ZIMBABWE HIV VIRAL LOAD SCALE-UP PLAN

2015 – 2018

MINISTRY OF HEALTH AND CHILD CARE

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List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral(s)
BRIDH	Beatrice Road Infectious Disease Hospital
CDC	(United States) Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
d4T	Stavudine
DBS	Dried Blood Spot
DLS	Directorate of Laboratory Services
EAC	Enhanced Adherence Counselling
EGPAF	Elizabeth Glaser Paediatric AIDS Foundation
EHT	Environmental Health Technician
EID	Early Infant Diagnosis
GF (ATM)	Global Fund against AIDS, Tuberculosis and Malaria
HEI	HIV exposed infants
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
LLU	Laboratory Logistics Unit
LSPF	Laboratory Services Partnership Forum
M6, M12, M24	Month 6, month 12, month 24 (on ART)
M&E	Monitoring and Evaluation
MoHCC	Ministry of Health and Child Care
MSF	Médecins San Frontières
NatPharm	National Pharmaceutical Stores
NMRL	National Microbiology Reference Laboratory
PC	Primary Counsellor
PCR	Polymerase Chain Reaction
PITC	Patient-initiated Testing and Counselling
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission (of HIV)
POC	Point-of-Care
QA	Quality Assurance
QC	Quality Control
RTI	Research Triangle Institute
SLMTA	Strengthening Laboratory Management towards Accreditation
ST	Sample Transportation
TaSP	Treatment as Prevention
TAT	Turnaround time
TB	Tuberculosis
TWG	Technical Working Group
UBH	United Bulawayo Hospitals
UNICEF	United Nations Children's Fund
VHW	Village Health Worker
VL	Viral Load
VL1	First Viral Load Test
VL2	Second Viral Load Test
VLIS	Viral Load Information System
WHO	World Health Organization
ZiLaCoDS	Zimbabwe Laboratory Commodities Distribution System
ZIMHISP	Zimbabwe Health Information Support Project
ZINQAP	Zimbabwe National Quality Assurance Programme

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Foreword

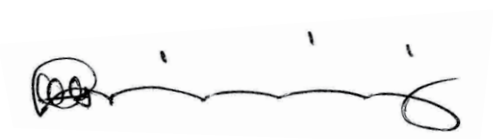
Following the World Health Organisation (WHO) recommendation of viral load (VL) testing as the preferred approach for monitoring anti-retroviral therapy (ART) treatment outcomes, Zimbabwe has adopted this gold standard and the government has made a commitment to increasing laboratory capacity and aggressively scaling-up VL testing to ensure access to VL testing services by at least 90% of people living with HIV (PLHIV) receiving ART by 2018. This is in line with the UNAIDS 90-90-90 global targets, which are aimed at ensuring that 90% of people living with HIV (PLHIV) know their status, 90% of those are on treatment and 90% of the people on treatment are virally suppressed, with the goal of ending HIV/AIDS by 2030.

This *Viral Load Scale-Up Plan 2015-2018,* which was developed through a widely consultative process with participation of different stakeholders and partners in the public and private sector, outlines a strategy to scale-up VL testing using an ambitious and targeted approach that balances achieving global goals of ART treatment monitoring with the limited resources available in the country. The main objectives of this plan are designed to assist in accelerating the scaling-up of VL testing through defining national testing targets and a timeframe for achieving those targets, improving stakeholder collaboration and facilitating the pooling of resources.

Included in the plan are details of activities required to strengthen key areas that are crucial to the success of VL testing scale up; such as laboratory infrastructure, sample transportation, data management, procurement and supply chain management, training and mentorship, quality assurance and monitoring and evaluation. Also included in this document is a costed workplan which highlights funding gaps and commitments made to date.

Although the importance of ensuring universal access to VL testing as a critical part of HIV care and treatment services cannot be understated, achieving universal access to ART still remains a key goal of the national HIV program. Therefore, the recommendations in this plan will guide continued prioritization of efforts to ensure the continued success of the national ART program and extreme care will be taken by the MoHCC and partners to ensure that funds allocated to expanding access to HIV treatment are not diverted to viral load testing.

The MoHCC hopes that this document will be useful in guiding all stakeholders and partners in the implementation and scaling up of viral load testing in Zimbabwe as we aim to end AIDS by 2030.



Brigadier General, Dr. Gerald Gwinji
Permanent Secretary, Ministry of Health and Child Care, Zimbabwe

Executive Summary

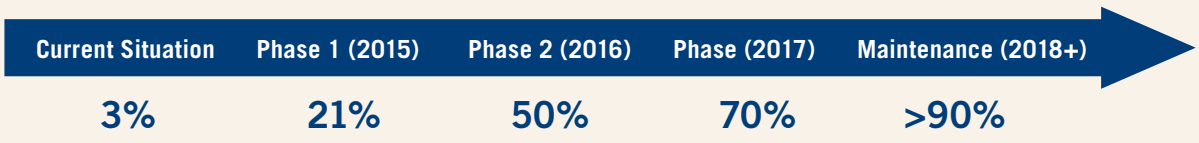
Zimbabwe is one of the countries worst affected by the Human Immunodeficiency Virus (HIV) epidemic, with an HIV prevalence among adults (15-49 years) of 14.9%. In 2014, approximately 1.4 million people, including 148,000 children below the age of 15 years, were living with HIV.

The Ministry of Health and Child Care (MoHCC) has committed itself to the provision of comprehensive HIV care and treatment services with an emphasis on achieving universal access to antiretroviral therapy (ART) for eligible patients. The country has made significant progress towards this goal, with 732,919 adults (61.5%) and 55,061 children (37%) receiving ART by the end of 2014.

With such a large ART cohort, there is a pressing need to effectively monitor response to treatment. Current methods used to evaluate treatment success based on clinical and immunological criteria have low sensitivity and low positive predictive value. In response to the need for a better treatment monitoring method, Zimbabwe has adopted viral load (VL) testing as the preferred approach for monitoring ART treatment outcomes.

This plan outlines a strategy to gradually scale up VL testing over three years using a phased approach. Initially, routine VL testing will be offered to selected patients, namely pregnant women, children and patients suspected of treatment failure. As more resources are mobilized, routine testing will be offered to all patients on ART.

FIGURE 1: **Coverage targets of people living with HIV (PLHIV) and receiving ART (%):**



The Plan has three main objectives designed to assist in accelerating the scaling up of VL testing.

1. Provide a road map to guide VL testing scale-up in Zimbabwe from the current 3% to 70% by the end of 2017 and 90% by 2018.
2. Establish collaboration and coordination between government and partners as they scale up VL testing in the country.
3. Support resource mobilization.

The achievement of these goals and the overall success of the plan hinges on the successful execution of planned activities in the crucial areas of laboratory infrastructure improvement, training and mentorship, sample transportation and monitoring and evaluation.

With the existing laboratory capacity, less than half of the phase 1 testing target can be reached. There is, therefore, an urgent need to significantly increase the laboratory capacity in the country through the purchase or leasing of additional equipment.

Throughout the 3 phases of scale up, equipment will be purchased or leased and placed in the various central laboratories across the country and point-of-care (POC) technologies will be deployed to lower level facilities as and when they become available. Additional equipment will however, introduce the need for renovation of laboratories and hiring and training of staff at all levels.

Groups of healthcare workers to be trained will include primary counselors (PCs), village healthcare workers (VHW), expert patients, community caregivers, nurses and clinicians, and laboratory assistants and technicians. PCs, VHWs, expert patients and community caregivers will primarily be trained on adherence counseling and support while nurses will be trained on the identification of patients in need of VL testing, sample collection, patient management and interpretation of VL results. Laboratory assistants and technicians will be trained on the integration and workflow optimization of early infant diagnosis (EID) and VL testing,.

An efficient and cost-effective sample transportation network is essential for the delivery of samples to the laboratories and return of results to the testing sites. Where possible, the various existing networks for transport of EID, TB and malaria samples will be leveraged in order to save money and reduce the duplication of efforts. Integration and improvement of the different networks will also be explored.

Lastly, comprehensive monitoring and evaluation activities will be carried out throughout the duration of scale up. Data collected from these activities will be used to inform further decision-making and to assess the switching of patients to second line treatment. Although this proposal does not cover the costs associated with patients switching onto second line ART, detailed information on the number of patients being accurately and appropriately switched will allow for improvements in the broader national ART program.

1 Zimbabwe National HIV Estimates, December 2013
2 MOH National_Provincial_District ART Coverage for year 2014.

1. Introduction

1.1 Background

A public health approach based on standardized treatment regimens, the use of affordable generic medicines and laboratory performance monitoring has been crucial to the successful scale-up of ART in Zimbabwe.

Recognizing the growing concerns of HIV drug resistance due to the highly mutative nature of the HIV virus and sub-optimal ART associated with poor adherence to treatment, the country has also established a strategy for monitoring HIV drug resistance. Early diagnosis, provision of high-quality care and treatment, and consistent follow-up, including VL testing, are necessary in preventing the emergence of drug-resistant HIV.

Zimbabwe adapted the 2013 World Health Organisation (WHO) *Consolidated guidelines on the use of antiretroviral drugs for preventing and treating HIV infections and launched them in December 2013.*

The main highlights of the Zimbabwe National HIV guidelines include:

- Strengthening patient-initiated testing and counselling (PITC), augmented by community-level HIV testing and counselling (HTC) approaches.
- Initiating treatment at a CD4 threshold of 500 cells/mm^3, prioritizing those with a low CD4 (<350 cell/mm^3) or clinical stage III or IV.
- Scaling up VL testing using a targeted approach initially, with the aim of phasing in routine VL testing in the near future to cover all central, provincial and district levels of care.
- Adoption of universal treatment of HIV-infected children less than 5 years old regardless of CD4 or clinical status
- Providing lifelong ART for all pregnant and breast-feeding women (Option B+) regardless of CD4 status.
- Decentralizing ART services.
- Refocusing on Treatment as Prevention (TaSP) among sero-discordant couples and sex workers

Zimbabwe adopted VL testing as the preferred approach to diagnose and monitor ART treatment failure and poor adherence[3]. In the past, the country relied mainly on clinical and immunological criteria for assessing HIV treatment response. However, studies have shown that clinical and immunological criteria used to define treatment failure have low sensitivity and a low positive predictive value. The country has therefore made commitments to building capacity and phasing in VL testing in a systematic manner to ensure equity and access to VL testing services for PLHIV receiving ART.

A VL stakeholders' consultative meeting was convened in July 2013 to discuss the parameters for introduction of the VL testing in the country. The meeting produced the following recommendations that formed the basis for this VL implementation plan:

- Enact transparent regulatory frame-works to enable rapid market entry of selected and suitable technologies into the county.
- Leverage existing systems to expand VL access and also ensure economies of scale or cost savings.
- Strengthen the laboratory quality assurance/quality control (QA/QC) systems.
- Build sufficient human resources capacity to implement VL testing.
- Procure appropriate Point-of-Care (POC) VL technologies as and when they become available.
- Develop an implementation plan for VL scale-up.
- Implement adherence counselling according to national standards.
- Maintain timely transportation and testing of samples, and result transmission.
- Develop post-marketing surveillance and monitoring systems to monitor program progress.

Due to limited resources, routing VL testing will initially be offered to select groups of patients; pregnant women, children and patients suspected of treatment failure based on immunological and clinical criteria and missed visits As additional resources are mobilized, routine VL testing will be offered to all patients.

The experiences with the national scale up of EID program in Zimbabwe from 2007 provided some important lessons on how to execute a VL national diagnostics scale up. Lessons learnt and incorporated into this plan include the need for:

- A national VL testing coordinator to ensure the smooth running of the program.
- Setting national testing targets to inform the planning process and mapping of needed resources.
- Clear human resource (HR) management to ensure that adequate capacity is available.
- Adequate funding to ensure the success of the program's implementation
- Adjustment and optimization of clinic workflow to accommodate increased workload.
- Careful monitoring of stock levels.
- An effective and efficient sample transport network.
- Periodic refresher trainings at testing sites to ensure adherence to proper protocol.

Historical testing data

Routine VL testing was offered to selected patients at 116 sites in 2014. All the sites sent their samples to the National Microbiology Reference Laboratory (NMRL). A total of 28,211 patients (3.3% of PLHIV on ART) had access to testing.

Zimbabwe adopted VL testing as the preferred approach to diagnose and monitor ART treatment failure and poor adherence.

TABLE 1: 2014 VL testing data

Number of Tests and Coverage	2014	Rationale/Source
Patients eligible for ART	1,339,678	MOHCC National Targets 2014 – 2017 Revised 25th March 2014
Actual number of patients on ART	787,980	MOHCC National data 2014
VL Testing Need (routine) =PATIENTS	787,980	Based on routine testing algorithm assuming 1 test per patient per year
Number of tests conducted	34,124	NMRL 2014 data.
Number of patients tested	28,211	Accounting for 8% repeat rate and 12% error rate.
Coverage of total patient testing need	3%	

3 Zimbabwe National Antiretroviral Therapy Guidelines for Preventing and Treating HIV, 2013

1.2 The Plan

Vision

Improved quality of care, improved survival rates of people living with HIV, reduced drug resistance in HIV treatment and as a secondary benefit, reduced HIV transmission in line with national, UNAIDS and WHO targets.

Goal

Zimbabwe aims to ensure universal access to routine viral load (VL) testing by 2018 as an important step in the proper monitoring and management of patients on ART as the country moves towards ending AIDS by 2030. To that end, the country has developed this plan to provide guidance in the rolling out of VL testing in the country.

Objectives

The main objectives of this plan are to:

1. Provide a road map to guide coordinated VL testing scale-up in Zimbabwe from the current 3% to 70% by the end of 2017 and universal access (90% coverage) by 2018.
2. Establish collaboration and coordination between government and partners in scaling up VL testing in the country.
3. Support resource mobilization for VL Scale-up through highlighting the funding gaps that will need to be closed in order to make this plan a success.

1.3 Approach and Strategy

Plan Overview

This plan is written to cover three main phases over the period January 2015 to December 2017 as well as a maintenance phase from 2018 onwards.

Due to the country's current limited testing capacity, scale-up has been divided into three phases to allow for time to build capacity and mobilize resources to support routine VL testing for all patients.

Phase 1: 21% of patients on ART will have access to VL testing.

Phase 2: 50% of patients on ART will have access to VL testing.

Phase 3: 70% of patients on ART will have access to VL testing.

Maintenance: > 90% of patients on ART will have access to VL testing.

Details of each phase are given in Table 2.

During phase 1, both dried blood spot (DBS) and whole blood (WB) samples will be collected for VL testing - DBS for the Biomérieux (BM) NucliSENS and Abbott m2000 platforms and WB for the Roche Taqman as well as the Abbott m2000 platforms plasma VL assays. From phase 2, it is assumed that the DBS technique on Roche platform and the single spot DBS assay on the Abbott platform will have obtained the necessary approvals and the sample type for the platforms will move from WB to largely DBS. The use of plasma specimens in VL testing is the gold standard but, due to resource and capacity constraints, DBS will be the preferred sample type. WB will be used where possible in order to leverage the Roche platforms.

Clinics chosen for WB will be able to rely on their proximity to the testing laboratories for ease of transport. Transport of DBS will be covered by the existing courier service which is currently being used for early infant diagnosis (EID).

The plan strongly recommends the use of a maximum of 3 different types of standardized high throughput conventional testing platforms. Standardization will be cost-effective and will allow for easier management of commodities, improvement of HR capacity and maintenance of quality.

These conventional platforms will be placed in high volume central testing laboratories and at recommended tertiary and provincial hospitals. Lower level sites such as district hospitals will be earmarked for lower throughput near-POC and POC technologies.

The success of this plan in ensuring universal access to routine VL testing by 2018 will largely depend on:

- Development of service delivery linkages and integration of VL testing into routine health services.
- Aggressive use of M&E data to inform program implementation decisions and make necessary changes to the scale-up approach before expanding to additional facilities. This will mainly be for testing capacity, training needs and human resources capacity.

The MoHCC plans to execute its vision of providing VL testing access to its entire ART cohort by increasing the skills of clinicians, laboratory staff, and counsellors to enable them to conduct the following activities with quality and efficiency:

- Health Facilities:
  - Identify patients in need of VL testing.
  - Correctly collect, label, document and send blood samples to testing laboratories according to standard operating procedures.
  - Appropriately interpret results and communicate them to patients or their caregivers in a timely manner.
  - Decide on appropriate next steps for patients that are customized to their needs.
  - Increase the skills of adherence counsellors to be more effective in ensuring patient retention to ART.
- Laboratories:
  - Process samples with accuracy and in the shortest possible time.
  - Send results via SMS, followed by hard copies from the lab, to facilities within 14 days.
  - Document and report procedures and testing volumes to inform national M&E efforts.

TABLE 2: Scale-up Phased Approach Structure

	2015 (Phase 1)	2016 (Phase 2)	2017 (Phase 3)	2018 > (Maintenance)
Tertiary/ Provincial Hospitals	Routine testing for selected patients, prioritising children and pregnant women	Routine testing for all patients served in tertiary and provincial hospitals	Routine testing for all patients served in tertiary and provincial hospitals	Routine testing for all patients served in tertiary and provincial hospitals
District Hospitals	No Testing	Routine testing for selected patients, prioritising children and pregnant women	Routine testing for all patients served in district hospitals	Routine testing for all patients served in district hospitals
Rural Clinics/ Health Centres	No Testing	Access to Routine testing for selected patients via facilitated referral of patients to district/ provincial hospitals or visits of mobile mentoring teams	Routine testing for selected patients ,prioritising children and pregnant women; with a gradual scale-up to routine testing	Routine testing to all patients served in rural clinics and health centres.
Testing targets (patients)	213,709	577,990	871,008	
Yearly % Coverage of Testing Need	21%	50%	70%	>90%

2. The Impact of VL Testing
on CD4 Monitoring and Second Line Drug Procurement

Clinician testing sample on the PIMA POC CD4 machine

As VL testing becomes more widely available, the use of CD4 testing as a routine monitoring tool for HIV-infected patients will decrease. Despite this, maintaining access to CD4 testing as a tool to assess patients eligible for initiation onto ART, or to determine baseline CD4 in case of a test-and-treat scenario, will remain necessary until VL testing is universally accessible.

The ideal system would see CD4 and VL testing operating in concert to provide a complete package of services to each and every HIV patient in the country.

The cost of second line medicines is not included in this proposal but an increase in demand should be anticipated when launching the VL testing roll out.

Experience from Buhera District's implementation of VL testing can guide the National Pharmaceutical Stores (NatPharm) when ordering second line medicines.

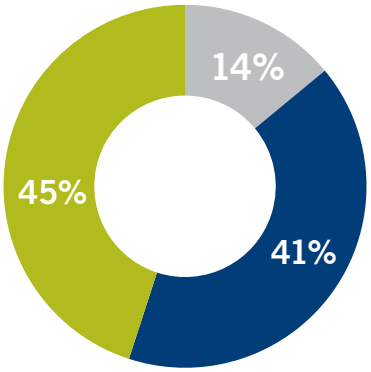
In Buhera District, from VL cascade data collected 18 months after running a routine VL testing program, it was noted that, of the patients who submitted a sample for routine VL testing, 15% had a detectable VL by their first test (VL1), 8% still had a detectable VL by the second VL test (VL2), and 5% were switched to second line treatment (see Table 1.1 in Appendix 1).

The ideal system would see CD4 and VL testing operating in concert to provide a complete package of services to each and every HIV patient in the country.

3. Scale-up Phase Descriptions

The plan for the phased approach is shown below in Figure 3. By the end of 2015, all tertiary and provincial hospitals should offer routine VL testing services to selected patients. In 2016, tertiary and provincial hospitals will move towards offering routine VL testing to all patients, while district hospitals will offer routine VL testing services to selected patients. Facilitated referral arrangements will be made for clinics to access VL testing services from higher centres. In 2017, routine VL testing for all patients will be accessible at tertiary/ provincial hospitals and district hospitals, while efforts will continue to widen access to VL services down to the clinic level. The analysis presented here assumes that the existing platforms will be used at only 90% testing capacity to account for lost capacity due to various systemic inefficiencies.The phased approach targets patients from throughout the country, with differing timing to launch routin VL testing for selected patients and routine VL testing for all patients depending on patient location.

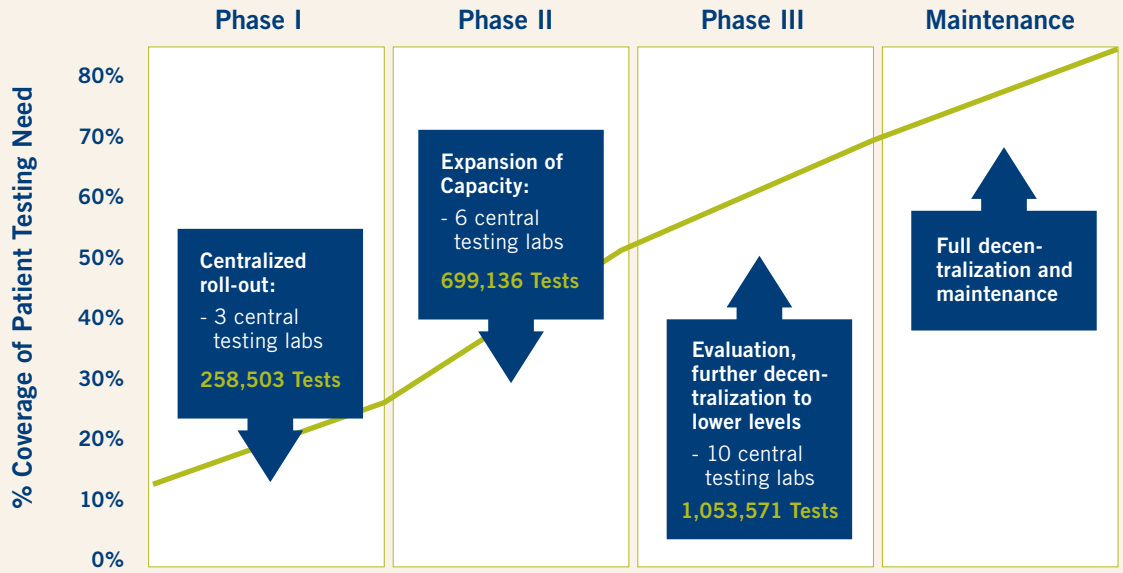
FIGURE 2: Breakdown of ART patient cohort by level of care



Based on July 2014 data, the Zimbabwe patient cohort on ART is divided as follows:

- Provincial/ tertiary hospitals: 14%
- District hospitals, Harare, Bulawayo and Chitungwiza urban clinics : 41%
- Rural hospitals/ health centres and rural clinics: 45%

FIGURE 3: A Phased Approach for VL scale-up



3.1. Phase 1 – Jan to Dec 2015

PHASE 1 offers VL testing to patients who are suspected of treatment failure, pregnant women, and children whilst piloting routine testing in three districts. There will be 116 ART sites included in Phase 1; site selection being based on sites already sending VL samples to the National Microbiology Reference Laboratory (NMRL).

Laboratory capacity for 2015

Currently, 1 NucliSENS platform setup (2 EasyMag and 1 EasyQ) is testing VL samples at NMRL. The Presbyterian Church clinic in Victoria Falls and Newlands clinic have acquired their own platforms, which will help in reaching the overall national testing targets. Equipment leasing will be prioritised over capital purchases to ensure the number of instruments is increased in the shortest time possible and allow for testing targets to be reached.

Training

All 116 sites included in Phase 1 are already sending samples and have been trained on proper technique and procedures. Refresher trainings will be provided as necessary. Training at all provincial hospitals will be completed in this phase. (See section on Human Resources, Training, and Mentorship below for details).

3.2. Phase 2 – Jan to Dec 2016

IN PHASE 2, tertiary and provincial hospitals will start offering routine testing to all patients, district hospitals will begin offering routine testing to selected patients, and selected patients at rural clinics/health centres will access routine testing via facilitated referral to provincial/ district hospitals or via mobile mentoring teams.

Routine testing for selected patients will be rolled out to an additional 47 new ART centres (all remaining district hospitals not covered in Phase 1), bringing the total to 163 facilities able to access VL testing. In this phase, 47 facilities will offer routine testing to selected patients and 116 will offer routine testing to all patients. Site selection for phase 2 will be based on the plan of moving from tertiary, provincial, district and then health centres over the phases of scale-up.

Laboratory capacity planned for 2016

Allocation of the existing Roche Taqman platforms testing capacity will be as below.

- **NMRL:** To cover Harare Central Hospital, Chitungwiza, Wilkins Hospital, and Harare council clinics patients.
- **Mpilo Laboratory:** To cover Mpilo hospital and Bulawayo council clinics patients.
- **Mutare Provincial Hospital Laboratory:** To cover Mutare Provincial Hospital patients.

Training will be provided to all new testing sites as well as new ART sites offering VL.

In 2016, tertiary and provincial hospitals will move towards offering routine VL testing to all patients, while district hospitals will offer routine VL testing services to selected patients.

3.3. Phase 3 – Jan to Dec 2017

IN PHASE 3, rural clinics/health centres will start offering routine testing to selected patients for monitoring, prioritising children and pregnant women, with a gradual scale-up of routine testing for all patients.

New ART sites included for testing

- Routine VL testing for all patients will be extended to all district hospitals from January 2017.
- Mission hospitals that do not act as district hospitals will continue to provide routine VL testing to selected patients.
- Routine VL testing for selected patients will be expanded to all rural hospital/health centres and clinics. These facilities will conduct DBS sample collection, address counselling needs, and switch to second line treatment at their respective clinics.

Laboratory capacity

The NucliSENS platforms that were functional in Phase 2 and solely used for VL testing, along with 4 new platforms, are expected to be functional from the beginning of 2017. New platforms will be selected that allow for integration of the VL and EID testing programs. Considerations will include training on sample collection and processing, sample requirements, and fleet of platforms already in country to allow for standardization and laboratory workflow optimization.

In 2017, routine VL testing for all patients will be accessible at tertiary/provincial hospitals and district hospitals.

4. Scale-up Plan Components

A Roche Taqman analyser at the National Microbiology Reference Laboratory

4.1 Laboratory Infrastructure, Equipment, Service and Maintenance

Overview

Selection of new equipment throughout the duration of scale-up will be based on the following criteria:

- Multiplex platforms to reduce capital investment
- Ability to process high sample volumes.
- Ability to process low volume samples e.g. paediatric samples.
- Walk-away testing platforms with high-level automation, which do not require high-level training like the Roche, Abbott or NucliSENS EasyQ/EasyMag combinations

Three platforms (Roche, Abbott and NucliSENS) will be considered in order to accommodate the different needs of various parts of the country. POC devices will also be considered as a supplement to the conventional, high-volume platforms. POC technologies could distribute the labour required for sample processing from scarce, highly skilled laboratory technicians to lower cadres of health care providers.

Existing Capacity

At the moment, 1 NucliSENS platform setup of 2 EasyMags and 1 EasyQ is available at NMRL. Three Roche Taqman platforms, one each at NMRL, Mpilo and Mutare hospital, are currently prioritized for EID but will start testing VL at 25% capacity early 2015. Testing capacity for both platforms is shown in Table 3.

At the end of 2014, Chitungwiza, Gweru, Chinhoyi, BRIDH and Parirenyatwa laboratories were assessed to determine the feasibility of placing VL platforms. BRIDH, Chinhoyi, Parirenyatwa and Gweru laboratories have sufficient infrastructure and space to install additional PCR laboratories with minimal renovations and will be prioritised for immediate placement. The Chitungwiza laboratory requires construction of an additional room before a PCR machine can be placed. All six labs will require additional staff to run VL samples.

TABLE 3: Zimbabwe current VL testing capacity

Lab	Testing Platform & Type	# of Platforms	Laboratory Capacity (# of tests)
NMRL	BM NucliSENS– DBS	1	72,000
NMRL- Mutare - Mpilo	Roche Taqman – WB	3	33,120
		Total	*105,120*

Phase 1

Decisions will be made on four new platforms to procure in 2016 for phase 3 and procurement of new equipment for 2017 will commence. Designs for workflow optimization models will be explored as integration with EID testing is considered. Renovation of 2 central labs will be completed and machines installed before end of 2015. Phase 1 will see the first POC VL technologies being piloted for roll out in the second quarter of 2016.

Phase 2

Equipment procured in phase 1 will be fully rolled out to selected sites and all corresponding training and workflow optimization will be conducted. Four new platforms will also be procured to be rolled out in phase 3 in order to accommodate the increase in testing targets. The Mpilo laboratory resources will be strengthened as it is currently the only central laboratory catering for the southern part of the country. Renovation of central labs that commenced in phase 1 will continue.

Phase 2 will see pilots on POC technologies expanding to analyse broader diversity of options for testing scale-up. Phase 2 will also see selection of POC VL platforms for use in phase 3. As recommended during the Laboratory Harmonization Workshop and based on PIMA CD4 roll-out experience, more than 2 POC VL platforms will be selected to ensure that competition between providers remains. Selecting POC platforms that allow for integration of EID and VL testing will be prioritized as this would help leverage on the existing EID program and shorten the implementation timelines and associated costs.

Phase 3

Phase 3 will see the four new high throughput platforms fully functional as well as the start of POC VL testing. During deployment of POC devices, sites outside of the catchment areas of NMRL, BRIDH, Newlands Clinic, and any other central laboratory testing VL will be prioritized. In this phase, ten central laboratory based high throughput platforms (seven fully VL and three shared with EID) and POC VL platforms will be functional. This will allow for analysis of cost effectiveness, turnaround time, and feasibility; knowledge which will then guide detailed planning & budgeting for 2018 and beyond.

Equipment Service and Maintenance Support

Service and maintenance (S&M) agreements for existing platforms will be prioritised to ensure that services are not disrupted.

The following will be in place before instrument procurement is done for all new equipment:

- Proposals for S&M options (bundled S&M, outright contract, warranty offers) drafted, accepted and signed by manufacturer.
- A preventative maintenance visit (scheduled maintenance) and an emergency or breakdown visit (curative maintenance) schedule.

Consideration will be given to transportation and specimen receipt at the laboratory to ensure prompt sample processing prior to testing

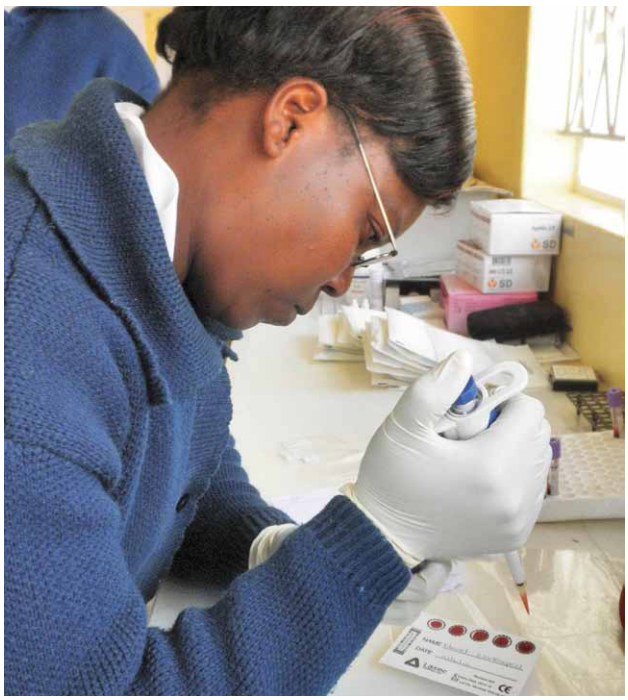
TABLE 4: **Summary of activities included in each phase – Laboratory infrastructure, Equipment, S&M**

Phase 1	Phase 2	Phase 3
• Selection of 4 new platforms for phase 2 and commencement of their procurement. • Commencement of leasing agreements with suppliers and subsequent placement of the equipment • Allocation and placement of the machine donated by MSF. • Commencement of laboratory renovations • Start of evaluation and pilot of POC technologies	• Rolling out of equipment procured in phase 1. • Procurement of 4 new platforms for rollout in phase 3. • Continued evaluation and pilot of POC technologies. • Selection of POC technology to be rolled out in 2017. • Continuation of laboratory renovations.	• Roll out of 4 platforms procured in phase 2. • Gradual introduction of POC VL.

4.2. Sample Type and Transportation

Overview

Patient samples will be transported from urban, peri-urban, and rural health facilities to designated laboratories for testing. In phase 1, both DBS and WB specimens will be used to fully utilize the current testing capacity.



▲
Preparing a DBS sample at a clinic in Buhera

WB specimens must be transported within 6 hours of collection from the health facilities to the central testing laboratory and therefore will only be used for walk-in patients at hospitals and clinics that are testing on the Roche platform or by hospitals/ polyclinics that already have existing daily sample transport in place (e.g Harare and Bulawayo City Clinics).

Careful logistical consideration will be given to transportation and specimen receipt at the laboratory to ensure prompt sample processing (plasma separation/ centrifugation) prior to testing. In addition, careful consideration has to be given to sample storage at the central labs; hence the preference to switch to full DBS once technology has been approved for all selected platforms.

DBS cards are an alternative to WB as they are easier to transport, particularly from remote health facilities to the centralized testing sites. A standardized approach for collecting, storing, and processing DBS samples is essential to successful implementation.

Currently, facility health workers are responsible for sample collection and are required to follow standard procedures for collecting, packing, and shipping DBS samples. The packaged DBS samples are transported to the central collecting point in the district and then sent to the laboratory for testing. Several transport mechanisms are already being used in country for the transportation of various specimens, including tuberculosis, HIV DNA PCR, and drug resistance surveys.

Venous blood sample collection at a clinic in Buhera

Existing Capacity

The transportation model used by the EID program, which is funded through 2015, will be adopted for the VL rollout in Phase 1 through to Phase 3. Under this model, sample transportation occurs through various district mechanisms that include use of motorised health personnel, e.g. environmental health technicians (EHTs), outreach teams, from the sites to central collection points. At the district collection point, a designated courier service, FedEx, then ships the samples to NMRL, Mutare and Bulawayo labs for testing. There are 217 central collection points across the country that were designated by the MoHCC and the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) for FedEx to collect samples from. Each of the designated collection points serves 3 –10 surrounding EID sites.

The remaining EID sites are peripheral sites that collect their samples and send them to the central collection point through their normal transport systems, which include ambulance transport, motorized EHTs, support and supervision and outreach team travels. In addition, all central collection points also collect DBS samples from the HIV exposed infants (HEI) they attend to. The courier system then collects the specimens from the central collection point and ferries them to the NMRL for testing.

Phase 1

The existing ST model will be used under Phase 1, keeping the target at weekly sample transport. Samples will be collected from the various ART sites through any of the designated points. All DBS samples will be transported using FedEx, ambulance transport, motorized EHTs, support and supervision, and outreach team travels. EHTs will be sensitized on the proper management of the additional VL samples they will be carrying. In preparation for 2016, resource mobilisation for continued use of the existing ST system will begin in collaboration with the technical working group (TWG) on ST set up by the MoHCC.

Phase 2

The existing ST model will continue to be used through the phases with extra support for motorbikes and re-fuelling. Funding to support the existing model will continue to be mobilised for phase 2 onwards. Improvements on the existing system will be made in preparation for 2017.The plan will be to continue using the 217 collection sites used for EID samples to minimize confusion and the need for additional training.

Phase 3

The existing ST system will continue to be used in Phase 3. The introduction of POC technologies in more remote areas is expected to reduce the burden on the courier transportation system and potentially reduce the overall cost of sample transportation.

TABLE 5: Summary of activities included in each phase – Sample transportation

Phase 1	Phase 2	Phase 3
• Use of existing ST system. • Mobilization of funds to continue the existing ST system. • Sensitization of EHTs.	• Continued use of ST system from phase 1 • Provision for extra motorbikes and refueling • Continuation of resource mobilization.	• Continued use of ST system already in use.

4.3. Procurement and Supply Chain Management

Overview

The Directorate of Laboratory Services (DLS) coordinates all stakeholders in the evaluation, selection and procurement of laboratory equipment, selection, quantification, procurement, storage, and distribution of reagents, and consumables, quality assurance, and maintenance of Laboratory Information Management Systems (LIMS). They also provide guidance on specifications for procurement where necessary. All procurement will be based on a supply plan provided by the Laboratory Logistics Unit (LLU). The DLS shall consult the HIV/TB and other programs on supply chain management (SCM) indicators that may need to be added on the LIMS. There is a significant funding gap that will prevent adequate procurement of commodities to match the testing targets if not promptly addressed. The national quantification is done annually, using assumptions that may need review as the program progresses. Quantification will also be reviewed quarterly based on consumption data from sites through the Zimbabwe Laboratory Commodities Distribution System (ZiLaCoDS) LIMS.

Existing Capacity

"ZiLaCoDS, which was piloted in Manicaland, Bulawayo and Matabeleland South provinces in 2014, will be rolled out nationwide in 2015" This is a system meant to be a central information system for laboratory commodities supply chain management. A fully fledged LLU is responsible for current commodity distributions.

Phase 1

A quantification review or update will be done quarterly as the program progresses for use in forthcoming phases of implementation. A quantification exercise for the Roche and Abbott platforms will be done to establish gaps for 2015 and 2016, and will be shared with the MoHCC and all partners.

Phase 2

The quantification review for VL will be based on targets and consumption data from Phase 1.All relevant prior procurement will be fed into the quantification pipeline to allow for adequate forecasting.

Phase 3

New equipment proposals and an update of the fundraising plan will be prepared.

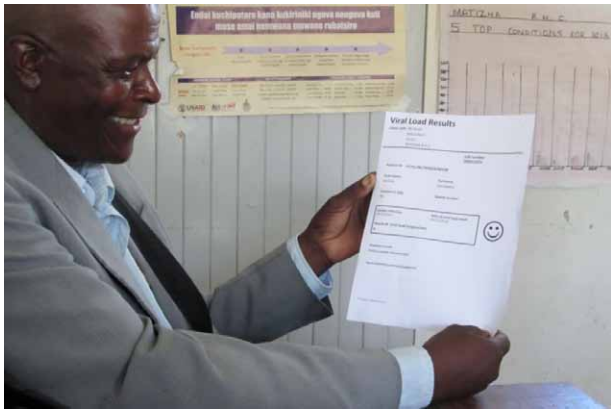
TABLE 6: Summary of activities included in each phase – Procurement and SCM

Phase 1	Phase 2	Phase 3
• Quarterly quantification review/update • Quantification exercise for Roche and Abbott platforms to establish gaps.	• Quantification review based on consumption from phase 1.	• Preparation of equipment proposals and update of fundraising plan.

4.4. Data Management and Results Transmission

Overview

VLIS, the current data management system used at NMRL for VL testing, relies on in-house software developed by the MoHCC and MSF. NMRL plans to implement a more robust LIMS with technical support from RTI International and other partners. Once the LIMS is in place, all tests run at NMRL will be integrated onto this platform. In the meantime, modification of the current EID data management system to handle VL testing will be explored.



▲ Man receiving a good viral load result

Existing Capacity

The flow of data for VL within the laboratory differs from EID data flow.

So far, four data encoders have been trained for VLIS; three work full-time on VL and one works on both VL and Frontline SMS roll out. From experience, two data encoders are able to encode 240 results per day.

Results transmission is fully integrated with EID and uses the same two methods for transmitting results:

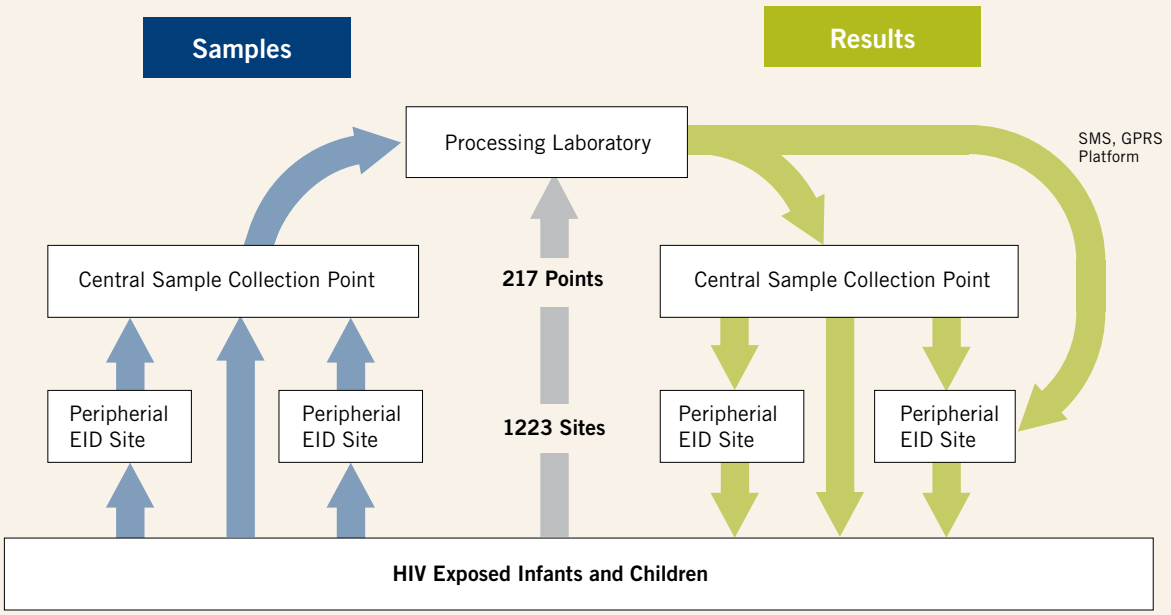
- **Paper results:** via courier
- **Electronic results:** via Frontline SMS to over 1500 health facilities which overlap with the ones targeted for VL testing (over the course of the 3 phases). Messages are sent via a central server managed by the Zimbabwe Health Information Support Project (ZIMHISP).

Challenges remain in the transmission of results, especially at facility-level where mobile phones are shared between programs and the final delivery of the result to the patient is largely dependent on who has the phone when the results arrive. Gaining insight into the actual performance and contribution of the results transmission system to program outputs could reduce or remove these challenges. Detailed assessment of the times taken at all the stages of the EID/VL process up to the client receiving results will assist in developing strategies to improve the turnaround time (TAT).

FIGURE 4: EID flow in the lab

FIGURE 5: VL flow in the lab

FIGURE 6: **The flow of samples and results**



Phase 1

Learning from the EID experience, mHealth technology will be used to decrease turnaround time for results to reach the health facility. In the two pilot districts, Buhera and Gutu, doing routine VL, results are sent through SMS to clinics. In addition, messages alerting patients of the availability of results at their clinic are sent to patients. This will be rolled out full-scale in this phase. A LIMS will be selected and piloted to assess its handling of laboratory information. During this phase the EID management system will be upgraded to handle the transmission of VL results.

Phase 2

The selected LIMS will continue to be piloted in Phase 2, with integration of VL into the EID testing platform happening during this phase.

Phase 3

LIMS will be fully implemented during Phase 3. This will include all health facilities with laboratories being connected to the LIMS and linked onto the national health database.

TABLE 7: **Summary of activities included in each phase – Data Management**

Phase 1	Phase 2	Phase 3
• Full-scale roll out of SMS to clinic for result transmission. • Selection and pilot of LIMS. • Upgrade of EID management system to handle transmission of VL results.	• Pilot of selected LIMS • Integration of EID testing in VL platform.	• Full implementation of integrated LIMS.

Educating kids on HIV using adapted training materials

4.5. PLHIV Education and Adherence Counselling and Support

Overview

Improving the literacy of PLHIV on the need for VL testing and the interpretation of VL results is essential to supporting the demand for VL, and is also likely to aid adherence. For many PLHIV, changes in CD4 levels have traditionally been used to understand treatment efficacy; changing this paradigm will require concerted PLHIV treatment literacy and counselling campaigns, both within the clinic (pre VL sessions) and in the community. Visual tools that explain the concept of viral load testing may aid in adherence management, as will clear written instructions on PLHIV-held records describing when viral load testing should be performed. The aim is to empower PLHIV to both request that a VL test be performed at the appropriate times and to understand the result and consequences.

> Visual tools that explain the concept of viral load testing may aid in adherence management

Adherence Counselling

Adherence counselling refers to the counselling intervention aimed at PLHIV with an elevated VL result. The Adherence Counselling and Support package consists of two or more sessions, which may be given individually or in a group. The objectives of these sessions are to:

- Assess the barriers to adherence (behavioural, emotional, and socio-economic).
- Together with the PLHIV, identify and evaluate strategies to overcome these barriers.

The first of these sessions is given on the day the high VL result is given to the PLHIV, with subsequent sessions following monthly drug refills. A repeat VL test is then performed 12 weeks after the initial VL result was given. Facilities will have recording tools to aid in the management of PLHIV with a high VL result, including the High Viral Load PLHIV Summary form and a clinic-based Enhanced Adherence Counselling (EAC) register, for all those PLHIV undergoing adherence counselling. This register gives an overview of all PLHIV being offered adherence counselling, whether they have attended their sessions or not, and the outcomes of their repeat viral load testing. In this way, the register also serves as a useful tool for close follow up of the patient by the counsellors performing the intervention and may be used as a supervision tool by program managers.

▲ Woman living with HIV educating her peers

TABLE 8: Summary of activities that will be included in each of the 3 phases – PLHIV Education and Support

Phase 1	Phase 2	Phase 3
• Development and printing of VL treatment literacy material for inclusion in the Treatment Literacy Package • Utilization of the same package for Expert Patient Trainers, VHWs and Secondary Caregivers to train PLHIV • Training of 170 Trainers (2 from each district/Health Facility) at the 116 central and provincial level centres • Training of 2,300 community-based workers, including the 51 Expert Patient Trainers, VHW, and other PLHIV members of support Groups, and Community Caregivers who support 116 hospitals and health facilities that are implementing routine VL testing for selected patients. • Production and printing of training package x 5,000 copies, 10,000 VL pamphlets and 3,000 posters for the health facilities. • Training of peer counsellors/expert patients on Enhanced Adherence Counselling.	• Training of trainers on VL treatment literacy for the additional 47 sites to implement VL district levels • Training of 2,160 additional community-based PLHIV Peer Educators, VHWs, and community-based caregivers to support clients with enhanced adherence counselling and treatment literacy for the remaining 47 centres • Training of peer counsellors/expert patients as Enhanced Adherence Counsellors. • Refresher training for PCs and nurses on Enhanced Adherence Counselling.	• Update Treatment Literacy Package as appropriate • Train and deploy 26,740 PLHIV VL Peer Educators to support clients on adherence counselling and treatment literacy • Print 35,000 copies of the updated Treatment Literacy Package, 40,000 pamphlets, 3,400 posters. Development and printing of 5,000 copies of Viral Load Treatment Literacy training package, 10,000 pamphlets and 3,000 posters. Continued training of peer counsellors/expert patients as Enhanced Adherence Counsellors

Adherence support to PLHIV should come from their immediate support group, Community ART Groups, peers, and family. In clinics, it is given mainly by primary counsellors (PCs) or nurses after training on EAC. It is important to have a PC or nurse available to offer EAC in the ART clinic when rolling out VL and as such refresher trainings for existing PCs/ nurses on EAC are budgeted.

To date, the MoHCC has trained 51 expert patients and 765 PCs who can assist in peer education and EAC (See Annex 7 for distribution of PCs). Batanai HIV&AIDS Support Organisation has trained 250 Enhanced Adherence Counsellors operating in Masvingo urban and rural, Gutu, Bikita and Zaka.4,650 village health workers (VHW), who are stationed at different ART initiating centres, and 12,500 community caregivers trained to provide ART Treatment Literacy and ART adherence will also assist in adherence counselling. Community-based counselling has also been done by community caregivers that have been trained mainly through the GF-supported adherence counselling program.

4.6. Human Resources, Training and Mentorship

Overview

In order for the scale up of VL testing to be successful, several groups of the healthcare workforce need to be trained on a variety of topics. The table below highlights the focus of trainings for 3 categories of health care workers (HCW). A standard curriculum will be developed for each level of health care worker in order to avoid duplication of efforts.

EAC, covered under PLHIV Education and Adherence Counselling and Support training, will begin with training the selected facilities for Phase 1 and including all relevant partners who provide district and facility-level training and clinical mentoring to ensure that scale-up can be supported operationally in the future. Nurses, clinical officers, and relevant facility staff from each of the facilities will be trained.

TABLE 9: Focus of trainings for the 3 tiers of HCW doing VL testing

HCW collecting blood samples at the facility level	Nurses and clinicians identifying and managing ART patients for VL testing	Laboratory assistants and technicians testing VL samples
• General VL testing theory and rationale • Milestone screening approach • Indications for VL testing – routine testing for all patients vs. routine testing for selected patients. • Operational and logistical steps for ensuring VL testing is properly implemented at facilities (assigning roles and responsibilities for sample collection, documentation, patient identification, patient follow up, etc.) • Patient flow and clinic workflow • Minimizing loss to follow up • Standard Operating Procedures for collecting DBS samples for VL • Key differences between collecting DBS samples for EID and VL • Completing relevant forms and documentation for VL sample collection and laboratory requisitions	• General VL testing theory and rationale • Milestone screening approach • Indications for VL testing – routine vs. testing for all patients vs. routine testing for selected patients. • Patient identification for VL testing • Operational and logistical steps for ensuring VL testing is implemented at facilities (assigning roles and responsibilities for sample collection, documentation, patient identification, patient follow up, etc.) • Adherence counselling • Understanding VL testing advantages compared to immunological monitoring. • Virologic and clinical failure • Results interpretation • Switching patients to second-line ART • Case studies in patient management • Second line regimens • M&E indicators.	• Protocol for receiving and prioritizing VL samples • Proper entry of VL samples into VLIS • Differences in testing protocols between DBS and plasma samples • Labelling and separating EID and VL DBS samples to ensure there is no cross-contamination or mislabelling of samples • Protocols around sample rejection and sample re-testing • Results transmission to facilities using Results160/LIMS • QC/QA on the platforms. • Requisition Forms QC • M&E indicators

Existing Capacity

Staff at the central laboratory (NMRL)

There are 15 laboratory scientists at NMRL working full-time on EID and VL testing (seven running EID tests and six running VL tests). Current VL testing on the set up of 2 EASYMAG and 1 EASYQ at NMRL is as follows:

- A day shift of four scientists can run up to five batches of 48 tests while an evening shift of 2 scientists can run 2 batches; for a total of up to 7 batches a day.
- One receptionist and four data encoders have been recruited for NMRL. From experience, two data encoders can encode 240 results per day. Two data encoders are needed for the present double encoding used for VLIS, but this could be reduced to one once LIMS use begins.
- Training: four-day training (with certificate) was provided by the local supplier on installation of the machine for the laboratory scientists. This training is free of charge; except for transport/ accommodation. This experienced team of laboratory scientists at NMRL can go on job mentorship visits to newly opening labs. Receptionist and data encoders can easily be trained on the job.
- With this capacity, NMRL was able to test 34,124 samples in 2014. Once additional central labs have been renovated, HR needs will be assessed and added to the implementation plan.

▲ On the job mentoring at a clinic in Gutu

Staff at health facilities

Successful roll out of VL monitoring will depend on increasing the numbers of clinicians and counsellors available at health facilities. Currently, there is a national shortage of human resources which will negatively affect the success of this plan. An important resource gap has been observed for counselling; there is insufficient staff to cover all aspects of both HIV testing (diagnostic component) and adherence counselling (treatment component). Adherence counselling comprises all counselling aspects needed once patients are put on treatment, including ART initiation, Prevention of Mother to Child Transmission (PMTCT) counselling, support to paediatric disclosure, and EAC, among others. A total of 765 primary counsellors (PC) are supported by GF. Minimum needs for PC are estimated by MoHCC as follows: 12 PCs per tertiary hospital, 10 per provincial hospital, 8 per district hospital, and 1 per clinic to cover HIV testing (including outreach) and general adherence support.

TABLE 10: Primary counsellors needed at facilities

Level of health care	Number of facilities	# PC needed/ level of facility	Total
Tertiary hospitals	5	12	60
Provincial hospitals	8	10	80
District hospitals	63	8	504
Rural hospitals	118	4	472
Clinics	1411	1	1411
	1605		**2527**

Note: Estimates of the gap and cost of increasing staff at health facilities are not included in this proposal.

4.7. Quality Assurance

Overview

All testing laboratories should have an on-going Quality Assessment Program that is designed to monitor, evaluate, and improve the quality of testing and to evaluate the competency of the laboratory staff. Any individual who performs VL testing on patient samples must adhere to the contents of the QA program. The aims of the quality assurance program are to establish, maintain, support, and document effective and systematic mechanisms for monitoring, collecting, and evaluating information about VL testing in order to identify opportunities for improving patient care. This will ensure that the VL testing QA activities are comprehensive and coordinated and that appropriate information is reviewed and reported. This will improve care by focusing on identification, assessment, correction, and follow-up of problems that affect VL testing.

Existing Capacity

Quality Management services are offered by CDC at central labs every quarter. VL testing is subjected to proficiency testing and quality control (QC) activities are currently in place. Most of the laboratories are implementing quality management activities in line with Strengthening Laboratory Management towards Accreditation (SLMTA).

Phase 1

There will be a need to ensure both DBS and WB are subjected to QA activities. In Phase 1, QA monitors will be actively evaluated to maintain an established standard of laboratory performance and compliance. Data from each monitored area will be collected, recorded, and analysed. The findings will be evaluated to detect trends and overall compliance. When required, appropriate corrective action will be implemented and documented.

Monitoring will continue through the duration of scale up to assure that the action is appropriate and any problems found are corrected. Proficiency testing programs will be used as an external check on the QC and QA of a test system. VL proficiency testing will be conducted a minimum of twice per year, with the recommendation being three times per year. The Zimbabwe National Quality Assurance Programme (ZINQAP) or a suitably qualified Proficiency Testing (PT) Scheme provider will be engaged to administer a PT program that is sufficient to check the quality of testing in the laboratories. Training and competency assessment will be conducted for all employees. New employees will be checked for competency before they report any patient results and existing employees will be checked annually and periodically as needed. Internal QC testing will be done for all testing. Standard operating procedures will be developed and these will outline the required control materials and analysis frequency for the tests performed in the laboratory or other testing location. It will be the responsibility of every testing person to ensure that the required controls have been performed and satisfactory performance has been obtained prior to the release of any patient results.

Phase 2

Phase 2 will see the implementation of comprehensive specimen management activities. Specimens sent to the laboratory will be monitored to determine the effectiveness of the collection procedures as well as the integrity of the specimens received. The following areas will be monitored, recorded, and investigated in a timely manner:

- Lost specimens (from point of collection to laboratory or within the laboratories).
- Rejected specimens.
- Missed testing (samples not tested by lab).
- Specimen integrity.

All testing laboratories should have an on-going Quality Assessment Program that is designed to monitor, evaluate, and improve the quality of testing and to evaluate the competency of the laboratory staff

Results released to the clinicians will be monitored through LIMS and surveys to determine the effectiveness of the laboratory review and reporting system. Laboratory supervisors will be responsible for ensuring that all results reported from their laboratories are correct and authorized. Technical delays will be monitored to help evaluate the overall effectiveness of the laboratory. Any time delay in reporting of patient test results due to a technical problem in the laboratory will be documented. This will include parameters such as; scheduled and unscheduled instrument down times, acute or chronic staff shortages, reagent shortages, failed quality control, and supply back orders. TAT will be monitored and reported on a periodic basis. Any time an instrument or methodology is changed within the laboratory, validation studies will be performed. All procedures used in the laboratory will be documented and reviewed on an annual basis, or more frequently if needed. All laboratory records inclusive of requisitions, patient results, QC logs, maintenance logs, and QA logs will be retained for a minimum set period. Maintenance of equipment will follow manufacturer recommendations at a minimum. All instruments used in the laboratory will follow a preventative maintenance program which must follow the manufacturer's recommendations. All temperature-sensitive equipment such as freezers and refrigerators will be monitored once daily.

> Laboratory supervisors will be responsible for ensuring that all results reported from their laboratories are correct and authorized.

Phase 3

Complaints received by the laboratory will be monitored for response, corrective action and follow-up across all 3 phases. Patient care/well-being will be taken into consideration in designing and responding to the corrective action. Phase 2 activities will be continued and strengthened. Quality management systems will be introduced in all on VL testing laboratories. All VL testing laboratories will also be put on the pathway to accreditation to ensure sustainability of the implemented quality assurance activities.

TABLE 11: Summary of activities included in each phase – Quality Assurance

Phase 1	Phase 2	Phase 3
• Evaluation of QA monitors. • Appropriate corrective action implemented where required. • Use of proficiency testing programs as an external check on QA and QC. • VL proficiency testing at least carried out at least twice a year. • Qualified Proficiency Testing Scheme provider engaged to administer PT program.	• Implementation of comprehensive specimen management. • Monitoring of specimens to determine effectiveness of sample collection. • Monitoring of all laboratory parameters affecting turnaround time. • Continuation and strengthening of phase 1 activities.	• Monitoring and follow-up on complaints received by the lab. • Continuation and strengthening of phase 2 activities. • Establishment of quality management systems in all labs. • All VL testing labs put on pathway to accreditation.

4.8. Program Management

Viral Load Technical Working Group

Formed and chaired by the MoHCC, the Viral Load Technical Working Group (VL TWG) will be a forum for the MoHCC and partners to discuss and formalize key decisions related to VL scale-up in Zimbabwe. One of the main activities under Phase 1 is to develop the terms of reference (TORs) for the Advisory Committee. All activities will be managed by a VL testing coordinator who will report to the DLS. The committee will meet whenever necessary but at least once a month in the first year of implementation. The VL TWG will be responsible for assessing technical and clinical evidence to make critical decisions surrounding the scale up of VL testing in Zimbabwe. All information and major decisions will be compiled and presented to a larger audience at the Laboratory Services Partnership Forum (LSPF) for review and final approval.

Key actions and decisions driven by VL TWG will include:

- Advising on adoption of relevant best practices from other countries.
- Assessing and selecting routine VL testing options.
- Calculating VL access coverage.
- Developing options for national VL testing scale up.
- Selecting commodities for VL testing.
- Developing quality assurance/controls for DBS/WB testing.
- Conducting site selection for equipment placement.
- Evaluating sample transportation needs for new VL testing facilities.
- Finalizing training and clinical mentoring materials and approaches.
- Forecasting and quantifying VL commodities needs.

The Viral Load Advisory Committee will be critical to the MoHCC's ability to solicit input and assistance from stakeholders. This committee will continue to meet monthly during the first year of implementation and quarterly beyond that to assess progress of the phases of testing scale-up, deploy clinical mentoring and training follow up visits, and prepare the strategy for the next phase of VL testing scale up.

4.9. Monitoring and Evaluation

Overview

The following major outcomes are the backbone of monitoring and evaluation (M&E) for VL testing:

- Scaled up access to quality VL testing.
- Accurate and early identification of patients who are failing treatment.
- Increased number of patients accurately and appropriately switched onto second line ART.

The impact of these outcomes will largely result in an improved quality of life and increased longevity for patients on ART. Data for the monitoring and evaluation of VL testing will be compiled on a quarterly basis. Key sources include ART supervision visit data (ART cards, ART registers) and LIMS data entered from requisition forms.

The MoHCC will work with partners to conduct operational research as questions/issues arise or as new technologies become available. Routinely collected data through M&E activities will be used to inform decision-making and further research at the national and global level

Monitoring

Viral Load Laboratory Requisition Form

- One of these forms is to be filled out for each DBS/WB sample collected that is sent to the lab. Key sections include health facility details, patient data, reason for test, specimen information, details of sample collector, and laboratory tests requested.

Viral Load Sample Delivery Checklist

- This form summarizes key information from all the laboratory requisition forms into one streamlined form to accompany the DBS/WB samples in transport to the laboratory.
- This checklist captures facility information, Patient Identification Numbers, and whether the samples were received and accepted or rejected at the lab. (If a sample is rejected, the laboratory will fill out a form and send it back to the facility via courier within a day of sample delivery.)
    - The health facility is meant to fill out this form in duplicate and keep one copy at the health facility for their records.

Viral Load Laboratory Results Report

One report is sent from the laboratory back to the health facility for each sample tested. This report will capture facility information, patient information, and specimen information for the sample that was collected for each individual patient. The report will also include whether the sample was rejected and the results of the test.

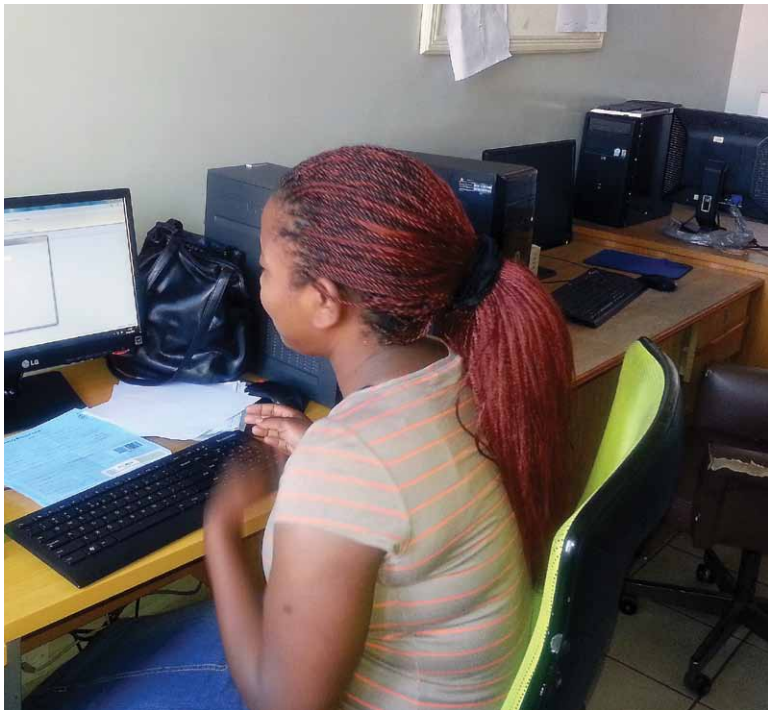
The key VL M&E indicators listed below will be used to report on the three outcomes mentioned above:

- Number and type of VL sample.
- Turnaround time between sample collection and result return to facility.
- Detectable VL level.
- Number of patients initiated on to second line treatment.

Access and Detectablity

Minimal data needed to evaluate the success of VL roll out (collected from all sites, including POC sites) will be collected by the MoHCC M&E department and evaluated to institute any identified corrective actions:

- ACCESS to VL (per site):
    - Number of VL test done for patients < 15 years
    - Number of VL tests done for patients≥ 15 years



▲
Data entry clerk capturing patient results after testing (NMRL)

- RATE OF DETECTABLE VL (per site):
  - Number of VL results <1000copies/ml
    - For patients aged < 15 years
    - For patients aged ≥ 15 years
  - Number of VL results > 5000 copies/ml.
    - For patients < 15 years
- For patients ≥ 15 years

Evaluation

Detailed data on rate of un-detectability in specific groups and clinical/ laboratory data collected from sentinel sites (heavy workload sites sending to conventional labs):

Clinical data:

- % of VL results < 1000 or > 1000 copies/ml disaggregated by age group and sex.
- % of VL results < 1000 or > 1000 copies/ml disaggregated by number of years on ART.
- % of VL results < 1000 or > 1000 copies/ml among pregnant and breastfeeding women.
- % of VL < 1000 copies/ ml by ART regimen in use.
- % of VL results < 1000 copies/ml for M6 VL, M12 VL, and early adherence.
- % of patient s requesting VL test by reason
  - Failing treatment
  - Routine
  - Other
- % of patients virally suppressed after adherence counselling sessions (in the case of repeat VL).
- % of patients consenting to SMS sending of results.

Laboratory data:

- % of samples run on each platform (Roche, BM, Abbott).
- % of samples disaggregated by type: DBS (venous or finger prick), DPS, plasma, WB.
- % of rejected samples.
- TAT of sample within the laboratory (= time between sample arriving in laboratory and result being transmitted by SMS/ courier to the site).

The LIMS database is designed to aid district mentoring teams in supporting the health facilities under their mentoring/supervision scheme by providing the following information/reports:

Report 1: Individual VL result form

- This will be sent only to the requesting health facility.

Report 2: Summary of monthly results per requesting facility -

- Will be sent to the requesting facility – but an e-copy will also be sent to the mentoring team.

Report 3: Patients with a high first VL result and no repeat VL sent for analysis in last 6 months.

- This report will help nurses to identify patients who had a high VL1 and did not come for VL2 within the last 6 months. This report is automatically generated by the computer and only aims to "help" nurses follow up on their most vulnerable patients.
- This report can also help mentors/ supervisors identify clinics that have problems in following up patients with high VL and help them to find solutions.

Report 4: Report for managers – total viral load tests performed per month per district

- At the beginning of each month, managers should identify the number of VL samples expected to be collected in the district from the actual cohort of patients on ART. Knowing the district target and each health facility target will help them to identify facilities that need extra support/ supervision due to increased workloads that may affect performance.
- This information is also the minimal data that should be provided by the sites using POC VL.

Report 5: Number of M6 VL performed

- For managers to closely follow up on the effectiveness of the implementation of VL testing, at month 6 (M6), VL tests will be done on patients on treatment, which is essential to the early identification of patients who are not adhering to treatment.

Activities will be the same across all the 3 phases of the implementation plan. To reduce workload for staff in the health facilities, detailed data will be collected from "sentinel" (heavy workload) sites sending VL samples for analysis to central laboratories. At central laboratories, data management will be assured by data encoders from the VL request forms; similar to what is being done for EID.

5. Implementation Plan and Budget (US$)

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
TOTAL				**$6,051,242**	**$15,238,545**	**$25,019,688**	**$2,949,981**	**$43,359,493**
A.1 Procure Sufficient Testing Platforms	A1.1	Procure 2 new BM platforms that will be placed in 2015/ Phase II (with support from GFATM)	Funded	$255 879	$0	$0	$255 879	$0
	A1.2	Select 4 additional platforms for 2016 and beyond	Not funded	$0	$700 000	$0	$0	$700 000
	A1.3	Procure equipment for Phase 3	Not funded	$0	$0	$1 050 000	$0	$1 050 000
	A1.4	Explore workflow optimization for EID and VL integration on testing platforms	Funded	$0	$1 500	$0	$1 500	$0
	A1.5	Meetings to develop procedures	Not funded	$0	$1 500	$0	$0	$1 500
	A1.6	Clinical/Laboratory consulation of plan	Not funded	$0	$5 000	$0	$0	$5 000
	A1.7	Print new guidelines	Not funded	$10 000	$0	$0	$0	$10 000
	A1.8	Implement training and workflow optimization	Not funded	$0	$27 360	$0	$0	$27 360
	A1.9	Support trainers at 10 provincial level trainings	Not funded	$0	$2 400	$0	$0	$2 400
	A1.10	Mentoring on the job	No cost	$0	$0	$0	$0	$0
	A1.11	Renovations	Partly funded	$60 000	$120 000	$0	$60 000	$120 000
	A1.12	Place Phase 2 equipment	Not funded	$0	$2 000	$0	$0	$2 000
	A1.13	Evaluate POC technologies	Funded	$0	$50 000	$0	$50 000	$0
	A1.14	Pilot POC technologies	Funded	$50 000	$50 000	$0	$100 000	$0
	A1.15	Roll out EID/VL integration	No cost	$0	$0	$0	$0	$0
	A1.16	Place 4 additional platforms selected in Phase 1 (A1.2)	Not funded	$0	$4 000	$0	$0	$4 000
	A1.17	Pilot new testing methodologies	Not funded	$0	$0	$50 000	$0	$50 000
	A1.18	Place additional equipment procured for Phase 3 (A1.3)	Not funded	$0	$0	$4 000	$0	$4 000
	A1.19	Spare parts and replacements	Not funded	$0	$50 000	$50 000	$0	$100 000

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
A.2 S&M	A2.1	Establish S&M need for existing platforms	Not funded	$1 500	$0	$0	$0	$1 500
	A2.2	Develop and sign S&M contracts prior to procurement	No cost	$0	$0	$0	$0	$0
	A2.3	Develop preventive maintenance schedule prior to procurement	Not funded	$1 500	$0	$0	$0	$1 500
	A2.4	Set up extra support for existing sample transport system (additional motorbikes and refueling)	Not funded	$248 000	$0	$0	$0	$248 000
	A2.5	S&M contracts	Not funded	$17 177	$68 709	$171 771	$34 354	$223 303
	A2.6	Servicing of existing motorbikes	Not funded	$12 500	$150 000	$150 000	$0	$312 500
B. Sample Transportation	B1	Begin planning for new sample transport system	Not funded	$1 500	$0	$0	$0	$1 500
	B2	Pilot new sample transport system	Partly funded	$88 260	$0	$0	$45 000	$43 260
	B3	FedEx costs - EGPAF up to end of 2015	Partly funded	$122 850	$0	$0	$122 850	$0
	B4	FedEx costs - Phase 2 and beyond	Not funded	$0	$122 850	$122 850	$0	$245 700
	B5	Implement new sample transport system	Not funded	$0	$0	$2 188 848	$0	$2 188 848
C. Procurement / Supply Chain Management	C1	Quantification support to Logisitics Unit	Funded	$1 500	$1 500	$1 500	$4 500	$0
	C2	Procurement of tests	Partly funded	$4 071 430	$11 011 407	$16 593 748	$1 655 056	$30 021 528
	C3	Procurement of DBS kits	Partly funded	$563 538	$1 524 119	$2 296 785	$225 548	$4 158 893

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
D. Data Management	D1	Utilize mHealth technology to reduce TAT of results back to facilities	No cost	$0	$0	$0	$0	$0
	D2	Select a LIMS	No cost	$0	$0	$0	$0	$0
	D3	Pilot selected LIMS	Not funded	$2 000	$48 000	$120 000	$0	$170 000
	D4	Upgrade EID management system to handle VL	Funded	$2 130	$0	$0	$2 130	$0
	D5	Integrate VL testing into EID platform	Funded	$1 650	$0	$0	$1 650	$0
	D6	Implement new LIMS	Not funded	$0	$0	$1 200	$0	$1 200
	D7	IT - computer, furniture	Not funded	$6 346	$25 384	$25 384	$0	$57 114
	D8	VL request form	Not funded	$43 093	$116 546	$175 630	$45 000	$290 269
	D9	Stationary used in M&E	Not funded	$95 646	$258 681	$389 821	$12 800	$731 348
	D10	SMS	Not funded	$23 265	$62 922	$94 821	$0	$181 009

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
E. Patient Education and Adherence Support	E1	Develop VL treatment literacy material for inclusion in the Treatment Literacy Package	Not funded	$1 500	$0	$0	$0	$1 500
	E2	Print VL treatment literacy material for inclusion in the Treatment Literacy Package	Not funded	$1 000	$0	$0	$0	$1 000
	E3	Train 170 Trainers (2 from each district/Health Facility) at the 115 centres that are in the central and provincial level	No cost	$0	$0	$0	$0	$0
	E4	Train 2,300 community-based workers who include the 51 Expert Patient Trainers, VHW, and other PLHIV members of support Groups, and Community Caregivers who support 115 hospitals and health facilities that are implementing targeted VL testing.	Not funded	$92 000	$0	$0	$0	$92 000
	E5	Produce and print training package x 5000 copies and 10,000 pamphlets on VL information and 3,000 posters for the health facilities	Not funded	$36 000	$0	$0	$0	$36 000
	E6	Train peer counsellors/expert patients as EAC	No cost	$0	$0	$0	$0	$0
	E7	Conduct ToT on VL treatment literacy for the additional 108 sites to implement VL district levels	Not funded	$0	$51 840	$0	$0	$51 840
	E8	Train 2,160 additional community-based PLHIV VL Peer Educators, VHWs, and community-based caregivers to support clients with enhanced adherence counselling and treatment literacy for the remaining 108 centres Training of peer counsellors/expert patients as Enhanced Adherence Counsellors.	Not funded	$0	$86 400	$0	$0	$86 400
	E9	Update Treatment Literacy Package as appropriate	Not funded	$0	$0	$1 500	$0	$1 500
	E10	Train and deploy 26,740 PLHIV VL Peer Educators to support clients on adherence counselling and treatment literacy	No cost	$0	$0	$0	$0	$0
	E11	Print 35,000 copies of the updated Treatment Literacy Package, 40,000 pamphlets, 3,400 posters for institutions,	Not funded	$0	$0	$201 800	$0	$201 800
	E12	Conduct additional ToTs and training	No cost	$0	$0	$0	$0	$0
	E13	Develop and print 5,000 copies of Viral Load Treatment Literacy training package, 10,000 pamphlets and 3,000 posters will also be required.	Not funded	$0	$0	$36 000	$0	$36 000

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
F. Lab Human Resources, Training, Mentorship and related	F1	VL coordinator	Partly funded	$32 400	$32 400	$32 400	$32 400	$64 800
	F2	Car and fuel for VL coordinator	Not funded	$0	$12 000	$12 000	$0	$24 000
	F3	Identify and train laboratory staff in Chitungwiza and Bulawayo	Not funded	$0	$80 688	$80 688	$0	$161 376
	F4	Identify and train laboratory staff for 2 more sites	Not funded	$0	$80 688	$80 688	$0	$161 376
	F5	Identify and train laboratory staff for 4 more sites	Not funded	$0	$0	$161 376	$0	$161 376
	F6	Existing lab staff (NMRL BM 2 shifts)	Partly funded	$87 412	$121 032	$121 032	$208 444	$121 032
	F7	Identify and train data staff in Chitungwiza and Bulawayo	Not funded	$0	$40 560	$40 560	$0	$81 120
	F8	Identify and train data staff for 4 more sites	Not funded	$0	$40 560	$81 120	$0	$121 680
	F9	Identify and train data staff for 6 more sites	Not funded	$0	$0	$121 680	$0	$121 680
	F10	Existing data staff (NMRL BM 2 shifts)	Partly funded	$21 580	$39 840	$39 840	$61 420	$39 840
	F11	Identify and train receptionist for 2 labs	Not funded	$0	$13 776	$13 776	$0	$27 552
	F12	Identify and train receptionist for 2 labs	Not funded	$0	$13 776	$27 552	$0	$41 328
	F13	Identify and train receptionist for 2 labs	Not funded	$0	$0	$41 328	$0	$41 328
	F14	Existing receptionist (NMRL BM 2 shifts)	Partly funded	$3 450	$6 900	$6 900	$10 350	$6 900
	F15	Conduct a four-day training for scientists by the local supplier at laboratory sites	No cost	$0	$0	$0	$0	$0
	F16	Conduct a training for lab scientists running EID samples on VL testing on the Roche platform	Funded	$3 600	$0	$0	$3 600	$0
	F17	Conduct on-the-job training of data encoders	Not funded	$320	$320	$320	$0	$960
	F18	Identify staff to fill the gap of counsellors needed at all hospital levels	No cost	$0	$0	$0	$0	$0
	F19	Recruit and train staff to fill the gap of counsellors needed at all hospital levels	Not funded	$13 600	$13 600	$13 600	$0	$40 800
	F20	Conduct one-day training on VL for Opportunistic Infection (OI) clinic staff	Not funded	$25 760	$8 800	$30 280	$0	$64 840

Strategy Objectives	Key Activities		Status	Budget			Available funding	Funding Gap
				2015	2016	2017		
(Continued) **F. Lab Human Resources, Training, Mentorship and related**	F20	Conduct one-day training on VL for Opportunistic Infection (OI) clinic staff	Not funded	$25 760	$8 800	$30 280	$0	$64 840
	F21	Conduct two weeks of on-the-job mentoring by experienced staff from NMRL at new laboratory sites	Not funded	$6 000	$2 000	$13 200	$0	$21 200
	F22	Conduct mentoring visits to sites prior to their switch from targeted to routin VL testing	Not funded	$2 400	$800	$5 280	$0	$8 480
	F23	Sign one-year contract for all laboratory staff	Not funded	$36 000	$144 000	$360 000	$0	$540 000
	F24	Conduct one-day VL training for nurses	No cost	$0	$0	$0	$0	$0
	F26	Studies related to VL	Funded, in place	$0	$15 000	$0	$15 000	$0
	F27	Toxic waste disposal at NMRL	Funded, in place	$500	$2 000	$0	$2 500	$0
	F28	Generator for NMRL: 100KVA	Not funded	$0	$20 000	$0	$0	$20 000
	F29	Generator fuel	Not funded	$6 000	$6 000	$6 000	$0	$18 000
	F30	Generator maintenance	Not funded	$1 500	$1 500	$1 500	$0	$4 500
G. Quality Assurance	G1	Evaluate QA monitors to ensure compliance with standard lab procedures	No cost	$0	$0	$0	$0	$0
	G2	Monitor data	No cost	$0	$0	$0	$0	$0
	G3	Evaluate results and determine appropriate corrective actions	No cost	$0	$0	$0	$0	$0
	G4	Develop and utilize proficiency testing programs	No cost	$0	$0	$0	$0	$0
	G5	Develop and complete competency assesments for all employees	No cost	$0	$0	$0	$0	$0
	G6	Develop and execute SOP for internal QC	Not funded	$456	$188	$2 908	$0	$3 552
	G7	Implement comprehensive specimen management activities	No cost	$0	$0	$0	$0	$0
H. Monitoring and Evaluation	H1	Compile M&E data on a quarterly basis	No cost	$0	$0	$0	$0	$0

Appendix

Appendix 1: VL Cascade and Projected 2nd Line ARV Requirements

TABLE 1.1: VL Cascade - Routine VL algorithm

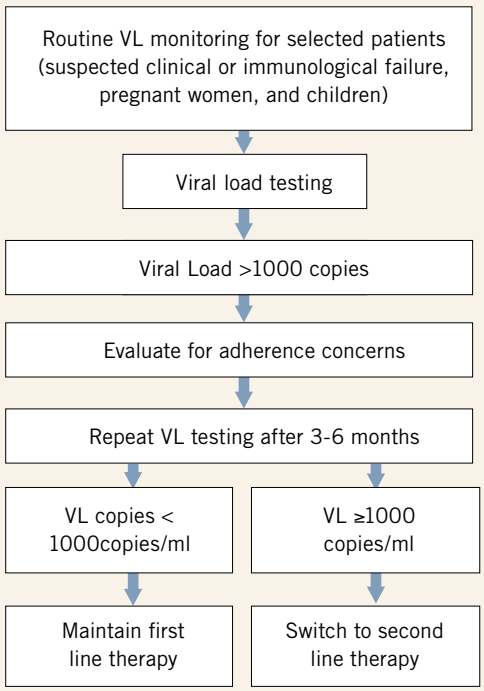
Patients with access to routine VL testing	Of 100 patients
No. with VL-1 detectable	15
No. expected to get EAC and have a 2nd VL test done	12
No. with VL2 > 1000	8
No. that move on to be switched to 2nd line treatment by clinician	5

TABLE 1.2: Projected 2nd line ARV requirements

2nd Line Requirements by Phase	No of patients
Projected 2nd Line requirements for Phase 1 (5% x 213,709)	10,685
Projected 2nd Line requirements for Phase 2 (5% x 577,990)	28,899
Projected 2nd Line requirements for Phase 3 (5% x 871,008)	43,550

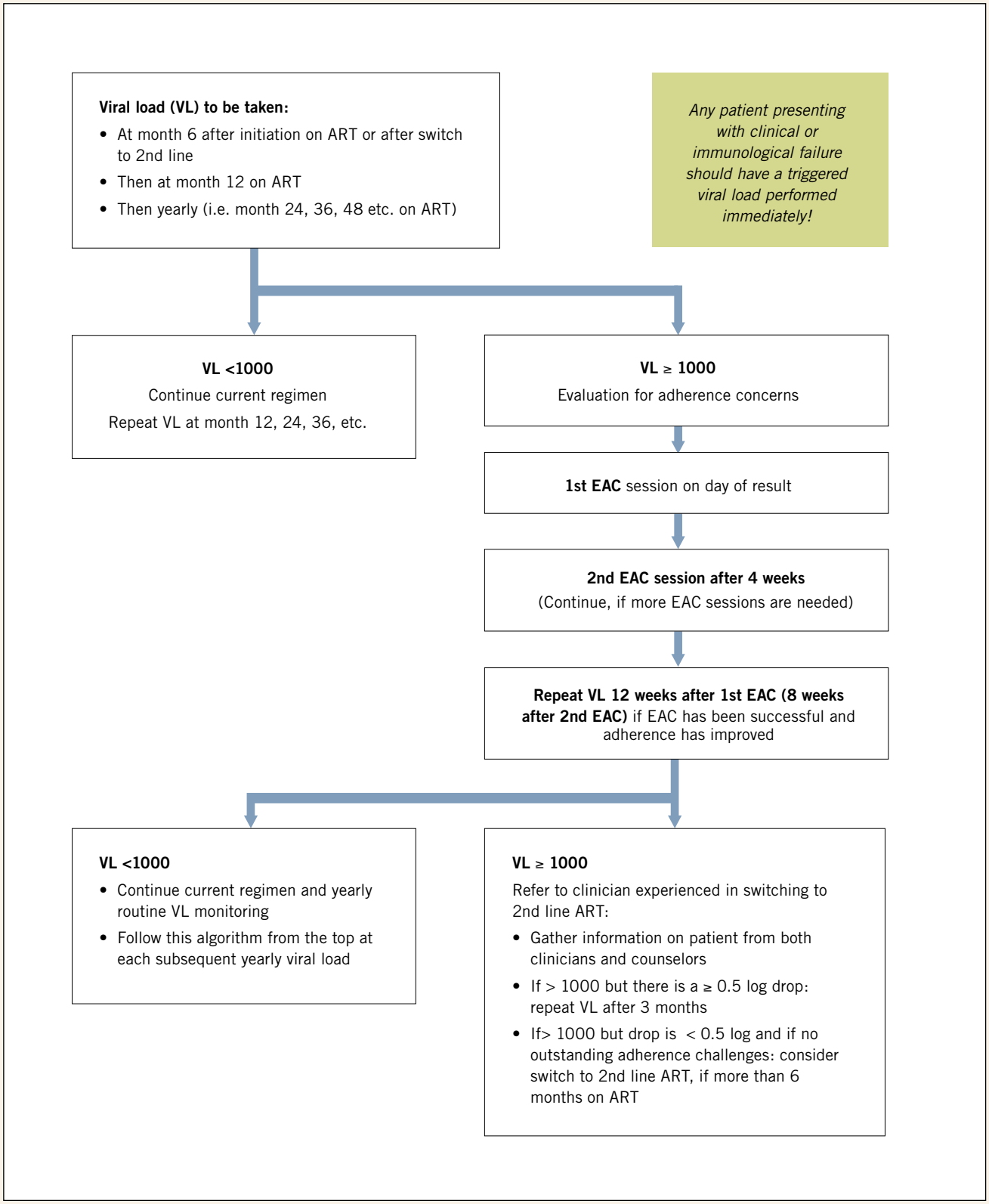
Appendix 2: VL Testing Algorithm and Definitions for VL Target Analysis

- ***Routine VL for selected patients:*** VL tests performed for patients with suspected ART treatment failure, based on either clinical or immunological criteria (as per Zimbabwe ART guidelines). From field experience on routine VL testing done by Médecins sans Frontières (MSF) in Buhera and Gutu districts, only 5% of patients will need a VL test based on clinical/immunological criteria (referred to as VL1 in the document).
- ***Routine VL for all patients:*** New patients tested at 6 months (M6) and 12 months (M12) post-initiation and all other patients tested once per year on the anniversary of the month of initiation. For calculation purposes, this is simplified to 1 VL test per patient per year.
- ***Error rate:*** At the National Microbiology Reference Laboratory (NMRL), testing experience suggests that a laboratory error rate of 12% can be assumed.
- ***Need for repeat VL (=VL2):*** Data from routine VL testing in two of the three pilot districts (Buhera, Gutu) show a virus detectability rate of 17% for VL1. A VL cascade analysis conducted in four clinics performing routine VL testing shows that, of those 17% of tests with a detectable VL1, only 60% of patients get enrolled into enhanced adherence counselling. Of those enrolled, only 80% get a VL2 sample taken. Therefore, the need for VL2 tests is estimated at 8% (0.17 x 0.6 x 0.8). As such, a total additional 8% repeat tests and then 12% error tests (also expressed as reagents in the tables) is calculated on top of the actual VL testing need.
- ***Treatment failure:*** Zimbabwe's guidelines on identification of treatment failure are based on the WHO 2013 definitions of treatment failure. In both children and adults, clinical failure occurs when the patient experiences a new or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4) . Immunological failure in children is defined as a decrease to pre-therapy CD4 or persistent CD4 below 200cells/mm^{3}or CD4% <10%. In adults, immunological failure is defined as decrease to baseline or persistent CD4 below 100cells/mm^3.[6]



6 Zimbabwe National ART guidelines 2013

Appendix 3: Algorithm for Routine Viral Load



Appendix 4: Phase 1 Overview and Capacity

TABLE 4.1: Phase 1 Overview

Estimated Number of Tests and Coverage	Phase 1	Rationale/Source
Patients eligible for ART	1,373,879	MOHCC National Targets 2014 – 2017 Revised 25th March 2014
Actual number of patients on ART	1,017,666	National target coverage rate of 74% for adults and 75% for children.
VL Testing Need (routine) =PATIENTS	1,017,666	Based on routine testing algorithm assuming 1 test per patient per year
Testing Need Phase 1	213,709	MOHCC National Targets 2014 – 2017 Revised 25th March 2014; assuming 21% coverage
Coverage of total patient testing need in Phase 1 (%)	21%	
Actual VL tests (reagents) needed, accounting for invalid tests 12% and repeat tests 8%	258,503	Accounting for invalid tests (12%) and repeat tests (8%).

TABLE 4.2: Phase 1 testing capacity

Lab	Testing Platform & Type	# of Platforms	Laboratory Capacity (# of tests)
NMRL	BM NucliSENS - DBS	1	72,000
NMRL-Mutare - Mpilo	Roche Taqman - WB	3	33,120
		Total	**105,120**

TABLE 4.3: Phase 1 participating facilities

Level of testing	Site	Timeline
Routine VL testing for all patients (continued)	Buhera, Manicaland (29 centres) Gutu, Masvingo (23 centres) Chikomba, Mashonaland East (20 centres)	Already in place Already in place Already in place
Routine VL testing for selected patients	*Hospitals* Harare Central Hospital Chitungwiza Hospital UBH Mpilo Ingutsheni Mutare Provincial Hospital BRIDH Wilkins Hospital All remaining provincial hospitals (7) *Clinics* Bulawayo Council clinics (15) Epworth clinics (5) Nyanga district via mobile mentoring team (1) Harare Clinics (8)	 Already in place Already in place Already in place Already in place Already in place Already in place Q2 2015 Q2 2015 Q1 2015 Already in place Already in place Already in place 2015
Total	**116**	

3 Zimbabwe National Antiretroviral Therapy Guidelines for Preventing and Treating HIV, 2013

Appendix 5: Phase 2 Overview and Capacity

TABLE 5.1: Phase 2 Overview

Estimated Number of Tests and Coverage	Phase 2	Rationale/Source
Patients eligible for ART	1,422,289	MOHCC National Targets 2014 – 2017 Revised 25th March 2014
Actual number of patients on ART	1,155,980	Coverage target of 81% for adults and 85% for children
VL Testing Need (routine) =PATIENTS	1,155,980	Based on routine testing algorithm assuming:1 test per patient per year
Testing Need Phase 2	577,990	MOHCC National Targets 2014 – 2017 Revised 25th March 2014; 50% of all patients on ART
Coverage of total patient testing need in Phase 2 (%)	50%	
Actual VL tests (reagents) needed	699,136	Accounting for invalid tests (12%) and repeat tests (8%)

Table 5.2: Phase 2 national testing capacity

Lab	Testing Platform & Type	# of Platforms	Laboratory Capacity	Tests Allocated
NMRL	BM NucliSENS - DBS	1	80,000	72,000
NMRL	Roche Taqman - WB	1	41,400	10,350
Mutare	Roche Taqman - WB	1	41,400	10,350
Gweru	BM NucliSENS – DBS	1	31,464	31,464
Mpilo	Roche Taqman - WB	2	82,800	41,400
Chinhoyi	BM NucliSENS – DBS	1	31,464	31,464
TBD (MSF-supported)	BM NucliSENS – DBS	1	31,464	31,464
Total			**339,992**	**228,492**

TABLE 5.3: Phase 2 participating facilities

Level of testing	Site	Timeline
Routine VL testing for all patients (continued)	Buhera, Manicaland (29 centres) Gutu, Masvingo (23 centres) Chikomba, Mashonaland East (20 centres)	Already in place Already in place Already in place
Routine VL testing for selected patients (moving gradually towards routine testing for all patients)	Hospitals Harare Central Hospital Chitungwiza Hospital UBH Mpilo Ingutsheni BRIDH Wilkins Hospital Mutare Provincial Hospital All remaining provincial hospitals (7) Clinics Bulawayo Council clinics (15) Epworth clinics (5) Nyanga district via mobile mentoring team (1) Harare Clinics (8)	Already in place Already in place Already in place Already in place Already in place Assumed in place Assumed in place Already in place Already in place Already in place Already in place Already in place Already in place Assumed in place
Routine VL testing for selected patients expanded	All remaining district hospitals (47) Facilitated access to target VL for rural sites	
Total	**161**	

Appendix 6: Phase: 3 Overview and Capacity

TABLE 6.1: Phase 3 Overview

Estimated Number of Tests and Coverage	Phase 2	Rationale/Source
Patients eligible for ART	1,463,879	MOHCC National Targets 2014 – 2017 Revised 25th March 2014
Actual number of patients on ART	1,244,297	Coverage target of 85% for both adults and children
VL Testing Need (routine) =PATIENTS	1,244,297	Based on routine testing algorithm assuming 1 test per patient per year
Testing Need Phase 3	871,008	MOHCC National Targets 2014 – 2017 Revised 25th March 2014; 70% of all patients on ART
Coverage of total patient need in Phase 3(%)	50%	
Actual VL tests (reagents) needed	1,053,571	Accounting for invalid tests (12%) and repeat tests (8%)

Table 6.2: Phase 3 testing capacity

Lab	Testing Platform & Type	# of Platforms	Laboratory Capacity	Tests Allocated
NMRL – Gweru- HRE	BM NucliSENS –DBS	3	240,000	216,000
NMRL	Roche Taqman –WB	1	41,400	20,700
Mutare	Roche Taqman -WB	1	41,400	20,700
Chinhoyi	BM NucliSENS -DBS	1	48,576	43,718
Mpilo	Roche Taqman -DBS	2	82,800	62,100
4 new sites	TBD	TBD	TBD	TBD
POC platforms sites	TBD	TBD	TBD	TBD
Total			**454,176**	**362,678**

TABLE 6.3: Phase 3 participating facilities

Level of testing	Site
Routine VL testing for all patients	All tertiary, provincial and district hospitals
Routine testing for selected patients.	Rural health centres/clinics

Appendix 7: Distribution of available Primary Counselors

Province	Total PCs (GF supported)
Manicaland	121
Mashonaland East	107
Mashonaland West	85
Matabeleland South	56
Matabeleland North	49
Midlands	66
Masvingo	87
Mashonaland Central	98
Bulawayo	20
Harare	76
Total	765

Appendix 8: Viral Load Scale up Plan Development Committee

Name of Person	Designation and Name of Organisation	Position
Dr.Tsitsi Apollo	Deputy Director - HIV/AIDS and STIs, AIDS & TB Unit: Ministry of Health and Child Care (MoHCC)	Chairperson
Raiva Simbi	Deputy Director - Directorate of Laboratory Services : MoHCC	Writing Team Member
Dr. Zinyowera	National Laboratory Coordinator - Laboratory Services: MoHCC	Writing Team Member
Agrippa Mtambara	Logistics Manager - Directorate of Laboratory Services Logistics: MoHCC	Writing Team Member
Peter Gumbo	Chief – NMRL, Laboratory Services: MoHCC	Writing Team Member
Caroline Sirewu	National Coordinator - Care & Support: National AIDS Council (NAC)	Writing team Member
Dr. Sandra Simons	Medical Coordinator; Médecins Sans Frontières (MSF)	Writing Team Member
Dr. Temba Ncomanzi	Technical advisor - Care and Treatment: Elizabeth Glaser Paediatric AIDS Foundation (EGPAF)	Writing Team Member
Dr. Tonderai Murimwa	HIV-AIDS Specialist: UNICEF	Writing Team Member
Phibeon Mangwendeza	Access Programs Manager: Clinton Health Access Initiative (CHAI)	Writing Team Member
Simbisai Kadye	Finance Officer: Clinton Health Access Initiative (CHAI)	Writing Team Member
Tonderai Chiduku	National Stigma Index Coordinator: Zimbabwe National Network of PLHIV (ZNNP+)	Writing Team Member
Sheetal Patel	Program Specialist – Laboratory: Centers for Disease Control (CDC)	Writing Team Member
Nyasha Sithole	Laboratory Logistics Advisor: John Snow International (JSI)	Writing Team Member
Dr. Megan Dunbar	VP Social Policy and Programs: Pangaea Global AIDS	Writing Team Member
Imelda Mahaka	Country Coordinator: Pangaea Zimbabwe AIDS Trust (PZAT)	Writing Team Member
Ana Svoren	Associate: Clinton Health Access Initiative (CHAI)	Writer
Tatenda Shoko	Analyst: Clinton Health Access Initiative (CHAI)	Writer
Jane Batte	Strategic Intervention Advisor: UNAIDS	Reviewer
Dr. Christine Chakanyuka	National Professional Officer – HIV/TB:WHO	Reviewer

MINISTRY OF HEALTH AND CHILD CARE