HIV training materials; INLS HIV tools and guidelines developed the HIV-RT- Quality Certification Training package for Angola. This training package is to be used to certify all HIV rapid testing sites, HIV testers and counsellors starting with the four PEPFAR

priority provinces. The training package is being used to create a database of master trainers (both laboratorians and counsellors) that will cascade the trainings to other health facilities and support competency assessments. A technical working group with INLS focal points, INIS and AFENET was set up to start the process of preparing trainings for Cunene and Huambo.

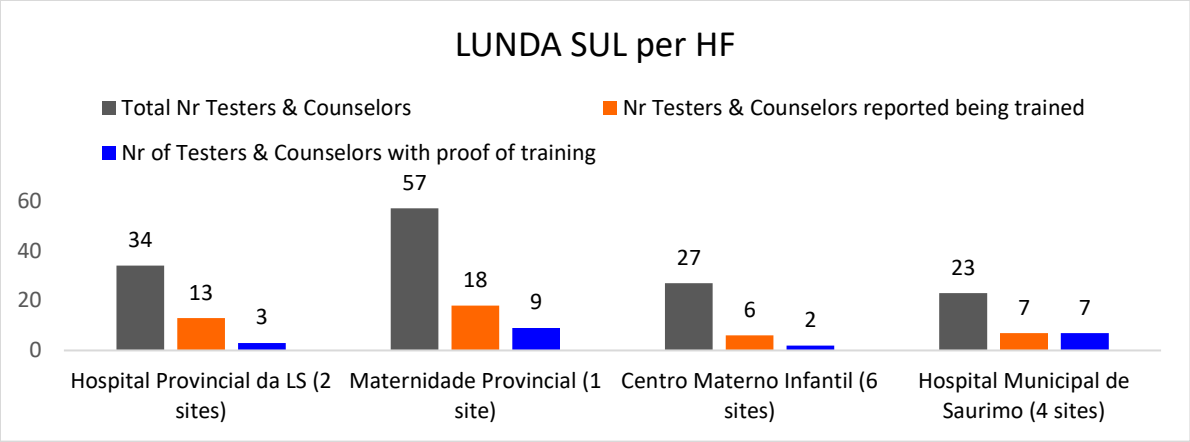
- Conducted a refresher *HIV-Rapid testing* training for seven mentors in Benguela from USAID community partner- Mothers to Mothers (M2M) in Benguela. These mentors were encouraged to attend the HIV-RT-Quality Certification Training in Huambo or Cunene to be certified.

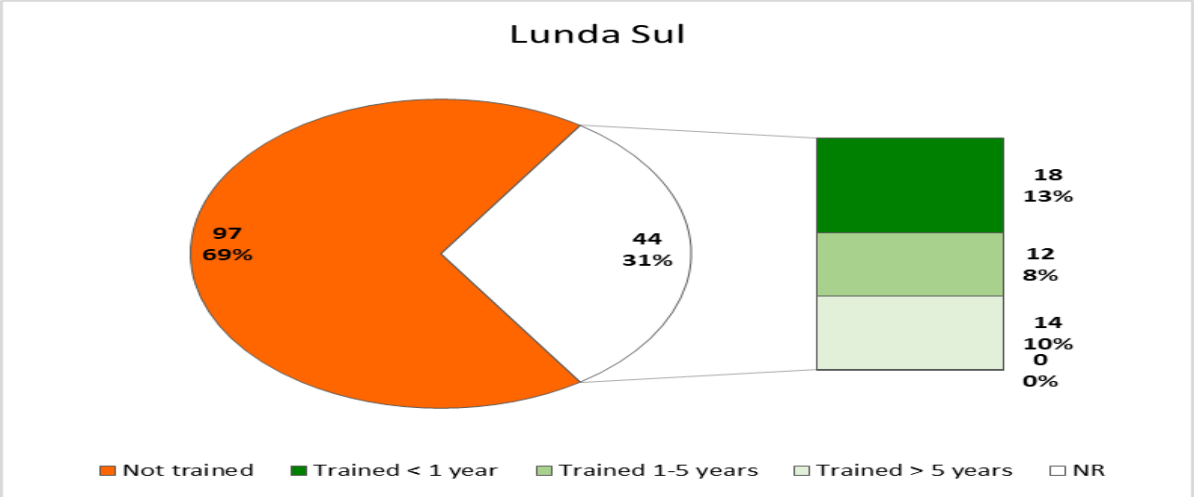
Photo L-R: Ms. Jandira Gambôa (AFENET mentor) conducting a training at Infant Maternal Center in Benguela

- Final revision of the HIV Testing Services Protocol and guidelines.

  INLS is in the process of revising the HIV testing algorithm to add a third test to the algorithm. AFENET provided technical support in the review of counselling and testing modules and changes to the national testing algorithm during a partners meeting convened by INLS on 12 March 2020.The second follow up meeting was postponed due to the Corona virus pandemic.

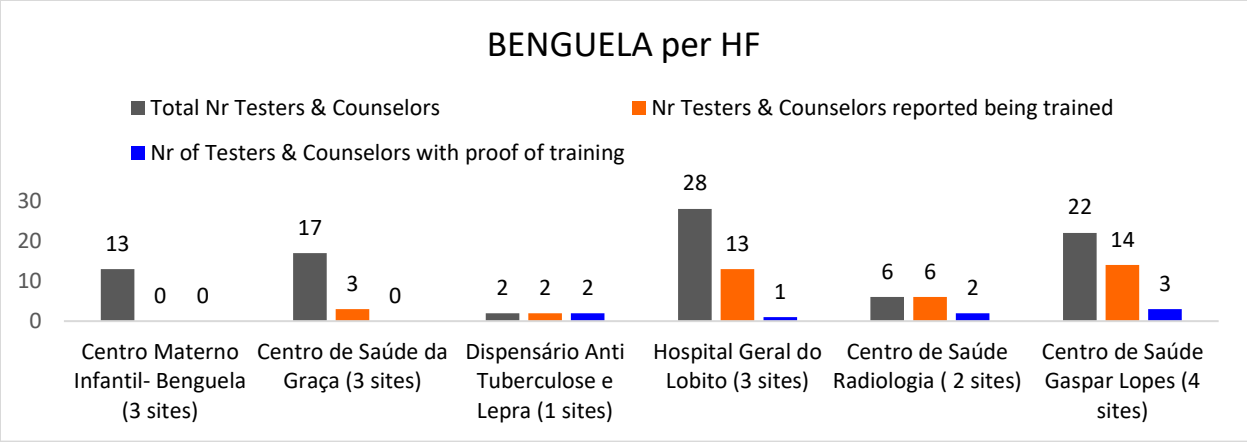
Figure 11: Mapping of RT Testing Sites and Testers/Counselors in Lunda-Sul

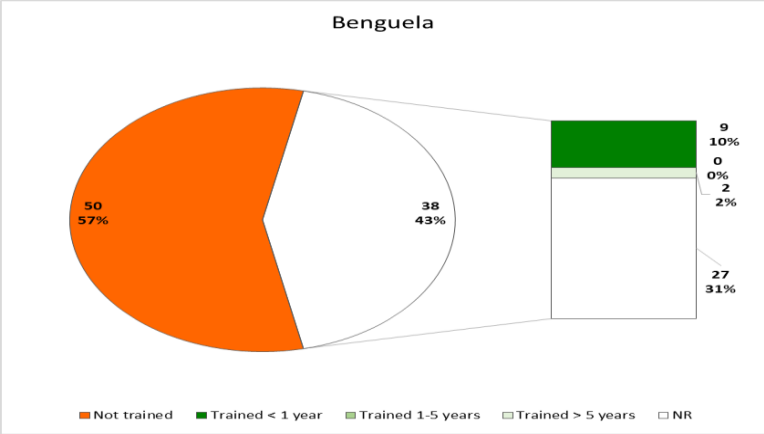




From the above figure, it can be noted that only 31% counsellors had ever attended an HIV rapid testing training. Out of the 31% testers, only 13% had attended an HIV RT refresher training in the last one year in Lunda- Sul. The majority of the HIV RT testers (69%) had never attended any HIV RT training.

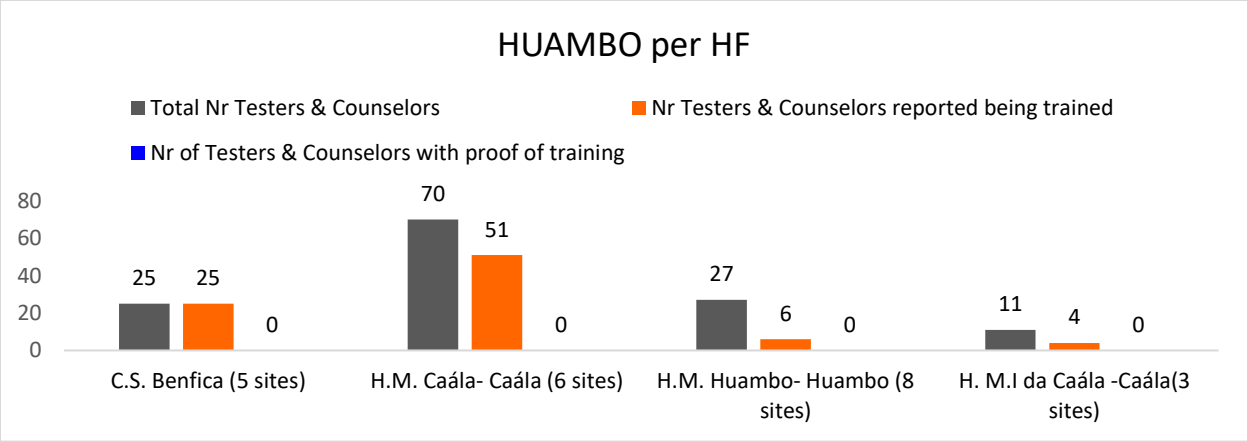
Figure 12: Mapping of RT Testing Sites and Testers/Counselors in Benguela

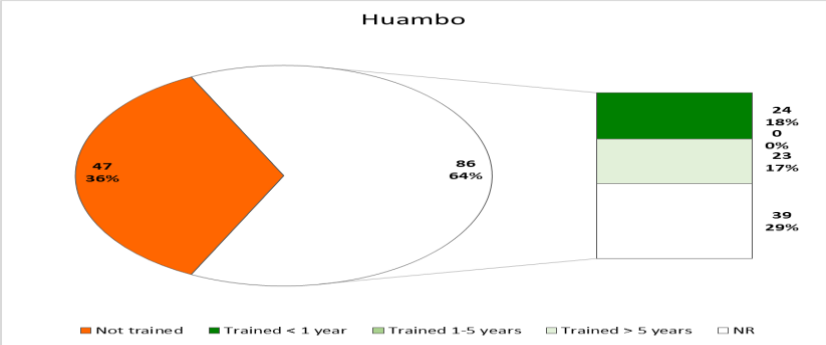




From the above figure, it can be noted that only 38% counsellors had ever attended an HIV rapid testing training. Out of the 38% testers, only 10% had attended an HIV RT refresher training in the last year in Lunda-Sul. The majority of the HIV RT testers (57%) had never attended any HIV RT training.

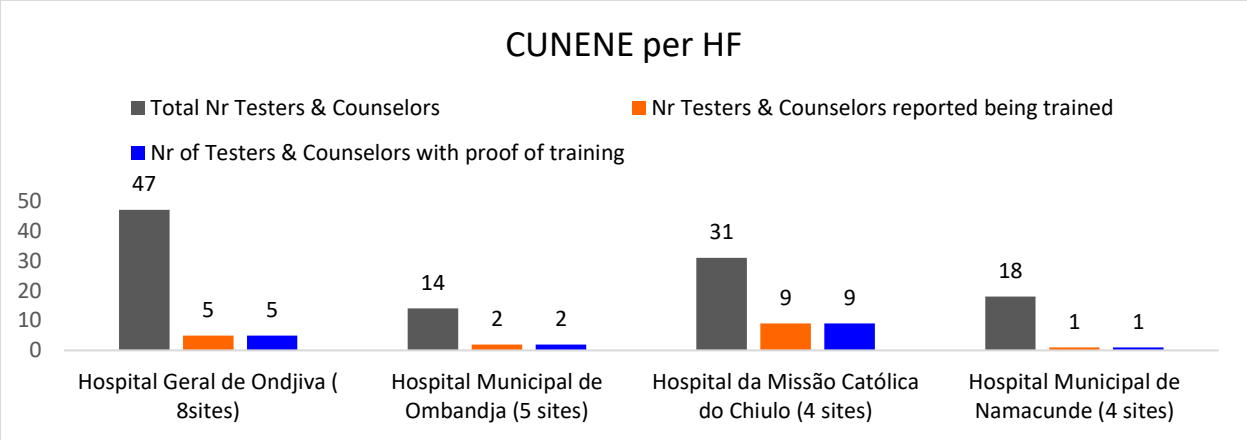
Figure 13: Mapping of RT Testing Sites and Testers/Counselors in Huambo

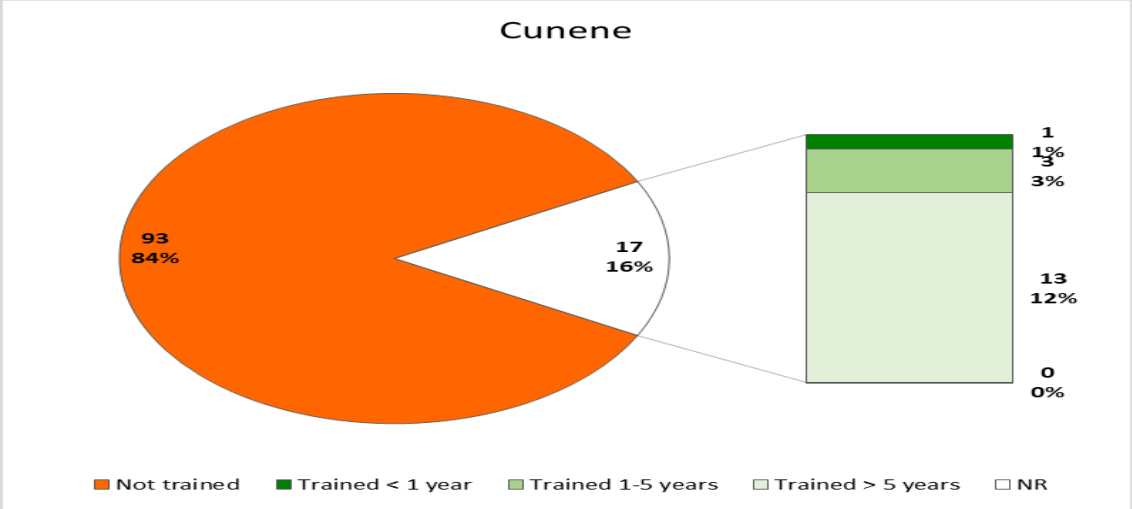




From the above figure, only 86 (64%) counsellors out of 133 had ever received HIV RT training. Only 24 counsellors out of the 64% trained had received refresher training in the last year in Huambo.

Figure 14: Mapping of RT Testing Sites and Testers/Counselors in Cunene





In Cunene, 117 HIV RT testers were assessed and only 16% of the counsellors had ever attended a refresher HIV RT training. Only 1% of the counsellors had received refresher training in the last one year.

The following challenges were encountered during this reporting period:

- Delays by INLS to approve the HIV-RT-Quality Certification Training package to Huambo and Cunene
- Delays by HIV facility focal points in Benguela Health Units to approve the HIV-RT national testing algorithm training
- Reduced availability of staff from HIV rapid testing points to attend trainings

2) SCOPE: HIV-VL

AFENET technical mentors provided technical assistance to MoH in order to expand access and ensure quality of VL monitoring: This was carried out in collaboration with staff from the INLS- Molecular Biology Laboratory (LBM) and the following were achieved:

- Benguela was the first province selected by INLS to expand HIV Viral load testing and as such, AFENET recruited two technical mentors to support these scale up efforts. The mentors conducted mentorships to Hospital Geral de Benguela and supported development of laboratory layouts to

improve sample flow processes. An additional six (6) technical mentors were recruited to support HIV VL scale up efforts in Lunda Sul, Cunene and Huambo,

- Provided supplies (desktop, printer) to improve data management and implementation of Viral Load Sample management system at Benguela reference laboratory.
- Provided technical assistance in the development of biosafety signs and implementation for the HIV VL laboratory package. A number of documents were developed and these covered the following areas; HIV VL sample collection job aids, communication registers and sample rejection forms.
- Procured and distributed 500 DBS cards to INLS- Molecular Biology Laboratory (LBM), this assistance was to help INLS mitigate the national stock outs of DBS kits in Benguela.

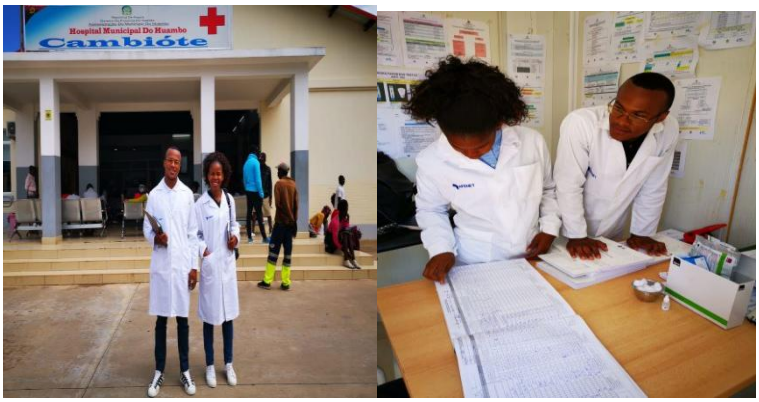


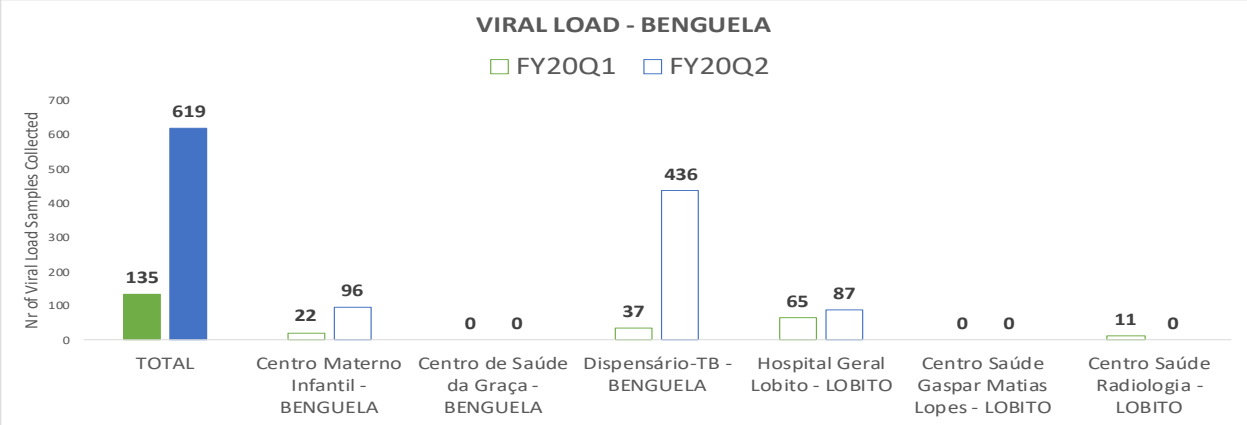
Photo: AFENET mentors conducting support supervision in one of the health facilities receiving AFENET technical support in Huambo

- Provided technical assistance to health facilities in Benguela to improve HIV VL data quality, this was through monitoring accuracy of HIV VL results recorded in the VL logbooks at sample collection sites and monitoring VL quality indicators such as sample rejection; results turn-around-times.
- Supported two mentors (Somerce França and Eduardo Muhongo) from Huambo province to participate in an HIV VL and EID National training in Huambo. The training was organized by INLS

The following challenges were encountered during this reporting period:

- Frequent stock outs of supplies at facility level such as stocks-outs of HIV VL sample collection kits for four months in Benguela.
- Slow expansion of VL services to the remaining provinces and health facilities supported by PEPFAR. Due the corona virus Pandemic, INLS postponed the VL trainings to other provinces
- Lack of standardized VL logbooks at facility level in Benguela. This is due to delays in printing the new adapted HIV VL logbook by the relevant authorities.
- Lack of a well streamlined VL sample transportation system.
- Lack of an LIS at reference laboratories. Due to the Corona virus Pandemic, activities for implementation of the VLSM were postponed

Figure 15: Number of Viral Load Samples collected in Benguela Province at PEPFAR supported Health facilities.



(3) SCOPE: CQI/SIMS

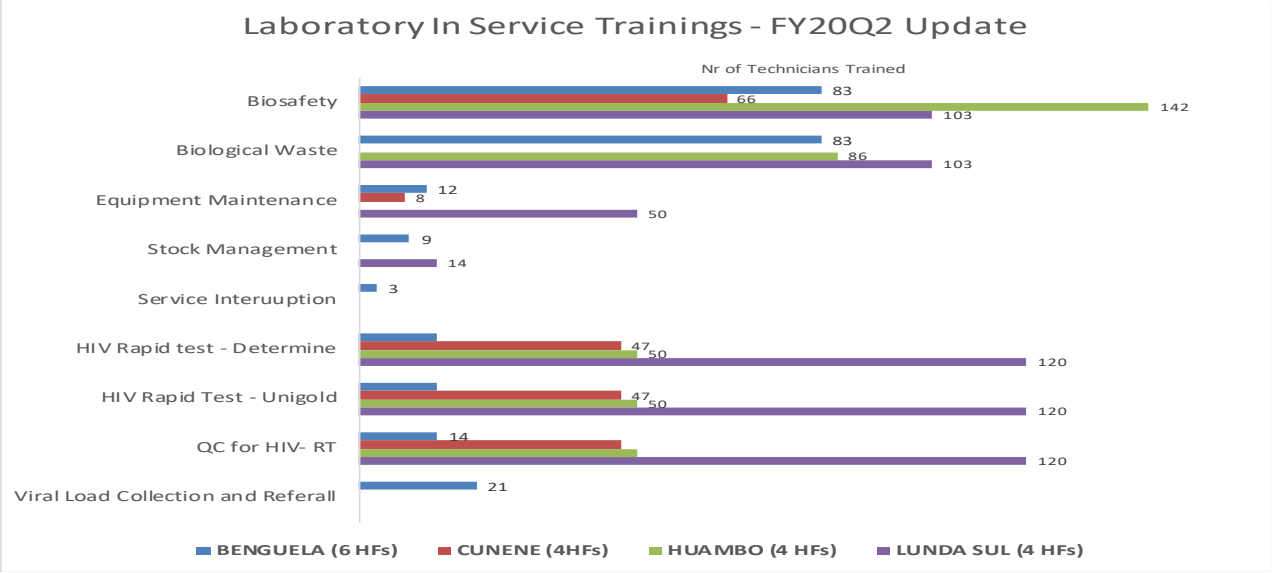
In order to develop laboratory QMS at the 18 PEPFAR supported facilities in the four provinces:

- AFENET mentors conducted trainings for staff in the 18 health facilities in the four provinces. The trainings covered different modules including biosafety/ biological waste management, HIV Rapid testing, stock management, quality control. This training was aimed at addressing gaps identified during the

SIMS assessment visits (Huambo and Benguela) and support supervision to Huambo, Benguela, Cunene and Lunda Sul.

Photo: *Participants attending a training in Cunene province. AFENET mentors in Cunene conducted the training to address identified QMS gaps.*

Figure 16: Number of health facility (HFs) technicians trained in laboratory procedures to address SIMS non-conformities.



The major CQI challenges were:

- Reduced availability of laboratory staff to implement CQI activities and participate in trainings
- Lack of buy in /involvement of facility manager in laboratory activities

- Reagents and supplies recurrent stock outs
- SIMS assessment to Cunene and Lunda-Sul was postponed due the Corona virus Pandemic.

RECOMMENDATIONS

- For RTQI activities, we recommend INLS and each Province management team to make a coordinated approach to improve the quality of HIV rapid testing such as adopting the full HIV RT certification package, performing regular competency assessments and improving supply chain.
- In order to strengthen and scale up HIV Viral Load testing, there is need to have a clear national plan for VL expansion, integrated solution to implement an adequate VL network, which guarantees supplies at facilities, reliable transport network to referral laboratories and/or point of care solution for VL/EID.
- For general CQI activities, we recommend management of health facilities to routinely conduct refresher trainings for laboratory human resources and follow up closely with the HIV health facilities focal persons, laboratory teams and testing point teams in order to maintain QMS efforts.

Photo: (R-L) Ms. Jandira Gambôa (AFENET Senior mentor) conducting a training in Benguela-Training

Photo: (L-R) Mr. Delgado – AFENET Senior Mentor conducting support supervision in one of the health facilities receiving AFENET technical assistance in Lunda Sul

SECTION II: NEW BUDGET PERIOD PROPOSED STRATEGIES AND ACTIVITIES

SLMTA SCOPE OF WORK

.AFENET has been supporting implementation of activities aimed at Strengthening Laboratory Management towards Accreditation (SLMTA). AFENET has been able to implement SLMTA in over seven countries with a number of laboratories achieving accreditation. During the 2020/2021 budget period, AFENET will continue implementing the following activities:

1. Conduct regional SLMTA trainings to support laboratories be able to attain accreditation (Quality Control and Method Validation, SLMTA ToT training, illuminating the Path to ISO 15189 Accreditation (SLMTA 3) training.
2. Support maintenance and routine updating of the SLMTA website
3. Support implementation of SLMTA ECHO

Expected Outcomes:

1. Increased capacity of senior level laboratory staff/ lab management to guide and implement activities to achieve accreditation
2. Increased number of laboratories implementing quality management systems and/or achieving international accreditation

CARIBBEAN SCOPES OF WORK

Objective one: To support Laboratory Quality Management Systems (LQMS) and accreditation in 2 countries (Jamaica and Trinidad)

This scope of work is a continuation from activities of 2019/2020 where AFENET will be a) providing continued mentorship assistance to the laboratories and conduct LQMS SIP assessments b) conducting targeted trainings for laboratory staff to close out any identified gaps and support capacity building and c) assisting and supporting labs to complete application process for accreditation

Outcomes:

- Implementation of a sound LQMS in the countries

- Quality Manuals and SOPs in place
- Accredited laboratories

Objective 2: To support Viral load strengthening and scale up

The three main areas of focus for this period include:

a) Building capabilities for viral load (VL) scale-up through assessing CD4 and VL sample management
b) TA to Viral Load testing sites and data Collection using the VL scorecard and QMT tools.
c) Conduct capacity building trainings (Biosafety, Waste Management, Quality control, Risk Management) and purchase of consumables.

Outcomes

a) Capacity of Viral load testing sites strengthened in proper sample testing and management
b) Capacity of laboratory staff strengthened in biosafety, waste management and risk management.

Objective three: To support implementation of HIV Rapid Test Quality Improvement Initiative (RTQII)

The Laboratory Strengthening Program will continue to provide quality Improvement technical assistance in support of the HIV Rapid Test Quality Improvement Initiative (RTQII). The following specific activities will be conducted in this period

a) Conduct assessments of HIV testing sites using the HIV SPRTI checklist.
b) Conduct HIV testing training for different laboratories to address all identified gaps.
c) Support procurement of supplies for development of HIV DTS PT panels.
d) Support distribution of HIV DTS PT panels to all the participating laboratories in Jamaica, Guyana, Trinidad and Barbados.

Outcome

a) Capacity of all supported HIV rapid testing sites strengthened to generate accurate and reliable HIV rapid testing results for patient management.
b) Corrective actions documented for all PT results
c) NRLs preparing and distributing DTS EQA panels.

Objective Four: Strengthen implementation of external quality assurance initiatives and Proficiency testing (One World Accuracy)

AFENET will continue to work with One World Accuracy (OWA) to prepare and distribute proficiency testing Panels to Bahamas, Barbados, Trinidad and Tobago, Jamaica, Antigua, St. Lucia and Dominica.

Outcome

a) Increased number of laboratories participating in EQA activities.

b) Improved capacity of laboratory staff

Objective Five: Calibration of measuring equipment (pipettes, scales, centrifuges, thermometers)

AFENET will continue to support Ministries of Health by maintaining equipment calibration contracts. Broken machines will be repaired and spare parts will be changed to prevent and minimize service interruption.

Outcomes:

- Service maintenance schedules developed
- Laboratory equipment routinely serviced and maintained to minimize laboratory service interruptions

Objective six: Implementation of the Lab Information System in 2 countries (Jamaica and Trinidad)

AFENET will support the expansion of the laboratory information system (Bika Open Source system) to the Western Regional Health Authority (WRHA) of the island. In this budget period, AFENET will roll out the LIS and monitor the installation and configuration of the LIS software for each participating laboratory while ensuring smooth functionality of the LIS system in each of the laboratories

Outcomes. These include a robust laboratory information system in use in these countries, Users trained on the LIS, timely technical support provided for smooth functionality of the LIS system and report of the LIS implementation

DOMINICAN REPUBLIC SCOPES OF WORK

Objective one: To provide Technical Assistance (TA) to the 74 accredited Integrated HIV Care Sites throughout the Dominican Republic in addition to the primary care centers that will be providing HIV services under PEPFAR, to achieve Viral Load Suppression

a) Conduct assessments in 74 testing sites using the VL checklist for lab and clinical HIV services: (two visits per year in each of the testing sites in close coordination with the Government of Dominican Republic (GoDR) regional and provincial health authorities.

b) Provide ongoing training to health care workers (HCWs) and clinic staff to increase the prescription of viral load tests to HIV patients on Anti-Retroviral Treatment (ART).

c) Streamline the process of delivering viral load test results to the HIV clinics and registering them in the corresponding information systems.

d) In coordination with community level clinical teams, follow-up in the community on patients that have not received a viral load test, and ensure that they receive one

d) Provide TA to the 4 laboratories that process viral load samples in the country (National Reference Lab Dr. Defillo, Gurabo, Porvenir and Centro Sanitario) to guarantee the quality in the processing of the samples and to ensure timely and reliable results.

Expected outcomes under Objective One:

a) 90% of all PLHIV identified and their Viral load routinely monitored as per the Government of Dominican Republic guidelines

b) Additional staff recruited to support to scale-up of VL testing and improve viral load suppression.

c) Improved results turnaround time for all Viral load samples tested in all the 74 accredited Integrated HIV Care Sites across Dominican Republic

d) Improved access to VL testing in the communities particularly for hard-to-reach patients.

e) Capacity of four Reference laboratories (National Reference Lab Dr. Defillo, Gurabo, Porvenir and Centro Sanitario) strengthened to guarantee quality of viral load sample processing and to ensure timely and reliable results.

Objective 2: To provide TA and support the implementation of Recency Testing in 23 PEPFAR-supported sites, to enhance and guide HIV index testing activities

1. Provide training on Rececy testing to laboratory personnel from all PEPFAR supported sites. (for 50 people in total)

2. Provide technical assistance to the GoDR and the National HIV Program in the updating of national norms and guidelines to include Recency testing
3. Monitor Recency test results in PEPFAR supported sites and their timely reporting using a custom indicator (23 visits per quarter = 104 visits in total)

Out comes:

a) Capacity of HIV testing sites strengthened to carry out quality HIV Rececy tests in the country (23 PEPFAR-supported sites).
b) Revised and updated national HIV testing guidelines to include HIV Rececy testing
c) 100 laboratory personnel trained in HIV Rececy testing
d) Increased number of HIV Rececy tests carried out (8000 Recency test kits procured)

TB CQI SCOPE OF WORK

Under this scope, the following activities are planned to be implemented:

1. Extend the Electronic Proficiency Testing (ePT) system for evaluating the quality of testing for tuberculosis using GeneXpert diagnostic instruments.

   Expected Outcomes:

   a) Increased number of TB testing laboratories submitting their results from performance evaluation panels provided by CDC Atlanta.
2. Use of an electronic meeting and tele-mentoring platform (ECHO) to rapidly, efficiently and economically improve the interface between HIV treatment clinics and tuberculosis diagnostic laboratories

Expected Outcomes:

a) Reduce turnaround times associated with screening of PLHIV for TB, TB laboratory receipt of specimens for testing, lab-confirmation of TB disease, return of TB laboratory test results.
b) Increased number of clinic/lab staff using monitoring tools to identify cascade gaps, propose and successfully initiate improvement projects.

LABORATORY PARTNERSHIPS TO SUPPORT THE DIAGNOSIS, TREATMENT AND MANAGEMENT OF PLHIV (EQUIPMENT MAINTENANCE)

The following activities are planned to be implemented in collaboration with respective Ministries of Health, Pan African Consortium (PAC) and local implementing partners:

1. Operationalize the equipment maintenance and calibration electronic monitoring tool in selected countries
2. Provide training and capacity building of laboratorians on the use of the etool
3. Coordinate with partners to update and collate data on laboratory equipment for incorporation into the electronic tool

Expected Outcomes:

1. Electronic tool finalized and fully operationalized in identified countries
2. Reduced service interruptions due to improved/timely servicing and maintenance of laboratory equipment
3. 100 in country biomedical engineers trained to support timely maintenance and servicing of laboratory equipment.

RT- CQII SCOPES OF WORK

The main aim of this project is to ensure the quality of HIV rapid testing and expand upon current in-country HIV rapid testing quality improvement work.

1. Support the maintenance and routine updating of the RT-CQII website maintenance and tools namely:
    a) All demo software (ePT, SPI-RT Tablet and Dashboard, Certification Training, Logbook Data management)
    b) Continue supporting the tester Certification and enhance current reports and SOP for implementation
2. Strengthen data Use and management to support policy decisions and patient care management.

3. Support continuous quality improvement for HIV rapid testing in Malawi and Uganda through project ECHO
4. Conduct HIV RT trainings for staff in testing sites leading to the HIV tester and site certification process.

Expected outcomes:

1. Up to date RT-CQII website with links to all RT-CQII tools and resources
2. Increased uptake of RT-CQII tools and coverage to demonstrate impact on quality of HIV rapid testing.

CLINIC – LABORATORY INTERFACE SCOPES OF WORK

This project seeks to strengthen the laboratory-clinic interface across the viral load cascade in order to achieve better patient results (i.e., viral load suppression). AFENET proposes to implement the following activities:

1. Partner with LARC to train selected health care workers in implementing CLI to improve the HIV Viral load cascade
2. Support establishment of ECHO platform to improve laboratory – Clinic interface
3. Support Printing and dissemination of CLI tools, guidelines

Expected outcomes:

1. Increased number of viral load tests collected from patients and viral load results recorded in their respective patient files.
2. Increased collaboration between clinicians and laboratorians to improve demand creation for viral load testing, result reporting and patient management.

BIOSAFETY AND WASTE MANAGEMENT SCOPES OF WORK

HIV VL scale-up initiatives have resulted in growing waste management (WM) and biosafety challenges in many laboratories and health facilities, especially those in low-income and middle-income countries.

This project seeks to provide expert guidance and build capacity of health facilities to implement sustainable, affordable biosafety and viral load waste mitigation strategies to prevent further exacerbation of public health impact in Africa.

We propose to implement the following activities in 6 selected countries:

1. Strengthen capacity of biomedical engineers and waste management professionals through conducting specialized trainings and certification
2. Support calibration and servicing of laboratory equipment including biosafety cabinets.= through establishment of equipment service contracts
3. Strengthening capacity of selected high volume viral load testing sites through provision of waste management supplies and tools.

Expected outcomes:

1. 150 Biosafety cabinets serviced and maintained routinely in 6 selected countries
2. Biosafety and waste management guidelines, policies developed and implemented by countries.
3. Improved capacity of selected laboratories to properly handle viral load and other related wastes and minimize impact on the environment.
4. Five biomedical engineers trained and certified in servicing and maintenance of biosafety cabinets.

LABORATORY INFORMATION MANAGEMENT SYSTEMS SCOPES OF WORK

LIMS also support the real-time monitoring of healthcare programs, facilitating the improvement loop and the continuous quality improvement of services. We propose to implement the following activities:

1. Conduct site assessments, site-specific system configuration, user training rolling out with on-the-job end-user training and post-implementation support.
2. Strengthen viral load data management capacity of five selected laboratories through installation of laboratory information management systems.

Expected Outcomes:

1. Improved real-time tracking of specimens and electronic delivery of results to healthcare facilities.

2. Improved laboratory-clinic interface and the optimal utilization of diagnostic results for patient management.

ANGOLA SCOPES OF WORK

AFENET through PEPFAR support will continue to implement activities four priority PEPFAR supported provinces of Angola (Benguela, Lunda-Sul, Huambo and Cunene). 18 health facilities will be provided with technical assistance in addition to National level reference Laboratories.

Objective One: Develop a TOT curriculum for HIV point of care (POC) testing (including rapid testing, and POC VL and EID) trainings at central level to implement at central, provincial, and municipal levels. Create a tracking and regular competency assessment system for certified facility-level HIV testers

Expected outcomes:

- HIV Rapid Testing Certification package complete and first regional RT TOT training conducted by INLS;
- All 18 PEPFAR supported facilities participating in EQA/PT for all POC tests;
- Competency assessment by INLS rolled out in all the 4 PEPFAR supported provinces;
- At least 90% of all POC labs and testing points with satisfactory performance in EQA/PT per type of test

Objective two: Fully implement viral load system management (VLSM), including dashboards for disaggregated data visualization, in central and regional laboratories. Train central and provincial level personnel for appropriate system use to ensure results are delivered to health facilities in a timely fashion

Expected outcomes:

- VLSM completely functional in both labs and all VL data visible on a national dashboard;
- Improved capacity of Central level monitoring VL quality metrics such as VL tests performed by type of specimen collected.

- Central and regional labs using VLSM to produce semi-annual VL reports disaggregated by age, sex and type of VL testing performed;
- Central lab reporting VL quality metrics quarterly and semi-annually

Objective three: Develop facility-level M&E tools for VL and EID testing and distribute them to sites

Expected outcomes:

- EID M&E tools finalized and approved;
- 18 PEPFAR facilities have VL and EID M&E tools in place and fully utilizing the tools for data reporting.

Objective four: Modernize EID policy; create central and provincial level systems for implementation of EID testing

Expected outcomes:

- Quarterly central level EID meetings;
- 100% of appropriate PEPFAR facilities' staff trained for EID collection and EID POC
- All lab implementation EID tools developed and implemented at illegible facilities of PEPFAR supported province;
- 50% increase in PMTCT_EID from baseline