



Technical Brief

Strategic Support for Integrated Laboratory Services

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PURPOSE: This briefing note aims to clarify the Global Fund's approach to laboratory systems investments by outlining:

1. The general principles, which underpin Global Fund's investments;
2. The different types of investments that may be supported; and
3. How the support offered by the Global Fund may vary according to the country context

The purpose of this note is to guide countries preparing funding applications to the Global Fund. It should be used as a basis for discussion and negotiation with stakeholders when developing funding applications. The disease specific and health systems strengthening information notes should also be reviewed in parallel with this document.

I. Background and rationale

01 Background

Efficient and reliable health laboratory services are an essential component of any resilient health system and are central to achieve the core mission of the Global Fund. Laboratory diagnostic capacity is critical towards reaching the global targets for Human Immuno-deficiency Virus (HIV), Tuberculosis (TB) and Malaria control. [1] Accurate and reliable diagnostic tests are critical for effective treatment. The UNAIDS targets of ensuring that 90% of people know their HIV status, 90% of those tested positive are receiving treatment and 90% of those on treatment are virally suppressed (90-90-90) by 2020 rely heavily on adequate laboratory services. [2] Similarly, the laboratory will play a critical role in achieving the Global Plan to Stop TB's targets of reaching 90% of all people who need TB treatment, and achieving at least 90% treatment success. The Global Technical Strategy for Malaria 2016-2030 [3] aims to accelerate progress toward malaria elimination based on three pillars: ensuring universal access to malaria prevention, diagnosis and treatment; accelerating efforts toward elimination and attainment of malaria-free status; and transforming malaria surveillance into a core intervention. This strategy, too, relies heavily on strong laboratory diagnostic capacity and systems to support diagnosis, surveillance and detection of drug resistance.

Disease surveillance, diagnosis, prevention, treatment and health promotion all require sound and reliable laboratory services, and, under the revised International Health Regulations (IHR), countries are required to develop the capacity to detect, investigate and report to WHO, potential public health emergencies of international concern, such as disease outbreaks. [4] The availability of laboratory services capable of producing reliable results in a timely manner is the cornerstone of any country's capacity to detect such outbreaks. [5]

02 Rationale for Global Fund's Investments in Laboratory Systems

The need to improve in-country laboratory services and systems to support service delivery is aligned to the Global Fund 2017-2022 strategy "Investing to End Epidemics." [6] The core objectives of the strategy are to:

- a) Maximize impact against HIV, TB and malaria
- b) Build Resilient and Sustainable Systems for Health
- c) Promote and Protect Human Rights and Gender Equality
- d) Mobilize Increased Resources

There have been major improvements in strengthening laboratory systems over the past decade with improved infrastructure, quality management systems, information systems, service delivery and the laboratory workforce. [7], [8], [9] However, more efforts need to be made to ensure the delivery of quality laboratory services in many Global Fund supported countries as laboratory systems face increasing pressure to meet the demand for the unprecedented scale-up of HIV, malaria and TB prevention, treatment and care interventions. There is growing acknowledgement of the need to invest in the laboratory area in a more strategic manner. [10]

Challenges are multiple and include: dilapidated infrastructures; lack of funding for developing and implementing national policies; inadequate strategic planning, quality management systems; unlinked referral and reporting services; inadequate human resources, including lack of organized in-service training and long-term career pathways; weak supply chain systems; equipment maintenance; weak specimen referral networks; weak laboratory information systems (LIS); weak links to care; and weak data management systems with linkage to program data. [11], [12], [13], [14]

Low access, both financial and physical, to laboratory services is another neglected but important challenge. Data on access to health laboratory services is scarce and limited to a few vertical programs. What data exists is not captured in an integrated fashion as laboratory services are disjointed and not appropriately aggregated. Furthermore, existing data shows that at peripheral level, for example, basic laboratory testing (CBC, smear microscopy for both for TB and malaria, RDTs, gram staining, basic clinical chemistry testing etc.) is not accessible to the majority of the populations. This is due to many reasons including lack of minimum essential

reagents and laboratory supplies, infrastructure, personnel and poor laboratory quality services in the public sector in general.

Laboratory services need to be fully integrated as a core component of health systems. Yet, few countries have clearly defined the role of laboratory services at each level of the health care pyramid. Most countries are not aware of what laboratory services are being offered to the population in terms of types of tests and their quality. As a consequence, national planning for laboratory personnel and support services is weak. The lack of a sector-wide approach, including laboratory services health services as a whole, is an important challenge to be addressed. In fact, laboratory priorities should be established jointly with other public health priorities at all the levels of the health system.

In many countries, the administrative structures of Ministries of Health only consider laboratories along with pharmacies, radiology and clinical services. Often, more attention is given to essential medicines rather than laboratory services. The challenge is how to advocate for representation of laboratory services at the highest decision-making level. The establishment of strong national laboratory leadership is necessary to ensure that the laboratory agenda is seen as a critical component of national health systems. The creation of a high-level, decentralized and coordinated structure led by the national laboratory directorate is the key to enabling national health laboratory services to play a significant role in disease control and prevention. A strong national laboratory directorate is essential to provide leadership and coordination and integration and efficiency of services.

This complex web of constraints has resulted in continued reliance on empirical patient care, often leading to misdiagnosis and inappropriate treatment – and, therefore, increasing the risk of poor patient outcomes, drug resistance and waste of already scarce resources. [15]

II. Guiding Principles for Investing in Health Laboratory Systems

03 Integration of Laboratory Services and Systems

While international funding has increased for disease-specific programming, many of these programs are often organized as silos. Although vertical approaches have improved disease-specific responses, in some cases they have also resulted in the fragmentation of laboratory services and duplication of efforts. In addition, they have often left very important gaps in the capacity of individual countries to perform crucial clinical and disease surveillance functions in a coordinated manner. Therefore, it is imperative to change the thinking around laboratory investments and move towards securing the establishment of integrated national laboratory services and systems. An integrated approach allows both programs and clinicians to use more comprehensive information that can lead to more informed clinical decision-making and more effective patient care.

Integrating diagnostic services for different diseases within the same facility avoids duplication of investments in infrastructure/space, equipment and laboratory supporting systems, such as specimen transport results delivery, supply chain management and information systems. [16] An integrated approach can also help ensure standardization of core laboratory systems, such as quality assurance and standard operating procedures, as well as ensure the more efficient delivery of training. Integrated laboratory services optimize quality, efficiency and cost-effectiveness for all its core functions. [17]

04 Country Ownership

Country ownership is a fundamental principle of the Global Fund model, in conjunction with performance-based financing and partnerships. Laboratory system improvements should be built on a common vision, which has been articulated in a costed national strategic plan with investments of partners and aligned to an implementation plan that has clearly defined milestones and objectives. Coupled with strong leadership, this ensures that the laboratory agenda is included in the national health sector strategy. [18]

Excessive dependence on donor and partner funding may create inadequate country-level ownership and will eventually lead to a lack of sustainable laboratory services for both routine clinical work and epidemic

response. Lack of ownership and leadership in some countries limits opportunities for resource mobilization and financing. Global Fund contributions should be complementary to domestic and other donors' investments and should be framed within a national strategic vision.

05 Partnership

There is a proverb “If you want to go fast, go alone; but if you want to go far, walk together.” It is recognized that partnerships are essential to achieve the common goal of strengthening laboratory systems and services. It is evident that no single entity can possibly work in isolation in laboratory system strengthening. This service delivery area is a cross cutting intervention, requiring coordinated and harmonized activities.

Strengthening of national laboratory services and systems depends on partnerships beyond the laboratory facility itself with technical and clinical professionals, healthcare managers at the community, regional and national levels, and public health programs. A strong laboratory-clinical interface should also be established to ensure that testing algorithms are appropriate and are based on sound evidence to inform clinical decision-making. Health systems vary from being primarily financed and delivered by the government, to being predominantly financed and delivered by the private sector. The laboratory, as part of the health system, is no different. Private and non-government laboratories play a significant role in the delivery of services and are part of the network of national laboratories. Thus, private labs are key partners in building national capacity, as well as through models that can increase access to diagnostic services and patient care. Countries are encouraged to think about ways to build and strengthen partnerships with private sector providers. The laboratory strategic plan should define the general relationship between public health and clinical laboratories (including government, private and research laboratories, where feasible), define the relationship between the different levels in a tiered manner of all systems, and determine who is responsible at each level and to whom they are responsible in the overall health system.

III. Scope of Global Fund Investments in Laboratory System Strengthening

The Global Fund, as a major financial partner, invests in building resilient laboratory systems to support service delivery. These investments have the potential of improving countries' health outcomes much beyond the three priority diseases (i.e., HIV, TB and malaria). In requesting laboratory development and system strengthening funds, countries must demonstrate how the Global Fund's investment fit within the national integrated laboratory policy and strategic plan, as well as the longer-term development of the health system. [18]

Specifically, investments should help reach the following objectives:

- Strengthen the performance of laboratory services and system components that are relevant for effective control and prevention of HIV, TB and malaria;
- Strengthen linkages between laboratory services and clinical care across all diseases;
- Foster synergies among laboratory components of three diseases, as well as between them and other health programs, by promoting integrated approaches of laboratory science and laboratory service delivery;
- Build the capacity of laboratory systems to scale-up integrated service delivery models and improve quality, equity, efficiency, effectiveness and sustainability of the laboratory services, particularly in hard-to-reach areas and those targeting key affected and underserved populations;
- Improve the managerial capacity across the laboratory network and systems through support to any of its key elements: procurement and supply chain management, integrated laboratory information systems, monitoring and evaluation systems, human resources training and supervision, quality management systems, biosafety/biosecurity and financial management;

- Support the selection of equipment (e.g., conventional versus Point of Care (POC) technology or others) using access and cost-effectiveness analyses, and context-appropriate contractual arrangements with providers;
- Utilize existing laboratory equipment more efficiently;
- Improve monitoring and evaluation frameworks for laboratory systems and services;
- Support community and civil society use of laboratory services, including community health workers, as well as the private sector, to enhance their engagement in the system and in HIV/AIDS, TB and malaria programs; and
- Improve coordinating mechanisms such as technical working groups. Although countries are usually the major investors in their own laboratory systems, other partners also may contribute. Therefore, it is essential that investments align with the national vision and are well coordinated with national and other partners' resources.

06 Types of laboratory systems investments that Global Fund may support

1. *Human resources for laboratory systems (including education and postgraduate education)*

In many countries the human resources crisis within the laboratory system is acute with an inadequate number of staff and inadequate skill sets. Many countries have limited laboratory education programs, with only basic training for technicians producing graduates with limited skill sets who are unable to operate modern sophisticated technologies. This has the effect of limiting the technology that they can use. Retention in the public sector is also a challenge as well trained laboratory specialists leave the country or migrate to better-paid positions in the private sector or research institute in the same country.

Activities that may be supported by the Global Fund include those that are aimed at improving the equitable distribution and retention of a skilled laboratory workforce, especially in hard-to-reach areas and those serving marginalized populations. This includes:

- Support for recruitment and retention strategies for laboratory career and leadership development provided there are clear career pathways with incentives and the potential for advancement for laboratory professionals (i.e., development of such laboratory leaders will not be successful if there are no health ministry positions for the leaders to assume);
- Laboratory educational interventions that promote the enrollment of students with various (especially rural) backgrounds and support the expansion of the laboratory education infrastructure, including special laboratory internships in training programs;
- Regulatory interventions such as enabling the implementation of task-shifting, introducing laboratory professional cadres with specific professional profiles and strategies to increase retention;
- Financial interventions that provide financial and non-financial incentives for retraining laboratory specialists at the various levels;
- Personal and professional support for safe and supportive working environment, outreach support, career development programs, professional networks and public recognition measures;
- Support for curriculum revision and implementation to align the required skills with testing needs and technologies;
- Support to national regulatory councils/authorities, including capacity-building of regulatory bodies and professional associations.

2. *Efficient and quality laboratory service delivery*

The demand for laboratory services to meet the diagnostic and treatment needs for HIV and TB, in particular, has helped drive investments in new and renovated infrastructure and technologies. This expansion and investment in laboratory capacity should be harnessed and optimized to serve the needs of other diseases of public health importance for both clinical diagnosis and disease surveillance. For example, an integrated

laboratory tiered network should be capable to provide all primary diagnostic services and referral of specimens without requiring patients to go to different laboratories for specific tests. The network should focus on providing quality-assured basic laboratory testing, as well as common specimen transport systems and diagnostic platforms that can be used across diseases (i.e. polyvalent platforms) within the same facility.

Polyvalent molecular platforms and other testing technologies can be used to rapidly detect a wide range of viral and bacterial pathogens. Their strategic placement requires careful planning of the anticipated numbers of different types of samples based on the testing of different patient populations, in order to match available machine throughput. For example, an instrument with capacity for TB detection as well as early infant detection of HIV should have adequate daily capacity to test all of the sputum specimens received from patients suspected of having TB at that site and in the referral network, as well as test all of the blood specimens received from newborn infants at risk of HIV.

Overall, there is a growing demand within the global health community for improved access to robust, quality-assured diagnostics in resource-limited settings. Manufacturers have slowly engaged, resulting in the emergence of a range of new technologies, as well as a dynamic pipeline. [19],[20], [21], [19] These include easy-to-manipulate point-of-care (POC) technologies and polyvalent platforms, suitable to respond to the needs of different levels of care. Along with improvements in sample transport and device and data connectivity networks, [22] advances in POC testing are likely to bring about significant changes in access to quality health care in resource-limited settings. Determining the optimal mix of centralized, high-volume diagnostics and POC diagnostics based on each country's unique needs is a challenge, as is assuring the quality. [23] As POC platforms are considered, there is the need for improved coordination and appropriate planning involving all stakeholders and ministries of health to ensure that the introduction does not disrupt the functioning of existing standard testing platforms. In light of this, there is the need for an in-country platform or instrument to determine needs and to ascertain where POC can be placed to add value to the national program. In particular, POC should not be seen as replacements for standard platforms. They are complimentary and should be placed only where absolutely needed and supported with data on gaps in service delivery. While preparing funding requests, challenges associated with POC rollout and sustainability should be considered.

Community laboratory systems capacity also plays an important role in facilitating disease detection, as well as the conventional laboratory service. A combination improved sample transport and simple rapid testing can provide greater access to quality testing in decentralized settings.

The Global Fund supports cross-cutting laboratory system investments conducive to maximizing impact against the three priority diseases, as well as coherent with the overall goal of building integrated and tiered national laboratory services including hematology, chemistry, bacteriology and parasitology laboratories. This includes but is not limited to:

- Supporting the establishment of an integrated laboratory capacity development within the context of tiered laboratory networks compatible with the Maputo Report. [24] This development should be integrated across diseases and centered around national laboratory strategic plans that are grounded by strong technical guidelines or standards feasible within a country and consistent with standards set by key international stakeholders, such as WHO.
- Ensuring all laboratory services are provided with, for example, essential reagents for bacteriology labs (e.g., antibiotic discs, reference strains for antibiotic sensitivity testing, anti-sera for serogrouping and serotyping of bacteria pathogens of public health importance, culture media etc).
- Implementing a quality management systems at service level [25], including participation in external quality assessment (EQA) schemes;
- Strengthening overall laboratory supportive supervision, service organization and management systems (e.g. logistics, waste management);
- Strengthening and integrating specimen transport networks and data networks;
- Developing systems for laboratory management at the point of care for improved patient retention and adherence to treatment;

- Building effective public–private partnerships for scaling up laboratory services, increasing coverage and improving quality of care;
- Implementing pilots for a phased approach towards the implementation of national tiered laboratory systems, including models involving the private sector and research institutions; and
- Introducing POC and polyvalent technologies.

3. *Improving laboratory infrastructure standards*

Appropriate building space and equipment are also essential to deliver safe and effective services. Laboratories must be fit for purpose. The infrastructure of a laboratory should ideally be designed in order to maintain appropriate biosafety standards and ensure quality delivery of results. [26], [27] The minimum number of rooms and their requirements according to function and equipment should be defined and there are particular requirements for molecular laboratories. [28] Global Fund investments may be used for interventions aimed at supporting the scale-up of laboratory services according to tiered level, whether facility-based or community-based. Such interventions may include, for example: upgrading infrastructure, including refurbishing facilities to comply with international recommendations; equipment; back-up power; furniture; and information communication technology (ICT), as well as connectivity for POC technologies.

4. *Procurement and supply chain management for laboratories*

Supply chain management is often the weak link in the laboratory systems. Between 15% and 45% of a laboratory’s budget is spent on supplies, including a complex combination of reagents, basic equipment and consumables, which are often test-specific. Therefore, careful stewardship of equipment and materials is crucial. Often delays in ordering the right supplies in the right quantities and/or in their delivery where they are needed results in interrupted testing. This negatively affects turnaround time of results and compounds the problem of work backlog. Conversely, over ordering supplies and wrong specifications lead to a waste of resources. Too large a variety of laboratory equipment and reagents in a country complicates procurement, development of specifications and the establishment of maintenance contracts. Recent efforts have, therefore, focused on the harmonization and standardization of the minimum package of supplies, tests, and equipment needed at each level of the tiered laboratory network, as well as ensuring alignment with the national policy. [24]

This approach requires strong leadership and coordination by the local ministries, along with partners and donors. It brings many benefits, such as reduced procurement costs for commodities, easier implementation of quality assurance programs and integration of multi-focused testing that uses shared equipment. In addition, it also allows for harmonized training, equipment maintenance, quality management systems and techniques across diseases. [29] A balance must be struck between standardizing equipment without creating overreliance on a single manufacturer or supplier. [30] Further information on strengthening procurement and supply chain management can be found in the *Information Note on Building Resilient and Sustainable Systems for Health*.

The Global Fund invests in the following activities:

- Support for the development of specifications for selection of equipment, reagents, consumables and accessories balancing cost effectiveness and access;
- Support for the standardization and harmonization of tests and technologies;
- Procurement planning including technical assistance on modalities for reagent rental or leasing, understanding of market dynamics for laboratory items and their impact on lead times needed for different laboratory supplies;
- Forecasting and quantification of needs; and
- Support for remote monitoring and data connectivity of equipment.

5. *Equipment management systems*

The availability and maintenance of laboratory equipment remains a challenge. Countries often do not have the minimum required equipment to provide quality diagnosis. Moreover, striking problems remain even when the equipment is available. A recent study that examined lab use for TB and HIV programs revealed major weaknesses in managing and utilizing existing lab equipment. Lack of reagents, purchased equipment not being installed or deployed, poor maintenance and no staff training on techniques and equipment were among the reported reasons for underutilization. The survey found a striking disconnect between capacity and utilization. It also showed that most machines were not covered by maintenance contracts nor were receiving the recommended service. [12], [13], [14]

Maintenance should be done on a preventive basis rather than a corrective basis, and any equipment procured should come with a maintenance contract. [31] Basic training is essential for laboratory technologists to operate laboratory equipment and perform preventive maintenance. In addition, countries should build internal capacity for preventative maintenance, and if possible secure reagent rental agreements that include service and maintenance for major equipment rather than outright purchases.

Connectivity through equipment-based testing devices are now widely available and such solutions should be harnessed to monitor consumption, quality and functionality of lab equipment.[22]

In light of these weaknesses, activities that may be supported by the Global Fund include the following:

- Support for equipment management systems including planning and negotiation of maintenance contracts, bundled maintenance agreements and reagent rental agreement;
- Training of biomedical engineers;
- Training of users of equipment;
- Support to calibration and maintenance contracts; and
- Connectivity solutions for laboratory equipment.

6. *Quality Management Systems (QMS) for all level of laboratories*

Quality assurance (QA) is the foundation of any laboratory management program. It aims to ensure that the results produced by the laboratory are truly representative and reliable. The QA process ensures greater consistency and trustworthiness of results. In developing countries, QA in laboratory medicine has been severely neglected and has become a serious impediment to effective healthcare delivery and disease surveillance. In fact, a vicious cycle has often been established whereby physicians in developing countries rely solely on history taking and physical examination for patient management, since they have little confidence in laboratory test results. There is now a greater recognition that quality is very important and many countries are currently making great strides in implementing quality management systems (QMS), which is leading to laboratory accreditation to international standards. [8], [9] [23], [32] Implementation of a QMS is one of the core indicators of the WHO Framework of Indicators and Targets for Laboratory Strengthening under the End TB Strategy. [33]

Over the past decade, quality performance-enablers have been developed to guide the implementation of a sustainable QMS leading to accreditation. These include: the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) [34], the WHO Laboratory Quality Stepwise Implementation tool (LQSI tool) [35], the Caribbean Laboratory Quality Management System – Stepwise Improvement Process (LQMS-SIP) towards Accreditation [36], and the Laboratory Quality System Handbook [37]. It is recommended that countries incorporate laboratory standards, comprehensive quality systems and goals for accreditation in their plans for laboratory development. Countries are encouraged to develop and implement accreditation programs, including country-specific standards and monitoring systems. [38] Mentorship should be incorporated into laboratory quality improvement and management training programs in order to accelerate the progress of laboratories towards achieving accreditation.

Although considerable resources are needed for quality improvement towards accreditation, these costs are much less than the costs of the adverse consequences of poor quality in terms of misdiagnosis, repeating tests unnecessarily, lost time and ultimately poorer health outcomes.

Activities that may be supported by the Global Fund include:

- Support for the establishment and implementation of national continuous quality programs including quality management systems towards accreditation;
- Support to national regulatory bodies, frameworks and minimum licensing requirements;
- Support to develop national standards;
- Support for improved access to laboratory services for all and especially the poorest at all levels of the health system; and
- Support for integrating laboratories into national health systems and services.

Figure 1 Case Study Implementing a Quality Management System towards Accreditation in the Caribbean

The World Health Organization has recommended that countries with limited resources consider taking a stepwise approach towards accreditation of laboratories to internationally recognized quality standards with recognition of achievements towards accreditation. [38], [39] This staged approach recommends developing a national laboratory standard as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189. It was agreed by CARICOM (Caribbean Community) to develop a stepwise process for implementing laboratory quality management systems. The Caribbean Community (CARICOM), a grouping of twenty countries including fifteen Member States and five Associate Members developed a framework to support countries in their efforts to strengthen national laboratory services through the stepwise quality improvement process towards fulfillment of the ISO 15189 requirements. The Laboratory Quality Management System–Stepwise Improvement Process (LQMS-SIP) Towards Accreditation is a comprehensive approach to strengthen medical and public health laboratory services and systems throughout CARICOM, and implemented by CROSQ. This was made possible through partnerships and collaboration between the Pan-Caribbean Partnership against HIV/AIDS (PANCAP) – a recipient of Global Fund support in the Caribbean Region – and other stakeholders including PEPFAR, PAHO, CARPHA and CROSQ. It is designed to recognize laboratories in the process of quality improvement assess their progress and recognize milestones towards meeting quality management system requirements of the ISO 15189 standard. This Stepwise Improvement Process provides for recognition of the implementation of Quality Management systems in CARICOM laboratories and acknowledges achievement of such in a three-tiered approach. The approach consists of a three tiered system with the first tier representing the minimum requirements, which should correspond to the mandatory ones required for the granting of a medical laboratory license based on legislation enacted by the Ministries of Health.

Figure 2 Case Study Implementation of Quality Management through partnership

The WHO/AFRO Stepwise Laboratory (Quality) Improvement towards Accreditation (SLIPTA) is an excellent example of partnerships and best practices in terms of laboratory accreditation process (see publication below). [40],[41]

7. Governance

Strong laboratory governance ensures that the laboratory is a central component of national health systems. However, in many cases, weak institutionalized laboratory leadership and poor coordination has resulted in duplication at all levels, and unsupervised district and peripheral laboratories with dubious quality of testing. With a number of different donors, implementers and technical partners involved across many programs, strong system coordination mechanisms need to be in place to ensure that efforts and funding align with national lab strategic plan. [18]

National laboratory systems must be capable of providing accurate and timely testing that is in line with each country's programmatic goals and available clinical interventions, as well as being able to conduct a disease surveillance role. A national laboratory policy should focus on the following: laboratory organization, structure and coordination; staff retention; quality management systems; integration of services; facilities; and biosafety

and biosecurity. Decisions to classify laboratory services in the tiered network and choice of technologies should be based on testing complexity, cost, throughput, specimen referral requirements, needs of the program and patient population being served.

Activities that may be supported with Global Fund grants include:

- Support to “Three One’s”— one (national) laboratory strategic plan, one coordination system, one evaluation plan – that will help countries manage and coordinate the efforts of multiple different partners who all contribute in some way to national laboratory systems; [42], [43]
- Laboratory governance support to establish national labs directorate for better coordination of laboratory services and development of comprehensive national laboratory polices and plans including support to operational management and technical assistance;
- Support for establishing a national laboratory network, including all the vertical programs with one coordination in the Ministry of Health, which will help in implementing the national laboratory strategic plan;
- Support for an inclusive coordination mechanisms and mapping of partners’ contributions;
- Support for legal, regulatory and policy reforms; and
- Support for the organization of and communication between the different tiers of the laboratory system.

8. *Laboratory Information Systems (LIS)*

The laboratory core business is to produce information for clinicians and for public health disease surveillance. With advances in information communication, technology (ICT) significant opportunities exist to harness the power of ICT as is widely done in the private sector. In addition, the use of mobile technologies for monitoring specimens and the return of lab results could be used to send results to the patients’ local clinics. Investments in laboratory information systems (LIS) must be interoperable with the electronic medical records (EMRs) and national health management information system (HMIS).

Measurement of progress and impact will be required throughout the process of strengthening laboratory services. This can be facilitated by selecting and defining a small set of indicators. Indicators should be objective and capable of measuring progress towards achieving the objectives in the laboratory services policy and strategic plan.

A well-functioning LIS ensures the production, analysis, dissemination and use of reliable and timely information. The use of healthcare system wide individual unique identifiers will improve the quality and coordination of service provision with individual longitudinal service records, as well as improve the effectiveness, efficiency, equity and acceptability of these services through ongoing monitoring and evaluation. Unique identifiers enable all data collected within a facility, including laboratory test results, to be attributed to a specific person. In addition, where persons receive services from a number of different facilities, relevant information can be more effectively and efficiently shared and linked across service sites to improve service coordination and strengthen monitoring and evaluation.

These national healthcare system wide unique individual identifiers can assist service providers to coordinate services and ensure that persons receive the full range of necessary services. Also, it can help strengthen fragmented health services in countries by linking data held within facilities and enabling the flow of information across the general health system and thereby enhancing the quality, comprehensiveness and continuity of specific services. Like all health information, the development and use of unique identifiers requires balancing the individual’s right to privacy and confidentiality with the need for individual-level information to optimize the provision of services to ensure their effectiveness, efficiency, equity and acceptability for both users and providers of those services. Therefore, development and use of these identifiers should be based on the principles confidentiality and security of health information.

Under the LIS component, the Global Fund supports the following interventions and activities:

Routine reporting

- Establishment, maintenance and strengthening of national LIS at all levels, including public-sector, private-sector and community-level reporting;

- Capacity building of M&E personnel on key laboratory indicators including support to data analysis and development of laboratory dashboards that are interoperable with national HMIS;
- Development of reporting forms and tools and data-quality assessment methods;
- Training of community health workers on relevant data gathering and reporting vital events;
- Training of staff at all levels to use data to make informed management and program decisions and monitor program progress;
- Introduction of widely used standardized LIS software that is open source and flexible; and
- Promoting use of technology and electronic systems (e.g. establishment of text messaging/SMS systems of reporting, diagnostic and decision-making algorithms and other innovative applications)

Information about laboratory system resources

- Establishment of systems for periodic reporting on key administrative and service availability statistics (e.g. lab workforce, inventory of lab care providers and relevant institutions);
- Establishment of laboratory financial reporting and accounting systems;
- Annual reviews of the laboratory budget and expenditures by funding source; and
- Laboratory expenditure studies

Registration systems

- Establishment, strengthening and scale-up of laboratory registration system; and
- Strengthened reporting of laboratory statistics, including disease identification, methodology and laboratory based surveillance data.

07 Programmatic Considerations for Laboratory System Support Funding Requests

Proposed laboratory system interventions should be linked to laboratory system gaps, which must be identified and prioritized at the funding request stage. Where possible, assessments should be part of a country's national HMIS, to avoid measuring additional indicators. It is also critically important that funding requests make clear how proposed improvements will be measured and how baselines will be established.

Investments may be assessed based upon evidence showing how specific weaknesses, gaps or bottlenecks in the targeted laboratory system components have been reduced as a result of the interventions, or based upon evidence that the performance of a specific component (or function) of the system has improved.

Figure 3: Case Study: Power of Partnerships and Strong Leadership in Implementing a Laboratory Information System in Kenya

Under the leadership of the Division of National Public Laboratories (NPHLS-MOH) in Kenya, the Global Fund collaborated with PEPFAR, the World Bank and a private-public partnership with Strathmore University (a local university) to support the rollout of a Laboratory Information Systems (LIS) in Kenya starting in 2010. The investment was aligned with Kenya's National Laboratory Strategic Plan as a high impact priority within the health sector plan. Its aim was to improve laboratories' operational efficiencies and information management processes to answer both clinical and disease surveillance needs, as well as strengthen laboratory testing and quality system to assure a holistic approach to results' integrity, reliability and patient safety in line with article 43(a) Kenya constitution 2010 which mandates access to quality healthcare for all persons living in Kenya. This investment in LIS helped to support evidence-based disease diagnosis, treatment and monitoring of communicable & non-communicable diseases as articulated in the Kenyan 2030 Road Map. To date, the Global Fund and other development partners have supported the ongoing installation of customized LIS in 22 sites already functional and 24 sites that are ongoing.

The Kenyan LIS implementation has been guided by the Association of Public Health Laboratories (APHL) model of LIS implementation in resource constrained settings, and the associated guidelines have helped the country in the planning and implementation of LIS. Laboratory selection was based on a mathematical model that factored in country priority diseases, county disease burden, population density and geographical representation for equity among other weighted programmatic indicators.

A LIS system is tailor-made to fit into both clinical and advanced laboratories requirements to efficiently manage workflow in the laboratory through integration with the hospital electronic medical record (EMR) systems, automatically receiving lab test requests from health providers and returning the results via a login ward or clinic window, emails and/or an embedded SMS notification to both patients and requesting providers. The system tracks the movement of specimens through pre-analytical, analytical and post-analytical processes providing respective turn-around-times for tests, as well as individual workload monitoring, test reporting and quality control. Programmed laboratory quality indicators that are selected by the respective laboratories are reported via LIS in line with requirements of ISO 15189 standard for medical laboratory quality and competency. This has seen the successful deployment of county referral laboratories and automated laboratory equipment (e.g., ELISA assays, haematology, chemistry, molecular and CD4 analyzers, etc.). Consequently, turn-around times have been reduced and patients' confidence in lab services has been boosted. LIS has also been expanded to manage inventories, blood transfusion services and bio-banking. Lab managers use data from LIS for real time quantification for supply planning and budgeting for reagents and consumables. LIS is evolving to be a critical tool in projecting and rationalising laboratory workforce based on workload data.

EQA and IQC tools have been also been embedded into the system so that labs are able to keep track of tests' reliability and take corrective actions. An API (Applications Program Interface) is being developed to transmit data to the national level HMIS (health management information system) through the DHIS platform. The Kenyan MOH is establishing a central data warehouse to which all the site reports will be fed, including logistics and service delivery data. The increased surveillance of emerging diseases will elicit efficient responses during outbreaks. The new frontier in LIS is integrated biometric systems for patient identification and longitudinal cohort monitoring to support ART monitoring, track referrals and link patients to care and treatment. Having a cohort of patient data will provide the MOH with information to inform policy formulation, review and implementation in a proactive approach. To date, the availability of in-country capacity to improve the system capabilities has ensured the existence of local knowledge for ownership and sustainability. The collaboration with key partners has been a power ingredient in the success of this collaboration.

08 Differentiated approach to laboratory system investments

In-country systemic challenges pose critical barriers to achieving national and Global Fund objectives. Maximizing the impact of investments in laboratory systems, as a pillar of resilient and sustainable systems for health, requires taking into consideration the country context. As countries have different laboratory system maturity levels, the type of interventions and investments will vary depending on the situation.

In all cases, a strategy and a gap analysis will support the investment cases in laboratory systems taking into account the country situation, the level of grant funds available, a country's vision to develop/update a laboratory strategy, synergies with partners at the global and country level to prioritize laboratory system strengthening and the Global Fund's vision to invest in sustainable solutions.

As part of the operationalization of the *Policy on Challenging Operating Environments* [46], maintaining or developing essential service delivery which includes diagnostic capacity will guide the laboratory systems investment such as strengthening the sampling transport system to facilitate access to diagnostic services. In acute emergency context and where risks are deemed high, service delivery might be temporarily delegated to service provider that are equipped for such activities. In more stable countries, developing or reviewing an integrated laboratory system strategy might be a critical investment for the future. In transitioning countries, the gap analysis with sustainability analysis should guide Global Fund investment in lab systems.

09 Conclusion

This technical brief should be read in conjunction with further guidance provided by the Global Fund and its partners. Access to more detailed information is provided via references and links to key documents. General

guidance on how to develop a funding request for the Global Fund is provided in the updated Global Fund's Applicant Handbook.

Investments in laboratory systems are critical to the successful delivery of HIV, TB and malaria programs, as well as other public health programs. Strengthening laboratory in countries requires many programmatic and operational activities under solid national leadership, such as advocating for and fostering government support and investments for laboratory strengthening, advocating for the inclusion of the laboratory in national health policies and strategies, coordinating the different partners involved in laboratory systems, resource mobilization, technical assistance and capacity building of laboratory workforces. Countries are encouraged to ensure that their requests for laboratory system support are strategic and aligned with national policy. Applicants should make full use of the information in this briefing note and other relevant Global Fund documents to ensure that investments in laboratory systems contribute to the building of resilient and sustainable systems for health.

IV. References

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