

LabCoP Cookbook of best practices

RECIPE #4: DECENTRALISING COVID-19 PCR DIAGNOSTIC CAPACITY TO SUBNATIONAL LEVEL



- Governance and coordination planning
- Expansion measures
- Testing site selection
- Testing site installation
- Routine testing operations monitoring

1 BACKGROUND

The Director-General of the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) outbreak a public health emergency of international concern under the International Health Regulations (IHR) (2005)¹ on 30 January 2020. As of July 31 2020, over **17 million cases** have been recorded worldwide despite the widely publicised measures to limit human-to-human transmission such as hand sanitation and social distancing, illustrated in Figure 1. Community-based transmission of COVID-19 is driving the outbreak in many countries, calling for an urgent need for substantial and rapid scale-up of testing capacity beyond the initial centralised testing sites to allow timely access to testing services nationwide.

Decentralised testing on a national scale will rely on expanding COVID-19 nucleic acid testing to include subnational-level laboratories. To effect this strategy, countries will need to balance the demand for direct response to COVID-19 through initiatives such as Africa Centres for Disease Control and Prevention's (CDC) *Partnership to Advance COVID-19 Testing* (PACT), which calls for increasing testing coverage to at least 8000 per million population and implementing coordinated action to *maintain essential health service delivery*, thereby mitigating the risk of healthcare system collapse.²



Molecular testing options are available to facilitate expansion of testing capacity and include both conventional laboratory testing platforms at the reference laboratory level and molecular point-of-care (POC) platforms. The strategy for expansion of COVID-19 polymerase chain reaction (PCR) diagnostic capacity is a stepwise process which should include:

- Governance and coordination planning
- Expansion measures
- Testing site selection
- Testing site installation
- Routine testing operations monitoring

Protect yourself and others from getting sick
Wash your hands

- after coughing or sneezing
- when caring for the sick
- before, during and after you prepare food
- before eating
- after toilet use
- when hands are visibly dirty
- after handling animals or animal waste

Protect others from getting sick

When coughing and sneezing **cover mouth and nose** with flexed elbow or tissue

Throw tissue into closed bin immediately after use

Clean hands with alcohol-based hand rub or soap and water after coughing or sneezing and when caring for the sick

Protect others from getting sick

Avoid close contact when you are experiencing fever and cold or flu-like symptoms

Avoid spitting in public

Seek medical care if you have a fever, cough and difficulty breathing

Figure 1. WHO COVID-19 *advice* for the public

Key to the expansion strategy is setting up a governance structure for national laboratory response to ensure strategic coordination and alignment with the national COVID-19 response. A country's Ministry of Health, through its Laboratory Directorate, Disease Surveillance Directorate, National Public Health Institute and National Public Health Laboratory or their equivalent should lead donors, the private sector, disease control programs and other sectors to coordinate efforts in drafting a road map for scale up. Political support and engagement are also crucial for governance and coordination planning. Most African countries now have COVID-19 task forces, led by their Offices of the President. The task forces include the Laboratory Directorate and sector experts to guide the pandemic response through coordinating, repurposing and mobilising of human, financial and material resources.



KEY CONSIDERATIONS

- Analyse risk-benefit analysis of testing expansion. Countries will need to consider the risk-benefit analysis of testing expansion to balance it with local transmission levels, and consider social and economic impacts of COVID-19 such as unemployment and inequality on the progress of the country.
- Define priority populations for testing (e.g. contacts of index cases, healthcare workers, populations with co-morbidities). The Africa Center for Strategic Studies highlighted relative *risk factors* for each African country, mapping country vulnerability by risk factors such as population age, urban density and health system strength to guide the response to healthcare expansion.
- Define testing methods to be used at each tier of the healthcare pyramid. Testing methods should include *newly recommended diagnostic tests* (e.g. rapid molecular tests, antigen serology testing³ and POC tests as they become available) in the national COVID-19 testing algorithm. The African Society for Laboratory Medicine's (ASLM) *ECHO Session #9*, 'Diagnostics in the COVID-19 Pandemic Response', offers further insight.
- Develop a national roadmap with objectives, interventions and timelines for extension of COVID-19 diagnostic capacity in alignment with existing laboratory strategic plans (priorities: access to specimen collection materials, packaging materials, reagents, supplies and laboratory protocols).
- Mobilise resources. Advocate and mobilise resources for diagnostics and laboratory testing through enhanced partnerships as exemplified by current *partnerships* with United Nation agencies and Africa CDC.



BEST PRACTICES

- Develop a national COVID-19 strategic preparedness and response plan. The plan should be inclusive of a national COVID-19 laboratory expansion plan (or roadmap), as exemplified by the Nigeria COVID-19 strategic plan.⁴ The response plan should also be catered to each transmission scenario (i.e., no cases, sporadic cases, cluster of cases and community transmission), adopting necessary measures from WHO COVID-19 response *recommendations*.
- Incorporate *WHO benchmarks for International Health Regulations* (IHR) capacities into the national response plan. Ghana's functional capacity to manage *COVID-19 health security* issues is based on WHO IHR.
- Utilise population studies and social vulnerability indexes. In Cape Town, South Africa assessed vulnerable populations data to inform decisions on the disbursement of community testing.⁵
- Consolidate healthcare experiences from previous pandemics. Nigeria quickly set up COVID-19 *isolation clinics* independent of the regular healthcare system using lessons from the 2014 West Africa Ebola outbreak.
- Leverage existing regional networks. Cross-border collaborations for response to COVID-19 are already in place. The Regional Disease Surveillance Systems Enhancement (REDISSE) *program* and East Africa Public Health Laboratory Networking *project* have mobilised resources to help over 18 East, West and Central African countries reinforce laboratory testing capacity.
- Exchange information between national response governance structures and regional technical committees. Examples include the COVID-19 national response governance structures in the *Southern Africa Development Community* (SADC) and *Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale* (OCEAC) in Central Africa.
- Support decentralisation of the coordination structure to the regional and district levels. In Ghana, regional rapid response teams are coordinating training of laboratory personnel at the subnational level.
- Establish continuous channels of communication. Communication and coordination among the laboratory response governance structures is key. WHO offers principles to ensure effective communication for healthcare programs.⁶
- Leverage on a supply chain national procurement mechanism. National procurement mechanism consolidated under a national action plan. The *Africa Medical Supplies Platform* (AMSP) set up by the African Union is a valuable tool to unlock immediate access to medical supplies through efficient volume aggregation and quota management.

Strategic planning considerations from the national COVID-19 laboratory response governance and coordination partners should guide the expansion measure best suited for the national objective and disease transmission levels. Africa CDC aims to increase testing capacity by supporting expansion of laboratory networks from central to subnational-level laboratories and expanding referral systems to feed central laboratories as key testing expansion measures.

I. EXPANSION OF LABORATORY NETWORKS FROM CENTRAL TO SUBNATIONAL LEVEL LABORATORIES

KEY CONSIDERATIONS

- Considering transmission scenarios. Different COVID-19 transmission scenarios (no cases, sporadic cases, cluster of cases and community transmission) should guide each stage of the laboratory network expansion. Ethiopia's network expansion transitioned from utilising regional referral testing services to activation of 27 subnational laboratories as guided by different stages of viral transmission.⁷
- Mapping of laboratory capacity. Most African governments are currently working with national stakeholders and funding partners to establish free testing capacity in laboratories with capacities to roll out COVID-19 testing.^{7,8}
- Enrolling private laboratories. To manage a surge in COVID-19 cases, *private laboratories* represent a useful resource in providing facilities, technical capacity, and resources to the national response as highlighted in the South Africa experience.
- Using mobile laboratories. Hard-to-reach areas can be accessed for COVID-19 testing using mobile laboratories. South Africa's National Health Laboratory Services (NHLS) has rolled out 67 *mobile units* for screening, swabbing and testing.



BEST PRACTICES

- See combined Best Practices on next page.

II. EXPANSION OF REFERRAL SYSTEMS TO FEED CENTRAL LABORATORIES

KEY CONSIDERATIONS

- Transmission levels. Countries with low/limited local transmission can opt for expansion of referral systems as a measure for expanding COVID-19 testing capacity. This is dependent on the central testing laboratory having the capacity to handle increased sample volume without straining their current testing capacity and resources. Botswana has managed the expansion of their sample referral system to their national health laboratory from their 5-tier health system.⁸
- Referral batching with existing HIV and tuberculosis (TB) program. Any batching of specimens should be properly planned to avoid overwhelming testing sites or transportation personnel, and where possible, specimens can be integrated for multi-disease testing devices. Lessons learned about the specimen referral systems of various African countries are highlighted in ASLM's Sample Transportation *Recipe*.
- Consider previous assessment recommendations. Countries need to consider recommendations from previous sample referral assessments to better manage local constraints in their COVID-19 response. Some West and Central African countries, including Burkina Faso, Côte d'Ivoire, Guinea Bissau, Senegal, Mali, Gambia and Cameroon, have well-documented sample referral *recommendations* from previous ASLM assessments.



BEST PRACTICES FOR BOTH EXPANSION MEASURES OF LABORATORY NETWORKS AND REFERRAL SYSTEMS

- Leverage capacity within HIV and TB programs, animal health laboratories and academic institutes. In Nigeria, Ethiopia, South Africa and other countries, expansion is being done by leveraging existing HIV molecular testing capacity and platforms, and *GeneXpert* POC TB testing platforms to increase COVID-19 testing.^{7,8} Integration of COVID-19 testing on multi-testing devices must take into consideration WHO *guidelines* on integrated laboratory networks.
- Ensure maintenance of *essential testing* for non-COVID-19 diseases. During leveraging of capacity within HIV and TB programs, countries should ensure the continuation of tuberculosis and HIV testing to preserve the health gains achieved.⁹ In Ethiopia, work shifts were increased to accommodate COVID-19 testing without disrupting HIV and TB programs.⁷
- Use a stepwise approach. Expansion measures should be introduced in a stepwise manner to allow lessons learned in the initially expansion sites to inform subsequent ones. Africa CDC shared recommendations for a *stepwise* approach to the COVID-19 response.
- Engage donors for financial support of sample referral systems. In February 2020, USAID engaged the Infectious Disease Detection and Surveillance (IDDS) project for sample referral and transport network technical assistance in Senegal, Cameroon, Mali and Tanzania.⁸
- Strengthen capacity through equipment and training. Strengthening of central laboratory capacity to support COVID-19 testing should be achieved through the addition of testing machinery and human resource training. This approach is exemplified by the East Africa Public Health Laboratory Network *Project*, which is providing testing equipment to Burundi, Kenya, Rwanda, Tanzania and Uganda.
- Evaluate current referral and transport networks versus capacity to meet increased sample referral needs. In Zambia a new COVID-19 courier system was introduced after evaluation of the current referral network highlighted existing sample referral system (SRS) had long turn-around time.⁹ Innovative measures can also be adopted as in the case of Ghana, which is currently using *drones* in COVID-19 sample delivery.
- Integrate COVID-19 data and sample transport system for HIV, TB and COVID-19. Nigeria integrated Sample Referral Network (NISRN) and GX-Alert system at state level to support rapid sample referral to central laboratories.⁴



4

TESTING SITE SELECTION

Accurate knowledge of pre-existing resources (infrastructure, equipment, workforce) within the national laboratory network is a pre-requisite for planning the setup of additional testing capacity. Capacity developed by national HIV/AIDS, influenza, Ebola and TB control programs with the support of their major partners (e.g. WHO, The Global Fund, CDC and World Bank) has been recognised as a critical resource which can be leveraged to support the COVID-19 response. Testing site capacity assessment should be done by visiting the proposed testing site and using laboratory mapping data (if available), or laboratories may do a self-assessment.



TOOLS TO AID TEST SITE SELECTION

- WHO assessment *tool* for COVID-19 laboratories.
- ASLM *LabMaP* data.
- National laboratory databases.

KEY CONSIDERATIONS

- Available capacity. Sites should be selected based on testing capacity available on HIV and TB multi-purpose testing platforms that can be assigned for COVID-19 testing. Special considerations are necessary to ascertain the needs of all relevant disease programmes at a particular site.
- Leverage existing information. Site selection should utilize testing site data and knowledge from diagnostic network optimisation (DNO) exercises. A number of sub-Saharan African countries, including Zimbabwe, Nigeria, Cameroon and Lesotho, have already conducted geo mapping of testing facilities and are at different stages of the DNO *process*.
- Infrastructure requirements. The availability of testing equipment and facility operational requirements like water and electricity must also be considered. This includes assessing the need for equipment and facility upgrades where necessary.
- Facility configuration. The laboratory *facility* should be appropriate for COVID-19 molecular testing, with a minimum of 2 segregated rooms, allowing unidirectional workflow from the pre- to post-PCR assay stages.¹⁰
- Location. The proximity of laboratory testing centres to public or private treatment facilities should be considered.
- Testing safety. The availability of safety equipment and safety *guidelines* for POC and near POC molecular testing must be considered. Additional precautions required include personal protective equipment (PPE) and physical barriers, like a splash shield.
- Human resources. The availability of staff trained on testing procedures and biosafety should be considered. Skilled staff can be mobilised from staff working on other disease programs like TB and HIV to make scale up easier.

BEST PRACTICES

- Use of geographic information systems and geospatial mapping for site selection. The population health unit in Kenya used spatial analysis to determine their vulnerability index, which informed molecular testing scale up response in all counties.¹¹
- Standardise and customise physical assessment tools for testing site selection. The Ethiopia Public Health Institute customised their WHO site readiness assessment checklist for in-country test site selection.⁷
- Perform a desk review of prospective test site status. Potential sites should be reviewed for registration and participation in national quality management programs.
- Be transparent about site selection. Test site selection should be transparent and based on factual evidence, in accordance with the principles of good governance.
- Attend to conflicts of interest. In the event of laboratory self-assessment due to the inability of central laboratory personnel to travel for the evaluation, minimum conflict of interest practices should be observed. Preferably, staff who are independent from the laboratory should assess the laboratory test site.

Prior to routine operations, all necessary capacity (material and human) should be available at selected testing sites to avoid disruption of current or future laboratory work.

KEY CONSIDERATIONS

- Install new equipment or upgrade existing machines. Equipment installation at the selected testing sites should be guided by the test site assessment. Equipment leasing is a viable consideration for resource-limited countries.¹²
- Consider personnel knowledge gaps in developing testing site training materials. Assess areas that need personnel attention in the COVID-19 testing algorithm.
- Determine alternative methods for provision of PPE to all testing staff. Given the global demand for PPE and adequacy level challenges, local production of PPE provides an alternative to ease shortages, as highlighted in the Zimbabwe *experience*.
- Address quality assurance and supply chain management challenges including:
 - a. Forecasting supply chain and inclusion in national procurement mechanisms
 - b. Participation in a national COVID-19 testing external quality assessment (EQA) program
 - c. Defining quality indicators and setting up mechanisms for reporting to national laboratories



BEST PRACTICES

- Follow WHO quality assurance guidelines. COVID-19 laboratory quality assurance should follow WHO's *recommendation* on confirming the first five positive specimens and 10 negative specimens by referring them to an in-country reference laboratory or a designated COVID-19 regional reference laboratory (e.g. National Institute for Communicable Diseases (NICD) in South Africa, Institute Pasteur in Dakar Senegal and other experienced COVID-19 testing *laboratories*).
- Customise training. Central laboratories should customise selected test sites training and develop capacity through training of trainers. South Africa's central laboratory, NHLS, *customised* WHO *guidelines* to suit national sample requisition, sample referral and transportation training materials for subnational-level laboratories. Training should be provided for COVID-19 diagnostic processes including:
 - a. Laboratory staff. Laboratory staff should receive training on testing procedures, specimen collection, results interpretation, biosafety, quality control and quality assurance
 - b. Support staff. Support staff, including couriers, should receive biosafety training on handling and transportation based on WHO, *Africa CDC* and International Air Transport Association *guidelines* assigned to UN3373 Biological Substance Category B.
 - c. Data management. Relevant personnel should receive training in proper management of COVID-19 testing data. In Ethiopia, the WHO country office technical support team offered *training* for COVID-19 electronic data management to country teams.



- Assess staff competencies before testing begins. Assess the competency of trained staff before any routine testing activity is started. Experience from Ethiopia highlighted the importance of testing the capability of staff proficiency as part of training certification.⁷
- Standardise procedures. Standardise sample collection, packing and transport; use of laboratory registers, test requisition forms and standard operating procedures (SOP) such as testing protocols; quality assurance (QA) testing; and waste management and results communication protocol. Use lessons from WHO technical *guidance*.
- Set up or update waste disposal protocol to meet COVID-19 needs. In South Africa, COVID-19 SOPs have been updated; waste is packaged in multiple layers of thick plastic and boxes and sterilised twice during the *process*. Assigned vehicles then transport the waste to one of eight hazardous waste sites under global positioning system (GPS) tracking.



6 ROUTINE TESTING OPERATIONS

Routine testing operations at all sites within the COVID-19 testing network require proper monitoring and evaluation (M&E), with a focus on promptly identifying and correcting challenges at new sites and during scale up of testing. A list of some of the challenges encountered during scale up is included in Table 1. The national COVID-19 laboratory taskforce should oversee M&E and use data to inform further expansion of testing in-country, while assuring quality of test results.

KEY CONSIDERATIONS

- Supervision. Perform dedicated supervision, especially during the early phase of scale up. Where possible, supervision should centre around on-site visits, but where impossible, due to travel restrictions, remote and digital options such as WhatsApp, Zoom or other online communication systems should be considered.
- Monitoring and evaluation tools. Consider improvement or development of new innovative monitoring and evaluation tools for monitoring progress of robust expansion. A *partnership* between South Africa's iThemba Laboratory for Accelerator Based Sciences and Botswana International University of Science and Technology has a project for visualising, monitoring and modelling the spread of the COVID-19 pandemic in Botswana. Such a dashboard can also be utilised to track laboratory testing performance after expansion.
- Laboratory information management systems (LIMS). An optimised LIMS supports real-time monitoring of healthcare programs and facilitating continuous quality improvement of services. Key *considerations* when selecting the most appropriate LIMS package for a particular setting include types of testing instruments, needs for testing integration, ease of use and security.



- Laboratory staff fatigue. Considerations should be made to manage risk for fatigue-related incidents and increased worker exposure to COVID-19 through mitigation *measures* such as shift rotations and reducing shift time.



BEST PRACTICES

- Ensure continuous quality assurance. Quality assurance should be done as guided by the central laboratory and quality assurance bodies. Ethiopia is managing COVID-19 quality assurance through ongoing proficiency testing using UK NEQAS and periodic confirmatory retesting at NICD in South Africa. An in-depth discussion on implementing a structured quality assurance program is available from ASLM's COVID-19 ECHO [session #10](#).
- Standardise key performance indicators within the M&E framework. Key performance indicators to include regular notification of testing volumes from new testing sites (number of tests performed/positive results/negative results) for accurate forecasting and procurement of supplies and consumables. Quality *indicators* for COVID-19 are proposed by ASLM.
- Maintain good clinical laboratory practice and ISO 15189 standards. Testing sites are expected to also comply with regulatory bodies governing COVID-19 testing. The Centers for Medicare and Medicaid Services (CMS) has amended the Clinical Laboratory Improvement Amendments (CLIA) *guidelines* to meet the needs of the current COVID-19 pandemic, and now stipulates best practices for COVID-19 testing sites.
- Ensure regular preventative and curative maintenance of instruments to avoid equipment downtime.
- Ensure mentorship/refresher training of laboratory staff as required.

Scale up Challenges		Mitigation measures
1	Reagent shortages	Reagent forecasting
		Local <i>production</i> of reagents as in the case of Nigeria
		Use of third part reagents from HIV PCR kits
		National taskforce to coordinate/liaise with diagnostic suppliers
2	EQA service provision	Collaboration with laboratories such as NHLS/NICD and Institute Pasteur
		Adopt ISO 15189 guidance on <i>alternative</i> approaches for external quality assurance
3	Disruption of TB and HIV programs	Increase number of working shifts to maintain program targets as Ethiopia has done ⁷
4	Laboratory downtime due to COVID-19 spread among laboratory staff	Reinforce the need for laboratory staff to self-monitor for COVID-19 symptoms
		Adopt CDC <i>consideration</i> for healthcare workers
		Develop sample referral contingency plans to compensate for laboratory downtime

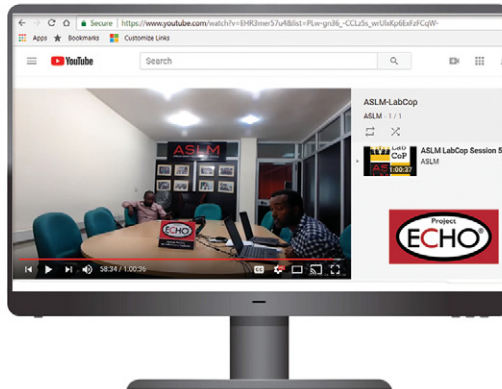
Table 1: Expected challenges during scale up and proposed mitigation measures.

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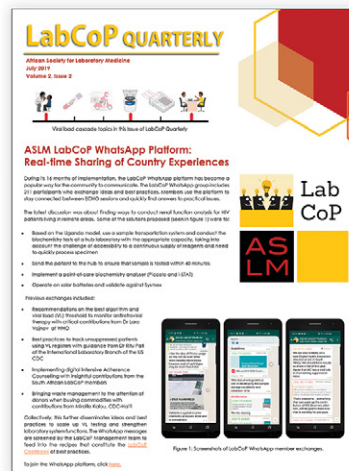
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ASLM and our partners thank the Bill and Melinda Gates Foundation for their generous support