UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE
NATIONAL AIDS CONTROL PROGRAMME

NATIONAL OPERATIONAL PLAN FOR SCALING UP HIV VIRAL LOAD TESTING

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NATIONAL OPERATIONAL PLAN FOR SCALING UP HIV VIRAL LOAD TESTING

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Any part of this National Strategic Plan for scaling up HIV Viral Load Testing to support HIV and AIDS Prevention, Care and Treatment can be used provided that the source which is the Ministry of Health and Social Welfare, National AIDS Control Programme is acknowledged.

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Abbreviations and acronyms

ART	Antiretroviral therapy
BF	Breast feeding
BMC	Bugando Medical Centre
CAP	College of American Pathologists
CD4	Cluster of differentiation
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHMT	Council health management team
CTC	Care and treatment centre
DACC	District AIDS Control Coordinator
DBS	Dried blood spot
DDP	Delivery Duty Paid
DHIS	District health information system
DLT	District Laboratory Technologist
DMO	District Medical Officer
DOD	Department of Defense
DSS	Diagnostic Services Section
EAC	Enhanced adherence counseling
EDTA	Ethylenediaminetetraacetic acid
EID	Early infant diagnosis
eLIMS	electronic Laboratory information management system
EQA	External quality assessment
Est.	Estimate
FEFO	First expiry first out
GF	Global Fund
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIS	Geographical Information System
GOT	Government of Tanzania
HC	Health centre
HCWs	Health care workers
HDR	HIV drug resistance
HR	Human resource
HSHSPIII	Heath Sector HIV Strategic Plan III (2013-2017)
HSPs	Health service providers
HVL	HIV viral load
ICAP-CU	International Center for AIDS Care and Treatment Programs, Columbia University
IP	Implementing partners
JSI	John Snow Inc
KCMC	Kilimanjaro Christian Medical Centre
km	Kilometer
LIMS	Laboratory information management system
LIS	Laboratory information system
M&E	Monitoring and evaluation
MDH	Management Development for Health
ml	milliliter
MNH	Muhimbili National Hospital

MOHSW	Ministry of Health Social Welfare
MSD	Medical Stores Department
NACP	National AIDS Control Program
NHLQATC	National Health Laboratory Quality Assurance and Training Centre
NMSF	National Multi-Sectoral For Framework
^{o}C	Degrees Celsius
PEPFAR	President's Emergency Plan for AIDS Relief
PHLB	Private Health Laboratory Board
PIMA	CD4 POC machine (Trade name)
PLHIV	People living with HIV/AIDS
PMORALG	Prime Minister's Office Regional Administration and Local Government
PMTCT	Prevention of Mother to Child Transmission
POC	Point of care
PPA	Public Procurement Act of 2011
PPP	Public private partnership
PSM	Procurement and Supply Management
QMS	Quality management systems
RACC	Regional AIDS Control Coordinator
RHMT	Regional health management team
RLS	Resource-limited settings
RMO	Regional Medical Officer
RTK	Rapid test kit
SOP	Standard operating procedures
TAT	Turnaround time
TFDA	Tanzania Food Drug Authority
THMIS	Tanzania HIV Malaria Indicator Survey
TNCM	Tanzania National Coordination Mechanism
TOR	Terms of reference
TWG	Technical working group
USD	United States Dollar
Utumishi	Kiswahili word for public service
VL	Viral load
VLAB	Viral laboratory
WHO	World Health Organization

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Last but not least the NACP would like to convey sincere thanks to all MOHSW staff from Departments, Sections, Programs and Professional Councils (appendix 1) for their valuable contributions towards developments of this Operational Plan. Specifically, the NACP commends the tireless efforts of the secretariat team for coordination process and finalization of the document.

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FOREWORD

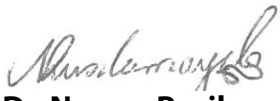
For more than three decades, since the first case of HIV was reported in Tanzania, HIV remains an epidemic which continue to claim lives of thousands of people living with HIV/AIDS.According to UNAIDS report 2014, currently there are about 1,411,829 people living with HIV and AIDS in Tanzania and the prevalence has been going down significantly from 7.1% to 5% in THMIS 2003 - 2004 to 2011 – 2012 respectively.

The prevalence has concentrated in different groups and geographical locations. Generally, HIV prevalence is higher in women (6.2%) than men (3.8%) (THMIS2011-12) and is higher in urban than rural areas. The National HIV/AIDS Care and Treatment Plan for Tanzania was launched in 2004, with the aim of providing quality care and treatment for all people living with HIV/AIDS (PLHIV) in Tanzania.

In 2014, the National HIV Viral load (HVL) guideline was developed to provide the guidance of how to manage the clients on ART through viral load testing. The development of the HVL guideline was informed by July 2014 WHO recommendation on monitoring ART clients. Therefore the Operational Plan for Scaling up HIV Viral Load comes to support the effective and efficient scaling up the utilization of the HIV viral load testing on monitoring the ART clients.

It is our sincere hope that by abiding to this plan will have an immense contribution towards provision of quality HIV care and treatment services in the country.

Therefore, I urge all of our treasured partners to take ownership of the document and use it as the guide as we make our contribution to the provision of quality HIV care and treatment Services.



Dr. Neema Rusibamayila
Director of Preventive Services

Section One: Background

Global developments in antiretroviral therapy monitoring

HIV viral load (HVL) monitoring is the gold standard for detection of treatment failure in patients on antiretroviral therapy (ART); however, its availability in resource-limited settings (RLS) has been severely restricted due to prohibitively high costs (*40-85USD/test*), complex specimen collection and transport requirements. Due to these financial and operational barriers, the World Health Organization (WHO) HIV treatment guidelines have historically focused on the use of clinical and immunologic criteria for determination of treatment failure. However, studies have demonstrated a poor predictive value of the WHO immunologic criteria for virologic failure and delayed detection of treatment failure that leads to HIV drug resistance (HDR).

Recent developments have made expansion of HVL testing in RLS more feasible. Prices for HVL technologies have fallen substantially, and the introduction of HVL quantification using dried blood spots (DBS) mitigates many specimen collection and transport issues. The June 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* reflect these developments and recommend HVL monitoring as the preferred monitoring tool for the diagnosis and confirmation of ART treatment failure.[1]

In response, the Ministry of Health and Social Welfare (MOHSW) included specific strategies in its Health Sector HIV Strategic Plan III (2013-2017) to draw attention on the importance of the HVL in ART treatment monitoring. The strategy, which states "Strengthen clinical management of HIV diseases; reduce adverse effects; increase adherence to treatment and mechanisms for early identification of PLHIV experiencing ART treatment failure and switching them to appropriate second line regimen" and the corresponding target, which states "50% of PLHIV on ART monitored using HVL by 2017" provides guidance to the ensure appropriate intervention are implemented to institute and scale up HVL in the country. As part of the implementation of the 2013 WHO recommendations and the HSHSPIII, the MOHSW developed the HVL strategic plan to leverage existing resources and the latest developments in HVL technologies and pricing in an effort to improve clinical outcomes and expand access to routine HVL monitoring.

[1] http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf

ART monitoring in the United Republic of Tanzania

The national HIV prevalence among adults is 5.1% (THMIS2011-12) with estimated 1,500,000 people living with HIV. Total of 560,641 patients were on ART by June 2014 receiving services in 1,209 facilities.

Current ART monitoring guidelines

The National Guideline for management of HIV and AIDS is currently under revision. Currently guideline uses CD4 level and clinical staging for initiation of treatment. After treatment has been initiated CD4 counting is done biannually for monitoring of treatment outcome. CD4 testing is widely available. Nearly 855 facilities are doing onsite CD4 testing through conventional and point of care test. All other facilities are linked to the next level through specimen referral network. Almost all patients have access to CD4 testing (more than 95 %) but in few exceptions and areas where CD4 testing is not possible WHO clinical staging remains the only option for initiation of treatment.

CD4 point-of-care machines like PIMA have been deployed to all medium volume sites and these sites support other peripheral sites where CD4 testing was not available. However, in the current system, challenges with frequent reagent stock-outs, equipment maintenance, quality assurance, and data management hamper reliable availability of immunologic monitoring.

Existing HVL testing capacity

Currently, HVL testing in Tanzania is recommended only to confirm treatment failure to the patients who have been confirmed to have clinical and immunological failure (through Clinical staging and CD4 count). Therefore, It is performed in relatively small number of patients suspected of failing treatment and for patients enrolled in research projects in eleven (11) laboratories: (six (6) government hospital laboratories and five (5) private hospital laboratories).

The most limiting factor for HVL scale-up so far has been the cost of HVL testing. In addition, low demand from the health care providers due to absence of the service nearby and lack of awareness and challenges related to specimen transportation are critical bottlenecks for use of HVL testing. Therefore, demand creation and strengthening of specimen referral

system will be central to ongoing efforts to implement the HVL testing scale-up plan. Recently, an announcement was made that enabled a significant reduction in the global price for HVL testing to less than USD10 per test. This removes one significant barrier to the scale up of HVL testing in Tanzania. The WHO July 2014 published guidance on implementation of HVL testing encourages use of dried blood spots for HVL testing at the same threshold as plasma (1000 copies/ml). This provides a significant advantage for the roll out and scale up of HVL testing in rural parts of Tanzania where transport of fresh plasma samples will be limited and DBS can provide much needed access to HVL testing. This document outlines the scale up plan for HVL testing to carry out routine monitoring of ART using HVL testing.

Proposed guideline revisions

MOHSW is currently revising the National ART Guidelines to recommend routine VL monitoring. The proposed clinical algorithm for children and adults, including pregnant and breastfeeding women, is illustrated in **Flow Chart 3**. As routine HVL monitoring is introduced, CD4 monitoring for patients on ART will no longer be performed. However, routine CD4 testing every six (6) months will be continued for pre-ART patients who require it for determination of ART eligibility. In addition, a baseline CD4 is recommended for "test and treat" populations (e.g., pregnant and breastfeeding women, TB-infected patients, children <15 years).

Section Two: HVL monitoring implementation strategy

To expand access to ART monitoring services and improve patient outcomes, the MOHSW proposes to build capacity for centralized HVL testing using DBS and plasma samples at one national reference laboratory and five (5) zonal PCR laboratories. However, in the next five (5) years, MOHSW plan to expand HVL testing capacity by strategically adding more HVL testing facilities (either conventional or POC as technology evolves) in different part of the Tanzania. MOHSW will support the scale-up of sample collection and associated programmatic changes in health facilities across the country in collaboration with health development partners and the ART Implementing Partners. Routine HVL testing should ultimately be available for all patients on ART.

Policy, Leadership and Management

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

The NACP at MOHSW will lead the HVL scale-up plan, and Regional Health Management Teams will manage the program in their respective region. MOHSW/NACP solicit funding for HVL scale-up plan, develop guideline on the use of HVL testing, work with IPs and other stakeholders to strengthen the specimen referral network, lead advocacy and training of health care providers on the use and interpretation of HVL tests using MOHSW approved training tools.

Education and advocacy of the public on HVL test results in relation to adherence to treatment will be an important activity. MOHSW and RHMTs/CHMTs will lead the development of critical monitoring and evaluation tools and collect data to measure the progress and impact of implementation of the HVL scale-up plan. NHLQATC will lead the laboratory component of HVL scale-up plan which includes training of laboratory personnel on the technology, development of laboratory logbook and database to capture critical information on the use of HVL testing, coordinate quality assurance program and specimen referral testing. Zonal HVL Laboratories and other designated testing facilities will lead the

actual testing process, report the result within the defined turn-around time (TAT), do internal and external quality assurance and work with the local courier system for smooth functioning of specimen referral system.

MOHSW/NACP will be responsible for forecasting, procurement and distribution of HVL testing reagents and DBS collection materials. In doing so, it will track consumption of HVL commodities accurately and timely. PHLB and TFDA will play the usual regulatory role of product registration, monitoring of the quality of reagents including their field performance (post market surveillance). The PEPFAR program will provide funding and technical assistance (TA) support for training of staff, quality assurance, procurement and supply chain, database creation, support specimen referral network and develop capacity at RHMTs and HVL laboratories. Global fund will provide resources for procurement of HVL reagents and DBS collection materials for plasma and DBS and avail second line drugs in enough quantity. CHAI will continue to provide TA to NACP on costing, use of database and reporting, SMS/GSM printer use to relay results, and global negotiation of costs for HVL.

For sustainable ART monitoring program through HVL testing, direct policy, leadership and management involvement is critical especially in the areas of availing resources and resource mapping, adoption of the WHO 2013 guideline for ART monitoring, creating awareness among health care providers and the public, cost negotiation and use of both plasma and DBS to expand HVL testing to periphery. Strong leadership and a well -designed approach will be needed to ensure proper uptake of HVL testing and effective management of patients with treatment failure at the lowest level of health care delivery system.

Clinical algorithm for HVL testing

The HVL testing will be performed six (6) month after initiation of ART. If HVL test results is less than 1000 copies per mL, a second HVL test performed six (6) months after the initial HVL test, and then annually thereafter. If HVL test results equal or greater than 1000 copies per mL, a second HVL test performed after three (3) months of intensive adherence counseling. If second HVL results are less than 1000 copies per ml continue monitoring of HVL annually, otherwise switch the patients to the next level regiment. If an annual HVL test results is equal or greater 1000 copies per ml, perform HVL test after three (3) months of intensive adherence counseling. For clients, who have been on ART and immunological monitoring for more than six (6) months an HVL test will be performed at any time in the

next scheduled visit. The recommended specimens for HVL testing are: plasma separated from EDTA and Dried Blood Spot (DBS) from whole Blood (**table 1)**.

The table below shows the summary of studies and manufacturer recommendations for time of transport and storage at various conditions for plasma, whole blood and Dried blood spot specimens for HVL testing

Table 1: Summary of studies and manufacturer recommendations

Temperature (in ^{o}C)	**37^{o}C (humid condition)**	**15-30^{o}C (room temp)**	**4^{o}C**	**-20^{o}C**	**-70^{o}C**
Time	**Whole Blood (Venous EDTA)**				
	6 hrs.	6 hrs.	N/A	N/A	N/A
	Plasma				
	24 hrs.	24 hrs.	5 days	1 year	5 years
	Dried Blood Spot				
	1-2 weeks	1-2 weeks	2-52 weeks	3-36 months	1 year

Source: WHO Technical and Operational Consideration for Implementing HVL testing, July 2014

Challenges and possible solutions for HVL scale-up

Like all intervention program, HVL the following challenges are anticipated in the HVL testing scale up plan at all levels: sample referral, results feedback and data quality management. To mitigate these challenges, good referral system by using standardized referral forms, a well-organized hubs management, where all data will be documented and the results feedback will use efficient means of communication will be put in place. Program coordination and oversight, insufficient funding and donor dependency affects sustainability. Therefore, management involvement to support a sustainability of HVL testing program is to ensure involvement of the CHMTs and partners to put into CCHP all HVL testing related activities, hence, accessibility of central government funding is possible. Supply chain management of commodities should be properly forecasted and sustainable supply of laboratory reagents and consumables ensured. Drug resistance surveillance needs to be put in place to ensure the success of HVL testing, where all patients monitoring on drug resistance. HVL focal person at district level through the DMOs office will closely monitor all HVL testing activities.

Product selection and strategic placement of HVL services

At present, there are two types of Roche platforms operating in the country at six (6) laboratories, which are: Muhimbili National Hospital, NHLQATC, Temeke Regional Referral Hospital, BMC, Mbeya Regional Referral Hospital and KCMC. In total there are six (6) CobasAmpliprep/TaqMan 48 machines in each of the current six (6) EID laboratories and three CobasAmpliprep/TaqMan 96 Dock System in three (3) laboratories.

The site selection has been made with consideration for the catchment area and strategic location for improving access to HVL testing services. The most challenging issue remains infrastructure.

Product selection will consider the following operational characteristics: infrastructure requirements, quality assurance, supportive logistics, availability of technical support, technically easy to use, safety and waste management, data management, durability, set up cost, polyvalence and consideration of performance characteristics (Refer WHO guideline on HVL testing of July 2014). POC product selection will adhere to National Generic POC Implementation guidelines. All product selection should be undertaken in consultation with the MOHSW, HIV and AIDS Development and Implementing Partners, with careful attention for the laboratory infrastructure at the selected facilities.

Type of sample

Dried Blood Spot (DBS) will be the preferred sample for HVL testing. However, plasma as gold standard will continue being used at facilities, which are close to the testing laboratories. Transportation of samples to testing laboratories will follow the established National for sample referral network.

Quality management system and training

All HVL testing laboratories shall implement a comprehensive Quality Management System that comprises of an ongoing cycle of quality assessment and process improvement so to monitor and evaluate their capacity at program and all functional levels, including the organizational and individual levels, equipment and reagent stock management, the use of quality control, data management and documentation, non-conformity management, specimen management, safety and waste management and participation in EQA.

This system should incorporate national standards for testing and training staff involved in external quality assurance and laboratory management and nontechnical staff involved in testing services.

Currently, there are six (6) laboratories performing HVL and are all enrolled in biannual Global Aids Program (GAP) proficiency testing panel provided by CDC Atlanta. These Laboratories includes BMC, KCMC, Temeke, Mbeya Referral Hospital Laboratory, Muhimbili National Hospital Laboratory and NHLQATC. Apart from GAP PT panels, NHLQATC receives an additional PT panels from College of American Pathologists (CAP) three times a Year.

Section Three: Forecasting, financing, and mapping the HVL network

Logistics management of HVL commodities

Financing and funding

The Government of Tanzania (GOT) through the MOHSW and donors such as PEPFAR and GFATM will fund the procurement, storage and distribution of the HVL reagents and supplies in a similar way to other HIV commodities. Funds for procurement of HVL commodities will include both product and PSM (Procurement and Supply Management) costs. Where the donor supports procurement, storage and distribution, the GOT will contribute 5.6% of the product cost (part of the PSM cost). The GOT through the TNCM and MOHSW will be responsible for resource mobilizations to ensure adequate funding for the country's HVL reagents and supplies requirements.

Quantification

Forecasting and Supply Planning

The MOHSW through the NACP and DSS will be responsible for forecasting and Supply planning of the HVL reagents and supplies in a similar manner to other laboratory commodities. Morbidity or service statistics forecasting method will be employed using simple excel tools. In this method, the estimated requirements will depend on the number of clients on ART and the proportion of the clients requiring the HVL test. Two scenarios will be employed in forecasting the needs: 1) Estimation of the cost of the reagent kits required to run the conventional machines which are not under reagent rental contracts (cost per kit system) and 2) Estimation of the cost of the total tests required to be done with conventional machines that are covered with reagent rental contracts (cost per test and service maintenance). Supply planning will be done using Pipeline Software with consideration to inventory parameters such as Maximum-Minimum stock levels at central level, procurement lead times and review periods.

Procurement, storage and distribution

Procurement of the HVL will be done together with other Laboratory commodity by MSD with accordance to Tanzania's PPA of 2011. Tendering will be done annually depending on the availability of funds and shipments will be delivered according to the supply plan. MSD

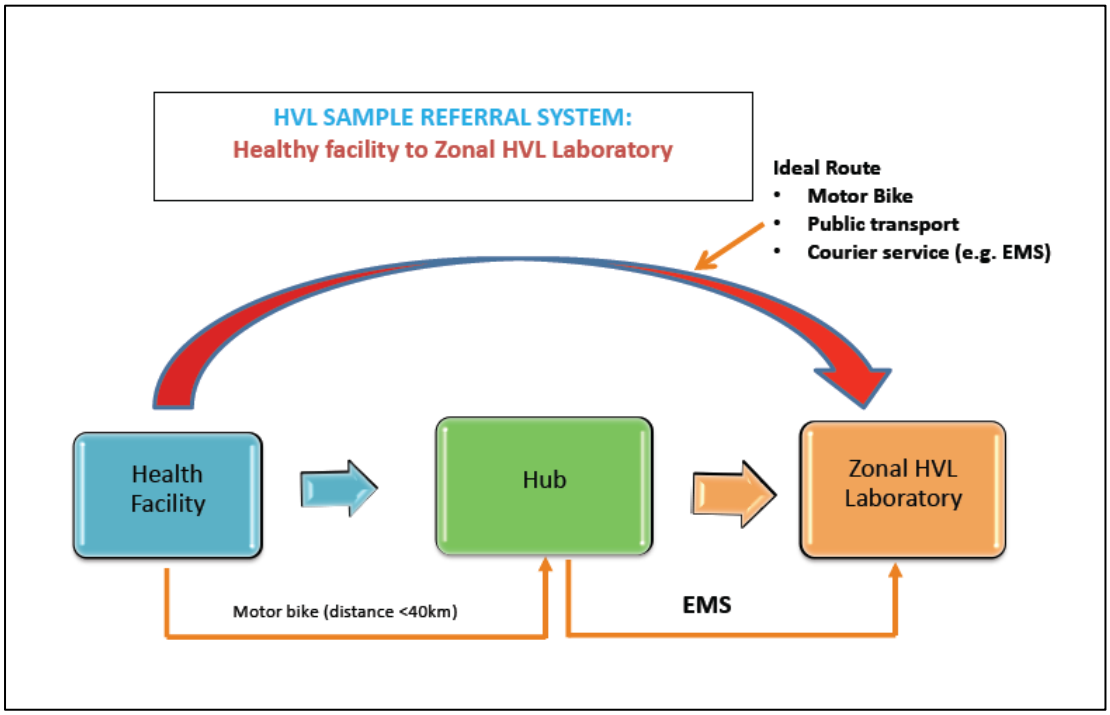
will use the DDP (Delivery Duty Paid) system where the supplier/seller delivers the consignment at MSD central warehouse and the procurement costs includes freight, insurance and clearance. MSD will also be responsible for storage of the HVL commodities at the central level (MSD central and Zonal warehouses) according to good storage practices. Distribution to zones will be carried out by MSD according to zonal requirements or with accordance to the allocation from the NACP. Once the HVL commodities are at MSD zones, health facilities will place orders together with other Laboratory commodities through Laboratory Report and Request forms. MSD will distribute the commodities directly to the facilities. At facilities, the HVL reagents and supplies will be managed like other Laboratory reagent by maintaining a ledger and adhering to specific storage requirements for the items.

Specimen referral network

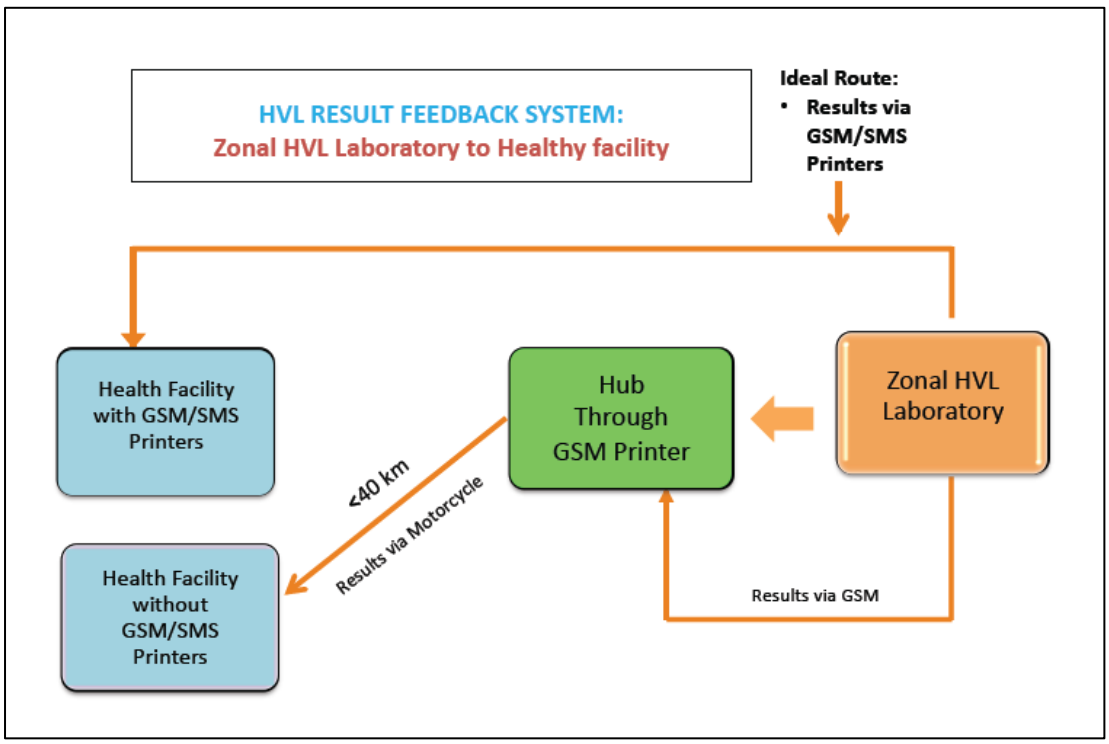
The new HVL sample referral system intends to increase the coverage of HVL testing in Tanzania using a HUB system. A Hub is designated facility with the capacity to collect from specific sites around 30-40 km radius and temporally store specimens from the lower facilities and transport them to the testing laboratory. The identification of hubs will be led by CHMT through involving the catchment area stakeholders. An estimated number of 500 hubs are expected to be working by end of 2017 based on three (3) hubs per district calculation.

From the facilities specimen will be transported to the hub through efficient public transport available in the specific area. The hub will have a focal person who will be responsible in coordinating the activities at the hub. Regional and District Laboratory technologists in collaboration with laboratory advisers from the Implementing Partners will be responsible for coordinating the specimen transportation to ensure the specimens reach the testing laboratory and results feedback reach the requesting clinicians. The results are expected to follow the same pathway back to the facility. Recommended HVL test results turnaround time (TAT) is 14 days.

Section Four: HVL testing HUB system in Tanzania



Flow Chart 1: HVL sample referral system



Flow Chart 2: HVL testing result feedback system

Mapping

Creation of HVL testing hubs

The mapping and identification of hubs will start from mapping the health facilities that could function as HVL sample transport 'HUBS', a hub being the coordination center of the sub district network. Using Geographical Information System (GIS) a catchment area of 30 to 40 km radius will be mapped around each hub. A total of 500 hubs are to be identified by end of 2017.

Sensitization of health care workers

To ensure smooth operations and to reach the expected efficiency, health care workers will need to be aware of the new system and continuously reminded through the existing supportive supervisions plans. The sensitization will be done to general facility staff and for the hubs their staff will also learn on how to coordinate the HVL samples and results. Additionally the staff from the designated laboratories will also be sensitized on the system to allow them to receive the samples as well as to coordinate the dissemination of results. The CHMT and other stakeholders will guide the sensitization

Training of couriers

Identified courier's staff will need to undergo training on safe sample handling and transportation.

Training of health care workers (clinicians, nurses) on HVL test results interpretation

Training on interpretation of results will go hand in hand with identification of who needs to be tested. This will in turn ensure the results are utilized and the patients who are required to receive the HVL test are tested.

Section Five: Human resource

HVL testing network will involve the hubs that have been created by health facilities and linked to the testing laboratories. The expected output is a functional human resource for HVL testing that is integrated in the health care delivery and laboratory information systems.

The human resource requirement will be based on the following levels of service:

At sample collection centres, it is expected to have at least two trained HCWs to be responsible for collection, packaging and transporting the samples to the hub using the most efficient and safe means of transport which is available at the specific area.

Hub will be expected to have a trained person with data entry skills including basic computer application under the coordination of DMO. Samples will be transported to the testing laboratories using the agreed transportation system in collaboration with Development and Implementing partners.

HVL testing laboratories are expected to have a minimum of three trained laboratory scientists, two laboratory technicians, two data clerks and one receptionist, in order to be able to receive, process samples and to be able to handle the results efficiently.

At the National level coordination, there will be one national co-ordinator to coordinate the whole programme and to ensure the implementation is in line with the National Strategic plans.

Task sharing has is accepted after training, competency assessment and certification by MOHSW. However, task sharing in conventional platforms testing sites has not been accepted.

Human resources retention

Future plans of integrating molecular testing in all levels of pre-service training are being considered; internship opportunities and volunteerism to the testing laboratories will be explored. In-service training of all laboratory practitioners on molecular testing for gap coverage is a requirement to support HVL testing. Strengthen place of work and continued medical education. In case the human resources is a crisis partners will be requested to recruit for a limited period and eventually be absorbed the into public service system.

Advocacy and education of health care providers

Currently, a country costed and detailed training plan with timelines are under development to ensure dissemination of accurate information to all relevant clinical, laboratory, Strategic Information, Supply Chain and administration staff

Clinical health workers play a central role in the uptake of HVL testing; therefore, training should focus on ensuring that providers understand the advantages of HVL testing (such as increased simplicity of interpretation compared with immunological monitoring) and the implications for improving patient management.

Training curriculum for clinical practitioners on the routine use of HVL testing in ART monitoring has been adopted from WHO Guidelines and includes:

- Guidance on providing clear messages on the reasons for HVL testing,
- Complying with the HVL clinical algorithm,
- Interpreting results for clinical management,
- Documenting follow-up and promoting adherence to ART and retention in care.
- Clear communication protocols and documentation
- Enhanced adherence counseling to clients receiving ART on HVL testing and results.
- Lifelong ART for pregnant, breastfeeding women (formerly “Option B+”) and key populations.
- Practical case studies

Laboratory service providers

Existing training for HVL laboratory Service is localized to the six (6) HVL testing laboratories including NHLQATC, Temeke Regional Referral Hospital, KCMC, MNH, BMC and Mbeya Referral. Plans are underway to develop national HVL testing training coordination mechanism.

Planned training for laboratory service providers

Training on HVL testing platforms, basic equipment maintenance and troubleshooting, Training on proper handling and processing of specimens to ensure accurate test results based

on SOPs that have been reviewed and approved by MOHSW. The approved SOP should address the following aspects:

- Troubleshooting protocols are highlighted during training, with laboratory management providing continual oversight and mentorship.
- Specimen handling (transporting, reception, accessioning, processing, testing and storage).
- Data reporting, archiving and technical support, etc.
- Criteria for accepting and rejecting specimens but also include follow up communication with collection sites and transporters if poor specimen quality is detected.
- All laboratory staff must be properly trained and competent assessed to perform their duties.

In addition, to laboratory staff, other service providers involved in HVL testing services will require targeted training for data management and entry, specimen collection and handling, specimen transportation and results interpretation depending on the group responsibilities.

For community sensitization of HVL testing, community outreach workers (e.g., local leaders, peer mentors, family support groups, people living with HIV and AIDS, community health workers), will implement the following:

- Outreach program for HIV and AIDS at several community structures such as prevention, testing, care & treatment, adherence, awareness creation, sensitization and mobilization.
- Educating people on the value and utility of HVL testing is key to a successful HVL testing program. Many people living with HIV and community stakeholders have traditionally focused on CD4 as a marker of their treatment success.
- Mobilizing facility and community support by ensuring understanding of the advantages and interpretation of HVL testing is key to successfully rolling out and maintaining the trust of people living with HIV and communities in the quality of service delivery.

National and regional mentors

Expanding routine HVL testing and ensuring that the scale-up plan is systematically and accurately implemented requires close supervision at the national, zonal, regional, district, facility and laboratory levels to prevent misinterpretation and deviation from standards. Training for mentors should include:

- Providing guidance on site-level supportive supervision to multiple types of health care workers
- Recognizing high performing sites and collecting data on the implementation of HVL testing at the site to inform the national program on the progress in roll-out.
- Using a structured approach that includes checklists, reviewing medical records and standardized visit templates, including a site supervisory logbook that remains at the facility.

Training plan approach at all levels

- By February 2016, each of the six (6) HVL testing must have trained and competent assessed 3 laboratory scientists and 2 technicians and data managers in all aspects involved in HVL testing as required by the National Strategic Scale up Plan.
- By March2016, CHMT members, two staffs from each of the sample collecting sites, and at least 50% of 500 hubs, must be trained on roll out of HVL testing.

Section Six: Information management system and M&E

The M&E framework adopts indicators and targets from HSHSPIII. The goal of M&E programme is to avail HVL testing information at all levels (program, laboratory, region, district and facility). These indicators have been identified from each of the section above as described in ***table 7*** to measure the goals and objectives as describe in the table below.

Table 2: HVL M&E framework

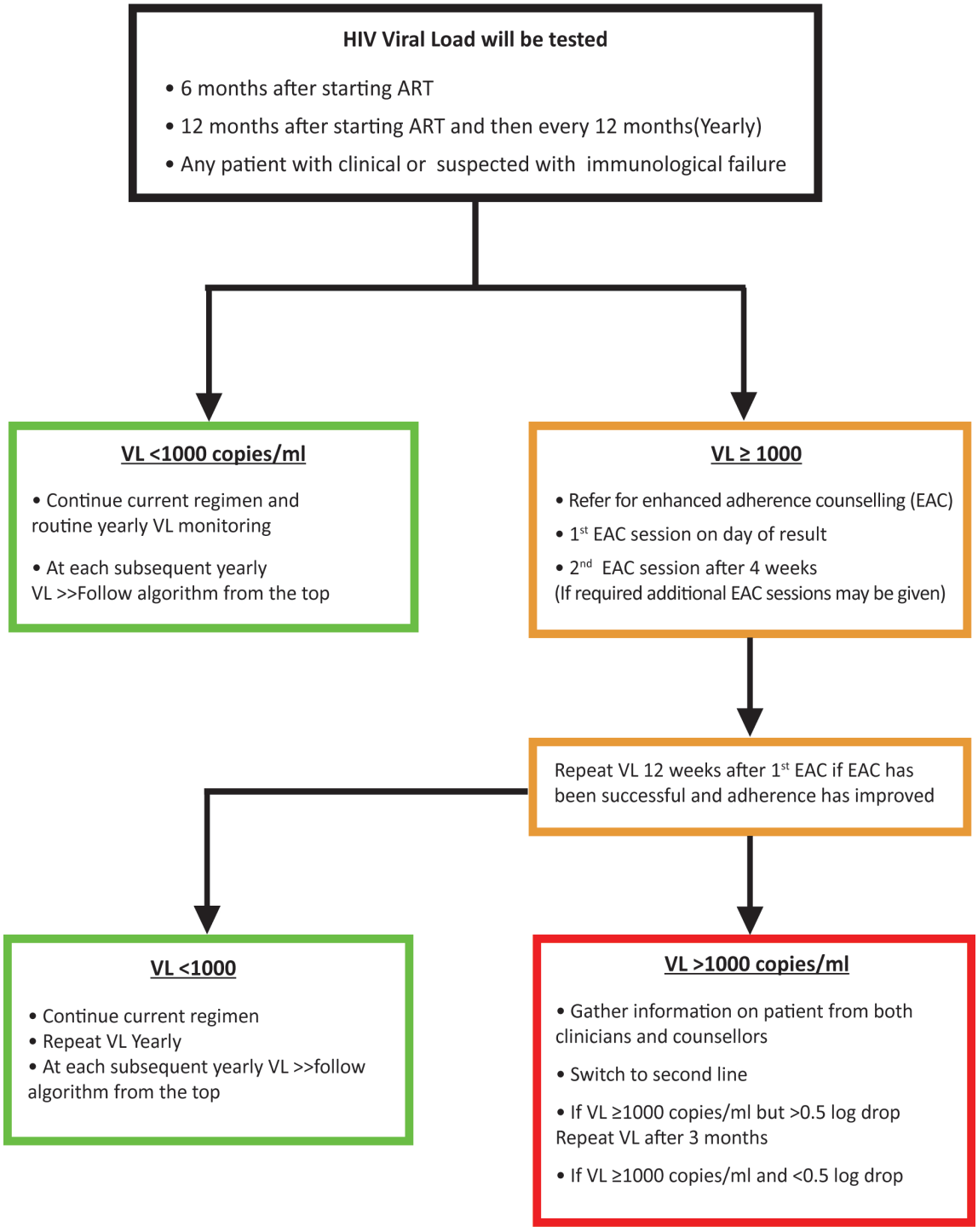
Section	Goal	Indicators	Source of data	Frequency of reporting
Policy leadership and management	• All eligible patients on ART receive quality HVL results within timely manner	• 100% of healthcare facilities have access to HVL testing by 2017	• HVL LIMS, DHIS	• Monthly
Product selection and strategic placement HVL services	• Identify and select appropriate platforms for HVL testing	• Number of HVL platforms selected and deployed in the country • Number of additional testing labs performing HVL testing	• LIMS,	• Monthly
Forecasting and Financing	• Uninterrupted supply of HVL testing commodities for monitoring clients on ART	• Supply plan in place	• NACP	• Annually
		• Consumption data from all testing sites	• LIMS	• Monthly
		• Stock out rates less than 1% of the targets	• MSD and facility	• Monthly
		• Funds availability	• NACP	• Annually
Human Resources	• A functional HR system for HVL testing that is integrated into health care delivery	• No of staff recruited for HVL testing at testing laboratory	• NACP	• Monthly
		• No of HCWs trained on	• NACP	• Monthly

	system	HVL testing training package		
Information management system and M&E	• Integrate and strengthen HVL testing in existing LIS • Integration of HVL LIS with CTC 2 database	• Number of laboratories trained and using LIS • Number of ART sites with HVL tools • Number of CTC sites integrated	• NACP	• Monthly
Advocacy and Education	• Sustainable and enhanced uptake of HVL testing	• Number of competent HSPs providing quality HVL testing	• NACP	• Annual

Appendices

Flow Chart 3: Clinical Algorithm for HVL monitoring in response to ART

Appendix 1: Proposed Clinical Algorithm for Monitoring Response to ART (Proposed)



Appendix 1: Budgets and costing tables

Table 3: Estimated HVL Testing Start-up Costs

Activities/Items	Estimated Cost (USD)
Laboratory renovation and office supplies	100,000
Additional accessories and equipment	0
Training / Mentorship (curriculum development)	759,459
Human Resources (Laboratory, facility and program coordination)	50,824
M&E costs (database development, data collection forms, etc.)	94,752
Sensitisation of health facilities	**0**
TOTAL	**1,005,035**

Table 4: Projected Spending 2015-2018 in USD

Items	Unit cost per test	Implementation years				TOTAL
		2015	**2016**	**2017**	**2018**	
Target Volume projections		87,589	254,297	575,412	743,963	**1,661,261**
Estimated reagent and consumables costs		1,596,544	4,870,040	11,373,901	14,934,531	**32,775,016**
Estimated sample collection costs		55,093	348,386	1,072,567	1,570,504	**3,046,550**
Estimated overhead costs						**0**
Estimated sample transport costs		374,400	468,000	585,000	731,250	**2,158,650**
Total		**2,113,626**	**5,940,723**	**13,606,880**	**17,980,248**	**39,641,477**

Cost of HVL testing compared to existing CD4 costs

Table 5: Comparison of estimated HVL vs CD4 testing cost for existing patients based on scale-up targets

	2015	2016	2017	2018	TOTAL
Testing Volume HVL	87,589	254,297	575,412	743,963	**1,661,261**
Estimated Total Patient Number	758,344	880,681	996,384	1,073,539	**3,708,948**
Estimated Total HVL Laboratory Diagnostics and Sample Collection Cost (+PSM) in USD	15,965,441	19,480,160	22,747,804	24,890,886	**83,084,291**
Estimated Total CD4 Laboratory Diagnostics and Sample Collection Cost (+PSM)	**16,811,374**	**20,615,138**	**24,319,600**	**26,708,388**	**88,454,500**

Table 6: Projected total HVL testing costs in USD

Items	**Implementation years**				
	2015	**2016**	**2017**	**2018**	**TOTAL**
Target Volume projections	87,589	254,297	575,412	743,963	**1,661,261**
Estimated reagent and consumables costs	1,596,544	4,870,040	11,373,901	14,934,531	**32,775,016**
Estimated sample collection costs	55,093	348,386	1,072,567	1,570,504	**3,046,550**
Estimated overhead costs	-	-	-	-	**0**
Estimated sample transport costs	374,400	468,000	585,000	731,250	**2,158,650**
Laboratory renovation and office supplies	100,000	-	-	-	**100,000**
Additional accessories and equipment	-	-	-	-	**0**
Sensitisation of health facilities	-	-	-	-	**0**
Total	**2,213,626**	**5,940,723**	**13,606,880**	**17,980,248**	**39,741,477**

Appendix 2: HVL Laboratory Request Form

JAMHURI YA MUUNGANO WA TANZANIA

WIZARA YA AFYA NA USTAWI WA JAMII

FOMU YA MAOMBI YA KIPIMO CHA HIV VIRAL LOAD KWENDA MAABARA

SEHEMU A: KUJAZWA NGAZI YA KITUO

Jina la Kituo: ______ Namba ya Kituo: ______ Ngazi ya Kituo: ______

Namba ya Utambulisho ya Mgonjwa: ______ Tarehe ya Kuzaliwa: Siku____ / Mwezi____ / Mwaka____

Tarafa: ______ Wilaya: ______ Mkoa: ______ Namba ya simu ya mteja: ______

Jina la Balozi: ______ Mteja ni mjamzito au ananyonyesha? Ndiyo ☐ Hapana ☐

Aina ya sampuli: Damu Kavu ☐ PLASMA ☐ Damu ☐

Jinsi: ME ☐ KE ☐

Mteja anamaambukizi ya Kifua Kuu? Ndio ☐ Hapana ☐

Tarehe ya kuomba Kipimo HVL: Siku____ / Mwezi____ / Mwaka____ /Muda____

Kama, ndiyo, yuko kwenye dawa? Ndiyo ☐ Hapana ☐

Dawa za ART Alizotumia Mtu (Mzima)		Dawa za ART Alizotumia Mtoto		SABABU YA KUAGIZA KIPIMO CHA HVL
Daraja la Kwanza	**Daraja la Pili**	**Daraja la Kwanza**	**Daraja la Pili**	
1. TDF + 3TC + EFV (1g-A) ☐	1. TDF + FTC + LPV/r (2f-A) ☐	1. AZT + 3TC + NVP (1b-P) ☐	1. ABC + 3TC + LPV/r (2g-P) ☐	Kipimo cha Kwanza ☐
2. AZT + 3TC + NVP (1b-A) ☐	2. ABC + 3TC + LPV/r (2g-A) ☐	2. ABC + 3TC + EFV (1k-P) ☐	2. AZT + 3TC + LPV/r (2n-P) ☐	Kipimo cha Marudio ☐
3. AZT + 3TC + EFV (1c-A) ☐	3. TDF + FTC + ATV/r (2h-A) ☐	3. AZT + 3TC + EFV (1c-P) ☐	3. NYINGINE (Taja): ______	Hisia za kufeli matibabu (Suspected treatment failure) ☐
4. TDF + FTC + EFV (1e-A) ☐	4. AZT + 3TC + ATV/r (2e-A) ☐	4. ABC + 3TC + LPV/r (2g-P) ☐		
5. NYINGINE (Taja): ______	5. NYINGINE (Taja): ______	5. NYINGINE (Taja): ______		

Kama ni kipimo cha marudio, Toa sababu: ______ Ufuasi wa dawa: Nzuri sana ≥95% ☐ Wastani (85-94%) ☐ Dhaifu <85% ☐

Jina la muhudumu aliyeomba kipimo cha HVL: ______ Taaluma (Taja): ______

Tarehe kipimo kilipotolewa: Siku____ / Mwezi____ / Mwaka____ /Muda____

Tarehe kipimo kilipotumwa maabara ya HVL: Siku____ / Mwezi____ / Mwaka____ /Muda____ Jina la aliyetoa kipimo (Damu): ______

SEHEMU B: KUJAZWA NA MAABARA YA HVL

Tarehe kipimo kilipopokelewa maabara ya HVL: Siku____ / Mwezi____ / Mwaka____ /Muda____

Tarehe ya majibu kutoka maabara ya HVL: Siku____ / Mwezi____ / Mwaka____ /Muda____

Tarehe ya kutuma majibu kwa SMS: Siku____ / Mwezi____ / Mwaka____ /Muda____

Tarehe ya kutuma majibu ya karatasi: Siku____ / Mwezi____ / Mwaka____ /Muda____

MAJIBU YA VIPIMO VYA HVL (Copies/ml)	
Kipimo cha Uchunguzi	______ cp/ml
Kipimo cha Marudio	______ cp/ml
Hisia za kufeli matibabu (Suspected treatment failure)	______ cp/ml

SEHEMU C: MAJIBU YA MERUDI KITUONI

Tarehe: majibu yalipofika kituoni: Siku____ / Mwezi____ / Mwaka____ /Muda____

Tarehe: majibu yalipotolewa kwa mgonjwa/mlezi: Siku____ / Mwezi____ / Mwaka____ /Muda____

Jina ya Fundi Sanifu Maabara ya HVL: ______ Sahihi: ______ Tarehe: Siku____ / Mwezi____ / Mwaka____ /Muda____

SEHEMU YA KUBANDIKA BARCODE NO.:

Document Title: FOMU YA MAOMBI YA KIPIMO CHA HVL; Document No.: HVL_PF_001; Effective Date: 2024
Revision No. 0; Section: Control Copy No. 0

Appendix 3: Names of Participants

1. Dr. Anath Rwebembera - NACP
2. Dr. Charles Massambu - MOHSW
3. Dr. Fausta Mosha - NHLQATC
4. Dr. Julius Muhuza - HJFMRI
5. Dr. Mtebe Majigo - MUHAS
6. Dr. Patrick Mwidunda - NACP
7. Dr. Peter Maro - CHAI
8. Dr. Robert M. Josiah - NACP
9. Mr. Abdul Mwanja - MSD
10. Mr. Abubakary Kiangi - NACP
11. Mr. Baraka Mpora - NACP
12. Mr. David Ocheng - Amref Health Africa
13. Mr. David Temba - MDH
14. Mr. Dickson Majige - MOHSW
15. Mr. Emmanuel Lesilwa - CSSC
16. Mr. Emmanuel Shayo - JSI
17. Mr. Haji Msuya - CHAI
18. Mr. Joseph Mziray - NHLQATC
19. Mr. Michael Mwasekaga - CDC
20. Mr. Pavel Mtango - NACP
21. Mr. Selestine Katto - NACP
22. Mr. Terito Madeye - THPS
23. Mr. Victor Muchunguzi - NHLQATC
24. Ms. BahatiMfaki - NACP
25. Ms. Carolyn Riwa - NHLQATC
26. Prof. Said Aboud - MUHAS

Table 7: Monitoring and Evaluation of scaling up HVL testing

Questions	Measures	Variables to Capture
What proportion of the population has access to HVL monitoring?	– # HVL Tests (disaggregated by site, district)	– Test(s) performed – Site – District
Is access to HVL testing equitable between genders? Are children receiving adequate access to HVL testing?	– # HVL Tests (disaggregated by age, gender and pregnancy/breast feeding status)	– Test(s) performed – Disaggregated by Age, Gender, Site – Pregnant/BF Women
What proportion of HVL testing has been for patients on first-line? Second-line?	– # HVL Tests (disaggregated by ART regimen)	– Test(s) performed – Regimen
What percent of patients on ART in Tanzania are virologically suppressed?	– Number of Virologically suppressed tests/number of tests performed	– Test(s) performed – Test results – Disaggregated by Age, Gender, Site – Pregnant/BF Women – ART Start Date – Regimen
What percent of pregnant or breastfeeding women on ART in Tanzania are virologically suppressed?	– Number of Virologically suppressed tests (disaggregated by pregnancy/BF status)/number of tests performed (disaggregated by pregnancy/BF status)	– Test(s) performed – Test results – Pregnant/BF Women – Site
What percent of children on ART in Tanzania are virologically suppressed?	– Number of Virologically suppressed tests (disaggregated by age)/number of tests performed (disaggregated by age)	– Test(s) performed – Test results – Disaggregated by Age, Gender, Site

Are there differences in virologic suppression rates between men and women on ART in Tanzania?	– Number of Virologically suppressed tests (disaggregated by gender)/number of tests performed (disaggregated by gender)	– Test(s) performed – Test results – Gender
Are there particular sites, which have particularly poor rates of virologic suppression?	– Number of Virologically suppressed tests (disaggregated by site)/number of tests performed (disaggregated by site)	– Test(s) performed – Test results – Site
Do virologic suppression rates vary by regimen?	– Number of Virologically suppressed tests (disaggregated by ART regimen)/number of tests performed (disaggregated by ART regimen)	– Test(s) performed – Test results – ART regimen
How do rates of virologic suppression change based on length of time on ART?	– Number of Virologically suppressed tests (disaggregated by ART regimen) – Number of tests performed (disaggregated by ART regimen)	– Test(s) performed – Test results – ART Start Date
How effective is adherence counseling interventions to re-suppress patients with a first positive HVL test?	– Percent re-suppressed after positive test: Number of patients with two consecutive positive tests <8 months apart/Number of patients with two consecutive tests <8 months apart	– Test(s) performed – Test results – Type of test (Routine vs. Follow-up of Positive Test)
Are adherence counseling interventions equally able to re-suppress children compared with adults (or men compared with women)?	– Above indicator disaggregated appropriately	– Test(s) performed – Test results – Type of test (Routine vs. Follow-up of Positive Test), disaggregated by Age, Gender, Site
Are some sites better than adherence counseling interventions equally able to re-suppress children compared with	– Above indicator disaggregated appropriately	– Test(s) performed – Test results – Type of test (Routine vs. Follow-up of Positive Test), disaggregated by Age, Gender, Site

adults (or men compared with women)?		
Do self-reported adherence rates predict viral suppression?	– Restricting calculation to patients with an adherence assessment of "Good" (or "fair" or "poor"), calculate the number of undetectable HVL results/number of total HVL test results	– Test(s) performed – Test results – Self-reported adherence – Site
As a measure of quality of HVL services, how effective is the centralized system at getting test results back to facilities in a timely manner?	– Length of time between sample collection date and date result is returned to facility	– Date of collection – Date test performed (LMIS) – Date test returned – Site
How effective are the hubs and transport network at getting results to and from facilities?	– Length of time between dispatch date and date result is returned to facility	– Dispatch Date – Date test performed (LMIS) – Date test returned – Site
As a measure of quality of HVL services, what percent of samples collected are rejected due to improper or insufficient collection?	– Number of rejected samples (disaggregated by site)/Number of HVL tests	– Test(s) performed – Rejected samples – Site
As a measure of quality of HVL services, what percent of acceptable samples require repeat collection due to errors within the laboratory?	– Number of repeat samples required/Number of HVL tests	– Test(s) performed – Repeat Samples

Table 8: HVL testing services, objectives, activities, indicators (results), targets, responsible and timelines

A. POLICY, LEADERSHIP AND MANAGEMENT					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
Objectives	– Finalise and disseminate the National HVL Monitoring Guidelines	– 100% healthcare facilities have access to HVL testing services.	– National HVL Monitoring Guidelines finalised and used	– NACP	– By March 2015
	– Establish HVL technical working group (TWG) to coordinate and oversee the implementation	– Better coordination of stakeholders	– HVL TWG members appointed by name	– DSS	
To identify and select appropriate platforms (EID and HVL) to meet the National testing, demand by Dec 201.	– Form a National EID/HVL TWG	– Country TWG on EID/HVL in place	– HVL TWG members appointed by name	– DSS	– By March 2015
	– Coordinate TWG by NACP to meet and evaluate products against the criteria	– Appropriate quality HVL technologies selected and used in country	– Acquire appropriate quality HVL technologies	– DSS	– By March 2015
	– Decisions of the TWG are shared and implemented	– Appropriate and affordable HVL testing services provided	– Decision of TWG on appropriate and affordable HVL testing documented	– NACP	– By March 2015

To enhance the capacity of the existing HVL testing laboratories with at least 2 different platforms by end of Dec 2016	– Acquisition of 6 new platforms	– 6 new platforms acquired, in place and operational	– Six (6) HVL testing platforms	– NACP	– By end of Aug 2016
	– Installation of the new platforms and user training at the existing laboratories	– Trained laboratory staff are Competent and certified on new platforms	– At least two (2) laboratory staff per each of HVL testing six (6) laboratories trained	– DSS	– By end of Dec 2016
To scale-up VL testing services through POC platforms to District levels in the Country by end of Dec 2018	– Acquire 25 POC platforms for regional laboratories	– 25 new POC platforms in place at regional hospitals and operational	– 25 regional hospitals equipped with HVL POCs	– NACP	– By Dec 2016
	– Install new 25 POC platforms and user training at the existing laboratories	– Trained regional laboratory staff are competent and certified on new POC platforms	– 25 new POC installed	– NACP	– By Dec 2016
	– Acquire40 POC platforms for district hospital laboratories	– 40 new POC platforms in place at district hospitals and operational	– 40 district hospitals provided with HVL POC	– NACP	– End of 2015
	– Install new 40 POC platforms and user training at the existing district hospital laboratories	– Trained district laboratory staff are competent and certified on new POC platforms	– At least two (2) laboratory staff from 40 district hospitalstrained	– NACP	– End of 2015

To establish quality management systems (proficiency testing, training, etc.)by end 2015	– Recruit and hire qualified laboratory staff for all HVL testing sites	– At least 50% of the required laboratory staffs hired and in place	– 18qualified staff for HVL testing services hired	– DSS	– By July 2015
	– Train laboratory staffs on QMS implementation	– Laboratory personnel implement QMS in HVL laboratories	– QMS curriculum for laboratory staff training developed	– NACP	– By Aug 2015
	– Enroll all HVL testing laboratory into the EQA schemes	– All laboratories are enrolled on EQA schemes	– 100% participation in HVL EQA	– NHLQATC	– By Aug 2015
	– Install laboratory LIMS and link to the HLIMS at all sites	– LIMS installed and operational at each HVL testing laboratory	– Procure approved LIMS	– DSS	– BY Dec 2015
Expand the HVL testing network in the country to increase access and coverage from 6 to 9 by the end of 2019	– Assess facilities in the proposed regions for establishment of new HVL testing laboratory	– Detailed assessment reports identifying the needs	– Nine (9) HVL testing network assessed	– NACP	– By Dec 2015
	– Renovate and/or construct of HVL testing laboratory facilities at the selected sites	– New HVL testing laboratories in place	– Renovate/construct nine (9) HVL testing laboratories	– NACP	– By Feb 2016
	– Equipment Installation and user training at new facilities	– HVL testing equipment in place and used	– HVL testing equipment in procured	– HCTS	– By end of April 2016
		– Competent and certified laboratory personnel performing HVL testing	– Competent and certified personnel employed	– DSS	– By end of April 2016
B. FORECASTING AND FINANCING					

UNINTERRUPTED SUPPLY OF HVL TESTING COMMODITIES (REAGENTS AND SAMPLE COLLECTION CONSUMABLES) FOR MONITORING CLIENTS ON ART					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
Forecasting and supply plan development for HVL testing commodities	– Collect of quality logistics data for forecasting (consumption, service level and demographic data).	– Logistic data available and used in forecasting consumption of HVL supplies	– HVL consumption data available	– NACP	– By end of 2015
	– Engaging all key stakeholders in development of consumption.	– Consumption data developed by stakeholders	– Consumption data developed	– NACP	– By end of 2015
	– Validating forecast results by conducting multi-method forecasting.	– Forecasting validated using multi-method	– Forecast validated	– NACP	– By end of 2015
	– Collecting consumption data from testing laboratories and sample collection sites to determine forecast accuracy and hence review and update supply plan accordingly.	– HVL consumption data collected from testing and sample collection sites	– HVL consumption data collected	– NACP	– By end of 2015
	– Procuring and distributing HVL commodities	– HVL commodities used	– HVL commodities procured and	– NACP	– By end of 2015

			distributed		
	– Managing flow of commodities from the manufacturers/suppliers to end users to ensure adherence to commodity delivery schedules and commodity inventory levels are maintained within adequate level.	– HVL commodity delivery schedule adhered to	– HVL commodity flow in place	– NACP	– By end of 2015
Managing commodities effectively at central and facility level	– Scheduling equipment maintenance as per contract to ensure that machines are operational at all times to avoid the risk of not using reagents, which might lead to expiry.	– No equipment downtime	– Equipment maintenance schedule developed	– DSS	– By end of 2015
	– Monitoring of equipment repair response time from equipment breakdown to repair in order to minimise equipment downtime and rescue the reagents from expiry.	– Equipment repair monitored and documented	– Reagents do not expire due to equipment downtime	– NACP	– By end of 2015
	– Enforcing FEFO practice in commodities issuing	– Documented use of FEFO at all levels	– FEFO use in place	– NACP	– By end of 2015

	and usage at all levels.				
	– Ordering right commodities at the right quantity and time (by MSD from supplier and by facility from MSD).	– HVL testing services are uninterrupted	– No stock outs	– NACP	– By end of 2015
	– Redistributing commodities between testing laboratories and sample collection sites whenever there is stock imbalance.	– HVL testing services are uninterrupted	– No expiry of commodities	– NACP	– By end of 2015
Issuing commodities as requested by laboratories and sample collection	– Submitting orders on time to the supplier by MSD and from facilities to MSD	– HVL testing services are uninterrupted	– Lead time observed	– NACP	– By end of 2015
	– Keeping adequate stock at MSD as per the national desired stock levels	– HVL testing services are uninterrupted	– Lead time observed	– NACP	– By end of 2015
	– Issuing commodities to health facilities as requested by the facility provided that the request and is representative of the demand of the facility.	– HVL testing services are uninterrupted	– Lead time observed	– NACP	– By end of 2015

To cost HVL implementation plan	– To acquire adequate funding for establishment of HVL testing infrastructure as stipulated in the guideline.	– HVL infrastructure established and used	– Funds available	– NACP	– By end of 2015
	– To mobilise adequate funding for procurement, storage and distribution of HVL testing equipment and commodities.	– HVL testing equipment and commodities in place and used	– Funds available	– NACP	– By end of 2015
	– To mobilise funds for recruitment and training of HR involved in HVL	– HR for HVL services trained	– Funds mobilized	– NACP	– By end of 2015
	– To mobilise adequate funds for sample transportation from collection hubs to testing laboratories and results feedback.	– Hubs for HVL services are established and function	– Funds mobilised	– NACP	– By end of 2015
National forecasting and supply planning for HVL scale ups	– Collecting data for accurate forecasting (data sources include consumption and service data from testing laboratories and sample collection site and issues data from MSD)	– Consumption data available and used	– Database in place	– NACP	– By end of 2015

	– Building consumptions on forecasting based on HVL guideline by all stakeholders.	– HVL services scaled up	– HVL forecasting based on guidelines	– NACP	– By end of 2015
	– Forecasting and supply planning	– Uninterrupted HVL services	– Forecasting and supply plans in place	– NACP	– By end of 2015
Mobilising resources for HVL implementation (donor and Government)	– Involving Government and key stakeholders in fund raising to meet financial requirements for HVL through meetings	– HVL services up and running	– Funds allocated to support HVL services	– NACP	– By end of 2015
	– Incorporating HVL testing component in the costed workplan of the MOHSW.	– HVL services up and running	– Costed work plan approved	– NACP	– By end of 2015
	– Recruiting national HVL coordinator and training of healthcare providers on HVL testing	– HVL services coordinated	– HVL services coordinator recruited	– NACP	– By end of 2015
Increased access to HVL test	– Map HVL testing sites (to create HUBS)	– Reduced TAT to 2 weeks	– Set TAT at 2 weeks	– NACP	– By 2017
	– Sensitise Health care workers on HVL testing	– Reduced rejection rate to about 2%	– Reduce sample rejection to 2%	– NACP	– By 2017
	– Train to courier on HVL sample transportation	– Increased HVL sample transportation efficiency.	– Train couriers on HVL sample transportation	– DSS	– By end of 2015
		– 640 hubs for HVL	– 640 identified	– NACP	– By end of

		services operational	hubs		2015
	- Train health service providers (clinicians, nurses) on HVL results interpretation	- Trained clinicians and nurses - Sensitised health care workers	- Train health service providers on HVL res	- NACP	- By end of 2015
C. HUMAN RESOURCES					
GOAL: A FUNCTIONAL HUMAN RESOURCE FOR VL TESTING THAT IS INTEGRATED IN THE HEALTH CARE DELIVERY SYSTEM INCLUDING THE DATA FLOW INTEGRATION INTO THE LABORATORY INFORMATION SYSTEM					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
Create efficient structured network for collection transportation and HVL testing in 25regions of Tanzania Mainland by July 2015	- Collect baseline information to understand the gap in numbers of skills sets at the sample collection sites, collection hubs, testing laboratories and national level	- Baseline information used to understand the gap in numbers of skills sets at the sample collection sites, collection hubs, testing laboratories and national level	- Baseline information collected	- NACP	- Dec-14
	- Develop job tasks per position/cadre	- Competent staff providing HVL services	- Job tasks developed	- NACP	- Dec-14
	- Appoint/ hire national HVL national coordinator	- HVL Coordinator in place and working	- Hire HVL national coordinator	- NACP	- Dec-14
	- Assign HVL coordination to RACC and DACC respectively (region and districts)	- HVL services coordinated by RACCs and DACCs	- RACCs and DACCs assigned HVL coordination	- NACP	- Dec-14

	– Recruit to fill the identified gap – work with PMORALG, Utumishi and Developing partners	– Competent staff providing HVL services	– Competent staff recruited	– NACP	– Mar-15
	– Develop/ adapt or customise training modules per specific cadre	– HVL services offered by trained staff	– HVL training modules customised	– DSS	– Mar-15
	– Develop national roll out plan using train the trainer approach	– HVL services scaled up	– Training rollout plan in place	– NACP	– April-July 2015
	– Monitor and evaluate training impact – supportive supervision, oversight and competency assessment	– Qualified and competent staff offer HVL services	– HVL services monitored and evaluated	– NACP	– After July 2015
D. INFORMATION MANAGEMENT SYSTEM AND M&E					
GOAL: INTEGRATE AND STRENGTHEN THE HVL TESTING INTO EXISTING LIS AT ALL 6 TESTING LABORATORIES IN THE COUNTRY BY 2017					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
Develop the HVL test requisition and reporting tool	– Form committee with members and TOR	– % of tools developed and printed.	– One committee with at least 10 members	– LIS Officer	– March 2015
	– Develop and print tools	– Tools available at HVL testing sites and used	– Number of tools	– LIS Officer	– March 2015

Incorporate the standardized requisition and reporting tools to training module to both service providers and laboratory staff	– Develop HVL testing curriculum	– VL testing incorporated into curriculum	– Incorporate curriculum	– LIS Officer	– March 2015
	– Train users on HVL testing requesting and reporting tools	– % of sites to be trained	– 6 sites will be trained	– LIS Officer	– March 2015
Incorporate the HVL testing into LIS	– Perform LIS need assessment	– Monitor the supply chain using LIS – % of staff trained,	– 6 sites will be upgraded – 6 sites will be trained (18staff will be trained), All supplies monitored through LIS	– LIS Officer	– January 2015
	– Upgrade and configure the existing LIS according to identified gaps	– % of eLIMS assessed	– Number and types of consumable monitored through LIS	– LIS Officer	– January 2015
	– Train laboratory staff to upgraded LIS	– % of eLIMS upgraded	– 6 sites will be assessed	– LIS Officer	– February 2015
Implement and sustain HVL Testing LIS	– Disseminate printed LIS tools to ART sites	– % of ART sites received tools	– All ART sites	– LIS Officer	– Ongoing activity -
	– Conduct ongoing Supportive supervision	– % of sites supervised and number of supervision conducted	– 12 support supervision annually	– LIS Officer	– Ongoing till 2017
	– Perform LIS annual evaluation	– Number of evaluation done	– 6 sites evaluated annually	– LIS Officer	– Ongoing

	– Perform Data Quality Assessment	– Number of data collection done	– Quarterly review of data quality	– LIS Officer	– Ongoing
	– Perform data backup and data achieve	– Records of data backup and archive	– All HVL testing sites	– LIS Officer	– By end of 2016
Incorporate the HVL testing data into NACP CTC database and CTC2 card.	– Review and update the NACP CTC database	– CTC reports used for management	– Updated NACP CTC database.	– NACP	– March 2015
	– Review and update the CTC2 card	– Reviewed and updated CTC2 card in place and used	– Reviewed CTC2 Card	– NACP	– March 2015
E. ADVOCACY AND EDUCATION OF HEALTH CARE PROVIDERS ON PATIENTS ON HIV HVL (HVL) TESTING					
1. ADVOCACY:					
GOAL: EDUCATED HCWS/HSPS ON THE VALUES AND UTILIZATION OF HVL TESTING FOR ART MONITORING IN TANZANIA					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
To awareness among the stakeholders on HVL testing and its use for patient monitoring in Tanzania by 2015	– Sensitization meetings, discussion forum (formal and informal)	– Stakeholders talk about HVL testing in public gatherings and functions in communities	– Policy/decision markers, program managers, development partners, private sector (PPP), users, stakeholders (local leaders, peer mentors and family support group) and clients	– NACP	– By end of 2015

2. **EDUCATION:**					
GOAL: SUSTAINABLE AND ENHANCED HVL TESTING AND UPTAKE TO SUPPORT INCREASED ART MONITORING IN TANZANIA					
OBJECTIVES	**ACTIVITIES**	**INDICATOR (RESULTS)**	**TARGETS**	**RESPONSIBLE**	**TIMELINES**
To create a competent HCWs/HSPs to provide quality HVL testing services in Tanzania by 2017	– Training sessions	– Clinical practitioners, laboratory, strategic information, supply chain and community health workers, and programme staff (for M&E)	– Competent HCWs/HSPs in place and providing quality HVL testing services	– All HSPs cadres competent in HVL testing services	– By 2017

References 1: For further reading

1. Tanzania HIV Malaria Indicator Survey 2003-04
2. Tanzania HIV Malaria Indicator Survey 2011-12
3. http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf
4. WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, June 2013
5. Interim Technical Update: Technical operational considerations for implementing HIV Viral Load Testing; Access to diagnosis, WHO July 2014
6. Heath Sector HIV Strategic Plan III (2013-2017)
7. MSF HVL Tool Kit
8. Ministry of Health, Uganda
9. Ministry of Health, Kenya