

Strengthening Laboratory Systems in Resource-Limited Settings

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Abstract

Considerable resources have been invested in recent years to improve laboratory systems in resource-limited settings. We reviewed published reports, interviewed major donor organizations, and conducted case studies of laboratory systems in 3 countries to assess how countries and donors have worked together to improve laboratory services. While infrastructure and the provision of services have seen improvement, important opportunities remain for further advancement. Implementation of national laboratory plans is inconsistent, human resources are limited, and quality laboratory services rarely extend to lower tier laboratories (eg, health clinics, district hospitals). Coordination within, between, and among governments and donor organizations is also frequently problematic. Laboratory standardization and quality control are improving but remain challenging, making accreditation a difficult goal. Host country governments and their external funding partners should coordinate their efforts effectively around a host country's own national laboratory plan to advance sustainable capacity development throughout a country's laboratory system.

Public health laboratories are a critical component of global communicable disease detection, prevention, and control. However, access to reliable laboratory testing remains limited in many resource-limited countries.^{1,2} This can result in delayed diagnosis, misdiagnosis, and ineffective and inappropriate treatment and can eventually lead to increased morbidity and mortality.

Many factors have been cited as contributing to limited laboratory access. Petti and colleagues³ identified numerous major challenges, including lack of laboratory supplies, lack of essential equipment, limited numbers of skilled personnel, lack of educators and training programs, inadequate logistical support, deemphasis of laboratory testing, insufficient monitoring of test quality, decentralization of laboratory facilities, and lack of government standards for laboratory testing.³

In part owing to efforts to improve diagnosis and treatment for people with HIV, enhancing access to diagnostic services by expanding laboratory capacity in developing countries has recently been the focus of many governments and their external partners. In 2008, an international conference convened by the World Health Organization (WHO) in Maputo, Mozambique, focused on laboratory challenges.^{4,5} This conference focused on diagnostic tests that should be available at each level in a tiered system, standardization of laboratory equipment and supplies, and key considerations to guide equipment maintenance and service contracts.⁶⁻⁸ It also identified laboratory strategic plans, human capacity, infrastructure, and management of quality systems as essential to laboratory capacity.^{9,10} Similarly, the WHO Regional Committee for Africa reported on critical needs for public health laboratories in Africa.¹¹

Efforts to improve laboratory capacity in resource-limited settings, including the focus of programming and coordination

among donors, have not been systematically examined or reported. We conducted a study focusing on 3 areas of laboratory strengthening—laboratory systems, including infrastructure, strategic plans, and personnel; coordination of laboratory efforts; and the adoption of quality systems, including laboratory standards and accreditation—to better understand how laboratory capacity is being developed in resource-limited settings and to identify opportunities for further improvement.

Methods

This qualitative study included 3 main data sources: published and “gray” literature on laboratory capacity in resource-limited settings (eg, reports from international conferences, the WHO and other organizations, national laboratory strategic plans, and national quality assurance documents), interviews with major donors involved in laboratory capacity development, and site visits to 3 countries in various stages of laboratory development.

We conducted telephone interviews with personnel at the headquarters level of 19 agencies and organizations, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), US Government agencies, organizations implementing the US President’s Emergency Plan for AIDS Relief (PEPFAR), multilateral organizations, nongovernmental organizations, and foundations (Table 1). Each interview involved 2 researchers and used a semistructured interview protocol.

Table 1
Donor and Technical Organizations Interviewed

Foundations
Bill and Melinda Gates Foundation
William J. Clinton Foundation
Institut Pasteur
Merieux Foundation
Wallace Coulter Foundation
International Public-Private Partnerships and Nongovernmental Organizations
Global Fund to Fight AIDS, TB, and Malaria
STOP TB Partnership
Global Health and Security Initiative of the Nuclear Threat Initiative
Multilateral and Other International Organizations
WHO Global Laboratory Initiative
World Bank
African Development Bank
PEPFAR Partners
American Society for Clinical Pathology
American Society for Microbiology
Association of Public Health Laboratories
Clinical and Laboratory Standards Institute
US Government
US Agency for International Development
State Department—PEPFAR
Department of Defense
National Institutes of Health

PEPFAR, US President’s Emergency Plan for AIDS Relief.

We also conducted case studies of laboratory systems in 3 countries. We selected Ethiopia, Kenya, and Thailand based on a detailed list of criteria, including the involvement of multiple donor organizations in-country, stage of laboratory development (to ensure that the case studies represented different stages), and noted successes in laboratory development. We reviewed written reports and documents specific to these countries. During our site visits, we visited 15 laboratories and conducted semistructured interviews with more than 60 people from the host governments and external partner organizations, including US government officials, PEPFAR implementing partners, foundations, and other organizations

Table 2.

The protocols for interviews with donor organizations and in the 3 countries included questions on the following: structure of the health ministries; laboratory systems, including infrastructure, strategic plans, and personnel; the mission of the organization (donor or partner); funding priorities, policies, and procedures; coordination with other funding agencies and host country(s); integration of laboratory services; support for international standards and accreditation; adoption of quality systems; and evaluation of the organizations’ programmatic efforts. We analyzed published reports and

Table 2
Donor and Technical Organizations Interviewed in Case Study Countries

Bilateral and Multilateral Organizations
World Health Organization
African Development Bank
Japanese International Cooperation Agency
Danish International Development Agency
Country Government Personnel
Ministry of health state minister (operations)
National laboratory directors
Regional, provincial, and district hospital laboratory directors
Health center laboratory technicians
Laboratory quality assurance directors
Health information management systems director
Medical technologist training director
Global Fund administrator
Foundations
William J. Clinton Foundation
African Medical and Research Foundation
PEPFAR and Global Fund Implementing Partners
Supply Chain Management Systems
Medical Supplies Agency
John Snow International
US Government
CDC Country Director
CDC DHAP, GDD, IEIP laboratory and program directors and staff
CDC GAP program/laboratory director and staff
President’s malaria initiative team leader
Department of Defense laboratory personnel
Other Organizations and Laboratories
Private laboratories director and staff

CDC, Centers for Disease Control and Prevention; DHAP, Division of HIV/AIDS Prevention; GAP, Global AIDS Program; GDD, Global Disease Detection; IEIP, International Emerging Infections Program; PEPFAR, US President’s Emergency Plan for AIDS Relief.

our interviews to identify themes and gaps and opportunities around our 3 key areas of interest.

Results

Laboratory Systems

The countries we visited are all developing laboratory systems in a tiered manner as recommended by the Maputo Conference.^{4,5} While all 3 countries have improved their laboratory systems in recent years, laboratory quality and capacity drop more rapidly than would be expected from the higher tier laboratories (eg, national and reference laboratories) to the lower tier, peripheral laboratories (eg, district hospitals and health centers). In addition to a lack of equipment and supplies at some peripheral laboratories, some differences between laboratories are due to staffing issues, complicated bureaucracies, and inadequate leadership.

Many laboratories are poorly staffed. Skilled laboratory professionals can be drawn away from lower paying government jobs to often higher paying nongovernment jobs, a form of in-country “brain drain.” In part, this is due to a lack of a defined career path for higher skilled laboratory professionals

in many health ministries, who are then attracted to nongovernment jobs with potentially more responsibility. In addition, getting approval for and hiring laboratory personnel is often cumbersome, especially in lower tier laboratories.

In addition to hiring delays, in-country bureaucratic issues were noted to cause a variety of complications and challenges in the countries we visited. In some cases, responsibilities for laboratories are fragmented across multiple health ministry agencies, leading to a lack of coordination and poor oversight. This was occasionally augmented by the process of decentralization, which, although in theory allows for local control, seemed to result in a loss of economies of scale for equipment purchases and made standardization of equipment more difficult.

Finally, laboratory system strategic plans from Kenya¹² and Ethiopia¹³ were consistent with most elements in guidance documents^{5,14-17} with regard to human capital and training, physical infrastructure, management of quality systems, standards/accreditation, and evaluation (Table 3).^{5,14-17} They were also developed with feedback from many stakeholders. However, some people we interviewed questioned whether the laboratory plans are actually being used as guidance documents. It is also not clear if there is

Table 3
Comparison of Guidance Documents With National Laboratory Strategic Plans From Kenya and Ethiopia

Category/Strategic Plan Guidance	Kenya	Ethiopia
Human capital		
Competent staff who are adequately trained and effective managerial staff ^{5,16}	✓	✓
Placement of skilled laboratory scientists/managers with sufficient authority in leadership positions in the ministries of health ^{15,16}	✓	
Staff performance monitoring system and transparent salary scales for the different levels ¹⁶	✓	✓
Creation of relevant career paths for all levels/types of staff ¹⁶		✓
Infrastructure		
Unified approach to procurement and distribution of laboratory commodities ^{14,16}	✓	✓
Laboratory environment with enough space to perform day-to-day operations safely and efficiently and to store supplies (including cold chain supplies) ⁵	✓	
Adequate laboratory facilities and infrastructure with common equipment that is properly maintained ^{5,14-16}	✓	✓
Management of quality systems		
Written quality control policies and procedures ^{5,16}		
A quality control system to test methods, equipment performance, measures, and procurement process according to established standards ^{5,14-16}	✓	✓
External quality assessments ^{5,15}	✓	✓
Process for monitoring laboratory performance and quality improvement ^{5,15}	✓	
Training		
Standardized laboratory best practices and related training ^{14,16}		✓
Standard operating procedures that are understood and implemented to ensure overall test reliability, which includes test accuracy and precision ^{5,17}	✓	✓
Long-range plans for ensuring adequate and sustainable numbers of properly trained personnel for conducting laboratory operations ¹⁵⁻¹⁷		✓
Evaluation		
Structured advisory network for laboratories ¹⁵	✓	✓
Strategy, aims, and measures of progress ^{15,16}	✓	✓
Standards/accreditation		
Accreditation standards ⁵		✓
Standards according to country-specific needs based on internationally agreed standards ¹⁵	✓	✓

sufficiently strong leadership throughout the health ministries, not just with regard to laboratories, to adequately operationalize and implement such plans and to help ensure that relevant stakeholders are aware of and guided by such plans.

Coordination

Donors can provide needed funds and/or technical assistance to support laboratory capacity building, but also can create challenges for host governments trying to coordinate laboratory system development across multiple funding sources.

PEPFAR requires that all US donor agencies working in the area of HIV/AIDS coordinate their activities and work within a host country's national health plan. The result is a US Government Country Operational Plan for HIV/AIDS.¹⁸ The Global Fund incorporates a country coordinating mechanism that attempts to ensure host country priorities are considered and, in some cases, that funding across donor organizations is coordinated for HIV/AIDS, tuberculosis, and malaria.¹⁹ These efforts to incorporate national strategic plans and host country priorities are commendable and are an improvement over previous donor activity. However, our interviews with donor organizations, corroborated by the case studies, indicate that there remain opportunities for improvement. In some cases, the funding and programmatic priorities of donors continues to revolve more around the donor organization's mission, history, and source of funding—what we call a “donor-driven” agenda—and less around a country's needs and requirements, an “owner-driven” agenda.

This donor-driven agenda results in several consequences, including the reluctance to engage in projects that obligate donors for extended periods; the need for a clear or identifiable exit strategy for donors, often based on funding cycles; a focus on infrastructure and equipment; and relatively little focus on host country leadership training and human capital management. Within countries, the main observation from interviewees from host governments and external funding agencies was the lack of coordination across external funding sources. This included suboptimal coordination among different program elements supported by the US government in a country across different diseases.

There are many important efforts underway, especially in the 2 African countries we studied, to organize laboratory capacity development across donor agencies. For example, interagency laboratory coordinating committees and supply chain management committees exist and have been helpful in organizing and implementing the case study countries' plans. However, our case studies suggest these committees are not completely successful, due to a variety of reasons, including lack of leadership (host country and/or donor organization), duplication of committees across donors, focus of committees on a single disease (often AIDS), and officials bypassing or ignoring the committee's jurisdiction.

As another example of how a donor-driven agenda can interfere with integration and coordination of laboratories within a host country, some donor organizations have built their own laboratories to perform clinical research, often funded and directed by the donor country. These laboratories are often the most advanced and sophisticated laboratories in these countries, but are not necessarily integrated with the host-country public health laboratories.²⁰ In some cases, these laboratories have been able to include more direct operational support for ministry laboratories through programs such as technical assistance, capacity for more advanced testing, training, and proficiency testing systems. Non-host government laboratories that seem to be more successful in integrating with national laboratory structures have well-qualified and dedicated personnel whose job it is to liaise with ministry laboratories.

Adoption of Quality Systems

Incorporation of quality systems is an important aspect of strong laboratory capacity. For this study, we focused on standardization of equipment, proficiency testing programs (internal and external), and adoption of standards-based accreditation schemes.

Many countries, including the 3 we studied, have attempted to standardize their laboratory equipment. Countries with more centralized coordinating committees, often driven by PEPFAR or Global Fund funding, have been more successful in adopting standardized equipment, especially relating to HIV, malaria, and tuberculosis testing. However, our study suggests that equipment donations and smaller scale programs developed and implemented independent of the national health system strategy and laboratory plans are persistent challenges to the desired standardization of equipment. In many resource-limited countries, donated equipment remains an important part of equipping laboratories, but the variety in donated equipment means a variety of manufacturers, different reagent and maintenance requirements, insufficient numbers of any one type of equipment to justify local service personnel, and instructions that are incomplete or in languages other than the one spoken in the recipient country.

Equipment standardization can lead to some unintended pitfalls, however, including manufacturer monopolies and potential long-term cost issues. Reliance on a single manufacturer places a laboratory system at the mercy of that one entity, which can be problematic for obtaining sufficient maintenance and reagents. Furthermore, without even a narrow range of manufacturers, there might be less leverage when negotiating contracts. Therefore, a balance must be struck that uses standardized equipment without creating overreliance on any single manufacturer or supplier.

National level laboratories are typically responsible for implementing comprehensive proficiency testing programs for their laboratory systems. Thailand has

developed and implemented such a system. However, we found that proficiency testing programs in Africa focus mostly on HIV testing. These programs typically rely on international external quality assurance (EQA) programs such as the UK National External Quality Assurance Service (NEQAS), Canada Quality Assessment and Standardization for Immunological Measures (QASI), and Australian National Serology Reference Laboratory. The few programs that exist are almost exclusively in national laboratories and some larger (regional and provincial) hospital laboratories, but have not been implemented in lower tier laboratories, with a few exceptions. For example, 52 ministry laboratories in Ethiopia participate in an EQA program organized by the Ministry of Health through NEQAS and QASI. A regional EQA program covering multiple laboratory tests developed by the African Medical and Research Foundation and implemented by ministry of health national laboratories in 4 east African countries is an example of a more comprehensive program.²¹⁻²⁵

International accreditation according to accepted standards (eg, ISO 15189) is considered the ultimate goal of many laboratories, but can also be viewed as providing a standards framework to drive the *process* to improve quality systems. In resource-limited settings, many countries have not developed their own national laboratory accreditation standards and programs.²⁶ We found this to be true in the African countries we visited in which the only laboratories accredited are a few national public health laboratories and donor laboratories accredited by international agencies such as the South African National Accreditation System. Thailand is an exception and has developed a national accreditation program.²⁷ The Bureau of Laboratory Quality Standards developed and is responsible for implementing Thai-specific standards based on ISO 15189 for laboratories in Thailand and is the accrediting body for laboratories. At the time the system was developed, many Thai laboratories were far from being able to attain accreditation. Therefore, the Bureau of Laboratory Quality Standards simplified the standards and developed a system to encourage laboratories to move incrementally toward specified quantitative goals.

Discussion

Public health laboratories around the world are a critical component of global communicable disease detection, prevention, and control. We identified major challenges in 3 main areas and offer recommendations applicable to host governments and external funding agencies to address the challenges.

Challenges Related to Laboratory Systems

Although countries are trending toward multitiered systems as spelled out in the Maputo Declaration, the national

laboratory strategic plans that exist are not being implemented consistently, infrastructure quality drops sharply at each successive laboratory tier level, and responsibility for laboratory oversight within national governments is fragmented in some countries.

Key human resource issues include the need to ensure that there are sufficient qualified laboratory personnel for existing laboratories, to create incentives to retain trained personnel within the public laboratory system, and to develop a well-defined career pathway with potential for advancement. The importance of laboratory leadership and management should not be underestimated, especially if organizations aim to build sustainable capacity that is eventually able to become less dependent on external support. Physical infrastructure issues include the maintenance of existing facilities and the development of much needed facilities appropriate for the area in which they are built and the population they are meant to serve.

Challenges Related to Coordination

By far the largest programs supporting laboratory development around the world are the multinational Global Fund and the US PEPFAR initiative. Although these programs were originally developed as largely disease-specific initiatives that were thus inherently vertical in nature, both are increasingly supportive of broader health systems strengthening. However, many people we spoke with still have the perception that PEPFAR is narrowly focused. In general, focusing on a specific disease by funding agencies and programs remains a well-recognized obstacle to integration and coordination of laboratory system development. Our findings indicate that coordination between host governments and their external funding partners and across external partners could be improved. At present, it seems that most donors continue to have their own agendas. Various coordinating committees exist, but an effective, well-coordinated, sustained, and integrated mechanism with health ministry leadership, organized by donors or by the host government, is lacking in most countries. As mentioned, the lack or perceived lack of host country leadership further compounds the problem, reinforcing a donor-driven agenda rather than an owner-driven agenda that is in line with a national health plan and responds more directly to national needs.

Challenges Related to Adoption of Quality Systems

Countries and donor agencies are increasingly aware of the need for more systematic and rigorous attention to improving laboratory quality systems. Standardization of equipment and operating procedures, as well as proficiency testing, can have significant benefits in terms of cost and patient care. As a result, quality systems initiatives by donors, technical agencies, and host country health ministries have been developed

and implemented with various degrees of success. However, these systems generally focus on a disease (often HIV), are not widespread, and rarely (if ever) permeate a country's entire tiered laboratory system.

Although laboratory quality systems are currently limited, laboratory accreditation—the international “gold standard”—is even more limited. Accreditation based on international standards presents a difficult if not nearly impossible task for many laboratories in resource-limited settings. Yet, the process of moving toward accreditation can have significant benefits for laboratory quality. The development of a step-wise approach toward accreditation using country-specific standards, as seen in Thailand,²⁷ represents a unique way of approaching this goal. In July 2009, laboratory officials from sub-Saharan African countries met in Kigali, Rwanda, to commit to the pathway toward accreditation.

Recommendations

Based on our findings, we offer 4 recommendations:

1. Support planned, integrated laboratory capacity development within the context of tiered systems compatible with the Maputo Report: External funding agencies should consider additional ways in which they can work with host government ministries of health and other organizations to contribute to the development and advancement of sustainable, integrated capacity at different levels of country laboratory systems, including national, provincial, district, and even health center laboratories. 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 espoused by key international stakeholders, such as WHO, the Global Fund, bilateral donors, and others. To build strong laboratory systems throughout a country, external agencies should balance their research-oriented activities with programmatic support that is conducive to host country laboratory system improvement.
2. Support laboratory career and leadership development: Host country governments and external funding agencies should commit themselves to building leadership and management skills within countries' laboratory cadres. External funding agencies can take explicit steps to build such skills via executive leadership and management training and support, whereas host country governments should develop clear career pathways with incentives and the potential for advancement for laboratory professionals. Development of such laboratory leaders will not be successful if there are no health ministry positions for the leaders to assume. Direct management support for high-level ministry officials, such as that

provided by the Clinton Foundation in some countries, is an example of a program that seeks to build leadership and management skills.

3. Support an owner-driven agenda based on countries' own national plans and organizations: The most logical and host country-friendly approach to the coordination of laboratory development efforts is for donors to respect and fit their own programming into host country national plans—an owner-driven agenda rather than the donor-driven agendas that have typified donor programming in past decades. Host countries or one or more donors can organize a coordinating mechanism (with leadership of host-country officials emphasized), but adaptation of the “Three One's” approach to HIV prevention and control—one (national) plan, one evaluation plan, and one budget with appropriate controls and measures in place—will help countries manage and coordinate the efforts of multiple different partners who all contribute in some way to national health programming.
4. Support laboratory quality improvement: Quality laboratory systems are key to sustainable laboratory capacity and capabilities within countries. Host countries and their external partners should incorporate laboratory standards, comprehensive quality systems, and even goals for accreditation in their plans for laboratory development. Countries should be encouraged to develop and implement attainable accreditation programs, including country-specific standards and monitoring systems like the one implemented in Thailand.

Conclusion

During the past decade, efforts have expanded to improve public health laboratory capacity in resource-limited countries. While we identified some challenges associated with laboratory-related programming in countries, we identified even greater opportunities for host governments and their external partners to improve laboratory systems, coordinate better across funding sources, and adopt quality laboratory systems. Appropriate leadership on the part of all stakeholders is critical. Our literature review and interviews with donor organizations were comprehensive across resource-limited settings attempting to develop laboratory systems. This, coupled with the in-depth case studies, suggests that our findings and recommendations are likely to be more broadly generalizable to other resource-limited countries that rely on external support to help build their laboratory capacity.

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