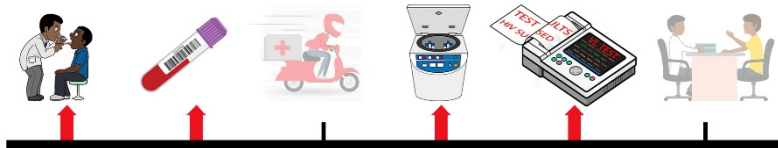


LabCoP QUARTERLY

African Society for Laboratory Medicine

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Viral load cascade topics in this Issue of LabCoP Quarterly

Highlights from the LabCoP 2020 Annual Meeting

The 2020 annual LabCoP meeting was held 24-25 November 2020. The meeting was a combination of virtual and face-to-face interaction due to restrictions on movement implemented by most countries in response to the coronavirus disease 2019 (COVID-19) pandemic. The meeting was attended by over 300 participants from the 14 member countries of the LabCoP and key stakeholders from the United States Presidents Emergency Plan For AIDS Relief (PEPFAR), the United States Centers for Disease Control and Prevention (CDC), Clinton Health Access Initiative, ICAP at Columbia University, The Global Fund (GF), World Health Organization (WHO), WHO Regional Office for Africa, International Treatment Preparedness Coalition and Africa

CDC, among others. Some of the highlights of the meeting included:

- **Identification of waste management, supply chain, sample transportation and national data on viral load testing and antiretroviral therapy as critical gaps in the effectiveness of the HIV viral load testing cascade.**

Country teams were assisted by subject matter experts and stakeholders to prioritize interventions addressing the identified gaps, and to find the correct angle to link them to the funding priorities of the PEPFAR Country Operational Plan 2021 and GF programming or reprogramming cycles.

- **Crystallisation of best practices emerging from the response to COVID-19.** Representatives from the Kenya

Ministry of Health, South African National Health Laboratory Service, Africa CDC laboratory division, Foundation for Innovative New Diagnostics and United States CDC shared their views on improved mutualising of resources and coordination of the diagnostic network to respond to the pandemic, as well as the acceleration of waste management strategies to cope with additional guanidinium thiocyanate waste. These are important lessons learnt that will continue to be applied to routine testing.

- **Two flagship activities planned for coming months.**

- Formation of a dedicated monitoring and evaluation sub-community of practice, which will directly support continuous quantitative assessment of the viral load testing cascade at the national level.

- Creation of a fit-for-purpose course, called 'LabNetLead', for member countries to support the management, coordination and optimisation of the tiered laboratory network based on evidence. The course will start touring from country to country in the first quarter of 2021.

Many more updates and lessons learned from the meeting were shared. These can be found in the meeting report, slides, resources and session recordings accessible [here](#).



Participants connected online for LabCoP's annual meeting, 24-25 October 2020

2020 Q 3&4 LabCoP ECHO Sessions

Lessons to Consider

LabCoP's Viral Load ECHO Sessions between July and October 2020 addressed key systems strengthening issues ranging from demand creation for HIV diagnostics services, to quality assurance to monitoring and evaluation of the HIV testing cascade and other co-morbidities.

Massive investments have been made for early diagnosis of HIV, prompt return of test results, and rapid initiation of treatment, as part of prevention of mother-to-child transmission (PMTCT) programs. Despite these efforts, the coverage of PMTCT remains insufficient with an unacceptable number of infants still exposed to HIV at birth. The Global Network of People living with HIV (GNP+) recently developed a [strategic framework](#) to guide formulation of clear, operational ideas for civil society representatives on how to improve engagement and guarantee demand creation for testing and sustain it. In the [July session](#), Georgina Caswell, Head of Programmes at the GNP+, encouraged country teams to continue to focus on early infant diagnosis, including the role of point-of-care testing and its ability to give same day and quicker diagnosis, which is key to reducing loss to follow up and prevent mortality. In the [September session](#), the International Treatment Preparedness Coalition's Pontsho Pilane demonstrated that demand creation depends on several pillars, including patient education, sensitisation and awareness of VL testing. Recognising the importance of these pillars is key to ensuring continued HIV and tuberculosis testing, especially in the context of the COVID-19 pandemic.

External quality assessment (EQA) is conducted by a third party and measures the performance of testing

laboratories to help identify deficiencies and opportunities for improvement. The [August LabCoP ECHO session](#) highlighted the need for a sustainable approach that allows countries to take ownership of and establish a VL proficiency testing program through technology transfer from current providers such as the United States Centers for Disease Control and Prevention. Daniel Taylor, co-founder of One World Accuracy,

GNP+ GLOBAL NETWORK OF PEOPLE LIVING WITH HIV

EARLY INFANT DIAGNOSIS: THE FACTS

Unitaid unicef for every child

In the Sub-Saharan region, in 2019:

- Only 61.2% of infants exposed to HIV were tested within their first two months of life
- Only 51.1% of children living with HIV were receiving antiretroviral treatment
- There were 130,000 new HIV infections in children aged 0-4
- There were 58,000 AIDS-related deaths in children aged 0-4

[HIV estimates for children dashboard - UNICEF](#)

Georgina Caswell
30 JULY 2020

NO TIME TO WAIT!

Slide from Georgina Caswell's July ECHO session [presentation](#)

explained one way of achieving this is through collaborative EQA, which helps governments start or improve national EQA programs by providing informatics, training and integrating economic principles into EQA to meet international standards with sustainable cost structure.

As countries continue to strengthen uptake of diagnostic services and ensure their quality, challenges remain for objectively demonstrating that after increased usage of testing services, the results are actually being utilised to inform patient management. Many countries struggle to track the viral load (VL) data necessary to do so. COVID-19 impacts general routine health care

services and risks to affect the capacity to utilize VL data for clinical decisions. The [October session](#) focused on one effort to address these gaps: ASLM's convening of a monitoring and evaluation (M&E) sub-community of practice to provide guidance and considerations to country teams as they develop, review, and/or strengthen their laboratory M&E systems. Some countries have made advances in this area, and Kenya provided a good example.

Watch the [July](#), [August](#), [September](#), [October](#) and other past ECHO sessions [here](#).

COVID-19 impacts general routine health care services and risks to affect the capacity to utilize VL data for clinical decisions.

Impact of COVID-19 on HIV Testing Services and Treatment Monitoring

ASLM asked Zack Panos, Senior Manager for the HIV Access Program at the Clinton Health Access Initiative (CHAI), to provide his perspective on the impact that coronavirus disease 2019 (COVID-19) has had on HIV testing and treatment.

Since being characterized by the World Health Organization (WHO) as a pandemic in March 2020, COVID-19 has impacted nearly all aspects of the HIV continuum of care. In fact, disruptions to HIV testing and treatment monitoring have topped the list of services disrupted by COVID-19, according to a WHO survey in June 2020.

With a model necessitating close contact between clients and healthcare workers, many countries in sub-Saharan Africa saw sharp decreases in professional HIV testing volumes as Governments initiated lockdowns and movement restrictions in April and May. This drop has been primarily attributed to declines in facility attendance, limited health care worker outreach and prioritization of other services. While HIV self-testing (HIVST) emerged as a logical way to ensure continued access to testing services and

minimize client-provider contact, quickly pivoting to widespread distribution of HIVST proved challenging. In many countries, it was not prioritized or supportive systems (e.g., guidance, trainings, commodity stocks) were not in place. Notable exceptions include Eswatini and Zimbabwe, where HIVST was scaled up quickly during lockdowns.

Given the clinical importance of timely diagnosis of HIV in infants, many countries prioritized early infant diagnosis (EID) services despite lockdowns. Data from Kenya, Malawi and Uganda's EID dashboards showed that, aside from slight decreases in monthly volumes starting in April, cumulative EID volumes have remained relatively consistent with those in 2019. However, it is possible that countries with less developed EID programs experienced more substantial disruption.



Dried blood spot test used for early infant diagnosis

While HIV self-testing (HIVST) emerged as a logical way to ensure continued access to testing services and minimize client-provider contact, quickly pivoting to widespread distribution of HIVST proved challenging.

Compared to EID, viral load (VL) testing seems to have been more acutely impacted by COVID-19. Dashboard data from Kenya, Malawi and Uganda shows more significant disruptions to cumulative VL volumes in 2020 compared to 2019. However, this is not necessarily surprising, as many programs prioritized testing for the most clinically relevant populations, such as pregnant women.

It is well-documented that COVID-19 has negatively impacted and continues to threaten critical HIV services, including diagnostics. While CHAI has seen firsthand and heard anecdotally that service delivery has begun to normalize in some countries, not all countries have made up for the setbacks experienced earlier in 2020.

Many are projected to identify and link significantly fewer people living with HIV to care than anticipated. Simply getting back to pre-COVID-19 testing levels alone will not be adequate as a catch-up strategy. Programs must push forward to continue to identify people living with HIV and further scale EID and VL testing to reach pre-COVID-19 targets set for 2020 and 2021. Additionally, innovative testing strategies that were developed to mitigate COVID-19's impact must continue in order to minimize the impact of any future service disruptions and bring services closer to people.



HIV self-tests can help offset disruptions from COVID-19

It is clear now that COVID-19 will likely be with us for years to come. As such, national programs and partners must adapt HIV testing and diagnostic services to be successful and robust under this new reality. CHAI believes that LabCoP has a role to play in identifying best practices and implementing innovative approaches supporting resilient testing services.

Country Self-Assessment Findings

Every year LabCoP countries conduct an annual self-assessment of their viral load (VL) testing cascade using the Rapid [Self-Assessment Checklist](#) for National Laboratory Systems and Viral Load Testing Scale-up. The purpose of the assessment is to identify critical gaps in laboratory systems, monitor progress towards improvement of HIV VL testing outcomes and identify best practices.

A total of 12 countries conducted a self-assessment. Nigeria and Cameroon conducted the assessment for the first time, having recently joined LabCoP. The results were shared during the virtual annual meeting held 24-25 November 2020.

Leadership and Management, and Demand Creation for HIV VL testing are the two domains that countries are doing well at with median scores of 4 and 3 (out of a possible 4), respectively. However, countries are lagging behind in three main domains, namely: Sample Transportation, Waste Management and Biosafety, and Supply Chain Management and Equipment Maintenance. A comparison of 2019 versus 2020 self-assessment results showed that

for every domain, there were at least two countries that recorded improvement. Additionally, while Waste Management remains an area where most countries are lagging behind, this is the domain that recorded the greatest progress with 50% of country teams recording a score improvement. (See Figure 1 below)

While all countries had data on laboratory and VL testing capacity, as well as data to track the cascade of routine VL testing and key indicators to track virally suppressed patients, data on suppressed clients who were referred to less intensive models of care was not readily available in most countries. Similarly, almost all countries have no data at



for patients with a non-suppressed VL test result. This illustrates monitoring and evaluation (M&E) gaps at the laboratory/clinic interface. The results are summarized in the [VL Assessments Summary Dashboard](#).

Countries utilized these findings to develop targeted action plans and address identified gaps. LabCoP and its partners will support country teams through a dedicated M&E sub-community of practice to help address the tracking and quantification gap challenges and increase data availability and use at the national level.

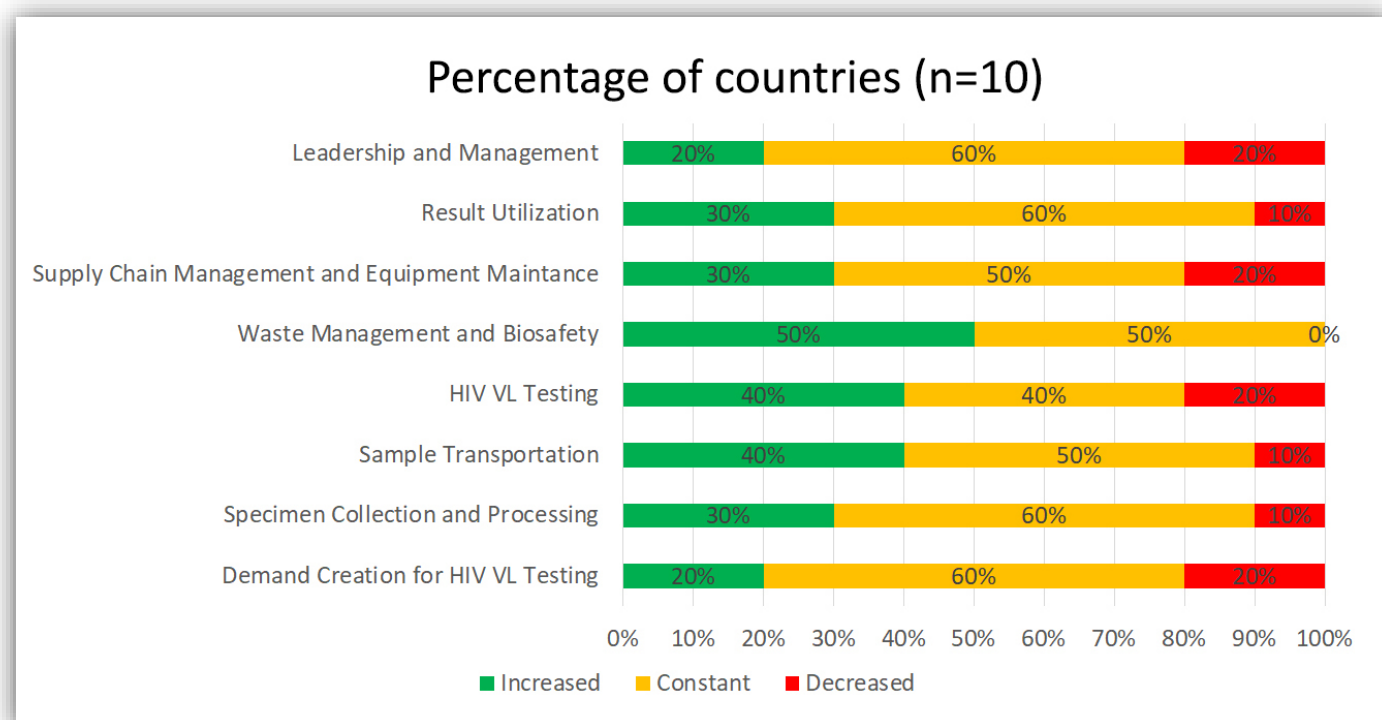


Figure 1: Percent of countries reporting an increase, constancy, or decrease in VL self-assessment score between 2019 and 2020, by domain.

Expert Experience



Pontsho Pilane

Recently, ASLM sat down with Pontsho Pilane, Communications Consultant with International Treatment Preparedness Coalition (ITPC), to discuss demand creation for routine viral load testing (RVLT).

ASLM: What does demand for HIV viral load (VL) mean?

Pilane: It means ensuring that people living with HIV know what viral load is and why it's important for them to know their VL. When recipients of care, in this case people living with HIV, know the importance of knowing their VL, then they can walk into their local health facilities and demand the service.

ASLM: Why is creating demand for routine HIV VL testing so important in the battle against HIV?

Pilane: It's important because it enables recipients of care to know their viral load, which further enables them and their healthcare providers to see how well the HIV treatment is working in their bodies. Demand creation, paired with effective literacy and awareness campaigns can result in more VL testing (VLT).

ASLM: How are ITPC and ASLM teaming up to help LabCoP

country teams create more demand for routine VL testing (RVLT)?

Pilane: We're partnering by training community organisations on the importance of VLT and how to run effective advocacy campaigns. Through virtual training, LabCoP country teams were trained on the science of HIV – especially focusing on VLT and then how to incorporate this information into an advocacy campaign.

ASLM: What are the most effective strategies to create demand for RVLT and how can these be adapted to different settings?

Pilane: The most effective way is to inform recipients of care and give them all the information they need to understand the importance of RVLT. It's also imperative to reach people through the most accessible means available to them. If internet is a challenge, then a digital-only strategy will not work. We need to be cognizant of all the limitations that may be in the way.

You need to identify which platforms they use to find information, understand what information they will want to receive, determine how they use that information and consider how - and where - they interact with that information.

ASLM: What is a media campaign and how can it help to create demand for RVLT?

Pilane: A media campaign is a coordinated marketing and advocacy communications plan that helps to get a certain message across. It involves five main components: Identifying your audience, determining the goals and objectives, developing the key messages you want to communicate, developing a plan to communicate the messages and designing measures to evaluate.

The LabCoP Management team is excited to see some of the country teams begin their RVLT awareness campaigns and circulate their messages online and beyond. LabCoP will continue to work with ITPC and country teams to monitor their campaign reach and impact as they progress into 2021.



ITPC trains Kenya's LabCoP country team how to manage a RVLT awareness campaign in August of 2020

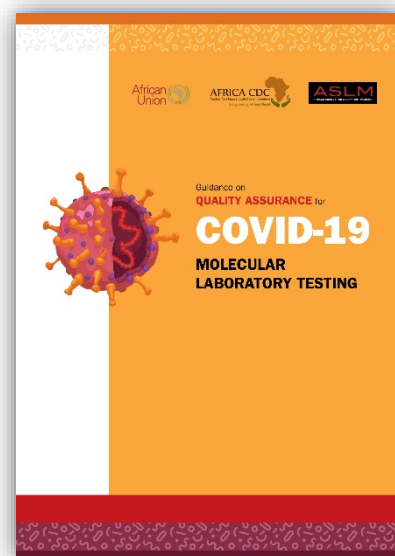
ASLM, LabCoP, and Partners Urgently Publish COVID-19 Guidance

LabCoP guidance and Cookbook of recipes are key products intended to accelerate the dissemination of best practices and ideas that are proven to work, in support of laboratory system strengthening. In the last half of 2020, ASLM's LabCoP and partners produced a number of key resource documents to guide the scale up of coronavirus disease 2019 (COVID-19) diagnostics. Some of these key documents were translated into French and Portuguese to increase access in non-English-speaking countries.

One of the first documents published was the [Guidance on Quality Assurance for COVID-19 Molecular Laboratory Testing](#). This document was developed by ASLM in collaboration with the Africa Centres for Disease Control and Prevention (CDC) and the Foundation for Innovative New Diagnostics (FIND) for the Africa CDC-led Africa Taskforce on Coronavirus Preparedness and Response (AFTCOR) for COVID-19. It

describes the key elements that laboratories should put in place to rapidly identify and minimise the risk of laboratory testing errors in the specific context of COVID-19 response. Notably, the document provides practical guidance regarding the establishment of external quality assessment, particularly where severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) proficiency testing panels are not available. A [COVID-19 quality assurance/quality control recipe](#) was also published in the [LabCoP Cookbook](#). The recipe outlines best practices along the entire COVID-19 testing cascade, from the pre-analytical to the post-analytical phase.

Another LabCoP Cookbook recipe was published to outline the process of decentralisation of COVID-19 PCR diagnostic capacity from the central to sub-national level. The recipe highlights how to mutualise existing testing resources across the network (e.g., molecular instruments from HIV and



Guidance on QA for COVID-19 Testing

Well validated in-house PCR tests can contribute to increase the overall capacity and the versatility of SARS-CoV-2 detection methods.

tuberculosis programmes) to quickly mount extensive coverage for COVID-19 testing and redistribute the workforce.

Addressing the lack of knowledge and capacity to develop in-house PCR testing, ASLM and FIND collaborated to produce a guidance document on [in-house test development for molecular detection of SARS-CoV-2](#). This document provides practical tips for the creation of new molecular diagnostic tests and other emerging pathogens for which genetic information is available. Well validated in-house PCR tests can contribute to increase the overall capacity and the versatility of SARS-

CoV-2 detection methods. The guidance is available in English, French and Portuguese and is intended to be made available as hard copies in 15 countries supported by LabCoP and/or by Resolve to Save Lives.

Lastly, LabCoP supported the production of a special COVID-19 issue of the Lab Culture, in which manufacturers of COVID-19 diagnostic products elaborated on the technical and field performance of their products. Additionally, scientists and opinion leaders provided their perspectives on the fight against the COVID-19 pandemic at the continental and global level.



Recipe #5 of the [Cookbook of Best Practices](#) 6

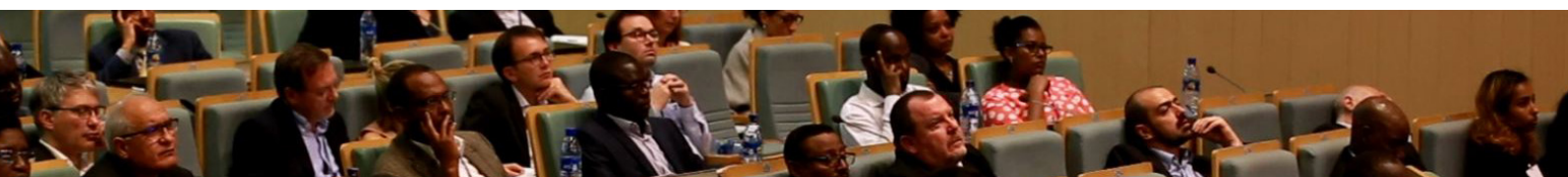
What's New at LabCoP

RVLT Awareness Campaigns Kickoff

In December of 2020 Kenya and Malawi kicked off their Routine Viral Load Testing awareness campaigns and are tweeting messages using the hashtags #BeHealthyKnowYourViralLoad and #WhyViralLoadMatters respectively. Scores of posts on Twitter and Facebook, from a wide array of stakeholder groups, have addressed the variety of benefits that RVLT has on people living with HIV. We look forward to more campaigns beginning in 2021.

PEPFAR 2021 COP/ROP Guidance is now Available

The PEPFAR 2021 COP/ROP Guidance is now available and can be accessed [here](#)! LabCoP country teams should explore linking prioritized activities from the self-assessment exercise to COP funding.



Looking Ahead

The New Monitoring and Evaluations Sub-community of Practice

New [Cookbook Recipes](#) will be released in early 2021! Topics will include how to maintain essential testing during a pandemic, laboratory waste management, the implementation of Point-of-Care testing, and more. LabCoP is working toward translating future recipes into French and Portuguese, including a few already-published recipes accessible [here](#). LabCoP will keep you informed as translations become available.

M&E Sub-community of Practice Kicks Off

The M&E sub-community of practice kicks off in early February 2021. If your country team has not yet formed an M&E CoP team, please consider this opportunity and reach out to Dr Collins Otieno via [email](#).

New LabCoP Extended ECHO Series Continues

More sessions of the new [LabCoP Extended ECHO series](#) will commence in 2021. These will be similar to the Viral Load and COVID-19 ECHO sessions you have become familiar with, but this new series will cover a wide variety of lab systems strengthening topics. Watch your email for more updates.

Lab Culture Issue 24 is Here!

Issue 24 focuses on external quality assessment and takes a closer look at EQA's impact on AMR and more. It can be downloaded [here](#). Article submissions for Issue 25, coming in March, are being accepted through the end of February. For queries regarding contributing to or advertising in *Lab Culture*, please contact [Ms Mah-Sere Keita](#) and copy [Dr Collins Otieno](#).



<https://aslm.org/what-we-do/labcop/>