Strengthening Laboratory Management Toward Accreditation, A Model Program for Pathology Laboratory Improvement

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KEYWORDS

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KEY POINTS

- Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Toward Accreditation (SLIPTA) have proved to be effective tools to empower laboratorians and improve laboratory quality in developing settings.
- Participants progressed more quickly when the laboratory leaders attended training and involved the entire laboratory staff in the improvements and changes needed.
- Access to mentors as well as supervisory visits were key to success.
- SLMTA/SLIPTA can serve as a useful model for improving laboratory quality across pathology disciplines.

BACKGROUND

Only 10 years ago, access to reliable diagnostic testing in sub-Saharan Africa was critically limited and misdiagnosis a common occurrence. Although reliable laboratory results can support clinical decision making and improve patient outcomes, unreliable

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laboratory results prolonged illness or resulted in unnecessary or ineffective treatment regimens. With the wrong treatment, time and financial resources were wasted.[1] If and when diagnostic testing was available, the results were suspect. It was common for clinicians to ignore test results and proceed with patient care using only the patient's symptoms and the physician's clinical impression. Reyburn and colleagues[2] found that, among 4670 patients admitted to hospitals in Tanzania and treated for malaria, less than 50% had malaria confirmed by a blood smear. In the absence of high-quality laboratory testing, disease surveillance and epidemiology programs also lag behind.

Shortly after the millennium, in response to the growing human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) epidemic, support for health systems strengthening in developing countries became a priority for many donors, including the World Bank; the United States (through the Global AIDS Program); and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Initially, funding was limited so efforts primarily focused on targeted technical assistance projects. With the introduction of the US President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, spending scaled up rapidly and monies were directed to procure medications and direct patient care supplies. In order to deliver care to the number of individuals supported by these programs, it was quickly realized that efficient and reliable health systems, including quality laboratory services, needed to be supported. Laboratory infrastructure and personnel in Africa were insufficient to fill their role in the accurate diagnosis and treatment of infectious and chronic diseases.[3]

The best way for laboratories to ensure the quality of their testing results is to implement a robust quality management system (QMS). The International Standards Organization (ISO) has adopted ISO 15189 as the standard for laboratory quality and competence and this is designed to provide laboratories and laboratory auditors with a common set of standards for assessing a laboratory QMS. At the outset of PEPFAR, however, achieving international accreditation seemed like a daunting task for many laboratories in developing settings. In response, the World Health Organization (WHO) Regional Office in Africa (WHO-AFRO) began developing a stepwise program toward accreditation that provided a framework for auditing and monitoring laboratory quality and that rewarded incremental progress. On completion of the WHO-AFRO process, laboratories were ready to go forward to potentially achieve accreditation through ISO 15189. This approach was ratified and gained consensus during 7 meetings that took place through 2008 to 2011.[3]

1. The Maputo Declaration (2008) included 33 countries with the WHO; the World Bank; and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. A declaration to strengthen laboratory systems was passed.
2. A meeting in Lyon, France, with WHO and the US Centers for Disease Control and Prevention (CDC) called for countries with limited resources to improve their quality systems by using a stepwise approach. It further recommended minimum standards be established.
3. At Yaoundé, Cameroon, in the 58th session of the Regional Committee (2008), a resolution was adopted emphasizing the urgency to strengthen laboratories with a request that WHO African Region support this effort to achieve improvement.
4. In Dakar, Senegal, at the fifth meeting of the Regional HIV/AIDS Network of Public Health Laboratories (2008), agreement was reached to support improvement for all laboratories without limitation to any specific disease.