Viral Load Cascade Self-Assessment Scorecard

Introduction

The African Society for Laboratory Medicine (ASLM), in collaboration with ICAP at Columbia University is conducting a rapid assessment of national laboratory systems supporting the HIV viral load test (VLT) scale-up in countries participating in the Laboratory Systems Strengthening Community of Practice (LabCoP). The rapid assessment is intended; (i) to assess strengths and weaknesses of the general laboratory system to support VLT scale up in a given country, and (ii) to monitor and demonstrate the degrees of improvement or continued challenges. The results will help determine the areas in which LabCoP will focus its resources and also opportunities for South-to-South sharing and co-creation of responses.

Instructions

- *Please read the contents of the checklist carefully before you complete the responses;*
- *All questions are referring to the national laboratory system*
- *You could consult the National HIV/AIDS Prevention & Control Unit at the Ministry of Health (MoH) and the National Reference Laboratory Center;*
- *Please refer to various data sources (routine laboratory & clinical data, reports, key informants, or other data sources) to come up with a reliable information/or answer.*

General Information

Date of assessment (dd/mm/yyyy): _____ / _____ /_____
Name of the country assessed: _____
Name of primary respondent: _____
Organization of primary respondent: _____
Position of primary respondent: _____
Contact address of primary respondent: _____

For each question, please check the box of the option that best describes your country setting or answers the question. You may provide additional explanation in the right side or on supplementary pages as needed.

S#	VLT Cascade Domains/Questions	1	2	3	4	Additional explanation whenever applicable
1	**Demand Creation for HIV VL testing**					
1.1	Is there a national strategy/procedure to increase demand of specialized or newly introduced lab tests by clinicians & clients at healthcare facilities (HFs)	☐ No standard operating procedure (SOP)/strategy to increase demand	☐ SOP/strategy developed, but not in use for updating clients, clinicians & stakeholders	☐ SOP/Strategy are used, and clinicians and clients actively seek such tests	☐ Most of facilities continuously monitor & evaluate test demands by clinicians and clients, and take actions to improve awareness	
1.2	Is there a national awareness creation initiative to PLHIV about VLT accessibility and its benefit?	☐ PLHIV unaware of the access to VLT and do not know its benefit	☐ PLHIV informed about the access of VLT but do not know its benefit	☐ Education/ awareness creation provided, and PLHIV actively seek VLT	☐ >75% of health districts management teams review data, work with stakeholders, and act to improve demand by clients/PLHIV	

1.3	Is there a national initiative/strategy that engages stakeholders (community leaders, HIV associations, …) to support demand creation for VL testing	☐ Stakeholders were not engaged, and there was no awareness initiative	☐ Strategy developed to advocate for VLT, but only a few stakeholders are engaged	☐ Workshops/Meetings convened or health education targeting VLT provided, & most stakeholders are engaged	☐ Stakeholders actively involved and advocate accessibility of VLT and its benefit	
1.4	Is there a national training or orientation to update/educate clinicians on the availability and importance of VLT?	☐ Clinicians are not updated on test accessibility & not educated on its significance	☐ Clinicians are not educated, but SOPs or training curricula available or under development	☐ Clinicians are trained/oriented & routinely order VLT, but they order occasionally	☐ Clinicians routinely order VLT to monitor ART as per the national guideline and educate clients on its benefit	
2	**Specimen Collection and Processing**					
2.1	Are there national guidelines or protocols addressing quality specimen collection and processing for all types of tests?	☐ No standard guideline or procedure for quality specimen collection and preparation	☐ Standard guideline and procedure are available or under development but do not cover all types of tests.	☐ Guidelines and protocols for quality specimen collection cover all type of tests and are applied everywhere	☐ All health district management teams continuously evaluate processes against the protocol, and use findings to improve quality specimen collection and preparation	
	Are specimen rejection rate routinely monitored as part of the quality improvement for sample collection and processing?	☐ Sample rejection rates are not being monitored	☐ Rejection rates are monitored in some testing facilities for some tests including VL testing	☐ Rejection rates are monitored in all testing facilities for some tests , including VL testing	☐ Rejection rates are monitored in all testing facilities for all essential diagnostic tests	
	What is the average of specimen rejection rates at national level	☐ Data are not available	☐ ≥10%	☐ between 5 and 10%	☐ <5%	
2.2	Is specimen collection procedure at facility level in compliance with the national protocols (guideline, SOPs or job aids) addressing the quality of VL specimen?	☐ No standard procedure for VL specimen collection and preparation	☐ Standard procedure available and applied in some facilities.	☐ Standard procedure available and applied in all facilities, with monitoring in some HF	☐ All HFs monitor sample collection & processing against the protocol, and take corrective action	
3	**Sample Transportation**					

3.1	Is there a national integrated sample referral network for essential diagnostics (TB, VL, chemistry, hematology, and others)?	☐ Sample Referral established only for specific tests like EID or VLT with incomplete coverage	☐ Sample Referral established only for specific tests like EID or VLT with >75% coverage of ART facilities	☐ Integrated sample referral system established, with 50-74% coverage of HF	☐ >75% coverage of the integrated sample referral system and continuous optimization to map routes & linkage of labs for improved access to specialized & essential tests	
3.3	Is there a well-established procedure for quality assurance of the transport system (complete documentation, packaging system, tracking system, quality control practices & others) for VL specimen?	☐ There is no procedure or monitoring system for packaging & transportation of VL specimen	☐ Procedure available and unstructured reporting mentions generally poor packaging & transportation	☐ Unstructured reporting mentions generally adequate packaging & transportation	☐ Adherence to standard assessed regularly to detect problems and initiate corrective actions	
3.4	What is the national average for TAT from sample collection to result return?	☐ >20 days and there is no system to monitor TAT at intermediate steps	☐ >20 days and there is a system to monitor disaggregated TAT steps	☐ 5– 20 days and there is a system to monitor disaggregated TAT	☐ 1-5 days with continuous review of disaggregated TAT and corrective actions	
4	**HIV VL Testing**					
4.1	Are clinical laboratories implementing Quality Management System (QMS) as part of a national program?	☐ No standardized QMS initiated in the country	☐ National QMS program in place and implemented in <50% of the facilities	☐ >50% enrolled in QMS	☐ All or >75% of the labs enrolled in QMS, with quality standard part of the requirements for national certification.	
4.2	Are VLT laboratories SLIPTA audited and certified?	☐ There is no SLIPTA program in the country.	☐ <50% of VL testing laboratories are SLIPTA audited and certified.	☐ >50% of VLT laboratories are SLIPTA audited and certified with 3-5 star ratings.	☐ >75% of the VLT laboratories are SLIPTA certified with 3-5 star ratings and reference laboratory (ies) achieved international accreditation	
4.3	Are laboratories performing VL enrolled in an established external quality assurance (EQA) or Proficiency testing (PT) for VLT?	☐ No national EQA or PT program established for VLT	☐ VLT EQA established but only <50% of VL testing laboratories participate	☐ >50% of labs performing VLT participate in the EQA but there is no monitoring for the implementation of corrective actions	☐ >75% of laboratories participate in EQA with a follow up and support of corrective actions	

4.4	How are VL test results being shared from the laboratory to the clinic where HIV care and treatment is provided?	Only physical return of written/printed results	Use physical return and SMS printer.	Most facilities use physical return but some facilities started using Email message, and online database.	All laboratories use online system including Email message online database.	
4.5	Are the following standard protocols (tools) put in place in the VL testing Laboratories? Mark that applies from the list: SOP for assessing specimen acceptability upon receipt in the lab Job aids for sample management from preparation to disposal VL testing algorithm VL Log Scale High VL Register SOP on VL Monitoring Internal auditing tool (e.g., VL scorecard or structured checklist) to assess the quality of VL testing	none of them are available	More than 3 are available and used in some facilities	3-5 are available and used in all facilities but results are not interpreted at national level	All are available and used in >75% of facilities and results are collated at national level	
	Waste Management and Biosafety					
4.6	Are there national policies, strategies, or guidelines for laboratory waste management and disposal, which are used in the VL testing VL laboratory	None	Waste management policy & strategy are under development, VL labs use facility SOP/guide	Policy and strategy are available, but generally not used/enforced in VL testing laboratories	Waste management and disposal is done in >75% VL testing laboratories as per national guidelines	
4.7	Is there a national on biosafety and biosecurity manual, which are used by VL testing laboratories?	No biosafety biosecurity manual	National biosafety & biosecurity manual is under development. VL labs use institutional SOP/guide	bio safety & biosecurity manual are available and is applied in all VLT laboratories	Biosafety & biosecurity manual is applied in all laboratories with a regular monitoring for compliance in place	
	Supply Chain Management and Equipment Mainenance					
4.8	Is there a national procurement strategy of reagent and consumable for laboratory testing?	No national strategy for procurement. VL testing laboratories	National Procurement strategy is available, but there were stock outs of VL reagents and	National Procurement strategy is available, and stock outs of VL reagents and supply are	No stock out is recorded in any VL testing laboratory and stockout for all essential tests are monitored and	

		procure reagent through fragmented systems.	supply recorded in >50% of VLT labs in the last 6 months	recorded in <50% in the last 6 months.	evaluated at the national level	
4.9	Are the VL national testing needs covered by the current VL testing capacity?	☐ The VL testing needs are not defined at national level	☐ Testing needs are defined and covered by testing capacity	☐ Testing needs are covered and needs are forecasted for the next 2 years	☐ Current and forecasted needs are covered and testing capacity is continuously optimized at national level	
4.10	Is the national lab maintenance plan/strategy implemented for VLT equipment?	☐ There is no plan and VL testing labs experience backlog testing due to lack of equipment maintenance	☐ Maintenance agreement in place, but scheduled service provided irregularly with interruptions of VLT still reported	☐ Schedule Maintenance provided as per agreement, and no specimen backlog reported due to service interruption in the last 12 months.	☐ Maintenance plan/strategy is available for all essential equipment (not only VL) and includes integrated pricing.	
4.11	Are VLT laboratories adequately staffed with skilled human resources?	☐ There is no data on HR available	☐ There is a shortage of staff (based on national norms) with training needs for VL testing identified in >50% of the VLT laboratories and not addressed by the national HR development strategy.	☐ There is no shortage of HR with current training needed for VLT addressed in the national HR development strategy.	☐ No shortage of human resources and no training needs with the national HR development strategy addressing forecasted staffing needs for VLT and other essential diagnostics.	
5	**Results Utilization**					
	Is there a national LIMS system to ensure swift delivery and notification of abnormal test results?	☐ No system in place	☐ Various LIMS are in place in some laboratories but are not institutionalized at national level	☐ A national standardized LIMS is in place but not fully implemented across laboratories	☐ All laboratories use the national LIMS, with clear roles and responsibilities established assigned at HF level.	
5.1	Are there protocols for the interpretation of VL results and utilization for client management	☐ No SOP or job aids are available, even at facility level	☐ National protocols are available but are used in <50% facilities delivering HIV care	☐ National guidelines are used in >50% facilities delivering HIV care	☐ National guidelines are used in all HF and improved client management is measured based on a review of program data measure	
5.2	Is there a strategy ensuring that clinicians are continuously trained for the interpretation of VLT results	☐ There is no strategy to ensure that clinicians are properly trained	☐ There are donor-initiated initiatives only in some HF.	☐ There is a strategy at national level applied in <50% HF delivering	☐ There is a national strategy in place, applied in >50% HF and regularly monitored and evaluated at national level.	

	and utilization for patient management?			HIV care and monitored in some HF		
5.3	Are there standardized Enhanced Adherence Counseling (EAC) strategies & tools for PLHIV with unsuppressed VL?	☐ No EAC strategy & monitoring registers/forms	☐ EAC strategy & tools available and used in some HF, but they are not standardized	☐ Standardized EAC strategy & tools are used in all HF and monitored in some facilities.	☐ EAC is routinely monitored and evaluated at national level and data with opportunities to improve patient management	
5.4	Are there standardized processes for referring patients with SUPPRESSED VL to less intense models of care	☐ There are no processes in place	☐ There are various processes at facility levels	☐ There is a standardized process at national level but it not yet monitored	☐ The standardized process is monitored and evaluated for continuous improvement of patient management.	
6	**Leadership and Management**					
6.1	Is there a unit at the MoH or technical working group TWG responsible for coordination and implementation of national lab system strengthening?	☐ No national TWG but there is focal person/ team at the MoH	☐ TWG is established but not functional	☐ National lab system coordinated and supported by TWG that has clear terms of reference	☐ TWG engages all lab stakeholders, review/evaluate system for improved quality lab services	
6.2	Is there a national plan or M&E framework for effective scale up of VL testing?	☐ VLT is not recommended by the national HIV treatment guidelines	☐ VLT is recommended by national HIV policy/guidelines but no specific plan or M&E framework	☐ VLT implementation plan and/or M&E framework integrated into the national HIV program guidelines, with a designated coordinating technical working group.	☐ All of before and results regularly analyzed at national level and used to improve the effectiveness of the VL scale up	
7	**National Data on VL Testing and ART**					
7.1	Number of Laboratories currently carrying out HIV VL testing ; _____ labs Number of VL testing Machines for different types; Abbott m2000 ……., Roche CAP CTM 96 ……., CAP CTM 48 ……., Cobas 4800……., Cobas 8800……., Seimens K-PCR ……. … Bio-muerex ……. …Caigen ……. Hologic ……. POC –Gene Expert …… SAMBA …… - Testing capacity of the national VL testing labs altogether: _____ tests/year - Total # VL tests done in the last 12 months: _____ tests/year - Please list the company (ies) for which there is a national reagent rental agreement in place. Name the company(ies): _____, _____"					
7.2	Estimated number of (PLHIV) in the current year: _____ - #/% PLHIV currently on ART: _____ - #/% PLHIV currently on 1st line ART regimen: _____ - #/% PLHIV on ART eligible for a routine VL test: _____ - #//% PLHIV on ART who received a routine VL test: _____ - #/% PLHIV on ART who are Virally Suppressed (<1,000 copies/ml) on routine testing : _____ - #/% Virally suppressed PLHIV referred to a less intense model of HIV care: _____					

	- #/% PLHIV on ART with a VL of ≥1,000 RNA copies/ml who received Enhanced Adherence Counseling (EAC) : _____ - #/% PLHIV on ART with ≥1,000 copies/ml who received a follow-up VL testing within 3-to-6 months of Enhanced Adherence Counseling (EAC): _____ - #?% PLHIV on ART with a follow-up VL test result of <1,000 copies/ml: _____ - #/% PLHIV on ART with two consecutive VL test results of ≥1,000 copies/ml who SWITCHED to a 2nd or 3rd line ART regimen: _____ Number of people with a VL >1000 copies/ml who had suppressed VL at follow-up testing*
	List 3-5 critical challenges of VL scale up in the country 1._____ 2. _____ 3. _____ 4. _____ 5. _____
	Any comments/best practices/recommendations for VL scale up that could be applicable in other settings? 1._____ 2. _____ 3. _____ 4. _____ 5. _____

Abbreviation: Lab = laboratory; VL=Viral Load,