Laboratory Challenges in the Scaling Up of HIV, TB, and Malaria Programs

The Interaction of Health and Laboratory Systems, Clinical Research, and Service Delivery

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Abstract

Strengthening national health laboratory systems in resource-poor countries is critical to meeting the United Nations Millennium Development Goals. Despite strong commitment from the international community to fight major infectious diseases, weak laboratory infrastructure remains a huge rate-limiting step. Some major challenges facing laboratory systems in resource-poor settings include dilapidated infrastructure; lack of human capacity, laboratory policies, and strategic plans; and limited synergies between clinical and research laboratories. Together, these factors compromise the quality of test results and impact patient management. With increased funding, the target of laboratory strengthening efforts in resource-poor countries should be the integrating of laboratory services across major diseases to leverage resources with respect to physical infrastructure; types of assays; supply chain management of reagents and equipment; and maintenance of equipment.

Reliable laboratory services in resource-poor settings are critical for meeting the health-related Millennium Development Goals of the United Nations.1 The development and execution of functional laboratory services at each tier of health care provision, from primary health centers to regional and referral centers, are the very underpinnings to successful care and treatment programs and will be critical in addressing future infectious diseases and long-term chronic disease prevention and treatment.2,3

After decades of limited resources or resources primarily focused on HIV, malaria, and tuberculosis (TB) research, there has been an unprecedented increase in funding for service delivery clinical programs to prevent, care for, and treat HIV, TB, and malaria.4,5 For example, 5 years ago, it was estimated that the combined budget for research and clinical services addressing HIV, TB, and malaria in resource-poor settings of the world was less than $1 billion. However, today, the combined total budget is estimated at $10 billion per year for HIV/AIDS alone, devoted primarily to service delivery.4,5 The increased funding places tremendous responsibilities on clinicians, researchers, and policy makers in each country to work closely with laboratory personnel to effectively and efficiently strengthen laboratory capacity that is critical to fight all 3 major diseases.

Because these diseases require similar types of laboratory support, it is imperative that efforts to strengthen laboratory systems transcend any single disease and address key laboratory needs at each care and treatment level in an integrated manner. These integration efforts will require joint planning for the required physical infrastructures, human capacity, and policies needed to comprehensively address major infectious diseases in a tiered network manner. Also key to addressing
these issues is the need to bridge the gap between care and treatment providers and the laboratories. Bridging the gap requires a strong partnership among physicians, nurses, laboratory technicians, and the community. This partnership will help educate and influence the knowledge and interpretation of key laboratory findings.

The concept of strengthening laboratories that integrate multiple major diseases at each level of a health service will also require that laboratory needs are matched carefully to the level of clinical interventions.

Thus, each country will need to develop a national laboratory strategy and policy and then work with partners and donors to implement it at each level of the health system. Key elements that need to be addressed in a laboratory strategic plan include physical infrastructure, human capacity, policy and advocacy, and roles of basic and clinical researchers.

Physical Infrastructure

Key points of discussion during the consideration of the integrated laboratory strategy should consider the following: (1) the physical infrastructure needed at each level for the laboratory to provide a safe and efficient work environment in which the physical space matches the equipment needed for laboratory assays, (2) the assays to be performed and the required throughput, (3) the supply chain of equipment and reagents to prevent stock depletion, and (4) the provision of routine equipment maintenance. Key to this opportunity is defining the expected assay throughput and matching the instrument specifications to the number of assays to be performed. This aspect is often overlooked, with other issues becoming the key areas of discussion.

Human Capacity

Throughout resource-constrained areas, there are inadequately trained laboratory technologists and technicians, and equally important, there are no clear service training and long-term career pathways. The recently reauthorized President’s Emergency Plan for AIDS Relief (PEPFAR) program calls for the training of 140,000 health care workers, including laboratory experts, to be trained in the next 5 years.

This is a unique opportunity to address a wider variety of laboratory training needs. Simply addressing the absolute number of laboratory professionals without dealing with career progression and continued education opportunities will not result in the development of a sustainable cadre of key personnel. Moreover, ensuring that trained laboratory staff have access to modern, well-functioning laboratory equipment is crucial.

Policy and Advocacy

The large investment in HIV, TB, and malaria programs has led to an expansion of creative services to remote populations; however, laboratory services have not always kept pace with this expansion. To sustain these programs in the next decade, we need to fully develop integrated laboratory systems for all 3 diseases. To ensure this, key policy guidance, standardized operating procedures for implementation, and national quality management systems incorporating local quality control and quality assurance programs will be critical.

Essential to the realization of the national laboratory plan is the full engagement and support of the World Health Organization and its regional offices, international donors, and implementing partners to support a coordinated tiered laboratory system that is sustainable with robust supply chains resulting in quality laboratory results. In this issue of the Journal, Nkengasong and colleagues review critical elements of a laboratory strategic plan that needs to be addressed in a comprehensive manner. They also highlight Ethiopia’s success in implementing its laboratory plan. Policies governing standardization of laboratory commodities need to be established as part of the broader strategic plan. Also in this issue of the Journal, Peter et al discuss opportunities and challenges in the standardization of laboratory commodities, and Abimiku and Massambu and Mwangi review country experiences in standardization in Nigeria and Tanzania, respectively.

Role of Basic and Clinical Researchers

Finally, in each resource-constrained setting, there are highly talented national scientists and international partners with sophisticated and well-equipped research laboratories, often with external accreditation. Although this expertise and its allied infrastructure should not be distracted from their focus on the research mission, these experts can provide an excellent resource for the needed national discussion of the laboratory system, participate in quality management systems, and provide a forum for open discussions between service delivery and research laboratories. In many countries, these resources have provided intellectual and sometimes physical support to the aggressive lifesaving service delivery programs. This should be continued and applauded, but equally important will be the long-term support and advocacy for integrated tiered clinical laboratory systems and intellectual support to develop national integrated national public health laboratory and quality systems as outlined in the Maputo Declaration.

Now is the time to build sustainable laboratory capacity in resource-poor settings that can be used to manage existing epidemics, fight multiple emerging and reemerging diseases, and provide local facilities for scientific investigators of all levels.
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