

Laboratory Systems and Services Are Critical in Global Health

Time to End the Neglect?

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Abstract

The \$63 billion comprehensive global health initiative (GHI) emphasizes health systems strengthening (HSS) to tackle challenges, including child and maternal health, HIV/AIDS, family planning, and neglected tropical diseases. GHI and other initiatives are critical to fighting emerging and reemerging diseases in resource-poor countries. HSS is also an increasing focus of the \$49 billion program of the US President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria. Laboratory systems and services are often neglected in resource-poor settings, but the funding offers an opportunity to end the neglect. To sustainably strengthen national laboratory systems in resource-poor countries, the following approaches are needed: (1) developing integrative national laboratory strategic plans and policies and building systems to address multiple diseases; (2) establishing public-private partnerships; (3) ensuring effective leadership, commitment, and coordination by host governments of efforts of donors and partners; (4) establishing and/or strengthening centers of excellence and field epidemiology and laboratory training programs to meet short- and medium-term training and retention goals; and (5) establishing affordable, scalable, and effective laboratory accreditation schemes to ensure quality of laboratory tests and bridge the gap between clinicians and laboratory experts on the use of test results.

In May 2009, President Barack Obama announced a \$63 billion comprehensive global health initiative (GHI) to focus attention on broad global health challenges, including child and maternal health, HIV/AIDS, family planning, and neglected tropical diseases, with cost-effective intervention. The GHI adopts an integrated approach to fighting diseases, improving health, and strengthening health systems. During the past 10 years, the field of global infectious diseases has witnessed tremendous challenges and opportunities, including the continuous struggle to control and prevent the HIV/AIDS pandemic and to tackle emerging or reemerging infectious diseases, including multidrug-resistant and extensively drug-resistant tuberculosis (TB),¹ novel emerging infections such as severe acute respiratory syndrome,² the avian influenza virus H5N1,³ and the current pandemic of novel influenza A (H1N1) virus.⁴ These infections have been well contained in developed countries, thanks to well-established laboratory-supported surveillance systems. However, laboratory services and systems are weak in resource-poor countries (RPCs). The new GHI, together with the surge in funding and commitment for programs to fight HIV/AIDS, TB, malaria, and flu in RPCs (an estimated \$10 billion per annum is devoted to tackling the HIV/AIDS pandemic^{5,6}), offers a monumental opportunity to strengthen laboratory systems in RPCs that could be used to combat multiple diseases.

Health system strengthening is a key area of focus for some of the major programs, including the GHI. For example, in 2009, the US President's Emergency Plan for AIDS Relief (PEPFAR) dedicated \$1.0 to \$1.4 billion to supporting health systems, of which 6% is earmarked for strengthening laboratory systems.⁷ The Global Fund to Fight AIDS, Tuberculosis and Malaria has also allocated a similar proportion to strengthening

laboratory services.⁷ In addition, the World Bank will be allocating \$63.6 million to strengthen laboratory systems in a regional program in East Africa.⁸ Together these increased resources offer an unprecedented prospect to strengthen, in a holistic and integrated way, multiple challenges facing the appalling national laboratory systems (NLSs) in RPCs. Strengthened NLSs will be critical to delivering reliable laboratory services to meet the Millennium Development Goals (MDGs) for health; fight multiple existing, emerging, and reemerging diseases; and achieve President Obama's GHI objectives.

Challenges Facing NLSs in RPCs

Despite substantial evidence that NLSs (comprising public health, government, private, and mission hospitals) are a key component of the overall health system; are needed to achieve the MDGs for health; are required for meeting universal access for treatment of HIV/AIDS, TB, and malaria; and are critical for achieving the objectives of the World Health Organization's (WHO) International Health Regulation (IHR), they remain one of the most neglected components of the health system in RPCs.^{9,10} Major challenges facing NLSs in RPCs include a shortage of skilled and trained personnel, an inadequate infrastructure (eg, consistent supply of electricity and water, physical infrastructure), a lack of equipment, inadequate supply-chain management for consumables and reagents, poor equipment maintenance, lack of clear policies, and insufficient leadership.^{9,10} Consequently, clinicians lack confidence in laboratory results¹¹ and often rely on clinical diagnosis and empirical treatment instead of laboratory-confirmed diagnosis. For example, few clinicians order sputum-smear microscopy for a TB diagnosis because the turnaround time for the results may be longer than the average hospital stay, and patients are often discharged or die before the results are received.

In addition, clinical diagnosis without quality laboratory testing often results in significant misdiagnosis and over-diagnosis, leading to inadequate or inappropriate treatment, drug resistance, and increased mortality.^{12,13} Reyburn and colleagues¹⁴ found that among 4,670 patients admitted and treated for malaria in a Tanzania hospital, fewer than 50% actually had malaria, as confirmed by blood smear. Similarly, a study in Ghana found that 40% of patients with a clinical diagnosis of malaria actually had bacterial sepsis,^{15,16} and the correct diagnosis of malaria leads to better treatment.¹⁷

Ending the Neglect and Building Sustainable Laboratory Systems in RPCs

In January 2008, the Maputo Declaration for a global commitment to strengthen laboratory services and systems in RPCs was issued and endorsed.^{18,19} With the surge in funding,

we believe that the following actions should be undertaken to strengthen NLSs in a sustainable manner in RPCs.

Develop Comprehensive National Laboratory Plans and Policies

As illustrated in **Figure 1**, countries and partners need to develop national laboratory policies and strategic plans¹⁹ as part of the overall health sector development investment. These plans should be comprehensive and not disease-specific and should integrate multiple diseases with the ultimate goal of establishing a functional tiered laboratory network in the country as proposed in **Figure 2**. Laboratory plans should also be considered a key component of implementing the WHO IHR, which is a legally binding agreement of all member states of WHO to help the international community

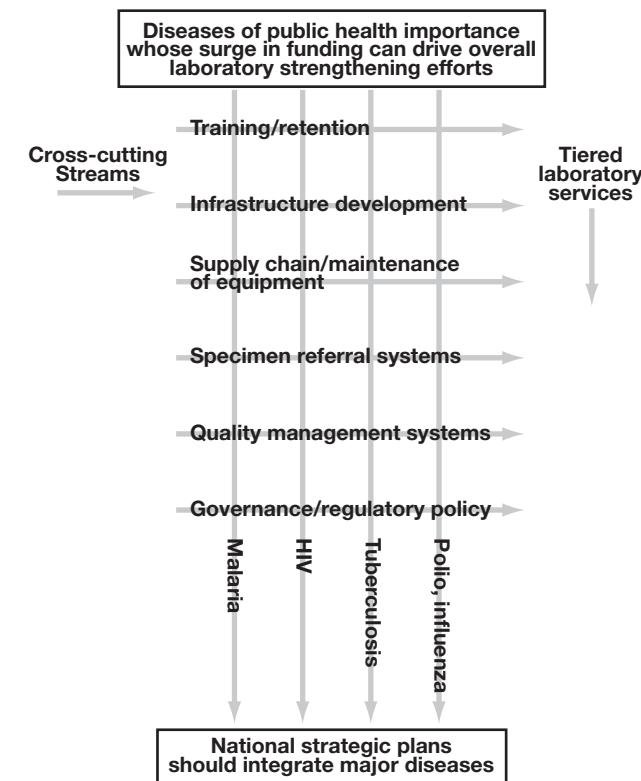


Figure 1 Core cross-cutting elements of laboratory health systems that should be strengthened to support multiple diseases of public health importance. Horizontal arrows indicate cross-cutting core elements that affect laboratories and need to be addressed in a national laboratory strategic plan, regardless of the disease. These core elements must be addressed at various levels of a tiered laboratory network. The vertical arrows are examples of major public health diseases that have seen a surge in funding that can drive the laboratory systems to be strengthened in resource-poor countries.

prevent and respond to acute public health risks with a global impact, such as influenza, multidrug-resistant and extensively drug-resistant TB, and other diseases.²⁰

As shown in Figure 1, a comprehensive national laboratory strategic plan should focus on strengthening core cross-cutting elements of laboratory health systems, including the following: (1) a framework for training, retaining, and career development of laboratory workers; (2) infrastructure development; (3) supply-chain management of laboratory supplies and maintenance of laboratory equipment; (4) specimen referral systems in an integrated, tiered NLS network; (5) standards for quality management systems and accrediting laboratories and facilities; (6) laboratory information system; (7) biosafety and waste management; and (8) a governance structure that will clearly address regulatory issues and define reporting structures, authority, and the relationship between private diagnostic and public health laboratories, to ensure a functional NLS network as illustrated in Figure 2. These regulatory frameworks are critical for guiding the implementation of laboratory quality management systems, accreditation of laboratories, defining certification process for technicians, and monitoring and evaluation.

Figure 3 is a proposed framework for strengthening laboratory systems in developing countries. If efforts are focused on strengthening core cross-cutting aspects of laboratory systems that are critical to ensure quality diagnostic services

(microscopy, flow cytometry, molecular diagnosis, serology, clinical chemistry, and culture), sustainable NLSs will emerge in RPCs that will benefit the fight against multiple emerging, reemerging, and existing diseases. In fact, because some HIV/AIDS laboratory investments had strengthened laboratory core systems in some RPCs, they have been instrumental in the past in supporting the investigation of other disease outbreaks.²¹ Moreover, with support from the World Bank's AIDS Program and PEPFAR, Rwanda developed a functional integrated national reference laboratory that is currently used to combat multiple diseases, including TB, malaria, and epidemic-prone diseases (eg, cholera), and priority diseases.

Finally, laboratory plans should aim at strengthening infrastructure in health facilities outside the public sector, especially private and mission hospitals that are critical to achieving universal access to care and treatment in RPCs. In fact, a sizable portion of persons in Africa receive health care in the private and rural settings in which, in some countries, 40% of all health care and more than 70% of care in rural areas is provided in mission hospitals.²²

Establish Public-Private Partnerships

Once developed, laboratory strategic plans can be implemented through a variety of ways. First, public-private partnerships (PPPs) have been shown to be effective in strengthening

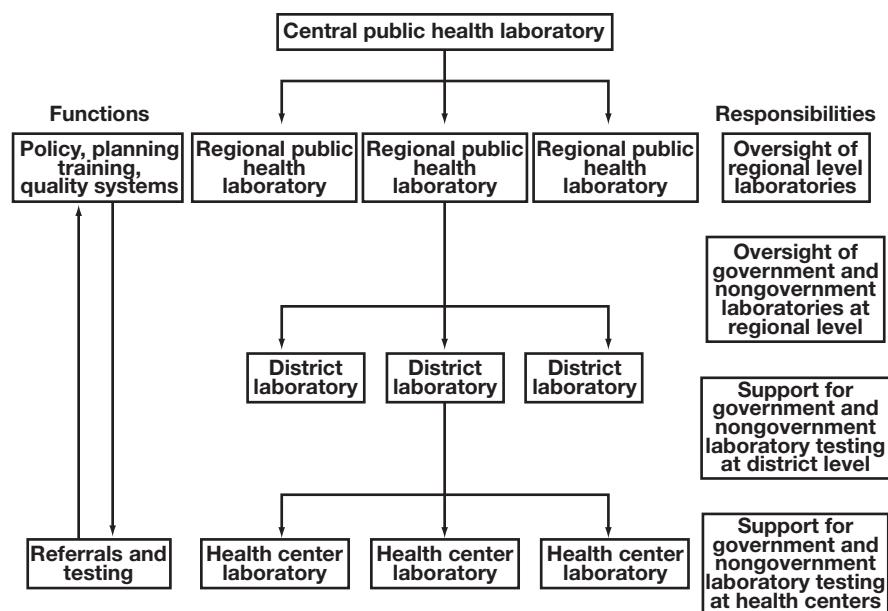


Figure 2 Potential structure of a national laboratory network system in resource-poor countries. In this structure, clear lines of functions, authority, and responsibility are outlined from the central public health laboratory (CPHL) to the primary health center (PHC). For example, the CPHL sets policy, conducts planning, and establishes appropriate quality management systems. In larger countries, regional public health laboratories may need to take on the responsibilities of the CPHL so as to reach the PHC.

health systems in RPCs.²³ Therefore, PPPs that focus on implementing established laboratory plans will be vital. In this respect, PEPFAR has entered into an \$18 million PPP agreement with Becton Dickinson, a private medical diagnostic company, to strengthen laboratory capacity in 8 African countries in the areas of training, development of referral systems for transporting samples, and quality management schemes.²⁴ Similarly, the Abbott Fund in Tanzania is developing laboratory infrastructure in the country, including a state-of-the-art reference laboratory in Dar es Salaam, and upgrading all regional hospital laboratories in the country.²⁵ Second, the Global Fund to Fight AIDS, Tuberculosis and Malaria Corporate Champions program for multinational corporations to fight HIV/AIDS, TB, and malaria, which gives companies the opportunity to significantly commit to global health, is another possibility for recipient countries to advocate for laboratory systems. Third, the GHI should devote particular attention to strengthening laboratory systems by establishing strategic PPPs. Fourth, effective partnerships with diagnostic companies can also help develop point-of-care machines that can be used for diagnostics across multiple diseases, an effort the Foundation for Innovative New Diagnostics has spearheaded in the last 5 years. Last, the recently established Health Funds for Africa²⁶ will be critical to developing laboratory services and systems in the private sector.

Effective Leadership, Commitment, and Coordination by Host Government of Efforts of Donors and Partners

Increased funding to combat HIV/AIDS, TB, malaria, flu, and global infectious diseases means that multiple international partners and donors will be present in a given RPC. The unintended consequences of uncoordinated efforts can be fragmented laboratory health systems. To avoid this shortcoming, the Maputo Declaration calls for increased collaboration and coordination of donors and implementing partners' activities, based on their comparative advantages, within the context of countries' national strategic laboratory plans. Therefore, host governments will need to show leadership and commitment by ensuring that laboratory plans are an integral part of the overall health systems strategy and investment for the country and that a functional department of laboratory services is established within the ministry of health, similar to other departments such as pharmacy and disease control.

Establish Field Epidemiology and Laboratory Training Programs and Centers of Excellence to Meet Short- and Medium-Term Laboratory Training and Retention Goals

There is an acute shortage of a well-trained national laboratory workforce to meet the expanding HIV/AIDS, TB, malaria, and flu programs. The WHO estimates that to meet the MDGs, approximately 1 million new health workers (including staff working in laboratories) will need to be

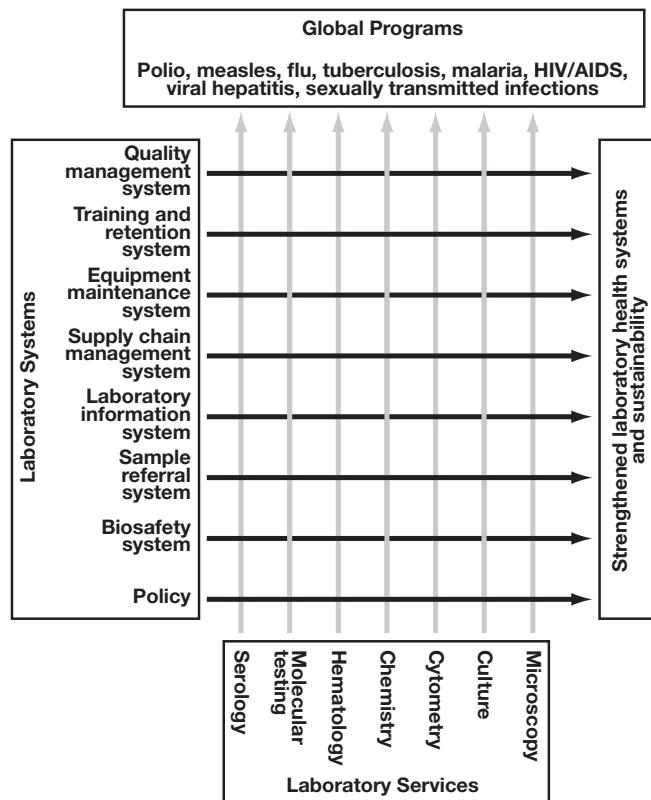


Figure 3 Proposed framework for strengthening laboratory systems globally showing the core elements of a laboratory system that need to be strengthened, with the surge in HIV/AIDS and tuberculosis funding, to provide broad-based, integrated, quality laboratory services and ensure sustainability of global laboratory investments. This approach will be needed to combat multiple global disease program needs, especially for infections that do not have specific funding. For example, for serologic diagnosis of any disease to be effective in a resource-poor country, there is a need to adequately address issues related to quality management, training and retention, equipment procurement and maintenance, supply chain management, laboratory information systems, biosafety, and policy.

trained and retained by the year 2010.²⁷ In this regard, the PEPFAR reauthorization legislation that aims to train 140,000 health care workers is a highly appropriate initiative.²⁸

Training and retention efforts for laboratory experts should focus on job redesign and use holistic approaches that address projected skill shortages, ie, based on an assessment and definition of critical gaps at the country or regional level. Any effective training strategy must proactively involve stakeholders (eg, national governments, the private sector, development partners, and multilateral bodies). To partly address the short-term laboratory needs and support current

program goals, centers of excellence are needed to provide specialized staff needs.

With funding from PEPFAR, the National Institute of Communicable Diseases in Johannesburg, South Africa, recently established the African Center for Integrated Laboratory Training (ACILT). The ACILT was created after in-depth consultation on laboratory training needs of several African countries, in collaboration with the WHO Regional Office for Africa. The courses used a competency-based approach for the trainees to obtain knowledge and skills at the National Institute of Communicable Diseases; attendees then returned to their countries and developed competencies while working under supervision and received follow-up visits by the core training staff of ACILT. This training approach is similar to the short-course component of the US Centers for Disease Control and Prevention-supported field epidemiology training programs in several RPCs. In these programs, field epidemiologists and public health laboratory staff are jointly trained in long courses (ie, 2-year public health leadership training) and short courses (ie, 1- to 2-week public health implementer training) to acquire skills and develop competencies while providing a public health service.²⁹ These were modeled on the US Centers for Disease Control and Prevention Epidemic Intelligence Service. Laboratory components of the field epidemiology training programs will need to be standardized and strengthened to address needs for technicians, managers, and policy makers.

Implement Practical and Affordable Quality Management Systems and Accreditation and Improve Clinician and Laboratory Interactions

Although implementing international laboratory standards, such as ISO 15189, has been shown to be possible in developing countries, implementation is not easily scalable in the laboratories of most developing countries. Thus, the WHO Regional Office for Africa stepwise laboratory accreditation program and the Thai Accreditation scheme, both described in this issue of the *Journal*, offer practical and affordable approaches to quality management systems that can be implemented and scaled up in developing countries. There is need to establish continuous laboratory medical education (CMLE) for clinicians so as to bridge the gap between laboratory testing and uptake for patient management. Regional societies for laboratory medicine or clinical pathology could serve as the appropriate vehicle to meet these critical gaps, including implementing CMLE and certification of training for medical technologists.

Conclusion

The new Obama GHI and the increased funding for HIV/AIDS, TB, malaria, and flu programs provide a monumental opportunity to build integrated and sustainable NLSs in RPCs,

which will help advance the goals of the MDGs for health, support universal access to treatment, meet the objectives of the Maputo Declaration, and advance the WHO IHR. The efforts of RPC governments and partners should be focused on developing an integrated and functional tiered NLS through a comprehensive national laboratory strategic plan and policy, establishment of PPPs, leadership and commitment of host countries that is needed to effectively coordinate donors and implement the efforts of partners, establishment of centers of excellence to meet urgent human capacity needs, and implementation of practical and affordable laboratory accreditation schemes and CMLE for physicians. Global efforts should center on strengthening critical cross-cutting core elements of laboratory systems (Figure 3) that are vital to support multiple global health needs and will ensure sustainability.

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