

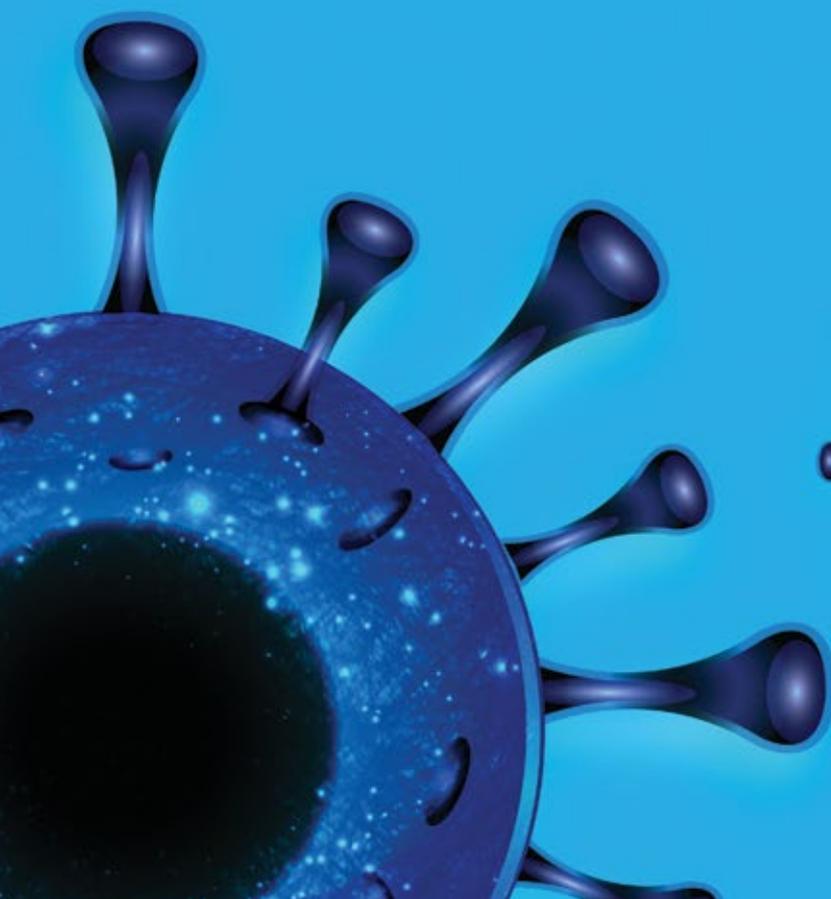
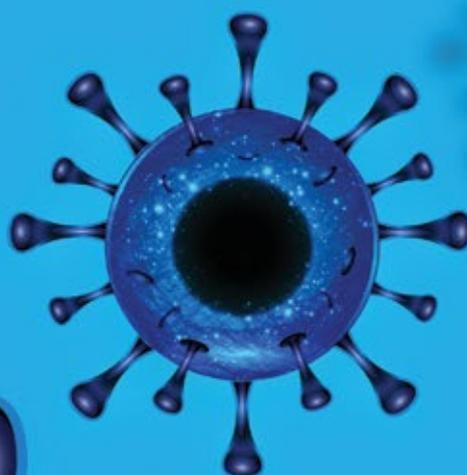


**MINISTRY OF HEALTH**

**National Public Health Laboratory Services**

**THE NATIONAL HIV VIRAL LOAD TESTING SCALE-UP  
IMPLEMENTATION GUIDELINES**

**2016-2020**



## Foreword

The development of the National HIV Viral Load Testing Scale-Up Strategic Plan 2015-2019 is guided by the UNAIDS 90-90-90 global target, World Health Organization (WHO) and Kenya National AIDS Strategic Plan (KNASP) framework. This targets that by 2020, 90% of all people living with HIV will know their HIV status; 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have durable viral suppression.

The Plan aims to set targets, strategies and activities along the treatment cascade to increase access to, coverage of, and quality of testing for viral load. During the scale-up process, there would be an ongoing monitoring and evaluation of activities and outcomes towards achieving viral suppression in 90% of HIV patients on ART.

Viral Load monitoring is the gold standard for detecting treatment failure in patients on ART but its availability in resource limited settings is restricted due to high costs, complex specimen collection and transport requirements, need for well-established laboratory infrastructure and well trained personnel. Delayed detection of treatment failure leads to accumulation of HIV drug resistance and costly switches to second-line ART. In June 2013, WHO recommended routine viral load monitoring as the preferred strategy for the diagnosis and confirmation of ART treatment failure (WHO 2013).

This Plan has been developed through a consultative approach involving all the key stakeholders. The Strategic Plan provides detailed description of the seven pillars namely: Policy guidance, leadership and Management of Viral Load Services; Product selection, site selection and laboratory capacity building mechanism; Forecasting and Financing requirements for VL scale up; Optimal specimen referral networks through mapping; Human Resource requirements and resources for their retention; Advocacy and Education targeting health care providers and patients; Monitoring and Evaluation.

Finally, NPHLS is grateful to its staff, partners and other stakeholders who contributed in shaping and in the development of this Plan. We look forward to working collaboratively across the VL testing network, partners and all other stakeholders to ensure its successful implementation.

Dr. Kioko Jackson K.

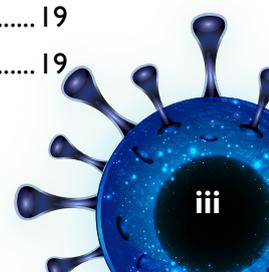
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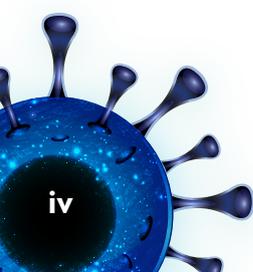


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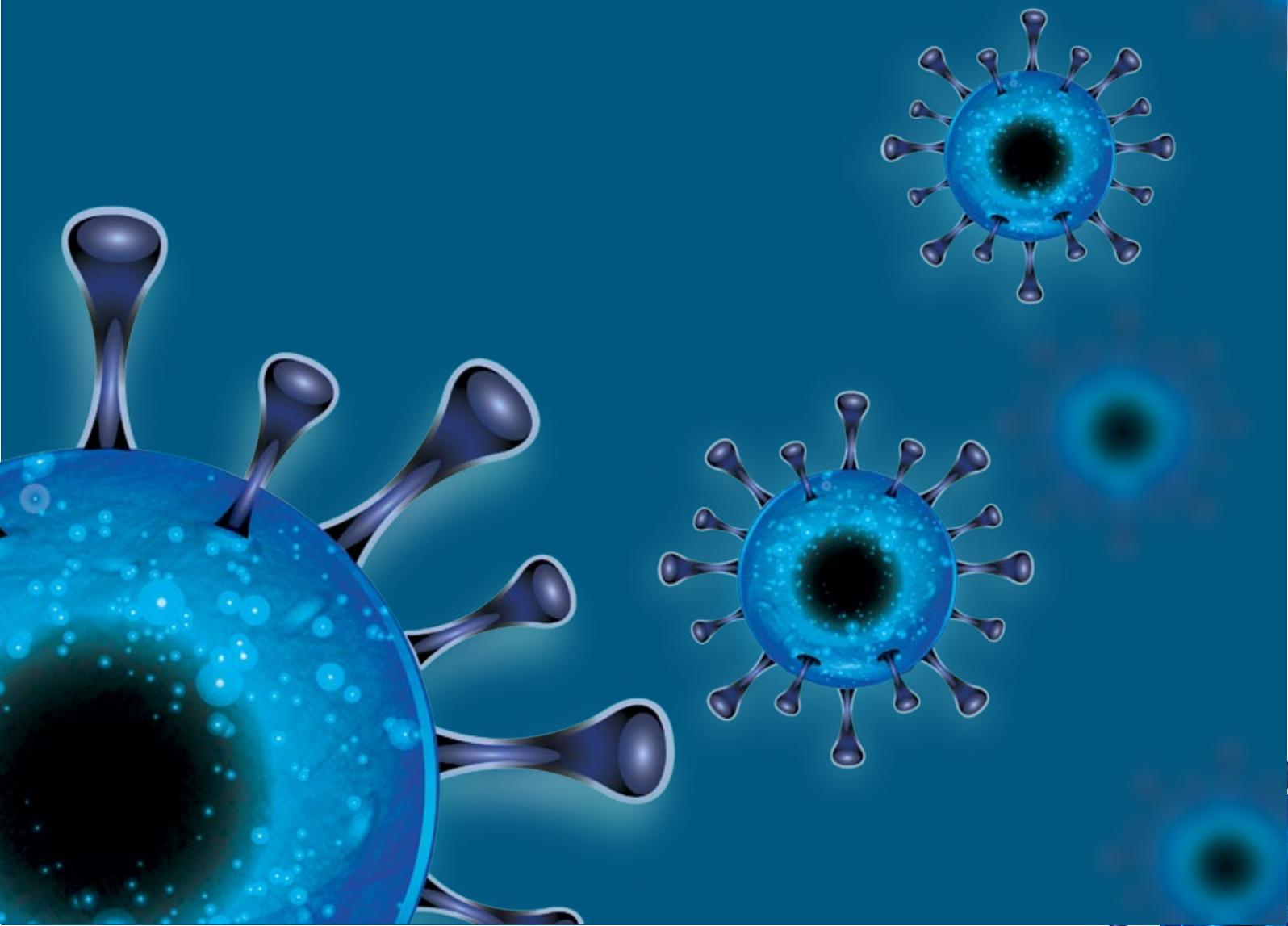
## Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CCC	Comprehensive Care Centre
CHMT	County Health Management Team
GOK	Government of Kenya
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
ICAP	International Center for AIDS Care and Treatment Programs
KNH	Kenyatta National Hospital
LIMS	Laboratory Information Systems
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Program
NHRL	National HIV Reference Laboratory
NPHLS	National Public Health Laboratory Services
PEPFAR	Presidential Emergency Program for AIDS Relief
PLHIV	People Living With HIV
QA	Quality Assurance
SWOT	Strength Weaknesses, Opportunities and Threats
TWG	Technical Working Group
UN	United Nations
UON	University of Nairobi
VL	Viral Load
WHO	World Health Organization



# Chapter I

## *Introduction*



## **I.1: Situation Analysis**

Prior to 2013, HIV Viral load (VL) testing was provided as a target intervention for patients suspected of failing antiretroviral (ARV) treatment in Kenya. Following the 2013 World Health Organization (WHO) revised guidelines on the use of ARV drugs (*Consolidated Guidelines for treating and preventing HIV, WHO 2013*), the Kenya Ministry of Health (MOH) through the National AIDS Control Program (NASCOP) released a rapid advice guideline on the use of ARV drugs for treating and preventing HIV infection in June 2014, (*Ministry of Health; National AIDS and STI Control Program (NASCOP) Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: A rapid advice, 2014*). The national guidelines recommend routine HIV VL testing for monitoring the response of HIV patients on treatment to identify potential treatment failure. The VL testing network is comprised of seven laboratories spread across the country with the potential of expansion to meet the testing demand.

The Kenya HIV AIDS Strategic Framework 2014/15-2018/19 is aligned with the UNAIDS 90-90-90 targets that stipulate that 90% of people living with HIV will know their HIV status, 90% of those diagnosed with HIV will be put on ART, and 90% of those on ART will be virally suppressed by 2020.

### **I.1.1: Current recommendations (National ART guidelines, 2014)**

- I. New Patients on ART: all newly initiated (1st, 2nd or 3rd line ART regimens) patients are to receive VL tests at 6 months and 12 months of treatment, and then annually thereafter.
- II. Patients continuing on ART: all patients on ART are to receive one VL test per year and a VL test before any single drug substitution to rule out treatment failure.
- III. Treatment failure: all patients on ART found to have detectable viral loads (>1,000 RNA copies/ml) during routine VL testing, are to receive a repeat VL test after 3 months. If 1<sup>st</sup> line treatment failure is confirmed, then patients are changed to an appropriate 2nd line regimen; if 2<sup>nd</sup> line treatment failure is confirmed, drug sensitivity testing (DST) is recommended to determine an appropriate 3<sup>rd</sup> line regimen.

### **I.1.2: HIV Burden**

The country had an estimated 1,380,929 people living with HIV (PLHIV) as of August 2015. Of those, 161,641 were children under 15 years and 1,219,288 were adults. Currently close to 747,468 adults and 70,619 children are on ART, and nearly 1,188,033 million are projected to be on ART by 2018 (*NASCOP August 2015*).

With the launching of the new ART guidelines, the demand for HIV VL testing has tremendously increased, and steadily continues to grow resulting in a scale-up process fraught with several challenges. As of June 2015 about 2515 facilities referred VL samples to the 7 testing laboratories compared to 2231 in 2014. A total of 456,033 VL tests were performed during the 2014/15 financial year (FY) (July 2014-June 2015) and the viral load suppression was 81.9% in all patients on ART. This is compared to 139,359 in 2013/14, and 39,378 in 2012/2013 FYs

(NASCOP VL website). The target for VL in 2015 is around 900,758 tests, 1,320,868 for 2016, and 1,463,717 2017. Kenya currently (June 2015) has a capacity to conduct about 700,000 tests per year with 21VL equipment in the network. This will slowly increase to accommodate the 90-90-90 by 2020 with the addition of new equipment and controlled decentralization of testing sites.

## **I.2: Purpose of this plan**

This National HIV VL scale-up strategic implementation plan sets out seven strategies and aligned activities to be implemented to scale up viral load testing in the country to help monitor progress towards the 90% viral suppression in patients on ART. It will be a guide for evaluating the implementation of VL scale-up in Kenya. The Ministry of Health (MoH) will prioritize strengthening of the national sample referral network system for HIV VL testing to ensure efficiency and effectiveness while maintaining quality during the phased expansion.

## **I.3: Specific objectives**

To increase access to quality VL testing in order to reach the 2015- 2019 targets and beyond

This will be achieved by the following

- 1) Strengthening the capacity of existing seven testing labs and ensuring that there is a tiered structure of the laboratory network.
- 2) Define the norms and standards of the molecular laboratories
- 3) Building capacity for selected new VL testing laboratories in response to the increased demands
- 4) Optimizing the VL network throughout the 47 counties, using new technologies when they become available at moderate and low HIV burden health facilities
- 5) Define a tiered laboratory quality management system for VL services
- 6) Improving commodity security
- 7) Engaging Stakeholder effectively at each step of the HIV treatment and care cascade
- 8) Improving data management and use for program decision making
- 9) Monitoring and Evaluation to ensure effectiveness and efficiency.

## **I.4: Challenges to VL scale-up implementation**

VL testing scale up was supposed to be in a phased in approach to ensure adequate laboratory preparedness for the envisioned increased testing volumes. The non-compliance to this phased approach and lack of proper dissemination and support packages resulted in

- a) Inadequate Commodity logistical support.
- b) Bottlenecks resulting in backlogs at the testing labs



Analysis of the lab capacity, and monitoring process have identified that the initial backlogs were attributed to the following challenges

- Insufficient technical personnel and data clerks
- Frequent equipment break down and down time due to mechanical pressure wear and tear.
- Equipment redundancy
- Commodity management and distribution inefficiency
- Inadequate storage capacity both for cold chain, and room temperature commodities and archiving space for documents.
- Inadequate functional space in the labs due equipment size and number.
- Lack of interoperability between Laboratory Information Management (LIMS) and NA-SCOP website
- Inappropriate sample management – barcoding, standardized sample labeling, handling, permanent markers.
- Inefficient sample networking structure –packaging, transportation and return of results
- Inadequate coordination at the National and County levels

### **I.5: Key thematic areas of the VL scale-up implementation plan.**

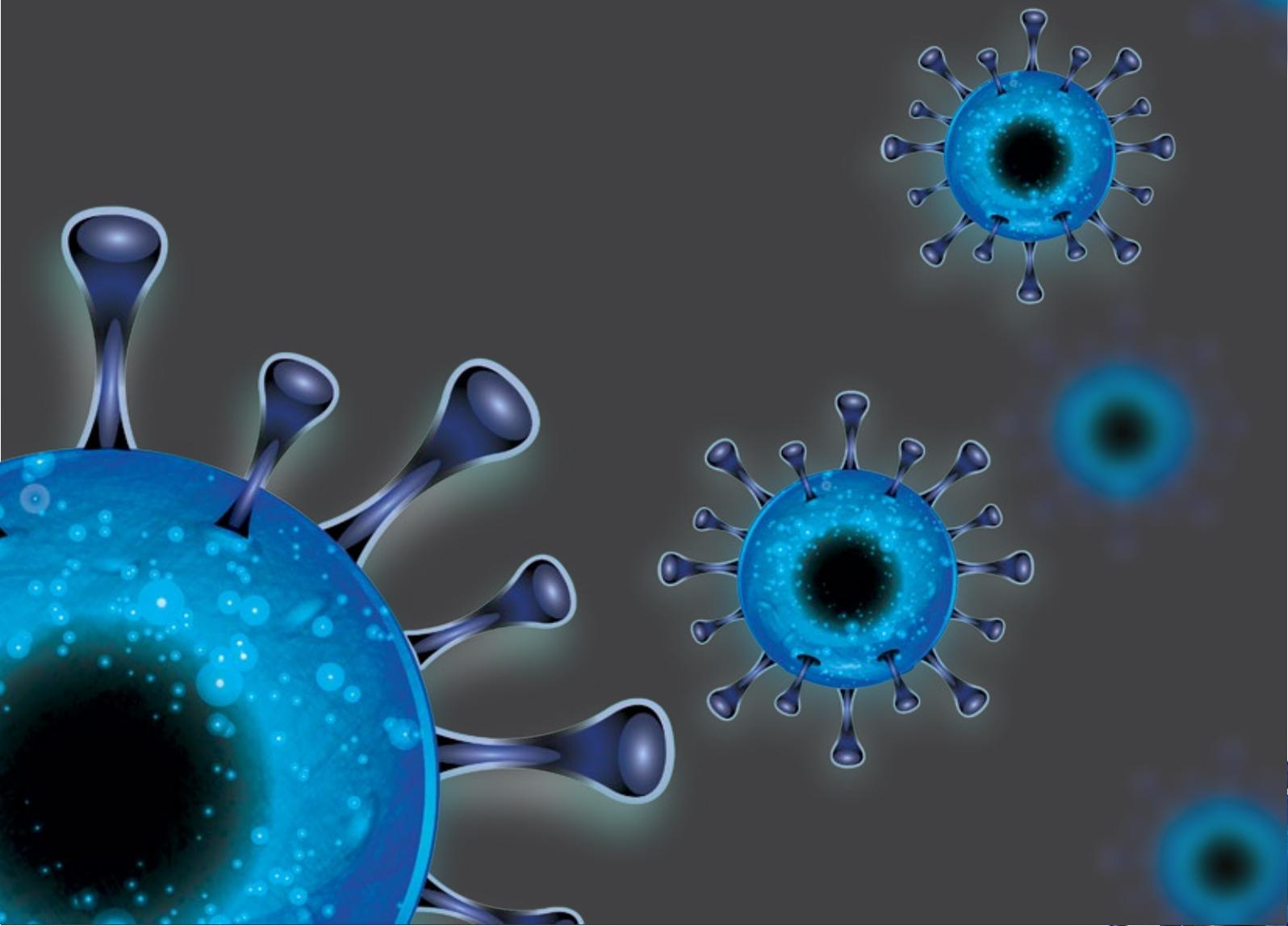
The implementation plan has been formulated to respond to the issues identified during the first phase of scale-up. Seven strategic areas have been identified as follows:

- 1) Policy guidance, leadership and Management of VL Services.
- 2) Product selection, site selection and laboratory capacity building mechanisms.
- 3) Forecasting and Financing requirements for VL scale up.
- 4) Optimal specimen referral networks through mapping.
- 5) Human Resource requirements and resources for their retention.
- 6) Advocacy and Education targeting health care providers and patients
- 7) Monitoring and Evaluation



# Chapter 2

*Policy Guidance, Leadership and Management of  
Viral Load Services*



## 2.1: Introduction

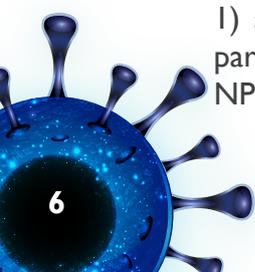
Kenya has several policies and guidelines in place, which outline the role of the National and County governments in the delivery of laboratory services in support of HIV management. In the past, the testing volumes were low because of targeted testing. The change in ART guidelines recommending routine VL testing for all patients on ART, require strengthening of the management, leadership and coordination of testing throughout the network.

## 2.2: SWOT analysis

Strengths	Weaknesses	Opportunities	Threats
<p>Policy: Existing policies and guidelines on delivery of lab services in place</p> <p>Established regulatory approval authority</p>	<p>Inadequate adoption and implementation of policies.</p> <p>Weak systems for enforcing regulatory policies with regards to technology uptake</p> <p>Poor laboratory infrastructure</p> <p>Lack of awareness on the national laboratory infrastructure guideline</p>	<p>Existing county laboratory leadership to facilitate implementation and adoption</p> <p>Upgrade of physical infrastructure for improved workflow, and safety</p>	<p>Sustainable financing and political goodwill.</p>
<p>Leadership: Existing supportive national and county leadership structure</p>	<p>Weak coordination of VL testing</p> <p>Parallel laboratory and HIV planning and programming</p> <p>Limited accountability, transparency and productivity</p>	<p>Existence of TWG, national VL laboratory coordinator, county health management teams (CHMTs)</p> <p>Devolution with opportunity of county ownership</p>	<p>Slow devolution process</p> <p>Vulnerability of systems</p>
<p>Coordination and management: Existence of broader stakeholder involvement</p>	<p>Poor harmonization and communication strategy, Multiplicity of systems</p>	<p>Increased focus on health strengthening</p> <p>Potential funding opportunities.</p> <p>Global initiatives to strengthen access to diagnostics e.g. Diagnostics Access initiative (DAI)</p>	<p>Kenya's new economic status (lower middle income country)</p> <p>Changing priorities</p>

## 2.3: Activities

To successfully scale up VL testing in Kenya, the national government through its various agencies in the Ministry of Health (NPHLS, NASCOP refer to MOH organogram in appendix I) shall be responsible for coordinating all stakeholders (county governments, development partners, funding agencies) that support VL testing. In addition, the coordinating mechanism of NPHLS will comprise of appropriate national and international stakeholders in the TWGs to



provide overall technical guidance and leadership in all aspects of VL testing at the National level. This will go hand in hand with recommended clinical algorithms and developed strategies to reach target populations. Respective Counties will establish TWGs to ensure dissemination, adoption and implementation of VL policy and guidelines.

#### *Role of NPHLS:*

- i. Provide oversight of the implementation process of the national VL testing scale up implementation plan.
- ii. Coordination of VL testing services.
- iii. Provision of technical assistance to the county implementation teams.
- iv. Stakeholder coordination to improve efficiency and effectiveness in viral load testing services
- v. Regular reviews of programmatic data on VL scale up process
- vi. Provide communication structures between MOH HQ, counties, and testing labs
- vii. Advocating and planning for resources in partnership with the National, county governments and development partners to support VL testing scale up.

## **2.4: Expected Outcomes**

#### *Short -term outcomes*

- Availability of the VL implementation plan at national, county and facility levels
- Increased awareness of the VL implementation plan at national, county and facility levels
- National and County TWGs established

#### *Intermediate outcomes*

- Improved coordination of Implementing Partners activities in support of VL testing
- Improved skills and expertise at the county level
- VL implementation plan adopted at the national, county and facility levels.
- Increased stakeholder coordination at all levels.
- Increased review of programmatic data on VL services
- Strengthened communication at all levels

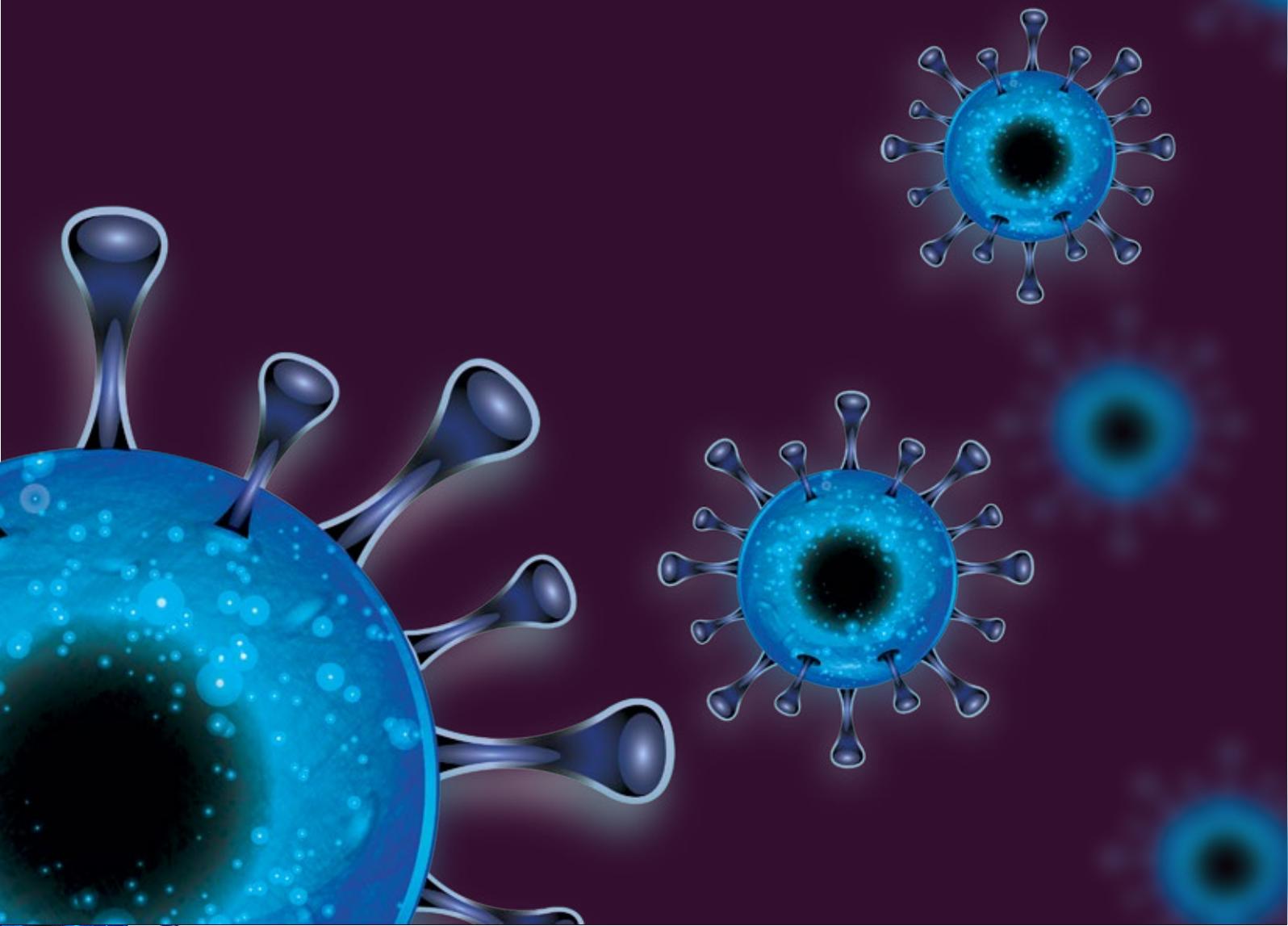
#### *Long term outcomes*

- Increased access to viral load testing
- Increased domestic resource allocation for the viral load testing



# Chapter 3

*Product Selection, Site Selection and Laboratory Capacity Building Mechanisms*



### 3.1: Introduction

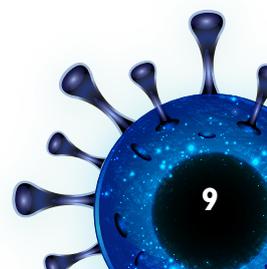
The selection of VL testing technologies for use in Kenya has been driven by available platforms. As we scale up, selection of equipment will require a systematic approach based on evaluating the technology on a set of criteria. (Annex 3) Site selection and capacity building processes will be managed by the national and county TWGs.

### 3.2: SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
<p>Product Selection: Existing TWGs at national and county levels</p> <p>Availability of functional testing platforms in the country</p>	<p>Lack of policies and guidelines defining criteria for product selection</p> <p>Independent county decision on acquisition of devices</p>	<p>Harmonization of product selection process</p> <p>Introduction of POC and near-POC devices to decentralize VL testing</p>	<p>Sustainable financing and political goodwill.</p>
<p>Site selection: Existing TWGs at national and county levels</p> <p>Existing relationships with device manufactures</p>	<p>Lack of framework for managing political expectations.</p> <p>Lack of guidelines and policies for site selection for technology placement.</p>	<p>Existing county health management systems</p>	<p>Vulnerability of systems</p>
<p>Capacity building process: Existing technical skills, expertise and understanding of the potential VL needs and testing targets to help inform program needs</p>	<p>Inadequate HR capacity to support VL testing labs</p> <p>High turnover of skilled laboratory</p>	<p>Stakeholder engagement and goodwill in HR support</p> <p>Existing capacity to train testing personnel.</p>	<p>Sustainable financing and political goodwill</p>

### 3.3: Activities:

- Develop policies and guidelines on product selection
- Dissemination of policies and guidelines at the national and county levels
- Collaboration between national and county government to enhance understanding of product selection and acquisition criteria.
- Broader stakeholder engagement and sensitization on site selection
- Develop a plan for hiring and advocate for VL testing personnel and data clerks.
- Develop staff retention plan to ensure sustainability.



### 3.4: Expected Outcomes

#### *Short term outcomes*

- Increased availability of policies and guidelines on product selection
- Increased awareness of policies and guidelines on product selection.
- Strengthen collaboration between county and national government on product selection and acquisition
- Increased stakeholder engagement, awareness and procedures on site selection
- Availability of a plan for hiring and advocating for VL testing personnel and data clerks
- Availability of staff retention plan.

#### *Intermediate outcomes*

- Adequate and increased number of VL testing personnel and data clerks.
- Increased evaluation of equipment and post marketing surveillance.
- Increased retention of HR

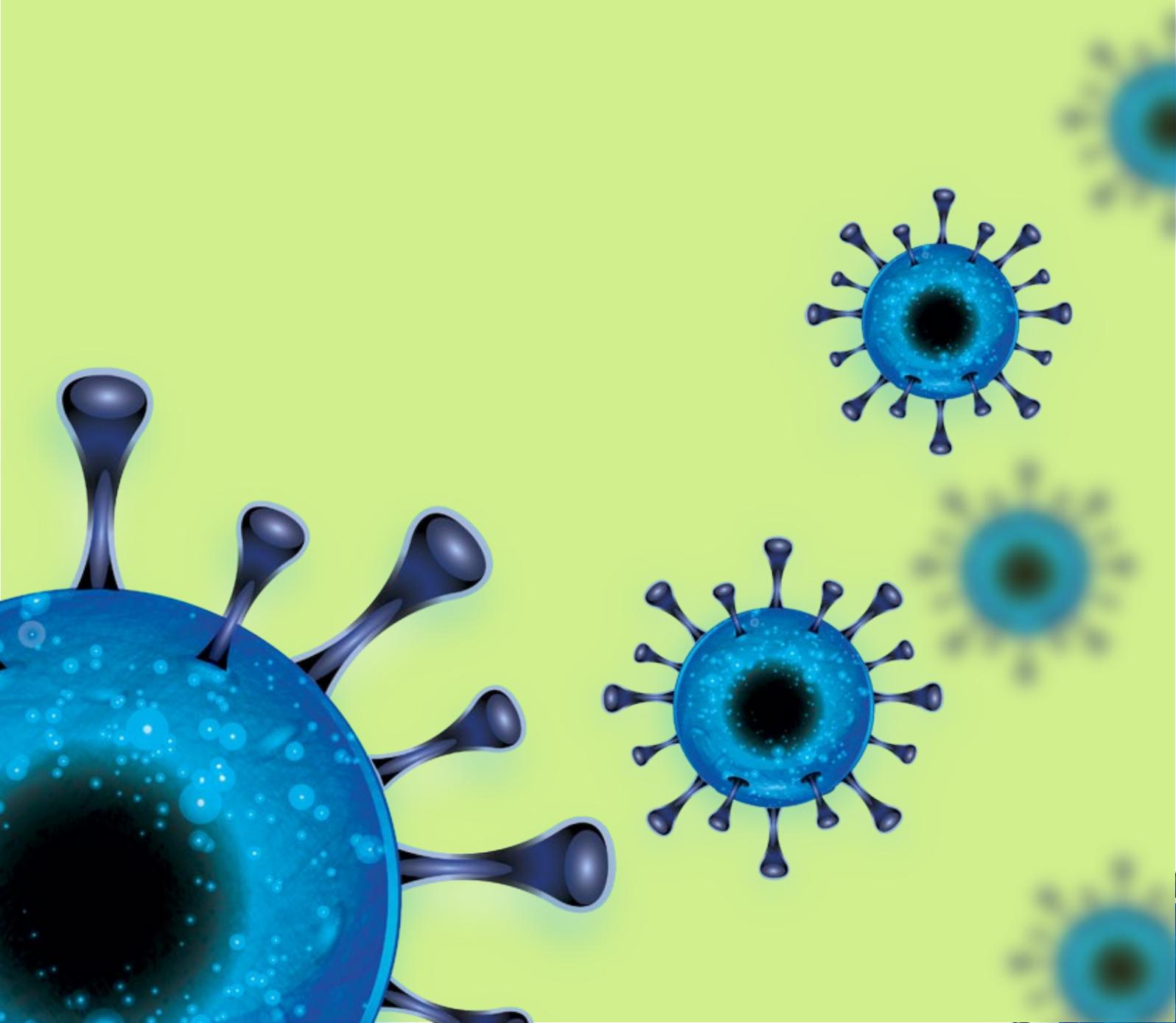
#### *Long term outcomes*

- Increased use of appropriate VL technologies to meet country needs
- Increased access to VL testing services.
- Improved TAT



# Chapter 4

*Forecasting and Financing Requirements for  
VL Scale Up*



## 4.1: Introduction

The planning for HIV related commodities including viral load is conducted through an annual forecasting and quantification by the commodity security TWG. Determination of needs is based on historical data covering a three-year period. There is an established robust web based reporting platform for consumption and service delivery data for efficient commodity planning.

Adoption of the 2014 Care & Treatment Guidelines has created an increased demand for VL services. For optimized commodity security, coordination of available financial resources is necessary between the National, County Governments and other stakeholders to ensure provision of uninterrupted VL services. To meet the growing demand for VL services there is need for increased financial allocations to support HR needs, information system, QA, sample referral network, infrastructures and logistics.

## 4.2: SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
<p>Forecasting: Existence of commodity security TWG</p> <p>Information systems: Existence of a web-based reporting system</p> <p>Planning: Consistent annual planning of commodity needs with stakeholder involvement.</p>	<p>Weak coordination at the national level</p> <p>Sub-optimal quality of consumption and service delivery data</p> <p>Untimely planning of schedules</p> <p>Inconsistent representation of key stakeholders.</p> <p>Inadequate county involvement in data monitoring and consumption.</p>	<p>Existing capacity within MOH to provide leadership in coordination</p> <p>Existing IT infrastructure that can be expanded</p> <p>It can integrated into existing systems</p>	<p>Sustainable financing and political goodwill.</p>
<p>Financing: Consistent resource allocation by GoK and stakeholders.</p> <p>Existence of a well-coordinated centralized procurement mechanism.</p>	<p>Inadequate coordination, accountability and monitoring</p> <p>Limited county involvement in forecasting and financing for VL scale up</p> <p>Untimely disbursement of finances leading to deficit in financing for commodity procurement</p>	<p>Consistent stakeholder financing e.g. Global fund</p>	<p>Sustainable financing and political goodwill.</p>

### 4.3: Activities

- Conduct regular coordination forums at the national and County level
- Conduct regular data quality review forums at national and county levels.
- Develop annual work planning schedule
- Advocate for consistent representation of key stakeholders
- Develop guidelines for reporting, forecasting and quantification at National level
- Dissemination of the developed forecasting and quantification guidelines at the county and facility levels
- Develop curriculum for forecasting and quantification
- Conduct training on F&Q
- Advocate and mobilize for timely resource allocation disbursement.

### 4.4: Expected Outcomes

#### *Short term Outcomes*

- Improved coordination at the national and County level
- Availability of annual work planning schedule at all levels
- Improved consistency in key stakeholder representation
- Availability of guidelines for forecasting and quantification
- Availability of forecasting and quantification guidelines
- Increased awareness about F&Q
- Increased allocation
- Improved timeliness in the disbursement of resources

#### *Mid - term Outcomes*

- Improved data quality at all levels
- Improved forecasting and quantification practices at all levels.

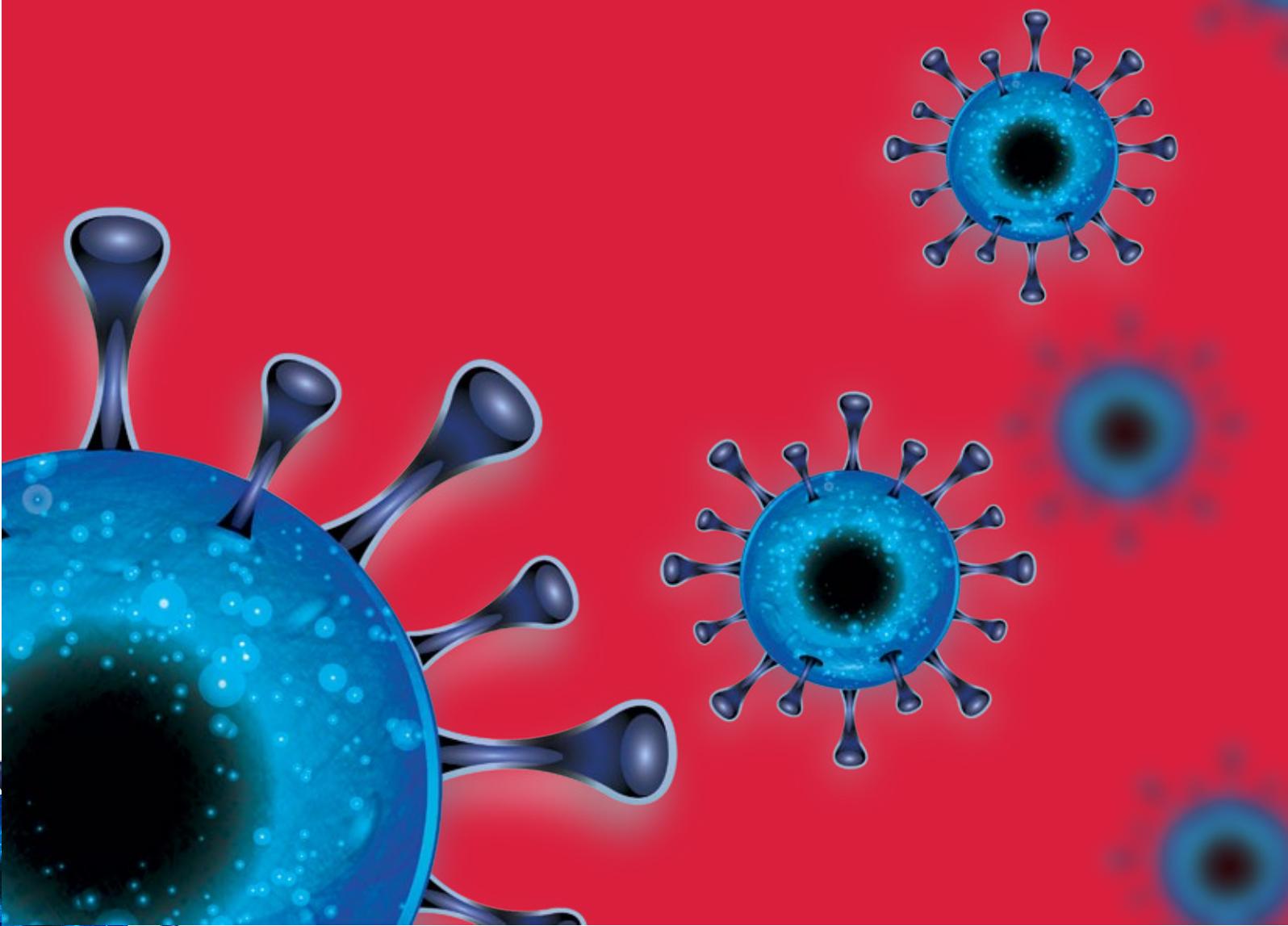
#### *Long -term outcomes*

- Improved commodity security at all levels.
- Integration of VL monitoring system into the National health systems



# Chapter 5

## *Specimen Referral Networks*



## 5.1: Introduction

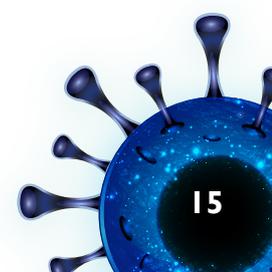
Sample referral network (SRN) is an integral part to the success of the VL testing program. The existing testing referral network is based on the National Specimen Referral Guidelines (2012). Specimen packaging supplies, transportation, cold chain, courier services, geographic terrains and insecurities are some of the challenges of SRN

The existing County plans and support, do not adequately address the requirements for an efficient SRN. This has led to an inefficient SRN contributing to delayed return of results and negatively impacting patient care

There is need for county and national government to address and own the effective management of sample referral. Develop effective mechanisms to integrate VL referral systems with existing referral systems.

## 5.2: SWOT Analysis

<b>Strengths</b>	<b>Weaknesses</b>	<b>Opportunities</b>	<b>Threats</b>
Guidelines: Existence of National specimen referral guideline	Low awareness of the existence of the National specimen referral guidelines.	Established courier systems for various samples (CD4, TB, EID)	Sociopolitical instability
Stakeholder: Defined County Health Management Teams (CHMT)	Lack of standard reporting and recording tools	Integrated SRN across VL, CD4, TBC, GeneXpert and EID	
Established Information systems for assessing results	Inadequate awareness and coordination	Devolved government structures	
	Lack of health worker training on online access of results	Integration of the VL information system to the existing MOH data centre	
	Inadequate and unreliable internet access.		
	Use of individualized emails.		
	Dysfunctional SMS printer		
Resources:	Inadequate budgetary allocation for Sample referral	Resource mobilization of domestic funds	
Existence of tiered VL laboratories.	Undefined VL tiered laboratory structures	Leverage on existing programs that support SRNs	



### 5.3: Activities

- Conduct dissemination of the National specimen referral guidelines to the county and facility.
- Develop standard reporting and recording tools.
- Conduct sensitization for sample referral, and use of back-up lab to the CHMTs.
- Conduct quarterly review of sample transportation networks with CHMT and facilities.
- Conduct health worker training on online access of results
- Provision of adequate and reliable internet access across all ART sites by the county
- Advocate for facility based emails on the specimen request forms
- Advocate for increased funding in the annual county and facility budget
- Define and develop the VL testing laboratories in the health tiered structure
- Develop and support an Integrated SRN for VL, EID and other referral networks across all level

### 5.4: Expected Outcomes

#### *Short term outcomes*

- Increased awareness of the National specimen referral guidelines to the county and facility
- Increased adoption of the National specimen referral guidelines at the county and facility
- Increased availability of reporting and recording tools
- Increased knowledge and skills for easier access of online results
- Gradual increase in the county budgetary allocation for sample referral network
- Availability of a defined VL testing laboratories tiered structure
- Available integrated sample referral networks for VL, EID and other referral specimen across all levels

#### *Mid-term Outcomes*

- Improved practices on specimen referral at all levels
- Improved quality of data at all levels
- Increased access to online access of VL results
- Increased access to VL testing

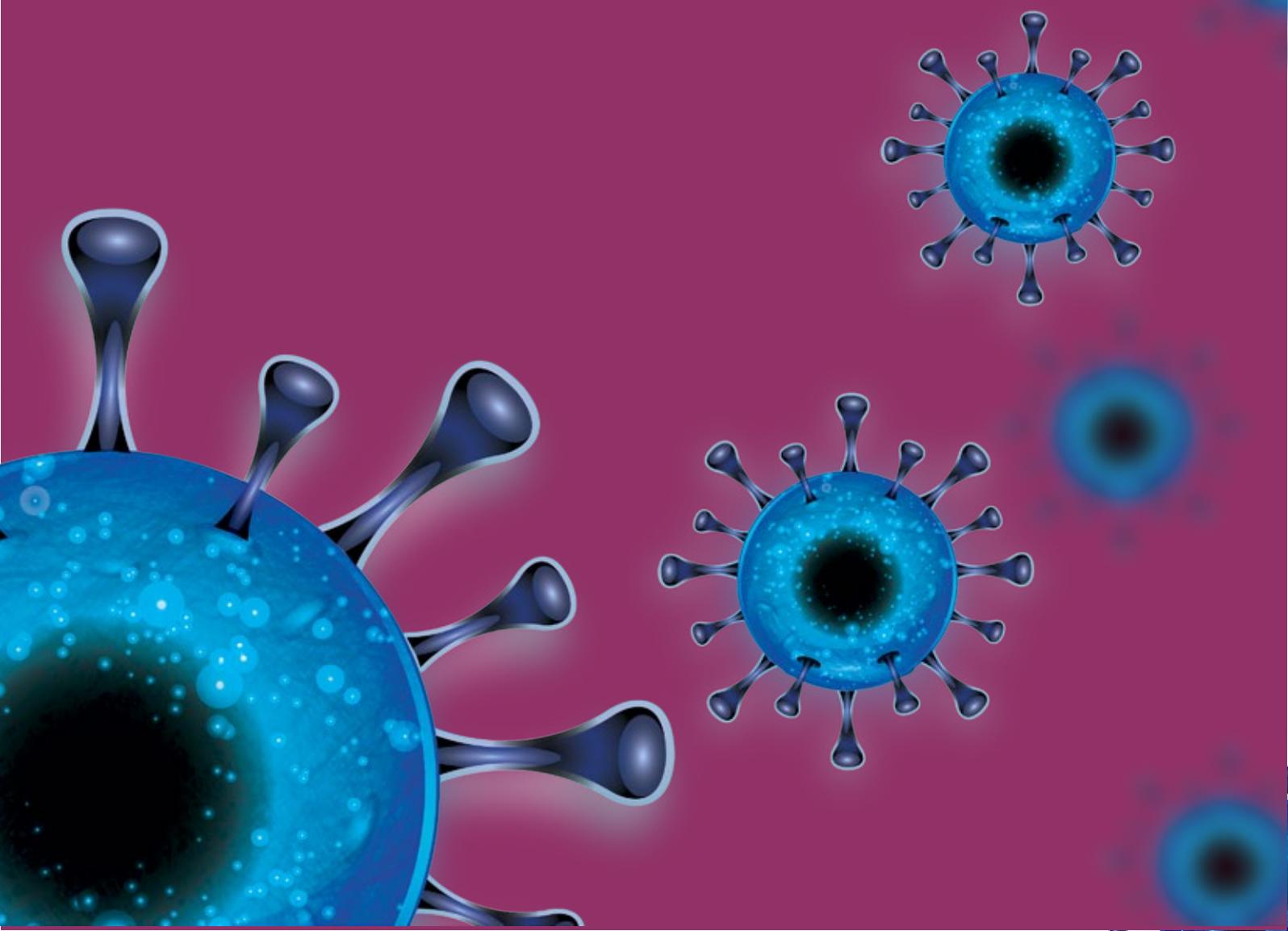
#### *Long -term outcomes*

- Increased VL suppression in ART patients
- Decreased HIV drug resistance in ART patients
- Decreased mortality of PLHIV



# Chapter 6

## *Human Resource Requirements and Retention*



## 6.1: Introduction

With the scale up of VL testing, and the addition of new equipment and testing sites, adequate skilled personnel is required to meet the increased demand for VL testing. The lack of adequate human resources remains a threat to the successful scale up of VL testing. Retention of staff at the facility level has been one of the major challenges to ensuring a sustainable, decentralized testing program. Chronic shortage of staff contributes to prolonged TAT of VL results.

## 6.2: SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
Existing HR at all levels	High turnover of HR at all levels  Limited molecular work experience among existing staff  Limited IT and data management system in the VL testing laboratories  Shortage of staff  Staff hiring largely dependent on donor funding	Holistic training package to be integrated with ART care and treatment  Enhance existing health-care remuneration package  Strengthening of existing pre-service and in-service curricula	Sustainable financing and political goodwill
System of governance – devolution through CHMTs	Undefined roles and responsibilities of HR for VL testing system	Mechanism and tool to cost staff requirements to resources based on workload	Sustainable financing and political goodwill
	Inadequate tiered laboratory HR network  Inadequate sensitization and dissemination of HR and healthcare worker safety guidelines	Existing policies and guidelines on HR at all levels  Availability of the HR policies and guidelines on occupational safety and health	Sustainable financing and political goodwill

## 6.3: Activities

- Develop a framework for VL testing laboratories human resource recruitment and retention.
- Disseminate the framework for VL testing laboratories human resource recruitment and retention.
- Advocate for increased allocation of resources for hiring of healthcare worker and provision of a competitive remuneration package.
- Develop in-service curricula for molecular testing laboratories.
- Conduct specialized molecular training for staff in the VL testing laboratories.
- Advocate for the integration of the molecular in-service curriculum into the existing pre-service Medical Laboratory Sciences curricula.



- Provide continuous mentorship at the VL testing laboratories.
- Strengthening HIV care and treatment curriculum to incorporate laboratory networking. .
- Define roles and responsibilities of HR for VL testing system.
- Provide leadership and management training to laboratory supervisors in the VL testing network.
- Provide QMS training to staff in the VL testing network.
- Mapping and assessments of human resource requirements to support VL testing scale up.
- Conduct sensitization and dissemination on guidelines of HR cadres and biosafety /biosecurity.

## 6.4: Expected Outcomes

### *Short term Outcomes*

- Availability of the framework for human resource recruitment and retention.
- Increased number of counties adopting the HR framework
- Sufficient HR to support VL testing
- Availability of curriculum
- Increased knowledge and skills on molecular testing among laboratory staff.
- Availability of defined roles and responsibilities of HR for VL testing systems.
- Increased awareness on adequate HR resource planning.
- Increased awareness of guidelines on HR cadres and biosafety/biosecurity.

### *Mid-term Outcomes*

- Improved HR remuneration and retention.
- Improved VL testing practices.
- Improved competency on VL testing.
- Increased access to VL testing services.
- Improved managerial and leadership skills among VL testing laboratory supervisors.
- Increased knowledge and skills in QMS.
- Increased budgetary allocation for VL testing HR at National and County levels.

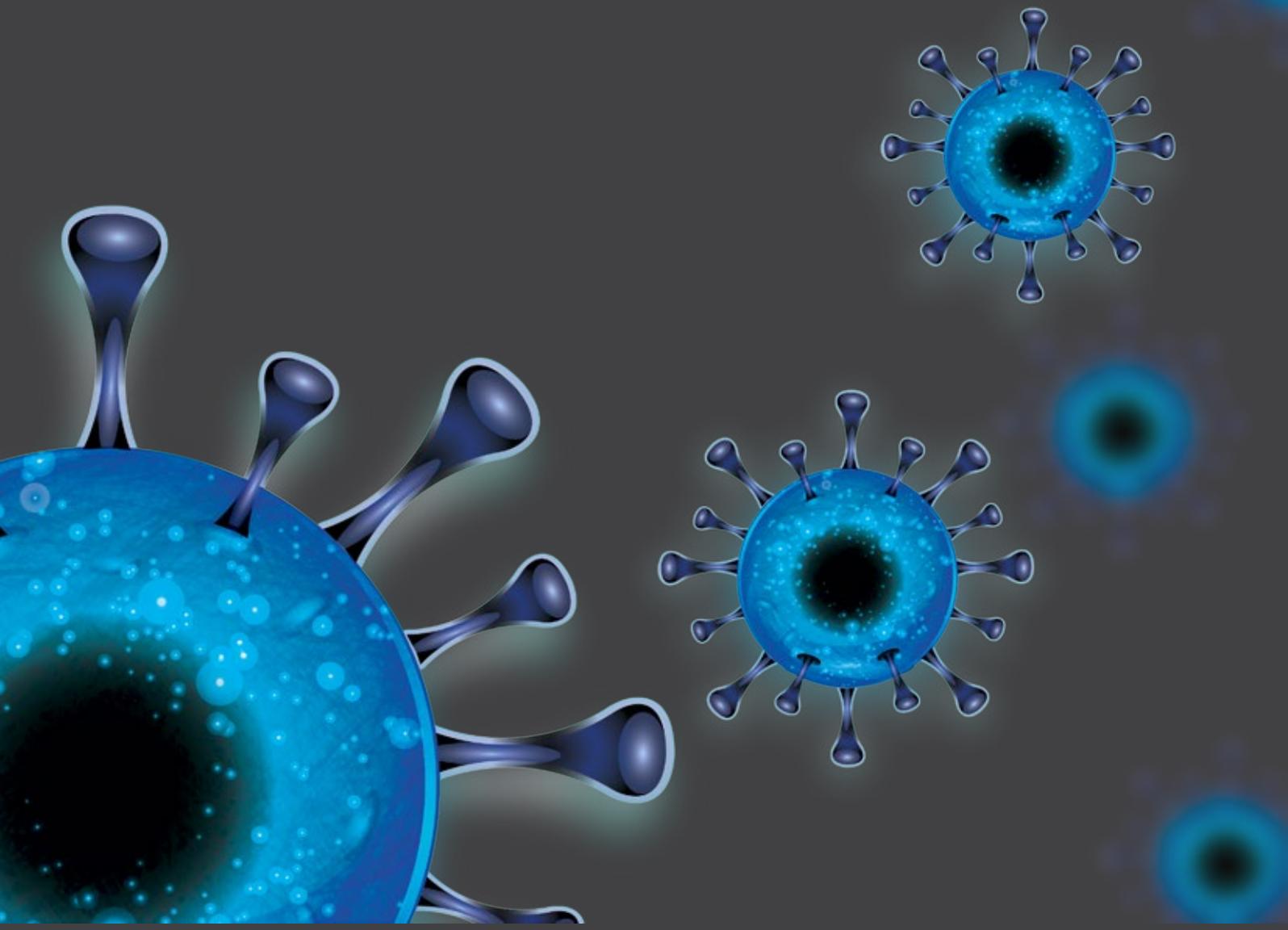
### *Long term outcomes*

- Improved quality of VL testing services.
- Increased staff and client satisfaction.



# Chapter 7

*Advocacy and Education of Health Care Providers  
and Patients On Viral Load*

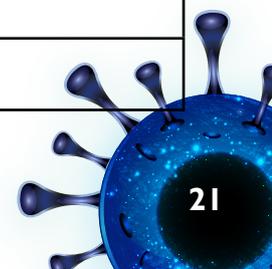


## 7.1: Introduction

The increased demand for VL services has created gaps in resource needs. Through advocacy, education and communication, the different stakeholders will have the opportunity to; access information and services, explore available choices and options, express their views, concerns, and this will enable them to defend and promote their rights and responsibilities. This plan will focus on the PLHIVs, community, civil society, healthcare providers, HMTs, development partners, County and National government as the main stakeholders;

## 7.2: SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
<p>Advocacy:</p> <p>Existence of strong Civil Society Organizations (CSOs)</p> <p>Availability of development partners who are interested in VL scale up activities</p> <p>Existence of the National VL testing TWG</p>	<p>Inadequate coordination between stakeholders</p> <p>Inadequate advocacy on the need to strengthen laboratory services</p> <p>Inadequate channels to advocate for VL laboratory services</p>	<p>Existence of robust media platforms</p> <p>Existence of good will in the UNAIDS fast track guidelines on 90-90-90 targets</p> <p>Availability of the National HIV treatment acceleration guideline</p>	<p>Sustainable financing and political goodwill</p>
<p>Education:</p>	<p>Lack of VL IEC materials</p> <p>Lack of IEC materials on referral network and structures</p> <p>Lack of a HCW awareness package on VL services</p> <p>Inadequate awareness on VL test results and its implications</p>	<p>Availability of laboratory data for decision making</p> <p>Existence of reasonable awareness HIV treatment literacy among clients</p>	<p>Sustainable financing and political goodwill</p>
<p>Communication:</p> <p>Existence of communication experts within the MOH</p>	<p>Limited Lab/clinician interface</p> <p>Lack of meaningful Laboratory and clinician engagement forums</p> <p>Inadequate SOPs/Job aids on standard materials for sample collection, packaging and transportation</p> <p>Lack of targeted communication messages to patients, healthcare providers and CSOs</p> <p>Lack of communication structures between testing laboratories and ART sites</p> <p>Lack of a structured help desk information services at VL testing laboratories</p> <p>Inadequate communication materials on the role of NPHLs/ NHRL with regard to VL scale-up</p> <p>Lack of a communication department at NPHLs/NHRL</p>	<p>Establish public/private partnerships for training</p> <p>Introduction of facility based patient online portal for easy accessibility of results</p>	<p>Sustainable financing and political goodwill</p>
<p>HMT forums could be utilized for lab/clinician</p>			



### 7.3: Activities

- Conduct coordination engagement forums for all stakeholders
- Advocate for adequate strengthening of laboratory services
- Develop effective channels to advocate for VL laboratory services
- Develop VL IEC materials on referral network, services and structures
- Develop a HCW awareness package on VL services
- Disseminate the HCW awareness package on VL services at the facility and County level
- Develop an awareness package on VL test results and its implications
- Disseminate the awareness package on VL test results and its implications to all stakeholders
- Conduct laboratory/clinician engagement forums
- Develop a laboratory and clinician engagement annual bulletins
- Develop SOPs/Job aids on standard materials for sample collection, packaging and transportation
- Print SOPs/Job aids on standard materials for sample collection, packaging and transportation
- Disseminate SOPs/Job aids on standard materials for sample collection, packaging and transportation
- Develop targeted communication messages to patients, healthcare providers and CSOs
- Develop SOPs/Job Aids communication structures between testing laboratories and ART sites
- Advocate for a VL testing laboratories help desk information services
- Develop communication materials/bulletins on the role of NPHLS/NHRL with regard to VL scale-up
- Establish a communication department at NPHLS/NHRL

### 7.4: Expected outcomes

#### *Short-term outcomes*

- Increased coordination among the VL service stakeholders
- Increased availability of VL IEC materials on referral network, services and structures
- Availability of HCWs awareness package on VL services
- Availability of VL test results interpretations awareness package for clients
- Availability of laboratory/clinician engagement annual bulletin
- Availability of SOPs/Job Aids on sample collection, packaging and transportation
- Availability of targeted communication messages to patients, HCWs and CSOs
- Availability of SOPs/Job Aids on communication structures between testing laboratories and ART sites
- Availability of a communication material/bulletin on the role of NPHLS/NHRL in VL scale up

*Mid- term outcomes*

- Improved laboratory services
- Increased awareness on VL referral network, services and structures
- Increased knowledge of the HCWs awareness package on VL services
- Increased Knowledge of the VL test results interpretations among clients
- Improved practices on sample collection, packaging and transportation
- Availability of a VL testing laboratories help desk information services
- Increased awareness on the communication structures between testing laboratories and ART sites
- Availability of a communication department at NPHLS/NHRL

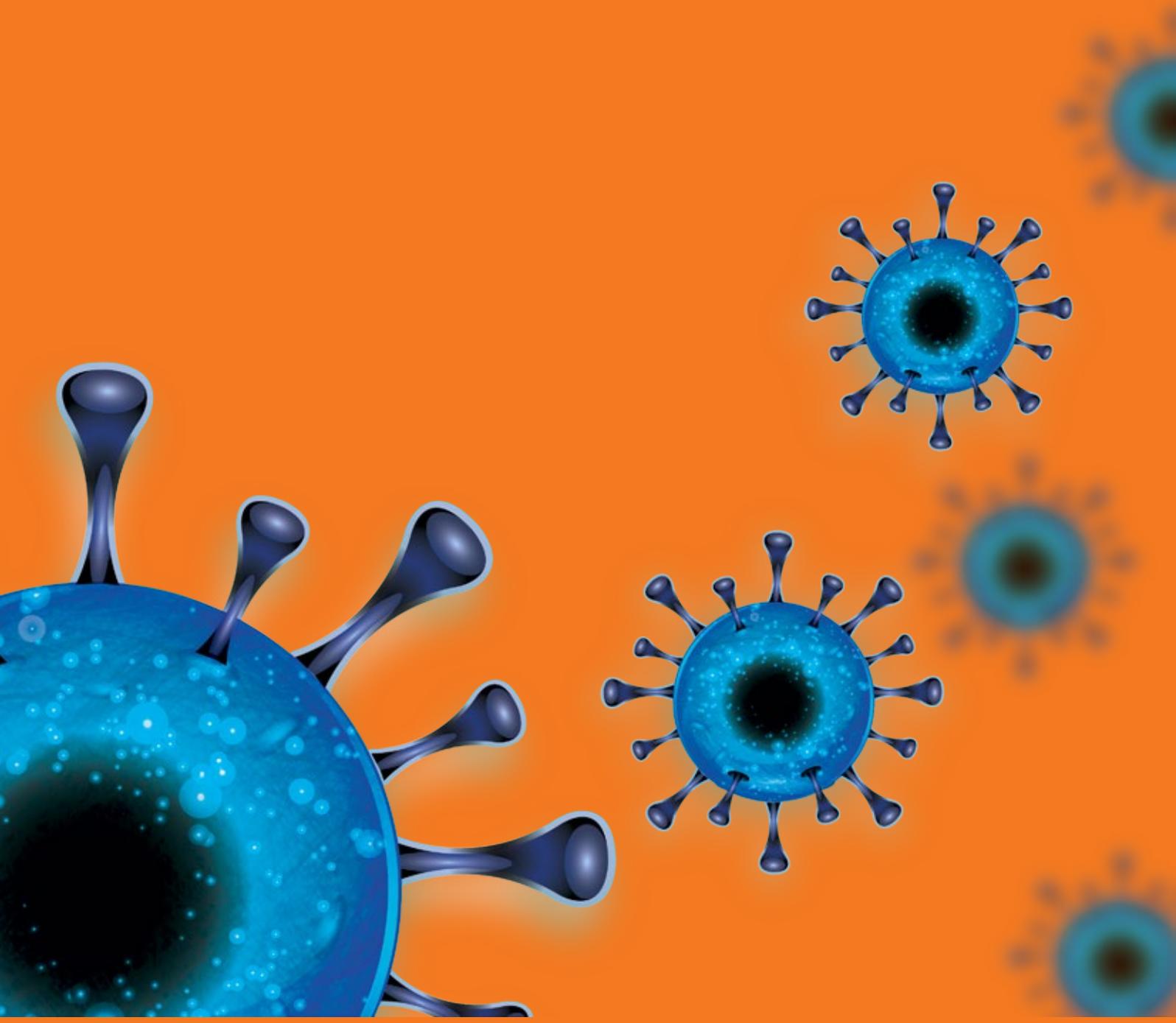
*Long term outcomes*

- Improved HCW practices on VL services
- Improved quality of VL testing services
- Increased involvement of CSO in advocacy for quality VL testing services



# Chapter 8

## *Monitoring and Evaluation*



## 8.1: Introduction

Monitoring and evaluation is a process that helps in tracking the performance of the program and achievement of set targets. Its goal is to improve current and future management of outputs, outcomes and impact. It is a continuous process that uses systematic collection of data to measure specific indicators.

This VL implementation plan will be monitored and evaluated to track down the performance of its implementation and achievements. Monitoring will be done through continuous collection of data to track down agreed key output indicators for each of the six strategic areas. The outputs are expected to lead to favorable outcomes and impact on VL access and suppression. The long- term outcome and impact indicators will be assessed through standardized means.

## 8.2: SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
Electronic reporting system is available	Poor data use in decision making	Improving ICT infrastructure in the country	Data security (hacking)
Data tools already developed	Poor data quality in request and reporting forms	Emerging mobile phone technologies	
Good ICT and LIMS structures in testing labs	Poor data management skills	Demand for information is on the rise	
Current VL equipment interfaced with computers	Poor internet connections at referring facilities		
Existence of LIMS in testing Labs	Lack of M&E plan and performance indicators		
Existence of VL dashboard at NASCOP VL database	LIS/NASCOP database not interfaced with DHIS		
Sharing of data is well enhanced through VL dashboard at Nascop database	Poor communication between testing labs and referring facilities		

## 8.3: Activities

- Review and standardized the existing data tools
- Conduct stakeholder engagement meetings to address their vested interests in the electronic systems.
- Build ICT capacity in the VL testing laboratories. (Hire ICT staff, Specialized ICT training, Procurement of ICT equipment and supplies, support ICT equipment and system maintenance)
- Develop M&E plan for the VL scale-up strategy
- Conduct quarterly data quality reviews at all levels
- Conduct semi-annual DQAs at the county levels



- Configure the electronic system to be inter operable at all levels
- Build capacity for data back-up at the national and testing laboratories
- Advocate for dedicated budget to support Internet connectivity at the county and facility levels.
- Develop VL Data Quality Assessment Checklist
- Develop evaluation protocol
- Conduct evaluation stakeholder meetings
- Support evaluation data collection site visits (baseline, mid-term and end-term)
- Disseminate evaluation reports (baseline, mid-term and end-term) to stakeholders
- Conduct data sharing through manuscript writing and conference attendance.
- Conduct TOT training/mentorship on data management

#### **8.4: Outcomes**

##### *Short-Term outcomes*

- Increased availability of standardized recording and reporting
- Improved stakeholder collaboration and understanding around ICT systems
- Availability of resident ICT at the national, county and testing laboratories
- Availability of M&E plan for VL scale up strategy
- Improved data Security
- Availability of the evaluation protocol
- Increased knowledge and skills on data management

##### *Mid-Term Outcomes*

- Improve data quality of all levels
- Increased availability of specialized ICT personnel at the national level
- Improved VL ICT support system
- Improved VL testing practices

##### *Long-Term Outcomes*

- Improved quality of VL services
- Increased body of knowledge about VL testing implementation scale up



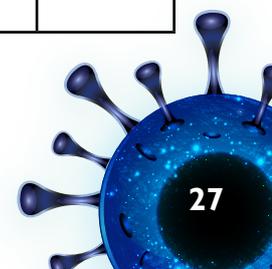
## 8.5: Key Performance Measures and Targets

### 8.5.1: Introduction

The six strategic areas of this VL implementation plan have key outcomes and performance indicators

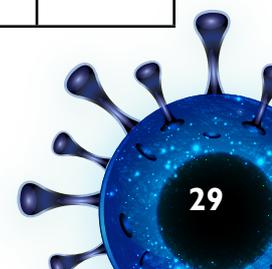
### 8.5.2: Performance Measures and Targets Matrix

Outcome	Indicator	Source of data	Targets				
			2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
<b>Policy guidance, Leadership and Management of Viral Load Services</b>							
National HIV Viral Load Testing Scale-Up Strategy available at national, county and facilities	Proportion of facilities with National HIV Viral Load Testing Scale-Up Strategy	VL plan dissemination reports, DHIS	50%	80%	90%	100%	100%
National and County HIV VL TWGs established	Proportion of counties with VL TWGs	National County coordination reports		100%	100%	100%	100%
Improved coordination of Implementing Partners activities in support of VL testing	Number of collaborative meetings of partners implementing VL activities	Partner work plans	4	4	4	4	4
Strengthened communication at all levels	Number of consultative meetings (National, county and partners) held	Minutes of meetings	4	4	4	4	4
Increased domestic resource allocation for the viral load testing	Percentage of GoK funding towards VL testing	Budget estimates	10%	20%	30%	40%	50%
<b>Product selection, site selection and laboratory capacity building mechanisms</b>							
Increased capacity for Viral load testing (products, sites and testing)	Availability of guidelines on product and site selection	Guideline	100%	100%	100%	100%	100%
	Number of VL testing sites	DHIS	7	7	21	21	21
Increased stakeholder engagement, in product and site selection	Number stakeholders meetings on product and site selection	Minutes of meetings	2	2	2	2	2



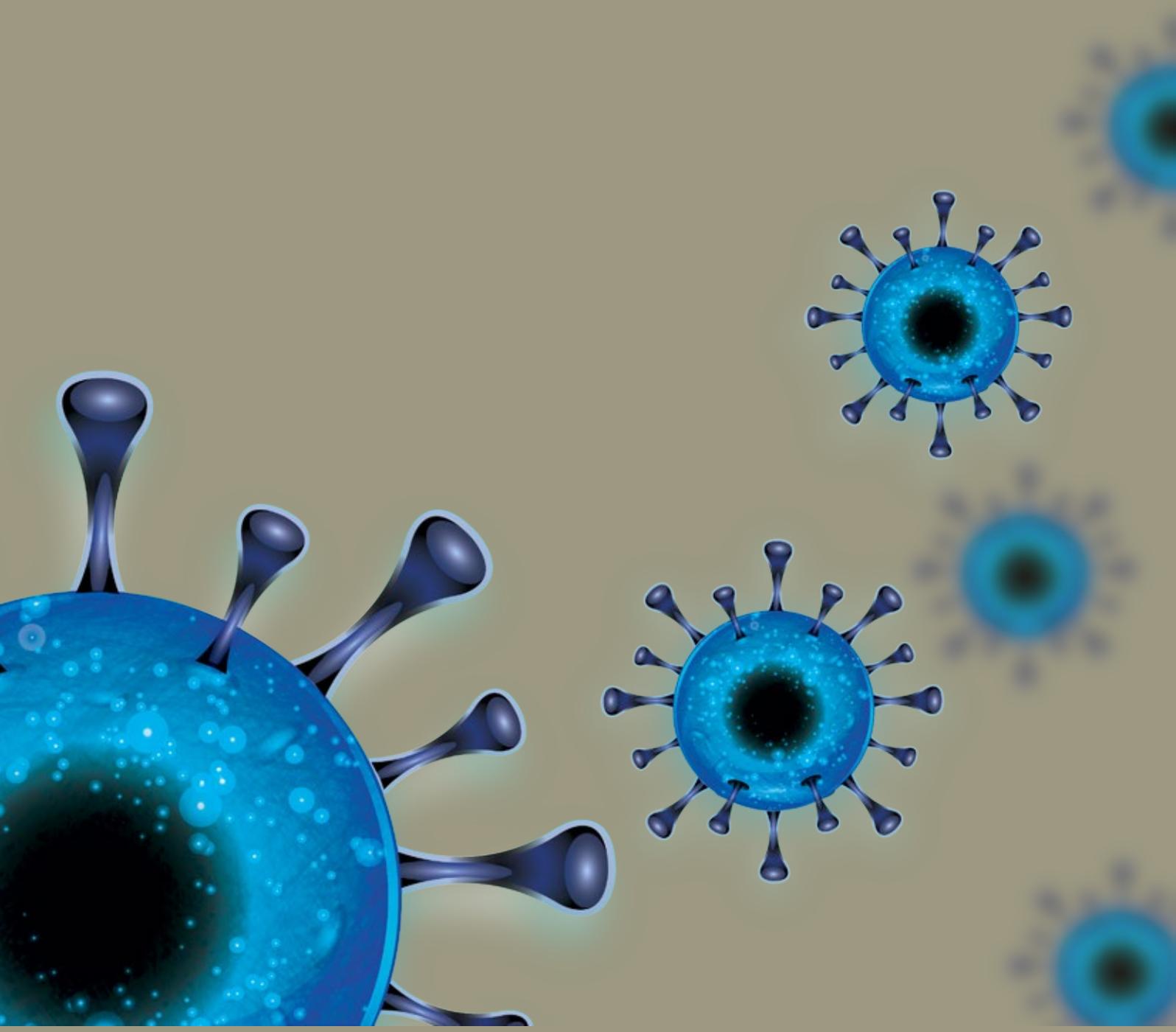
Product selection, site selection and laboratory capacity building mechanisms							
Increased access to VL testing services.	Number of VL tests conducted		460,000	700,000	1,200,000	1,330,652	1,500,000
	Proportion of ART clients accessing viral load test (disaggregated by county)	DHIS	57%	65	80	90	100
Improved quality of VL test results	Proportion of VL testing equipment evaluated	Equipment evaluation reports	100%	100%	100%	100%	100%
	Proportion of sites where post market surveillance is conducted for VL testing commodities	Post market surveillance reports	100%	100%	100%	100%	100%
	TAT in days from sample receipt to sample processing at the testing lab	VL database	20 days	10 days	8 days	6 days	5 days
Forecasting and Financing requirements for VL scale up							
Ensure Viral load commodities and supplies are available	Annual VL Forecasting and quantification report	F&Q report					
	Annual VL procurement and supply plan	Procurement, supply report					
Improved commodity security at all levels.	Number of days of stock out of VL commodities annually (disaggregate by commodity)	Stock status reports	80 days	40 days	20 days	10 days	5 days
Specimen referral networks							
Increased sensitization of specimen referral procedures to the National, county and facilities.	Proportion of facilities with National specimen referral guidelines	assessment reports	100%	100%	100%	100%	100%
Increased adoption of the National specimen referral guidelines at National, county and facilities.	% of sample rejection rate by facility	VL database	1%	0.50%	0.50%	0.25%	0.25%
	TAT in days from sample collection to receipt at the testing lab	VL database	8 days	6 days	4 days	3 days	3 days

Specimen referral networks							
Improved relay of VL test results to referring sites	TAT in days from processing to result dispatch	VL database	5 days	1 day	1 day	1 day	1 day
Human Resource requirements and retention							
Adequate HR to support viral load testing	Number of staff Conducting viral load testing (disaggregated by facility)						
	Ratio of staff to VL workload						
Increased benchmarking among facilities and testing labs.	Proportion of staff mentored on VL testing by site		40%	40%	100%	100%	100%
Advocacy and Education of health care providers and patients on viral load							
Availability of information, education and communication ( IEC) material on viral load services	Proportion of counties with information, education and communication (IEC) material on viral load services	Assessment	0	40%	70%	100%	100%
	Regular mentorship and supervision visits conducted by counties	Number of mentorship and supervision visits conducted by counties	Supervision reports	4	4	4	4
Monitoring and Evaluation							
Increased availability of Viral load service and commodity data in the DHIS	Number of facilities with VL data in the DHIS	DHIS. HCMP,VL database	0	2	7	21	21
Availability of resident ICT at the national, county and testing laboratories	Number facilities with a resident ICT staff	HR reports	7	7	21	21	21
Improved data quality at all levels	Number of sites attaining satisfactory DQA scores	VI request forms, HCMP, DHIS, VL database			10	15	18
Improved VL data analysis, sharing and utilization all levels	Number of VL data sharing meetings held	VI request forms, HCMP, DHIS, VL database	4	4	4	4	4



# Chapter 9

## *Implementation of the National Viral Load Scale Up Strategy*



## 9.1: Introduction

A Viral Load TWG will be formed consisting of laboratory and HIV care and treatment members drawn from both national and county governments, implementing partners, civil society groups and networks of PLHIV. Led by the MoH, this TWG will be responsible for providing policy direction and technical guidance on viral load scale up implementation. The VL TWG will link to other care and treatment technical working groups including the National ART TWG and will report to the National Steering Committee that oversees laboratory services. For the success of this implementation plan, it is important to delineate the roles and responsibilities of different entities involved in addition to the TWG's.

## 9.2: Roles and responsibilities

### 9.2.1: National Public Health Laboratory Services (NPHLS)

- Development of the national laboratory policies.
- Offering specialized laboratory services through reference laboratories.
- Strengthening of laboratory networks both in the public and private sector.
- Provision of technical guidance and coordination of the national VL testing quality assurance (QA) programs
- Training, mentorship and capacity building for VL testing services.
- Evaluation and validation of equipment, and reagents for, and reporting from all testing laboratories both private and public.
- Participation in updating of national HIV VL testing algorithm.
- Provide oversight and coordination in HIV VL testing scale up and sample referral networks.
- Monitoring and Evaluation of VL services.

### 9.2.2: National AIDS and STI Control Programme (NAS COP)

- Define status, gaps, and actions along the cascade of care and health systems for acceleration of VL services uptake.
- Ensure commodity security.
- Provide relevant policies, and guidelines.
- Provide technical support to counties for the acceleration.
- Undertake routine target and work plan performance monitoring for all counties



### 9.2.3 Development and Implementing Partners

The Government of Kenya (GoK) will collaborate with the private sector, development and implementing partners to accelerate the VL testing implementation plan. Their role will include

- Provide financial and technical support to the National and County Ministries of Health in scaling up treatment and access to VL testing services for all clients through
- To advocate for domestic resources mobilization
- Strengthening of county and national leadership
- Participation in the review and development of guidelines
- Dissemination of guidelines
- Capacity building of health care providers through training, continuous quality improvement, mentorship
- Provide assistance in sample transportation networking
- Support the MoH at national, county and facility level to monitor and evaluate progress of the VL testing services to meet national and global targets
- Assist in planning and forecasting and procurement of VL commodities and equipment.

### 9.2.4: County Governments and Health Facilities

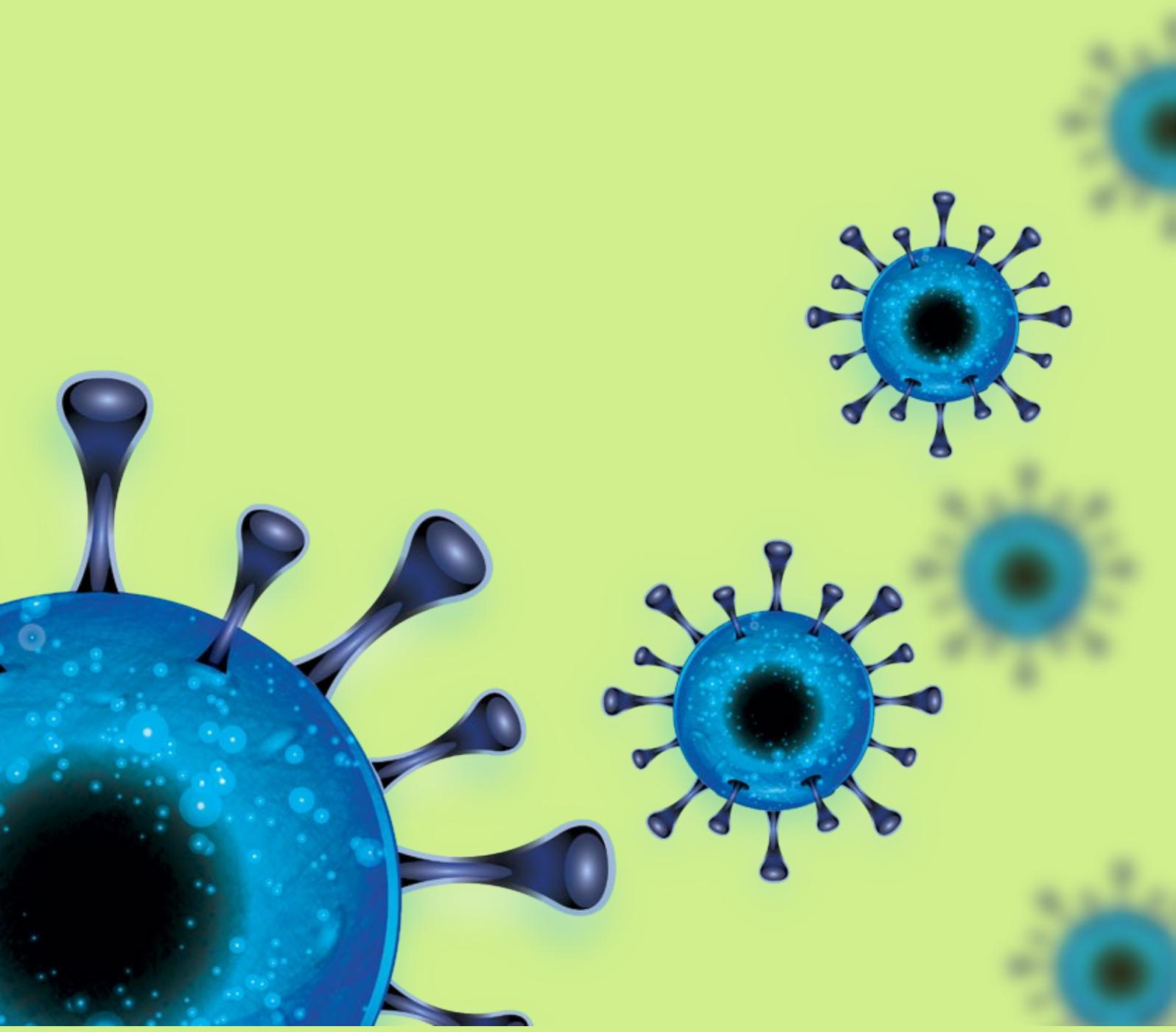
- Undertake routine performance work-plan and monitor target achievement at county, sub-County and facility level.
- Determine resources needed and identify gaps for acceleration plan, and mobilize support from county, and partners.
- Utilize existing Maternal Newborn and Child Health, sector collaboration platforms for acceleration.
- Identify best practices for scaling- up along the cascade of care.
- Actively participate in the VL acceleration agenda.
- Ensure appropriate generation and reporting of data.

## References

1. Consolidated Guidelines for Treating and Preventing HIV,WHO 2013
2. Ministry of Health; National AIDS and STI Control Program (NASCOP) National ART Guidelines: A Rapid Advice, 2014
3. Ministry of Health; National AIDS and STI Control Program (NASCOP) Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection:A Rapid Advice, 2014
4. <http://www.nascop.org/aid/viraloverall.php>
5. NATIONAL AIDS CONTROL COUNCIL- MOH Kenya. Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19.

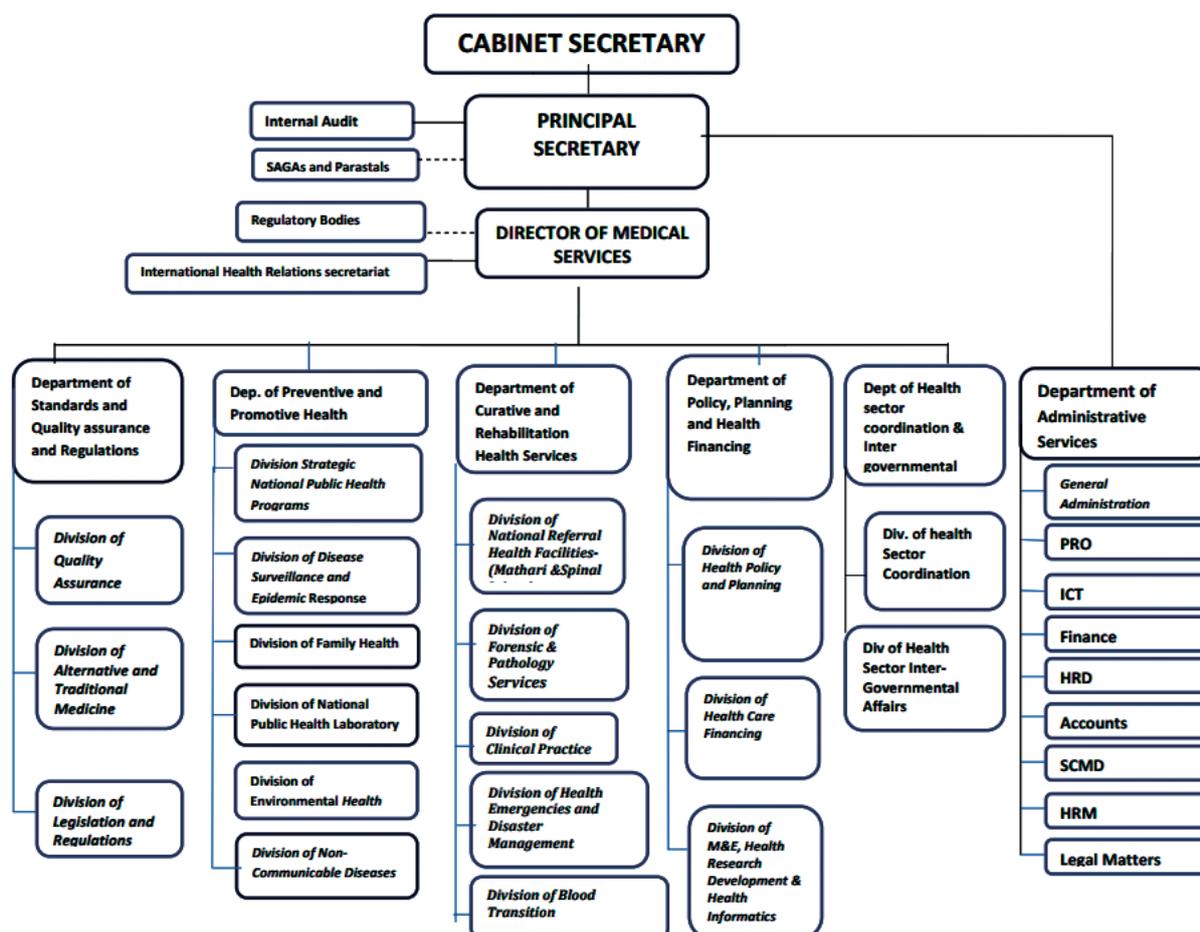


# Appendices



## Appendices

### Appendix 1: MOH Organizational Structure



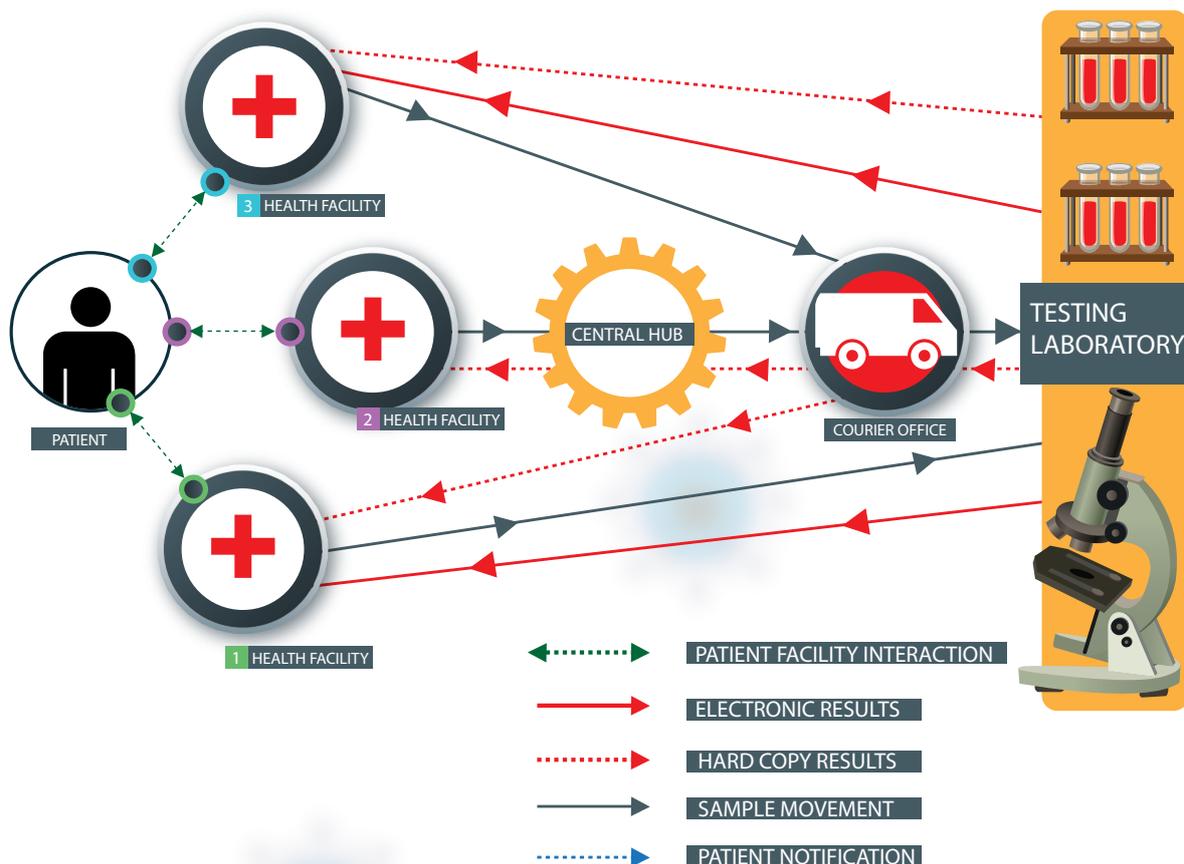
### Appendix 2: National Viral load targets 2014-2017

Forecasts	2014/2015	2015/2016	2016/2017
Adults: Total VL tests required	629,608	1,158,573	1,406,419
Paeds: Total VL tests required	32,008	51,213	95,690
% Adjustment / Allocation for QA	8%	8%	8%
Adjustment for QA for Adult & Paed tests	2,561	4,097	7,655
% Adjustment for Wastage	2%	2%	2%
Adjustment for wastage	640	1,024	1,914
<b>Total VL Tests required</b>	<b>664,817</b>	<b>1,214,907</b>	<b>1,511,678</b>

Source: National HIV Forecasting and Quantification Report 2015-2017



### Appendix 3: Sample and test results flow



### Appendix 4: Product selection Criteria

Status of regulatory approval in country	Ancillary equipment or consumables required
Components included within the cost of the test	Quality Assurance/Quality Check requirements
Logistical/transportation of reagent requirements	Training requirements
Manufacturer supply chain capability	Laboratory infrastructure required
In-country evaluation performance	Life span of the device
Length of reagent shelf life	Service and maintenance requirements
Specimen type	Technical support available from the manufacturer in-country
Analytical Performance (sensitivity, specificity, reliability, level of detection)	Data management capabilities (interfacing capability)
Turnaround time of the device per sample	
Device Throughput	

### Appendix 5: Site Selection Criteria

- Laboratory infrastructure available
- Human resources available
- Accessibility to patients
- Workload
- Potential facilities to benefit (network)



# Appendix 6: Viral Load Lab Request form

Version- March 2015



Ministry of Health  
Viral Load Lab Requisition Form

Date samples were dispatched:.....

County:.....	Sub-County:.....
Facility Name.....	Contact name.....
Facility MFL code.....	Health Care Provider mobile number:.....
	Facility Telephone.....
	Facility email address.....

<b>Sample collection Material Requisition</b> (please indicate the quality required ) 1. DBS blood collection (50/pack) <input type="checkbox"/> 2. DBS blood collection (20/pack) <input type="checkbox"/> 3. Plasma Preparation Tubes (50/pack) <input type="checkbox"/>	<b>Comments:</b>
---	------------------

Serial No.	CCC No	Sex	D.O.B	Date of collection	Sample type <small>(select from code below)</small>	Date started on ART	Current ART Regimen <small>(select from code below)</small>	Date Initiated on current regimen	Indicate if 1st Line (1) or 2nd Line (2)	Justification code	
										code (1)	code (2)
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

<b>Code for Sample Type:</b> 1= Frozen plasma 2= Venous blood (EDTA) 3= DBS capillary (infants) 4= DBS venous	<b>Codes for Justification:</b> 1= Routine VL 2= Confirmation of treatment failure (repeat VL at 3M) 3= Clinical failure 4= Immunological failure 5= Single Drug Substitution 6= Pregnant Mothers 7= Lactating Mothers 8= Baseline VL
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ART Regimen Codes	1=AZT/3TC/NVP	2=AZT/3TC/EFV	3=TDF/3TC/NVP	4=TDF/3TC/EFV	5=AZT/3TC/LPVr	6=AZT/3TC/ABC	7=TDF/3TC/LPVr	8=AZT/3TC/ATVr	9=TDF/3TC/ATVr	10= ABC/3TC/ATVr	11= ABC/3TC/NVP	12= ABC/3TC/EFV	13= ABC/3TC/LPVr	14= Other (please specify)
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<b>AMPATH CARE LAB</b> Nandi Road, off Nairobi-Uganda Road, Eldoret Tel: 0733-787-710 <a href="mailto:email:aid-ampath@googlegroups.com">email:aid-ampath@googlegroups.com</a>	<b>COAST PGH LAB</b> Molecular Section, Hospital Road, Mombasa Tel: 0722-207-868 <a href="mailto:email:aid-coast@googlegroups.com">email:aid-coast@googlegroups.com</a>	<b>KEMRI HIVR LAB</b> Kisian Road, Kisumu-Busia Road, Kisumu Tel: 0719-867-752 <a href="mailto:email:aid-kisian@googlegroups.com">email:aid-kisian@googlegroups.com</a>	<b>KEMRI ALUPE LAB</b> CIPDCR, Busia-Malaba Road, Busia Tel: 0726-156-679 <a href="mailto:email:aid-alupe@googlegroups.com">email:aid-alupe@googlegroups.com</a>	<b>KEMRI HIV P3 LAB</b> Mbagathi Road, Nairobi Tel: 0725-793260 0725-796842 <a href="mailto:email:aid-nairobi@googlegroups.com">email:aid-nairobi@googlegroups.com</a>	<b>NHRL LAB</b> KNH Complex, Nairobi <a href="mailto:email:nhrl@nhrls.or.ke">email:nhrl@nhrls.or.ke</a>	<b>WALTER REED LAB</b> HIV Lab Hospital Road, Kericho Tel: 0716-430261 <a href="mailto:email:aid-wr@googlegroups.com">email:aid-wr@googlegroups.com</a>
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**MINISTRY OF HEALTH**  
**National Public Health Laboratory Services**