

Directors of Clinical Services Meeting

Réunion des directeurs des services cliniques

Laboratory Quality Assessment

Laboratory services are an essential and fundamental part of the health care system by providing evidence-based diagnosis for detecting, managing, and preventing diseases. Reliable and timely results are critical for clinical management and are essential for the surveillance and control of public health diseases and emerging infections.

The initial WHO Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015), endorsed at the WHO Regional Committee meeting in 2009, highlights the importance of quality in the functioning of health laboratories. Laboratories that provide accurate, timely and reliable test results for diagnosis, treatment and monitoring of diseases, whether in public health or clinical services, are the aim of every efficient health laboratory system.

Additionally, the Pacific Island Countries & Territories (PICs) are working on strengthening health laboratory performance and quality in line with the International Health Regulations (2005), Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSED III) and ISO 15189.

1. BACKGROUND

The PICs are facing a triple burden of disease – communicable diseases, noncommunicable diseases and the health impact of climate change that causes high morbidity and mortality. Therefore, coordinated efforts of many different agencies are needed to evaluate and build a sustained and responsive quality laboratory system. Moreover, the unpredictable nature of public health events and emergencies throughout an increasingly connected world demands vigilance and constant development of core capacities to manage these threats, a mandate under the IHR (2005) and framework of APSED III and ISO 15189.

As part of the 12th Pacific Heads of Health meeting endorsement on building sustainable systems and advancing Universal Health Coverage (UHC), partners are investing in strengthening laboratory systems to ensure timely, accurate and reliable disease diagnosis. In addition to the Laboratory Quality Management System (LQMS) training, one of the major activities is to systematically assess PICs laboratories' performance using the WHO Stepwise Laboratory Improvement Towards Accreditation (SLIPTA) audit tool and initiate corrective actions to improve laboratory work processes and their outcomes. Over the last years, WHO has initially assessed several laboratories and developed national laboratory policies. From 2015 to 2022, SPC, PPTC and PIHOA have conducted 38 assessments in 13 Pacific Island Countries using the SLIPTA audit tool. Note: SLIPTA audit tool is a more stringent assessment tool aligned to ISO 15189 developed for assessing laboratories in countries that do not yet have the infrastructure to undergo ISO accreditation.

2. PROGRESS AND ACHIEVEMENTS

Out of the 13 countries assessed, two laboratories scored higher ratings while other countries were improving their national standards. The ratings are proportionate to the quality of laboratory service and the capability to provide high-quality test results for patient management and public health measures. The assessment scores also indicate the capacity of the laboratories to respond to changes in a timely manner and implement new technologies whenever the need arises to ensure health security in the region.

The improved laboratory standards in PICs contributed to the efficient implementation of COVID-19 testing in 2020. Additionally, few other PICs laboratories progressed to establish manual RTPCR testing like in the Cook Islands, Fiji, Solomon Islands, Tonga and Vanuatu. For instance, the early identification of standard quality needs in Tonga ensured the timely re-modification of existing

laboratory infrastructure, request for equipment, consumables and reagents, the set up of RTPCR testing and training of laboratory staff through virtual assistance from reference laboratories.

Lastly, the locally initiated laboratory progress and maintenance of high-performance quality will commit member states to utilize and sustain this new investment and expand RTPCR testing to other clinical and public health priority diseases for better healthcare service.

3. CHALLENGES

3.1 Lack of resources to support LQMS implementation

- Most countries still do not have dedicated National laboratory Quality Manager to be responsible of training, implementing and monitoring laboratory quality system and ensures continuous improvement of laboratory service towards ISO 15189 standard. PICs Laboratory policies that was developed by WHO in 2010-2012 stated that each country should have a laboratory quality manager.
- Common to PICs is the limited financial support and other physical resources; laboratory infrastructure, equipment, consumables and reagents that enable laboratories to consistently meet the demands for testing from both clinical and public health services.
- Inadequate resources to support regular LQMS training, SLIPTA assessment and technical assistance to quality managers to monitor and sustain the improvement of countries' laboratory standards.

3.2: Partial commitment of Countries' laboratory services to implement LQMS and improve the quality of laboratory service due to various factors such;

- lack of ownership on the quality of service by laboratory leaders
- the disconnection between laboratory and clinical/public health service results in the lack of understanding of the negative effect that poor quality laboratory service has on clinical service and public health programs. This could be related to the shortage of Pathologists in the region.

4. FUTURE DIRECTIONS

4.1 Recommendations for governments

- MOH administrators to advocate at the national level to recognise the vital role laboratory service plays in both clinical service and public health programs and support LQMS implementation and continuous improvement of the quality of laboratory service in PICs.
- MOH to develop, update and endorse national laboratory policies initially developed in 2010-2012.
- An interim Pacific Island laboratory Standard using SLIPTA assessment tool is to be developed and accepted as the standard for PICs that do not yet have appropriate infrastructures for ISO accreditation.

4.2 Recommendations for development partners:

- Provide and/or support technical assistance to Member States to strengthen LQMS implementation, development of PICs laboratory standard and conduct SLIPTA/LQMS standard assessment.
- A dashboard of countries laboratory performance to be presented to MOH administrators for awareness of the quality of countries of laboratory service and further assistance that maybe needed.