



# HHS Public Access

Author manuscript

*Lancet*. Author manuscript; available in PMC 2018 May 21.

Published in final edited form as:

*Lancet*. 2018 May 12; 391(10133): 1873–1875. doi:10.1016/S0140-6736(18)30308-8.

## Laboratory medicine in low-income and middle-income countries: progress and challenges

**John N Nkengasong, Katy Yao, and Philip Onyebujoh**

Africa Centres for Disease Control and Prevention, African Union, Addis Ababa W21K19, Ethiopia (JNN, PO); and US Centers for Disease Control and Prevention, Atlanta, GA, USA (KY)

Laboratory medicine is essential for disease detection, surveillance, control, and management.<sup>1</sup> However, access to quality-assured laboratory diagnosis has been a challenge in low-income and middle-income countries (LMICs) resulting in delayed or inaccurate diagnosis and ineffective treatment with consequences for patient safety.<sup>1</sup> In the new *Lancet* Series<sup>2–4</sup> on pathology and laboratory medicine (PALM) in LMICs, Michael Wilson and colleagues<sup>2</sup> provide a comprehensive analysis of the challenges and gaps that limit access to PALM services. Some of the challenges include the absence of essential infrastructure, laboratory supplies, basic equipment, skilled personnel, supply chain management, and equipment maintenance; reliance on empirical treatment; inadequate quality management systems; and no government standards for laboratory testing. In their Series paper, Shahin Sayed and colleagues<sup>3</sup> provide a roadmap to solutions for improving laboratory medicine, and Susan Horton and colleagues<sup>4</sup> call for all stakeholders to ensure the effective provision of PALM services in resource-limited settings.

Reductions in funding for global health could erode the substantial gains made so far in advancing PALM in LMICs. The progress made over the past decade was driven largely by four factors: global investment, advocacy, laboratory innovation, and common commitment. Substantial global investments in vertical health programmes, such as the US President's Emergency Plan for AIDS Relief (PEPFAR),<sup>5</sup> the Global Fund for AIDS, Tuberculosis and Malaria, and the World Bank, have transformed the PALM landscape. Furthermore, strong political advocacy by regional commitments such as the Maputo Declaration<sup>6</sup> and the ministerial declarations by the WHO Regional Office for Africa (WHO AFRO)<sup>7</sup> and the African Society for Laboratory Medicine (ASLM),<sup>8</sup> further galvanised investment in laboratory medicine.

Innovative tools, exemplified by the Strengthening Laboratory Management Toward Accreditation (SLMTA) and the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA), enhanced the quality and reliability of laboratory diagnostic findings.<sup>9</sup> SLMTA empowers laboratory managers to initiate immediate laboratory

Correspondence to: John N Nkengasong.

JNN is the Director of Africa CDC. KY is a public health educator at the US Centers for Disease Control and Prevention who conceptualised the SLMTA programme and serves as its global programme director. PO is senior policy and strategy adviser in the Office of the Director of Africa CDC. We declare no other competing interests.

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the US Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

improvement measures even without additional resources through training and mentoring, whereas SLIPTA serves as a framework of auditing laboratories in line with international standards.<sup>9</sup> SLIPTA measures the progress of laboratory quality systems and awards a certificate of recognition based on the audit results. Together, SLMTA and SLIPTA have revolutionised laboratory improvement in LMICs. When SLMTA was launched in 2009, no government clinical laboratory in sub-Saharan Africa outside of South Africa was accredited to international standards. As of December, 2017, 49 countries, including 23 in sub-Saharan Africa, have implemented the SLMTA programme with 5049 people trained, and 54 of 1150 SLMTA laboratories have achieved accreditation to ISO 15189 standards. There has been an unprecedented unity of purpose between many organisations in collaborations using the SLMTA/SLIPTA tools to drive laboratory improvements. As the global community considers the call to action by Horton and colleagues,<sup>4</sup> lessons learned from the past decade's successes will be crucial in facilitating progress in the years ahead.

Flagship programmes such as SLMTA and SLIPTA must continue to be supported and scaled up. Tools similar to SLMTA/SLIPTA could be developed to strengthen microbiological laboratories for antimicrobial resistance testing and testing of other diseases.

It is important that vertical programmes such as PEPFAR, the Global Fund, and others continue to invest in important horizontal determinants of laboratory health systems, such as workforce development, infrastructure improvement, and innovation. For example, studies have shown spillover-effects in overall health-system improvement due to PEPFAR-supported HIV programmes.<sup>10</sup> Thus, investment should be prioritised to support innovative tools and approaches that benefit the overall health system. For instance, the use of drones to move health products and specimens to and from remote areas might be a solution to logistical challenges, thereby strengthening the laboratory referral network.<sup>11</sup>

Integration of point-of-care diagnostics into national laboratory tiered networks, with a focus on connectivity for rapid transmission of test results, will facilitate effective uptake of diagnostics for programme impact. Likewise, strengthening the interface between diagnostics and clinicians will lead to improved uptake and use of laboratory test results. A laboratory medicine leadership programme, similar to the US Centers for Disease Control and Prevention's Field Epidemiology Training Program,<sup>12</sup> will provide an opportunity to enhance collaboration between clinicians and laboratorians.



The Africa Centres for Disease Control and Prevention (Africa CDC) is well positioned to lead and facilitate sustained advocacy in promoting the centrality of laboratory medicine to help achieve the UN's Sustainable Development Goals for health and universal health coverage. The creation of the Africa CDC in 2017 provides an opportunity to drive the laboratory medicine agenda in Africa in partnership with WHO and ASLM. The recently established Regional Integrated Surveillance and Laboratory Network by Africa CDC<sup>13</sup> can play a key part in mobilising resources regionally by harnessing the existing assets in the various regions to effectively respond to disease threats.

Coordination within, between, and among governments, donor organisations, and public private partnerships<sup>14</sup> will be crucial for any call to action to be effective. Regional economic bodies and host country governments must also show strong leadership in raising domestic funding for laboratory medicine and coordinating donor efforts around a common national laboratory plan to ensure sustainable capacity. Sustaining the gains made in improving laboratory medicine should be the concern of all global public health stakeholders, especially given their role in combating communicable and non-communicable infections in LMICs.

## References

1. Nkengasong JN, Nsubuga P, Nwanyanwu O, et al. Laboratory systems and services are critical in global health. *Am J Clin Pathol.* 2010; 134:368–73. [PubMed: 20716791]
2. Wilson, ML., Fleming, KA., Kuti, M., Looi, LM., Lago, N., Ru, K. Access to pathology and laboratory medicine services: a crucial gap. *Lancet.* 2018. published online March 15. [http://dx.doi.org/10.1016/S0140-6736\(18\)30458-6](http://dx.doi.org/10.1016/S0140-6736(18)30458-6)
3. Sayed, S., Cherniak, W., Tan, SY., et al. Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. *Lancet.* 2018. published online March 15. [http://dx.doi.org/10.1016/S0140-6736\(18\)30459-8](http://dx.doi.org/10.1016/S0140-6736(18)30459-8)
4. Horton, S., Sullivan, R., Flanigan, J., et al. Delivering modern, high-quality, affordable pathology and laboratory medicine to low-income and middle-income countries: a call to action. *Lancet.* 2018. published online March 15. [http://dx.doi.org/10.1016/S0140-6736\(18\)30460-4](http://dx.doi.org/10.1016/S0140-6736(18)30460-4)
5. Institute of Medicine of the National Academies. [accessed Feb 12, 2018] Evaluation of PEPFAR. 2013. [http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2013/PEPFAR/PEPFAR\\_RB.pdf](http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2013/PEPFAR/PEPFAR_RB.pdf)
6. World Health Organization Regional Office for Africa. The Maputo Declaration on Strengthening of Laboratory Systems. Brazzaville: World Health Organization Regional Office for Africa; 2008. [http://www.who.int/diagnostics\\_laboratory/Maputo-Declaration\\_2008.pdf](http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf) [accessed Oct 12, 2017]
7. World Health Organization Regional Committee for Africa. Resolution AFR/RC58/R2: strengthening public health laboratories in the WHO African region: a critical need for disease control. World Health Organization Regional Committee for Africa. Final Report: 58th Session of the WHO Regional Committee for Africa; Brazzaville: World Health Organization Regional Office for Africa; 2008. p. 11-13.
8. African Society for Laboratory Medicine. African Society for Laboratory Medicine to hold its first international conference; Cape Town, South Africa. December 1–7, 2012; <http://www.aslm.org/stay-informed/press-room/press-releases/african-society-for-laboratory-medicine-to-hold-its-first-international-conference-in-cape-town-south-africa-december-1-7-2012/>
9. Yao K, McKinney B, Murphy A, et al. Improving quality management systems of laboratories in developing countries: an innovative training approach to accelerate laboratory accreditation. *Am J Clin Pathol.* 2010; 134:401–09. [PubMed: 20716796]
10. Justman JE, Koblavi-Deme S, Tanuri A, Goldberg A, Gonzalez LF, Gwynn CR. Developing laboratory systems and infrastructure for HIV scale-up: a tool for health systems strengthening in

resource-limited settings. *J Acquir Immune Defic Syndr.* 2009; 52(suppl 1):S30–33. [PubMed: 19858935]

11. Fonjungo PN, Alemnji G, Kebede Y, et al. Combatting global infectious diseases: a network effect of specimen referral systems. *Clin Infect Dis.* 2017; 64:796–803.
12. US Centers for Disease Control and Prevention. [accessed Feb 15, 2018] The Field Epidemiology Training Program. Jul 19, 2017. <https://www.cdc.gov/globalhealth/infographics/uncategorized/fetp.htm>
13. Amukele T. Africa CDC: establishing integrated surveillance and laboratory networks for rapid disease detection and response, control, prevention, and clinical care in Africa. *Afr J Lab Med.* 2017; 6:a638.
14. Shrivastava R, Gadde R, Nkengasong J. Importance of public-private partnerships: Strengthening laboratory medicine systems and clinical practice in Africa. *J Infect Dis.* 2016; 213(suppl 2):S35–40. [PubMed: 27025696]