ASLM

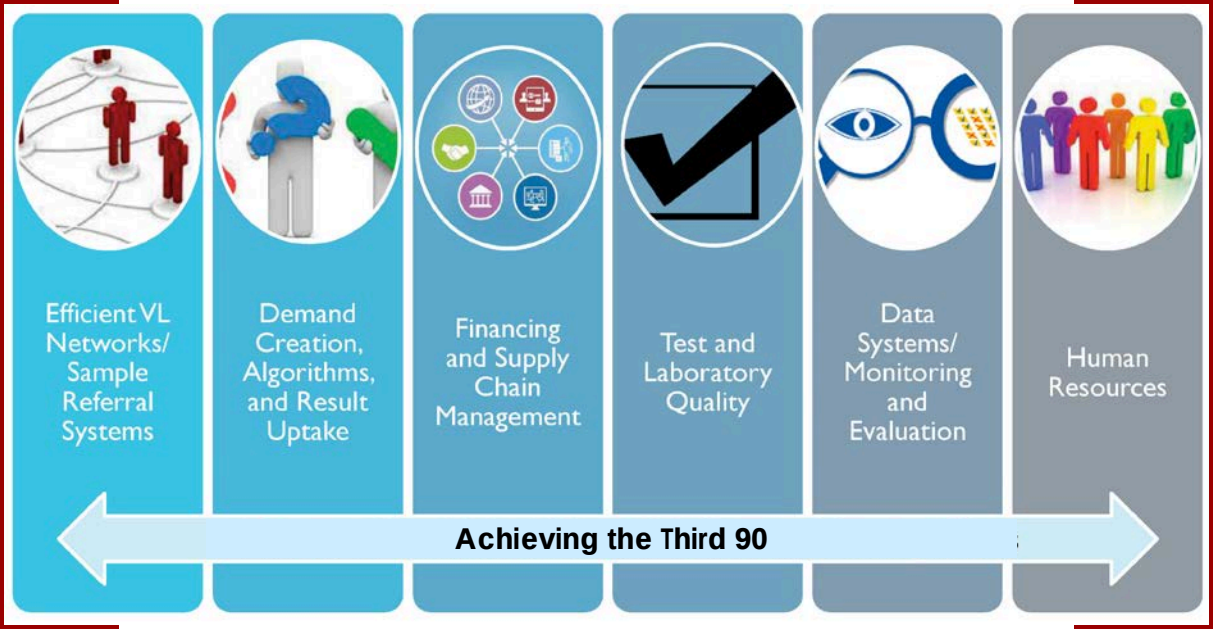
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Regional Workshop on HIV Viral Load Scale-Up

Addis Ababa, Ethiopia

23-25 October 2017

MEETING REPORT



ABBREVIATIONS

AJLM	African Journal of Laboratory Medicine
ANC	Antenatal care
API	Application programme interface technology
ART	Antiretroviral treatment
ASLM	African Society for Laboratory Medicine
BMGF	Bill & Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CEO	Chief Executive Officer
CROI	Conference for Retroviruses and Opportunistic Infections 2018
CQUIN	Commissioning for Quality and Innovation
DBS	Dried blood spot
EAC	Enhanced adherence counselling
ECHO	Extension for Community Health Practices for Outcomes
EID	Early infant diagnosis
EMR	Electronic medical record
ESARO	Regional Office for Eastern and Southern Africa (UNICEF)
ICASA	International Conference on AIDS & STIs in Africa
IVT	Infant virologic testing
LabCoP	Laboratory Systems Strengthening Community of Practice
LabEQIP	Laboratory Efficiency and Quality Improvement Planning
LARC	African Regional Collaborative for Laboratory Technologists and Technicians
LIMS	Laboratory information management systems
M&E	Monitoring and evaluation
MOH	Ministry of Health
MOHSS	Ministry of Health and Social Services
NHLS	National Health Laboratory Service
OGAC	Office of the US Global AIDS Coordinator
PEPFAR	US President's Emergency Plan for AIDS Relief
PMV	Post-market validation
POC	Point-of-care
QA	Quality assurance
SLMTA	Strengthening Laboratory Management Toward Accreditation
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SOP	Standard operating procedure
STI	Sexually transmitted infection
TAT	Turn-around time
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNM	University of New Mexico
USAID	US Agency for International Development
VL	Viral load
WHO	World Health Organisation
WHO/AFRO	World Health Organisation, Regional Office for Africa

CONTENTS

BACKGROUND

HIV viral load (VL) testing—the determination of how many viral particles of HIV are circulating in blood plasma—plays an essential role in HIV/AIDS programmes. HIV VL testing can help healthcare providers predict disease progression, determine risk of opportunistic infections, evaluate prognosis in the early stages of HIV infection, and measure patient response to antiretroviral treatment (ART).[1]

To ensure patients are responding to ART and to achieve the third goal of the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 target (See Figure 1)—achieving viral suppression in 90% of HIV-positive patients who are on treatment—healthcare providers must have access to and make use of HIV VL testing.[2] Delayed or unprovided HIV VL testing can lead to drug resistance and failure to switch patients to more appropriate ART, resulting in treatment failure and poor patient outcomes.[3]

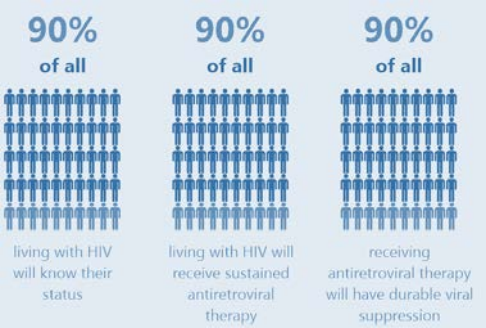


Figure 1. The UNAIDS 90-90-90 goals.

To effectively monitor people on ART using HIV VL testing, many African countries have engaged in VL testing scale-up efforts. Health stakeholders in the African region now aim to address identified barriers in HIV VL scale-up, closing implementation gaps along the HIV VL cascade (See Figure 2).[4]

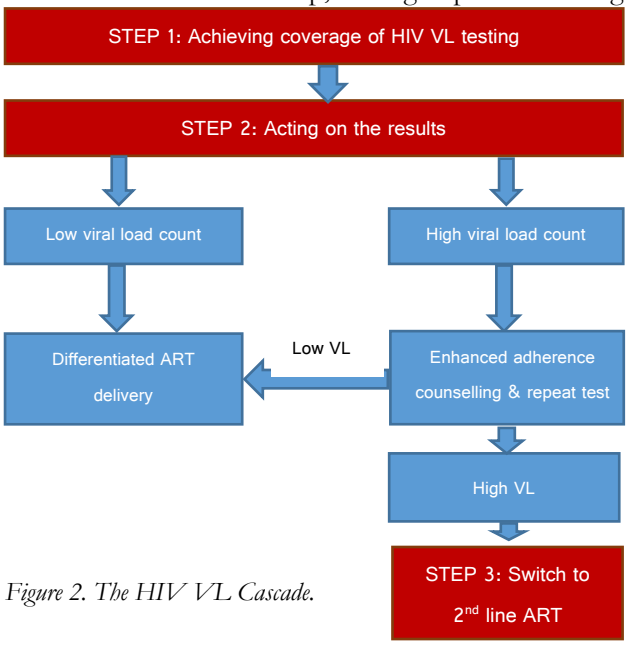


Figure 2. The HIV VL Cascade.

[1] NAM Publications. (2017). Uses of viral load testing. Retrieved 12 December 2017 from: https://www.aidsmap.com/Uses-of-viral-load-testing/page/1729306/
[2] Alcorn, K. (2017, January 4). Viral load testing capacity still weak in sub-Saharan Africa, 7-country study finds. Retrieved 12 December 2017 from: https://www.aidsmap.com/Viral-load-testing-capacity-still-weak-in-sub-Saharan-Africa-7-country-study-finds/page/3107907/
[3] Alcorn, K. (2017, January 4). Viral load testing capacity still weak in sub-Saharan Africa, 7-country study finds. Retrieved 12 December 2017 from: https://www.aidsmap.com/Viral-load-testing-capacity-still-weak-in-sub-Saharan-Africa-7-country-study-finds/page/3107907/
[4] ASLM. (n.d.). HIV Viral Load Scale up Tools. Retrieved 12 December 2017 from: http://www.aslm.org/resource-centre/hiv-viral-load-testing/hiv-viral-load-scale-tools/

EXECUTIVE SUMMARY

From 23-25 October 2017, the African Society for Laboratory Medicine (ASLM), a pan-African medical laboratory association at the leading edge of issues of public health importance in Africa in collaboration with CDC, convened a regional meeting around the theme of HIV VL testing scale-up in the African region. Over 137 stakeholders from 26 countries gathered in Addis Ababa, Ethiopia for the meeting, which included participants from African Ministries of Health (MOHs), the US Centers for Disease Control and Prevention (CDC), the US President's Emergency Plan for AIDS Relief (PEPFAR), the World Health Organisation (WHO), implementing partners and professional organisations representing healthcare professionals, policy makers and researchers.

The purpose of the meeting was to discuss and evaluate recent progress in HIV VL scale-up efforts, share best practices and new strategies for VL implementation, and launch a new ASLM initiative to support HIV VL scale-up, known as the Laboratory Systems Strengthening Community of Practice (LabCoP) initiative.

Opening presenters for the regional meeting included Dr Kebede Worku, State Minister of Health for Ethiopia, Lolem Ngong, Coordinator of PEPFAR Ethiopia, and Dr Ali Elbireer, former Chief Executive Officer (CEO) of ASLM. In his welcoming remarks, Dr Elbireer greeted partners and attending organisations, thanking them for their participation and reaffirming ASLM's commitment to quality laboratory and diagnostic systems in Africa. He highlighted key ASLM strategic goals including healthcare workforce development and laboratory accreditation, which also bolster regional capacity for HIV VL scale-up.

Dr Heather Alexander, Branch Chief of the International Laboratory Branch of the US CDC, provided a keynote address to begin the meeting and summarized the successes and remarkable progress that has been made in reaching the 90-90-90 targets. She cautioned that systems remain vulnerable, e.g. stock-outs, and emphasised a pressing need for to use test results to provide improved patient outcomes and not simply to focus on testing capacity or the number of tests performed.

Throughout the three-day meeting, workshop speakers and attendees highlighted cross-cutting country findings from national approaches to HIV VL scale-up. Across settings and countries, participants found that HIV VL coverage continues to pose challenges, as does long turn-around times (TAT) from testing to return of results. Furthermore, meeting stakeholders concluded that lack of coordination among stakeholders leads to unnecessary procurement of instruments, stock-outs, inadequate service coverage, and fragmented quality and data systems.

To address remaining gaps identified during the meeting and improve ongoing scale-up of HIV VL testing, participating stakeholders agreed on the following recommendations and steps moving forward:

- Invest in healthcare systems;
- Improve VL data collection, management, and use;
- Strengthen clinical and laboratory systems interfaces to improve data use and patient outcomes;
- Create greater patient demand for HIV VL services;
- Develop innovative resources and enhance use of available tools, monitoring and evaluation (M&E) and datasets to reinforce existing VL programs;
- Optimise sample transport and result reporting.

To facilitate the implementations of shared goals, partners and stakeholders will be able to leverage a new platform from ASLM and partners, the LabCoP initiative, which was officially launched during the meeting. Moving forward, LabCoP will serve as a collaborative knowledge-sharing system for strengthening laboratory system functions and accelerating the scale-up of HIV VL testing for improved patient management.

LABORATORY SYSTEM STRENGTHENING COMMUNITY OF PRACTICE (LabCoP)

During the HIV VL regional meeting, Dr Pascale Ondoa, Director of Science and New Initiatives at ASLM, formally launched ASLM's new Laboratory System Strengthening Community of Practice (LabCoP) initiative.

"LabCoP is a shared learning network for knowledge creation and dissemination through interaction between field workers and subject matter experts and from peer to peer," said Dr Ondoa. "This multi-country platform intends to gather the different stakeholders and disciplines involved along the HIV VL cascade. It will contribute to reinforcing the laboratory-clinic interface and bridging the gap towards the third 90 target of UNAIDS."

Dr Ondoa went on to describe how LabCoP will be a means for stakeholders from different countries to share their successes and best ideas, initially around HIV VL scale-up, with the goal of improving HIV patient care (See Figure 3). Without the means of identifying and disseminating best practices and innovations between countries, HIV programme stakeholders across Africa will inevitably duplicate efforts and operate in silos, resulting in lost opportunities and wasted effort. LabCoP will fill the current vacuum for collaborative platforms and multidirectional learning around laboratory systems and HIV VL testing scale-up.

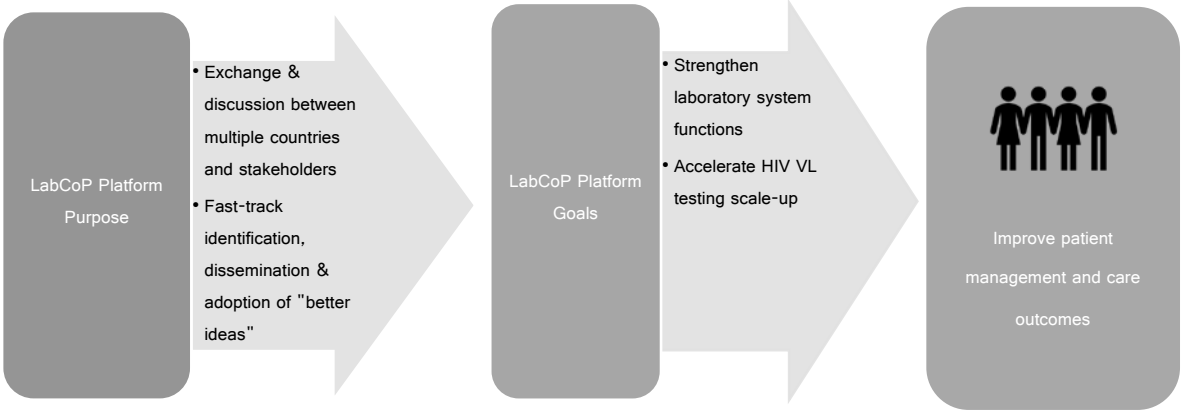


Figure 3. ASLM Laboratory System Strengthening Community of Practice (LabCoP) overview and purpose.

ASLM will lead and implement the LabCoP, with the Bill and Melinda Gates Foundation (BMGF) providing funding. ICAP will provide scientific and technical assistance to the knowledge creation component of LabCoP based on its experience with convening the Commissioning for Quality and Innovation (CQUIN) network for HIV differentiated care. The University of New Mexico (UNM) School of Medicine, will supply technical assistance for knowledge dissemination, following the Project Extension for Community Health Practices for Outcomes (ECHO) model.

LabCoP is an outcome of the regional VL meeting of Swaziland in 2016, and will address topics including the laboratory-clinic interface, VL testing demand creation, sample referral systems, supply chain management, quality assurance and workforce development. LabCoP will be organised around four activity packages: identification of best practices, dissemination of best practices, implementation of M&E frameworks, and development of investment cases and advising on specific interventions (See Figure 4).

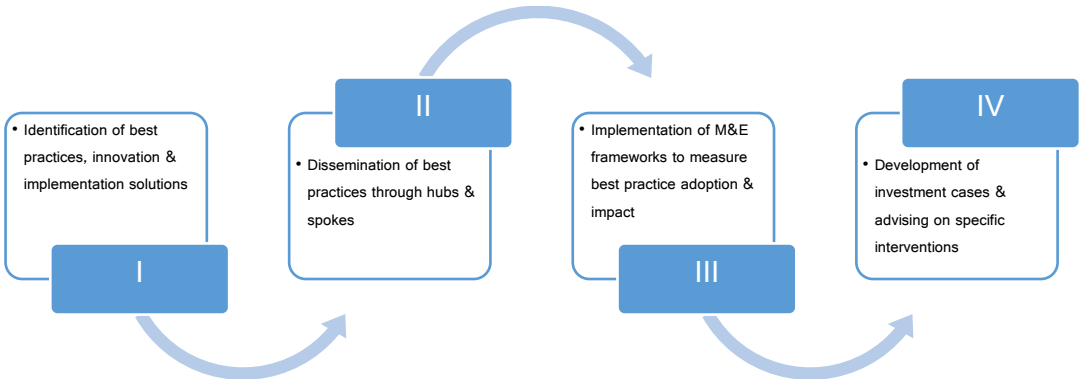


Figure 4. Activity Packages of LabCoP.

LabCoP members will consist of country teams rather than individuals, incorporate interactive online seminars, and promote but not fund the implementation of best practices. Member countries will benefit from access to the following:

- Video conference sessions once a month to discuss key issues around VL testing;
- Resource materials available on the project website (hosted by ASLM);
- Framework for country self-assessment of the VL cascade;
- Linkage to other relevant shared learning networks.

The LabCoP is "the result of months of very hard work, goodwill and vision from many people who are here today," said Dr Ondoa during her speech. "I hope that you appreciate this moment as much as I do."

For more information about the ASLM LabCoP, please visit: http://www.aslm.org/what-we-do/aslms-laboratory-systems-strengthening-community-practice-labcop/.

Meeting attendees from 26 countries gathered in Addis Ababa, Ethiopia.

PRESENTATIONS

Where made available by participants, PDF versions of the presentation materials used at this meeting are available at: http://bit.ly/2017VLMeetingReport. In the descriptions of the sessions below, presenter names and titles are shown in bold to allow the materials to be easily referenced.

DAY I SESSIONS

Day 1 of the regional meeting included three sessions entitled "Reaching the Third 90," "Country Progress with Viral Load Scale-Up," and "Point-of-Care (POC), The Network Approach and Supply Chain."

SESSION I - Reaching the Third 90

The first session, "Reaching the Third 90," marked the start of the meeting and included welcoming remarks and an opening address. **Dr Kebede Worku**, State Minister, MOH Ethiopia, gave **Welcoming Remarks**, during which he spoke of the progressive transformation of the regional agenda for HIV prevention, detection, and response, in which VL testing has a key role. Dr Worku described the progress made in Ethiopia in expanding laboratory systems and specimen referral network. He noted a steep increase in VL testing coverage in the last year alone, and emphasised plans to use dried blood spots (DBS) and POC testing in VL scale-up. Concluding his remarks, he acknowledged the timely nature of the meeting to share progress and best practices and charged the attendees with using the coming days and discussions to continue the strong forward progress to roll out VL testing. Following Dr Worku was Lolem Ngong, PEPFAR Ethiopia Coordinator who highlighted major accomplishments in terms of national VL expansion and transport system strengthening for VL testing reinforcing that these efforts can only succeed with strong partnerships. ASLM CEO, Dr Ali Elbireer, also gave remarks, welcoming participants to the meeting, stressing the range of organisations and nations in attendance and underscoring the role of ASLM and its broad commitment to achieving the 90-90-90 goals and national HIV VL scale-up targets.

Following the welcoming remarks was an opening address by **Dr Heather Alexander**, Branch Chief of the International Laboratory Branch of the US CDC, "**Reaching the Third 90: Progress, Innovation, and Partnerships Across the Viral Load Spectrum**". Dr Alexander reviewed global progress towards achieving UNAIDS targets and regional progress towards attaining PEPFAR HIV VL scale-up goals in Africa, reflecting on progress since the process accelerated following a consultation on VL scale-up in Cape Town, South Africa, in 2013. She also discussed gaps in programme progress and challenges to VL

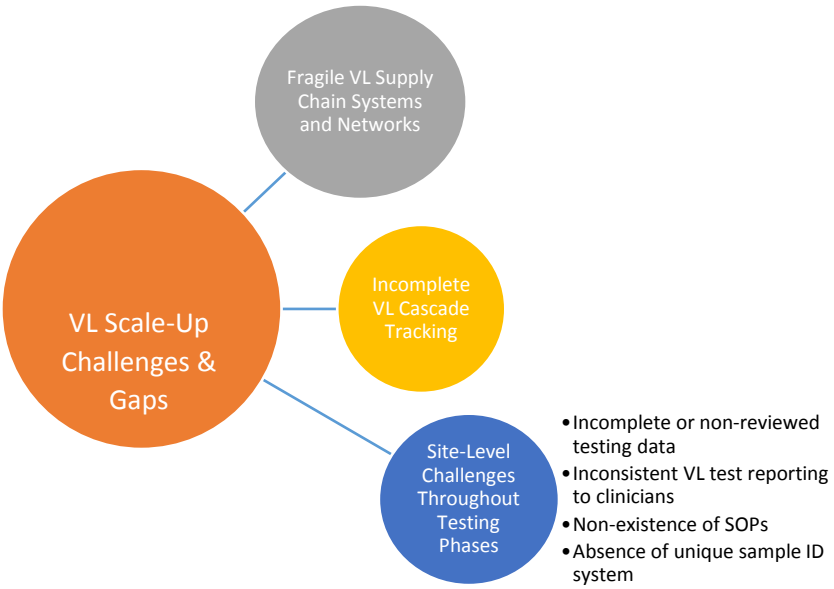


Figure 5. Gaps in VL testing progress and challenges to scale-up.

scale-up (See Figure 5) before turning to the multi-disciplinary approach, which includes innovations, tools and resources, that are helping to resolve identified challenges (See Figure 6).

Network optimising	• Map testing sites & referral networks • Near-POC testing for priority populations • Calculate current & maximum testing capacity
Facility readiness	• Facility Readiness Assessment Tool: o 5 sections: facility traits, clinical care, lab, M&E o Gives score indicating readiness for VL scale-up
Patient education	• Standardised enhanced adherence counselling for patients with high VL • Different learning content for children, adolescents & adults
VL forms	• Individual high VL form: Placed in patient chart to track patients with high VL • High VL register: Longitudinally tracks patients with high VL
Lab-clinic interface	• Lab-Clinic Interface Continuous Quality Improvement (CQI) project: Learning collaboration using proven CQI methods to strengthen lab-clinic interface
Lab CQI	• VL/Infant Virologic Testing Lab Scorecard & Hub Checklist: o Pilot Findings: Highest scores among accredited labs or labs enrolled in SLMTA
PT	• Proficiency testing for HIV VL testing ensures quality assurance & CQI
M&E	• Quarterly Monitoring Tool: o Routine tracking of VL scale-up & results o Analysis of VL risk factor data o Standardised backlog ID & rapid mitigation
Information management	• Integration of electronic lab & clinical information systems

Figure 6. Multi-disciplinary innovations, tools and resources used by CDC and partners to advance HIV VL scale-up and address challenges.

Dr Alexander stressed that while significant gains in VL scale-up have been made, there is still much work to be done to meet VL testing targets. She noted key challenges in meeting testing targets, including supply stock-outs and backlogs, and the complexities of using an interdisciplinary approach for scale-up. Dr Alexander noted that testing capacity alone is insufficient; it is also vital that VL test results are used to improve patient outcomes and maintain viral suppression. Leveraging tools and solutions, such as network optimisation, facility assessments, quality control and external quality assessment, and electronic information systems will be essential to closing gaps, Dr Alexander stated. She reminded participants at the meeting that this work is not the responsibility of laboratories alone, nor is it the job of only

clinicians. National plans must include examinations of site-level challenges and use data to review, adjust and refine implementation efforts. As an example, she noted the work piloted in Malawi, Mozambique and Kenya under the Laboratory Regional Collaborative (LARC), which has strengthened the laboratory-clinic interface in those countries using data and information management. She described a hope that this meeting and LabCoP will allow these and other successes to be discussed and built upon.

Dr Shirley Lecher of the CDC followed the opening address, outlined the **Workshop Objectives** (See Figure 7) before passing the baton to Dr. Fatim Cham-Jallow of the WHO Regional Office for Africa (WHO/AFRO).

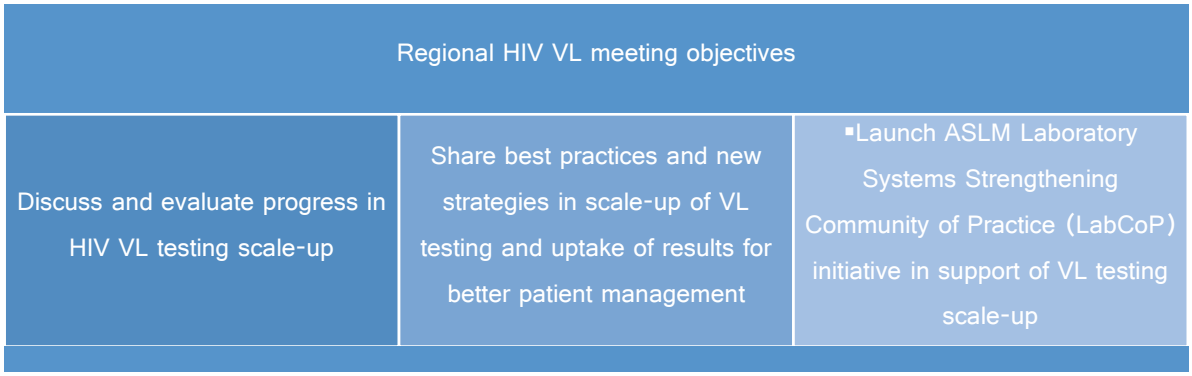


Figure 7. Objectives of the October 2017 regional HIV VL testing scale-up meeting in Ethiopia.

Dr Fatim Cham-Jallow's presentation, "**90-90-90 Current Status**" outlined efforts towards achieving the UNAIDS treatment targets for HIV and remaining gaps to be addressed.[5] She took note of ongoing gaps impeding the realisation of the 90-90-90 targets, such as late treatment initiation, drug resistance and suboptimal funding for HIV programmes. Of concern is that, while steady progress towards the targets is being made, there still remain significant gaps in Africa, particularly in the Western and Central parts of the continent. Additionally, the spread of resistance to first-line drug regimens will further complicate the challenge of achieving sustained viral suppression and meeting the third 90. To close the gaps, she said, stakeholders must undertake innovative strategies, including near-POC infant virologic testing (IVT) and self-testing to meet the first 90 target, integrated service delivery and the development of new, cost effective ART to meet the second 90 target, and mobile tools, peer support groups and the appropriate use of second- and third-line ART to meet the third 90 target.

> "Global solidarity and shared responsibility will be key to closing the remaining gaps to meet the 90-90-90 goals", Dr. Cham-Jallow

[5] "By 2020, 90% of all people living with HIV will know their HIV status. By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy. By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression." Source: UNAIDS. (2017, January 1). 90–90–90 - An ambitious treatment target to help end the AIDS epidemic. Retrieved from: http://www.unaids.org/en/resources/documents/2017/90-90-90.

Dr Ali Elbireer then presented an **ASLM update**, and laid out ASLM's ongoing goal of ensuring system-wide healthcare improvements through investment in laboratory workforce development and service quality in Africa. By relying on the WHO/AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), Dr Elbireer said, African laboratories can move towards readiness for international accreditation. International accreditation has been attained by 522 African laboratories to date, of which approximately 21% are located outside of South Africa. There is a need to expand access to SLIPTA beyond the focal points located within MOHs, and ASLM plans to work with WHO and Africa CDC to achieve this. ASLM is also aware that SLIPTA is used outside of the official programmes and PEPFAR-funded work, and they hope to collect this information as part of ongoing effort to map laboratory systems via a project funded by the BMGF, which will allow counties to self-report data. He also upheld the vital role of the ASLM scientific journal, the *African Journal of Laboratory Medicine* (AJLM), which is now indexed on PubMed. AJLM publishes research papers and science editorials from African scientists with the goal of advancing the eminence of Africa-based laboratory science contributions to research literature and to provide a voice for African scientists.


Dr Ali Elbireer, former CEO of ASLM

Dr Lara Vojnov of the HIV Department of WHO then presented on "**Clinical considerations in scaling up viral load testing**," in which she explained the problem that a relatively small proportion of patients found to have an elevated VL count receive a second, confirmatory VL test, which results in delays in connecting patients to second-line ART. Dr Vojnov stated that delays in initiating second-line ART with patients may be due to underutilisation of VL testing results by clinicians. Loss of patients to follow-up testing and treatment occurs at even the best funded sites and hampers the effective treatment of patients and maintenance of viral suppression. "We have had huge achievements in scaling up viral load testing capacity," she said. "Now we need to ensure that clinicians are using the results." Dr Vojnov concluded her presentation with a call to action for attendees to identify and implement solutions to strengthen the laboratory-clinic interface and address the issue of underuse or non-use of test results.

The nex presentation, "**Community Engagement – An Essential Component of VL Scale-up Success**," included three speakers from three countries--**Rumidzai Matewe** (Zimbabwe), **Patricia Asero** (Kenya) and **Jacqueline Alesi** (Uganda). Matewe remarked that people living with HIV in remote communities often have insufficient knowledge about HIV; thus, public health stakeholders must increase health education among targeted sub-groups to facilitate uptake of HIV services. Asero presented on the need to address clinicians' reluctance to switch patients from failing treatment regimens to second-line ART, stating that educating communities on available HIV services can help create consumer demand in communities. Finally, Alesi advised attendees to remember that behind HIV targets are people living with HIV, who should be approached as partners with realistic and appropriate approaches and interventions.

SESSION II - Country Progress with Viral Load Scale-Up

Session II, "**Country Progress with Viral Load Scale-Up**," consisted of three groups representing a total of 22 African countries and incorporated presentations on country VL successes and potential solutions to identified challenges. The session was facilitated by speakers and moderators from ASLM, country MOHs, the CDC, the Global Fund, PEPFAR, UNM's Project ECHO and UNITAID, among others.

During the session, country presenters reviewed their national HIV VL strategies and updated participants on VL progress over the past year, sharing the successes and challenges of HIV VL scale-up. Each presenter spoke on HIV VL platforms, sample referral networks and result return networks used for country implementation of VL scale-up. Presentations revealed that most countries have not yet implemented DBS testing for VL and that they face similar and overlapping challenges, including inadequate human resources, test service interruptions, insufficient sample transport systems and ineffective workflow processes. As a result, session participants agreed on the need to improve electronic systems for data tracking, tools to manage non-suppressed patients, sample management and results networks, DBS scale-up, POC testing integration and M&E processes.

Following the country presentations, speakers sought to respond to challenges identified by countries in the course of their HIV VL scale-up. **Eileen Burke** of the Global Fund gave a presentation entitled, "**The Global Fund plan to reach the third 90**." The presentation highlighted current funding proportions in HIV programs and a lack of precise data on specific funding allocated for VL testing, which can be improved with more emphasis on VL scale-up and better data collection. Burke also highlighted the importance of assuring transparency in costing by creating agreements with manufacturers. She also underscored a key guiding principle of her organisation that existing machines must be optimised prior to investment in additional instruments. Finally, the presentation emphasised that GeneXpert system access should not be expanded without first considering the system investment required; thus, Burke proposed supporting both CD4 and VL testing where appropriate. Given the finite funding available, she strongly recommended a focus on data driven approaches for the optimisation of existing equipment and integration of services including transportation, training and maintenance to strengthen systems over the continued development of new molecular biology laboratories. These data would be very well received by Global Fund in support of funding requests, and she emphasised that all stakeholders within a country should play a part in finalizing grant applications to ensure that a holistic approach to service provision is proposed.

"**Global Diagnostic Procurement Consortium**" was presented by **Dr George Alemnji** of the Office of the US Global AIDS Coordinator (OGAC), which leads PEPFAR implementation. Dr Alemnji discussed the procurement consortium, which was created to address lack of coordination among HIV stakeholders. Referring to data showing equipment underutilisation in resource-limited settings, the speaker stated that POC and innovative technologies should fill gaps in HIV care, but not replace conventional technologies. He also touched upon the idea of multiplexing technologies such that platforms can be used for HIV, tuberculosis and other disease testing to leverage service and running costs for equipment. He concluded with brief remarks on the importance of supply-side price strategies for integrated diagnostics, and mentioned waste management challenges related to lack of country capacity for safely removing waste from VL testing.

Dr Pascale Ondoa provided an overview of the "**ASLM Community of Practice**", LabCoP, which is described earlier in this report. She explained that surveys have been distributed to assist with the development of LabCoP and asked that participants follow the emailed link which had been sent. The survey results would be presented during the formal launch of LabCoP at the dinner on the evening of Day 2 of the meeting. A phased roll out involving stakeholders for a diverse group of disciplines in pilot countries will be used to trial the community of practice and fine tune the approach. The end goal is to disseminate best practices, develop framework documents and share information on approaches via regular, structured, moderated discussions and electronic communications.

Dr Bruce Struminger of UNM presented "**ECHO Case Based Models to Share Best Practices for Program and Laboratory Improvement**" describing successes of ECHO, a programme that harnesses virtual communication (including video conferencing), training, mentorship and M&E to expand healthcare access in the US and abroad (See Figure 8). Dr Struminger shared background on the Project ECHO model, which relies on case-based learning and sharing of best practices to improve and expand HIV programmes in African countries, including Kenya, Namibia and Uganda. Significant achievements in increasing engagement, decreased staff feelings of isolation and multidisciplinary efforts to align fragmented systems have been recorded to date. Project ECHO is a technical partner on the ASLM LabCoP project and will bring skills in leveraging technology, including multidirectional learning and multipoint videoconferencing, to bridge the geographical gap between field sites, hubs and technical experts.

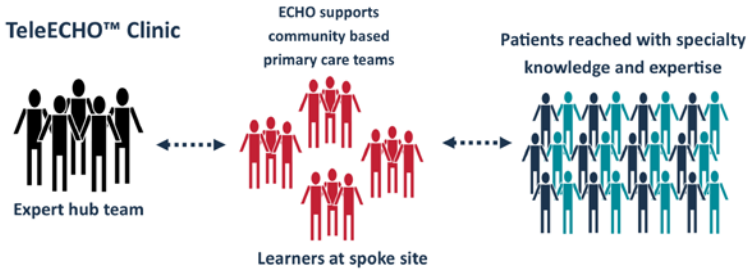


Figure 8. The Project ECHO platform.

Next**, Frank Basiye** of the US CDC, Kenya presented around the theme "**Viral load champions**." Focal personnel which are part of Kenya's national HIV program. that closely monitor the VL cascade can serve as VL champions, said Basiye, which will allow the identification and communication of scale-up issues to different levels of the healthcare delivery system. He highlighted recent successes of using VL champions in a Kenyan context, which have helped to distribute responsibilities to identified personnel rather than falling upon overloaded laboratory leadership. These champions communicate results with clinicians, track sample transportation, return of VL results and monitor system status on a daily basis. The National Champion analyzes this information to identify trends and report status to a leadership level allowing any bottlenecks or issues to be quickly identified and addressed.

SESSION III – Point-of-Care (POC), The Network Approach and Supply Chain

Session III was based around the title, "**Point-of-Care (POC), The Network Approach and Supply Chain**." The session included four speakers and was moderated by representatives from the MOH of Kenya, UNITAID and the CDC.

With "**Considerations for Introduction of Point-of-Care Testing in National Diagnostic Network**," speaker **Dr Clement Zeh** of CDC Atlanta presented on the role of POC for early infant diagnosis (EID) and VL, the lessons learned from rapid HIV POC testing scale-up, introduction of POC testing through a consensus framework, and quality assurance and improvement for POC and VL testing. He also introduced the planned launch of a POC toolkit at the Conference for Retroviruses and Opportunistic Infections 2018 (CROI 2018) in Boston, Massachusetts, United States. The POC toolkit will address considerations for POC testing, including policy framing and development, strategic planning, regulatory approval, quality assurance and data management, procurement and supply chain management and implementation. Dr Zeh wrapped up the presentation with a word on the importance of device connectivity for real-time quality and data monitoring.

Seth McGovern, of the Clinton Health Access Initiative (CHAI), , gave the subsequent presentation, "**Accelerating access and integration of innovation POC HIV technologies in national diagnostics programs**." Even though POC EID is shown to increase ART initiation for HIV-positive infants, McGovern noted, half of EID results never reach patients, resulting in lost opportunities to initiate infant HIV treatment early. To address this gap and accelerate uptake and correct use of POC technologies, including CD4, EID and VL tests, CHAI has collaborated with the United Nations Children's Fund (UNICEF) on a POC project since 2012, joining forces to integrate POC testing into existing networks. McGovern shared the successes, goals, and next steps of the project, which is in effect until at least 2020. He added that, while costly on a per test basis, POC provides results at the time of visit, reducing TAT and the risk of loss of patients to follow up. Additionally, POC tests usually do not require the purchase or maintenance of complex equipment; thus, costs must be weighed with these additional factors in mind, not just the simple cost per test when compared to conventional laboratory systems.

Continuing the discussion on the CHAI-UNICEF partnership for POC scale-up was **Geoffrey Chipungu** from the UNICEF Regional Office for Eastern and Southern Africa (ESARO), in place of Dr. Chewe Luo on the agenda. Chipungu's presentation, "**Paediatric HIV POC diagnostics and the status of viral load suppression**," covered background information around the issue of low viral suppression among children with HIV, as well as the role UNICEF is playing to address POC, VL and treatment gaps through its project with CHAI. Suppression rates in paediatric populations are often low and this is exacerbated because of challenges with adherence to treatment in this group as medications are unpalatable, dosing changes with the child's weight and reliance upon a responsible caregiver or guardian. Capacity for testing must be coupled with capacity to interpret results, to provide infant-specific adherence counselling and capacity to provide the most appropriate formulation of ART. He also made a recommendation for POC programs to incorporate more routine testing and monitoring in antenatal care (ANC) and in postnatal/breastfeeding women.

"**The Network Approach and Supply Chain Considerations for Successful VL/IVT Scale-Up**," a presentation from **Jason Williams**, from the US Agency for International Development (USAID), covered the concepts of a network approach and supply chain management. Williams described the network approach as leveraging an in-depth knowledge of "the national laboratory network and supportive systems to inform efficient and effective programme growth and instrument expansion." To implement a baseline approach requires baseline mapping of country laboratory systems, available laboratory instruments, and use of available instruments. This can be used, accompanied by usage rate data, to determine if equipment has been deployed in the correct locations and to identify system efficiencies. Mapping laboratory instruments through resources such as the Laboratory Efficiency and

Quality Improvement Planning (LabEQIP) tool facilitates laboratory network understanding, Williams noted, and helps ensure that POC and VL programme strategies are consistent with country goals and capabilities. By mapping existing capacities and comparing this to a map of planned capacities, it is possible to forecast project impacts and make a robust case for investment. Additionally, supply chain considerations such as price variations, forecasting and procurement must be well-understood for programme scale-up to be possible. Williams noted the importance of tackling challenges such as unpredictable demand, inadequate tracking of laboratory supply use, and weak or non-existent service contracts for equipment and reagents. It may be possible to ask for assistance in this regard from service providers and vendors, and to periodically revisit and review terms of contracts, particularly when planning maintenance contracts where clarity in expectations are key, particularly regarding provisions for spare parts and response times.

DAY II SESSIONS

Day 2 of the regional meeting on 24 October included three sessions on HIV VL M&E, clinical care, and laboratory medicine.

SESSION IV – Viral Load Monitoring and Evaluation (M&E) Progress, Ongoing Challenges, and Future Focus

Session IV included presentations on the theme of "**Viral Load Monitoring and Evaluation (M&E) Progress, Ongoing Challenges and Future Focus**."

Nadia Solehdin of CDC Atlanta took the podium to discuss "**Viral Load M&E Progress and Existing Challenges**". Emphasising that M&E systems have been significantly strengthened in recent years including the development of specific plans, indicators, forms, and tools, she cautioned that further work is likely required to capture all relevant data. She listed ongoing M&E challenges related to unlinked data systems, data quality and poor use of data. Particularly important, she noted, is consistent application of the same set of indicators at all sites, e.g., PEPFAR indicators to allow direct comparison of data and the inclusion of numerator and denominator designations, so that data can be understood by all stakeholders. Solehdin also provided suggestions on future priorities for M&E, including improved data collection and use, use of standardised data quality checks, visualisation of data on dashboards, triangulation of data from multiple sources and programme areas to validate trends, and prioritisation of interfaces with existing in-country data systems. Solehdin also stressed the necessity of taking an interdisciplinary approach to VL target setting and monitoring. She concluded by asking participants to consider what M&E may look like in the era of widespread POC testing and how they may need to revise data collection and systems to address the changes.

Jonathan Ntale, CDC Uganda, presented on "**Viral Load M&E Plan Development**," stating that programs must balance feasibility and comprehensiveness when developing M&E plans for VL testing. He reminded participants that, as was stated by the community engagement speakers on Day 1, M&E data are not just numbers—they represent individual's health status. Ntale then presented Uganda's VL scale-up plan for 2015 to 2016, which included an M&E plan involving tracking of key indicators including VL coverage, suppression, sample rejection, results TAT, and others. M&E has been cascaded to all regional sites in the country to assist in data collection. Ntale also explained how the country uses an electronic VL dashboard for real-time facility-level M&E, and described which stakeholders are involved in M&E at the national and facility level. The electronic system is used to identify trends and challenges, while a simple system of coloured stickers flags patient records for follow up testing. He noted it is important to use the correct systems in the correct place and not over complicate approaches, as this reduces compliance. He emphasised that the start of the M&E process in this instance is the test request form. When designing their process, they spent significant time ensuring that the form captured all the necessary information, providing a strong foundation for data collection, engaging with stakeholders at all levels of implementation, and not just leadership to obtain commitment and buy in.

> M&E promotes equality and equity of service allowing best practices to be identified and disseminated.
> Jonathan Ntale

Nadia Solehdin of CDC Atlanta returned to the podium to discuss the challenge of "**Viral Load target-setting**". VL target-setting requires a specific, context-sensitive approach, said Solehdin, and must incorporate considerations such as national testing guidelines and algorithms, cohort size, sub-population needs, and more. Behind every target is an individual and those targets allow for tracking of program progress, drive the allocation of resources, and ultimately are used to hold programs accountable; targets are not arbitrary they have power and must be set with care. Targets should be comprehensive, i.e., consider subpopulations within the target group. While this approach involves significantly more data than simple, high-level targets, it provides greater coverage and insights into program performance. It was recommended that an interdisciplinary team be convened to set targets for different sectors, including

laboratory personnel, clinicians, procurement/commodities, and transportation specialists. Solehdin concluded with a reminder that all formulas and assumptions used in setting targets should be documented to simplify the review and revision of targets in subsequent years.

CDC Tanzania Laboratory Advisor **Michael Mwasekaga** gave the next presentation, "**Overcoming Laboratory Challenges: The Tanzania Experience**." Mwasekaga provided an overview of Tanzania's PEPFAR-supported HIV programme before delving into the M&E framework and tools implemented by the programme to assist in addressing stock-outs and commodity challenges. By providing a detailed description of the manner in which Tanzania set their 2017 testing targets, he provided the meeting attendees with a framework around which they could similarly set realistic testing targets and forecast budget and commodity needs. Emphasising the previous speaker's statement that a multidisciplinary team is needed for setting appropriate goals, he went on to say that this approach also meant that there was a mutual understanding of the goals, which assisted in implementation during the year. He conceded that this is a laborious and time-consuming process, particularly when considering the makeup of subpopulations of people living with HIV, the effort is necessary to make realistic predictions of the number of tests to be performed. For the FY18 targets, which are currently being set, the same assumptions and methodology will be used, with refinements made based on the 2017 experience. By building on their previous work, the process can be completed more quickly. Thus, from the experience in Tanzania, he strongly recommended taking the time to carefully set goals in the first instance and documenting the process and assumptions, as this sets a programme up for subsequent years and future success.

"**Viral Load reporting: Tracking Number of Tests Versus Individuals**" was the subject of the next presentation by **Seyoum Dejene**, HIV and Tuberculosis Advisor for USAID Uganda, in place of Jonathan Ntale. Dejene spoke of the utility of using an electronic VL dashboard (also mentioned by Jonathan Ntale during his presentation), to view data on numbers of samples tested and patients tested. Further analysis can identify patients who have had more than one VL test in a given period. During the initial investigation of the ability of the system in Uganda to track individual patients, it was discovered that samples were often not linked to the correct patient identification number. This meant that duplicate tests were often ordered and results were not received, leading to patients being lost to follow-up. Once this had been resolved through training and the use of alternate identification numbers like telephone numbers, the level of sample rejection was significantly reduced. As Uganda now works to deploy electronic medical records (EMR), this experience and the VL dashboard will be used to aid and validate the roll out. Data points from the dashboard and the EMR will be triangulated to identify areas in which data are not properly shared or standardized. The main lesson learnt by Uganda in this process has been the need for careful coordination of efforts, the use of correct patient and site identification numbers and regular feedback from all stakeholders. The data collected by the system are now used at quarterly meetings to track the status of VL testing, Dejene concluded by saying that this quarterly reporting requirement must be considered when undertaking software updates to avoid clashes, which can delay data calls.

Alice Maida, CDC Malawi, discussed data use to determine site performance and issues with data quality in her presentation, "**Collecting and Using Viral Load Data to Monitor and Manage Non-Suppressed Patients in Malawi**." She highlighted that the data allowed their program to perform four important tasks.

- Assess the overall performance of the ART program
- Estimate the additional workload to meet 90-90-90 goals
- Estimate reagent needs for testing of patient samples
- Project future need for second- and third-line ART drugs

In terms of care provided by facilities, Maida revealed key areas for improvement, including TAT for VL testing, VL testing and treatment initiation for paediatric cases, and switching appropriate patients to second-line treatment. Low data quality, incorrect site coding, incomplete data entry and incomplete documentation were listed as pain points, which they are seeking to resolve through training and mentorship. Data findings drive quality improvement activities and optimize the national algorithm and the VL cascade. Maida noted, there will be ongoing efforts to improve data completeness and increase interoperability between EMR systems and laboratory information management systems (LIMS).

The final presentation for the session, "**VL M&E to Monitor Clinical Outcomes and Management of Non-Suppressed Patients**," was from **Dr Ndapewa Hamunime**, Chief Medical Officer of the National HIV/STI/Hepatitis Control Programme of the Namibian Ministry of Health and Social Services (MOHSS) who presented in place of Gram Mutandi. Dr Hamunime spoke on M&E resources used to support use of VL results for patient management and monitor the quality of patient management and outcomes. These included examples of the record keeping systems (paper based and electronic) and the colour coding used to highlight the level of circulating virus detected in patients during VL testing, allowing them to be quickly placed on the most appropriate intervention. Because of the high cost of VL testing, it is important that the test results are used to improve patient outcomes and that tests are requested appropriately. He also spoke of challenges with ensuring that patient VL results are correctly recorded and able to be used, resulting in the roll-out of approaches to improve provider use of VL results. Finally, the speaker laid out future plans for VL M&E and VL testing implementation in-country, including site-level mentoring, introduction of an electronic laboratory VL dashboard, and linkage of different electronic systems to improve data collection and management.

SESSION V – Laboratory Breakout Session

Session V was divided into two breakout groups to separately discuss laboratory and clinical issues.

The Laboratory breakout sessions provided an overview and discussion of the frameworks used by several countries to strengthen and monitor aspects of their VL laboratory network. In most presentations, case studies and real-life experience were used to illustrate and emphasise the points being made.

Presenter: Dr. Leigh Berrie
Country: South Africa
Affiliation: National Health Laboratory Service (NHLS)
Topic: Evaluation, Validation and Verification: What you need to know?
Key Themes: The presentation explored the importance of the evaluation, validation and verification of examination methods and procedures to ensure testing efficiency, accuracy, and cost-effectiveness. Although manufacturers perform validation, the final responsibility for adequate validation and verification of measurements is borne by the laboratory itself. To achieve these processes, laboratories must: a) refer to internationally accepted norms and standards, b) engage in continuing education and training, c) implement regular quality controls, and d) revise standard operating procedures (SOPs) and other documents as needed.

Presenter: Dickson Adegoke
Country: Nigeria
Affiliation: CDC
Topic: **[Quality Assurance]** QA Strategies for Reagents
Key Themes: The presentation described the need for post-market validation (PMV) for IVT and VL reagents. The current country plan for IVT/VL PMV roll-out in Nigeria was offered as a case study. The use of national-level PMV will prevent large-scale system issues by preventing low quality reagents being sent to sites. Site-level PMV detects issues in transit or with equipment/testing at sites. PMV for reagents should be complementary to all other activities and must be allocated within the budget.

Presenter: Jonathan N'tale
Country: Uganda

Affiliation: CDC
Topic: Uganda's Specimen Referral and the Hub Transport System
Key Themes: Uganda has transitioned their sample and results transport network to a hub-and-spoke model which facilitates optimization and integration of VL platforms. Training, including in Biological Safety & Security, was provided to all parts of the system, including drivers/riders and postal workers. When designing a hub-and-spoke model, consider the radius of responsibility for each site and introduce via scaled rollout to allow systems to be refined. Communication with stakeholders and communities helps to introduce new systems and minimizes concerns, particularly around safety and security.

Presenter: Dan Mfanfikile Gama
Country: Swaziland
Affiliation: CDC
Topic: Optimisation and Integration of Viral Load Platforms
Key Themes: The presentation described Swaziland's VL scale-up activities, including work flow optimization and service decentralization. Noted challenges included human resource limitations, inconsistent completion of VL requisition forms, equipment downtime, inadequate sample transport, and lack of use of VL results. Moving forward, the HIV VL programme will place a higher-throughput VL platform at the National Molecular Reference Laboratory, scale-up DBS VL testing and pilot WHO prequalified VL POC testing.

Presenter: Charles Massambu
Country: Tanzania
Affiliation: Ministry of Health & Social Welfare
Topic: Laboratory Challenges: Specimen Management, Connectivity, and Results Return
Key Themes: The presentation noted that to improve a system, deficiencies must be defined and recommendations must be made to address gaps and set timelines and responsibilities for activities. In Tanzania, this was achieved through the use of a VL scorecard and checklists to identify gaps. Innovative measures were developed, including an electronic sample referral system and a system for barcoding specimens, which will improve overall HIV VL processes.

Presenter: Commander Edward Abayomi Akinwale (Rtd)
Country: Nigeria
Affiliation: Nigerian Air Force
Topic: CQI and Accreditation
Key Themes: A case study was presented using the SLIPTA and Strengthening Laboratory Management Toward Accreditation (SLMTA) frameworks at the 445 Nigerian Air Force laboratory in Ikeja, Lagos. These frameworks have allowed the laboratory to show data and statistics highlighting return on investment to funders. Collaboration and exchange with international partners allowed the laboratory to develop a core of committed and motivated staff, essential to accreditation.

Presenter: Frank Basiye
Country: Kenya
Affiliation: CDC
Topic: Continuous Quality Improvement for VL: Kenya
Key Themes: Many laboratories in Kenya have already achieved accreditation and are networked to provide mutual support and minimize sample backlogs. Key areas and quality indicators in the pre-analytical, analytical, and post-analytical testing phases were presented (see slides for details). By collecting and reviewing data, laboratory professionals and programme stakeholders can overcome existing assumptions and improve efficiencies in VL scale-up. Joint laboratory-clinician meetings have been pivotal to improving laboratory-related issues and TATs.

Presenter: Henry Mbah

Country: Malawi
Affiliation: CDC
Topic: Use of a Laboratory Score Card and Quarterly Monitoring Tool for Programme Monitoring
Key Themes: A review of the outcomes of field implementation of a VL score card and quarterly monitoring tool was presented. It is important to note that there is crossover with existing tools, e.g., SLIPTA, and care must be taken to ensure data are useful and not being collected for no reason. Key lessons learned and recommendations from the scorecard and tool include the need to properly use data collected and account for gaps in the tool by using complementary methods of data collection and tracking. Future expansion will examine equipment utilization rates to assist with considerations of throughput and staffing levels.

Presenter: Souleymane Sawadogo
Country: Namibia
Affiliation: CDC
Topic: Equipment Maintenance, QA, Training, Reagent Inventory and Procurement
Key Themes: Different options exist for equipment procurement: lease or outright purchase. Depending on the situation, one may be more cost effective than the other, but any analysis must include consideration of training and maintenance options. At a national level, it is important to have a mixture of platforms from different manufacturers for testing to avoid a single point of failure in the testing chain in case of reagent challenges. Key recommendations for laboratories for the topic areas covered, included: leasing or renting of equipment rather than purchasing; developing a twinning agreement with another VL laboratory to mitigate supply backlogs; taking advantage of global negotiated pricing for tests; holding suppliers accountable; and collecting and using quality indicators to improve HIV VL testing processes (See Figure 9).

Figure 9. Recommendations for laboratories conducting HIV VL testing.

SESSION V – Clinical Breakout Session

The Clinical Breakout Sessions focused on service delivery models, adherence counselling, patient management and VL monitoring in the context of HIV clinical care related to VL testing.

Dr Tom Heller of CDC South Africa started off the session with a discussion of "**VL in the Context of Differentiated Service Delivery Models**," which was focused on questions around 1) how to utilize VL results to help define patients who may be eligible for differentiated service delivery models, 2) how to

determine the most appropriate differentiated service delivery model for individuals or sub-populations, and 3) how to manage patients who subsequently have a non-suppressed VL within a differentiated service delivery model. Dr Heller provided South Africa's experience with implementing the Central Chronic Medicine Dispensing and Distribution Programme, where over 1 million people living with HIV have been categorized as 'stable patients' and thus made eligible for referral out of overburdened health facilities. He described implementing key strategies that can result in more time dedicated to patients who are not stable. One strategy is to reduce overall patient volume by scheduling stable patients for semi-annual visits with the healthcare provider and interim two-month prescriptions via fast-lane approaches at the facility pharmacy or commercial or community-based pick-up sites, along with adherence clubs that are community or facility-based. He raised key requirements for robust monitoring and evaluation systems for referred-out patients and the clinical service quality they receive.

"**Experiences with Enhanced Adherence Counselling – Does One Size Fit All?**" was the theme of the subsequent presentation by CDC Namibia representative **Gram Mutandi**. Dr Mutandi profiled Namibia's ART programme, discussed the status of VL testing access in the country, and reviewed approaches to enhanced adherence counselling (EAC) (for patients with high VL) utilizing the High Viral Load Register and a simple coloured sticker system to help track patients with high VL, focus site-level efforts towards patients with high VL, help ensure patients receive EAC and follow-up VL testing, as well as track outcomes. Dr Mutandi went on to identify future requirements for quality improvement to include routine VL cascade analysis for patients with initial high VL, additional tools for patient education on VL and assurance of completeness of data collection systems to facilitate data use.

Acting Director of the HIV/AIDS/STI Department of the South Sudan MOH, **Alex Joseph Nyniyal** presented on "**Optimizing Management of Patients with non-Suppressed VL**". He showed the operational best practices for the management of patients with non-suppressed VL results, particularly efforts to optimise the return of results and use of this information for improved patient care. This was clearly illustrated with the flow charts and SOPs that have been developed to strengthen the systems in South Sudan. Dr Nyniyal underscored the importance of engaging all partners, establishing clear roles and responsibilities at the site level, and providing on-site training and subsequent close mentorship to ensure adequate staff knowledge and understanding for standard implementation of SOPs. He also discussed the utilization of EAC flipcharts for the specific sub-populations and the use of the Individual High VL form to ensure the delivery of quality and timely EAC, emphasizing process improvements are needed to ensure the sub-population of non-suppressed patients receive the attention and quality interventions for an opportunity to suppress or re-suppress.

Identification of necessary interventions and innovations along the HIV VL cascade, scalable methods for addressing gaps, and impact assessment methods was the focus of "**Innovative Approaches in the VL Cascade**," presented by **Evelyn W. Ngugi**, CDC Kenya. Dr Ngugi identified strategies used in Kenya to address gaps in the HIV VL cascade, specifically the delivery of VL results, including the provision of facility-based access to the VL dashboard, development of an application programme interface technology for electronic medical records, piloting SMS-based transmission of test results to clinicians, as well as exporting direct transmission to patients. In addition, she described success around the establishment of national and facility-based VL champions, and highlighted how the findings from a VL service quality assessment informed quality improvement interventions to ensure timely EAC, repeat VL and regimen switches in patients with persistent virologic non-suppression. Dr Ngugi highlighted key change interventions such as restructuring clinic dates and patient flow for non-suppressed patients, intensifying paediatric and adolescent follow-up, appointing facility-level, second-line ARV champions and scaling patient-focused multi-disciplinary team and ART switch meetings.

Rumbidzai Matewe, from Zimbabwe, **Patricia Asero Ochieng,** from Kenya, **and Jacquelyne Alesi,** from Uganda, advocates and treatment educators, shared their perspectives on the role of people living

with HIV in the era of VL monitoring and highlighted key aspects and desires for people living with HIV to be regarded as partners, with a desire to be trained, recognized with compensation for their significant contributions to supporting patients. They reminded the group of the key aspect of respecting human rights and client-centred care, and encouraged the use and strengthening of existing community support systems, such as mentor mother clubs and adolescent support groups.

Charity Alfredo discussed "**Partner management in the era of VL monitoring**" in Mozambique. Dr Alfredo described the key VL cascade gaps (See Figure 10) and proposed strategies to address the gaps in Mozambique and described the incorporation of the monthly VL cascade monitoring into the national Quality Improvement strategy. She described an ongoing effort through enhanced monitoring of key indicators in the VL cascade through various data sources such as laboratory, clinic registers, and electronic patient databases disaggregated by adults, children, and pregnant women to identify gaps and challenges in the VL cascade. Dr Alfredo shared future perspectives on the expansion of this enhanced monitoring to all ART sites, as well as optimizing the use of the VL dashboard and second-line ART portal to improve the timely identification and follow-up of patients with high VL and ART switches. Given the number of implementing partners working with different provinces or health systems in Mozambique, it has been essential that all activities are well coordinated to create a harmonized system.

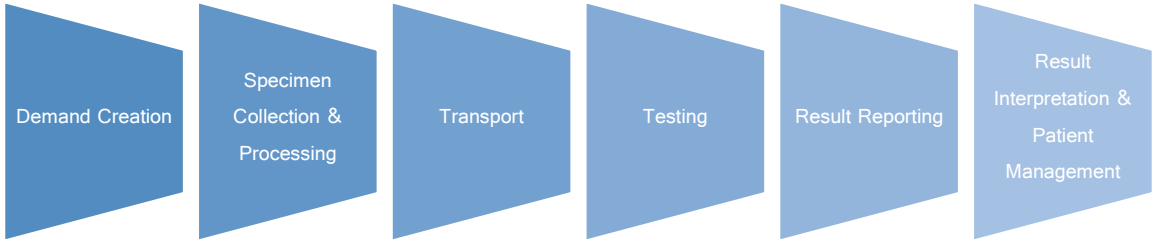


Figure 10. Gaps in the HIV VL cascade.

Dr Laura Broyles, Maternal and Child Health Branch Chief at CDC Atlanta, spoke on VL monitoring in the maternal-child context by discussing **"Key Considerations for VL Monitoring in Pregnant/Breastfeeding Women, Children and Adolescents"**. Dr Broyles stressed the urgent need for acting on non-suppressed VL in pregnant and breastfeeding women, as well as children and adolescents. She highlighted the need for greater disaggregated data collection and analysis for countries to monitor these specific sub-populations. She also highlighted ongoing discussions in many countries and by many stakeholders on the changing landscape for VL monitoring, and expressed that future updates are to be expected.

DAY III SESSIONS

October 25 marked the last day of the regional meeting, which included an ASLM announcement about the LabCoP platform, country reports from breakout sessions and review discussions of HIV VL testing topics covered during the meeting.

SESSION VII – Country Reports from Breakout Sessions

During Session VII, whose rapporteurs were Alice Maida and John Mondi, ASLM made an announcement, inviting experts to join the organisation's community database to support the LabCoP by registering on the ASLM database: https://aslmexpertdb.org/guest.php.

Session VII also featured HIV VL scale-up country reports from participants. Due to time constraints and participant travel, not all countries present at the meeting were able to present their challenges,

solutions and next steps. Country representatives identified their successes, challenges, and next steps for HIV VL scale-up at the clinic level, laboratory level, laboratory-clinic interface, and supply management level (See Table 1). Next steps were presented as near-, mid- and long-term objectives where possible. Challenges varied by country and programme, but many countries experienced similar or overlapping challenges, such as supply stock-outs and equipment downtime, inadequate numbers and qualifications of personnel, sub-optimal utilisation of results and failure to transition patients into second- and third-line ART once treatment failure had been confirmed.

Far from simply identifying their challenges, country representatives pinpointed the changes that would be needed to address gaps and strengthen HIV VL programming, making suggestions for next steps and identifying key players in each proposed activity. For example, multiple countries identified additional staff training and mentorship as a means of addressing human resource gaps and increasing use of VL results, in addition to enhancing implementation of mHealth and eHealth technologies to improve data management.

Table 1. HIV VL Scale-Up Challenges & Solutions/Next Steps from Session VII Country Reports.

Country Name	Challenges	Near-Term Next Steps	Mid-Term Next Steps	Long-Term Goals
Angola	• Meeting PEPFAR targets • Stock-outs • Laboratory & clinic services not optimised	• Laboratory workflow optimisation & staff retraining • Improve tracking of high-VL patients • Train staff on revised VL request form • Develop dashboard for VL reagent tracking & forecasting • Increase patient education	• Implement LIMS • Ensure all patients in the active file list are part of the Human Virology Laboratory register • Monitor by site VL completion rates and review data during monthly interdisciplinary meeting • Completion of VL DBS validation	• Improve TAT • Ability to analyse VL data, disaggregated by key variables • Develop a backlog prevention plan. • Develop an early warning system with reagent buffer level. • Pilot DBS implementation in 2 facilities.
Botswana	• Commodities & equipment management • Results management & TAT • Specimen transport • VL result monitoring	• Budget for buffer stock from PEPFAR • Rollout of IPMS laboratory module • Improve M&E, particularly to improve TAT and result utilization • Develop national specimen transportation plan		
Burundi	• Inadequate sample referral and return result system • Low demand for testing • Long TAT for results return • Inadequate supply chain management	• Establish a mixed technical working group (TWG) • Conduct gap analyses • Develop SOPs & results tracking logs • Quantify VL reagents and consumables	• Strengthen sample transport • Train staff • Provide patient education sessions • Train nurses to receive results, place in patient	• Monitor the implementation of developed strategies • Install electronic system to report test results • Quarterly monitoring of VL reagent and supply consumption

	• Equipment breakdowns	• Review equipment service contracts	folder and notify clinician • Develop Key Performance Indicators to monitor equipment maintenance	• Quarterly monitoring of Key Performance Indicator
Cameroon	• Lack of programme coordination • Incomplete data & M&E systems • Low demand creation for VL testing • Poor patient tracking • Long TAT for results return • Inadequate sample referral network	• Define roles and responsibilities of the VL TWG • Validate and disseminate the M&E tools • Validate and disseminate SOP for clinical management of patients with VL test results • Design a sample collection and transportation network adapted to the context of each district /region • Develop harmonized national SOP for platform utilization	• Revise national HIV care and treatment (ART) guidelines to introduce new operational strategies to increase uptake of VL testing • Train healthcare workers and community on M&E tools and importance of VL testing to increase uptake and achieve the third 90; • Roll-out of DBS by training regional trainers, laboratory technicians, clinicians • Put in place a periodic district meeting with all stakeholders for M&E of performance • Reduce the cost of VL testing for children and pregnant women to increase uptake	• Increase storage spaces at reference laboratory • Advocate for waste management (in order to set up a centre for the treatment of toxic waste) • Optimise the use of existing testing platforms in the country to reach their full capacity by modifying the patient / sample referral systems, by modifying the workflow of the laboratories • Set up a QA programme for VL testing
Democratic Republic of Congo	• Long TAT for results return • Long reagent procurement process • Need for more accurate data	• Complete laboratory assessments to identify gaps • Implement training with clinical staff, including TOT • Conduct monthly monitoring of result TAT • Create SOP for & discuss supply chain management solutions	• Identify 5 gaps causing long TAT and do retraining • Provide information technology equipment with internet connection at high volume sites • Apply supply chain SOPs and track progress (time commodity ordered to time of	• Establish tracking of VL testing relative to individuals eligible for VL trough M&E • Quarterly review of tracking by SI / clinical / laboratory / SC-team • Quarterly monitoring of third 90 VL results

		• Acquire & use M&E tool for data triangulation	arrival at the site level)	
Ethiopia	• Data & specimen backlogs • Equipment breakdowns • Long laboratory TAT • Lack of system for notification of patients with high VL • Inadequate awareness of VL testing by clinical providers • Low staff motivation • Low community engagement • Specimen and result transportation • Stock-outs & inadequate supply tracking	• Ensure additional human resource commitment for data management & specimen backlogs • Adhere to supply management guidelines • Implement QA for high VL reporting processes • Train staff on completion of request forms • Assign focal persons for VL tracking	• Standardize TAT • Implementation of standard tools • Provide back-up power systems • Improve enforcement of equipment maintenance agreements • Establish TWG	• Identify motivational mechanisms to encourage staff • Improve adherence to MOH guidelines
Kenya	• Need to better target by population and location • Lack of unique patient identifiers • Prolonged time for clinical intervention • Labour unrest	• Introduce patient-friendly processes & literacy education • Improve clinical competencies • Introduce unique identifiers; use barcodes • Use eHealth to improve result return	• Practitioner mentorship • Develop SOPs • Develop key performance indicators for monitoring the process • Colour code patient files depending on availability of results and outcome of results	• Secure funding for reagents, human resource needs, waste management & external quality assurance panels • Use of barcodes for patient identification to reduce transcription errors
Lesotho	• Suboptimal testing capacity / testing backlogs • Inadequate inventory management • Lack of community engagement / knowledge around VL testing • Results TAT and result use • Lack of adherence to VL algorithm/ guidelines • Poor laboratory-clinic interface	• Train all healthcare workers involved in VL cascade • Implement DBS VL testing for hard to reach sites • Use electronic results reporting tools & ART registers • Implement electronic LIMS • Engage supply chain TWG	• Improve procurement processes for VL testing • Sample collection schedules in use by the sample transporters Riders for Health	• M&E tools • Unique identifiers / duplication of ART number/de-duplicating the results

	• Incorrect completion of request forms • Commodity stock-outs • Inadequate VL testing coverage			
Malawi	•Human resource management •Need for better procurement & logistics •Subpar data quality & M&E systems •Quality management & assurance needed •Inadequate reporting systems •Lack of collaboration at the laboratory-clinic interface	• Specimen transport system quality improvement • QMS: training; develop refined lab quality standards, quality indicators and VL score card utilization • Draft operational guidance for clinical-lab interface • Strengthening mentoring for clinical and lab • Establish a joint clinical and lab forum for sharing best practices at district level	• Improve TAT • Optimise connections of all laboratories to national LIMS • Establish mentor-mentee pairs • Scale-up LARC best practices • Increase access to VL results by clinicians • Link LIMS and EMRs • Introduction of data quality assessments and service quality assessments	• Labs on SLIPTA towards accreditation • Solar power • Install water tanks • Recruit human resources • Biological waste management: procure high temperature incinerators • Build in-country capacity and budgets for product validation
Namibia	•Delayed or incomplete updating of electronic patient management system •Need for additional educational tools	• Continued use of VL registers & other useful tools • Routine VL cascade analysis for patients with high initial VL • Updating of the electronic patient management system with complete VL results • Investment in edutainment materials		
Nigeria	• There is a clear need to fully map terrain in the country, in order to plan transportation routes. Not all roads and highways are in the same condition, so using coordinates and maps do not reflect the reality of travel times • Procurement planning should be improved, so that reagents and consumables required to perform testing arrive together rather than spaced out, which can lead to issues with shelf life. • QA of reagent lots should occur at a national level when buying in bulk to provide efficiencies and prevent each site performing testing when items are received.			
South Sudan	• No VL testing at public health laboratory • Patient tracking after results available at facility level • No contingency plan for stock-outs • Slow adoption of VL testing	• Install equipment & train staff on VL testing at public health laboratory; approve VL testing SOPs & train staff • Follow-up training and mentorship of facility staff • Establish monthly data reviews • Develop contingency plan for stock-outs • Develop & train staff on SOPs on updating of patient	• VL results begin to be sent to patients • Strengthen patient tracking in the era of VL monitoring. • Training of IPs/clinic mentors (training of trainers) • Development of supply chain SOPs • Establish monthly data reviews	• Increase testing capacity (DBS & plasma) • Monitor result return to patients by site and review by all stakeholders • Implement new process and begin M&E

		contacts, results flow & patient file management		
South Africa	• Gaps in access to VL testing • Ensuring specimen integrity and timely results delivery • Inadequate M&E indicators for adherence and retention rates • Lack of unique sample ID system • Viral load specimen rejections	• Install pre-analytics systems for the 3 highest throughput laboratories • Expand access to NHLS web viewer for timely access to VL results • Implementation of electronic gate keeping by NHLS	• Strengthen and monitor delivery of 'results for action' • Strengthen and expand the specimen tracking and cold chain monitoring system • Improve mechanisms for use of mHealth application • Incorporate unique identifiers into Tier.net and increase utilization on laboratory requisition forms to 50% completion rate • Mentor facility operations managers to hold data capturers accountable for prompt entry of VL results on Tier.net	• Sustain the provision of access to VL in the 13 hard to reach districts • Build viral load external quality assurance capacity within the NHLS QA department • Release new version of Tier.net and NHLS CDW data integration pilot • Further data interrogation for de-duplication • Incorporate unique identifiers into Tier.net and increase utilization on laboratory requisition forms to 90% completion rate • Develop reporting indicators for stable referred-out patients
Swaziland	• Lack of results return & use of results for clinical decision-making • Implementation of DBS VL testing • Laboratory-clinic interface communication	• Laboratory: Provide training; develop SOPs, job aids & monitoring systems • Test mapping, quantification & procurement for DBS VL testing • Use of unique identifiers on test forms • Develop SOPs to address results management at the laboratory-clinic interface	• Develop M&E benchmarks for distribution of test results • Roll out DBS VL testing • Discuss gaps and improvements in results utilization at clinical meetings	• Extend Defense Information System Agency-link points to give e-access to results by clinicians • Evaluate coverage of VL testing and DBS • Integrate reporting of patients with high VL in routine reports • Monitor TAT
Tanzania	• Delayed use of DBS for VL testing • Inadequately qualified/trained laboratory personnel • Lack of coaching for clinical staff • Slow results return • Stock-outs	• Ensure hiring & adequate training of qualified laboratory personnel • Provide mentorship to clinical staff • Implement the electronic laboratory referral system • Expedite VL dashboard development • Engage national VL TWG meeting to strengthen laboratory-clinic interface • Coordinate and oversee standardization exercise for laboratory equipment • Install sample tracking system at additional sites		

	• Laboratory equipment not standardised or optimised • Equipment breakdowns • Delayed roll-out of VL dashboard, sample tracking and result return systems • Weak laboratory-clinical coordination	• Replace old equipment through reagent rental / lease		
Uganda	• Laboratory: Lack of sample tracking system • Clinic: Poor utilisation of results • Lack of unique patient identifiers • Low VL testing coverage for paediatrics, adolescents, pregnant & lactating women	• Introduce Health Management Information System tool to track VL coverage • Revise algorithm for children, adolescents, pregnant and lactating women • Hold monthly VL commodity meetings	• Introduce unique identifiers & barcodes for test & sample tracking • Standardize facility ART numbers • Complete equipment procurement	• Provide community sensitisation • Support health staff supervision & mentorship
Zambia	• Inadequate laboratory infrastructure for placement of VL equipment • Lack of dedicated equipment service contracts • Difficulty monitoring VL suppression levels • System for results collection & management not standardised • Commodity stock-outs	• Ensure that existing equipment is used to full capacity before investing in additional equipment • Strengthen VL / EID TWG at all levels • Raise awareness among people living with HIV to increase VL testing demand • Pre-test eLab system • Strengthen adherence to VL / EID guidance documents • Improve sample storage conditions at collection points	• Improve sample transportation and supply chain system • Improve laboratory physical infrastructure and power back up • Implement electronic Laboratory information system for all VL testing sites • Work towards equipment rental agreements • Extend VL cascade monitoring to clinical utilization	• Continue assessing current infrastructure needs • Explore the use of POC testing and develop POC implementation plans
Zimbabwe	• Sample transportation & waste management challenges • Inadequate data management /	• Generate reports from existing laboratory information system • Strengthen communication	• Monitor TAT • Train clinicians on DBS • Establish joint forum for the	• Develop integrated transportation system • Use VL dashboard • Roll-out electronic health record systems

	partial implementation of laboratory information systems • Commodity stock-outs • Shortage of qualified clinical staff & laboratory scientists • Knowledge gap on use of DBS for VL testing • Results TAT • Lack of M&E tools	channels between the laboratory & clinic	laboratory-clinic interface	

MEETING CLOSURE AND NEXT STEPS

Meeting hosts from ASLM led the meeting closing presentation, drawing together participants to review outcomes from the workshops and highlight key recommendations and next steps for HIV VL scale-up in the African region.

Closing presenters reiterated key messages on HIV VL scale-up from the workshop, underscoring the need to further invest in laboratory and clinical staff and services, integrate service delivery, improve supply chain management, target underserved populations and remote locales, and assure quality throughout the HIV VL cascade.

Several South-South collaborations were established or strengthened through networking and discussions which took place during this meeting:

- Cote d'Ivoire made plans to visit Kenya for help with the creation of a VL dashboard
- Mozambique will collaborate with Kenya on the establishment of VL Champions
- South Sudan will continue to work closely with Kenya for technical and practical assistance in VL scale-up
- The Democratic Republic of Congo intends to use a tool created by Uganda to help with VL tracking and demand creation.
- Launch of LabCoP which will facilitate the expansion of South-South collaborations

Moving forward, participating African countries will leverage the lessons learned and professional connections made during the meeting to advance HIV VL scale-up and ensure continuous service improvements throughout the implementation process. Through engagement with the ASLM LabCoP platform, HIV VL specialists will continue sharing their programmatic lessons, successes, tools and recommendations with other health stakeholders across the continent, ultimately strengthening laboratory and clinical system functions toward improved management and outcomes for people living with HIV.

Beyond Africa: ASLM Hosts HIV VL Meeting in Southeast Asia

Building on lessons and outcomes from the Addis Ababa HIV VL meeting, ASLM hosted an HIV VL regional workshop in Bangkok, Thailand from 12-14 December 2017. Recognising that the African region can draw lessons from HIV VL scale-up efforts in other regions, ASLM convened representatives from the global health community and health stakeholders from Asian countries to present on HIV VL scale-up efforts. The objectives of the workshop were to discuss and evaluate progress, challenges, and next steps in HIV VL scale-up in a number of countries, including Cambodia,

India, Indonesia, Lao PDR, Myanmar (Burma), Papua New Guinea, Thailand, and Vietnam. By learning about HIV VL scale-up programmes around the world, ASLM will be prepared to introduce and facilitate the dissemination of best practices.

ACKNOWLEDGEMENTS

This regional meeting would not have been possible without the meeting supporters and sponsors, to whom ASLM offers its thanks.

Organisations that provided conference support or sponsorship include: Centers For Disease Control and Prevention and President's Emergency Plan For AIDS Relief

MEETING SPEAKERS

Dr Alex Joseph Nyniyal holds a Medical Degree from Juba University and MPH from Deakin University in Australia. He resourceful and knowledgeable about public health practice, health promotion, service delivery and community development with 10 years cumulative clinical work experience as a Medical Officer with competency and proficiency in communicable and non-communicable diseases. He has 2 years' experience as the head of a Pediatrics Department in a state government hospital, 1 year of experience in maternal and child health service at the state and county level, 3-4 years of experience in medical administration of health centers and rural hospitals in limited and poor resource settings. He has a cumulative 5 years' work experience with non-governmental organizations and the private health sector and a cumulative 4 years' experience in HIV/AIDS treatment and program management. Currently, he is the Acting Director for the HIV/AIDS/STIs Department in the national Ministry of Health of South Sudan.

Dr Ali Elbireer holds a Master of Business Administration (MBA) degree and a doctoral degree in healthcare administration (PhD). He held positions in several healthcare establishments, including medical laboratories, research facilities, centres of excellence, and hospitals in the United States and Africa. He is a dedicated advocate for laboratory systems strengthening. Dr Elbireer is the former Chief Executive Officer of ASLM. Before joining ASLM in November 2016, he was a faculty member of Johns Hopkins University (JHU) School of Medicine, Baltimore in the United States. He worked in East Africa for over a decade as the Country Director for a JHU non-governmental organization in Uganda. He was the Laboratory Administrative Director for Makerere University-JHU at the Infectious Diseases Institute (MU-JHU/IDI) in Kampala, Uganda. He was also the Chairman of the American Society for Clinical Pathologist (ASCP) Advisory Board of Certification in Uganda.

Alick Austine Kayange obtained his Mphil Global health from the University of Oslo-Norway, Post graduate Diploma in Global TB epidemiology from the University of Bergen-Norway, Post graduate Diploma in Advanced clinical HIV /AIDS management at University of the Witwatersrand, Johannesburg, South Africa and Doctor of Medicine (MD) from Muhimbili University in Tanzania. Dr Kayange works with US CDC in Tanzania under the care and treatment branch as the public health specialist overseeing adult HIV care and treatment. He also work as the CDC Tanzania acting paediatric focal person and interagency Care and Treatment TWG lead. He is the branch's point of contact for VL scale up activities and the differentiated service delivery model development.

Dr Alice Maida is a Medical Program Specialist and has worked at CDC Malawi since 2011. With a focus on HIV care and treatment, she is supporting the Malawi Ministry of Health and CDC implementing partners to optimize ART service delivery through accelerated ART initiation under Test and Start, active linkage and retention systems, and VL cascade optimization (in collaboration with CDC lab advisors) and differentiated service delivery models.

Dr Bruce Struminger graduated from Harvard College with a degree in Art History and from the Harvard Graduate School of Arts and Sciences with an MA in Medical Anthropology and earned his MD at Johns Hopkins School of Medicine. He completed his residency in Internal Medicine at the University of Michigan in Ann Arbor. Dr Struminger is an Internist and public health practitioner who served for six years with the US Indian Health Service on the Navajo Indian Reservation and for six years with the US CDC, as the Country Director in Cote d'Ivoire and in Vietnam. Dr Struminger transitioned to the University of New Mexico in 2014 as an Associate Director of Project ECHO and an Associate Professor of Internal Medicine in the Department of Infectious Diseases. His clinical practice is focused on the primary care of patients living with HIV. At Project ECHO his work focuses on providing support and oversight to the New Mexico ECHO clinics and on collaborations with the Indian Health Service and CDC, including both domestic and global initiatives related to TB, HIV, laboratory services, population health, and global health security.

Dr Clement Zeh, PhD, MPH, is the CDC Atlanta Team Lead for HIV Viral Load and Early Infant Diagnosis. He is responsible for evaluating new technologies, supporting VL infant virologic testing scale-up, ensuring the quality of testing and providing subject matter expertise to PEPFAR supported countries. Previously, Dr Zeh was the CDC Ethiopia Laboratory Associated Director, supporting PEPFAR and the laboratory component of the Global Health Security Agenda. Dr Zeh was the CDC Division of HIV/AIDS Prevention (DHAP) Laboratory Advisor in Kisumu, Kenya, and served as the acting Program Director for DHAP activities in Kenya. He has over 20 years of experience in HIV/AIDS and STI. He has previously served as Principal Investigator (PI) and co-PI in several clinical trials. Dr Zeh established the ISO15189-accredited laboratory Kenya designated as the National and Regional reference laboratory for HIV drug resistance testing. Dr Zeh has served in many key international organizations.

Dr Cham-Jallow, BSc Biochemistry, MSc Molecular Biology and PhD Biomedical Sciences (Molecular Virology), has more than more than 21 year's progressive experience in public health laboratory systems strengthening, infectious disease immunology and HIV vaccine research and development. She held several posts with The Medical Research Council, The Gambia and The Henry F Jackson Foundation (HJF) for the advancement of Military Medicine. At HJF, she was assigned to the Makerere University Walter Reed Project (MUWRP) where she provided leadership and guidance in the development, implementation and evaluation of laboratory services in support of HIV/Ebola vaccine trials. Currently, she is the WHO/AFRO laboratory technical adviser with the HIV, TB and Hepatitis (HTH) unit under the communicable disease cluster.

Dr Charity Ndalama Alfredo, MBCHB, MPH-CTS, is a Contractor for CDC Mozambique where she serves as Senior Treatment Coordinator. Her medical career spans over 20 years, having worked as a clinician in various disciplines during the early years and later as public health practitioner in Zambia, Zimbabwe and Mozambique. For the past 15 years, her work has focused on HIV and AIDs care and treatment programs. She is currently responsible for supporting VL scale-up in Mozambique.

Charles Kiyaga BSc, MSc, MPhil, is the National Coordinator for Early Infant Diagnosis at the Central Public Health Laboratories, Uganda Ministry of Health. He has a BSc in Biomedical Laboratory Technology and a MSc in Biomedical Sciences and Management from Makerere University, as well as a BSc in Health Systems Management from the University of Manchester and a MPhil in Medical Science from the University of Cambridge.

Charles Massambu is at the Ministry of Health & Social Welfare in Tanzania.

Dan M. Gama holds a Ph.D. in Stem Cell Biology, an MSc in Microbiology and Immunology, BSc in Medical Laboratory Sciences. He has worked for both the public and private sectors in diagnostic laboratories, blood transfusion services and academia for a period of +/-17 years. Dr Gama Joined PEPFAR in December 2012 and is currently employed as the CDC/PEPFAR Laboratory/Blood Safety Specialist in Swaziland, where he provides leadership in scientific policy development, works with partners to provide management training and consultation as needed by the Swaziland MOH.

Dennis Ellenberger is Associate Chief of Science at the United States Centers for Disease Control and Prevention's International Laboratory Branch.

Dickson Adegoke is at CDC Nigeria.

Air Commodore Edward Abayomi Akinwale (Rtd) is a Fellow Member of the Medical Laboratory Science Council of Nigeria. He holds a Masters degree in Biochemistry, a Masters degree in Public Administration, and PhD in Haematology. He was commissioned into the Nigerian Air Force (NAF) in December 1985 and rose to the rank of Air Commodore in December 2009. He voluntarily retired from the NAF in October 2015. During his tour of duty in the NAF he commanded most of the medical laboratories in the Service. His final command was the 445 NAF Hospital Laboratory Ikeja, which won many laurels under his command. These include the 1st 5 star Medical Laboratory adjudged by both the Medical Laboratory Science Council of Nigeria and the African Society for Laboratory Medicine.

Eileen Burke is a Laboratory Specialist at the Global Fund based in Geneva since 2015. She has over 25 years of experience in laboratory and supply chain systems in Europe, Australia, Africa, Asia and the Caribbean with bilateral and international organizations. Previous to joining the Global Fund, Eileen was working with CDC in Uganda. She also worked in Kenya and Zimbabwe with CDC on the PEPFAR program and with WHO in the Caribbean.

Dr Evelyn W. Ngugi, MBCHB, MPH, is the Deputy Branch Chief-Adult Treatment Lead at the HIV Service Delivery Branch, DGHT CDC Kenya and has over 10 years' experience in HIV care and treatment programming. She provides technical leadership to the adult HIV care and treatment team, directly managing the Ministry of Health and care and treatment implementing partner cooperative agreements. She leads and guides the adult treatment team to participate in design, implementation of impact structural care and treatment programs with other partners in Kenya, in accordance with CDC-DGHT, MOH and PEPFAR priorities. She currently leads the clinical VL scale up team at CDC and is also a member of the national VL TWG and the clinical Interagency Technical team.

Frank Basiye holds a MSc in Medical Lab Technology. He has 19 years combined experienced in laboratory sciences of which 10 years were spent in clinical research and 8 are in CDC and program, and therefore is well rounded in clinical research, routine diagnostics, molecular, and national public health laboratory programs work. He also has experience in the evaluation of new diagnostic assays, both in the field and in laboratory set-ups. For the last 9 years, he has been with CDC Western Kenya as a Technical Advisor for Lab, based in DGHT Western Kenya region. He also works as the CDC Kenya DGHT program point of contact for VL testing in Kenya and serves as the Co-chair of the National VL-TWG- Lab directors team in Kenya. He has participated in supporting VL testing and networking expansion in Kenya. He is also a member of the inter-agency ITT teams.

Dr Geoffrey Chipungu is an HIV/AIDS Specialist (Diagnostics and Paediatrics) with the East and Southern Africa Regional Office of UNICEF and the regional focal person for the Point of care Project. He was previously Laboratory Advisor with CDC Malawi.

Dr George Alemnji, PhD, MPH, is Senior Technical Advisor for Laboratory Services at the Office of the Global AIDS Coordinator and Health Diplomacy (SGAC) Washington. He is also Lab lead of the PEPFAR Epidemic Control Team 2. Until more recently, he served as Ex-Officio for the PEPFAR Laboratory Technical Working Group. Furthermore, he has been coordinating the PEPFAR Interagency Viral Load (VL) and Early Infant Diagnosis (EID) Task Force. He is at OGAC on detail from CDC Atlanta. Before coming to OGAC, he was Associate Director for Science and Laboratory Advisor for the CDC Caribbean Regional Office; chairing and overseeing the entire PEPFAR Caribbean scientific and laboratory portfolio. He briefly as acting Regional Director for the same office. Prior to joining the CDC Caribbean Office, Dr Alemnji worked as Laboratory Director, NIH (DAIDS) Harare Zimbabwe HIV Network clinical trial site (HPTN, AACTG, IMPAACT, MTN); Laboratory Director, CDC Cameroon office; Senior lecturer in chemical pathology, faculty of medicine, University of Yaoundé, Cameroon; and consultant in global clinical and public health laboratory services and systems strengthening to many international organizations. Dr Alemnji's research has been on HIV clinical trials, molecular epidemiology, quality systems strengthening, evaluation of novel diagnostic platforms, and establishment of models to improve efficiency of laboratory services.

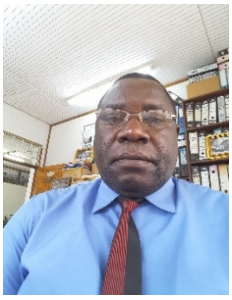
Gram Mutandi, MBchB, Dip HIV Man, MPH, is a Medical Officer with Post-Graduate Public Health Training who is the Team Lead for HIV Prevention, Care and Treatment Team at CDC Namibia. He has worked with the Namibia National HIV Program since 2004 in various capacities ranging from direct HIV clinical service provision, continuous quality improvement and more broadly provision of technical assistance to the national HIV treatment program. Dr Mutandi is a member of the PEPFAR Namibia Interagency Technical Team as well as sits on various MOH National Technical Working Groups.

Dr Heather Alexander serves as the Branch Chief for the International Laboratory Branch, Division of Global HIV and TB at the US CDC. In this capacity, Heather leads more than 60 staff engaged in microbiological and public health science and innovation, program implementation, and impact assessment in the areas of HIV diagnostic and incidence testing; HIV viral load monitoring and early infant diagnosis; HIV drug resistance testing; molecular and phenotypic detection of TB and drug-resistant TB; and laboratory and point of care testing site continuous quality improvement (CQI) for HIV and TB diagnosis and treatment monitoring in PEPFAR-supported and CDC global TB focus countries. Heather holds a PhD in Microbiology and Molecular Genetics from Emory University in Atlanta, Georgia, USA.

Dr Helen Chun is a medical officer in the HIV Care and Treatment Branch at the US CDC. She has over 17 years' experience in the field of HIV/AIDS, and currently provides technical assistance to countries for HIV treatment scale-up, HIV viral load monitoring, and HIV drug resistance. Helen holds an MD in Internal Medicine and an MPH and is fellowship trained in Infectious Diseases.

Dr Henry Mbah has over 26 years of professional experience and began his carrier in the early 90s as a Veterinary Surgeon and later studied molecular biology and went into trypanosomiasis and HIV research, AIDS clinical trials support and teaching. For the past 12 years he has been providing TA, supporting and strengthening clinical laboratory programs in developing world. He is currently the Senior Lab advisor for CDC Malawi.

Dr Kebede Worku is the State Minister of Health for Ethiopia.



James Kandulu is an efficient, organized and self-motivated Biomedical Laboratory Technologist. Currently working as the Deputy Director of Diagnostics in the Ministry of Health, responsible for supporting the policy direction of issues in the management of diagnostics services in Malawi. He coordinates the viral load & EID testing scale up implementation plan which includes supply chain management activities and laboratory partners' activities implementation.

Jacquelyne Alesi is the Executive Director of the Uganda Network of Young People Living with HIV/AIDS (UNYPA). She has years of advocacy and organizing experience on behalf of the sexual and reproductive health rights of young people at the national and global levels. Ms Alesi has a Bachelor of Arts degree from Kyambogo University, and previously worked as an advocacy and psychosocial support manager at the Namugongo Fund for Special Children.

Jason Williams currently holds the position of Senior Advisor for Laboratory Supply Chain System Strengthening within the Office of HIV/AIDS at USAID. Jason serves as a liaison between country programs, ministries of health, USG PEPFAR and other external collaborators. Jason's primary responsibility is to provide technical leadership and advocacy to advance laboratory service delivery and laboratory supply chain support in PEPFAR countries. Jason has more than 25 years experience in clinical, research, and programmatic laboratory development and public health based management experience.

Jonathan Ntale, Jonathan Ntale is a multi-skilled public health specialist working with CDC-Uganda with a passion for laboratory technology, monitoring and evaluation of public health programs as well as health information systems strategy, implementation and adoption. His collaborations span from agency partnerships such as MOH, USAID, Global Fund , WHO, and various implementing partners such as Uganda Virus Research Institute, Makerere School of Public Health, CHAI, ASLM, APHL and AFENET. He shares hands-on experience in the steering of the aggressive viral load scale up campaign in Uganda in which there was development and tracking of monitoring frameworks for the national roll out, drafting of national sample transport network guidelines. Being passionate about health information systems, he takes part in regular business and systems requirements gathering, took part in the development of the Uganda national laboratory enterprise architecture (LIMS masterplan), deployment of the web based EID & Viral Load results download system across the country. He participates as national trainer in the WHO-SLMTA program and advisor to MOH. He is keen on implementing a multi-disciplinary communities of practice approach to public health project implementation, in-depth information systems adoption and quality improvement activities right from health facility level to international level.

Dr Lara Vojnov is the Diagnostics Advisor in the HIV and Hepatitis Department at the World Health Organization. In this position, Lara leads normative guidance development and country support for HIV diagnostics, including viral load and early infant diagnosis as well as laboratory quality.

Laura Broyles, MD, is the Chief of Maternal and Child Health Branch in the Division of Global HIV and TB (DGHT) at CDC headquarters in Atlanta. She joined DGHT in 2010 and has focused on expanding viral load monitoring in PEPFAR ART programs in Africa with particular attention to ensuring appropriate clinical utilization of viral load results to improve patient outcomes. She is particularly interested in issues related to VL monitoring in pregnant/breastfeeding women, children, and adolescents. Dr. Broyles served as an Epidemic Intelligence Service Officer in the CDC Division of HIV/AIDS Prevention from 2001-2003 after completing residency in internal medicine. She is board-certified in infectious diseases and has been on the faculty of the Emory University Division of Infectious Diseases since 2006.

Dr Leigh Berrie, is currently the Head of Grants and Special Programs for the National Priority Programs of the National Health Laboratory Service, South Africa, where she leads a team in the implementation and monitoring of National HIV and TB laboratory programs in the public health sector. In addition, she is the Chief Operations Officer for the NHLS-EQUIP program run through Wits Health Consortium which is involved with scale-up of access to HIV viral load monitoring in Africa. Her research efforts have included evaluation of new technologies for TB, HIV VL monitoring and EID, which can be supported by various publications and conference presentations. She has 16 years of expertise with various commercial molecular diagnostic laboratory technologies available for HIV and TB, and 8 years of experience in the public health sector and working with National TB and HIV programs. She is currently a committee member of the National Task team for Improvement of HIV and TB services in the Department of Correctional Services and Chairs the Lab and Infection Control Working Group of this Task Team. She is also the Chair of the Viral Load Scale-Up Technical Working Group for EQUIP.

Lolem Ngong, PEPFAR Coordinator for Ethiopia

Michael Mwasekaga is the Laboratory Branch Chief for CDC Tanzania with a High National Diploma in Microbiology from North East Surrey College of Technology (UK) and more than 30 years laboratory experience in tuberculosis, influenza, and HIV. Prior to joining CDC, he worked with MOH Tanzania as the National Laboratory Quality Systems Coordinator, and MOH Botswana as Laboratory Director for the National Tuberculosis Reference Laboratory in Gaborone – Botswana.

Miriam Rabkin, MD, MPH, is Director for Health Systems Strategies at ICAP and an associate professor of medicine and epidemiology at Columbia University's Mailman School of Public Health. Her work focuses on strengthening health systems, improving access to HIV services in resource-limited settings and the design, delivery and evaluation of chronic care programs for HIV and non-communicable diseases. She has supported the implementation of HIV programs across sub-Saharan Africa, as well as health systems research and training in multiple countries. Her current research focuses on implementation science and ways in which to leverage the lessons of HIV scale-up to strengthen broader health systems, and to enhance the quality of programs for HIV, maternal/child health, non-communicable diseases and infection prevention and control in sub-Saharan Africa and the Middle East.

Nadia Solhedin, MPH, is an Epidemiologist with CDC Atlanta. Prior to working with CDC, Ms Solhedin worked as a health scientist for PEPFAR, and as an M&E associate at the University of Washington. Ms Solhedin received her Master of Public Health from the University of Washington.

Dr Ndapewa Hamunime is the Chief Medical Officer of the National HIV/STI/Hepatitis Control Programme of the Namibian Ministry of Health and Social Services (MOHSS).

Nqobile Ndlovu serves as an ASLM Program Director. He is a public health professional with 10+ years of experience managing regional laboratory strengthening programs in resource-limited areas. Before joining ASLM, Mr Ndlovu served as the Laboratory Project Coordinator for the African Field Epidemiology Network (AFENET) in Kampala, Uganda, where he spearheaded laboratory strengthening programs in Africa and the Caribbean region. He also served as Assistant Field Coordinator for the Master in Public Health (FETP) training program at the University of Zimbabwe. Mr Ndlovu holds a bachelor's degree in medical laboratory sciences and a master's degree in public health from the University of Zimbabwe.

Dr Pascale Ondoa holds a medical degree from the University of Yaoundé, Cameroon, and doctorate degree in Biomedical Sciences (Virology) from the University of Antwerp, Belgium. Dr Ondoa has worked in academic research at the Institute of Tropical Medicine from 2002 to 2009. Between 2010 and 2016, she served as senior scientist/assistant professor at the Amsterdam Institute for Global health and Development (AIGHD), University of Amsterdam. Her work covered research and implementation aspects of various projects looking at HIV drug resistance in sub-Saharan Africa, exploring ways to mitigate barriers to laboratory test uptake, and addressing gaps of the laboratory systems in resource-limited setting of Africa. Since December 2016, Dr Ondoa provides scientific leadership to the ASLM team as the Director of Science and New Initiatives.

Patricia Asero Ochieng is a staunch advocate on access to medicines, a treatment educator and a mobilizer. She is also the vice chair of the international community of women living with HIV Kenyan Chapter, a member of the technical working group on CSS in Kenya and a Coordinator of DACASA. She has years of experience and knowledge on issues of treatment, access to medicines and intellectual property. Patricia holds a diploma in medical counselling and psychology.

Peter Ehrenkranz, MD, MPH, is Senior Program Officer for HIV Treatment at the Bill & Melinda Gates Foundation. From 2010 to 2015, he worked in Swaziland with CDC, first as the PEPFAR Care and Treatment Lead, and later as the Country Director. Prior to that, he spent two years in Liberia with a joint appointment as the senior advisor to the National AIDS Control Program and the medical director for CHAI-Liberia. He earned an undergraduate degree in history from Yale, medical and public health degrees from Emory, and trained in internal medicine and completed the Robert Wood Johnson Clinical Scholars Program at the University of Pennsylvania.

Dr Rituparna Pati, MD, MPH, is an infectious disease physician and HIV Treatment Technical Advisor in the Division of Global HIV and TB at the Centers for Disease Control and Prevention in Atlanta. She provides technical assistance for HIV care and treatment programs in PEPFAR countries, including support for scale-up of routine VL monitoring and models of remote clinical mentorship. Before joining the CDC, Dr Pati was Director of Research at the Spencer Cox Center for Health, Mount Sinai Institute of Medicine, in New York City.

Rumbidzai Praise Matewe holds a Master's Degree in development studies. Rumbi has more than 10 years working experience in community development. She has contributed immensely to advocacy, accountability, and transparency in the HIV response over the years. Currently employed by Zimbabwe National Network of People Living with HIV, she has been instrumental in advocacy for routine VL testing availability and demand creation among people living with HIV linked to it was the rolling out of differentiated service delivery in Zimbabwe. Over the past 3 years she has worked in improving the programme design and monitoring for community ART refill groups and knowledge generation for Routine Viral Load from a community perspective.

Seth McGovern has worked in health services for eight years, four on HIV Diagnostics, including two years managing the CHAI laboratory program in Malawi and two years as a member of the global Laboratory Services Team. He holds a MSc in Health Economics, Policy, and Management from the London School of Economics. Seth is happily married to his wife, Serena, and they have a dog, Lou. Seth is also an avid skier, mountain biker, and hiker.

Seyoum Dejene, HIV and Tuberculosis (TB) Advisor for USAID Uganda

Shirley Lee Lecher MD, MPH, is an Associate Chief for Clinical Laboratory Practice for the International Laboratory Branch, Division of Global HIV and TB at the US Centers for Disease Control and Prevention. She has over 15 years of experience in HIV/AIDS as an Infectious Diseases physician, basic scientist and public health leader. Prior to working in the International Laboratory Branch she held other positions at CDC including Deputy Branch Chief for Research in Kenya and Director of the Caribbean Regional Office. Prior to working at CDC she was employed as a Senior Scientist for the US Military HIV Research Program and Senior Research Investigator for the US Food and Drug Administration. She completed training in Infectious Diseases at the National Institutes of Health and received a Medical Doctorate and Masters in Public Health from Yale University.

Souleymane Sawadogo, Lead Technical Advisor Laboratory Services at US Centers for Disease Control and Prevention, Namibia

Tom Heller, MD, MPH, joined CDC-South Africa as Branch Chief for Care and Treatment in May 2016, prior to which he had been Associate Director for Care & Treatment for CDC-Ethiopia for the prior four years. In South Africa he leads a team that oversees Cooperative Agreements worth more than 100 million dollars. He's played an instrumental role in developing the Same Day ART initiation policy following the implementation of UTT and is promoting use of linkage coordinators and Viral Load Champions and sensitization of public facility staff to provide kind and respectful care as keys to linkage and retention at facilities. In Ethiopia he played a significant role in moving the government to adopt PMTCT Option B+ and subsequently to adopt the "Test and Start" treatment policy.

Prior to working in Ethiopia, Tom spent two years as Senior Clinical Advisor for I-TECH at the University of Washington in Seattle and 5 ½ years as a contracted employee of CDC-Cambodia, where he helped establish HIV treatment services, promoted TB/HIV integrated care and treatment, assisted in strengthening PMTCT performance, and helped establish a national continuous quality improvement plan for HIV treatment sites. He has contributed abstracts on TB/HIV and PMTCT to PEPFAR Implementers meetings and IAS conferences and has published on impact of training midwives to perform point-of-care HIV testing.

Prior to pursuing global HIV work, Tom worked for 20+ years as a primary care internist caring for marginalized populations and has been caring for people living with HIV since the mid-1980s. He received his BA degree from Yale University, his MD degree from the University of Illinois, and MPH from University of Washington.

APPENDIX: Meeting Agenda

HIV Viral Load Regional Workshop
Addis Ababa, Ethiopia
October 23-25, 2017

Time	Day 1	Presenters
	Monday, October 23, 2017	
0800-0830	**Registration**	
SESSION 1: Reaching the Third 90 **Moderators**: MOH Ethiopia, Ndlovu Nqobile ASLM, George Alemnji OGAC **Rapporteurs**: McPaul Okoye and ASLM		
0830-0840	Welcoming Remarks	MOH Ethiopia PEPFAR Ethiopia ASLM
0840-0855	Keynote Address	Heather Alexander, CDC
0855-0900	Workshop Objectives	Shirley Lecher, CDC
0900-0910	90-90-90 Current Status	Fatim Cham Jallow, WHO-AFRO
0910-0920	ASLM Update	Ali Elbireer, ASLM
0920-0930	Clinical considerations in scaling up viral load testing	Lara Vojnov, WHO
0930-1000	Community Engagement – An Essential Component of VL Scale-up Success	Rumbidzai Matewe, Zimbabwe Jaquiline Alesi, Uganda Patricia Asero, Kenya
1000-1015	**Discussion**	
1015-1030	Tea Break	
SESSION 2: Country Progress with Viral Load Scale-up **Moderators**: MOH Namibia, WHO AFRO, Peter Fonjungo CDC **Rapporteurs**: S. Sawadogo, Mary Nalguzza		
1030-1150 **Group 1**	1) Ethiopia 2) Rwanda 3) Tanzania 4) Zambia 5) Malawi 6) Mozambique 7) Cote d'Ivoire 8) Lesotho 9) Cameroon 10) Nigeria 11) Zimbabwe	Country representatives
1150-1205	**Discussion**	
1205-1250	Lunch	

SESSION 2: Country Progress with Viral Load Scale-up (continued)

Moderators: MOH Malawi, Eileen Burke GF, Laura Broyles CDC
Rapporteurs: Yenew Kebede, Christiane Adje

1250-1345 **Group 2**	1) Angola 2) Burundi 3) Democratic Republic of Congo 4) Mali 5) South Sudan 6) Sierra Leone	Country representatives
1345-1400	**Discussion**	
1400-1410	Global Fund Plans to Reach the Third "90"	Eileen Burke, GF
1410-1420	Global Diagnostic Procurement Consortium	George Alemnji, OGAC
1420-1430	ASLM Community of Practice	Pascale Ondoa, ASLM
1430-1440	ECHO Case Based Models to Share Best Practices for Program and Laboratory Improvement	Bruce Struminger, UNM
1440-1450	Viral Load Champions	Frank Basiye, CDC-Kenya
1450-1500	**Discussion**	
SESSION 2: Country Progress with Viral Load Scale-up (continued) **Moderators**: MOH Lesotho, Jennifer Malia DOD, Spencer Lloyd CDC **Rapporteurs**: Bernard Nkrumah, Henry Mbah		
1500-1545 **Group 3**	1) Namibia 2) Uganda 3) Kenya 4) Botswana 5) South Africa 6) Swaziland	Country representatives
1545-1555	**Discussion**	
1555-1610	Tea Break	
SESSION 3: POC, The Network Approach, and Supply Chain **Moderators**: MOH Kenya, Smilijka de Lussigny UNITAID, Dennis Ellenberger CDC **Rapporteurs**: Luciana Kohatsu , Dan Gama		
1610-1640	Point-of-Care testing • Considerations • HIV Diagnostics Project (UNITAID, CHAI, UNICEF, ASLM)	 • Clement Zeh, CDC • Trevor Peter, CHAI

	• Pediatric HIV POC Diagnostics and Status of VL Suppression	• Chewe Luo, UNICEF

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1640-1655	The Network approach • Understanding Your Existing Network and Future needs (GIS based tools) • Integration of POC Platforms into Current Networks Supply Chain and Procurement • Understanding Pricing Variations, Forecasting and Procurement, Maintenance Challenges, Manufacturer Engagement	Jason Williams, USAID
1655-1715	**Discussion**	
1715	Close	

Time	Day 2 Tuesday, October 24, 2017	Presenters
0815-0830	Day 1 RECAP	Ritu Pati CDC

Session 4: Data & Monitoring and Evaluation

Moderators: MOH South Africa, Trevor Peter CHAI, WHO Geneva

Rapporteurs: Karidia Diallo, Yohannes Eshete

0830-0840	Viral Load M&E Progress and Existing Challenges	Nadia Solehdin, CDC
0840-0900	Viral Load M&E Plan Development	Jonathan Ntale, CDC-Uganda
0900-0910	**Discussion**	
0910-0930	Viral Load Target Setting	Nadia Solehdin, CDC Michael Mwasekaga , CDC-Tanzania
0930-0945	Viral Load reporting: Tracking Number of tests vs. Individuals	Jonathan Ntale, CDC-Uganda
0945-1000	**Discussion**	
1000-1015	Tea Break	
1015-1040	Viral Load M&E to Monitor Clinical Outcomes and Management of non-Suppressed Viral Load	Gram Mutandi, CDC-Namibia Alice Maida, CDC-Malawi
1040-1050	**Discussion**	
1050-1055	Instructions for breakout sessions (laboratory and clinic)	Dennis Ellenberger, CDC
1055-1105	**Group Photo**	

Session 5: Breakout Session (Laboratory)

Moderators (laboratory): Lara Voynov WHO, Jason Williams USAID, Clement Zeh CDC
Rapporteurs (laboratory): Michael Mwasekga, Richard Mwesigwa

1105-1205 1300-1400	**Concurrent Breakout Sessions:** • Laboratory sessions (Room TBD)	
	Evaluation, Validation and Verification: What you Need to Know	Leigh Berrie, S. Africa
	QA Strategies for Reagents	McPaul Okoye, Nigeria
	Specimen Referral Practice: Country Best Practices including Remote Accession	Jonathan N'tale, Uganda
	Optimization & Integration of Platforms	Dan Mfanfikile Gama, Swaziland
	Laboratory Challenges: Specimen Management, Connectivity, and Results Return	Michael Mwasekaga, Tanzania
	CQI and Accreditation	Air Cdre Edward Abayomi Akinwale (Rtd), DOD
	HIV VL CQI Collaborative	Kenya
	Use of Laboratory Scorecard and Quarterly Monitoring Tool for Programme Monitoring	Henry Mbah, Malawi
	Equipment Maintenance, QA, Training, Reagent Inventory and procurement	Souleymane Sawadogo, Namibia
1205-1300	**Lunch**	

Session 5: Breakout Session (Clinical)

Moderators (Clinical): Helen Chun CDC
Rapporteurs (clinical): Fred Asiimwe, Abraham Katana

1105-1205 1300-1400	**Concurrent Breakout Sessions: (See attachment for details)** • Clinical sessions (Room TBD)	
	VL in the Context of Differentiated Service Delivery Models	Tom Heller, CDC S. Africa
	Experiences with Enhanced Adherence Counseling – Does one Size Fit All?	Gram Mutandi, CDC Namibia
	Optimizing Management of Patients with non-Suppressed VL	Alex Joseph Nyniyal, MOH South Sudan
	Innovative Approaches in the VL Cascade	Evelyn Wangari, CDC Kenya
	The Role of Civil Society Organization and Community Cadres in the Era of VL Monitoring for Patient	Rumbidzai Matewe, Zimbabwe Patricia Asero Ochieng,

	Management. Strengthening CSO Support for VL Suppressed/non-Suppressed Patients & Best Practices	Kenya Jacquelyne Alesi, Uganda
	Partner Management in the Era of VL Monitoring	Charity Alfredo and Luciana Kohatsu, CDC Mozambique
	Unique Facets of VL Monitoring in the Maternal-Child Context	Laura Broyles, CDC Atlanta
Session 6: Working Group Sessions		
1400-1410	Instructions for country working group sessions	Shirley Lecher, CDC
1410-1510	Working Group Sessions: 1) Greatest Challenges with VL Scale-up 2) Meeting PEPFAR Targets 3) Develop Action Plan	
1510-1525	Tea Break	
1525-1655	Continue Working Group Sessions	
1655-1710	Reassemble for Instructions on Community of Practice Evening Event	ASLM (Mah-Sere Keita)
1710	Close	
18:30-21:30	**Dinner and launch of the Laboratory System Strengthening Community of Practice (LabCoP) at the Radisson Hotel** • Keynote presentation: the Importance of a Shared Learning Platform to Support the Scale-up of VL (Peter Ehrenkranz, BMGF) • Results of ASLM Survey on LabCop - Introducing the LabCoP (Legese Mekuria/Pascale Ondoa, ASLM) • Presentation of the CQUIN Project: Example of a Successful Community of Practice (Miriam Rabkin, ICAP at Columbia) • Viral Load Success Stories from Uganda (Charles Kiyaga, ASLM) • Concluding Remarks (Heather Alexander, CDC) • Questions and Answers on the Goals and Priorities of the CoP	Event organized by ASLM, BMGF & ICAP ******* Hosted by Ms. Mah-Sere Keita (ASLM) *******

Time	Day 3 Wednesday, October 25, 2016	Presenters
0900-0915	Day 2 RECAP	Helen Chun

Session 7: Country Reports from Breakout Sessions

Moderators: MOH Cameroon, Rebecca Bailey EGPAF, Peter Ehrenkranz, Gates
Rapporteurs: Nadine Abiola, CDC, Charity Alfredo CDC

0915-1030	Report from Day 2 Working Group Sessions - Present Action Plan for the Next Year • Group 1	5 countries
1030-1050	**Discussion**	
1050-1120	Tea Break	
1120-1220	Report from Day 2 Working Group Sessions - Present Action Plan for the Next Year • Group 2	4 countries
1220-1230	**Discussion**	
1230-1330	Lunch	

Session 7: Country Reports from Breakout Sessions (cont)

Moderators: MOH Botswana, Bruce Struminger UNM, Niko Gaffga CDC
Rapporteurs: Alice Maida, John Mondi

1330-1430	Report from Day 2 Working Group Sessions - Present Action Plan for the Next Year • Group 3	4 countries
1430-1445	Meeting Summary	ASLM
1445-1500	Closing Remarks	
1500	Meeting close	

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