Strategic Decision Table for Strengthening Laboratory systems

September, 2022

S#	Strategic areas	Strategic options*	Priority action items for improvement**
I	**Demand Creation (HIV intervention)**		
1	Leadership and Coordination	• Review demand and service availability • Mobilize district health officers (DHO) and IP support	• Develop a plan for demand creation based on availability and capacity to balance with the demand • VL dashboard to track coverage alongside denominator of # of ART clients per facility • Share VL coverage targets for national, regional, district and facility teams
		• Understand the community perceptions • Advocacy structures at national, district and community level • Specific funding for demand creation	• Review survey results or conduct mini-survey to understand community perception • Use of existing organizational structures from national to community level for demand creation. • Community-based structures of PLHIV for demand creation. • Resource mobilization for demand creation targeting frontline healthcare teams and civil society • Strengthen the lab clinician interface for effective planning and results utilization • Giving priority to pediatrics and adolescent communities
2	Capacity of healthcare providers	• Training • Review meeting • Viral load campaigns • Site visits	• Training of trainers (national, regional and facility trainings) • Monthly national level data review meetings for IPs/districts. • District/hub level review meetings to review coverage, suppression, and rejection • Districts set up quarterly testing targets per facility with ART numbers as denominators.
3	Engaging civil society for demand creation	• Involvement of civil society to create awareness among civil society & PLHIV networks/groups for advocacy and adherence support	• Ensure to have PLHIV civil society or recipients of care involved in strategic development and initiatives for demand creation at different level • Technical working group decisions and plans, e.g., TLD roll out • Use of peer support and health workers to return results • Engaging civil society in strategic planning and policy development • Convene review meeting with stakeholders for targeted action plan development
4	Community sensitization, mobilization and patient education	• Use media • Standardized messages • Community-Facility linkage facilitators, DSDM (chairpersons of the groups) • CQI through community • Client champions • Focus-group awareness on behavior change from national level to the community level	• Health talks on radios, TVs, • Develop standardized messaging material for clients and respective communities • Mobile phone ringtones specific to VL • Reminder SMS and appointment dates • Increase community sensitization on the importance of VL • Forum for faith-based leaders who are supported to create IEC materials for them to communicate VL & other HIV issues. • Facilities call up clients for VL appointments or use community health worker visits.

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			• Clinics aligned demand creation around the differentiated service delivery model of drug refill days • Use faith-based and community-based organizations to reach those who have not come to facilities
II	**Viral Load Result Utilization (HIV specific)**		
1	Result tracking and delivery	• Documentation of results in source documents/requests • CQI projects on VL cascades focusing on leakages	• Develop and introduce a high viral load register • Identify indicators for monitoring VLT result utilization: EAC, repeat VL test, Switching-ART • Review meeting with clinicians and lab professionals • Engaging management for interventions • Implement QI projects on identified gaps
		• Electronic results transmission to clients and clinician • Sorting and prioritize results in the laboratories • Proper handover and dispatch processes	• Notifying patients to return and communicate to the clinician • Using stickers or priority filing for non-suppressed clients • Online databased and Barcode system to track sample and results movement • A logging system for sample and results transmission (by date, high-viral load, …) • Physical return of written results, • Scale up and use of SMS and mobile app to access results esp. for remote sites e.g. Zimbabwe and South African models
3	TAT from labs to clinicians	• Lab and sample transport optimization • Aligning patient appointments with results • MOU between laboratory and clinical team on TAT • Prioritization of results	• Aligning patient appointments with results • MOU between laboratory and clinical team on TAT • Communicating to clinicians by the laboratory for any un-intended incidences • Document communications between labs clinicians especially for un-intended incidences and delayed result delivery • Electronic alert systems between testing and referring labs
4	Coordination and management	• VL champions/Focal person to link lab results with patient files and flagging out high viral load clients • Regular multi-disciplinary viral load team meetings	• Clear terms of reference (TOR) for the focal person, • Develop SOPs for result delivery and monitoring process • Scheduled supervision for proper coordination of the result delivery process • Regular meeting of multi-disciplinary viral load teams (labs, clinicians, management, …) • Managing commodity security, and improving fore-casting by multi-disciplinary teams • Phone calls for critical results
5	Human resources at facilities	• DSD models • Task shifting and sharing Use case managers	• Decanting of patients (DSD models) • Advocate task-shifting • Support case managers assigned for each non-suppressed client and advanced illness care
6	Routine VL test results utilization by clinicians	• SOPs and Job aides • On-job mentoring • Blended learning	• Develop/review SOPs and job aids • Schedule CME sessions and case discussions: face-to-face, and virtual discussion using experts via Project ECHO

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III	**Waste Management and Biosafety (across diseases)**		
1	Policy and regulatory frameworks	• Update/establish national legal policy, and regulatory framework to address waste segregation, audit trail to waste destruction, and defined roles and responsibilities of stakeholders • Review legal, regulatory and policy framework to address GTC and other chemical waste across all sectors • Review practical guidance for WM at both national and facility level	• Develop standards for national WM, with support from LabCoP and other collaborating partners on the ground e.g., US CDC, MSF, CHAI, UNICEF etc. • Adapt regulatory or legal frameworks from other countries (e.g., Basel Convention signing as South Africa and Mozambique) • Include WM in national laboratory policy and strategic plan • Include guidance /SOPs on chemical waste management – examples from Malawi and Zimbabwe
2	Operationalization of waste management policies	• Establish technical working group (TWG) for national coordination • Assign roles and responsibility for WM at all levels of the laboratory system (central, regional, district, facility) • Involve manufacturers or suppliers in the disposal of waste (consider reverse logistics)	• Consider/advocate for a dedicated office of waste management and biosafety at national/regional, facility level on the South Africa and/or Kenya models. • Update JD for biosafety officers to include WM Functional Training on SOP and guidance (for lab technical and non-technical staff , Incinerator staff) • Establishment of functional national TWG, including implementing partners and stakeholders (on the model of Kenya) • Assign roles and responsibility to stakeholders e.g., Kenyan model where disposal of expired products (reagents, drugs) is the responsibility of the central supply agency • Leverage well-established systems for transporting essential medicines and other medical supplies to health care facilities to transport waste • Design clear job descriptions and provide necessary training for WM at all levels using the entry point of the HIV program including a maintenance team to service incinerators using the ASLM/PEPFAR collaboration model. • Estimate the volume of GTC waste using available tools (e.g Roche software) and calculate the cost of waste management
3	Financing	• Leverage current funding opportunities from PEPFAR, the GF and donors around HIV, TB, Malaria work • Request fund from manufacturers as part of their social duty	• Review costs associated with WM (e.g., VL machine specific WM) e,g., using the Clinton health Access Initiative model used in the Zimbabwe costing exercise. • Establish contact with private companies for an efficient way of handling waste e.g., public-private partnerships (LabCoP to facilitate follow up meeting and summarise efforts through a white paper) • Obtain clear cost estimate of differentiated laboratory waste management as part of the overall testing services

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4	Infrastructures for waste management	• Mapping existing infrastructure location and capacity • Expand the implementation of onsite conventional systems for waste disposal • Leverage the utilization of cement factories for high temperature incineration • Install new systems and innovative strategies • Improve the transportation system for waste from place of generation to place of destruction	• Optimize number and location of incinerators for managing the waste including the VL waste - GTC extraction of DNA and RNA , using GIS based modelling (e.g Labmap, OptiDx) • Pilot systems such as drainage, or charcoal absorption, solvent recovery and immobilization options. • Transport of waste to local cement factory • Design a cost-effective waste transportation system on the model of sample transport in Uganda or South Africa. • Develop standards for infrastructure (e.g., drainage and WM systems) • Comply with recommendations and standards of the WM system, and strict consideration in the design phase of new laboratories and renovation. This includes the complete flow of waste from generation to disposal areas (e.g., storage, treatment, and disposal) • Update inventory of essential spare parts for the range of incinerators in-country.
5	Partnerships and collaboration	• Collaboration between disease programmes for cost sharing • PPP for transportation and disposal of waste • Cross border collaboration • Include WM cost as part of contractual agreements with manufacturers	• Include manufacturer take-back schemes into contract agreements • Select diagnostic technologies with less toxic chemical alternatives to GTC in diagnostic tests, e.g., Guanidine Hydrochloride, and Sodium Hypochlorite. • Manufacturers to conduct research and development on effective WM solutions • Manufacturers and donors install high temperature incinerators in low-to-middle income countries as part of their social responsibility and aligned with national policies . • Manufacturers revise cost per test according to the 'polluter pays' principle, where they share responsibility for the cost of WM of their products.
	Monitoring and Evaluation of WM activities	• Reduce opportunities for non-compliance to good WM practices at national and facility level • Monitor (GTC) waste from generation to processing to destruction • Assess the cost effectiveness of various methods of WM	• List and prioritize measurable indicators for monitoring WM against set standards (e.g 'certificate of destruction' used as proxy for waste destruction by NHLS, South Africa) • Implement use of waste calculator to quantify amount of waste generated by testing facilities (e.g., SAWIS used to monitor amount of waste generated monthly in South Africa) • Implement WM dashboard at facility and national level for ease of monitoring. • Design audit and assessment schedules using the South African model. • Compare the cost of various WM method in relevant set up (e.g., Zimbabwe, Malawi, Mozambique costing models) • Establish baseline, and introduce regular monitoring using standard checklists for example the GF capacity assessment for health care WM, or the tool for VL and EID molecular WM considerations
IV	**Network Optimization**		

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1	Up take of Diagnostic network optimization as a network management and CQI (DNO sub CoP)	• LIMS • Lab-clinic interface • Robust systems for GIS data management • Evidence based reconfiguration of diagnostic and laboratory network • Advance diagnostic integration in support of improved access to essential diagnostics • Improved coverage and integration of specimen referral systems • Improved supply chain • Population coverage of essential diagnostic services	• Use GIS location of Labs, and facilities to continuously assess the coverage and capacity of the network • Design and optimization of Information systems, LIMS • Integration of Lab and Clinic (Lab Clinical interface) electronic • Pilot and scale-up of cost-effective specimen transport systems • Identify reliable courier system, vehicles, and bikers • Mapping of referring sites to testing laboratories • Best placement of technology as a function of maximum population coverage • Build the capacity of the national TWG to use GIS-associated evidence on laboratory capacity (LabNet Lead, GLLP, DNO sub community of practice)
2	Communication and partnership	• Engage stakeholders • Communication structure	• Engage stakeholders for increased uptake, coverage, implementation, and monitoring and evaluation including public-private partnership (PPP) • Maintain communication between referring sites and testing lab(s) to resolve challenges any problem that are identified • Develop/adapt and use communication strategies for sharing best practices, opportunities, and challenges
3	Maintaining HIV, tuberculosis and other essential testing during outbreak response	• Mutualize available diagnostic testing capacity (including testing platform and HR),	• Utilize available information from network mapping exercises such as population served, projected testing volume, available technologies, capacity, etc. • Optimize the network to mutualize testing resources: adopt multiplexing and integration solutions on existing diagnostic equipment with attention to achieve various testing targets • Strengthen equipment maintenance services • Ensure strong coordination between ministries of health, disease programmes and other stakeholders • Extend working hours to meet testing service demand, e.g., by means of a shift system, and limiting non-essential leave • Implementation task shifting of routine services to less experienced staff • Provide financial and/or non-financial incentives, performance-based incentives or other methods as means by which to retain and enhance the performance of health workers

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			• Mobilize staff from the private sector, including military, academia and faith-based organisation to mitigate staff shortages • Call back retired or non-assigned personnel that are listed on national professional registries
V	**Monitoring and Evaluation**		
1	M&E systems and Data Management	• Validate national indicators for VL cascade • Review of monitoring tools and integration into HMIS • Data management quality assurance (DQA)	• Develop/review defined indicators for VL cascade • Establish indicators for monitoring process at national and facility level. Indicators at facility level may include disaggregated indicators. E.g. Turn Around Time (TAT) – (specimen collection to delivery to the lab, from lab to result delivery/release, result delivery to referring sites…), specimen rejection rate, number of clients seen, etc. • Reviews of national M&E tools to integrate VL indicators in the HMIS • Regular DQA at national and facility level to improve documentation and data validation • Provide mentorship and supportive supervision on DQA • Ensure registers and tools are distributed to each facility, and uniform system is used for the national aggregate data collection
2	Comprehensive assessment and regular review of VL scale up	• Comprehensive assessment of the VL cascade • Monthly/quarterly review of data • Identify and prioritize gaps for improvement • Use evidence-based information and initiate implementation of QI	• Routine monitoring of VL scale up at national and district level using assessment tools (e.g. LabCoP assessment score card) to evaluate performance • Review and analyze assessments to identify gaps • Review data in the country about the lab and use evidence-based decision for improvement • Prioritize gaps and provide evidence for initiating QI project implementation • Monitor progress of QI projects and disseminate best practices supported by data • Assess impact on capacity building and sustainability
3	Electronic database and dashboard development	• Provincial/district Lab Information System (LIS) data repositories • Development of dashboards • Real-time analysis of specimen-level data for detailed monitoring • Leverage on SMS-based system of return of results	• Conduct situational assessment and establish LIS data repositories • Engage key people in the process and train staff on LIS and its significance for effective system data management system • Analyzed aggregate data from each repository and utilize for decision making • Dashboards that facilitates drilling to view data from the national level down to each laboratory • Manage to extract detailed LIS data for gaps identified with dashboard for root cause analysis.

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			• Regular review and update of electronic data base, and utilization of dashboard for data visualization
VI	**Quality Management System Implementation**		
1	Policy and Governance	• Inclusion of QMS and Accreditation as an objective in the National Medical Laboratory Policy and National Laboratory Strategic Plans.--> Advance the ASLM national laboratory quality framework endorsed by Africa CDC,. • Organize national structures to support laboratory quality system • Adapt and implement ISO 15189, ISO 17043 or ISO/IEC 17025 as applicable based on the intent of the laboratories. • Implement a national licensing system of public and private laboratories , based on quality requirements	• Use the results of the LABNET scorecard assessment to inform the development of a national quality strategy • Develop national laboratory quality policy, guidance or strategy. • Determine the tier of laboratories that will be supported through the QMS and accreditation process and any quality requirement as defined by national norms. • Develop technical and managerial documents appropriate for the tier and scope of laboratories within the network. → the GBEA or the manual for users of laboratory network • Establish or strengthen a directorate, department or section responsible for QMS programs. • Identify external or establish a national accrediting body • Establish and independent quality to unit to coordinate the implementation (i.e, development of various documents and systems, including the laboratory quality manual, quality policies, various standard operating procedure manuals, staff competency assessment guidelines, complaint/incidence reporting systems, quality indicator systems, internal QA auditing systems, and documents and records control systems). • Maintain a national database/dashboard of QMS advancement in the national laboratory network
2	Implementation of QMS at facility level	• Implement QMS towards ISO accreditation in selected reference, HIV or TB laboratories as an entry point to the broader national quality programme • Develop in country workforce in support of QMS implementation at facility level. • Facilitate QMS procedures at the laboratory clinic-interface	• Engage laboratory management in awareness meetings to make sure they understand the processes and ensure availability of resources required to enable QMS implementation process. • Conduct structured routine QMS assessment through ASLM or ASLM trained SLIPTA auditors to undertake gap analysis, develop improvement plan and monitor QMS progress • Roll out LQMS and other available QMS training package (e.g ASLM training pacakges for staff, auditors and mentors) in various categories of laboratory staff • Establish General templates for key QMS Documents. • Identify a laboratory mentor and an advisor to guide laboratory management during the development of laboratory policies and procedure documents • Engage staff in policies and procedure training and ensure consistent implementation among laboratory staff • Update Clinicians on the elements of a laboratory quality management system & their role in assisting with the establishment, implementation and maintenance of the QMS • Establish Mechanism for ongoing joint decision-making among clinicians and laboratory staff.

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3	Coordinated mentorship and general supervision of laboratories	• Ensure adequate mentorship (mentorship programme?) to move selected laboratories towards accreditation • Establish a national programme ensuring the supervision of lower tiers by higher tiers.	• Develop a national QMS mentorship strategy and guide for all tiers • Develop a pool of local mentors that can be mobilized by MoH • Establish a national dashboard monitoring QMS implementation and mentoring activities in the network
4	Quality Assurance of laboratory tests	• Validation and/or verification of qualitative and quantitative tests • Implement internal quality control everywhere • Ensure participation to external quality assessments programmers as per national quality standards • implement QA fit for various test modalities (such as POC, RDT)	• Define minimum standards for introduction of new tests at national level • Procure and perform internal quality controls as documented in the established internal quality control procedure. • Train laboratory staff on interpretation of IQC results including LJ-charts and Westgard rules. • Participation in inter-laboratory comparison including enrolling facilities into external quality assessment (EQA) schemes and process EQA samples within the deadline, and review results from EQA providers to identify opportunities for improvement. Document any deficient EQA result as a nonconforming event, and perform a root cause analysis and implementation an identified corrective action • Implement national or enroll in regional EQA programmes • Conduct cost analysis for the feasibility of national EQA programmes • Deploy SPI RT tool (e.g for HIV or for COVID-19) and RT-CQI packages to ensure quality assured test at the point of care.
VII	**Access to essential diagnostics (across diseases)**		
1	Integrated specimen referral	• Evidence based design/expansion of the specimen referral • Skilled Workforce for specimen referral • Operationalization of the specimen referral	• Conduct a situation analysis of the specimen referral network in the laboratory network • Harmonize sample transportation systems across the nation and regions/ programs using evidence • Develop national guidance documents (policies and strategies) for the harmonization, integration (multidisease and clinic/surveillance)of specimen transport system). E.g Expand on Africa CDC guideline for the transportation of CO Biosafety procedure and labeling for the handling of specimens COVID-19 specimen) • Develop SOPs with clear roles and responsibilities at each step of the process for packaging, transportation, and reception of specimens including community healthcare workers, drivers and others involved. Use an already working system and expand to other diseases or programme. • Provide training and regular refresher to individuals at a different level based on their scope of work

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			• SOPs and job aids for packaging of specimens, biosafety procedure and labeling for the handling of specimens/ specimen container. IATA training packages. Ensure the tracking and monitoring of staff trained (ASLM Academy) • Development and introduction of requisition forms and transport logs for documentation
2	Availability of essential diagnostics	• Develop enabling policies in support of UHC • Promote strategies for point of care testing	• Develop national essential diagnostic lists (NEDL) and sufficient accompanying operational guidance (Global Fund priority for NMF4!) • Conduct DNO exercise in support of improving access to essential diagnostic (including use cases for HIV, TB and other individual diseases) • Conduct a national prioritization of diseases for routine clinical care and for epidemic response (Africa CDC has a list of priority disease for outbreak response) • Develop national strategies for the scale up of relevant RDTs, POC and self-test • Develop national KPI to monitor the implementation of essential diagnostic. Use GIS system already in place whenever possible
3	Advance integration of diagnostic services	• Assess integration readiness of the whole laboratory system • Implement integrated laboratory systems	• Assess national readiness for integrated diagnostic service (ASLM integration readiness tool) • Develop and implement LIS allowing return of results for multiple tests • Adapt national laboratory strategy and other testing guidance to factor in test integration • Develop generic SOP in support of selected test integration use case (e.g HIV and TB; HIV and HPV; Flu and COVID-19).
4	Improve access to tuberculosis diagnostic	• Uptake of diagnostic innovation • Develop enabling policies for the availability of useful innovation	• Introduce new technology such as TrueNAAT • Explore the benefit of TB and HIV test integration on the existing fleet of molecular instruments • Ensure that National EDL or harmonization document include all recommended test for Tuberculosis at the relevant tier • Conduct TB network assessment using the LABNET scorecard TB tool and develop evidence based improvement plans • Continuously monitor achievement of national testing norms in the network using systems such as the ASLM/Africa CDC LabMap.

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5	Implement or consolidate task shifting for essential diagnostic	• Improve task shifting in support of access to essential diagnostics	• Develop national guidance to organize and coordinate POC testing in communities from the laboratory governance • Mechanisms for the continuous professional development and supervision of community health workers conducting the test • Develop a cadre of laboratory workforce to supervise and support community testing

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