LabCoP Cookbook

of best practices

Delayed Switch

Long TAT

etC

Lab CoP

ASLM

The increasing availability and affordability of HIV viral load (VL) testing presents exciting opportunities for national HIV programs, as well as challenges for many countries, as the focus shifts from access to VL testing (VLT) to utilisation of VL test results to improve the management and outcomes of patients. Studies from settings where VL monitoring is widely available reveal that patients often remain on failing treatment regimens for too long, despite access to VL services. Optimising utilisation of VL test results represents a high-priority challenge to achieving the UNAIDS 95-95-95 Fast-Track Targets.

95%
Diagnosed

95%
On Treatment

95%
Virally Suppressed

Studies from settings where VL monitoring is widely available reveal that patients often remain on failing treatment regimens for too long, despite access to VL services.

VL result utilisation steps include: accessing test results on time; correctly interpreting and communicating the significance of the results; and swiftly acting on the results (whether suppressed or unsuppressed) for patient management. Routine VLT is critical for monitoring viral suppression and guiding antiretroviral treatment (ART). If appropriately used, VLT has the potential to optimise the effectiveness of ART by assisting clinicians to: a) detect ART failure and provide rapid and appropriate adherence counselling and ART management to avert HIV drug resistance and b) identify patients who are virally suppressed and eligible for differentiated service delivery (DSD) models. In recent years, countries and partners have made enormous efforts to scale-up the availability of VLT for routine monitoring. However, without appropriate utilisation of VL test results, increased VLT coverage will not have the desired impact.

Reports indicate that utilisation of laboratory test results is often suboptimal, especially in sub-Saharan Africa. For example, approximately 50% of CD4 and early infant diagnosis tests performed in sub-Saharan Africa were never used[1]. Similarly, early reports indicate VL test results are often underused, or not used, due to the absence of systems and monitoring. In Kenya, only 4% of patients with unsuppressed VL (UVL) had a repeat VL test, of which only 1.6% occurred within four months[2]. In Mozambique, only 35% of patients with UVL had a repeat VL test[3]. Conversely, in Swaziland, 70% of patients with UVL had a repeat test, and 38% had treatment failure, but only 15% were switched to a second-line ART, and the majority were re-referred to more adherence counselling[4]. These studies illustrate how lack of VLT result utilisations impacts patient management and appropriate support of patients with UVL.

Without improvements in VLT utilisation, the large-scale investments in routine VLT scale up will be wasted. This recipe provides an overview of essential interventions and practices for effective and efficient utilisation of VL test results to improve patient management and achieve improved clinical outcomes.

VL TEST RESULT UTILISATION CASCADE

Figure 1. VL test result utilisation cascade
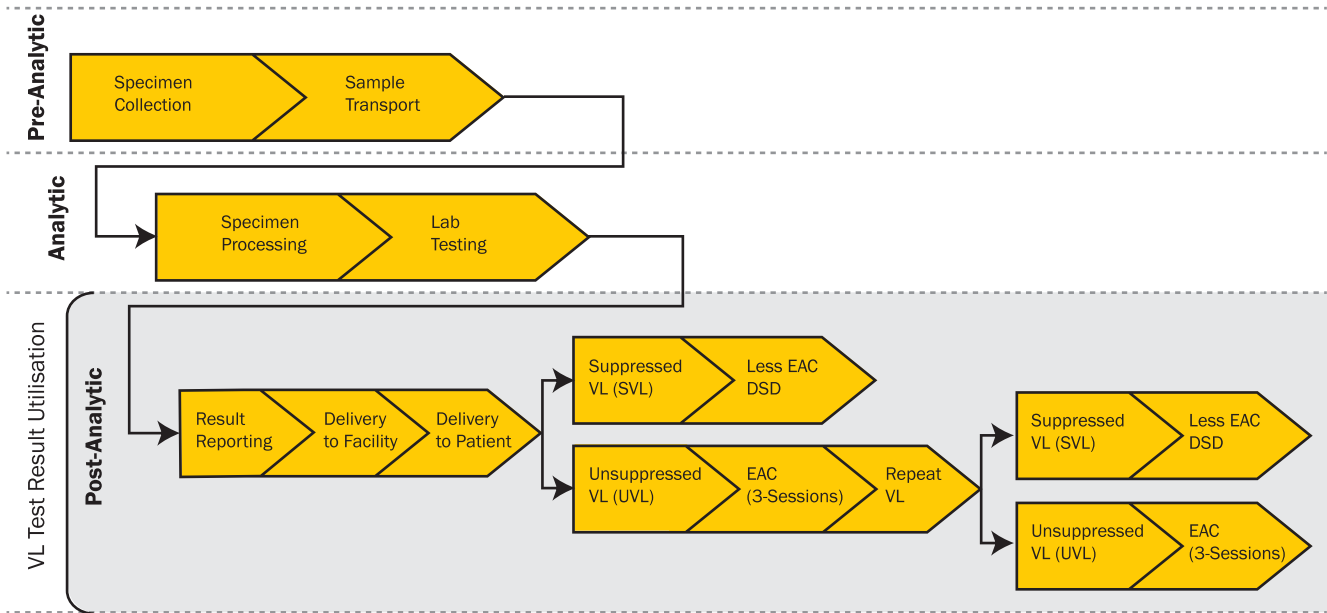
The VL monitoring cascade is a management process from laboratory result reporting to patient management actions, including all the management actions of the laboratory's post-analytical phases (Figure 1). If a first VL result is high or shows unsuppressed VL (UVL), enhanced adherence counseling (EAC) is offered. If a follow-up VL result is high, after completing three consecutive successful EAC sessions, the patient should be considered for switching to second-line ART. Patients whose first VL test indicates viral suppression may be eligible for referral to differentiated service delivery (DSD) models. Unfortunately, there is a drop off at every step of the UVL cascade (Figure 2), and early data suggest that many patients with suppressed VL (SVL) are not appropriately referred to DSD models.

Figure 2. Unsuppressed VL Cascade (Illustrative data)
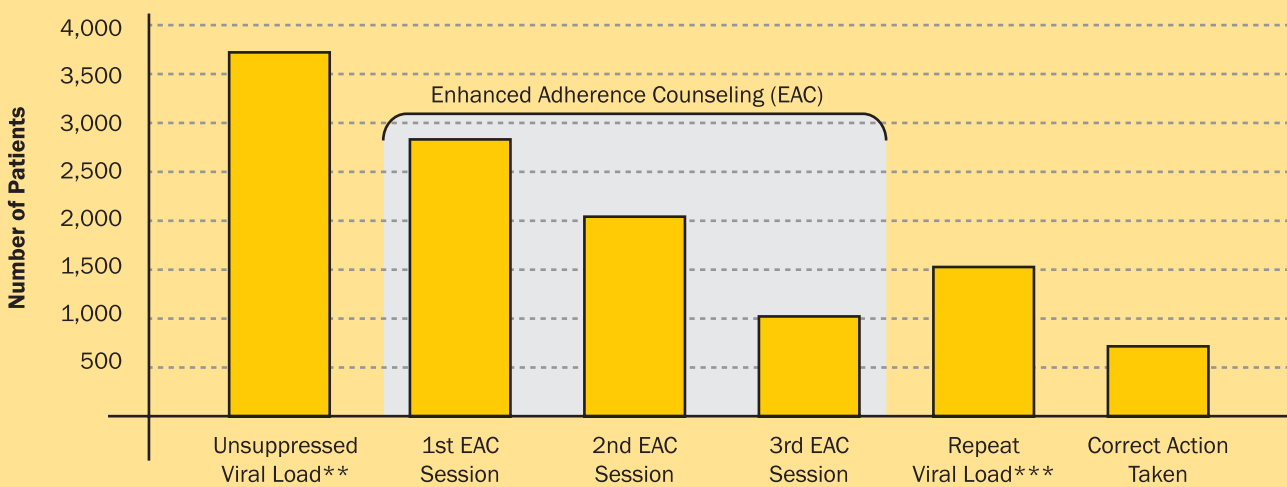
*   EAC: adherence interventions provided to persons with high blood viral loads (≥1000 copies/ml) in three sessions for 3-4 months in order to achieve VL suppression (<1000 copies/ml) on re-assessment.

**   Unsuppressed viral load: a high viral load (VL) test result – generally defined as a viral load of 1,000 copies/ml or more.

***   Repeat VL: VL test performed after three, successful, consecutive EAC sessions are completed.

INTERVENTIONS TO IMPROVE VL TEST RESULT UTILISATION

The critical challenges in VL test result utilisation can be categorised as a) difficulties related to result reporting, b) correct interpretation and communication of results to guide patient management, and c) patient follow-up and support.

- Test result reporting challenges include gaps in result sorting and processing, poor laboratory-clinic interface and suboptimal systems at the health facility/program level. These factors contribute to extended turn-around times (TAT), loss or switching of results, incorrect documentation, failure of results to be documented in the clinical record (e.g., registers, patient charts), and failure to 'flag' or prioritise critical results (e.g., unsuppressed VL).

- Once clinicians have seen the VL test results, the next challenge is for them to act upon them swiftly and accurately. Although training is required to support the interpretation of VL results, experience shows that this is rarely the primary barrier, especially when results are formatted as 'unsuppressed' vs. 'suppressed'. Instead, what is needed are the systems capable of supporting routine and timely action.

- Effective engagement of recipients of care is critical to maintaining viral suppression. Proficient patient education, support, and monitoring can make the difference between the success or failure of the UVL cascade.

A management system that improves VLT (and other laboratory test utilisation) helps not only patients but also health providers and health facilities. A successful implementation strategy requires the empowerment of site-level teams to tailor-make contextually appropriate systems, a careful data-driven process, and ongoing monitoring and evaluation (M&E). A compressive list of interventions and strategic options are described in the attached table at the end of this recipe (Table 1). The 'recipe' below describes the minimum package of strategies and systems needed for a successful program. It requires a multidisciplinary approach, with coordinated efforts from laboratorians, clinicians, and facility leadership, along with other partners and stakeholders.
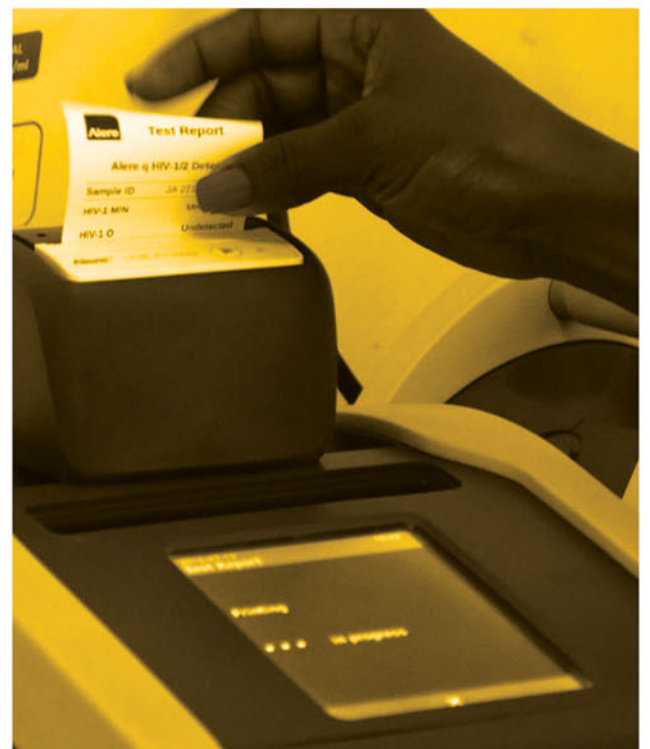
From the laboratory perspective, result delivery is often conceptualised as a process by which laboratory test results are documented in the laboratory and relayed to a health facility. In practice, much more is required. Whether delivered by hand, fax, text or email, or available on a web-based laboratory information system (LIS), test results need to be 'received' in a way that promotes correct and timely action. Similarly, missing or late test results need to be flagged and acted upon. These systems are the heart of the laboratory-clinic interface.

It is essential to establish a strong patient tracking management system to ensure that VL test results are used effectively, and patients are placed on the best possible treatment. Such a system includes processes that connect results to patients, appropriately document data into a chart or register, and flag UVL for prompt action.
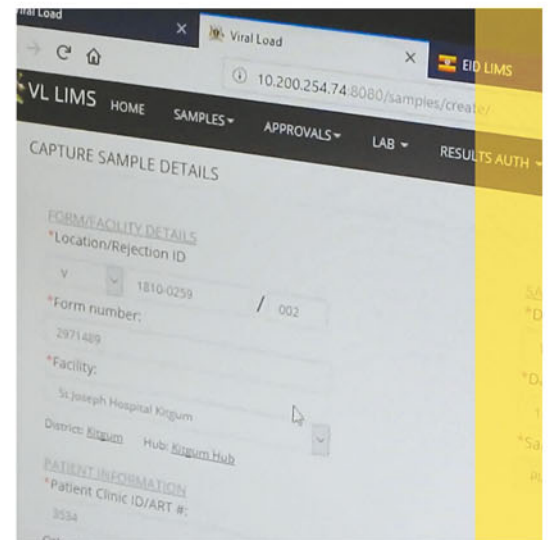
DELIVER RESULTS IN A TIMELY FASHION

The International Treatment Preparedness Coalition (ITPC) reports that people living with HIV/AIDS often wait six weeks to six months to receive their VL results – if they receive them at all. Delays in result delivery include both delays in transmitting results to the health facility and delays between receipt at the health facility and review by the responsible clinician. If test results sit in a stack of papers, or are documented in a chart or register, but not reviewed, lapses will occur.

Result transmission from laboratory to facility can be streamlined by utilising a LIS that uses unique patient identifiers. Electronic reporting systems can link test results to patient's medical records for faster turn-around times (TAT) as well as for continuity of care. Other approaches to rapid result delivery include using SMS printers, fax, email, telephonic inquiries, and web-based databases that can be accessed via computers, tablets and/or smartphones. In settings with weak or no internet or mobile coverage, the innovative use of local bikers/drivers (e.g., 'Riders for Health') has been validated as an effective approach to decrease TAT[5].

CRITICAL RESULT NOTIFICATION

Critical laboratory test results, in this case (UVL), must be immediately flagged and communicated to clinicians and multidisciplinary teams for immediate action. These systems should be optimised at the site level to match the local context and resources. Several simple approaches have been found to be highly effective, including:

• Use of a separate UVL register
• Mobile texting
• Reports designed to highlight UVL (e.g., color coding, unique tagging, symbols)
• Using stickers on charts
• Labelling results with 'Urgent'' or 'ASAP', or other methods to expedite linkage of results with action.
• Routine audits of time between receipt of critical results to time clinical action is taken.

STANDARD OPERATING PROTOCOL

Development of a guide or standard operating procedure (SOP) for reporting VL and/or other laboratory results, and monitoring its implementation facilitates the sustainable delivery of results. Engagement of clinicians, counsellors, laboratorians, and recipients of care in the development of SOPs helps to ensure they are practical and feasible at the site level.
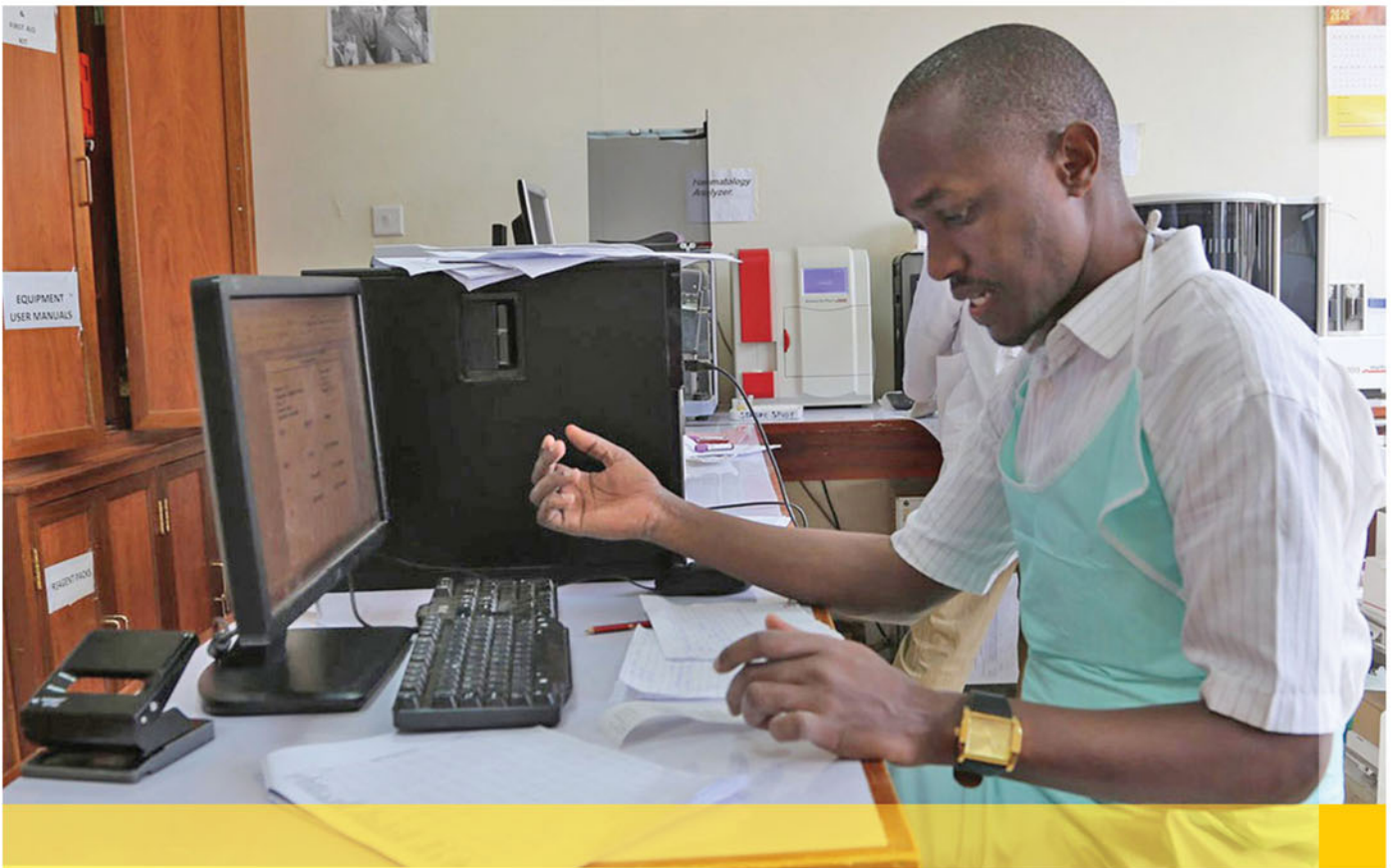
VL FOCAL PERSON OR CHAMPION

Assigning a responsible individual who can monitor and sort high VL results, and document and alert clinicians for immediate action has been proven to improve VL test result utilisation in multiple settings.

TIMELY RESULT REVIEW AND INTERPRETATION

Clinicians should receive, review, and interpret test results based on national/local patient management guidelines. Key interventions to support timely and accurate use of VL test results include:

- Critical result notification systems and SOPs ensure clinicians and multidisciplinary teams see results and prioritise them appropriately.
- Training, ongoing supportive supervision and development of job aides support appropriate action – whether VL is unsuppressed or suppressed.
- Routine review of patient management by site-level multidisciplinary teams should include assessment of VL-guided services.
- Routine review of program level data at the health facility and program levels (see Section 4, Monitoring and Evaluation below).

CONNECTION OF RESULTS, CLINICIANS, AND PATIENTS

Once results have been reviewed by lab personnel, prompt action to connect results, clinicians, and patients is required. In some settings, patients receive timely follow-up appointments after VL specimen collection, i.e., they are scheduled for VL results review within 1-2 weeks. In this context, a systematic review is needed to make sure those appointments occurred, and the loop has been closed. In other settings, a VL result requires scheduling an urgent appointment with patients. In either case, understanding the current process is the first step towards improving it. At many facilities, this is complicated, as processes may be implicit or misunderstood. It may not be clear who is responsible for each step. Additionally, what is actually happening may be very different from what is supposed to happen. Experience shows that:

- Develop a process map with site staff and patients to enable program managers to identify gaps and opportunities for improvement.
- Review data on an ongoing basis, whether in the context of routine M&E or quality improvement activities, to identify what proportion of patients receive results within the appropriate timeframe.

APPROPRIATE AND TIMELY CLINICAL SERVICES

The World Health Organization and national guidelines generally recommend that patients with SVL (and other criteria for 'stability') be referred to DSD services, although these vary substantially between and within countries. Guidelines also recommend that patients with UVL receive 3 EAC sessions within approximately 3 months, followed by a repeat VL test and either referral for DSD (if suppressed) or switch to a new ART regimen (if persistent UVL is documented).

- UVL management should be guided by step-by-step SOPs, including systems and tools to support EAC.
- Sites and programs can adapt existing UVL toolkits, such as the one developed by ICAP at Columbia University (see Resources on next page).

CASE MANAGERS

Assigning case managers to UVL clients helps to provide improved care. Case managers make periodic contact with patients to assess and monitor changing needs and provide care as needed.

It is critically important to engage and empower patients to be active participants in their own care, including both demand creation and result utilisation for routine VL testing. Patients should know when VLT is planned, the estimated TAT for results, and what the results will mean for their HIV management. Encouraging patients to get involved in the follow-up process does not relieve healthcare providers of their duty to follow up, but it may add a layer of patient care management to the test results management system, and may be empowering for patients.

Recipients of care must always be the focus of all processes and outcomes, and need to receive correct and clear information. Programs and sites must therefore update and adapt their support strategies to include VL test utilisation strategies.

BEST PRACTICES INCLUDE:

- Tailoring EAC sessions to the local context with input from recipients of care
- Communicate VLT results via phone to those individuals who welcome the opportunity to phone in for their result
- Utilisation of multidisciplinary teams, including case managers and peer educators
- Development of tailored support for patients with UVL
    o Specialised peer educators for patients with UVL or on second-line ART
    o Specialised clinic days/sessions for patients with UVL
    o Tailored health talks, posters and text messages

RESOURCES

- ICAP toolkit includes training materials, flip charts, job aids, and tools for health workers
  https://icap.columbia.edu/tools_resources/viral-load-toolkit-english/
- International Treatment Preparedness Coalition Activist Toolkit provides up-to-date information that provides the knowledge and skills needed to advocate for access to routine VLT.
  http://itpcglobal.org/wp-content/uploads/2016/04/ITPC-RVLT-Toolkit-English.pdf

Monitoring and evaluation (M&E) of the VLT cascade is essential to ensure consistent, effective delivery of services and to assess program progress towards goals and objectives. Depending on the context and resources available, this may include routine M&E of all patients or more targeted sampling/quality assurance strategies. A list of indicators on test coverage and test result utilisation is included in Table 1. These strategies may focus on baseline, process and/or outcome variables.

PROCESS MEASURES MAY INCLUDE:

- Test coverage
  - Number of people tested per number of people eligible
  - Number of results returned per number of tests sent
- Test turn-around time
- Patient management
  - Number of people receiving EAC per total number of people with UVL
  - Number of people receiving a second VL test per total number of people with UVL
  - Number of people switched to second-line ART per total number of people with second UVL test

KEY CONSIDERATIONS FOR OPTIMISING VL TEST RESULT RETURN INCLUDE:

- Ensure institutional leadership support and the presence of adequate infrastructure
- Define the problem with the current local or national standard of practice and establish the need to address it
- Decide on the types of interventions that will address identified problems
- Review the current clinical practice guidelines and SOPs
- Formulate a data-driven, evidence-based strategy
- Engage stakeholders and share with them the proposed result utilisation strategy or plan of action for improvement
- Consider the implementation of continuous quality improvement (CQI) for appropriate utilisation of VLT
- Regularly audit the result utilisation process in the VLT cascade
- Re-evaluate implementation strategies on a quarterly or annual basis

Table 1: List of indicators for monitoring VL test result utilisation include:

| SN# | Indicators | Numerator | Months | | | |
		Denominator	1	2	3	4
Test Coverage						
1	% of people eligible for routine VL test who receive a VL test (all)	# of routine VL tests done during the reporting month				
		# people on ART eligible for a routine VL test				
2	% of viral load test results received	# of routine VL test results received during the month prior to the reporting month				
		# of VL tests collected and sent during the month prior to the reporting month				
Patient Management and TAT						
1	% of patients with UVL receiving required number of EAC sessions within 3-6 months results being recorded	# of patients with UVL who received three EAC sessions within 3-6 months of results being recorded during the month				
		# of patients with UVL recorded during the month				
2	% of patients whose repeat VL test shows viral suppression	# patients on first-line ART regimen with repeat VL test result of SVL recorded this month				
		# of patients on first-line ART regimen with repeat VL test result recorded this month				
3	% of patients whose repeat VL test shows UVL who are switched to second-line ART	# of patients on first-line ART regimen with repeat VL test result of UVL whose regimen was switched this month				
		# of patients on first-line ART regimen with repeat VL test result of UVL recorded this month				
4	% of patients with SVL referred to DSD models	# of patients with SVL referred to DSD models				
		# of patients with SVL				
5	% of patients with UVL receiving a repeat VL test within 4 months	# patients with UVL receiving a repeat VL test within 4 months during this month				
		# patients with UVL receiving a repeat VL test during this month				
6	% of VL test results returned to patient within 4 weeks	# VL test results returned to clinic within 4 weeks this month				
		# VL test results returned to clinic this month				
7	% of VL test results returned to clinic within 2 weeks	# VL test results returned to clinic within 2 weeks this month				
		# VL test results returned to clinic this month				
8	Time from UVL test result to final EAC session	Median Time from UVL test result to final EAC session				
9	Time from final EAC session to repeat VL test	Median Time from final EAC session to repeat VL test				

Table 2. Viral load test result utilisation management toolbox*

1

STRATEGIC AREA:
Result tracking and prioritising of UVL results

STRATEGIC OPTIONS**:
- Establish a result tracking system and prioritise results
- Electronic result delivery to clinicians and clients
- Proper handover and dispatch processes

ACTION ITEMS FOR IMPROVEMENT***:
- Track unsuppressed (high) VL results by introducing register, stickers or priority filing for UVL results
- Online database and barcode system to track samples and results in delivery processes
- Logging system for sample and result transmission (by date, unique identifier, clinic)
- Electronic alert systems between testing and referring laboratories
- Notify patients to return and communicate to the clinician
- Physical return of results on hard copy or use SMS printer
- Develop SOPs for result delivery and monitoring process

2

STRATEGIC AREA:
TAT from laboratory result release to delivery

STRATEGIC OPTIONS**:
- Align patient appointments with VL test results
- Agreement between laboratory and clinics on TAT

ACTION ITEMS FOR IMPROVEMENT***:
- Align patient appointments with result delivery time
- Memorandum of understanding between laboratory and clinics on the expected TAT for delivery of results
- Direct communication between laboratorians and clinicians through phone or email for any unintended incidents like sample rejection, lost results, delayed results, UVL results
- Document communications between laboratorians with clinicians

3

STRATEGIC AREA:
Routine VL test result utilisation by clinicians

STRATEGIC OPTIONS**:
- SOPs and job aides
- On-the-job mentoring
- Blended learning

ACTION ITEMS FOR IMPROVEMENT***:
- Develop/review SOPs and job aids, provide available guiding tools and protocols from internal organisations
- Regular supervision and mentoring to support clinicians on the interpretation of VL test results and compliance to guidelines on clinical decisions
- Schedule CME sessions and case discussions: face-to-face, and virtual discussion with experts via teleconferencing (e.g., ECHO sessions)

*   Synthesised from group discussion at the LabCoP regional meeting in Uganda, 15-17 October 2018.
**   Strategic options are defined as alternative strategies that affect key factors that determine the success of an outcome or desired goal.
*** Priority action items are defined as implementation steps required to achieve the strategic option/decision that leads to the goal.

4

STRATEGIC AREA:
Coordination and management

STRATEGIC OPTIONS**:
- Assign VL champions/focal persons for coordination
- Regular multi-disciplinary viral load team meetings
- Commodity management

ACTION ITEMS FOR IMPROVEMENT***:
- Identify and assign focal persons to link laboratory results with patient files, flag high viral load clients, and trace patients
- Clear terms of reference for VL focal person
- Regular meeting of multi-disciplinary viral load teams (laboratories, clinicians, management, etc.)
- Schedule supervision for proper coordination of result delivery process and redesign workflow
- Manage commodity security and improve forecasting via multi-disciplinary teams

5

STRATEGIC AREA:
M&E systems and data management

STRATEGIC OPTIONS**:
- Document results and test requests
- Monthly data review
- Implement improvement projects on VL cascades

ACTION ITEMS FOR IMPROVEMENT***:
- Regular data quality assurance at the facility level to improve documentation and data validation
- Reviews of national M&E tools to integrate VL indicators in the health management information system
- Identify indicators for monitoring VL test result utilisation
- Conduct continuous quality improvement (CQI) on identified challenges
- Data review meeting with clinicians and laboratory professionals
- Engage managers and leadership for interventions

6

STRATEGIC AREA:
Human resources at facilities

STRATEGIC OPTIONS**:
- DSD models
- Task shifting and sharing
- Use case managers
- Policy changes for task shifting and data access

ACTION ITEMS FOR IMPROVEMENT***:
- Transition stable ART clients to alternative modes of service (DSD models)
- Advocate task shifting and include nurses and trained lay workers to administer testing and treatment
- Assign case managers to each UVL client for improvement of advanced stages of illness care
- Stakeholder engagement
- Advocate for policy changes to ease result utilisation
- International collaboration to influence policy

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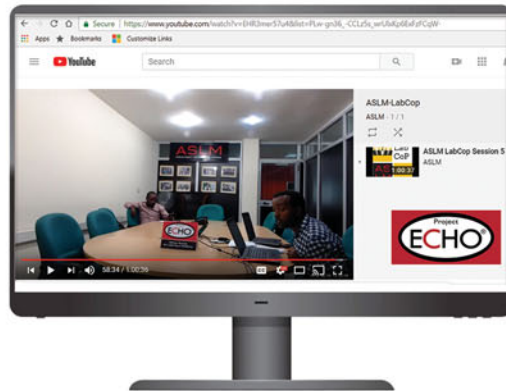
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