NATIONAL OPERATIONAL PLAN FOR SCALING-UP ROUTINE HIV VIRAL LOAD MONITORING

SWAZILAND

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Swaziland Health Laboratory Services

ICAP
GLOBAL. HEALTH. ACTION.
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Abbreviations and Acronyms

ARVs: antiretroviral drugs

ART: antiretroviral treatment

WHO: World Health Organization

NMRL: National Molecular Reference Laboratories

SHLS: Swaziland Health Laboratory Services

SNAP: Swaziland National AIDS Program

DBS: Dry Blood Spot

PCR: polymerase chain reaction

HIVDR: HIV drug resistance

DR-TWG: Drug Resistance Technical Working Group

CDC: US Centers for Disease Control and Prevention

PEPFAR: Presidents Emergency Plan for AIDS Relief

CSM: Clinical Systems Mentoring

EDTA: Ethylenediaminetetraacetic acid

FVE: Free virus elution

MSF: Médecins Sans Frontières

SHIMS: Swaziland HIV Incidence Measurement Survey

NSTS: National Specimen Transport System

EID: Early Infant Diagnosis

VL: Viral Load

EQA: External Quality Assurance

LIS: Laboratory Information System

SID: Strategic Information Department

HMIS: Health Management Information System

APMR: ART Patient Management Records

LDMS: Laboratory Data Management System

DISA: Data Intensive Systems and Applications for the Lab

Section One: Background:

By end of December 2015, 147,274 adults and children were regularly taking ART across Swaziland. This notable achievement was possible due to the political commitment and leadership of the MoH/SNAP together with support from PEPFAR and implementing partners. The notable expansion of HIV services was achieved due to effective task shifting to nurses to initiate or refill ART for stable clients, thus increasing the ART coverage to over 80%. The national HIV treatment program achieved this remarkable ART coverage using CD4 count eligibility of 350 cells/μL. The country is committed to further expand ART access at a higher CD4 count threshold of 500 cells/μL. Consequently, the 2015 National Guidelines for Integrated Management of HIV were developed based on new WHO recommendations. As a result, from October 2015, Swaziland began implementing ART initiation at a new CD4 threshold of 500 cells/mm^3.

Even though the above mentioned achievements are outstanding, the need to strengthen monitoring of response to ART by introducing routine viral load monitoring remained a critical gap. Clinical and immunological parameters often lack sensitivity to detect early biological failure and may delay the diagnosis of first line regimen failure. This can contribute to the accumulation of mutant virus. Obviously this will compromise options for second line regimen. Accordingly, Swaziland has adopted new WHO recommendation for routine viral load monitoring of response to ART.

The MoH recognizes the challenges that lie ahead in rolling out viral load monitoring routinely for patients taking ARVs. The complexity of molecular tests and the coordination of timely specimen transport to the national reference lab require meticulous leadership and management. However, multiple studies have shown that routine viral load monitoring is feasible and cost effective even in resource limited settings like Swaziland.

In order to overcome these challenges, the MoH and partners developed this national routine viral load roll out plan including a system for specimen collection and transport. This operational plan is part and package of strategies to overcome the anticipated challenges when implementing these new recommendations.

1.1: ART Monitoring in the Kingdom of Swaziland

Measurement of the concentration of HIV RNA in blood, referred to as "viral load", is a valuable marker of a patient's response to ART and predicts the risk for clinical progression to AIDS[1, 2]. Viral load is a more sensitive and reliable means of determining success of treatment or determining treatment failure (i.e. higher sensitivity and positive predictive value) compared to clinical and immunologic criteria[3]. Viral load can detect treatment failure earlier than using clinical or immunologic failure and thus helps prevent accumulation of resistance mutations. As a result, the 2015 World Health Organization (WHO) policy brief re-affirmed earlier recommendations to use viral load (VL) testing as part of routine therapeutic monitoring for all HIV infected children and adults on ART in order to correctly assess response to treatment, detect treatment failure and determine the need to switch to second line regimens in a timely manner.

[1] Marschner IC, Collier AC, Coombs RW, et al. Use of changes in plasma levels of human immunodeficiency virus type 1 RNA to assess the clinical benefit of antiretroviral therapy. J Infect Dis. Jan 1998;177(1):40-47.

[2] Thiebaut R, Morlat P, Jacqmin-Gadda H, et al. Clinical progression of HIV-1 infection according to the viral response during the first year of antiretroviral treatment. Groupe d'Epidemiologie du SIDA en Aquitaine (GECSA). AIDS. May 26 2000;14(8):971-978.

[3] Kantor R, Diero L, Delong A, et al. Misclassification of first-line antiretroviral treatment failure based on immunological monitoring of HIV infection in resource-limited settings. Clin Infect Dis. Aug 1 2009;49(3):454-462.

Prior to 2016, access to HIV viral load testing in Swaziland was restricted to individuals with suspected treatment failure and for women who become pregnant while taking ART. However, with the launch of Swaziland's new Guidelines for Integrated Management of HIV, routine viral load monitoring was adopted as standard of care.

Although routine viral load monitoring entails increased cost of care, the early detection of poor adherence or 1st line ART regimen failure is valuable for the patient as well as for the ART program. The monitoring provides information to reinforce adherence and congratulate the client when the virus is undetectable. When it is above the accepted detection limit, routine viral load result provides an opportunity to administer enhanced adherence counseling (EAC). Moreover, the early detection of poor adherence will prevent the accumulation of mutant virus. In summary, routine viral load monitoring improves the quality of care by allowing early detection of poor adherence or treatment failure due to accumulation of viral mutations.

1.2: Program Objectives:

The goal of this operational plan for routine HIV viral load monitoring is to ensure early detection of virologic failure (defined as > 1,000 copies/mL) to 1st line ART regimens so that timely EAC or switching to 2nd line regimens can be instituted. The specific objectives of the plan include the following:

- Expand clinical and laboratory capacity for routine HIV viral load monitoring in Swaziland by June 2016.
- Conduct at least 180,000 viral load tests in one year as part of routine viral load monitoring for all patients on ART.

2.0: Routine versus targeted viral load monitoring :

When resources allow, viral load testing for *all* individuals receiving ART at scheduled intervals is the preferred approach and is referred to as 'routine' viral load, monitoring. At initial roll-out of viral load monitoring, pregnant women and children (including adolescents) the priority groups for routine viral load monitoring. However, if routine viral load monitoring is not available, viral load testing may be used in a more limited and 'targeted' manner for patients in whom treatment failure is suspected. In targeted viral load testing, *all* individuals are assessed for treatment failure using CD4 and clinical criteria. For those suspected of treatment failure using these definitions, a viral load is sent to confirm treatment failure or look for evidence that there is actually no treatment failure.

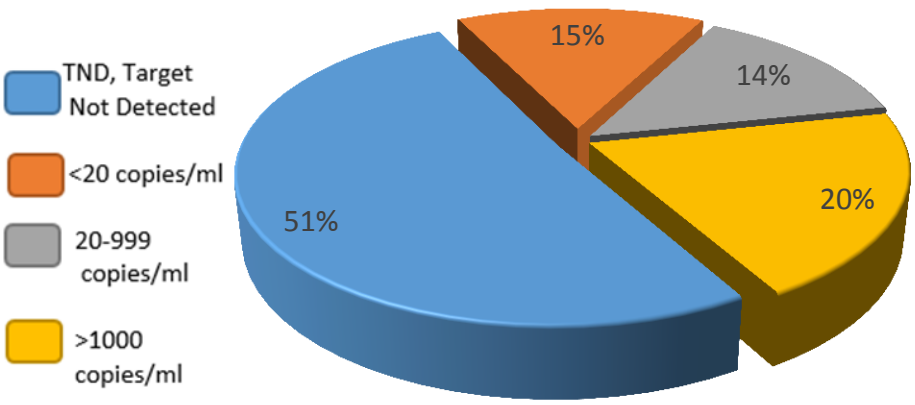


Figure 1: Results of Targeted Viral Load Monitoring In Swaziland, Jan to Dec 2015

2.1: Targeted Viral Load Monitoring in Swaziland:

In 2015, a total of 28,187 specimens were received by the NMRL for viral load testing and of these 5,722 (20%) were not virologically suppressed. Out of the 222,465 tests that had a viral load of <1000 copies/ml, 51% were target not detected (TNDs), while 15% and 14% were <20copies/ml and < 20-999copies/ml respectively (Figure 1)

In response to a survey conducted in February 2016 across 24 large volume facilities, clinicians reported that the majority of targeted viral load monitoring during this period was prioritized for suspected treatment failure (49%), pregnant women, adolescents and children under 5 (see Table 1 below):

Table 1: Targeted VL prioiritization by Health Facilities, Jan – Dec 2015

VL prioritized to:	# of facility	%
Suspected treatment failure	18	49%
Pregnant women	10	27%
Children < 5 years	3	8%
Children ≥5 < 10 years	2	5%
Adolescents	3	8%
Other_priority *(DR TB and HIV coinfection Management)*	1	13%
Total	37	

Even though this data are for targeted viral load monitoring, the fact that 20% of all tests were >1000 copies/mL underscores the importance of mentorship and supportive supervision to ensure that timely EAC is provided, and where necessary, patients are switched appropriately.

Section Three: The Process of Development of the Implementation Plan:

3.1: Context Analysis:

The WHO advises national HIV programs in resource limited countries intending to scale-up routine viral load monitoring to consider using a three-phased approach: (1) planning; (2) scale-up; and (3) sustainability.

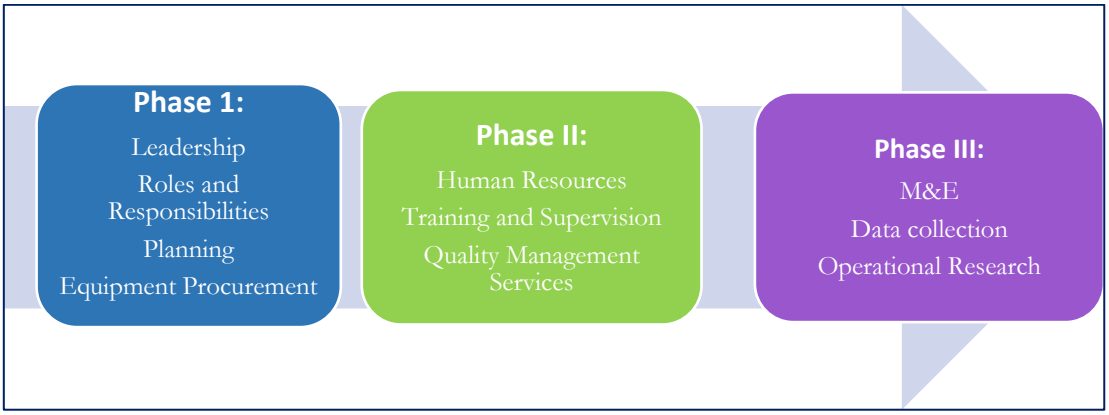


Figure 1: Proposed Implementation Approach for Routine VL Monitoring

The significant challenge to successfully implementing and scaling up viral load testing to reach everyone receiving ART is adequate strategic planning. This implementation plan provides a framework for key areas to be considered and addressed during the planning phase for implementing and scale up of viral load testing in Swaziland, and highlights the elements critical to supporting a sustainable viral load testing network.

3.2: POLICIES, LEADERSHIP AND GOVERNMENT COMMITMENT:

Current National guidelines for testing and treating HIV and AIDS in Swaziland have largely followed the WHO guidelines, within the limits of available resources. Following the release of the WHO 2013 Guidelines, the National ART Guidelines were updated to include VL testing as the gold standard for monitoring the effectiveness of ART in HIV infected individuals.

Leadership at the national level by SNAP and the SHLS is critical to optimize both the implementation of clinical programs and management of laboratories. PEPFAR regional clinical partners work closely with SNAP to establish standards for service provision at facilities, including: pre-service and in-service training, guidelines and clinical algorithms development and assurance of implementation, development of workforce standards, targets, monitoring and evaluation (M&E), and quality improvement (QI).
Likewise, ICAP will work closely with the SHLS to strengthen its role to oversee standards for laboratory management, training, M&E, quality assurance and improvement (QA/QI).

SNAP, working closely with the SHLS, will lead the implementation of viral load monitoring, convene stakeholders for technical working group (TWG) meetings, and lead working groups dedicated to development of the following:

- Policies outlining VL processes and procedures
- Clinical guidelines, standard operating procedures (SOPs) and job aids including human resource training plans for national guideline compliance
- Laboratory viral load testing capacity (specimen collection, processing, results return, training)
- Commodities forecasting plans
- Guidance and activities for viral load testing demand creation
- Guidance for viral load M&E (clinical, laboratory, commodities) and process and outcome evaluations
- Standards and processes for the management of patients with virologic failure including EAC and ART regimens changes

3.3: SWOT Analysis:

Even though routine viral load monitoring is valuable for the patient as well as the ART program, there are necessary steps that need to be accomplished in countries with limited resources. The following key milestones are critical to ensure the seamless implementation of routine viral load monitoring in the country.

- A national viral load implementation plan is developed.
- Technical leadership is in place to monitor the efficiency and efficacy of the implementation plan at the site, regional and national levels.
- Appropriate equipment platform/s for VL testing are available in the national lab with appropriately trained individuals who can perform quality testing and workflow is optimized to provide the recommended volume of tests over time.
- Job aids and SOPs are available to ensure access to quality plasma or DBS specimens that respond to SHLS required standards and are collected and shipped to the National Molecular Reference Laboratory (NMRL).

- Site specific plans are developed and regularly reviewed including targets, defined roles and responsibilities and processes for specimen collection and results management.
- Clinical mentors are strategically directed to regularly guide QI activities and mentorship to clinical providers using site level results and provide data driven approaches to improve VL testing compliance and quality for sites.
- Adequate and trained human resources are available for all aspects of the VL cascade: VL test ordering, specimen collection, transport, specimen processing, specimen storage before testing, safe disposal of left-over specimens, results transmission, documentation and utilization of results for patient management.
- A system for VL test results delivery is established and monitored that ensures sites and patients receive results in a timely fashion for clinical action.
- SOPs and job aids for EAC and management of first line ART failure are developed within a system that ensures the timely identification and management of patients who may be virologically failing.
- Health care provider (clinicians, data managers, laboratorians and phlebotomists) training is conducted with plans for ongoing supportive supervision and mentorship.
- A system for commodities management including consumables and reagents is in place.
- An M&E framework including tools, registers and database are developed and harmonized with existing CMIS to ensure accurate documentation of VL test results and enable the capacity to measure the progress and outcomes of routine viral load monitoring.

The following table summarizes the contextual analysis derived from scanning both the internal and external environment in Swaziland:

Table 2: SWOT Analysis

STRENGTHS	**WEAKNESSES**
• Routine VL monitoring recognized by MOH as a critical program component with the additional resource allocation to support its rollout. • VL task force with defined terms of reference to monitor implementation routine viral load monitoring in Swaziland is established. • Training of health workers on the guidelines for monitoring patients using viral load results is initiated. • Molecular lab equipped with 4 PCR machines. • The NMRL staffed with 5 trained technologists, with additional technologist to be acquired. • Clinical and laboratory SOPs and job aids developed to support routine VL testing rollout • SHLS- and SNAP led HIV DR-TWG in existence with a renewed focus on reviewing VL data to inform programmatic implications for HIVDR. • Molecular lab workflow optimization activities initiated to increase the number of viral load tests to at least 10,000 tests/month. • In country DBS validation plans underway with initial promising results that will allow for DBS specimen collection.	• Limited coordination of key stakeholders for VL rollout. • Limited optimization and trained HR to maximize VL testing platform capacity to meet programmatic VL demand. • Lack of trained human resources to collect, prepare, store and ship DBS specimens. • Lack of system to quickly deliver VL results back to health facilities within one week. • Lack of VL M&E plan. • Lack of systems that connect the laboratory information system with clinical sites for site and patient VL test monitoring and targeted identification of patients with virologic failure. • Lack of existing site level data utilization for clinical mentoring efforts directed at site level VL performance and follow up of patients with virologic failure. • Weak national specimen transport system • Limited clinical guidelines, SOPs and job aids for routine viral load monitoring.
OPPORTUNITIES	**THREATS**

• Strong commitment from PEPFAR, its implementing partners and USG HQ for provision of resources and technical assistance for routine VL testing scale up. • Many interested implementing stakeholders and partners are present. • GF dedicated resources for viral load that can be jointly leveraged for programmatic impact • Strong political will at the highest levels of Ministry of Health. • Significant momentum catalyzed from global, regional and local demand for action on routine viral load monitoring.	• Uncertainty of the impact of the drought currently affecting the country. • Lack of policies that guide SHLS workflow to optimize testing output. • Current LIS inability to ensure accurate and timely results delivery. • Weak logistics management system for HIV supplies, consumables and commodities, including ART drugs. • Weak feedback communication from SHLS to clinical service providers.

3.4: Site Readiness Assessment:

With TA from CDC Atlanta, a VL site readiness assessment was conducted in 23 large volume facilities in Hhohho, Manzini and Lubombo regions by a combined team of clinical and laboratory mentors from the MoH and PEPFAR regional clinical partners.

Table 3: List of Facilities that were assessed for VL Implementation Readiness (# on ART by Dec 2015)

Hhohho	Lubombo	Manzini
1. Baylor Clinic	1. Cabrini	1. FLAS
2. Dvokolwako	2. Good Shephard	2. KSII
3. Emkhuzweni	3. Lomahasha	3. Luyengo
4. Horo	4. RSSC-Simunye	4. Mankayane PHU
5. Lobamba	5. Siphofaneni	5. Mankayane Hospital
6. Mbabane PHU	6. Siteki PHU	6. Phocweni
7. Mbabane Government	7. Sithobela	7. RFM Hospital
8. Piggs Peak Hospital		8. National TB Hospital

The main findings from this assessment include the following:

1. **Sub-populations prioirtized for VL**: In nearly 50% of facilities, VL is prioitized for patients suspected of treatment failure, followed by pregnant women on ART (27%) adoolescents and children under 5 (13%).

2. Cadre reponsible for identifying patients for VL: In over 50% of sites, the main cadre responsible for ordering and reviewing VL results are nurses.

3. **Turn-around time for receiving VL results:** In 50% of facilities, VL results are returned within 2 weeks. While in 30% of facilities, it takes more than 2 weeks but less than 4 weeks, and in the remaining 20%, it takes longer than 1 month.

In 80% of facilities, VL results are reviewed by the nurse assiatsnt, the nurse or the doctor within one week. However, only 50% of assessed facilities ensure patients receive their VL results within 2 weeks.

4. **Enhanced adherence counselling:** Nearly 90% of facilties reported that they implement enhanced adherence counslling for patients with a viral load of >1,000copies/mL. Simliarly, nearly 90% of facilities

reported that they have a sytem for expert consultation for patients with a VL >1,000copies/mL. In contrast, only 30% have access to expert consultation for patients on 2nd line, whose VLs are persistently >1,000copies/mL despite EAC. However it was found that the facilities lack specific content/approach for EAC/SUAC due to lack of training, mentoring and availability of job aids and tools.

3.4: SOPs and Tools Development:

Over a period of three days, the VL Task Force brought together technical advisors to develop SOPs and tools to guide both laboratory and clinical processes for VL implementation:

Table 4: Laboratory and clinical tools that have been developed

Laboratory	Clinical
1. Laboratory request form (revised) 2. Viral load test ordering 3. SOPs for specimen collection, storage, and transport (DBS and plasma) 4. Log sheets for VL specimen referral and result record 5. Job aids for specimen collection, storage, and transport (DBS and plasma) 6. NSTS specimen delivery checklist VL lab testing SOPs (DBS and plasma) 7. VL log sheet for VL specimen referral and results recording	1. SOP for VL ordering in the clinic 2. SOP for return of high VL result to the facility 3. SOP for handling VL results at the facility level after they are returned from the laboratory 4. SOP for returning VL results to patient with a VL < 1000 copies/ml 5. SOP for returning VL results to patient with a VL ≥1000 copies/ml 6. SOP for returning VL results to patient with a 2nd VL ≥1000 copies/ml 7. High VL register 8. High VL form

3.5 Viral Load Testing Capacity at the National Molecular Reference Laboratories (NMRL)

The NMRL is one of the national reference labs under the Swaziland Health Laboratories Services (SHLS). Currently, there is capacity to do the following molecular tests:

- HIV DNA PCR for Early Infant Diagnosis (EID)
- HIV viral load
- Loop Mediated Isothermal Amplification (LAMP)-Malaria PCR

3.5.1: VL Testing Equipment and Platforms:

a. Viral Load Analyzers: The NMRL has 4 viral load analyzers:

1. Roche COBAS Ampliprep/COBAS TaqMan 96 **(3)**: Out of these three Roche platforms, one is dedicated for EID, but HIV viral load testing may be run on this platform when EID specimen have been processed. EID and viral load specimen may be run on the same platform simultaneously if the specimens are placed in separate instrument racks. The other two Roche platforms can process 21- 63 specimens per 6 hour cycle/per machine. If extended to 8 hour

cycles, 168 specimens can be analyzed per day per machine, equivalent to approximately 44,352 specimens per year (3,696 per month) per machine.

2. **Biocentric Generic HIV Charge Virale** (1): This analyser can run specimen186 specimens per day or 44640 specimens/year.

In total, at current capacity, provided all machines are up and running, the NMRL can conduct **133,344** per year, equivalent to 11,000 tests per month. Please note that these numbers require full implementation of laboratory workflow optimization strategies.

With support from PEPFAR through ICAP, two additional *Roche COBAS Ampliprep/COBAS TaqMan 96* analyzers will be procured and installed at the NMRL, along with a service contract from Roche**.**

b. **Centrifuges and Refrigerators:**
Plasma remains the preferred and gold standard specimen for VL testing. In order to avail and scale-up VL testing services for monitoring and diagnosis of treatment failure, the capacity of facilities need to be strengthened to conduct blood collection, processing and shipment to the NMRL. Health facilities should, therefore, have bench-top centrifuges and refrigerators critical for correct plasma collection, processing and storage.

A rapid assessment was conducted by ICAP in August 2015 that provided very useful information on equipment inventory at facility level. Out of the 60 main and mini laboratories that were assessed, only 16 did not have centrifuges, while 2 lacked a functional refrigerator.

Both PEPFAR and the Global Fund will provide funds to support procurement of additional refrigeration and centrifugation.

3.5.2: Human Resources for VL Testing in the Lab:

In order to utilize the existing laboratory infrastructure and increase efficiency to meet VL testing demands, the NMRL should be properly staffed by qualified and well trained laboratory professionals.

1. **VL Technologists**: The current staffing plan for VL technologists for the NMRL is summarized in Table 5 below:

Table 5: Staffing plan for VL Lab Technologists at the NMRL

Name of mechanism	Number supported
MoH	1
ICAP/PEPFAR	3
Global Fund	5
Total	**9**

The NMRL requires at least 9 lab technologists to run the 4 VL machines, for conducting both viral load and EID. Note that one VL machine and one lab technologist will be fully dedicated for the EID program. For VL testing, 2 lab techs will be dedicated to each VL machine. Another lab technologist will be dedicated to specimen reception, quality control and barcoding, and the remaining technologists will be assigned as a quality officer of the NMRL who will be in charge of ensuring the implementation of laboratory quality management systems and providing additional technical support when either of the other lab techs are not available. As part of workflow optimization, the EID technologist and platform

may be used for viral load testing when daily EID specimens have all been tested and the instrument is subsequently available, and when EID testing is not done daily, allowing the technologist and platform to be be employed.

ICAP will support the SHLS will as much as possible, to ensure that the number of VL lab techs is maintained at 9 at all times. The SHLS will ensure that the staff are well trained and their competency maintained at all times.

2. **Phlebotomists**: ICAP, through funding from CDC, is currently providing salary support to 46 phlebotomists to support specimen collection in all mini labs and in some major health facilities.

3. **Data Clerks**: Currently the SHLS does not have any data clerk focusing only on VL statistics. With support from PEPFAR, ICAP will hire 10 data clerks for VL. Their placement will strategically be in the NMRL and selected VL hubs across the country.

3.5.3: DBS Validation Study:

A DBS validation study is currently being conducted to inform adoption as an alternative specimen for VL. 241 patients have been enrolled. Results of venous DBS and finger prick DBS are being compared with matched plasma.

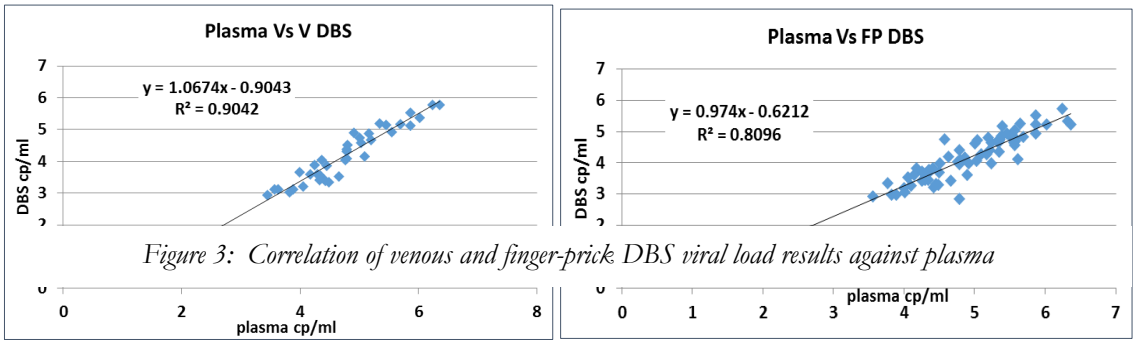


Figure 3: Correlation of venous and finger-prick DBS viral load results against plasma

So far, preliminary results show a correlation of up to 90% between venous DBS and plasma and 80% for finger prick DBS (see figure 3 above).

3.5.4: Type of Specimen:

Using plasma specimens for viral load testing is the preferred monitoring approach to determine viral failure at the threshold of 1000 copies/mL among people living with HIV in accordance with the 2013 WHO consolidated antiretroviral drug guidelines, and remains the gold standard.

However, where logistical, infrastructural or operational barriers to performing viral load testing using plasma specimens have not yet been resolved, DBS specimens for viral load testing can be used effectively at the threshold of 1000 copies/mL on most laboratory-based platforms. Since nearly all facilities with a lab (mini and major labs) will have a refrigerator and a centrifuge, it will therefore be possible to process and store plasma on days when there is no national sample transport to ship to Mbabane. However, for facilities without a mini lab and where whole blood cannot be processed (centrifuged) within 6 hours, DBS will be the specimen of choice. DBS will also be a specimen of choice for children <5 years of age for whom venipuncture may not be readily performed.

3.5.5: VL Scale-up & Work Flow Optimization:

The current monthly testing volume of the NMRL is limited to 3,000-4,000 VL tests, well below its true optimal capacity. In January/February 2016, CDC-ILB and ICAP worked closely with the SHLS to develop strategies to optimize workflow optimization for VL testing. *Provided there are 8 fully trained lab techs and at least 3 fully functional Roche COBAS Ampliprep/COBAS TaqMan 96* analyzers, the existing capacity of the NMRL can be boosted up as in the following scenarios, described in Box 1.

Box 1: NMRL VL Testing Capacity Scenarios

Scenario 1: Monthly capacity of the SHLS with regular 8-hour work schedule = **11,088**, equivalent to an annual volume of 133,056 VL tests

Scenario 2: Monthly capacity of the SHLS with a shift system enabling 12 hours of work = **15,246**, equivalent to an annual volume of 182,952 VL tests

Scenario 3: Monthly capacity of the SHLS with shift system 24 hrs of work = 24,948, equivalent to an annual volume of 299,376 VL tests

In addition, in order to meet these different scenarios, a high level of commitment from at least 9 fully trained VL technologists, timely technical assistance through supportive supervision and close follow up by the leadership are required. Each machine will be manned by two lab techs, loading 21 specimens to 8, 11 and 18 racks for 22 working days per month in each of the three scenarios above (see figure 4 below).

It should be noted that SHIMS2 VL tests are also expected to demand about 9,600 tests that should be considered within the discussed capacity of the NMRL. A shift system might be suitable to entertain the test demands of SHIMS2, which will enable avoidance of overlapping activities with routine VL testing. Weekend days can be considered for SHIMS2 lab testing to avoid overlapping and allow for smooth laboratory operation.

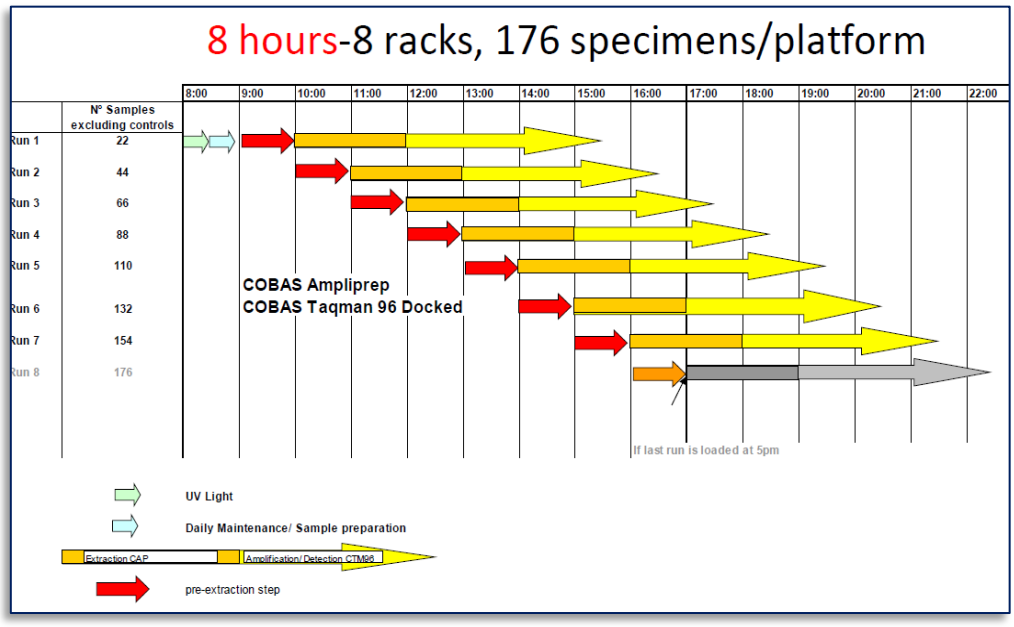


Figure 4: An 8-hour work schedule at the NMRL can be easily optimized to generate 176 test runs per day, with 3 machines and at least 8 technologists (see narrative for details)

3.5.6: NSTS and Return of VL Results:

Currently, the SHLS has 8 functional vehicles dedicated for specimen transport. Two of these cars are old and have high maintenance costs, but the other six are in good working condition. These vehicles transport laboratory specimens twice a week from peripheral facilities to the hubs/mother labs.

Vehicles are maintained through the government central pool which frequently results in delayed time of maintenance services and subsequently hindering their availability for NSTS. In the past, the absence of back up vehicles created a problem in addressing gaps due to unexpected incidents (e.g. car accidents) and inevitably led to interruption in specimen collection. For now, a private courier company, DHL, picks up specimens from the hubs twice a week for delivery to the NRL.

Once funding for VL scale-up is approved by O/GAC, ICAP will further strengthen the NSTS by procuring 4 additional refrigerated vehicles. The plan is to move to daily specimen transportation, instead of 2x a week.

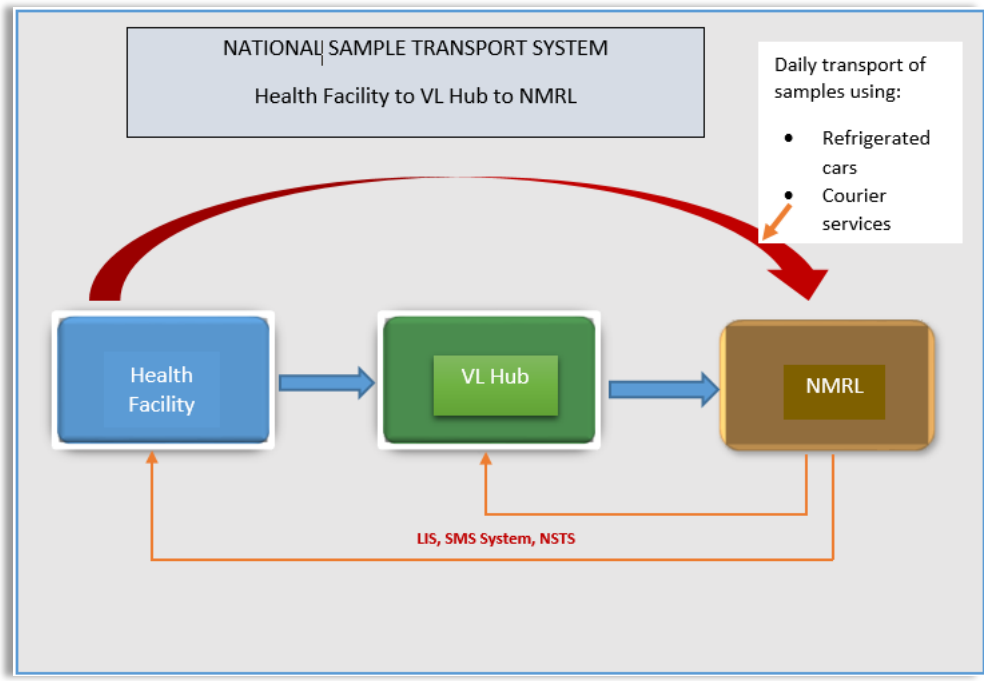


Figure 5: The "viral load test cascade": National Sample Transport System and Results Delivery

The innovative approaches of results delivery using SMS that are currently being piloted by URC will be rolled out by each regional clinical partner to reduce turnaround time (TaT), alongside strengthening laboratory information system (LIS).

SECTION 4: Implementation Approach:

4.1: A Phased Approach for Swaziland:

At the National C&Tx TWG meeting held on 10th March, 2016, the Swaziland National AIDS Program emphasized that the objective of VL scale-up is to achieve **the highest patient coverage for routine VL monitoring.** The committee then critically reviewed several implementation scenarios and provided guidance as follows:

1. Swaziland will implement scale up of routine VL monitoring starting with the 23 high volume ART facilities that were assessed by the VL taskforce in Feb 2016.
2. Routine VL monitoring will continue to be implemented in Shiselweni by MSF, with oversight from the SHLS and SNAP.
3. The VL specimen of choice will be plasma. However, once the DBS validation study is complete, DBS will be the preferred specimen for facilities without capabilities for centrifugation and refrigeration and for children < 5 years of age, and other circumstances that will be continuously re-evaluated over time to ensure greater VL testing access.

The first phase of the scale-up will cover start The following populations were identified as highest risk and therefore highest priority for routine VL monitoring:

1. **In ALL Facilities:**
   - Adult (non-pregnant, >19 years of age) suspected to be at risk for treatment failure either through clinical or immunological criteria
   - Pregnant and lactating women on ART
   - Pregnant and lactating women new initiations
   - Paediatric patients on ART (<19 years of age) on ART
   - Paediatric patients on ART (<19 years of age) new initiations

2. **In 23 CDC Facilities only:**
   - All Adults (non-pregnant, >19) on ART
   - Adult (non-pregnant, >19) New Initiations

Estimation of VL Testing Volumes:

Patients on ART: APMR data as of Q4 2015 was used to calculate patients currently on ART (by facility)

- Adults at risk for treatment failure: calculated as 20% of total adult population currently on ART[1]
- Pregnant & Lactating Women: calculated as 8.5% of total adult population currently on ART
- New Initiations: Data from Q3 2015 (~4,500 total new initiations) was used as a proxy for the number of patients to be initiated each quarter in 2016

The following principles will guide National scale-up of viral load monitoring in Swaziland:

1) Achieve the highest patient coverage possible
2) Cover all populations:
   - Targeted VL, for suspected treatment failure
   - Pregnant women, VL should be done as part of baseline tests at first ANC. For pregnant women newly initiating ART, VL should be done 6 months after ART initiation.
   - Pediatrics including adolescents: VL at 6 months after ART initiation, and if suppressed, continue to monitor every 6 months.
   - New Initiations: 6 months after ART initiation

- All other patients who have been on ART for > 6months.
- Most importantly, ensure implementation of proven workflow optimization solutions, in order to efficiently conduct as many VL tests as possible.
- Strengthen clinician capacity to integrate VL into patient management

Table 6: Number of patients active on ART by the end of Dec 2015

Facility	Population	Estimated Population Size
23 selected high volume ART facilities only	Adults on ART	65,944
	Adult New Initiations	5,874
All Facilities excluding the 23 high volume ART facilities only	Adults on ART at risk for treatment failure	8,032
All Facilities	Pregnant & Lactating Women on ART	9,917
	Pregnant & Lactating Women New Initiations	1,506
	Paeds (<19) on ART	9,790
	Paeds (<19) New Initiations	1,164
	TOTAL	**102,227**

Estimate Number of Tests per patient per year

- Used 2015 HIV management guidelines to determine number of VL tests in year 1 for suppressed
- Suppression Rates:
- **80% initial suppression** (at VL test 1) assumed for **all adults**
- **88% initial suppression** (at VL test 1) assumed for **all paediatrics**
- Test Coverage is assumed to be 100%; LTFU rates not accounted for

Estimate Number of Tests per patient per year

Facility	Population	VL Tests in Year 1 *(assuming 100% suppressed at VL test 1)*		VL Tests in Year 1 *(incorporating assumptions for suppression rates at VL test 1 & subsequent cascade for unsuppressed)*
		#	Timing	
23 CDC Facilities only	Adults on ART	1	at next ART appointment	1.40
	Adult New Initiations	1	6 months after ART initiation	1.09
All Facilities excluding 23 CDC Facilities	Adults on ART at risk for treatment failure	1	Immediately following indication of potential treatment failure	3.0

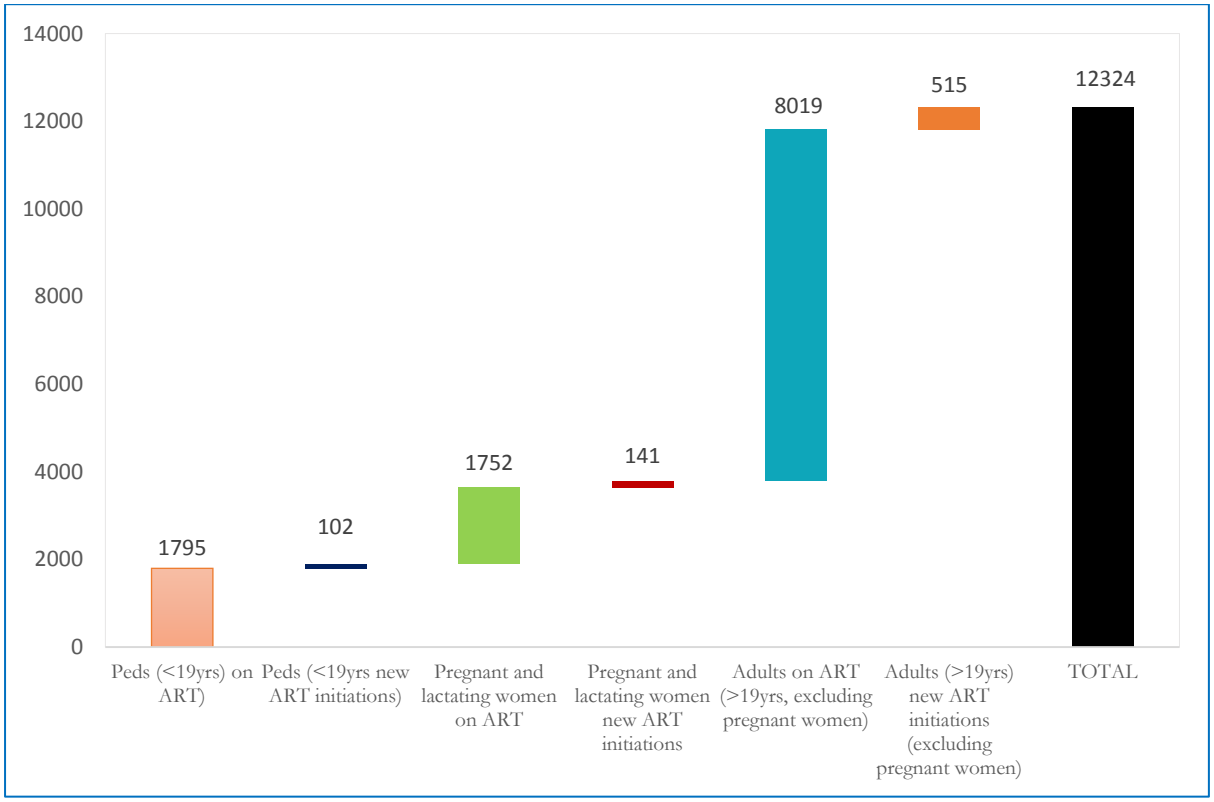
only				
All Facilities	Pregnant & Lactating Women on ART	2	at next ANC / ART appointment + 6 months later	2.20
	Pregnant & Lactating Women New Initiations	1	6 months after 1st ANC / ART initiation	1.20
	Paeds (<19) on ART	2	at next ANC / ART appointment + 6 months later	2.12
	Paeds (<19) New Initiations	1	6 months after ART initiation	1.09

A total of 23 selected facilities were selected for phase 1 of routine viral load scale-up as listed in table 3 above. Across these 23 facilities, the total number of patients active on ART by the end of December 2015 was 70,865, equivalent to 58% of all patients on ART in Lubombo, Hhohho and Manzini, and 48% of all patients on ART in Swaziland. (SID National HMIS data).

Prior to this, I wanted to share the updated (and hopefully final) VL estimates with you. We adjusted the suppression rates to more closely align to the MSF study outputs (88% suppression for adults, 80% suppression for paeds; this means the percentage of adults on ART at risk for Treatment Failure was decreased from 20% to 12%). This decreased our monthly estimates from 14,038 to 12,324.

The number of VL tests to be conducted annually for these 23 facilities was calculated using the following assumptions:

1. Total current on ART = 70,865
2. Proportion of patients with a first viral load above 1000 copies/mL = 20% (14,173)
3. Proportion of women on ART who become pregnant = 8.5% (6,024)
4. New ART initiations are estimated at 17,279 annually across the 3 regions. The 23 facilities account for 58% = 10,080
5. Viral load monitoring for patients on ART in Shiselweni will be implemented by MSF.



The total number of viral load tests to be conducted annually adds up to 101,142 tests, equivalent to 8,429 tests monthly and within the capacity of SHLS provided the needed HR, equipment and workflow optimization strategies discussed above are implemented (See scenario 1, Box 1 above). *(To be updated with figures from CHAI)*

Once routine VL monitoring is rolled out to these first batch of 23 facilities, the VL taskforce will engage the National C&Tx TWG on new sites to be added, in tandem with expansion of testing capacity at the NMRL, adequate NSTS, and effective utilization of VL results for patient management at facility level.

4.2: Engagement and Communication: The success of the implementation plan will depend on effective engagement of key stakeholders. Key to this process is the clear understanding of and division of service delivery roles and responsibilities. The following table summarizes the stakeholders' expectations and priority activities:

TABLE 6: Roles and Responsibilities of Viral Load Implementation Key National Stakeholders

Stakeholder	Responsibilities	Priority
National AIDS Program	• Collaborate with SHLS • Provide national guidance and coordinate oversight of systems and processes for site	• Lead establishment/revision of patient level files, registers, forms to ensure proper documentation of VL test orders, results, EAC/EAC and patient management

	implementation compliance and quality clinical management of patients who receive viral load testing	• Coordinate training of health care providers on viral load testing and results interpretation • Monitor the process and outcomes of routine VL monitoring at site, regional and national levels • Approve, lead planning and coordination of clinical mentoring and supervision framework • Provide quota for health facilities to start routine viral load monitoring at the selected facilities
SHLS	• Collaborate with the ART program during planning, implementation and monitoring of routine VL monitoring scale up • Oversee the development of laboratory capacity for routine viral load monitoring (specimen collection, accessioning, processing, results return) • Strengthen the national specimen transport system	• Increase the number of VL tests through work flow optimization • Improve VL test result delivery to facilities by strengthening the NSTS • Improve the quantification and procurement of VL laboratory commodities • Lead proficiency testing (PT), and laboratory mentorship and supportive supervision as part of lab quality management system (LQMS).
CDC/ICAP	• Provide technical assistance and resources to support routine VL monitoring across clinical, laboratory and monitoring and evaluation areas	• Support facility clinical and lab mentorship and supportive supervision activities • Provide guidance on quality of clinical services incorporating VL monitoring in PEPFAR supported facilities • Support the VL task force for increased responsibilities in VL testing, planning, implementation, and M&E • Collaborate with CDC Atlanta for continued clinical and technical assistance for VL scale up • Procure one VL machine and fill VL testing reagents' gap
PEPFAR clinical partners	• Provide technical assistance to ensure quality implementation of all components of the VL cascade (lab ordering, results documentation, interpretation, utilization, M&E) for improved clinical care quality.	• Support training of health care providers on VL algorithms, enhanced adherence counselling, virologic failure management, M&E,. • Monitor the outcomes of individuals with VL results >1000 copies/mL. • Support the function of MDTs, including switching to 2nd line regimens after a documented 2nd VL > 1,000 copies/mL. • Support problem based learning via local and virtual CME.
Clinton Health Access Initiative	• Participate in VL commodities quantification and forecasting	

- Forecasting and quantification of VL reagents and consumables
- Supplier Performance monitoring (In-country Distributor for Roche platform)
- Assessing possibility of new diagnostic platforms for SHLS to meet national testing demands

• National Sample Transportation System (NSTS) optimisation to meet VL scale-up plans		
Health Education unit/MOH	• Lead the development of communication strategies for patient education and demand creation. • Coordinate the development of communication tools	• Coordinate the development of communication strategies(including new content/tools) for clients' literacy of use of ART and VL testing
The Media	Support the communication strategy Use different media outlets for messaging • Support the development of messages around routine viral load testing in relation to ART.	• Coordinate regular radio and TV spots. • Conduct regular dialogues on routine VL monitoring (significance and access) • Provide information to clients in anticipation of increased VL testing/ordering capacity to improve clients' literacy of VL.

4.3: TRAINING PLAN

1. **Laboratory staff:** The SHLS will take the lead to identify training gaps in specimen collection, transportation, storage and processing. The training needs will be identified from site readiness baseline assessment reports and supportive supervision and mentoring visits. CDC/PEPFAR through ICAP will provide necessary technical and logistic support for the training of different health cadres which will include laboratory professionals (lab technologists & phlebotomists), as well as clinicians *in facilities without a laboratory*, NSTS drivers (and other drivers) who are potentially involved in specimen handling and transportation, and couriers (DHL).

   Newly hired VL technologists will be trained (or re-trained, where necessary) in updated VL testing methodologies, including DBS as appropriate.

2. **Clinical:** Clinicians (nurses, doctors), counsellors and Expert Clients, will be trained in the following areas:
   - Viral load algorithms for the different sub-populations
   - Interpretation of viral load results
   - Clinical SOPS for viral load monitoring (what to do with a detectable viral load)
   - Patient education
   - Enhanced Adherence Counselling
   - Switching patients appropriately, when they fail first or second line therapy
   - VL M&E and quality improvement activities utilizing site specific VL data.

4.4: Clinical and Lab Mentorship Framework for VL monitoring:

It is important to establish an efficient and effective system of clinical systems mentorship (CSM) for health facilities in Swaziland along the health network model to ensure high quality ART services provision.

Laboratory:

Laboratory and non-laboratory personnel will require different levels of training and supervision, depending on which stage of the VL testing process they are involved:

- **Phlebotomists/Nurses:** Basic understanding of specimen handling, specimen collection and processing, storage and delivery via NSTS, receipt and recording of results
- **Mother facility laboratory technologist/assistant:** Higher level understanding of testing processes, specimen processing, plasma handling and storage, delivery practices via DHL, receipt and recording of results
- **National Molecular Reference Laboratory Technicians:** In addition to above, specimen receipt and coordination, test method validation as well as inter-instrument correlation activities, internal/external quality assurance and good laboratory practices.
- **NMRL data clerks:** Results recording and delivery via NSTS, prioritizing critical results

The mentorship strategy will follow two prongs:

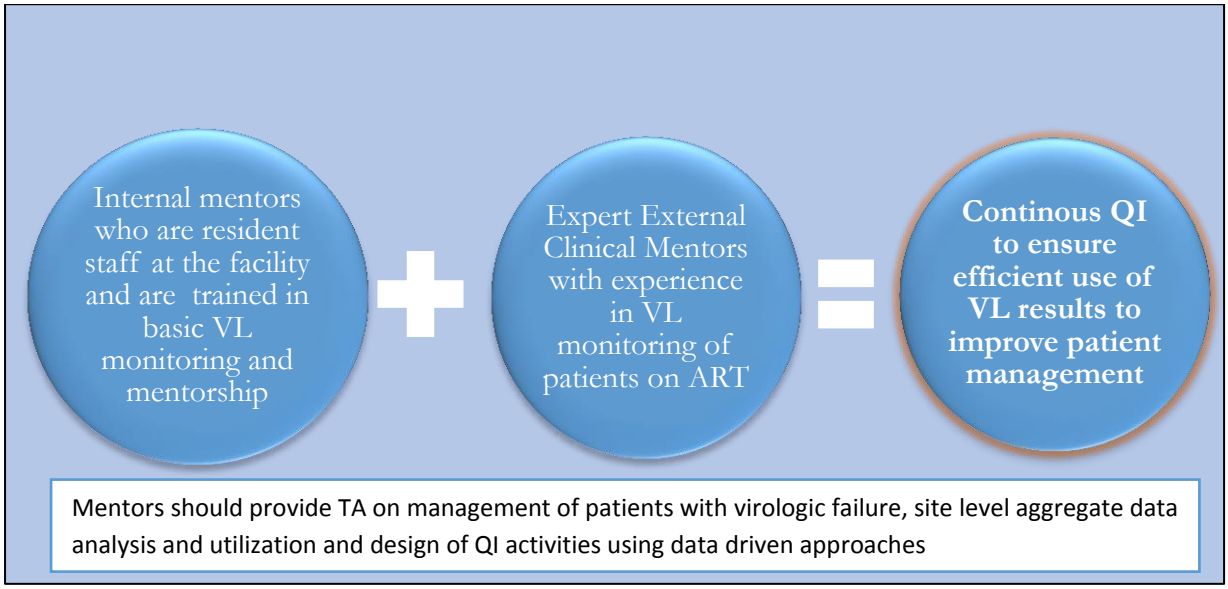
1. **Specialized structured mentorship specific to VL monitoring:** Good Laboratory Practices (Quality systems), Documents & Records, Management Reviews, Organization & Personnel Competence, Customer Service, Equipment, Internal Audit, Inventory/Stock management, IQC, EQA, Information Management, Corrective Action, Occurrence/Incident Management & Process Improvement, Facilities and Safety, Ethics, Specimen collection/processing, Specimen handling/referral and chain of custody, Data Collection and M&E, Forums to share best practices (Mentors forum)
2. **Regular supportive supervision** will be performed by capable mentors with generalized training and checklists. They will oversee: Specimen collection/processing, Specimen handling/referral and chain of custody, Information Management, Inventory/Stock management, Customer Service

Implementation of Laboratory Quality Management Systems (LQMS) is a holistic approach which improves the quality standard of the laboratory process in facilities starting from specimen collection to result reporting. ICAP will provide TA to the SHLS to strengthen the mentioned activities to continually improve and maintain quality in laboratories across the tiers. Implementation of quality standards in the main laboratories will be reinforced using "embedded mentorship" and supportive supervision. The mini laboratories will also be provided with a laboratory mentorship using a nationally standardized checklist which is specifically designed for the mini laboratories. Clinics without laboratories, but engaged in VL specimen collection and referral to the NMRL, will also receive regular supportive supervision by the SHLS and other stakeholders. To strengthen the capacity of supportive supervision and program monitoring by the SHLS, ICAP with funding through the PEPFAR, will procure two vehicles.

Clinical:

Clinical mentorship becomes even more critical when routine VL monitoring is implemented. The following framework and approach to clinical mentorship and supervision is imperative to ensure effective use of VL testing.

Figure 7: Proposed framework for VL clinical mentoring in Swaziland:



Each of the regional clinical partners will support SNAP to provide training and mentorship to facilities implementing routine viral load. ICAP will support the SHLS to ensure that a VL e-dashboard is established, from which VL data can will be readily available for mentors to review prior to conducting planned mentorship visits.

Regional clinical partners will work closely with the National AIDS Program to mentor implementing facilities to revitalize MDTs and empower them to meet regularly to review site data and specific clinical cases with viral loads above 1,000 copies/mL to decide on specific patient management and site level process improvement.

At the national level, SNAP and PEPFAR regional clinical partners should strengthen the HIVDR committee to become a National Expert Committee that will review complicated cases emanating from facilities, some of which may require third line ART.

Section 5: Monitoring and Evaluation Plan for Viral Load testing scale up and implementation

Purpose of the M&E Plan

The following monitoring and evaluation (M&E) plan describes the channels of information and the types of data to be collected and reported to monitor viral load testing and monitoring in Swaziland. The purpose of this M&E plan is to outline the steps that need to be taken to establish an M&E system for the programme; delineate responsibilities for data collection, reporting, analysis and dissemination; outline performance indicators and data collection tools; and discuss implementation and follow-up activities.

LOGICAL FRAMEWORK APPROACH (LFA) TO VIRAL LOAD TESTING AND MONITORING: KEY M&E TERMS AND CONCEPTS

Program process monitoring, also referred to as monitoring, investigates the extent to which the logical framework building blocks: inputs, activities, and outputs; were available, carried out, and delivered as intended.

- Inputs: are the various resources needed to run the program, e.g., money, facilities, program staff, supplies and equipment, etc.

- Activities: the set of activities in which program resources (human and financial) are used to achieve the results expected from the program, e.g., number of training courses conducted, number of materials developed and disseminated, number of workshops and conferences organized, etc.

- Outputs: are the immediate results obtained by the program through the execution of activities, e.g., people are trained, national guidelines on VCT have been developed, the quality of services has been improved, and the population's knowledge about HIV/AIDS prevention has increased.

Outcome evaluation investigates systematically the effectiveness of a program. It involves measuring two distal building blocks: outcomes and impact.

- Outcomes: are the intermediate results obtained by the program through the execution of activities, e.g., changes in behavior (sexual behaviors, health care seeking behaviors, etc.).

- Impact: is the long-term result obtained by the program through the execution of activities, e.g., changes in disease morbidity and mortality, social norms.

Table 7: Project Logic Model

INPUTS

- Funding
- Staff (e.g., Lab Techs, Transport Network, Clinic Staff, etc.)
- Policies
- Partnerships
- Equipment, Supplies, Reagents etc.
- Lab/Specimen Transportation Network

ACTIVITIES

Planning:

- Assess capacities of staff, existing specimen transport network, infrastructure, molecular labs, testing modalities, IPs, and M&E system
- Assess clinical site and program readiness
- Select specimen type and platform or assay, and VL technologies for VL testing
- Develop clinical algorithms and quality standards for VL monitoring
- Review and update clinical and lab monitoring and reporting (M&R) tools for VL monitoring
- Develop training materials and plan for training staff at national, sub-national, and site levels
- Develop costed, phased implementation plan with targets; determine criteria to guide phased implementation (e.g., geography, priority pops, etc.)
- Develop/revise plan for lab accreditation and Quality Improvement/Quality Assurance system to ensure quality of VL testing
- Identify current and future limitations of equipment, infrastructure, funding, policies, and HR
- Identify and prioritize evaluation questions (processes and outcomes) for VL monitoring and health outcomes

OUTPUTS

Planning:

- Comprehensive costed, phased, and strategic VL testing implementation plan with targets developed
- Training materials and training plan for staff at labs and facilities developed
- Revised monitoring and reporting (M&R) forms, and updated M&R SOPs for national, sub-national, and site levels to ensure complete and quality data available for VL monitoring
- M&E plan for VL testing developed
- Quality management system and external QA plan in place

Implementation of VL Testing and ongoing Monitoring:

Systems and Capacity Strengthening:

- Quality standards and SOPs established
- M&R forms and SOPs updated
- Molecular labs identified for VL testing and lab/specimen transport network strengthened
- Staff trained in VL testing procedures, including completion of M&R tools
- Clinical and program readiness assessed for phased implementation of VL testing

Service Delivery:

- Viral Load Testing available and scaled up

OUTCOMES/IMPACT

Short-Term Outcomes

System Outcomes:

- Increased capacity of lab techs. HCWs, data clerks, etc. to request, conduct, verify, and/or monitor outcomes of VL testing
- Increased ability to consistently provide supplies, transport specimens, and return results to sites for VL testing

Health Outcomes:

- Increased access of HIV+ patients on ART to routine VL testing
- Increased %age of patients with documented VL results
- Improved treatment recommendations and quality of care for HIV+ patients

Mid-Term Outcomes

System Outcomes:

- Increased volume of VL testing
- Increased quality of VL testing
- Increased routine and strategic use of quality data

Health Outcomes:

- Increased coverage of VL testing among HIV+ patients on ART
- Increased patient adherence to ART regimen
- Improved quality of care for ART patients
- Improved ART outcomes

Long-Term Outcomes (Impact)

Reduction in morbidity and mortality

Decreased numbers of AIDS-related deaths

Reduction of new HIV infections

Increased survival of patients on ART

Increased numbers of infections averted

Indicator protocol

The following dimensions will be used to describe the performance indicators used for program monitoring.

Name of indicator. This descriptive name will provide enough detailed information to ensure that different people at different times, given the task of collecting data for a given indicator, would collect identical types of data. The indicator shall also define the precise parameter used to describe the magnitude or size of the indicator.

Logic Model component (Output/outcome/impact). This describes whether the indicator is output, outcome or impact indicators as per the logic model.

Denominator (where applicable). This represent the bottom statistic in a fraction or a percentage.

Numerator. This is the top statistic in an indicator that is expressed as a fraction or percentage.

Disaggregated by: Identify how data will be separated to improve the breadth of understanding of results reported (for example: administrative region, sex).

Baseline: The baseline is the value of the indicator prior to an action. The baseline value establishes the starting point from which change can be measured. Put the date of the baseline in brackets.

Target: The target is the expected value of the indicator after an action. Put the date of the target in brackets.

Data source: The data source is the entity from which the data are obtained (e.g., a government department, an NGO, other donors, etc.).

Frequency of reporting: Describe how often the indicator shall be reported.

Individual responsible: Describe who will take the lead for collecting this indicator.

Program Relevance/Importance: This indicator is especially important in the planning stages. It describes why it is important to track the indicator in assessing and monitoring program performance.

Performance Framework

Table 8: Performance Framework for Monitoring VL Scale-Up and Implementation

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
# and (%) of sites being covered in lab/specimen transport network for VL testing	**N:** # of sites being covered in lab/specimen transport network for VL testing D: # of ART sites	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area			N: Lab Information System (LIS)	Quarterly until all sites are covered in lab/specimen transport network for VL testing		This indicator allows programs to track the scale-up and coverage of sites for VL testing. This is particularly relevant for programs utilizing a specimen transport network. The indicator will allow programs to track progress with including all sites in the specimen transport network.
# and % of sites that are included in the specimen transport network that are submitting specimens for VL testing	**N:** # of sites conducting/submitting specimens for VL testing **D:** # of sites being covered in lab/specimen transport network for VL testing	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area			N: Lab Information Management System (LIMS)	Semi-Annually until all sites are covered in lab/specimen transport network for VL testing and are submitting specimens		This indicator allows programs to track the scale-up and coverage of sites for VL testing. This is particularly relevant for programs utilizing a specimen transport network. The indicator will allow programs to track how many sites within the specimen transport network are regularly submitting specimens for VL tests. It may also be helpful to track this over time to inform site-level service delivery (e.g. if the patient volume at sites is very low and that is why specimens are not being collected, it can inform programs in broader strategic planning).
# of VL tests collected from	**N:** # of VL tests collected from sites by	Level of Facility (e.g.			N: Lab Information Management	Semi-Annually until all sites are		This indicator allows programs to track the scale-up and coverage of sites for VL

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
sites by lab/specimen transport	lab/specimen transport	Hospital, Clinical etc.) Level of SNU/Geographic Area			System (LIMS)	covered in lab/specimen transport network for VL testing		testing. This is particularly relevant for programs utilizing a specimen transport network. While as a stand-alone indicator, this does not provide a lot of information-but in tracking scale-up among different types of sites (e.g. Regional Hospital vs. Health Facility III) it may be helpful to track and compare to overall patient volume.
# of VL tests results returned to health facilities	**N:** # of VL tests results returned to health facilities	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area			N: VL Register at Sites Note that the data source for the indicator is the register at the facility, not LIMS. This is because the indicator is tracking what actually reached the facility and was recorded in the facility register.	Semi-Annually until all sites are covered in lab/specimen transport network for VL testing		This indicator allows programs to track the scale-up and coverage of sites for VL testing. This is particularly relevant for programs utilizing a specimen transport network. While as a stand-alone indicator, this does not provide a lot of information-but in tracking scale-up among different types of sites (e.g. Regional Hospital vs. Health Facility III) it may be helpful to compare to the number of tests collected (previous indicator) to determine how many results were returned to sites/health facilities.

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
# (%) of VL tests requested using DBS vs plasma vs both plasma and DBS collected specimens	**N:** # of VL tests requested using DBS vs plasma vs both plasma and DBS collected specimens **D:** Total # of VL tests requested	Type of VL test requested: -DBS -Plasma -DBS and Plasma			N&D: Lab Information Management System (LIMS)	Annually		This indicator assesses the type of VL tests requested. It may be helpful to monitor this in programs that are using different types of specimens for VL tests. It may inform forecasting and commodities.
% of specimens rejected by lab	**N:** # of specimens rejected by lab **D:** # of specimens sent to lab	**Reasons for Rejection: -** • Incomplete Lab Requisition Form • Inadequate VL specimen • Poor specimen Quality Type of Specimen (DBS or Plasma)			N&D: Lab Information Management System (LIMS)	Quarterly Review (at least)		This indicator will track the # and % of specimens rejected by the lab and the reasons why the specimen was rejected. This will help to monitor and improve quality control for specimens that are sent to the lab for testing.
% of specimens with detectable VL	**N:** # of specimens with detectable VL **D:** # of specimens tested for VL	Demographics: -Age -Sex -Pregnant, BF Type of Test: -Routine -Targeted -Follow-up VL test 3-6 months after 1st test result detectable			N&D: Lab Information Management System (LIMS)	Quarterly Review (at least)		This indicator will provide the number of specimens with a detectable VL. It should be noted that this is specimens, not individuals. From a lab electronic system, in all likelihood, even if patient information is included, it may be challenging to track only individuals. It would be helpful for programs to assess how easy or difficult it is to track individuals in a lab electronic system. If feasible to track individuals in a lab electronic system, then this indicator would not be required.

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
Length of time between specimen collection date and date result is returned to facility [turnaround time]	**N:** # of days spent between specimen collection and specimens return results	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area SSpecimens/Results Transport Points			N&D: Lab Information Management System (LIMS)	Quarterly Review (at least)		This indicator will be a quality control measure-to be able to track the # of days from when a specimen is collected to when results are returned to sites. Efforts to collect this indicator will be more intense for programs that physically return results to sites (vs. electronically provide results to sites).
% of sites unable to request VL tests for 1 or more consecutive weeks due to stock-outs and other supplies required for requesting VL tests	**N:** Sites doing VL unable to request VL tests **D:** Total # of sites doing VL (i.e. collecting specimens for VL testing)	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area			N&D: Lab Information Management System (LIMS)	Quarterly Review (at least)		This indicator will be a quality control measure-to be able to track the % of sites that were unable to request VL tests due to stock-outs and other supplies needed for VL testing. It should also help to improve forecasting and procurement of commodities. It will also help to flag sites that may require additional support for forecasting. This may be an indicator that is used for enhanced monitoring during scale-up and early implementation.
# of testing facilities (laboratories) with capacity to perform clinical laboratory tests [MER:	# of PEPFAR-supported testing facilities with capacity to perform clinical laboratory tests	Type of testing facility: -Clinical laboratories -Point-of-care testing sites			N: Lab Information Management System (LIMS)	Annually		Countries are encouraged to monitor the numbers of laboratories and testing sites performing HIV/AIDS-related testing as well as the capacity of these sites. This effort seeks to evaluate support for laboratory capacity that will provide access to high quality, rapid, affordable diagnostic

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
LAB_CAP]								tests for care, treatment, prevention, and surveillance for HIV/AIDS. Knowing the number of HIV/AIDS clinical laboratories and testing sites can indicate if testing coverage is adequate or if more capable laboratories are needed.
# and % of staff dedicated to VL testing	**N:** # of staff dedicated to VL testing **D**: # of staff working in HIV facilities and labs	Type of Cadre: -Lab Tech -Clinician -Nurse -M&E Staff at Site -District/SNU Staff Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area			MOH HR systems PEPFAR Implementing Partner HR Systems	Annually		This indicator will allow for tracking of the proportion of HIV staff that are actually doing VL testing
# and % of staff dedicated to VL testing that have been trained on SOPs for VL testing	**N:** # of staff that are dedicated to VL testing that have been trained in SOPs for VL testing **D**: # of staff dedicated to VL testing	Type of Cadre: -Lab Tech -Clinician -Nurse -M&E Staff at Site -District/SNU Staff Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic			MOH HR systems PEPFAR Implementing Partner HR Systems	Annually		This indicator will allow for tracking of the proportion of HIV staff that are doing VL testing and have been properly trained in SOPs for VL testing. This is particularly important in quality control. It will be a continuous process of training, given turnover of staff at facilities and in labs. As a stand-alone indicator, it is not very helpful. However, it will be helpful when considering with other quality control

Name of Indicator	Numerator/Denominator	Disaggregation	Baseline	Target	Data Source and Considerations	Frequency of Reporting	Individual responsible	Program Relevance/Importance
		Area						indicators.
# and (%) of ART providers trained to interpret VL results	**N:** # of ART providers trained to interpret VL results **D**: # of ART Providers	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area				Annually		
# (%) ART providers trained to deliver enhanced adherence counseling for patients with documented VL > 1,000 copies/mL	**N:** # of ART providers trained to deliver enhanced adherence counseling for patients with documented VL > 1,000 copies/mL **D**: # of ART Providers	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area				Annually		
# (%) ART providers trained in patient management switching from 1st to 2nd line ART with documented virologic failure	**N:** # of ART providers trained in patient management switching from 1st to 2nd line ART with documented virologic failure **D**: # of ART Providers	Level of Facility (e.g. Hospital, Clinical etc.) Level of SNU/Geographic Area				Annually		

COORDINATION OF THE M&E PLAN

This M&E plan will be implemented as part and parcel of the national roll out of routine viral load testing. Key MoH programs are involved in the planning, implementation and monitoring, including SHLS, SNAP, and SID. The HMIS sub-unit within SID is the custodian of the health information system and will eventually take ownership of the system to monitor the viral load testing that just as applies to APMR. The M&E unit (another sub-unit within SID) shall be responsible for generating (quarterly and annual) and sharing regular reports with programs (SNAP, SHLS) to inform program performance.

DATA MANAGEMENT PLAN

Data will be collected at various sources as outlined in the performance framework (Table 8). The implementing partners will work together to develop new M&E tools, or update existing ones (Table 9 and 10). This process will depend on the levels of data and system in use in different facilities.

Table 9: M&E tools to monitor key Viral load implementation functions

SERVICE LEVEL	FUNCTION	M&E TOOLS
FACILITY	All patient samples packed and dispatch date added to package as samples are dispatched	Sample requisition form
	Sample collected (with sample collection date added by collector)	Sample requisition form
	Clinician orders VL test and completes requisition form	Viral load testing register
	Samples arrive at the laboratory hub	Daily sample log
HUB LABORATORY	Hub dispatch date added for when samples were sent to the centralized laboratory for testing	Sample dispatch log
CENTRAL LAB	Form entry into electronic data system (i.e., LIS) with data entry review for errors	Sample requisition form, Laboratory Information System (LIS), routine dashboard
	Test performed and result added within the LIS	Daily lab testing register
	Quarterly analysis of key indicators using electronic system for lab data	LIS
	Central lab sends VL results and data for associated indicators related to sample testing to sub-national units, lab hubs, and/or sites (where electronic access is available, otherwise hubs will return results to facilities)	LIS Viral load test result form
HUB	Hub receives compiled report from central lab of turnaround times for sample testing and sample results for facilities under the hub	LIS Viral load tests results form
FACILITY	Facility receives VL results from central lab via transport network and/or electronically	Viral load test results form VL dashboard
	Staff at sites transfer the relevant data from dashboard to ART registers and chronic care file, and APMR where applicable	VL testing register VL testing log book Chronic care file ART registers, high viral load results follow up register, APMR
	Staff at sites prepare aggregated routine reporting based on site-level routine monitoring data for regional-level reporting	ART quarterly report
REGIONAL/NATIONAL LEVEL	Regional Health Management Team (RHMT) receives facility level data from facilities for inclusion in national HMIS	SID quarterly reports Annual reports

Table 10: Key components of VL Dashboard

KEY MODULES	DATA FIELDS
Demographic Information	National ID number (unique) Names Sex Date of birth Date of HIV diagnosis Date of ART initiation ART number
Baseline clinical information	Patient's current CD4 count Patient's current Regimen Patient's current age (using the date of birth) Patient Type (Pregnant/Breastfeeding, infant, etc) Other illnesses (including co-infection) Chemistry tests/results Adherence assessment
Viral load tests and results	Date of VL test Type of test (routine, targeted) VL result (absolute and log value) Next test date Current regimen Illnesses Pill count (adherence assessment)
Stepped up adherence counseling	Date of counselling Patient's self-adherence assessment Adherence problems found Referral to social worker or psychologist
Treatment failure review	Date of review Possible course of viral load detectable Decision (change to second line, etc) Date of regimen change Comments

M&E Data Flow and Data Capture

In Swaziland several approaches are used to deliver lab samples and results to and from facilities and labs (Figure 8.)

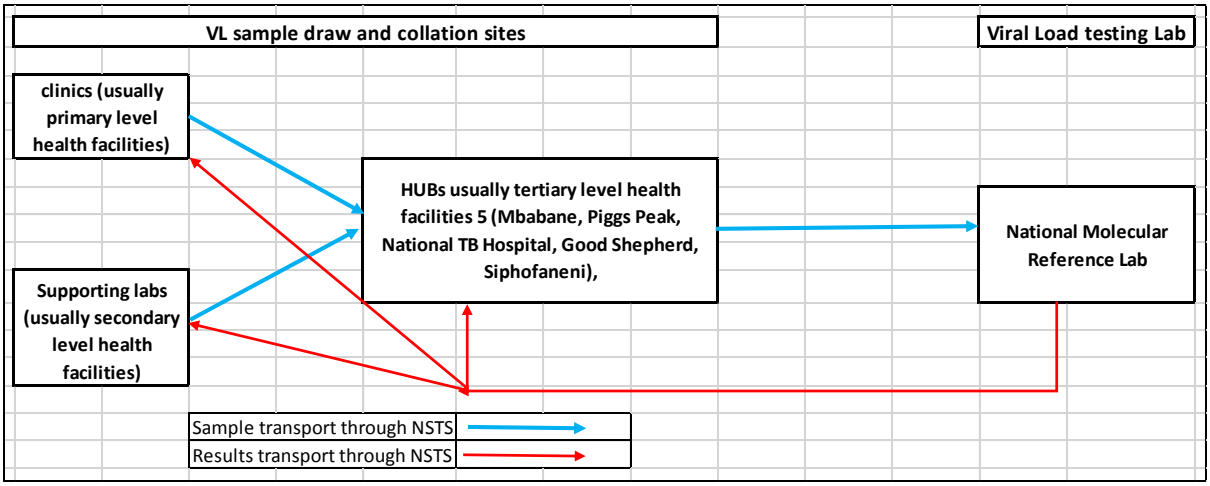


Figure 8: Schematic Flow of National Sample Transport System (NSTS) and Results Return for VL Testing

Facility data management processes

Facilities are the primary source of supported program data. Support to strengthen data management at facility level is therefore very critical in ensuring high quality program data. Data are generated through patient health care provider interaction. These data documentation procedures are guided by specific thematic area/tool SOPs (appendices #, #) developed in conjunction with the MOH HMIS unit and stakeholders and strengthened through routine refresher trainings and through M&E mentorship and supervision.

At facilities, viral load samples will be drawn from patients and data on the sample captured in sample logs (appendix). Samples are transported to the hub labs through the NSTS or in some cases through DHL. At the hub, the pooled samples are then transported through the NSTS to the national reference lab.

Regional data management processes

Implementing partners M&E staff will closely support the regional SID office in ensuring timely receipt of all facility reports and subsequent upload of data into the national system within set timelines. Further technical support shall be maintained to extract data from the system toanalyze for programmatic use at the regional level. Data quality improvement activities will include routine mentorship and supportive supervision of facility staff.

National data management processes

At the national reference laboratory, the samples will be logged in and processed through the LIS. The results will be printed out and batched to facilities through the NSTS back to the facility (some times through the hub facility)

The national SID office will continue to be supported in:

- Refined data analysis processes for production of monthly/quarterly/annual reports.

- Development and review of data management SOPs.
- Development and review of electronic systems at facility/regional/national levels.

Data storage and confidentiality plan

The MoH places high importance on secure storage of all collected data and maintenance of confidentiality on information the staff encounters in the course of offering TA and manipulation of data. All health care workers handling patient data will undergo training on security and confidentiality procedures. All health information systems are password protected and regular off-site back-up procedures are in place to ensure that data will not be lost in case of system failure.

QUALITY ASSURANCE AND IMPROVEMENT ACTION PLAN

TProgram implementation will ensure that patients and programs data are:

- Valid-measures what they are intended to measure
- Accurate-all data fields contain correct data
- Complete-there are no missing data
- Available-health information system will be able to report the data, that all sites will have reported the data, and data trail will be available to validate the data

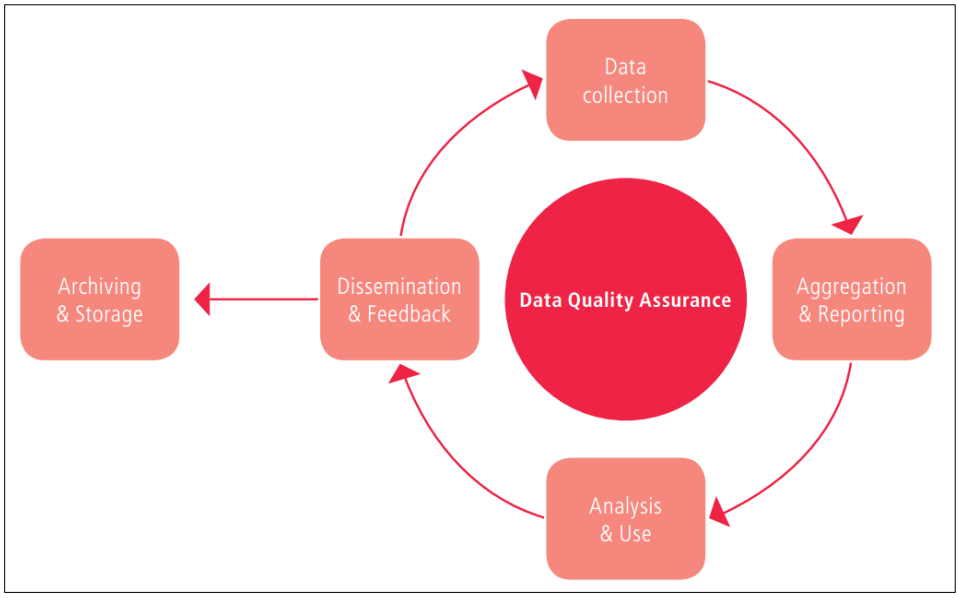


Figure 9: Data quality assurance framework[4]

Data quality will be measured at various levels (facility, region, and national) for program data review. The national DQA SOP and tools will be used to validate routine monthly data with facility records and continuosly address identified gaps. At the end of three consecutive months that make a reporting quarter,

[4] Data Quality assurance Standard and tool for PMTCT programmes, WHO, Geneva, 2005

the facility level monthly aggregation will be validated againsts the national level quarterly reports. Similar validation will also be incorporated into existing quality assurance frameworks: Regional HIV Semi-Annual HIV data Review (REHSAR) and National HIV Semi-Annual HIV data Review.

EVALUATION PLAN

Process Evaluation:

Process evaluation will focus on describing how the VL implementation activities are being implemented and will assess dose, fidelity, and reach of VL monitoring activities. The process evaluation will consist of two components: 1) review of documents and project data; and 2) stakeholder analysis. These data sources will be used to assess if TA was delivered and received during the project period (dose), implemented as designed (fidelity), and available and accessed by the intended patients (reach).

Illustrative process evaluation questions:

- Was VL testing scaled-up and implemented as planned? Why? What worked? What did not work?
- How are M&E, program/clinical, and lab staff working closely together to review viral load performance?
- Were staff trained or educated to the right level for implementing VL testing? Was there **adequate** support for VL testing (includes the service providers at sites, lab transporters, lab technicians, and M&E staff)?
- Which models of sample transport result in more people receiving VL tests and results?
- As a measure of quality of viral load services, how effective is the centralized system at getting test results back to facilities in a timely manner?
- How effective are the hubs and transport network at getting results to and from facilities?

The outcome evaluation will focus on assessment of short, medium, and long-term outcomes such as the change in clinical outcomes. The outcome evaluation will include: 1) review of documents and project data; and 2) stakeholder analysis. These different approaches will allow for the assessment of the project's short, medium, and long terms outcomes.

Illustrative outcome Evaluation Questions:

- Are there observed good/best practices to ensure patients receive VL testing and results in a timely fashion, understand VL results, receive adherence counseling that improves ART adherence and subsequent documentation of viral suppression?
- Was VL testing more successful with certain groups of people than with others? Were there significant differences in VL test results between different populations? Why or why not?
- How has quality of HIV services, particularly adherence counseling and support changed as a result of routine VL testing?
- What are the optimal model(s) of enhanced adherence counseling to ensure patients are adhering to HIV treatment and are virally suppressed?
- Do self-reported adherence rates predict viral suppression?

- Has sexual transmission of HIV reduced as a result of VL monitoring and increased rates of VL suppression in the population?
- Has the implementation of VL testing decreased the unnecessary switching of patients to second-line therapies?

A protocol to conduct the process and outcome evaluation will be written and ethical approval to conduct the evaluation sought from all relevant SEC, CUIRB and CDC ADS.

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Activities	Responsible	Q1				Q2			Q3			Q4			Measurement Indicators
		M	A	M	J	J	A	S	O	N	D	J	F	M	
Conduct situational analysis through site readiness assessment for VL scale up															
Conduct site assessment															
• Develop site readiness assessment checklist	VL Task Force	x													Checklist finalized for conducting site assessment
• Conduct consultative meeting on finalization of checklist	VL Task Force	x													
• Prioritize facilities to conduct the first round baseline assessment	VL Task Force	x													Facilities identified for first round of assessment
• Conduct training to mentors on checklist use for site assessment	SNAP, SHLS, IP Technical Directors														Mentors trained on site assessment checklist
• Facilitate data collection	IP Technical Directors														Data collection completed
Conduct data entry, analysis and preparation of baseline report															
• Receiving collected data from all partners	Harrison, ICAP	x													Data analysis completed
• Conduct data entry	Harrison, ICAP	x													
• Conduct data cleaning and data analysis	Harrison, ICAP	x													
• Prepare baseline assessment report	Harrison, ICAP	x													Baseline report written
Strengthen the national Laboratory technical working group and viral load task force and harmonization of efforts by different stakeholders															
Support the establishment of national Laboratory technical working group															
• Strengthen the national VL task force	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# VL Task Force meetings regularly conducted
• Develop TOR for National Laboratory TWG	SHLS/ICAP	x	x	x	x										TOR for NLTWG developed
• Identify roles & responsibilities of different stakeholders	SHLS/ICAP	x	x	x	x										
Strengthen the capacity of VL testing and national level and specimen referral from facilities															

Activities	Responsible	Q1				Q2			Q3			Q4			Measurement Indicators
		M	A	M	J	J	A	S	O	N	D	J	F	M	
Assess existing infrastructure for VL testing and selection of platforms															
• Develop a checklist to assess the capacity of the NMRL	ICAP/SHLS	x	x	x	x										# Regular assessments conducted
• Conduct regular assessments to identify areas for improvement early	ICAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	
Support the finalization of VL DBS validation study															
• Provide technical & logistic support in the collection of DBS specimens	ICAP	x	x												DBS specimen collection completed
• Provide technical support in data analysis	ICAP	x	x	x											Data analysis completed
• Make recommendations on the future use of VL DBS	VL Taskforce		x	x	x										Report written and shared with stakeholders
Procure additional Roche molecular systems															
• Procure and install an additional Roche COBAS Ampliprep/COBAS TaqMan 96 analyzer	ICAP/SHLS		x	x	x										# Roche COBAS Ampliprep/COBAS TaqMan 96 installed
Support the Equipment maintenance of VL machines															
• Strengthen the preventive maintenance of the VL machines	ICAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Service contract executed
• Establish a MOU with the local vendor for equipment maintenance	SHLS	x	x	x	x	x									
• Support the local vendor's capacity of biomed engineers in machine maintenance	ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	
Procure reagents and consumables for specimen collection & VL testing															
• Provide TA to support proper quantification and forecasting	ICAP. ??CHAI	x	x	x	x	x	x	x	x	x	x	x	x	x	# Stock-outs of Reagents and consumables
• Provide TA to the SHLS to place procurement orders on time	ICAP, ??CHAI	x	x	x	x	x	x	x	x	x	x	x	x	x	
Strengthen plasma specimen collection and processing on facilities															
• Procure & provide refrigerators & centrifuges	ICAP, GF		x	x	x										# Refrigerators and centrifuges procured
Strengthen the capacity of NSTS to meet volume of VL test															
• Procure and provide 4 refrigerated vehicles to the NSTS	ICAP		x	x	x	x	x	x							#Refrigerated vehicles for NSTS procured
• SHLS to liaise with the MOH for a priority NSTS vehicle service	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	
• Regularly review NSTS performance to identify challenges early	ICAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	
Strengthen the supportive supervision & mentorship activities															
• Procure and provide 2 vehicles for strengthening Lab mentorship	ICAP		x	x	x	x	x	x							#Refrigerated vehicles for mentorship procured
• Hire 3 additional Laboratory mentors	ICAP		x	x	x										# Lab mentors hired
• Increase frequency of supervision	ICAP					x	x	x	x	x	x	x	x	x	# Mentorship visits conducted

Activities	Responsible	Q1				Q2			Q3			Q4			Measurement Indicators
		M	A	M	J	J	A	S	O	N	D	J	F	M	
Ensure the availability & use of VL related laboratory SOPs, laboratory request form, laboratory VL register and specimen delivery checklists at all facilities															
• Develop all required SOPs & job aides for plasma & DBS specimen collection, storage and shipment	ICAP/SHLS	x	x												Updated SOPs & Job aides available
• Facilitate the revision of SOPs for VL testing NMRL	ICAP	x	x												Updated VL testing SOP available
• Support the revision of Laboratory request form to reflect the need of VL testing	ICAP	x	x												New lab request form in use
• Support the development and printing of facility maintained VL laboratory register	ICAP			x	x										VL lab register available in facilities
• Support the revision of specimen delivery checklist and use by the NSTS	ICAP	x	x	x	x										Revised specimen delivery checklist being used
Strengthen human resource capacity in VL specimen collection & testing															
Staffing and training of Laboratory technologists at NMRL															
• Train newly recruited lab technologists in VL/EID	SHLS/ICAP	x	x	x	x										New lab technologists' trained on VL
• Identify and assign a lab personnel to be dedicated for VL specimen reception	SHLS/ICAP	x	x	x	x										Lab technologist dedicated at VL specimen collection
• Identify and assign a lab personnel as a quality officer	SHLS/ICAP	x	x	x	x										Quality officer assigned at NMRL
Train health workers on specimen collection, processing, storage and transport															
• Train all laboratory personnel in high burden facilities	SHLS/ICAP			x	x										# of lab personnel trained
• Train at least two clinicians from the high burden ART sites without labs	SHLS/ICAP			x	x										# of clinicians trained
• Train all drivers & Couriers involved in specimen transportation	SHLS/ICAP			x	x										# of drivers & couriers trained
Strengthen innovative result delivery system to reduced turnaround time															
• Introduce innovative technologies (SMS, etc.) for result return	SHLS/SNAP/URC/ICAP/AIDSFree			x	x	x	x	x	x	x	x	x	x	x	Results returned via SMS
• Strengthen the result return using LIS, NSTS	SHLS/ICAP			x	x	x	x	x	x	x	x	x	x	x	90% of test results returned with established TAT
Optimize VL laboratory test work flow															
Strengthen the productivity of lab technologist & efficiency of machines															
• Develop a clear work schedule to the lab staff	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Updated work schedule available all the time
• Establish a shift system regularly revised to be able to absorb in testing	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Absence of back logs

Activities	Responsible	Q1				Q2			Q3			Q4			Measurement Indicators
		M	A	M	J	J	A	S	O	N	D	J	F	M	
volumes															
• Outline how SHIMS2 VL tests are conducted vis-à-vis increased routine VL monitoring	SHLS/ICAP			x	x	x	x	x	x	x					Work schedule for SHSIMS2 VL outlined
Support the uninterrupted electric power service for the NMRL															
• Conduct regular service maintenance of generators	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Absence of downtime of generators
• Ensure proper budgeting of fuel & service maintenance costs	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Running cost identified
Improve decision making through enhanced information management system															
Establish VL eTool - Dashboard at the SHLS															
• With TA from CDC-Atl, develop a VL e-dashboard	SHLS/ICAP	x	x	x											Dashboard developed
• Establish a VL database	SHSL/SID/ICAP			x	x	x	x	x							VL Database available
• Pilot the eTool Dashboard	SHLS/ICAP/SID				x	x	x	x							Dashboard piloting finalized
• Outline an SOP how different stakeholders access the eTool to guide a better patient management	SHLS/ICAP/SID					x	x	x							User guide for eTool defined
• Conduct monthly site level VL aggregate data analysis to inform site mentorship for patients with virologic failure	SNAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Proportion of patients with viral loads <1000copies/mL
• Mentor sites to develop data driven QI activities	SNAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	# QI projects implemented
Strengthen the M & E office of SHLS															
• Hire Database manager	SHLS/ICAP		x	x											Database manager hired
• Generate data and support the use of data for patient level clinical decision making	SHSL/SNAP	x	x	x	x	x	x	x	x	x	x	x	x	x	VL Database used for patient management
• Generate data for monitoring of program implementation	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	VL program monitoring indicators generated
Conduct operational research															
• Utilize secondary data for evaluating program implementation	CDC/ICAP/SNAP	x	x	x	x	x	x	x	x	x	x	x	x	x	Secondary data analyzed
• Grant proposals developed for HIV DR survey	SNAP/SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	Proposal developed
Develop projected specimen collection and referral schedule for facilities															
Assess existing HIV disease burden in facilities															
• Identify ART sites	SNAP	x	x	x	x										# of ART sites updated
• Organize data and project number of VL tests expected per facility every month	SHLS	x	x	x	x										# of expected VL test requests projected

Activities	Responsible	Q1				Q2			Q3			Q4			Measurement Indicators
		M	A	M	J	J	A	S	O	N	D	J	F	M	
Improve laboratory quality management system & accreditation															
Strengthen the QMS implementation at the NMRL															
• Conduct embedded SLMTA mentorship towards accreditation	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of stars achieved over the year
• Conduct technical supportive supervision & required trainings	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of supportive supervision conducted
• Conduct inter platform comparison among the 3 Roche machines quarterly as part of IQA	SHLS	x	x	x	x	x	x	x	x	x	x	x	x	x	# of times comparison conducted
Strengthen the supportive supervision and embedded mentorship in health facilities															
• Conduct embedded mentorship in the main laboratories/mother hubs	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of facilities received embedded mentorship
• Conduct supportive supervision in baby facilities	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of facilities received supportive supervision
• Implement LQMS in laboratories	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of laboratories implementing LQMS
• Provide TA and logistical support for laboratory managers & safety officers regular review meetings	SHLS/ICAP	x	x	x	x	x	x	x	x	x	x	x	x	x	# of review meetings (lab managers & safety officers) conducted
• Procure and provide two vehicles to the SHLS for capacity building to strengthen supportive supervision	CDC/ICAP			x	x	x	x	x							# of vehicles procured

(*Insert logos of all organizations that are partnering with the MoH on VL*)