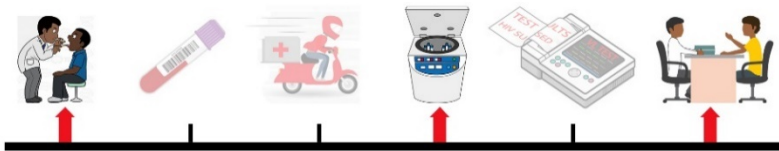


# LabCoP QUARTERLY

African Society for Laboratory Medicine

March 2020

Volume 3, Issue 1



Viral load cascade topics in this Issue of LabCoP Quarterly

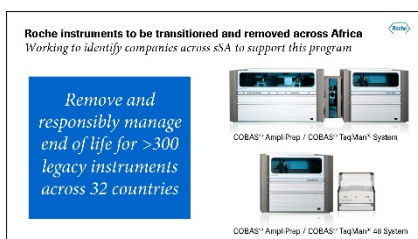
## Waste Management Series

January – March 2020:

### Sharing best practices in laboratory waste management

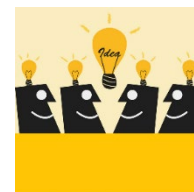
Between January and March 2020, ECHO sessions about medical laboratory waste management featured perspectives from two diagnostic manufacturers, Roche Diagnostics International Ltd. and Hologic, Inc., and a country presentation from Kenya.

In January 2020, Joni Zurawinski, Project Manager of Virology and Systems, and Kevin Gara, Chief Product Stewardship Officer from [Roche](#), shared their experiences and best practices on waste handling. They spoke about end-of-life management of Roche equipment in the field, proportions of hazardous components in their products, and their safe disposal. They proposed several solutions to manage waste, including the development of a waste volume calculator, waste management vendor checklist, and more. Download the presentation [here](#) and watch the January waste management session [here](#) on ASLM's YouTube channel.



Slide from Roche ECHO presentation.

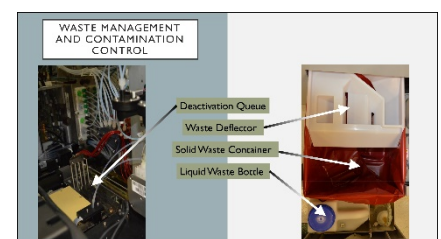
In February, Kennedy Yatich, Head of the Biosafety and Biosecurity Program at [National Public Health Laboratory Services](#), Ministry of Health, Kenya, shared findings from an assessment of waste handling practices in laboratories that conduct viral load (VL) and early infant diagnosis (EID) tests in Kenya. Kenya was among the first countries to pilot a new assessment [tool](#) developed last year by ASLM, the [United States CDC](#), [The Global Fund](#) and the [Integrated Diagnostics Consortium](#) to assist with identifying gaps and creating awareness of best practices for waste management processes in VL and EID molecular testing laboratories. Mr Yatich described how they used the tool to carry out the self-assessment, and detailed the findings, challenges, solutions and next steps, then provided recommendations for other countries. Download the session presentation [here](#) and watch the February waste management session [here](#) on ASLM's YouTube channel.



Lab  
CoP



In March, Todd Richmond, from [Hologic](#), described the waste management and contamination control process for their Panther instrument. Todd outlined the liquid waste composition created by the Panther, which is one of the few high-throughput instruments producing waste free of guanidinium thiocyanate (GTC), often used as a general protein denaturant. GTC is a reagent that is toxic to aquatic life and requires hazardous waste management. Mr Richmond explained that the Panther uses bleach instead of GTC. Download the presentation [here](#), and watch the March waste management session [here](#) on ASLM's YouTube channel.



Slide from Hologic ECHO presentation.

# 2020 Q1 LabCoP ECHO Sessions

## Lessons to Consider

Between January and March 2020, LabCoP's ECHO sessions featured topics relevant to viral load (VL) programs and laboratory systems, diagnostics for Advanced HIV Disease (AHD), and innovative interventions for results utilisation.

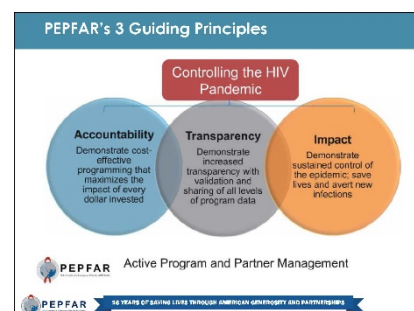
**In January**, Dr George Alemnji, Senior Technical Advisor for the [President's Emergency Plan for AIDS Relief \(PEPFAR\)](#) Laboratory Services, presented the PEPFAR Country Operational Plan (COP) 2020's laboratory systems strengthening priorities to help countries prioritise challenges that can be addressed through PEPFAR funding. These included among many strategies: improving access to VL testing via dry blood specimens and point-of-care (POC) testing among pregnant and breastfeeding women, infants and virologically non-suppressed patients, as well as increased access to testing for HIV and tuberculosis through optimising diagnostic networks and testing integration. For more details, watch the session [here](#), and download the presentation [here](#).

**In February**, Mr Zibusiso Ndlovu, Epidemiologist and Laboratory Advisor at [Médecins Sans Frontières \(MSF\)](#) presented MSF's experiences in implementing the AHD package of care over the past few years. Many people continue to develop AHD, despite the maturity of many antiretroviral therapy programs. MSF's

framework for implementation of AHD diagnostic testing defines whom to test, where to test within the tiers of care, what test to perform, who administers the testing, and sets the test timing. Mr Ndlovu emphasised that both laboratory-based and POC-based reflexive testing, coupled with provider-initiated requests for serum cryptococcal antigen and urine tuberculosis lipoarabinomannan tests should be performed for all patients with CD4 cell counts >200cells/ul. Additionally, he shared community-level interventions, and efforts that eliminate barriers to testing and care. For a detailed explanation of these and other critical elements of the framework, watch the February session [here](#).

**In March**, Dr Samanta Tresha Lalla-Edward, the Head of Research Development, Ezintsha division of [Wits Health Consortium](#) at the University of the Witwatersrand, South Africa, presented results from a pilot study on the feasibility and acceptability of iThemba, a mobile application to support results utilisation and engagement in HIV care and suppression. HIV results utilisation is a challenge in many parts of the continent, and iThemba is one solution that can mitigate this problem. The results showed that iThemba is a feasible way to deliver HIV VL results to users' smartphones. Increasing the speed of HIV VL result return accelerates clinical decision

making and empowers patients to remain engaged in care. Ninety-eight percent of surveyed users were interested in continuing to use iThemba at the end of the pilot. As a result, the Wits Health Consortium is preparing for wider enrolment in iThemba and will assess a routine implementation model at scale, determine clinical management and workflow improvements, and operational and human resource requirements for routine implementation of iThemba. For more email on this pilot project, [email Dr Edwards](#). The recorded ECHO session will be made available ASAP.



PEPFAR Guiding Principle slide from Dr George Alemnji's January ECHO presentation.

'iThemba is a feasible way to deliver HIV VL results to users' smartphones. Increasing the speed of HIV VL result return accelerates clinical decision making and empowers patients to remain engaged in care.'

# ASLM and ICAP's CQUIN Conduct Joint Visit to Sierra Leone

From 22 to 24 January 2020, ASLM's LabCoP and ICAP HIV Coverage, Quality, and Impact Network (CQUIN) teams conducted a joint visit to Sierra Leone to support the country's effort to scale up differentiated service delivery (DSD). [CQUIN](#), a LabCoP sister project funded by the [Bill and Melinda Gates Foundation](#), is a multi-country learning network dedicated to expanding and improving DSD for people living with HIV. Sierra Leone is a member of LabCoP and is in the process of joining CQUIN.

The joint visit was informed by the realisation that the two networks co-exist in nine of the 11 LabCoP countries, and that viral load (VL) scale-up is a common entry point. Additionally, the same national stakeholders including the ministry of health and civil society are involved in activities supported by the two networks. The objective of the visit was to meet with stakeholders and

implementing partners, help the country team identify and disseminate best practices related to laboratory enablers of DSD, help them finalise their LabCoP work plan for year 2020, and ensure activities are aligned with the Global Fund planning process.

The joint team was able to meet key stakeholders in HIV response, including the leadership of the National AIDS Control Program (NACP) and representatives from [UNAIDS](#), Networks of HIV Positives in Sierra Leone, the [World Health Organization](#), the [University of Sierra Leone](#), and others. Participants were able to learn more about the objectives of the two networks and the need for in-country teams to work together. During the visit, the country team completed a baseline assessment of DSD and identified critical gaps that were prioritised for action, including better engagement of recipients of care.



LabCoP and CQUIN team introduction meeting with Sierra Leone MoH and implementing partners.

**'During the visit, the country team completed a baseline assessment of DSD and identified critical gaps that were prioritised for action, including better engagement of recipients of care.'**

The Sierra Leone country team also finalised their LabCoP 2020 work plan to improve the scale-up of HIV VL testing. The January LabCoP ECHO session on country operational plans for PEPFAR-supported countries was hosted at the NACP offices. The LabCoP team were able to connect NACP leadership with the PEPFAR contact person for further deliberation on program funding opportunities for Sierra Leone.

Going forward, CQUIN and LabCoP will continue to engage the Ministry of Health and offer direct technical

assistance support in monitoring and evaluating country progress toward the scale-up of VL testing and DSD. LabCoP and CQUIN will also support the country to develop a comprehensive national strategic plan to guide DSD and VL testing scale-up among other priorities. In conclusion, such joint visits may help bridge the laboratory-clinic interface by bringing together laboratorians, clinicians and recipients of care to engage in developing a more holistic strategy for strengthening the VL testing cascade and DSD scale-up to meet patient needs.

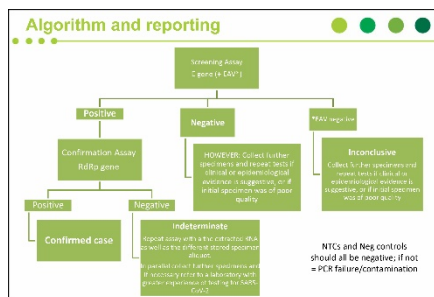


LabCoP's Dr Collins Otieno presents to Sierra Leone's country team and stakeholders.

# Special COVID-19 ECHO Sessions Launch

After the January 2020 World Health Organization declaration of the 2019 novel coronavirus outbreak as a Public Health Emergency of International Concern, the [Africa Centres for Disease Control and Prevention](#) (CDC) lead a coordinated, continental response to ensure that at least one reference laboratory in each [African Union Member State](#) was trained on PCR-based detection of SARS-CoV-2, the causative agent of coronavirus disease 2019 (COVID-19). After training sessions facilitated by the South Africa [National Institute For Communicable Diseases](#) (NICD), [Institut Pasteur de Dakar](#), and the [West African Health Organization](#), validated test kits were provided to support timely detection of COVID-19 cases. Upon returning home to implement testing, trainees faced questions about platforms, nucleic acid extraction steps, and quality assurance. In response, ASLM's [LabCoP](#), the [Korea World Bank Partnership Facility](#), [Africa CDC](#), [IQVIA](#), [NICD](#), and the [Foundation for Innovative New Diagnostics \(FIND\)](#) launched a special series of ECHO sessions on COVID-19 diagnostics in March.

The 25 March session covered troubleshooting common challenges to establishing diagnostic testing for SARS-CoV-2. Dr Jinal Bhiman, Director of the National Influenza Centre at [NICD](#), presented practical solutions to the most common challenges, issues around producing quality-assured test results and possible solutions. Countries and laboratories were advised to consider using tests listed on the FIND webpage of [molecular diagnostic evaluations](#) as well as the World Health Organization provided [SARS-CoV-2 diagnostic protocols](#). Discussion centred on limited performance evaluation data for alternative rapid diagnostic tests (molecular and serological), regularly-updated guidance from [Africa CDC](#), and taking measures to prevent disruption of testing for other priority diseases. Watch the recorded video session [here](#). Download the presentation slides [here](#).

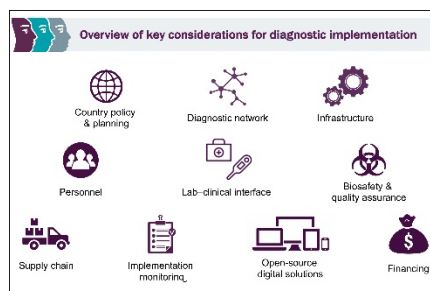


Slide from Dr Bhiman's presentation.

**Use Case 1: Confirm Infection in Patients fulfilling the COVID-19 Case Definition**

- **What type of test is needed?**  
Molecular tests with high sensitivity and specificity to detect viral RNA (optimally within 5-7 days post onset of fever)
- **Where can it be done and by whom?**  
Typically in a laboratory by trained laboratory staff using specialised equipment
- **How long does it take?**  
1-2 hours before the results are available

Slide from Prof Peeling presentation.



Slide from Dr Kelly-Cirino's presentation.

In the 30 March session, Dr Cassandra Kelly-Cirino from FIND and Professor Rosanna Peeling from the [London School of Hygiene & Tropical Medicine](#) gave an overview of the latest COVID-19 diagnostic technologies and recommendations for clinical care and surveillance. They addressed the four scenarios in which testing is required:

- **Confirming** infection in patients fulfilling the COVID-19 clinical case definition
- **Rapid triage** of suspected cases for swift management
- **Screening** for infection in asymptomatic contacts of confirmed cases
- **Determine exposure** (current and past) to SARS-CoV-2 to understand the true extent of the outbreak, map the pandemic, monitor trends, and trace contacts

Discussions underscored supply chain issues, the need to keep up with demand, and ensuring all countries have access to necessary diagnostic tools. Watch the recorded video session [here](#). Download presentation slide deck 1 [here](#), and slide deck 2 [here](#).

The special sessions on COVID-19 demonstrate the utility of the LabCoP community for practical knowledge sharing and its potential to be quickly mobilised around strengthening laboratories to respond to a variety of issues, including outbreaks.

## Expert Experience



Recently, ASLM sat down with Zibusiso Ndlovu, Epidemiologist and Laboratory Advisor at [Médecins Sans Frontières](#), to discuss Advanced HIV Disease and LabCoP's role in disseminating best practices.

**ASLM:** MSF has been a leader in innovative solution for HIV diagnostics, care and treatment. Can you give an overview of your work on managing Advanced HIV Disease (AHD)?

**Zibusiso:** MSF has been implementing the AHD package for the past few years, mostly within programs in sub-Saharan Africa. Our goal is to see its implementation at the core of the global response towards ending AIDS as a public health threat. Part of my role is providing technical guidance for implementation of AHD diagnostics in MSF-supported programs, within primary health care (PHC) facilities and mobile clinics, secondary, and up-to tertiary facilities in different countries.

**ASLM:** AHD can be identified through clinical signs and laboratory test such as CD4 testing. Viral load testing also plays a role in identifying patients at risk of progressing toward AHD. Can you briefly share your field experiences in implementing laboratory diagnosis for AHD?

**Zibusiso:** A minimum set of AHD diagnostic tests, including HIV, CD4 cell count, urine TB LAM and CrAg, are easily implementable at all healthcare facility tiers. Both laboratory- and point-of-care (POC)-based reflexive testing, coupled with provider-initiated requests for CrAg and urine TB LAM tests, should be performed for all patients with CD4 cell counts  $<200$  cells/mm<sup>3</sup>. Implementation of the AHD package should be intensified within PHC, as these facilities are predominantly the first point for seeking healthcare among HIV-positive patients. Task shifting is important in order to facilitate access to rapid results and minimize under-utilization of these tests at the POC by trained lay cadres.

**ASLM:** In your view what are the respective roles of the clinicians, laboratories and the local community in improving access to and utilization of laboratory diagnostics for the identification and management of AHD?

**Zibusiso:** Laboratories should audit and consolidate CD4 testing capacity in their districts to optimize utilization of existing capacity. Higher-tier laboratories play an essential role in ongoing quality control support for AHD testing at lower-tier PHCs, while also playing a crucial mentorship role for testing scale-up. Implementation of facility- and community-based differentiated service delivery (DSD) models for antiretroviral therapy (ART) could allow clinicians enough time to focus on management of patients with AHD. Mentorship in provision of AHD services should focus on good linkage to care, especially after inpatients are discharged and on patient psychosocial support. Development of appropriate patient-centric AHD literacy will increase the demand for the AHD package within community ART groups and key populations.

**ASLM:** What are some best practices for addressing AHD?

**Zibusiso:** Best practices include the use of lay cadres (especially at PHC levels) to conduct AHD testing, prompt testing result issuance for quick clinician auctioning, optimal implementation of DSD models for ART, and supporting functional tiered laboratory systems for roll-out of AHD in PHC and decentralized clinics. Using different CD4 testing devices according to the healthcare tier level and testing volume will ensure competitive pricing of commodities. Finally, it is critical to reactive national supply chains for testing commodities.

**ASLM:** What are your hopes for the future of LabCoP and how can the LabCoP be leveraged to contribute to the identification of and dissemination of best practices for addressing AHD?

**Zibusiso:** As the HIV epidemic matures, LabCoP (with help of implementing partners) must continually support national HIV/TB programs to identify AHD patients, encourage countries to embrace successfully piloted tests approved by the World Health Organization (WHO), and lead network optimization initiatives to ensure CD4 device placement is informed by patient cohort sizes. I hope that LabCoP will engage in advocacy for swift market demand creation and the catalytic procurement for AHD diagnostics products in low- and middle-income African countries. LabCoP needs to continue to encourage different country programs to share best practices, as we understand that no single glove can fit all. LabCoP should also urge countries and regions to use proven cost-lowering mechanisms, such as pooled procurement, competition, and price transparency, to waive taxes and duties on products critical to global health, etc. It would also be good to see LabCoP work with WHO to draft target product profiles for needed tests for AHD.

## What's New at LabCoP

### Nigeria and Eswatini Join LabCoP

LabCoP welcomes its newest country teams, Nigeria and Eswatini to our community of practice! This brings the total number of LabCoP member countries to 13. The Nigeria team is led by Dr Deborah Odoh, and Eswatini led by Sindisiwe Dlamini. The LabCoP Management team will work with them to conduct baseline self-assessments, so their progress can be tracked. It is exciting to see the LabCoP community grow and we look forward to working with our newest members!

### New LabCoP Resources

See the latest LabCoP resources, including new tools, reports, guidelines, and links to the special series of COVID-19 ECHO sessions posted [here](#). More resources are added weekly.

### LabCoP 2020 Work Plans

All country teams have submitted their 2020 work plans, pending the plans of the new Nigeria and Eswatini teams. The LabCoP Management team will now follow the progress of implementation as country teams put their plans into action.



## Looking Ahead

### LabCoP: Phase 2

Phase 2 of the LabCoP project began in April 2020, and will continue for a period of at least 3 years, with expanded scope beyond viral load (VL). It will promote implementation of existing tools and frameworks addressing the scale-up of VL and other priority diagnostic testing, such as tuberculosis and HIV early infant diagnosis. LabCoP will continue to promote the transition of [PEPFAR](#) and [The Global Fund](#) support to regional and national ownership, and will align to the objectives of the Africa VL movement, led by the [Africa Centres for Disease Control](#). LabCoP will also prioritise the monitoring and evaluation of the core indicators of laboratory systems and networks strengthening, including the key disease areas related to HIV control programmes.

### ITPC Joins RVL Demand Creation Campaign

[International Treatment Preparedness Coalition \(ITPC\)](#) is now partnering with LabCoP to work with the Democratic Republic of Congo, Kenya, Malawi, Tanzania, Zambia, and Zimbabwe to advance their routine viral load testing demand creation campaigns. In the next phase, ITPC will provide virtual training to assist participating country teams with developing their campaign plans.

