

Inquiry into Australia's response to the priorities of Pacific Island countries and the Pacific Region

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NRL is a World Health Organization (WHO) Collaborating Center and a member of the Australian Global Health Alliance. Its mission is to promote the quality of tests and testing for infectious diseases globally, achieving this mission by providing novel, scientifically robust quality assurance products and services to laboratories, test kit manufacturers, regulators, NGOs and ministries of health. NRL works closely with WHO Head Office (Geneva, Switzerland), the Southeast Asian Regional office (SEARO, Delhi, India) and the Western Pacific Regional Office (WPRO, Manila, Philippines), as well as groups such as Global Fund, US CDC and Foundation for Innovative and New Diagnostics (FIND, Geneva, Switzerland).

Predominantly through WPRO, but also through Pacific Public Health Surveillance (PPHSN) LabNet & Laboratory Surveillance Network, of which NRL is a member, NRL has contributed to laboratory capacity projects in the Pacific region and can provide insight into the identified gaps in capacity. Of note, in collaboration with WPRO, NRL conducted a capacity gap assessment of countries in the region, including two Pacific Island countries. The findings indicated that in making good progress towards the improvement of laboratory testing access at all levels of the healthcare system, the major challenges identified could be categorized into three thematic areas: a) strengthening primary healthcare systems, b) empowering communities and individuals, and c) addressing socio-economic barriers.

Strengthening of laboratory capacity would require improved quality management systems, a move away from vertical disease programs to whole of laboratory programs, improved human resourcing of laboratories and supply chain management, coordinated sample referral systems, and laboratory information systems that integrate into national surveillance systems. Individuals and communities can be empowered by having affordable and accessible testing services, reducing stigma and discrimination around infectious diseases. Community engagement is required to overcome these barriers, while social and economic barriers can be reduced through national funding of healthcare. Preparation to manage outbreaks is important in the Pacific Island context, where resources are limited.

To support Pacific Islands, NRL has developed and provided quality assurance services specific to low- and middle-income countries. In particular, NRL has developed a quality assurance service specifically designed for point of care testing (PoCT). This program utilises samples that are inactivated and can be stored at ambient temperatures, reducing the cost of shipping and storage. The PoCT QA program uses novel mobile phone-enabled software to collect and analyse the data, facilitating a more immediate intervention, should the test fail. A project funded by FIND used this PoCT QA to monitor COVID-19 antigen testing in nine countries, including Samoa and Cook Islands. A significant finding indicated that the test kits used in Samoa were not fit for purpose and the majority of individuals testing positive by molecular testing were being missed by antigen testing. The outcome of the QC program was that the Samoan ministry of health changed its testing algorithm, potentially saving resources and lives. Without the QA program, the issue would not have been detected.

The use of external quality assurance schemes (EQAS) to monitor and assure the quality of laboratory testing processes and the effectiveness of test kits is an essential part of a quality management system. In NRL's experience, EQAS providers in the Pacific Islands generally have a basic working knowledge of EQAS production processes for simple serology panels such as HIV, however there can be gaps in the quality assurance of these panels, results analysis and reporting



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processes. EQAS providers also face challenges when expanding their production to include HIV Viral Load and Malaria panels. Effective support to these providers requires both theoretical training, which can be delivered virtually to address all identified gaps, and on-site practical training. NRL's capacity building programs for EQAS providers are customised for each provider and are based on three components: virtual theoretical training, on-site practical training and subsequent mentoring sessions held virtually to support the provider through implementation of their new or improved processes and expansion of their program.

Most medical decisions for infectious diseases are based on laboratory or PoC testing. False negative results cause further spread of disease, where false positive results cause unnecessary treatment and patient concern. Incorrect test results waste resources, skew epidemiological studies, and ultimately reduce confidence in laboratories. It is important in the Pacific Island context that gaps in laboratory capacity are identified and addressed.