Diagnostic Integration Efforts in Seven LabCoP-Participating Countries

Between June and November 2021, the LabCoP Management Team visited seven LabCoP participating countries, Burkina Faso, Burundi, Eswatini, Nigeria, Sierra Leone, South Sudan, and Tanzania, to facilitate country self-assessments, discuss progress in the implementation of work plans, and better understand country priorities. The Management Team also conducted high-level advocacy for laboratory systems strengthening, engaged implementing partners and stakeholders from the tuberculosis programme, and identified best practices for sharing in future ECHO sessions.

In line with LabCoP’s expanding scope and following the laboratory service disruptions experienced during the COVID-19 pandemic, the country visits focused on strengthening diagnostic integration. The team reviewed integration use cases, the stakeholder landscape, national policies/regulations supporting integration, and implementation considerations.

Diagnostic integration was already being implemented for HIV and tuberculosis in six countries, and for COVID-19 in five of those six. Some countries also included Ebola and human papillomavirus. In all six countries, the GeneXpert instrument was selected for decentralised testing, in addition to centralised platforms from Roche and Hologic. Diagnostic integration was coordinated by technical working groups comprising members from disease programmes, with meetings held bi-annually (e.g., Burkina Faso) or quarterly (e.g., Tanzania). Regarding policy and regulation, more effort is needed to include diagnostic integration into national laboratory strategic plans and develop priority diagnostic lists. Currently, only Nigeria has a national essential diagnostics list.

Most countries were aware of the number and capacity utilisation of instruments within the country. All the GeneXpert instruments in Tanzania had existing maintenance contracts. At least two countries, Burkina Faso and Nigeria, possessed a geographic information system that maps laboratory capacity and can inform integration toward expanding population coverage for laboratory services.

At least four countries had developed or expanded their integrated specimen referral system to support testing. Clear guidance on testing prioritisation was also available in two countries: Tanzania (tuberculosis>COVID-19>early infant HIV diagnosis>vitral load) and Burkina Faso (COVID-19>tuberculosis>early infant HIV diagnosis>vitral load). One stakeholder from Nigeria indicated that supporting systems for integrated testing needed to be addressed to maintain testing targets for integrated tests.

While great effort had been made by these countries, none were conducting monitoring and evaluation of key indicators of integration, including cost savings, population coverage of testing services, testing levels across diseases/programmes, and the number of evidence-based clinical management cases. LabCoP is developing an Integration Readiness Assessment tool, based on the capability maturation model, to assist countries to self-assess their progress toward diagnostic integration. LabCoP also intends to facilitate the sharing of best practices for optimising integration services and update the decision-making matrix for the improvement of integration services.
Key Takeaways from LabCoP’s ASLM2021 Satellite Session

On the closing day of ASLM2021, LabCoP held a satellite session on the Role of Diagnostic Integration in Strengthening Laboratory Systems. Panellists comprised of donors, programme managers, and representatives from Abbott, Cepheid, Hologic, and Roche, who shared unique perspectives on the need to promote testing integration.

The molecular testing instrument marketplace has evolved to allow integrated testing in recent years, and integrated testing on existing platforms has been critical to the COVID-19 response in resource-limited settings. Shared experiences from Tanzania and Burkina Faso demonstrated benefits such as lower testing costs, greater access, and better patient management, without overwhelming device capacity. Manufacturers continuously support testing integration by providing extensive platform networks and timely access to engineers to ensure uninterrupted service.

Manufacturers have also been very open to new approaches to promote integrated testing, mainly through facilitating more inclusive and lower pricing deals. For example, Abbott, Cepheid, Hologic and Roche have each introduced pricing mechanisms that ensure that key elements like service, maintenance, training, and spare parts are bundled in one price without hidden costs. Manufacturers also partner with countries to identify challenges and co-create solutions and innovations for sample collection, transport, and testing, and to develop digital tools for utilising results of multiple tests run on the same instruments.

A representative from the tuberculosis programme described the ‘fear’ of possible deprioritisation of tuberculosis testing in favour of HIV testing as one key barrier to testing integration. A lack of coordination between disease programmes has also contributed to delays in implementing integrated testing.

Some levels of coordination have been realised nationally at the funding application stage (e.g., The Global Fund applications) but not at the implementation stage. Disease programmes should define national goals for integration and not simply a combined list of goals from different disease programmes.

Funders have set key performance measures that manufacturers strive to achieve in support of integrated testing. However, some systemic and structural issues in the design of funding for diagnostics still need to change. Funding for diagnostics should target integrated diagnostics, rather than being disease-specific as is currently the case.

Although countries and stakeholders are willing to redesign laboratory networks based on evidence, the traction of this change is slow and needs to build momentum. A diagnostic network optimisation approach should also be adopted to identify opportunities for the targeted integration of (components of) diagnostic network optimisation diagnostic systems.

To fully achieve the benefits of testing integration for all patients, assessments of the feasibility and opportunity to expand testing integration should go beyond diagnostic instruments.

Manufacturers have expressed willingness to collaborate more and should be included in discussions around integration to support global health and people-centric healthcare. To reach more people, testing needs to be decentralised. Manufacturers’ research and development portfolios thus strive to produce smaller instrumentation to reach decentralised settings. ASLM LabCoP and partners have started developing a tool to allow countries to track and monitor progress by measuring integration through the patient lens using a standardised approach. LabCoP is committed to engaging all stakeholders to improve service delivery.
The LabCoP piloted its laboratory network leadership (LabNetLead) course in Zimbabwe between 21 and 26 February 2022. The LabNetLead course introduces essential concepts and activities to design, optimise, lead, and manage functional, high-quality laboratory networks. The system is part of the African Society of Laboratory Medicine’s (ASLM) Laboratory Systems Strengthening Community of Practice (LabCoP) program that focuses on human health laboratory network management.

Zimbabwe’s Director of Laboratory Services, Dr Raiva Simbi, and the ASLM CEO, Mr Nqobile Ndlovu, officially opened the training. Twenty technical working group (TWG) members responsible for managing the laboratory network in Zimbabwe attended the training. Dr Raiva thanked ASLM for their efforts to strengthen laboratory networks and expressed his excitement that the participants will use the acquired knowledge from the course to optimise Zimbabwe’s diagnostic network. Mr Ndlovu thanked the Zimbabwe Ministry of Health for allowing the pilot of the course there and for continued collaboration to strengthen laboratory networks for quality patient care.

Mrs NoraTh Vere, Laboratory Scientist at the National Microbiology Reference Laboratory, and the Zimbabwe LabCoP team lead noted the opportunity for the TWG to gain a deeper understanding of the network systems that must be in place for a well-functioning laboratory network. Therefore, at the end of this six-month course, with a built-in mentorship component, the TWG is expected to: contribute to the development and optimisation of the laboratory network in Zimbabwe, using evidence-based approaches; contribute to the implementation of the tiered-laboratory-networks planning cycles such as preparing, implementing, monitoring and evaluating tiered-laboratory network-related national laboratory policies, strategies and action plans; and more.

The training also has a trainer-of-trainers component to train future course trainers. The first trainer-of-trainers batch includes nine ASLM staff and two Zimbabwe TWG members. The next iteration of the training will occur in mid-April in Malawi.
Diagnostic testing produces potentially hazardous biological and chemical wastes, of which improper management poses significant safety risks to staff, the public, and the environment. Therefore, a structured and effective waste management system at national and sub-national levels is necessary, including developing and consistently using comprehensive waste management guiding policies and procedures and the availability of waste management facilities and trained staff.

The LabCoP Management team observed a waste management challenge in South Sudan during a visit in Sept 2021. Wastes requiring incineration; infectious and chemical wastes (including guanidinium thiocyanate (GTC)), were not incinerated by the central and peripheral laboratories, resulting in stockpiling of hazardous wastes.

Further discussion with the team revealed specific challenges, including the breakdown of the old incinerator, incomplete installation and commissioning of a new high capacity incinerator at the National Public Health Laboratory, and the absence of a structured system for moving wastes from the lower to the central laboratory for incineration.

The LabCoP Management team consulted other LabCoP country teams and identified a Zambian healthcare waste management team from within the Ministry of Health with incinerator installation, maintenance, repair, and modification expertise. With support from ASLM, the Zambian team visited South Sudan, provided technical assistance, and restored the country’s central laboratory’s incineration capacity. Specifically, the Zambian team: shared customisable standard operating procedures, guidelines, and job aids for the operation and maintenance of incinerators with the South Sudan team; assessed, completed the installation of and commissioned the new incinerator; repaired the faulty motor of the old incinerator; trained one site engineer and five other waste handlers in the proper operation and maintenance of the incinerator; and conducted a general waste management training session for the waste management technical working group.

To sustain the gains of this South-South collaboration, the South Sudan team will completely incinerate the waste stockpile at the central level; procure axillary equipment for good incineration practices, including waste weighing scale and appropriate personal protective equipment; and change the current switchboard to a simpler waste-handler friendly version. Further on, they will also sponsor the current site Engineer for future incineration management training. Lastly, the Zambian team should conduct a monitoring visit within the next three months.
ASLM: LabCoP uses the WhatsApp platform to keep country teams connected in between meetings, and you are one of the most prolific participants. What kinds of resources and information are shared, and which have you found most useful?

Mr Twebaze: Information shared across the WhatsApp platform include scientific publications highlighting new diagnostic research, technological advances and innovations, as well as links to past ECHO session recordings, resources, training and opportunities. The experiences shared often highlight best practices that can be adopted for laboratory systems strengthening and resource optimisation. The ECHO sessions have been carefully designed to address specific challenges in laboratory operations and have been most useful.

ASLM: How do you use the WhatsApp group to benefit or enhance your job at your organisation?

Mr Twebaze: I support more than 60 laboratories and hubs, providing technical assistance to strengthen laboratory quality management systems, support SLMTA implementation, and support several other laboratory functions. In my role, I find most things to be dynamic, requiring frequent learning, updating and experience sharing; resources for these are at my disposal in the LabCoP WhatsApp platform. I use the content accessed there, alongside other materials, to prepare continuous medical education sessions on waste management, infection prevention and control, laboratory quality management systems and SLMTA, etc., which I deliver during on-site visits to colleagues, laboratory staff, and others involved in any of the analytical stages (pre-analytical, analytical and post-analytical) at supported health facilities.

ASLM: Why do you think it is important to stay connected to the other LabCoP country teams on WhatsApp?

Mr Twebaze: Learning about other countries’ best practices provides information on effective, tested, and minimal-effort (no cost and restriction) approaches to various challenging situations for process and resource optimisation. I draw deep inspiration from what others do well, whatever their style or approach, because I believe that progress is very much about continuous quality improvement.

ASLM: How can country teams join you in the conversation happening on WhatsApp?

Mr Twebaze: We’re always looking for more members to join and share information, so contact your in-country LabCoP coordinator for support. They have administrator rights to the WhatsApp platform and will admit new interested and eligible members.
**What’s New at LabCoP**

**2021 LabCoP Meeting Report**
LabCoP is excited to publish the meeting report from our 2021 Annual Meeting held virtually and in-person. It’s jam packed with session summaries, key takeaways, outcomes, recommendations and next steps. There’s even a link to the new LabCoP song, produced by ASLM’s HIV Awareness Ambassador, Moses ‘Supercharger’ Nsubuga. Download the full report [here](https://aslm.org/what-we-do/labcop/).

**Diagnostic Network Optimisation Sub-Community of Practice**
LabCoP continues to grow with our latest Sub-CoP focusing on diagnostic network optimization, in collaboration with FIND. The SubCoP will facilitate various activities (including dedicated tasks, webinars, presentations at conferences or other meetings) on relevant topics, themes, use-cases and case studies addressing integration and network optimizations at large.

**Viral Load Testing Demand Creation Campaigns**
LabCoP country teams that participated in the routine viral load testing demand creation campaigns reached over 79,000 people combined during Phase II of the project. Social media proved the most efficient method to reach people, but in-person peer education and support meetings resulted in the most engagement of people living with HIV. LabCoP thanks [International Treatment and Preparedness Coalition (ITPC)](https://itaslm.org) for assisting the participating country teams through small grants and technical assistance.

**IAS Industry Liaison Forum hosted roundtable on end-to-end diagnostics roundtable**
LabCoP Program Manager, Anafi Mataka, presented ASLM's perspective of addressing the data gap to facilitate the regulation and uptake of IVD at the IAS Industry Liaison Forum roundtable on end-to-end diagnostics in February 2022. ASLM called for partners to collaborate towards the increased availability and accessibility to context-relevant data on test performances across diseases, and cost effectiveness of adopted tests for African settings, with disease burden justifying the prioritisation of tests for adoption and implementation.

**Looking Ahead**

**Integration Readiness Tool**
LabCoP is developing a tool to assess the level of country readiness and maturity to implement diagnostic integration. The tool will gather key information in support of diagnostic network optimisation exercises. It will be piloted in LabCoP-participating countries and rolled out as part of the structured LabCoP annual laboratory system assessment. Thanks to WHO, FIND, Clinton Health Access Initiative, the Global Fund and US CDC for their support in designing the tool.

**ECHO Sessions**
Be on the lookout for announcements about exciting ECHO sessions on the horizon. In April we will feature presentations about drug-resistant TB (MDR and XDR), guidance on selection of TB tests, and the Assay Verification Tool designed to help laboratories implementing new tests.

**LabNetLead Picks up Momentum**
The Laboratory Network Leadership and Management (LabNetLead) course kicks off in Malawi with Phase 1 and 2 this April, while Zimbabwe enters Phase 3 and 4 of the course. The course introduces concepts and activities essential to adequately design, optimise, lead and manage functional, high-quality laboratory networks. It is tailored to members of the National Laboratory Working Group (NLWG) and is designed to complement the WHO Global Laboratory Leadership Program (GLLP) in Africa.

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