LabCoP QUARTERLY

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Viral load cascade topics in this Issue of LabCoP Quarterly

Waste Management Series

May – June 2020: Sharing best practices in laboratory waste management

The LabCoP sub-community of practice on waste management (WM) held two ECHO sessions in the second quarter of 2020. Here are some of the highlights of the sessions.

The May 2020 WM session led by David Bressler (United States Centers for Disease Control and Prevention (CDC)), focused on guidance on biosafety for laboratories testing for SARS-CoV-2 (the causative agent of COVID-19). Mr Bressler highlighted the World Health Organization (WHO) and CDC's guidelines on handling and processing COVID-19 specimens, including packaging and transportation based on International **Transport** Association (IATA) regulations. Emphasis should be placed on conducting developing and laboratory site-specific risk of standard assessments, use operating procedures and implementation of decontamination protocols, as well as adherence to safe WM practices, when performing COVID-19 diagnostic processes. For laboratory activities that have a

RISK MANAGEMENT PROCESS

Assess
Hazards

Make Risk Decision & Develop Controls

Implement Controls

Supervise
& Evaluate

Risk Assessment
steps

Slide from **David Bressler's presentation**.

high likelihood of generating aerosols or droplets, the use of either a certified Class II biological safety (BSC) additional cabinet \circ r precautions to provide a barrier between the specimen personnel are recommended. The requirement of a BSC should be well understood in the context of the need to decentralise and accelerate the use of point-of-care (POC) molecular testing technologies in COVID-19 related testing. Where a BSC may be unavailable, staff should determine whether the processes pose a risk to testing personnel. WHO guidance published in May 2020 recommended that 'POC or near-POC assays can be performed on a bench without employing a biosafety when the local risk cabinet. assessment so dictates, and proper precautions are in place'. You can watch the May 2020 session on ASLM's YouTube channel here. Download the slides **here**.

The June 2020 WM session focused on the Global Fund to Fight AIDS, TB and Malaria (GF) technical guidance and tools for sustainable healthcare waste management. Presentations were made by Dan Jacobs (Mott MacDonald), Dr Anne Woolridge (Independent Safety Services



Slide from the Global Fund's presentation.

Limited), and Franziska Fuerst (GF). GF prioritised environmental concerns and introduced an intervention package to avoid, reduce and manage laboratory waste in all its funding projects to countries. The package emphasises developing systems or sustainable approaches healthcare WM, rather than simply acquiring infrastructure equipment such as incinerators. To implement this new intervention package, the GF developed a technical brief that was released in February 2020. The brief aims at guiding countries to introduce sustainable healthcare WM systems, including technical aspects of waste treatment and disposal techniques. It highlights fundamental principles, capacity assessment and planning tools, **leaislation** and development standards that can be used to design WM interventions and address system gaps. Underpinning good basic practice of healthcare WM, the classification of waste informs how to handle, transport, treat and recover medical waste. You can watch the June 2020 session on ASLM's YouTube channel here. Download the presentation here.

2020 Q2 LabCoP ECHO Sessions

Lessons to Consider

LabCoP's standard monthly ECHO sessions held between April and June 2020 focused on how to maintain HIV and tuberculosis (TB) care services, including other essential clinical services, in the context of the increasing demands on the healthcare system due to the COVID-19 pandemic.

The April 2020 ECHO session featured the World Health Organization (WHO) and the United States President's Emergency Plan for AIDS Relief (PEPFAR) perspectives on maintaining HIV and TB testing in the context of the COVID-19 pandemic. Dr Lara Vojnov (WHO) indicated that HIV/TB immunodeficient patients could be at higher risk of further complications with infectious diseases such as COVID-19. She shared updates on the race to find treatments for COVID-19, including the possible efficacy and safety of antiretroviral drugs for treatment and prevention of COVID-19, and WHO COVID-19 technical guidance, including an operational guide on maintaining essential services. Dr George Alemnji (PEPFAR) urged participants to ensure COVID-19 testing does not negatively impact existing HIV and TB testing by developing standard operating procedures to guide existing testing, adjustment of staff management (work shifts, extended hours, overtime, etc.), considering integrated diagnostic approaches, anticipating supply chain delays and disruption, and coordinating with key stakeholders. You can watch the session here and download the April session slide deck here (WHO) and here (PEPFAR). You can find the the discussion responses to questions here.

In the May 2020 ECHO session, Dr Marguerite Massinga Loembé (ASLM and Africa Centres for Disease Control and Prevention (CDC)) outlined the coordinated strategy of Africa CDC to scale up diagnostic capacity for COVID-19 testing in Africa to at least 10 million tests within the next six months, sufficient to effectively curb the number of infections through detection and quarantining of identified cases, as well as isolating exposed individuals. To achieve this target, and following initial capacity building at the central level, countries are decentralising COVID-19 PCR diagnostic capacity to sub-national levels. Mr Adisu Kebede (Ethiopian Public Health Institute) shared Ethiopia's experience on decentralising COVID-19 PCR testing. He described considerations for selectina testina laboratories, including updates on current testing laboratories and various testing platforms in Ethiopia and outlined the integration of COVID-19 testing with HIV programs, issues of quality assurance, specimen referral mechanisms and linkages, including the challenges associated with these interventions. You can watch the session here. You can access the Dr Massinaa Loembé's slides here, and Mr Adisu Kebede's slides here.

The June 2020 ECHO session focused on key considerations for differentiated service delivery (DSD) in the context of the COVID-19 pandemic. Dr Peter Preko (The HIV Coverage, Quality, and Impact Network (CQUIN) Project, ICAP at Columbia University) discussed DSD policy and practice adaptations and the rationale for implementing DSD. DSD has the potential to modulate



Why Differentiated Service Delivery? Different



subopulations have different needs

Slide from Dr Peter Preko's DSD presentation

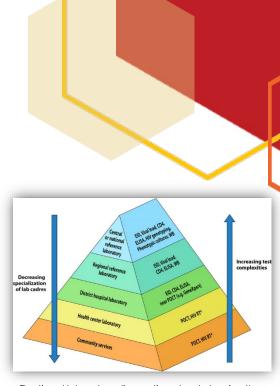
care to different patient needs based on disease stage, age and response to treatment, thereby improving quality of life, enhancing patient and provider satisfaction through patient-centred care, and improving the overall efficiency of the health sector by expanding the numbers of patients on treatment, reducing funding focusing resources on the neediest recipients. Dr Hervé N. Kambale (Ministry of Health, Eswatini) shared Eswatini's DSD and HIV policy changes in response to COVID-19 to protect both providers and recipients of care, including relaxation of eligibility criteria for DSD models, scaling-up commodity distribution for HIV, TB, and noncommunicable diseases, policy changes for the provision of multiple months dispensing (MMD) for specific groups. You can watch the June session and download the session slides here.

'Dr Lara Vojnov (WHO) indicated that HIV/TB immunodeficient patients could be at higher risk of further complications with infectious diseases such as COVID-19.'

Laboratory Network Leadership and Management Training and Mentorship Course

national tiered laboratory network is the vehicle for both laboratory, clinical and public health functions. The tiered laboratory network is the entity through which the diagnostic services of various programmes, such as HIV and tuberculosis control, are or should be channelled in order to achieve integrated diagnostic delivery, so that any patient at any point can access quality laboratory services. The tiered network provides a unique opportunity to mutualize scarce resources and do more with less. Due to the history of global programmes to combat tuberculosis and malaria. diagnostics services continue to operate in a 'vertical' manner, whereby services are provided with a focus on a single or small group of diseases. This arrangement results in missed opportunities for leveraging resources, skills and technology to the general tiered network.

LabCoP and ASLM have determined that one critical barrier to achieve a functional and resilient laboratory system is the lack of a comprehensive overview of the national tiered laboratory network and the management skills to coordinate the networks. Often, laboratory stakeholders at the central level lack the knowledge of where resources and capacities are located across the network, and how they can be leveraged to support the various functions of the laboratory systems and quickly surge response in case of a health emergency. The recent COVID-19 pandemic has, again, highlighted the need for countries to have an accurate understanding of how instruments and skilled human resources for molecular testing are distributed, and how testing needs can be estimated based on the population coverage in a particular region. This knowledge gap constitutes a barrier to optimal testing service delivery in both routine



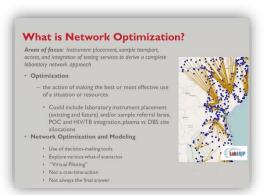
The tiered laboratory diagnostic network showing the different laboratory tiers, community services, and tests performed at each tier. Early infant diagnosis; Point-of-care testing (instrument based). *, HIV RT is the HIV rapid test and refers to strip-like devices. Credit: Bharat. \$. Parekh, et al., Diagnosis of Human Immunodeficiency Virus Infection

'One critical barrier to achieve a functional and resilient laboratory system is the lack of a comprehensive overview of the national tiered laboratory Network and the management skills to coordinate the networks.'

and emergency situations. It is also a barrier to achieving Universal Health Coverage and meeting the requirements of the World Health Organization's (WHO) International Health Regulations.

While many programmes successfully address the strengthening leadership at the laboratory facility level, the skills required to manage the national tiered laboratory networks is still lacking. ASLM and partners including the WHO, the Association of Public Health Laboratories, the Africa Centres for Disease Control and Prevention, Foundation for Innovative New Diagnostics, Fondation Mérieux, ICAP at Columbia University and the United States Centers for Disease Control and Prevention are joining

forces to build capacity in leadership and management through provision a Leadership training and mentorship course tailored towards optimising laboratory networks. A tailor-made curriculum specific to management of laboratory networks is under development and training is scheduled to begin in the first quarter of 2021. Trainees will learn the concepts of laboratory programme design and implementation at the national level, including laboratory network optimisation and testing integration. The course will enable leaders to design relevant, fundable and sustainable system-strengthening interventions to accelerate the scale up of viral load and other diagnostic and monitoring tests.



Slide from LabCoP's <u>April 2019 Laboratory</u> <u>Network Optimisation ECHO session</u> presentation

Mobilising the LabCoP to Support the COVID-19 Response

Since the beginning of the COVID-19 pandemic and resulting travel restrictions, lack of access to clear information and practical guidance on how to select, conduct and interpret diagnostic tests has complicated response efforts. The Africa Centres for Disease Control and Prevention (CDC) provided leadership to coordinate the response in Africa based on providing training on performing diagnostic tests and supporting availability of testing reagents, reliability of results and specimen transport for testing and research.

Combined with the efforts of other partners like the World Health Organization (WHO) and the Institut Pasteur International Network, this strategy increased the number of countries with at least one laboratory able to perform COVID-19 testing from two to 43 within a couple of months of the start of the pandemic. For maximum impact, the initial guidance and trainings needed to further disseminated with opportunities to identify and address emerging questions and concerns countries and frontline healthcare workers. However because of travel restrictions, trainings, technical support and practical guidance could not be conducted in person.

ASLM, in collaboration with Africa CDC, the Foundation for Innovative New Diagnostics (FIND) and other partners were able to mobilise subject matter experts and use the LabCoP ECHO model to support virtual trainings, information and knowledge dissemination, and technical assistance. To date, 22 ECHO sessions have been provided to the African community with a median of 681 participants per session from at least 100 countries (Figure 1).

build To the capacity and confidence of the laboratory workforce to conduct and release reliable results, initial webinars focused on testing instrumentation set-up and troubleshooting, as a follow up to the Africa CDC training provided soon after COVID-19 was declared a Public Health Emergency



of International Concern in February 2020. Subsequent webinars focused on information about COVID-19 diagnostic test kits with priority given manufacturers with Emergency Use Authorisation from the United States Food and Drug Administration or the WHO and/or whose test kits were independently validated by FIND. These sessions were aimed at ensuring that country-level decision makers had sufficient knowledge on available test kits to make informed decisions on what tests to procure. These provided sessions also an opportunity for test users to interact directly with manufacturers and address technical concerns about testing and supplies.

A few sessions focused on serological tests, following queries from countries about their utility as an alternative to polymerase chain reaction (PCR) testing, given the limited supply of PCR-based tests. Additional sessions focused on ways to maintain essential testing for tuberculosis, HIV and other priority diseases and not lose the gains already realised in achieving the UNAIDS 95-95-95 targets.

More sessions are continuously being added based on needs highlighted by the laboratory community through analysis of the questions posted during session. LabCoP has proven to be a useful platform and promises to be a sustainable option future trainings, exchanges of best practices, dissemination of up-todate guidance and technical support.

Expert Experience



Recently, we sat down with Anafi Mataka, LabCoP Project Manager at ASLM, to discuss the COVID-19 ECHO session series launched in March 2020, dedicated to diagnostics of the pandemic.

ASLM: How do the COVID-19 ECHO sessions benefit the participants?

Mataka: The virtual sessions have covered a wide range of topics, including the COVID-19 diagnostic landscape, real-life country experiences, key ecosystems of national diagnostics programs, data and quality management, and how these have been leveraged to quickly respond to the pandemic. LabCoP has connected manufacturers with users in the field, policymakers and Dedicated scientists. manufacturer-based sessions allowed program leads and users to make decisions based on information shared directly by manufacturers regarding specimens, management of and reagents equipment, performance, biosafety, test systems, procedures and controls, and result interpretation.

ASLM: What have some of the most popular questions been?

Mataka: The most common questions have been about test performance: how good are the diagnostics measured sensitivity and specificity, positive and negative predictive values, etc. Some questions have been related to procurement with participants worried about availability to meet demand, particularly for low- and middleincome countries that rely on diagnostics produced in highincome countries, where similar products are also in high demand.

ASLM: What are some of the lessons you have learned from hosting the COVID-19 ECHO sessions?

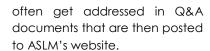
Mataka: There is a lot of expertise in Africa that can be leveraged to boost the continental response. Virtual sessions can be a key tool for disseminating this expertise during public health emergencies. Continuing these sessions will be vital for preparing for the next pandemic. The interface between users and manufacturers appears to have improved flexibility in some cases, for example, opening some diagnostics to third party reagents, which is rare for closed systems.

ASLM: What have been some of the highlights for you?

Mataka: It's been rewarding to watch a modest platform for sharing real-time information and best practices among member countries in Africa quickly become a global platform of the diagnostic response to the pandemic. Data indicates that in several sessions regular total attendance has grown to over 800 participants from every continent across the globe.

ASLM: How has the audience been engaging, and what have they been most responsive to?

Mataka: During the sessions, fellow participants have often responded to one another's questions in the chat box well before they have been posed to session panelists. This has been helpful in many sessions where there have been too many questions to address them all in the allotted time. Questions that have gone unanswered in the sessions



ASLM: What are some indications that the information has resonated with participants?

Mataka: Surveys show that most participants have found these sessions very valuable. The sessions are available in the ASLM Academy, where attendees can claim continuous professional development evidence; participation has been increasing as indicated by the total number of certificates issued.

ASLM: What are some future COVID-19 ECHO session topics you look forward to?

Mataka: I'm looking forward to the possibility of serology and surveillance sessions, which will soon become a very hot topic. We also plan to have sessions to disseminate results of the several independent evaluations being carried out, to answer the many questions on test performance that have come up often.

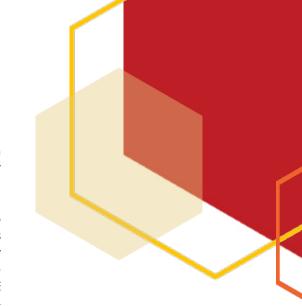
Recordings, PowerPoint slides, and Q&A documents for selected sessions are available in <u>ASLM's Resource Center</u>.

Establishing the M&E Sub-community of Practice

During LabCoP's last face-to-face meeting in Addis Ababa, Ethiopia in October 2019, LabCoP country teams identified monitoring and evaluation (M&E) of the viral load (VL) cascade as a critical gap in their programming. Many countries reported challenges in tracking VL testing cascade data, demand creation to utilisation of results for clinical decision-making. With the emergence of COVID-19 and its potential impact on public health services, including HIV and tuberculosis services, availability and use of data for performance tracking at all levels for clinical and public health action has become more urgent.

To address this gap, LabCoP is working with its 14 country teams to establish a M&E sub-community of practice. This sub-community of practice will be a forum for subject matter experts from partner organisations (e.g., United States

Centers for Disease Control and Prevention, ICAP at Columbia University, World Health Organization) and member country teams to discuss common challenges, share best practices, and co-create knowledge to address the M&E needs of countries scaling up VL testing. Country teams will consist of three to five members currently involved in M&E activities at the national level. A fitfor-purpose eTraining curriculum will be delivered by subject matter experts in four to six months, aimed at addressing the specific M&E needs of each country scaling up VL testing. Since VL testing networks are being re-purposed for the COVID-19 response, the course will incorporate concrete examples and elements that are applicable to M&E of COVID-19 testing, and for the need to maintain a minimum support level for HIV VL testing. In addition to the training, country





LabCoP country teams meet face-to-face in Addis Ababa, Ethiopia in October 2019

'The course will incorporate concrete examples and elements that are applicable to M&E of COVID-19 testing, and for the need to maintain a minimum support level for HIV VL testing.'

teams will be mentored and assisted to implement M&E activities (including the development of a dashboard whenever needed) as part of a problem-solving approach for their respective countries.

LabCoP recognises development of laboratory M&E systems is a long-term endeavor multiple stakeholders, involving government, including development partners, implementing partners, the private and public sectors, communities and others. The country teams will identify strategic stakeholders to support the operationalisation of the content covered in the training curriculum. The curriculum will be

delivered through a series of webinars for a period of four-six months starting in last quarter (Oct-Dec) of 2020. Technical assistance will be provided to countries upon request, and during a final face-to-face meeting all countries teams will come together to share their progress and develop action plans.

LabCoP's M&E curriculum is part of the <u>ASLM Academy</u>, and participants will obtain certificates once they complete the training. It is expected that the skills and competencies acquired will contribute to more robust M&E systems for VL and other essential testing services in participating countries.



Screenshot of the new $\underline{\mathsf{ASLM}}$ Academy web page

What's New at LabCoP

Cameroon Joins LabCoP

LabCoP welcomes its newest country team, Cameroon, to our community of practice! This brings the total number of LabCoP member countries to 14. The Cameroon team is being coordinated by Dr Vandi Deli of Direction de la Pharmacie du Médicament et des Laboratoires. The LabCoP Management team will work with the Cameroon team 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 in Cameroon!



In August the LabCoP team began production on a series of COVID-19 animations that will describe the PCR testing procedure to our community of laboratory professionals. The series will include topics like quality assurance requirements for SARS-CoV-2, an overview of controls in PCR, troubleshooting failed runs, causes of false positives and false negatives, and verification of test methods. The LabCoP team is also producing an impact video that documents the past year of LabCoP activities that have helped you prepare to battle COVID-19 in your communities. We are excited to release these videos over the next few months, so stay tuned for more announcements.

ITPC Training for Demand Creation Campaign

LabCoP has been working with the International Treatment Preparedness Coalition (ITPC) to train country teams who expressed interest in participating how to increase demand in their communities for routine VL testing. Kenya, Zimbabwe, Malawi, South Sudan, The Democratic Republic of the Congo and Sierra Leone have received training. Each training session was customised to address the specific country's needs. A generic sample of the training materials developed by ITPC will be shared via ASLM's listserv next month. To receive these materials, please sign up for ASLM's mailing list here. The Bill & Melinda Gates Foundation has funded ITPC to support the Community/Recipient of Care Working Group across both The HIV Coverage, Quality, and Impact Network (CQUIN) and LabCoP. ITPC will coordinate a Community Advocacy Network to enable meaningful community engagement and targeted action relevant to CQUIN and LabCoP.



Looking Ahead

The New Monitoring and Evaluations Sub-community of Practice

The LabCoP team is working with the 14 country teams to establish a new monitoring and evaluations (M&E) sub-community of practice. It will be a forum for subject matter experts from partner organisations and member country teams to discuss common challenges, share best practices, and co-create knowledge to address the M&E needs of countries scaling up viral load (VL) testing. Country teams will consist of three to five members currently involved in M&E activities at the national level.

LabCoP 2020 Annual Country Self-assessments

As we move towards the end of the year, all country teams will soon be conducting the self-assessment of their country's VL program. The outcome of this program assessment will inform the areas of focus for the next face-to-face meeting and the action planning that will be done for each country's VL program.



