ORIGINAL ARTICLE

The Pacific Pathology Training Centre external quality assessment programme

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ABSTRACT

The Pacific Pathology Training Centre (PPTC) external quality assessment programme (PPTC-EQAP) commenced in 1985 as an evaluation process of students attending residential courses. This was enhanced when the PPTC was conferred Collaborating Centre status by the World Health Organization and is now the main EQA provider to the laboratories in the Pacific region.

The PPTC accommodates seven medical laboratory science disciplines within its EQA programme, and these include serology, blood bank, microbiology, haematology, biochemistry, anatomical pathology, and molecular SARS—CoV-2. Samples for each survey are dispatched from Wellington, in lyophilised form or as a whole specimen, following the IATA shipping of biological substance guidelines. All disciplines are delivered over three cycles except for biochemistry, which consists of two cycles with four analyses. The PPTC contracts consultants (registered New Zealand Medical Laboratory Scientists and a Pathologist) who are specialists in their selected disciplines for analysis and reporting of the results.

Participating laboratories are given five weeks to process the samples and return their results to the centre. Interim reports are provided a week after the due date for all programmes. A final report compiled by the appropriate PPTC consultant is sent to each participating laboratory for the specific discipline that the laboratory has participated in and each report sent details the laboratory's score for the respective cycle, their accumulated score for the previous cycle in that discipline, and the average score for all participating laboratories. This year (2021) there are 86 laboratories from 22 countries participating in all or part of the PPTC EQA programme. The New Zealand Government, through the Ministry of Foreign Affairs and Trade (NZ-MFAT), provides funding to the PPTC to deliver the EQA programme at no cost to 31 laboratories in 17 countries, while the rest of the laboratories are privately enrolled through their own funding or through donor partner funding. The PPTC provides a free external quality assurance programme for government owned and operated medical laboratories in the South Pacific region.

Keywords: external quality assessment, medical laboratory science, Pacific.

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INTRODUCTION

Assessment is a critical aspect of laboratory quality management, and external quality assessment (EQA) is one of the most commonly employed assessment tools for clinical laboratories. Proficiency testing is a process whereby an external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analysed, compared and reported to the participating laboratories. This is the most common type of EQA employed by medical laboratories as it efficiently addresses multiple laboratory methods (1,2).

An EQA programme provides valuable information to the participating laboratory. It allows comparison of performance and results among different test sites, provides early warning for systematic problems associated with kits or operations, provides objective evidence of testing quality, indicates areas that require improvement, and identifies training needs. EQA helps to ensure customers, such as physicians, patients and health authorities, that the laboratory can produce reliable results. Individual laboratories can use EQA to identify problems in laboratory practices, allowing for appropriate corrective action. EQA participation will help to evaluate reliability of methods, materials and equipment, as well as evaluate and monitor training impact (1).

International standards organisations recognise the importance of proficiency testing and EQA. ISO/IEC 17043:2010 quote that "*Proficiency testing schemes are inter-laboratory comparisons that are organised regularly to assess the performance of analytical laboratories and the competence of the analytical personnel*" (1,2,3). The Clinical and Laboratory Standards Institute define EQA as: "*A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value and reported to the participating laboratories and others"* (1,2,4).

The PPTC External Quality Assessment Programme (PPTC-EQAP) commenced in 1985 as an evaluation process of students attending residential courses. This was enhanced when the PPTC was conferred collaborating centre status by the World Health Organization (WHO) in 1990. The PPTC is now the main EQA provider to medical laboratories in the Pacific region. Pacific laboratories differ considerably in the levels of instrumentation, equipment, methodology, and expertise available to them and thus the evaluations of the responses received from them must recognise these different levels of technology (1).

The major purpose of this programme is to actively assist and suggest ways in which a laboratory can improve the quality of its service to the patient. The PPTC-EQAP is provided at no cost to 31 government laboratories in the Pacific Island region, and four government laboratories in the Southeast Asian region. Funding is received from the New Zealand Ministry of Foreign Affairs & Trade (NZAID) for the provision of this programme. Furthermore, private registration of laboratories is welcomed at a nominal cost. Further support is provided to the PPTC's EQAP by the New Zealand Institute of Medical Laboratory Science (NZIMLS), Royal College of Pathologists of Australasia Quality Assurance Programs (RCPA-QAP - Sydney, Australia), Wellington Southern Community Laboratories (WSCL - Wellington Hospital, NZ), Canterbury Health Laboratories (CHL - Christchurch Hospital, NZ), New Zealand Blood Services (NZBS - Wellington and Christchurch, NZ), Whangarei Hospital, LabPLUS (Auckland Hospital, Auckland, NZ) and Institute of Environmental Science and Research – (ESR - Wellington, NZ).

MATERIALS AND METHODS

All laboratories are required to complete an EQA enrolment form for each dispatch year, providing information on the programmes they wish to enrol for, and the updated shipping and contact details for key laboratory personnel. The dispatch schedule for each year is discussed in the annual EQA consultants meeting held at the PPTC at the beginning of each year, and this schedule is shared with all participants once they have completed the enrolment form.

The PPTC EQA programme includes seven panels in the medical pathology disciplines of anatomical pathology, biochemistry, blood bank, haematology, microbiology, molecular SARS–CoV-2 and serology. Samples for each survey are dispatched from Wellington, in lyophilised form or as a whole specimen, following the IATA shipping of biological substances guidelines. All disciplines are delivered over three cycles except for Biochemistry which consists of two cycles with four analyses (1).

The PPTC EQAP is managed by the PPTC's Programme Manager, Navin Karan, through assistance from Filipo Faiga, Biochemistry Technical Specialist.

Disciplines in the PPTC EQA programme

The anatomical pathology panel consists of four to six unstained tissue biopsies mounted on microscopic slides from cases common to the Pacific region. The participating laboratories are required to perform haematoxylin and eosin (H&E) stain on the slides, and report back on target diagnosis, grade, stage of tumour/ disease, and adverse factors. The slides are prepared at Whangarei Hospital and sent to the PPTC for relabelling and preparation for dispatch. The anatomical pathology consultant is Dr Vladimir Osipov, Anatomical Pathologist, Whangarei Hospital, Northland District Health Board.

The biochemistry panel offers testing for general chemistry analytes and HbA1C. Each general chemistry panel contains four lyophilised serum samples. The first lot of the samples are to be analysed immediately on receipt and the second lot of samples are to be analysed one month later. The HbA1C panel includes three lyophilised whole blood samples. The samples used for this panel are donated by the RCPA-QAP. The biochemistry consultant is Mr Filipo Faiga, PPTC Biochemistry Technical Specialist.

The haematology panel consists of three stained blood films. Participating laboratories are required to perform a differential count as well as identify and interpret WBC, RBC and platelet population abnormalities with the suggestion of a most probable diagnosis where possible. From time to time, blood films are replaced by a selection of photomicrographs from which participants will be required to answer a series of questions relating to the cell populations presented. Patient samples are obtained from the WSCL and LabPLUS, Auckland Hospital, and staining and preparation of slides are performed at the PPTC. The haematology consultants are Mr Philip Wakem, PPTC CEO and Haematology Specialist and Ms Elizabeth Tough, Haematology Specialist/Senior Morphologist and retired senior Medical Laboratory Scientist.

The microbiology panel consists of three pathogenic organisms for identification and antimicrobial susceptibility testing. A range of both Gram-positive and Gram-negative organisms are included and on occasion a more fastidious organism is included. Cultures are either lyophilised or sent on solid media. A parasitology case study with pictogram is included with each survey. On occasion mixed cultures, samples requiring urine cell count, and Gram stains may be included as sample types. The bacterial cultures are prepared at the microbiology laboratory, WSCL or are donated by the RCPA-QAP. The PPTC prepares and performs in-house lyophilisation of cultures in multiple transportation vials, and these are prepared for dispatch and testing by the participating laboratories. Consultant for the Microbiology programme is Ms Nicky Beamish, senior Medical Scientist, WSCL.

The molecular SARS–CoV-2 panel consists of three heat deactivated nasopharyngeal samples in VTM from anonymised potential positive COVID-19 patients, supplied by ESR-NZ. Each sample has a reproducible Ct value within a range of moderate to weak positive Ct values. The QC material must go through an extraction process, similar to patient samples. Samples are suitable to use with open RT PCR platforms and with the other point of care RT-PCR technology, such as Gene Xpert/ Biofire analysers. Stability testing is carried out by ESR for each sample prior to dispatch. Samples used for the molecular COVID-19 rounds are also sent to 28 IS015189 accredited laboratories in New Zealand as part of the ESR's New Zealand SARS-CoV-2 EQAP. Results generated from the Pacific cohort are compared to those from New Zealand accredited laboratories for validation purposes only. All results from the participants are shared with ESR for marking and report generation.

The transfusion science/ blood bank panel consists of blood and plasma from a 'recipient' and three samples of red cells from possible 'donors'. Blood products (donated by the NZBS) are used in the preparation of the samples. The participants are required to carry out blood grouping (ABO and Rh), antibody screening on each sample, and cross match the donor's samples with those of the patients. From time-to-time antibodies are included to ensure some donors are incompatible. Initial sample selection is carried out at the Wellington blood bank, which are then aliquoted into smaller volumes and prepared for dispatch and testing. The blood bank consultant is Mr Dan Gyles, Team Leader and Medical Scientist, Wellington blood bank, NZBS.

The serology or infectious diseases panel consists of seven serum samples per cycle. Target infectious diseases include HIV, Hepatitis B, Hepatitis C, Syphilis and Dengue. Expired plasma blood products (donated by NZBS) are spiked with patient samples positive for the target agent. These are prepared at CHL and sent in bulk to the PPTC where they are aliquoted into smaller volumes and prepared for dispatch and testing by the participating laboratories. The PPTC Consultant for the Serology programme is Ms Donna Mitchell, senior Medical Scientist, CHL.

Participating laboratories are given five weeks to process the samples and return their results to the centre. Results are submitted to the PPTC via email on a respective worksheet provided for each discipline. Sample selection, bulk preparation, testing and development of referee reports, and formalisation of the final reports are carried out by individual PPTC contracted consultants (senior registered New Zealand medical laboratory scientists and a pathologist) who are specialists in their selected discipline. A referee's report (reference results are developed from test results reported by ISO 15189 accredited laboratories in New Zealand. For biochemistry, RCPA-QAP validated results are used) is provided with the correct answers to all laboratories enrolled in each of the respective disciplines immediately after the due date to encourage corrective action. Results received from each participant are evaluated by the appropriate PPTC consultant, and a final report is prepared. Laboratories who have not participated are encouraged to use the referees report to undertake corrective action. Each laboratory is identified by a unique code number and their generated results are kept confidential by the PPTC, the WHO regional adviser of health laboratories at the regional office in Manila, and the relevant department at the NZ Ministry of Foreign Affairs and Trade in Wellington.

RESULTS

This year (2021), there are 86 laboratories from 22 countries participating in all or part of the PPTC EQA programme. The New Zealand Government, through the Ministry of Foreign Affairs and Trade (NZ-MFAT), provides funding to the PPTC to deliver the EQA programme at no cost to 31 government owned and operated laboratories in 17 countries, while the rest of the laboratories are privately enrolled through their own funding or through donor partner funding (1,6,7).

Table 1. Laboratories per country along with their appropriate funding sources for EQA.

Country	Number of laboratories	Funding source
South and North Pacific Region		
American Samoa	1	MFAT
Cook Islands	1	MFAT
Federated States of Micronesia	4	MFAT
Fiji	9	4 MFAT, 5 Self-funded
Kiribati	2	MFAT
Marshall Islands	2	MFAT
Nauru	1	MFAT
Niue	1	MFAT
Palau	1	MFAT
Papua New Guinea	2	1 MFAT, 1 Self-funded
Samoa	2	MFAT
Solomon Islands	3	MFAT
Tonga	2	MFAT
Tuvalu	1	MFAT
Vanuatu	3	2 MFAT, 1 Self-funded
Wallis and Futuna	1	MFAT
Tokelau	1	MFAT
Asia Pacific Region		
Bhutan	3	1 PPTC, 2 Self-funded
Cambodia	40	Self-funded
Laos	3	PPTC
Maldives	1	Self-funded
Timor Leste	2	PPTC

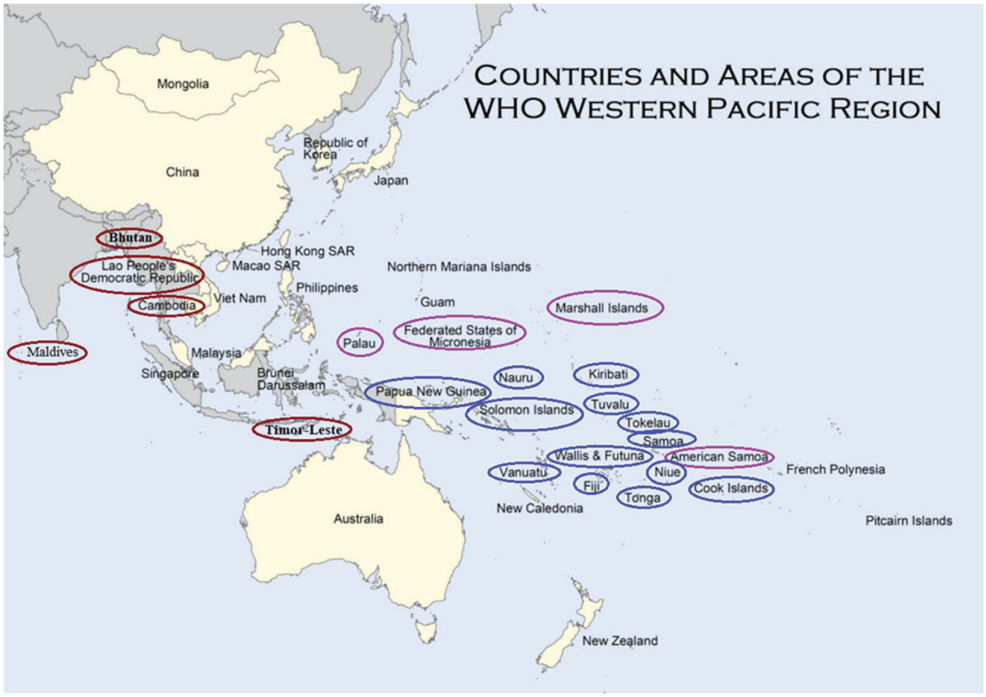


Figure 1. Geographical distribution (WHO Western Pacific Region map, 2009) of Asia-Pacific nations registered on the PPTC REQAP.

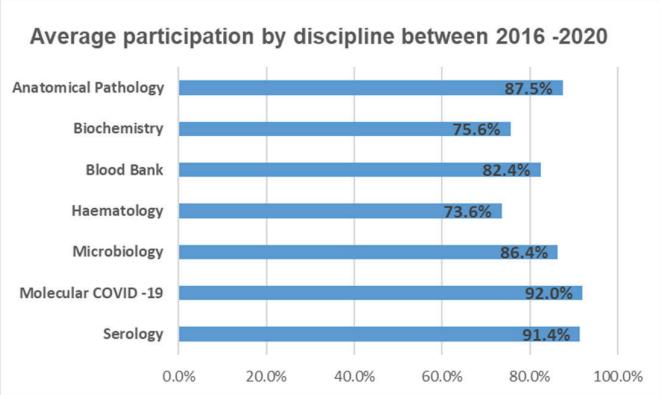
Participation

Most laboratories who enrol in the PPTC EQA programme recognise the importance of participating in it. As the Pacific countries progress in the implementation of ISO 15189 standard, there has been a greater awareness of the EQA programme in recent years. The following tables and graphs demonstrate the participation rates and performance rates of all participants in the Pacific region over the last five years. The results displayed represent all laboratories registered in the PPTC's REQA programme including those funded by the New Zealand Government and supported by the PPTC (1,6,7).

Table 2. Participation achieved in each discipline per year (2016-2020).

Participation rates – 2016-2020					
	2016	2017	2018	2019	2020
Anatomical pathology	-	-	-	94%	81%
Biochemistry	70%	67%	88%	86%	67%
Blood bank	79%	84%	90%	87%	72%
Haematology	75%	73%	76%	81%	63%
Microbiology	82%	82%	91%	93%	84%
Molecular COVID-19	-	-	-	-	92%
Serology	84%	95%	93%	91%	94%

The above table indicates an 11% (across discipline average 78%) improvement in participation when comparing 2016 (78%) to 2019 (89%). Participation dropped down to 10% in 2020 (79%) from 2019 (89%) due to the challenges brought by COVID-19 (6, 7).



Graph 1. Five-year average participation by discipline between 2016 -2020.

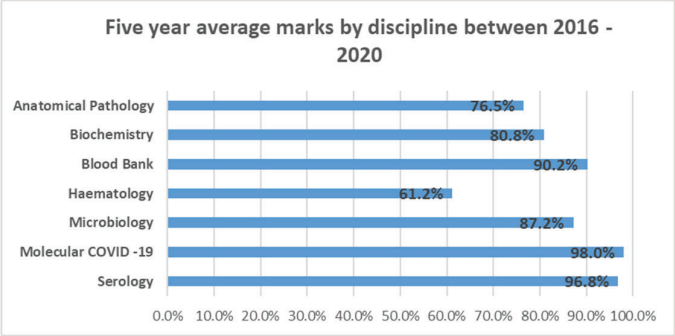
The average participation is now sitting at 84% average. The PPTC continues to email constant reminders to the laboratories to participate. Some of the reasons cited by non-participating laboratories include the availability of reagents, analyser malfunction/ breakdown and human resource issues.

Performance

Variation of marks achieved over the five years across all laboratories shows little significance except for haematology (Table 3 and Graph 2).

Table 3. Marks achieved by discipline per year (2016-2020).

Performance rates – 2016-2020					
	2016	2017	2018	2019	2020
Anatomical pathology	-	-	-	77%	76%
Biochemistry	81%	79%	81%	75%	88%
Blood bank	91%	93%	93%	91%	83%
Haematology	75%	65%	55%	55%	56%
Microbiology	88%	88%	88%	87%	85%
Molecular COVID -19	-	-	-	-	98%
Serology	96%	98%	97%	97%	96%



Graph 2. Five-year average mark achieved by discipline between 2016 -2020.

Where performance is concerned, average data over the past five years indicate that all laboratories tend to perform well in molecular (98%) followed by serology (97%), blood bank (90%), microbiology (87%), biochemistry (81%), while anatomical pathology (77%) and haematology (61%) display poor performances (6,7).

Performance in haematology

Haematology continues to be weak in performance and this is due to a devastating lack of expertise and interpretative skill in blood film examination and interpretation throughout the Pacific. The PPTC offers a six-week training course each year at its centre in Wellington but can educate students only to a certain level given such a limited time frame. Blood cell identification and interpretation is a continual learning process and unfortunately Pacific Island laboratories do not have resident experts who are able to mentor and add to this learning experience (6,7).

A comprehensive knowledge (theory and practice) of both normal haematology and pathological haematology is a building process and excellence in proficiency can take several years to achieve. The PPTC recognises that long term New Zealand consultancy attachments in the Pacific would be of enormous benefit but would require extensive financial resource which unfortunately, taking into consideration PPTC's current budget, is not a reality at this time. It is hoped that in the future, a PPTC facilitated haematology strengthening programme could be developed for the Pacific, which would enable New Zealand consultants to be attached for up to six months to Pacific laboratories where comprehensive teaching and training could be offered, and skills development could be made in blood film interpretation and diagnosis (6,7).

To continue haematology strengthening in the Pacific within the realms of its financial capability, the PPTC, in addition to its on-site training commitment, introduced to Pacific Laboratories in 2018 a change in the assessment of haematology EQA. The marking schedule was reviewed by the PPTC resulting in higher expectations in terms of excellence in laboratory practice. The marking criteria is more critical and less accommodating when compared to previous years and aligned more closely to current international standards of reporting. This can be challenging, as reflected in haematology average scores for both 2018 and 2019, but with PPTC's guidance and support, laboratories accept the challenge and strive for higher quality in the results that are presented (6,7). Furthermore, since 2020 the PPTC's Haematology Specialist provides a regular remote online teaching session for the Pacific Island laboratories on morphology and cell population recognition.

Performance in anatomical pathology

There is an overwhelming deficiency of specialist and general pathologists in the Pacific region, and this has been an unresolved issue for many years. Junior pathologists who are employed in Pacific laboratories often do not have the support or ongoing mentorship essential for their individual professional development and this is reflected in their lack of cellular recognition, identification of disease patterns, and interpretative expertise. This can result in prolonged illness, misdiagnosis, and mismanagement of treatment (6,7).

In 2021, the PPTC is introducing a Motic automatic slide scanner with tele-pathology capability in Tonga, Solomon Islands, and Vanuatu. The PPTC is also working with pathologists in New Zealand to form a functional pathology working group to provide a tele-referral service to these countries. This will develop in an extensive teaching and upskilling opportunity for the junior pathologists currently working the Pacific region.

Performance in biochemistry

For biochemistry there can be a general lack of equipment maintenance (including annual preventative maintenance programmes) and assay reagents are not regularly checked and calibration that is often overlooked. Moreover, insufficient operator and troubleshooting training is provided to staff which further compromises assay performances and patient results. Regular review of the internal quality control is encouraged through the EQA programme (6,7).

To address the deficiencies in biochemistry, the PPTC's Biochemistry Technical Specialist provides remote online training workshops addressing quality control, calibration, and troubleshooting guidelines. When approached by the countries the PPTC provides analyser selection advice as well to ensure the most appropriate analysers are purchased by laboratories.

Performance in microbiology

In microbiology organism identification and antimicrobial susceptibility testing (AST) interpretation can be challenging for some laboratories. Limitations in AST is the lack of knowledge and understanding of intrinsic resistance versus in vitro test results, the use of correct disc concentrations, and the application of disc diffusion versus MIC testing. As with other programmes the use of in-date reagents and consumables and performing regular internal quality control is encouraged (6,7).

Performance in blood bank and serology

In blood bank and serology expired kits may be infrequently used and internal quality control on occasion is overlooked. The participating laboratories are encouraged to implement an expired kit/reagent policy in the laboratory stating that routine testing should not be performed on expired reagents/kits. A procurement strategy to ensure in-date kits are available for routine testing is also recommended (6,7).

Performance in molecular COVID-19 testing

Both participation rates and performance rates overall can be considered to be excellent since the programme's implementation in 2020. Lack of participation or a delay in returning results, if it does occur, can usually be attributed to delays or failure in the delivery of samples. This can be caused by long transit times and courier disruptions as a direct result of the current pandemic (6,7).

At the end of each year, participating laboratories are provided with individualised, discipline specific annual reports with recommendations for improvement. A summary report is also presented to the Ministry of Health and hospital administrators for their information (1).

CONCLUSIONS

Through the financial support of the New Zealand Government, and support from the NZIMLS, RCPA-QAP, WSCL - Wellington Hospital, CHL - Christchurch Hospital, NZBS - Wellington and Christchurch, Whangarei Hospital, LabPLUS - Auckland Hospital, and ESR, Wellington the PPTC has been able to provide a free external quality assurance programme for government operated medical laboratories in the South Pacific region. As the Pacific countries progress in the implementation of ISO 15189 standards and work their way towards accreditation, awareness has improved in recent years in the importance of participating in a proficiency testing programme. Furthermore, performances have improved in all disciplines as quality standards are improved. It is hoped that participation and performances in the poor performing disciplines will also improve as the PPTC continues to offer professional development opportunities for the Asia-Pacific region through its distance taught Diploma programme, discipline specific centre based (Wellington) short term courses, remote online teaching, and through in country training visits.

ACKNOWLEDGEMENTS

The PPTC would like to take this opportunity to thank all the participating laboratories who continue to seek excellence in their performances to improve patient outcomes, the donor agencies, supporters, and friends of the PPTC in the provision of this programme to the developing nations.

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