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Minimum Package for Sustainable Laboratory Systems

A Framework for Prioritizing Laboratory Systems Strengthening in the context of Reduced External Funding

Lab CoP

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Introduction

Diagnostics play a central role in ensuring quality health care and are fundamental to achieving the 2030 Sustainable Development Goals and meeting disease elimination targets, including UNAIDS 95-95-95 and the End TB Strategy. The recent World Health Assembly resolution on strengthening diagnostics capacity highlighted the importance of incorporating diagnostics into universal health care packages and prioritising their accessibility at the primary health care level. Medical laboratories are essential, not only for supporting patient diagnosis, prognosis, and monitoring, but also in pandemic preparedness, emergency response, and healthcare delivery, particularly in resource-constrained countries. Moreover, critical public health decisions concerning health security, national development and meeting international obligations, such as those established in the International Health Regulations (2005), depend upon quality and timely laboratory results.

Despite widespread recognition on the importance of strengthening public health systems to address global health needs [1,2], the recent disinvestment in key foreign aid mechanisms including PEPFAR and the dismantling of USAID, pose a threat to the sustainability of laboratory services and threatens to reverse the gains in meeting the global health targets [3,4]. One key impact of funding cuts on diagnostics in LMICs is the disruption of diagnostic service continuity, particularly for diseases like HIV, TB, and malaria. These cuts can lead to reduced availability of essential test kits, reagents, and technical support, compromising timely diagnosis, treatment initiation, and disease surveillance, and ultimately reversing progress made in controlling infectious diseases.

The African Society for Laboratory Medicine (ASLM) is a pan-African organisation committed to achieving a healthier Africa by increasing access to quality laboratory services for all. ASLM works with key global, regional, and country stakeholders to strengthen laboratory and diagnostic services and

1 The Lancet Commission on diagnostics: transforming access to diagnostics. Fleming KA et al Lancet (2021) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00673-5/fulltext

2 Moving the dial on diagnostics: an update from the Lancet Commission on diagnostics. Horton S et al Lancet (2025) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)00804-9/abstract

3 Impact of an international HIV funding crisis on HIV infections and mortality in low-income and middle-income countries: a modelling study. Brink D et al Lancet HIV (2015) https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(25)00074-8/fulltext

4 Tuberculosis Program Impact Tracker: Estimated impact associated with funding discontinuation. https://tb.impactcounter.com

networks, and to ensure that country needs, and priorities are reflected in the global laboratory and diagnostic agenda.

In 2017, ASLM established the Laboratory Community of Practice (LabCoP), now comprised of 24 countries, with the goal of co-creating solutions and sharing knowledge to strengthen service delivery for HIV, TB and broader national laboratory needs. Due to the unprecedented shifts in the funding landscape, LabCoP countries are currently operating in an environment of significant uncertainty.

Following the announcement of the funding cuts, ASLM conducted a survey through the Laboratory Directors Forum (LabDF) to assess the potential impacts of the PEPFAR funding freeze on laboratory operations[5]. Considering that in many countries, the funding for laboratory commodities, laboratory information systems and sample transport networks is partly through PEPFAR, USAID and Global Fund mechanisms, only 12.5% of countries reported their ability to maintain services for more than 12 months without USG support. Additionally, 44% of countries indicated that an extended pause in USG funding would contribute to significant staff attrition.

Therefore, there is an urgent need for prioritization of services to be continued as domestic funding may not be readily available to plug the funding gap. In order to maintain the critical role of medical laboratories in provision of quality diagnostics, maintaining the capacity for testing to support disease programs and protecting the laboratory workforce and the environment, ASLM proposes a minimum package of care that countries should consider as they prioritize activities to sustain provision of healthcare services (Annex 1). This document outlines the guiding questions and core components of the minimum package of care, offering a framework that can be used by Laboratory Directors, policymakers and technical working groups to sustain laboratory services in the context of reduced funding.

5 The impact of a temporary suspension of United States Government (USG) funding on laboratory services in African partner countries. ASLM (2025) https://aslm.org/wp-content/uploads/2025/05/Impact-Report-USG-.pdf

Rationale

To assist countries proactively plan and navigate this period of uncertainty and budgetary constraints, ASLM will facilitate connections with potential funding partners to enable diversification of funding sources, strengthen regional collaborations, and engage governments of member states at various levels to advocate for investments in laboratory services. In addition, ASLM has developed a minimum package of laboratory care framework that provides a structured and evidence-based approach to prioritize and sustain critical diagnostic services in the face of reduced funding.

It enables laboratory leaders, policymakers, and partners to identify and protect essential tests and capacities that are vital to public health, while optimizing the use of limited resources through integration, standardization, and strategic investment. This framework also supports informed decision-making, enhances system resilience, and ensures continuity of care, particularly for high-burden and epidemic-prone diseases, thus safeguarding health outcomes even in resource-constrained environments.

The minimum package is based on insights gathered during the LabDF survey and identifies four priorities to ensure continuation of laboratory services:

Procurement of tests for priority diseases guided by the National Essential Diagnostic List (NEDL)

Basic equipment maintenance services

Core staff training and retention

Quality control and assurance measures

Guidance for prioritization of laboratory systems and services

National programs are currently reprioritising activities in line with Global Fund GC7 Programmatic Reprioritization Approach[6] as well as UNAIDS and IAS HIV sustainability guidance[7, 8]. National laboratory leadership (e.g. Directorate of Laboratory services) should be actively involved in these planning and discussion processes to ensure alignment of programmatic and laboratory-specific priorities. This will guide the laboratory leaders to make informed decisions to implement sustainable and cost-effective laboratory networks and services making reference to the proposed minimum package in annex 1 and the self-assessment in Annex 2.

6 Global Fund: GC7 Reprioritization and revision of grant activities. 2025 https://resources.theglobalfund.org/en/gc7-reprioritization/

7 UNAIDS: HIV Response Sustainability Primer. 2024 https://www.unaids.org/en/resources/documents/2024/20240117_HIV_response_sustainability

8 IAS: The PATHS – Planning and Action Toolbox for HIV Sustainability. 2025 https://www.differentiatedservicedelivery.org/resources/the-paths-planning-and-action-toolbox-for-hiv-sustainability/

Key questions to consider during prioritisation of program and laboratory services

Who is represented in the technical working group responsible for developing the minimum package for laboratory networks and services?

- Does the group include disease program technical experts across the full cascade of services and populations currently served?
- Are civil society and community representatives meaningfully included in the process?
- Is there representation from planning and policy departments, and the Ministry of Finance, to ensure alignment with funding, domestic financing and broader health system considerations?

What are the criteria guiding prioritization discussions?

- What data is reviewed and leveraged on (e.g., disease epidemiology, annual or quarterly statistics and reports, country's progress against global and national targets, lab mapping data).
- How will decisions be made on which areas to maintain scale up, scale down, reprioritize, or deprioritize?
- Consider priorities and needs of programs as well as any minimum packages developed at program level.

Which diseases or conditions are highest priority and require uninterrupted laboratory supply?

- Which services must be maintained at each level of the health system?
- What are the different scenarios considered during prioritization?
    - **E.g. resource optimization -** what are the priorities if only 50, 30 or 20% of the 2024 operational budget was available, or international funding was withdrawn completely?
    - **E.g. disease integration –** which diseases/ tests? how will this be done? what are the cost efficiencies?
    - What assumptions are guiding the process and what are the tradeoffs?

What is the evaluation framework to continually reassess changes made to reduce risk of adverse patient outcomes or reversal of program gains?

- What indicators should be tracked to monitor performance and inform adaptive planning?

What are the strategies for political advocacy to increase sustainable domestic funding?

- Is there a sustainability financing roadmap?
- What partnerships, innovations or domestic financing mechanisms can be leveraged to fill funding gaps?

How can quality and safety be ensured despite resource limitations?

Diagnostics Situational analysis:

1. Is the structure of the current laboratory network mapped out and is an analysis of the services offered available?

- Include review of diagnostic network optimization and/or assessment data and reports, laboratory annual reports and/or laboratory mapping data and reports e.g. from ASLM LabMap, FIND OptiDx, etc

Essential data includes:

Laboratory capacity including:

- Location (Master Facility list with GIS if available)
- Number and type of equipment (Equipment Lists)
- Human resources /cadres
- Infrastructure
- Numbers of laboratory investigations performed (Test menu/NEDL)
- Number of diagnostic tests performed
- Cost data for each element of the laboratory network and services package

If Lab Mapping has been conducted, this information should be readily available.

- **Have the following domains been considered in the prioritization analysis?**
  - **Epidemiological analysis:** Which diseases or conditions are highest priority for national health outcomes and require uninterrupted laboratory support?
  - **Cost effectiveness and resource optimization:** What processes can be implemented to reduce duplication and optimise resources?
  - **Ethical and equity considerations across the health system:** How can access to diagnostics for all be maintained in the context of reduced funding?
  - **Acceptability and community engagement:** How can engagement with communities increase acceptability and success of program reprioritisation?
  - **Social and economic impact:** How can the impact of program reprioritisation on quality of services and access be effectively measured?

2. **Has a minimum package been agreed upon (See Annex 1 below for proposed minimum package)?**

3. **Which elements of the minimum package above are/ were supported through external funding? Which ones have been affected by the current funding cuts?**

4. **How will any changes in the laboratory network and service delivery package be communicated to stakeholders (laboratory staff, clinicians, recipients of care, others)?**

5. **What will be the impact of these changes on e.g., laboratory operations, patient outcomes be measured?**

Annex 1:

Minimum Package for Laboratory Service provision

The proposed minimum package provides an initial framework that countries can use for prioritising laboratory services, guiding planning and policy dialogue. It is intended to be a living document that can be adapted and updated according to local context.

Priority area	Justification	Sustainability plan	Practical solutions
Diagnostic testing for priority diseases guided by NEDL	NEDL should be informed by program priorities and testing services adjusted accordingly to ensure timely diagnosis and disease management.	Advocate for domestic funding for laboratory commodities.	• Laboratory involvement in program reprioritization discussions to ensure alignment and consideration of laboratory budget Refer to practical guidance for NEDL development.
	Integrated testing on existing instruments can improve utilization.	Leverage on existing LabMap, DNO, DNA data and/or reports where available to determine sites where integrated testing might have the most impact.	• Review NEDL/test menus against existing capacity and align with programmatic changes. • Important to keep track on test volumes and turnaround times. • Maintain laboratory network equipment registry. • Leverage on private sector capacity Refer to ASLM LabMap program.
Basic equipment maintenance and repair	Uninterrupted testing requires functional equipment to ensure reliability of results.	Leverage biomedical engineering units and calibration centres (established under PEPFAR program) for equipment service, calibration and maintenance.	• Consider establishment of rental agreements/contracts for all equipment with local agents and the use of national equipment repair, maintenance and calibration centres. • Consider training staff and ensure implementation of preventive. maintenance on all major equipment • Can the established national calibration centres also outsource services to like non-government institutions to raise funds for self-sustenance.

Priority area	Justification	Sustainability plan	Practical solutions
Retention of core staff	Trained and competent staff are essential to quality laboratory testing. Staff retention fosters institutional knowledge and ensures continuity of testing.	Redeploy laboratory staff (including technical, Administrative and other support staff) to affected laboratories to fill gaps due to reduced external funding. Leverage on virtual/online continuous professional development courses (e.g. ASLM Academy).	• Defined minimum staffing per lab tier. • Cross-training personnel to perform multiple functions. • Strengthen laboratory oversight (training, monitoring for non-laboratory professionals). • If insufficient staff numbers as per the staffing norms, consider task sharing and or shifting where possible e.g. use of community health workers to support sample collection. Refer to WHO guidelines on task sharing[9].
Quality Control and assurance measures	Quality, reliable testing is essential for patient management I. IQC.	Implement use of commercial IQC for selected priority tests and in-house IQC for other tests.	• Consider using commercial or in-house prepared IQC materials. Guidance on preparation of in-house IQC can be found on ISO/TR 33402:2025 document [10].
	II. EQA - Program can include inter Lab comparison, onsite and remote mentorship/ supervision etc).	Leverage on local or regional PT production if it exists.	• Consider "tiering PT participation" from international through regional to in-country level providers enrolment.
		Leverage on accredited private sector laboratories if available.	• Consider accreditation of at least one national reference laboratory as an EQA provider.
		Consider expansion of participation in regional inter-laboratory comparison (re-testing) to more laboratories where possible.	• Designate Inter laboratory comparison coordination units/laboratories and make use of the integrated sample transport network to move comparison materials, results and feedback.
		Build on experience from the remote audits implemented during COVID-19 lock down.	• Consider remote supervision methods, telemonitoring and mentoring. Refer to QMS considerations and guidance for COVID-19 molecular testing laboratories[11].

[9] https://www.who.int/publications/i/item/9789240111486 [10] https://www.iso.org/standard/84227.html [11] https://aslm.org/resource/labcop-recipe-5-quality-management-system-considerations-and-guidance-for-covid-19-molecular-testing-laboratories/#:~:text=ASLM%20and%20its%20partners%20have,virus%20that%20causes%20COVID%2D19%2C

Priority area	Justification	Sustainability plan	Practical solutions
	III. Establish a National Certification Program.	Maintain laboratories already enrolled into a National Certification Program leveraging on existing tools e.g. WHO/ AFRO SLIPTA and SLMTA programs.	• Consider establishing a national certification program if not in place • Consider accreditation for higher tier laboratories and certification of intermediate and lower tier laboratories based on a nationally established standard. Refer to Africa CDC guidelines on establishment of a national laboratory quality framework[12].
Sample collection and storage	Sufficient sample collection materials and adequate temporary and long-term storage capacity.	Consider limiting sample collection to locations where other services are provided. Leverage on available biobanks and cluster long term storage if feasible.	• Consider other sample types like dry blood/plasma spots, etc depending on available storage options.
Sample referral system	Integrated specimen referral system can improve laboratory services efficiency and reduce costs.	If disease specific, consider integration or leverage on existing system not affected by funding cuts. If no referral, consider integrated testing on near-POC or POC instruments or nearby private laboratories.	• Prioritise integrated specimen referral and communication of test results. Refer to sample transport recipe[13].
Procurement and supply chain	Accurate forecasting of standardized reagents/ consumables and timely procurement of required commodities ensures uninterrupted testing.	Accurate and timely procurement of reagents and consumables in line with the revised programmatic testing needs.	• Consider integrated procurement utilising regional pooled procurement mechanisms. across diseases and countries to achieve cost-savings e.g. Partnership for Supply Chain Management (PFSCM).

12 https://aslm.org/wp-content/uploads/2022/06/Guidance-for-Establishing-a-National-Laboratory-Quality-Framework-1.pdf?x61029

13 https://aslm.org/wp-content/uploads/2019/11/BookletLabCoPCookbook1-2018-07-20-Web.pdf

Priority area	Justification	Sustainability plan	Practical solutions
		Leverage existing resources for logistics (freight, warehousing/ storage and distribution).	• Maintain minimum stock levels; buffer stock for emergencies. • Consider digital tools for accurate forecasting and commodity management if not already in use. • Consider commodity redistribution to avoid stockouts.
Biosafety and biosecurity (BSBS)	Established Coordination Structure to oversee implementation and compliance to BSBS requirements.	Leverage existing relevant TWG to coordinate BSBS activities. Conduct risk assessment or leverage on existing reports and implement corrective actions including provision of occupational health package e.g. vaccination.	• Consider establishment of national policies and regulations on laboratory safety and waste management, in compliance with national or international occupational health, safety and environmental standards, using a consultative process, including the national environmental authority. • Consider inclusion of compliance with laboratory safety and waste management policies and procedures as part of national registration and licensing requirements, including the private not-for-profit and private for-profit sectors. Refer to WHO laboratory biosafety manual (https://www.who.int/publications/i/item/9789240011311). Refer to WHO laboratory biosecurity guidance (https://www.who.int/publications/i/item/9789240095113). Refer to Africa CDC guidance on development of a national BSBS strategy. https://internationalbiosafety.org/wp-content/uploads/2022/06/DEVELOPMENT-OF-A-NATIONAL-BIOSAFETY-AND-BIOSECURITY-STRATEGY_English.pdf.

Priority area	Justification	Sustainability plan	Practical solutions
	Laboratory safety.	Provide basic PPE package per laboratory tier requirements e.g. gloves, coats, masks, etc.	• Consider inclusion of laboratory safety and waste management procedures in all pre- and in-service laboratory training programmes.
		Leverage on existing Biosafety programs established via PEPFAR funding to ensure certification of Biosafety cabinets based on frequency of use and type of materials handled.	• Consider at least annual certification of ALL Biosafety cabinets. • Leverage on regional expertise in biorisk management[14] established and biosafety cabinet certification[15] by Africa CDC. • Leverage on established Regional Centres of Excellence for BSBS (3 exist for Southern, Western and East Africa) where servicing and calibration tools for BSCs maybe available.
	Proper laboratory waste management.	Ensure provision of basic waste management requirements including sharps containers, segregation bins, etc. Leverage on integrated specimen referral system to refer waste to nearby sites with incinerators, autoclaves, etc.	• Consider procurement of autoclaves, incinerators, etc where feasible. Refer to Management of GTC containing waste from testing laboratories recipe[16].
Laboratory Information management system	Establish a standardised national laboratory information management system.	Leverage existing local or regional LIS or connectivity solutions for sustainability.	• Consider integration with patient management systems and national systems (e.g. DHIS2). • Consider harmonisation with the national laboratory supply chain management system, to guide commodity management. • Routine data collection and reporting on test utilization, turnaround time, and quality indicators. • Use of digital tools for efficiency and decision-making.

[14] https://africacdc.org/wp-content/uploads/2023/07/List_of_Africa_Regional_Subject_Matter_Experts_Biorisk_Management1.pdf

[15] https://africacdc.org/wp-content/uploads/2023/07/List_of_Africa_Regional_Subject_Matter_Experts1.pdf

[16] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://aslm.org/wp-content/uploads/2023/05/BookletLabCoPCookbook7-EN-2023-10-25.pdf?x79169

Priority area	Justification	Sustainability plan	Practical solutions
Laboratory Governance and Management	Well established and adequately resourced (financial and human), stand-alone Directorates of Laboratory Services at the Ministry of Health, fully mandated to oversee all national (private and public) diagnostic services.	Strengthen existing unit and support budgeting for effective oversight of the laboratory network.	• Consider establishing/strengthening a laboratory department or unit within the central Ministry of Health with a designated head responsible and accountable for managing and coordinating the national health laboratory system with clear roles and responsibilities. • Ensure adequate financial and logistical support for the functions of the national laboratory department or unit, and effective operations of the laboratory services at every tier level of the national health system. • Costing of the minimum package for advocacy and planning • Domestic resource mobilization (e.g., insurance schemes, performance-based financing). • Donor coordination and targeted investment for high-impact areas. Refer to ASLM's blueprint on laboratory leaders of the future. https://aslm.org/resource/blueprint-laboratory-leaders-of-the-future/
	Governance structures and instruments that reflect the dynamic service delivery space.	Provide for or strengthen available governance structures e.g. laboratory TWG.	• Consider shared governance across vertical programs to reduce redundancies. • Consider where partnerships can cover gaps and strengthen laboratory systems.

Annex 2:

Country Self-Assessment Tool

Please use this link to access the minimum package self-assessment tool:

https://ee-eu.kobotoolbox.org/x/9x11YgUb

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