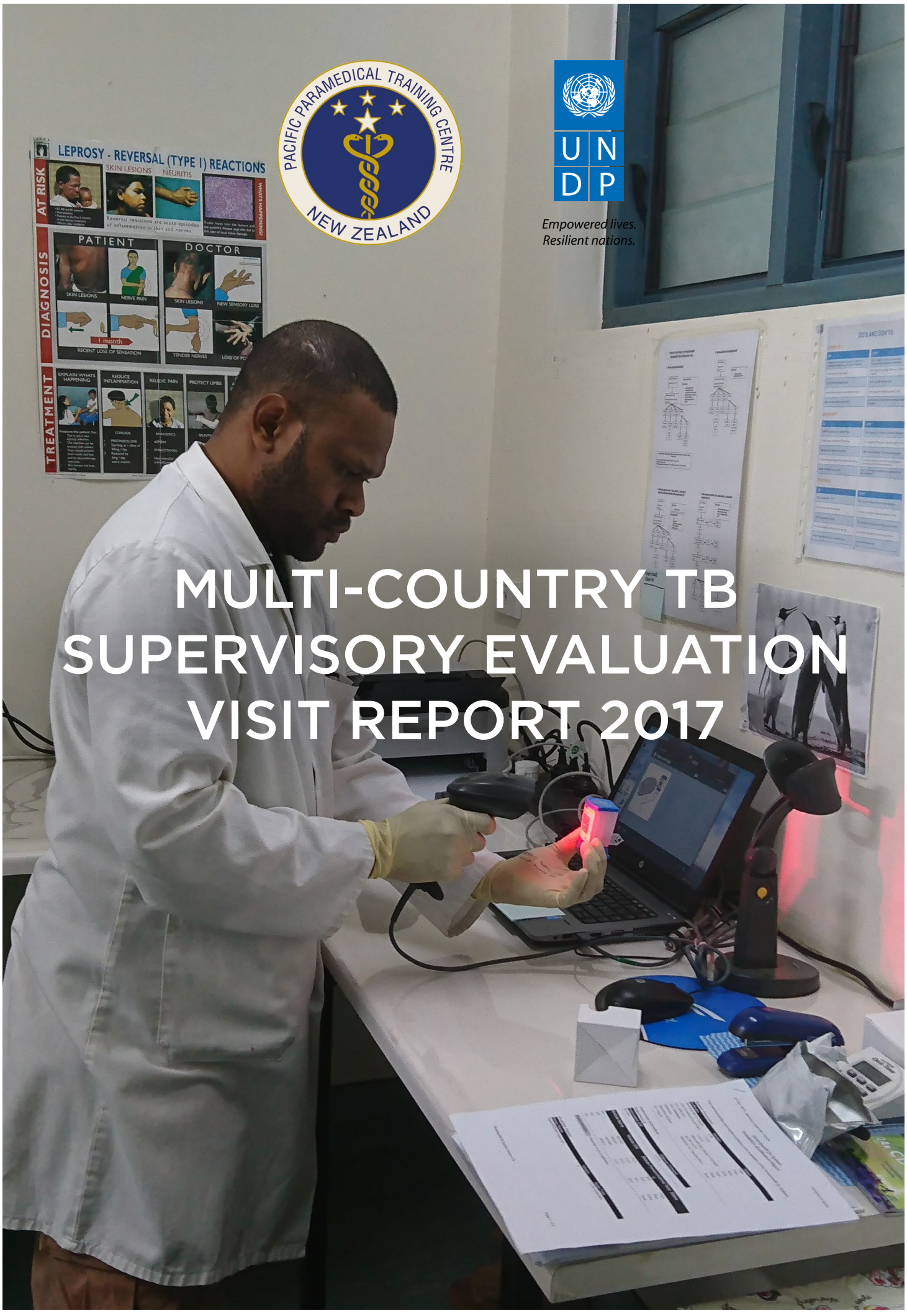

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MULTI-COUNTRY TB SUPERVISORY EVALUATION VISIT REPORT 2017

Proposed citation:

UNDP, PPTC (2017). *Multi-Country TB Supervisory Evaluation Visit Report 2017*.

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This document was supported by UNDP under the Multi-Country Western Pacific Programme (###).

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MULTI-COUNTRY TB SUPERVISORY EVALUATION VISIT REPORT 2017

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Contents

Introduction

Western Pacific Multi-country Integrated HIV/TB Programme funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) and implemented by the United Nations Development Programme (UNDP) provides support to improve and maintain quality of TB laboratory services in the Pacific Island Countries (PIC's) through external quality assessment (EQA). This activity is to achieve a larger goal to promote universal and equitable access to quality diagnosis and appropriate treatment of TB, MDR-TB, TB/DM and TB/HIV patients across 11 Pacific Island Countries (PIC). EQA is understood as a combination of three major elements:

- On-site (in-country) evaluations
- Blinded smear rechecking,
- Panel tests

For the purposes of the contract between UNDP and the Pacific Paramedical Training Centre (PPTC) (PO: FJI10-0000038673), National laboratories performing TB testing (smear and GeneXpert) in 8 PIC's (Cook Islands, Kiribati, Nauru, Niue, Samoa, Tonga, Tuvalu and Vanuatu) were included to provide on-site supervisory evaluation visits. On-site evaluation has been defined as a combination of supportive supervision and hands-on training for the laboratory staff, and serves to guide and assist countries in providing enhanced and effective laboratory services for the national TB programmes.

Terms of Reference

As per the UNDP contract for external quality assessment in-country evaluation visit, the terms of reference (TOR's) were as follows:

- To review and assess existing laboratory facilities;
- To assess current staffing situation, also to assess knowledge and qualifications of the laboratory personnel;
- To review technical conduct of specimen processing and use of safe working practices;
- To review consumables and reagents inventory, processes for ordering and receiving of supplies;
- To review preparation and storage of in-house prepared reagents;
- To review management of infectious and laboratory waste;
- To review present EQA principles and advise revisions as per the newer recommendations if necessary; also with regards to efficiency/suitability/need to continue blinded smear rechecking and panel testing as EQA elements for the particular laboratory;
- To discuss ways and means of increasing sample numbers tested in the laboratory;
- To provide immediate advice and on-site coaching whenever possible in the areas where gaps were identified;
- To prepare the evaluation report and action plan to address any quality issues identified during the visit.

Cook Islands TB Supervisory Evaluation Visit Report

Background

The PPTC has worked with the Rarotonga Hospital laboratory since the 1980's in the capacity of strengthening medical laboratory services and providing specialised training in the various disciplines of medical laboratory sciences, either in-country or at the PPTC centre in Wellington. Since 1990, the PPTC has and continues to provide an EQA programme for Microbiology, Serology, Transfusion Science, Haematology and Biochemistry to the Medical Laboratory Department. Rarotonga Hospital laboratory technicians have participated in the distance taught PPTC Diploma in Medical Laboratory Sciences programme in the past, with five diploma graduates, who completed their studies in 2009.

This visit was specifically for TB technical support and assistance. The previous EQA TB assessment and training of the laboratory staff was carried out by LabPLUS TB staff – Mr Ross Vaughan and Ms Sandie Newtown. LabPLUS, Auckland is the TB laboratory's reference centre for all direct antibiotic susceptibility testing (DST), blind smear rechecking, and panel tests. Rarotonga Hospital is covered under the long term agreement with UNDP global fund programme.

Cook Islands' current enumerated population is estimated to be 17,794. There is a low incidence rates of TB amongst indigenous population in the Cook Islands. The high risk TB group is from migrant workers and expats from high TB burden countries i.e. Philippines, Kiribati, Tuvalu and Fiji. Between 2011 and 2016, a total of 113 patients were tested for TB by the hospital microbiology section, with four (4%) positive cases, one of which was a MDR case (1%). Majority of the specimens received for processing at the laboratory is from the Rarotonga hospital, followed by samples received from 13 health clinics present on outer islands.

Executive Summary

This onsite TB EQA evaluation visit was successful in enhancing specific technical support and assistance to the microbiology laboratory at the Rarotonga hospital. It was very timely and well appreciated by the public health and the laboratory staff for an external review for their processes and the training opportunity which came with it.

All TB investigations are carried out by the Microbiology section, which has two permanent staff members. The microbiology section operates well and has well qualified and experienced staff. All AFB smears is processed by the laboratory and positive sample is referred to LabPlus for confirmation, culture and sensitivities. The week long workshop had four participants which included the 2 permanent microbiology staff, 1 new graduate trainee and the public health TB focal point. Unfortunately the HOD had fallen ill half way through the week, but the rest of the staff participated in the week long training. Presentation on sample quality, collection procedures were delivered to the nursing staff at the hospital and to the public health staff at the community health services. A presentation was also given on the capabilities of the GeneXpert to the clinician staff during the hospital plate round.

Strengthening of the TB EQA programme was the main focus of this visit, and an annual work plan was created as a guide for when each EQA programme participation were due. Participation in the TB EQA programme has had an obvious gap in the last two years, with the EQA processes being largely ignored by the staff.

The AFB staining procedures were reviewed and refresher training was provided to the staff. Importance on continuous monitoring of the quality of slides has been encouraged, and the need to filter the stains regularly as well. Work was also carried out on developing and outlining the standard operating procedures for this section, with a number of documents being drafted and printed. Outline of other documents which were not prepared was given

to the section for further amendments. Turnaround time is variable depending on work load and results can take up to 72 hours before being released by the section, and this needs to be improved on. A few recommendations have been made in this report to avoid any interruption in the provision of services.

The TB EQA evaluation visit was timely and all the objectives and TOR's were met for this visit and these are discussed in detail in this report.

Activities

The week long TB EQA evaluation visit was carried out from Monday 8 May till Friday 12 May. The agenda for this visit is attached as annex 1. The subheadings below address each of the terms of reference outlined earlier. An audit was carried out using WHO DOTS programme "on-site evaluation report checklist" [Annex 2] and the laboratory was requested to complete the self-assessment checklist. [Annex 3].

Laboratory Facilities

All TB testing is carried out as part of the Microbiology section in the main medical laboratory department of the hospital. The microbiology section is allocated enough space for its operation and all specimens received for TB testing is processed as per other diagnostic specimens received by this section. This section is well organised with areas allocated to various stages of laboratory investigation for clinical specimens, from specimen receipt and registration to specimen processing and preparation, culture and smear/ slide preparation to microscopy. There are two ventilation fans units installed on the exterior wall at the back of the laboratory, near the staining sink and smear preparation area. This section has adequate air conditioning as well.

An equipment inventory for the Microbiology section was created and is attached as annex 4. All laboratory equipment's need to undergo annual electrical checks from a service engineers based at the hospitals maintenance unit. There is adequate backup power via generator available for the whole hospital including the laboratory.

The sink level for staining is adequate and there is a slide rack available for staining procedures, and spirit burner is used for heat fixing slides and for heating the slide during the staining procedure for AFB.

The section has an excellent microscope setup for all microbiology microscopy work. This Olympus CX41 microscope is dark field, phase contrast, bright field microscope with 4x, 10x, 20x, 40x and 100x objectives and was purchased by the global fund TB programme in April 2015. The microscope is kept in a clean condition, and protected from dust when not in use. A maintenance log for the microscope was created and shared with staff. The setup is ergonomical and a height adjustable chair is available for the user. The microscope was cleaned and serviced during this visit, and staff were shown how to carry out preventative maintenance, and how to set up kolher illumination. Microscope maintenance log was created and shared with the staff. A cleaning kit, including lens cleaning solution, lint free tissues and a brush has been left with the laboratory for future use.

The biological safety cabinet class II (Vokes AES environmental PTY LTD) is not operational and needs servicing. It has not been certified and fumigated since its installation – 19 March 2002. This needs to be addressed immediately by the laboratory management.

Following recommendations are made under this section:

- Maintenance log for the microscope to be implemented and used.
- Biological safety cabinet to be serviced and certified for use.
- Electrical check to be organised at an annual interval for all equipment.
- Purchase of printer ink cartridges (no black toner available for the Canon PIXMA MG2260) for printing of quarterly workloads and request forms when required.

Laboratory Personnel

The microbiology section of the medical laboratory has two personnel Mr Geoffrey Wuatai (head of section) and Ms Peia Ben (staff scientist). Both are qualified with a diploma in medical laboratory sciences. Geoffrey is responsible for performing TB sputum samples and AFB smear preparation and reading. On occasion and during Geoffrey's absence, Peia will assist in processing specimens for TB investigations. Ms Eva Vakalalabure, a recent graduate from the Fiji National University has joined the workforce in early 2017 and will be on rotation through the microbiology section in the near future. She participated in the week long workshop. Staff list and their qualifications are included as annex 5.

Staff training and competency log [annex 6] was introduced, and all tasks were taken through for the TB investigation. This must be used for any future training of staff and to assess competency of current staff.

The laboratory has a general microbiology SOP's outlining all procedures performed in this section. The ZN smear preparation and smear reading section needs an immediate update, as the reading criteria is out of date and the staining procedure outlines the previously recommended reporting guidelines. The SOP outline on creating a separate TB procedures manual was discussed and shared with the staff, and electronic copies was provided to Douglas to place on the shared files for the microbiology section to access. Some documents were printed and included in a newly created SOP folder.

The following recommendations are for this section:

- Ensure completion of SOP's for processing sputum samples using the templates provided.
- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training.
- Complete the staff competency log for current staff members.

Specimen Processing and Health and Safety

Test requests are ordered electronically via the hospital MedTech32 information system which the laboratory staff have access to. A form is generated by the ordering physician and the laboratory will receipt the sample onto MedTech. A episode number is assigned to the specimens at this stage at the reception area, and the samples are delivered to the microbiology section for processing.

All samples received in the microbiology section are then processed as per routine testing. The samples are processed and results are recorded in the printed test request form. Once the testing has been completed and the results finalised, it gets recorded on the section register, and gets entered into the MedTech and reported to the clinician. The patient result register is now kept electronically on an excel file, where all microbiology test results are recorded. The excel workbook captures the following information for TB: Date of receipt, lab number, patient's TB No., month, date specimen collected, date of specimen tested, description of sputum, name of patient, sex, age, name of treatment unit, reason for examination (diagnose/follow-up), AFB result, positive AFB control result, mantoux test result, HIV test result, culture result for positive samples referred for culture (including sensitivities), and date reported and a comments column. The electronic register captures information as per WHO guidelines.

A separate "laboratory sputum form for TB investigation" may be used by the laboratory to capture patient information and test results for reporting to requestors. This form needs to be modified slightly, with only two columns to be allocated for result for the 2 sputum samples (not three), and the grading system needs to be changed for the reporting of scanty AFB seen to "recording the exact number of AFB count).

Majority of the specimens received for processing at the laboratory is from the Rarotonga hospital, followed by samples received from 13 health clinics present on outer islands – Aitutaki, Mangaia, Atiu, Mauke, Mitiaro, Palmerston, Penrhyn (2 clinics), Manihiki (2 clinics), Pukapuka, Nassau and one clinic on Rarotonga. Turnaround time (TAT) is variable depending on work load and results can take to 72 hours before being released by the section. It is strongly recommended that the TAT is improved on, reducing the TAT to 24-48 hours. All positive results are phoned through to the requesting clinician and the public health team will be informed as well for follow up on treatment.

Handwashing basin, and soap is available in this section. Adequate PPE's including face masks, correct size gloves and laboratory coats are available. Health and safety audit was carried out for the laboratory using the WHO LQMS Handbook guide checklist [Annex 8]. 70% alcohol is used as disinfection. Bleach is also used as a disinfectant, and staff were advised on how to achieve a 1% concentration of chlorine solution to use as disinfection solution, which must be prepared fresh every second day. Staff were reminded to have a fresh working solution of bleach.

Mantoux testing has always been offered as test by the laboratory. The laboratory management and the public health team has been recommended to offer this test to staff working with TB cases on a regular basis as part of the health risk screening programme for employee's.

Recommendations include:

- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant area's such as fire/ safety drills, storage of chemicals etc. [Annex 8].
- Prepare fresh working chlorine solution for disinfectant use with cleaning up specimen spills and for cleaning bench as per discussions.
- Wear correct PPE, closed footwear and gloves when performing diagnostic tests.
- Public health to establish protocols and procedures for Mantoux tuberculin test for staff working with TB cases.
- Improve the turnaround times due to the nature of the TB infection and the threat it has on a patient's life and spread.
- Microbiology staff need refresher training in reading AFB slides. More training sessions and time must be allocated.

Consumables and Reagents Inventory and Ordering/Receiving of Supplies

The laboratory has an excellent procurement system in place for all laboratory consumables and reagents. Each section is required to carry out their own stock take at the end of each month and provide this data to the laboratory manager who then places the order with various suppliers in New Zealand. Most of the microbiology consumables and test reagents are purchased from Fort Richard, and supplies are delivered to the hospital within 2 weeks of placing an order.

All the TB testing consumables are ordered through the microbiology section and the costs are met by the laboratory budget. ZN stains kits are purchased from Fort Richard (BD product). The concern is the short shelf life of the ZN stains. A new set of stains had been received by the laboratory in Feb 2017 and it expires on the 31 July 2017. It is important that the laboratory purchases reagents and stains which have longer shelf life as the usage rate is very low for this section. If the shelf life is inadequate the management must follow this up with the supplier.

Recommendations include:

- Purchase prepared ZN stains and other reagents with longer self-life.

Preparation and Storage of Reagents

The laboratory does not prepare any reagents and stains for AFB. The ZN staining kit for AFB are purchased pre made from Fort Richard, NZ. Storage is adequate, and not in use reagents are stored in closed boxes, protected from direct light.

The current set of in use stains had expired on 30 September 2015. These were almost finished, and we replaced them with the newer ZN stain in stock (expiring 31 August 2017). Staff were taken through the smear preparation and staining procedure. The panel sides received from labPLUS were stained using these new stains, including 3 patient slides. Stain deposits were still observed on these slides. Staff was taken through the filtering process, and larger funnels were purchased from a local hardware shop for this purpose. Large stain deposits were filtered out of the carbon fuchsin bottle and very small particles were filtered from the methylene blue stain. The bottles were

cleaned thoroughly and all stain deposits were washed out, before the filtered stains were poured back into them. The bottles were dated with the "filtered" date.

Positive control slides (a set of 50) was received by the laboratory from labPLUS (together with the panel tests). The microbiology section now has a large selection of unstained positive controls for use for their internal quality control (IQC). An IQC is performed with every batch, however recording of the IQC result is not consistent. Staff were reminded to record the IQC in the result register.

The following recommendations are for this section:

- Continuously monitor expiry date of the reagents.
- Monitor stain quality on a regular basis, and filter stain when required.
- Perform IQC once monthly and when new stains are opened.
- Record IQC result in the laboratory register.

Management of Infectious and Laboratory Waste

All biological wastes for the laboratory are discarded in a bin with biohazard bag liner within the section. These are then disposed of into the Bio-Hazard wheelie bin in the hall way, which is collected by hospital maintenance staff on a regular basis and incinerated. A printed and electronic copy of the WHO Tuberculosis Laboratory Biosafety Manual was shared with the laboratory for reference use. There are no recommendations under this section.

EQA Principles, Blinded Smear Rechecking and Panel Testing

The EQA principles was explained to the laboratory staff and the importance of actively participating in the EQA programme was impressed upon. Rarotonga hospital laboratory's reference laboratory is LabPLUS, Auckland Hospital, New Zealand. This arrangement is covered by the long term agreement (LTA) with the Pacific TB Laboratory Initiative (PATLAB) which provide EQA and direct laboratory support to the national TB Laboratories as a part of the Global Fund HIV/TB grant implementation in Western Pacific Region, organised by UNDP. The SOP on "using DHL for PATLAB" and the SOP for "using Long Term Agreement with PATLAB participating laboratories to provide external quality assessment (EQA) and direct laboratory support to the national TB laboratories as a part of the Global Fund HIV/TB grant implementation in Western Pacific Region" was shared with the laboratory and the public health staff (TB focal person).

LabPLUS provides the relevant EQA services to Rarotonga hospital laboratory which includes blind smear rechecking, and panel tests. The shipment with the panel slides (10) and 50 control slides has been received by the laboratory this week. The panel slides were stained by staff and the laboratory staff were encouraged to individually read the slides and record their results for comparison in the future.

Last blind smear testing was carried out in 2014 according to the filed reports, and no quarterly reports had been prepared since then as well. The quarterly report for the first quarter was prepared with Geoffrey, and he was encouraged to email this to labPLUS and also prepare and send all the slides form the first quarter for BSR (15 slides were tested from Jan to March 2017 on 8 patients). Unfortunately Geoffrey had fallen ill half way through the training workshop and he was unable to finish reading the panel tests and prepare the BSR slides, therefore I was unable to bring these to New Zealand for posting to labPLUS.

The work plan [Annex 7] incorporates the dates for BSR dispatches, and this was shared with the laboratory staff and management and with the public health. The laboratory and the public health (TB focal person) were encouraged to be in regular communication with each other, and public health was encouraged to follow up on due dates with the laboratory staff.

The public health officers and the laboratory staff were very appreciative of this timely visit and to receive an update on TB EQA processes and re training on performing AFB smears. Post assessment feedback is inserted to this report as annex 9.

Recommendations for EQA include:

- Participate in BSR, and send the blind slides to labPLUS.

- Return the panel slides to labPLUS for evaluation.
- Complete regular quarterly report for public health and labPLUS as per the agreed work plan.

Increasing Sample Numbers Tested in the Laboratory

There is a low incidence rates of TB amongst indigenous population in the Cook Islands. The high risk TB group is from migrant workers and expats on island who are from high TB burden countries i.e. Philippines, Kiribati, Tuvalu and Fiji. TB testing therefore is not a priority amongst indigenous population, and with low incidence rates, sample numbers are not high.

In 2011, 18 patients were tested for TB with 1 positive. 12 patients were tested in 2012 with one positive MDR case, 22 patients were tested in 2013 with 1 positive TB case, 33 patients were tested in 2014 (all testing negative), 10 patients were tested in 2015 (all testing negative) and 18 patients were tested in 2016 with 1 positive case.

	TB Cases	MDR Case	Total Patients Tested
2011	1	0	18
2012	1	1	12
2013	1	0	22
2014	0	0	33
2015	0	0	10
2016	1	0	18
Totals	4 (4%)	25% of all cases	113

A presentation on the background of tuberculosis and on sputum collection and quality was given to ward staff at the hospital on Monday afternoon. 14 staff attended this one hour session, with 10 nursing staff from medical, surgical, maternity, outpatients and public health units. The sputum collection procedures and sputum quality was discussed with the staff. Ms Edwina has been advised to contact the global fund UNDP team for more copies of the placards of "TB cough check – specimen collection" procedures, which can be placed in the wards and in the general specimen collection areas where TB samples are being collected to ensure good quality samples are sent to the laboratory for testing. The need to collect two sputum samples was impressed upon as well. Electronic copies of the collection procedure was shared with Edwina and the laboratory staff.

The same presentation was given to the public health team (15-20 staff) on Friday morning upon request by Edwina. This was a great opportunity to talk to the public health team who may go out in the community to carry out DOT's and collect sputum samples.

The public health team is working on increasing community awareness on TB symptoms via media and with community outreach. This will hopefully encourage the local population to seek medical care and advise when feeling unwell and when they match the symptoms of TB, which in turn will increase the number of samples received for testing by the laboratory.

Recommendations include:

- Displaying collection placards in the relevant sections of the hospital (wards and phlebotomy area).
- Continue to increase awareness of TB symptoms in the community.

Advice and On-site Coaching on Gaps Identified

The laboratory staff were taken through the week long TB evaluation workshop, which included discussions on EQA processes, TB epidemiology, performing ZN stains and filtering stains, and reading and reporting AFB smear's. Microscope maintenance and setting up kolher illumination was also demonstrated and staff were trained on both.

The current microbiology SOP was updated in 2015, and includes a section on "Acid Fast Ziel Neelson Stain". The staining procedure is outdated, and the reporting criteria needs updating as well. The "Laboratory Diagnosis of

Tuberculosis by Sputum Microscopy – The Handbook, Global Edition 2013" was used as the reference guide, and staff were advised to update the current SOP's and develop additional documents outlining the EQA processes.

Outline of a number of TB SOP documents have been shared with the laboratory and all documents drafted for the laboratory was given to staff on a USB drive, which were uploaded on the laboratory shared drive. The documents were created in accordance with the ISO 15189 medical laboratory international standards. A table of contents was created for this SOP manual and for those documents which were not drafted, template examples were given electronically for adaptation into the laboratory's own documents. Timeline was established for the completion of the SOP's and the PPTC will be able to guide the laboratory and provide remote assistance in its development. The action plan [annex 7] outlines the timeframe allocated to SOP development.

Another presentation was delivered to the clinicians and ward staff during their plate round meeting on Wednesday at the hospital. The laboratory manager and the TB focal point had requested a presentation to be made to hospital staff on the GeneXpert technology. The advantages of having such technology on island was explained, and the testing algorithm explained to all. A cost analysis must be carried out if Rarotonga was to acquire a GeneXpert for TB testing. Given the current rates of TB on island, additional parameters must be tested on the GeneXpert (such as chlamydia/ gonorrhoea etc.) to make it a viable option for MTB/RIF testing.

The laboratory staffing appears to be adequate, however with electronic entry of all reports and data, the Microbiology section may warrant a 0.5 of a full time employee. E person to assist the current staff and act as backup for when staff are on leave. Furthermore, diligence is required from the staff to achieve the laboratories quality goals. The EQA programmes needs to be addressed and better compliance must be demonstrated by the laboratory for all the EQA processes.

Challenges faced with Specimens

The laboratory processed 40 sputum samples since 2016, of which 15% (or 6) samples were salivary. Majority (50%) of the specimens received for TB investigations are purulent and mucoid, with the rest being mucopurulent, bloodstained etc. Therefore it can be said that the quality of samples have been reasonably good. The nursing staff however need to be reminded on the specimen requirements, and on good quality collection protocols as mentioned earlier. Specimen acceptance and rejection criteria has been created to implement rejection of samples guidelines as per TB handbook.

Recommendations include:

- Continuously educate collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Implementation of the specimen acceptance and rejection criteria, and making the collection staff aware of this policy. – this criteria can be modified to incorporate all of the specimen types received for laboratory tests.

Summary

The summary of all recommendations are listed below. The laboratory staff together with the public health staff must modify the current work plan to incorporate the recommendations listed in this report. The key recommendations include:

- Maintenance log for the Microscope to be implemented and used.
- Biological Safety Cabinet to be serviced and certified for use.
- Electrical check to be organised at an annual interval for all equipment.
- Purchase of printer ink cartridges (no black toner available for the Canon PIXMA MG2260) for printing of quarterly workloads and request forms when required.
- Ensure completion of SOP's for processing sputum samples using the templates provided.
- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training and complete the log for current staff members.

- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant areas such as fire/ safety drills, storage of chemicals etc. [Annex 8].
- Prepare fresh working chlorine solution for disinfectant use with cleaning up specimen spills and for cleaning bench as per discussions.
- Wear correct PPE, closed footwear and gloves when performing diagnostic tests.
- Public health to establish protocols and procedures for Mantoux tuberculin test for staff working with TB cases.
- Improve the turnaround times due to the nature of the TB infection and the threat it has on a patient's life.
- Microbiology staff need refresher training in reading AFB slides. More training sessions and time must be allocated for refresher training.
- Purchase prepared ZN stains and other reagents with longer self-life.
- Continuously monitor expiry date of the reagents, and monitor stain quality on a regular basis, filtering stain when required.
- Perform IQC once monthly and when new stains are opened and record IQC result in the laboratory register.
- Participate in BSR by sending the blind slides to labPLUS.
- Return the panel slides to labPLUS for evaluation.
- Complete regular quarterly report for public health and labPLUS as per the agreed work plan.
- Displaying collection placards in the relevant sections of the hospital (wards and phlebotomy area).
- Continue to increase awareness of TB symptoms in the community.
- Continuously educate collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Implementation of the specimen acceptance and rejection criteria, and making the collection staff aware of this policy.

Conclusion

The laboratory is well designed and organised. Stock supplies are ordered well in advance and there is adequate stock for all consumables. Staffing appears to be adequate, however with electronic entry of all reports and data, the Microbiology section may warrant a 0.5FTE person to assist the current staff and act as backup for technical staff when the permanent staff are on leave. Some key recommendations needs to be addressed as discussed in this report and the laboratory must continue to participate in the EQA programmes for TB investigations.

I am confident that once the above recommendations have been actioned by the microbiology section, the laboratory can confidently request for an external audit to gauge it's pathway to vertical accreditation for TB testing in the near future.

Acknowledgments

My sincere thanks to the staff at the Rarotonga Hospital laboratory staff, the public health TB focal point, and the UNDP GF Programme Management staff, for your valuable contributions and hospitality shown during this visit.

Kiribati TB Supervisory Evaluation Visit Report

Executive Summary

The PPTC has worked with the Tungaru Central Hospital (TCH) since the 1980's in the capacity of strengthening medical laboratory services and providing specialized training in the various disciplines of medical laboratory sciences, either in-country or at the PPTC centre in Wellington. Since 1990, the PPTC has and continues to provide an EQA programme for Microbiology, Serology, Transfusion Science, Haematology and Biochemistry to TCH. To date, 7 laboratory technicians have graduated with the distance taught PPTC diploma in medical laboratory sciences, with 6 more students expected to graduate from the 2015-2016 diploma programme this year.

This visit was specifically for TB technical support and assistance. The previous EQA TB assessment of the laboratory service was carried out in 2015 by Mr Richard Lumb - South Australia (SA) Pathology, Adelaide, Australia. In the past, due to its role as the blind slide reference centre for Kiribati (2010 – 2014), the PPTC have also carried out audit activities for the TB laboratory. SA Pathology remains the laboratory's reference centre for all direct antibiotic susceptibility testing (DST), blind smear rechecking, and panel tests. The current contract between Kiribati's NTP and SA Pathology has been extended until the end of 2017.

Kiribati's current population is estimated to be 113, 473 with case notification rates for TB in 2014 was reported as 375 per 100,000 (*2014 TB data, Global TB Report, WHO 2015*). The number of TB cases in 2014 was 432 cases, in 2015 – 516 cases and in 2016 – 518 cases, which shows a steady increase in new case notifications. The NTP's TB laboratory is part of the DOT's clinic which was purpose built in 2010. The TB Laboratory consists of 3 rooms and has separate office for the laboratory supervisor. Tests carried out for TB investigations include TB acid fast bacilli (AFB) smear microscopy together with molecular testing on the GeneXpert platform for MTB complex detection and rifampicin resistance. Culture and sensitivity was carried out at the laboratory, but this was stopped in early 2015 when molecular technology was made available to the laboratory. Specimens are referred to SA Pathology for culture and DST.

This onsite TB EQA evaluation visit was timely since the last visit occurred in 2015. The TB laboratory operates exceptionally well, and AFB staining, slide reading and reporting and GeneXpert testing are all operating well. All the TOR's were met for this visit and these are discussed in detail in this report.

Activities

The week long TB EQA evaluation visit was carried out from Tuesday 14 February till Monday 20 February, 2017 due to flight schedules for Tarawa. The agenda for this visit is attached as Annex 1. The subheadings below address each of the terms of reference outlined earlier. An audit was carried out using WHO DOTS programme "on-site evaluation report checklist" [Annex 2] and the laboratory was requested to complete the self-assessment checklist. [Annex 3].

Laboratory Facilities

The NTP's TB laboratory is part of the DOT's clinic, purpose built in 2010. The TB Laboratory consists of 3 rooms and an office for the laboratory supervisor. Room 1 is allocated to staining and storage of reagents and consumables. All laboratory consumables, reagents, chemicals are stored in a cupboard, protecting these from direct light. The room is bright and has adequate lighting. It is well ventilated with a wall fan ducted outside. Room 2 is allocated to sample preparation for smear's and GeneXpert testing. A biological safety cabinet (BSC) class II cabinet is available where all sample preparation occurs. Room three is allocated to GeneXpert testing, smear microscopy reading and this is also

where the result register is stored. There are 2 microscopes present in this room, both operational and functioning well. Both microscopes are kept covered and were reasonably dust free. An adjustable height chair is available for the Microscope placed at knee level bench and a stool available for the other microscope placed on the high bench. Ergonomical practises was observed and encouraged while reading smear's. All three rooms have functioning air conditioning unit. Incubator's and equipment for culture is still present in the laboratory but unused since the laboratory stopped performing culture.

Preventative equipment maintenance is carried out for GeneXpert, Microscopes and the BSC class II cabinet, and recorded on a blank sheet. The GeneXpert required annual calibration test to be carried out, for which the laboratory had informed PPTC that it will be carried out during this scheduled visit with the PPTC's assistance. A presentation on running Xpert check was made to staff and the calibration was successfully run on all 4 modules with the laboratory staff. Cepheid has now emailed back the calibration report which has been scanned into the analyser by the laboratory staff. Maintenance log was created (using Cepheid's outline) for the GeneXpert outlining the tasks for daily, weekly, monthly and annual requirements. This will replace the current record sheet.

Microscope maintenance log's with scheduled tasks was also created and staff were taken through the cleaning procedure. Lint free lens cleaning tissue was provided to staff for cleaning oil lens, and this needs to be purchased by the laboratory in the future. Both microscopes were cleaned thoroughly. (Upon request, PPTC staff were taken through the microscope maintenance and cleaning process by Ms Lee Botes – Olympus Microscope Specialist, New Zealand, in January 2017 to prepare for these TB evaluation visits). Temperature recording chart was created for the specimen fridge and a cleaning schedule chart was created for the BSC cabinet (both based on the manual charts used by the laboratory). A printer/scanner/ photocopy unit was purchased by the laboratory in late 2016, however had ran out of ink. A set of black and colour cartridge was purchased and donated to the laboratory. An equipment list and service records log was created for all laboratory equipment [Annex 4]. Two (2) power adaptors were purchased and donated to the laboratory to replace the rusted adaptors.

Overall the laboratory staff are to be complimented on their standard of work and in performing preventative maintenance on all equipment. Following recommendations are made under this section:

- All maintenance log's created are used by the laboratory for recording preventative maintenance.
- All maintenance records to be filed in an equipment maintenance folder (allocated during this visit).
- A desktop computer be purchased and placed in the laboratory for electronic recording of results, and for drafting laboratory documents. The printer must be attached to this computer. Room 3 will be the ideal location for it.
- All equipment and facilities document to be filed in the department SOP as per the shared SOP outline setup.
- The BSC class II cabinet be arranged for certification and service – it was last tested and serviced on 22/7/2014 by Cleanroom Systems International LTD, Auckland, New Zealand.
- Request hospital biomedical engineer to check "electrical fault's and connections" for all electrical equipment – this should be carried out annually.

Laboratory Personnel

The NTP currently employs two permanent laboratory staff, Mr Tekaibeti Tarataake who is the laboratory supervisor and Ms Ruta Karawa as laboratory technician. Both perform laboratory duties and are assisted by two volunteers who are attached to the TB laboratory under a "work experience" scheme, and are not salaried. The staff list with their qualifications are attached to this report [Annex 5]. Ms Karawa has enrolled for the laboratory technology module in the PPTC diploma programme for 2017. She will also be given the opportunity to complete the "laboratory quality management systems" module. Unfortunately, all other diploma modules require practical attachment in a medical laboratory, a requirement she will not be able to meet in her current role.

High turnover of work experience staff makes it difficult to retain unsalaried staff. The current "work experience" staff are being trained in receiving and processing samples, and preparing smear's for AFB staining. In 2016, the laboratory processed 3825 sputum samples for AFB and 522 samples on the GeneXpert, which equates to 4347 specimens received in total. The workload can be high during busy periods and the NTP TB laboratory is exploring the possibility of training staff from TCH medical laboratory, who can assist the NTP lab during busy periods and

provide leave cover. A 3 day workshop has been planned for the last week of March, whereby 5 shift staff from the TCH laboratory will trained in the NTP TB laboratory procedures, which is an excellent initiative by all involved.

Staff training and competence log has been created for the laboratory [Annex 6]. Ms Karawa was taken through this training log by Tekaibeti and her 10 microscopy slides were checked. She was competent in all tasks and is able to train others.

The following recommendations are for this section:

- Implement the staff training and competency log for all personnel (volunteer's included) and use this log to training train staff from the TCH laboratory.
- Review this training log every 6 months for all staff as per work plan [Annex 7].
- Consider external training courses to upskill current staff members.
- Ensure completion of SOP's to coincide with the training workshop for TCH laboratory staff.

Specimen Processing and Health and Safety

All samples received in the laboratory are registered in the log book, which captures the assigned laboratory number (this is recorded on the form by the laboratory when the specimen is received), date of receipt and collection, description of sputum, patient's full name, gender, age or DOB, treatment unit and location, and episode type: diagnosis or follow-up specimen type, allocation for smear and GeneXpert test results and the date results are being reported including space for the technician to sign their names when the results have been entered. This log was modified to include: DOB, and GeneXpert test result columns.

Adequate handwashing basin, placards and is soap available. PPE's available with correct glove size and face masks. Health and safety audit was carried out for the laboratory using the WHO LQMS Handbook guide checklist [Annex 8]. A 2l household bleach was purchased and donated to the laboratory, and staff were shown how to achieve a 1% concentration of chlorine solution to use as disinfection solution which is to be prepared fresh every second day.

TCH medical laboratory staff had raised concerns that ward staff were using routine laboratory test request form for TB investigations and would prefer the TB request form to be used. This will allow for better follow-up as the TB form captures detailed information on the patient making it easier to find patients who return a positive test result. An incident occurred highlighting the need to use TB forms. A patient had tested positive on the GeneXpert from the out-patients at the TCH. The patient was an outer island resident and the NTP had difficulty tracing the patient due to limited information provided on the routine laboratory request form.

Recommendations:

- Review the request forms to include collection of date of birth information– incident at the NTP clinic when samples were received on two different patients with similar first names and same surnames. One patient was positive and the other negative for AFB smear. The person who tested positive was rightly treated for TB, however the treatment notes were recorded under the incorrect patients name.
- Implement the use of the reviewed laboratory result register which now includes a section for GeneXpert results and has the update "legend" for smear reporting (for 1-9 AFB smear's seen replacing "scanty").
- TB request forms to be made available in respective wards and hospital ward staff informed of the importance of using the appropriate request form for laboratory TB investigation.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant area's such as fire/ safety drills etc. [Annex 8].
- Continue to prepare 1% chlorine solution for disinfectant use.

Consumables and Reagents Inventory and Ordering/Receiving of Supplies

The laboratory historically has always struggled with supplies, with long lead times for ordering consumables and reagents, shortened usage time and reagent expiry and shipment delays which has threatened stock outs. Larger

buffer stocks have been required to combat these challenges. Mr Tarataake is currently placing order's every three months, with enough stock to cater for the lead times. The laboratory deals with the one supplier: South Austral, Maroubra, Australia for all their consumables. The laboratory is well supplied to see them through the next 6 months and beyond for some items. A stock take and consumable list was created with Mr Tarataake, which incorporates the following information:

i. Test Kit and manufacturer
ii. Product Code
iii. Pack Size
iv. Approx. 3 Monthly Targets
v. Stock Take count's for each month (x3) with expiry dates
vi. Monthly Usage (x3)
vii. New order amount and date

Recommendations include:

- Stock take is carried out every month as per work plan [Annex 7].
- Place orders every 3 months as per work plan.

Preparation and Storage of in-house Prepared Reagents

All reagents are stored in a tall cupboard in Room 1, where stains are prepared and staining procedure is undertaken. The laboratory uses Ziehl-Neelsen (ZN) staining to perform its AFB smear staining, which are all prepared in house. The TB handbook 's reagent preparation instructions are used to prepare the ZN reagents for which the laboratory has plenty on stock of. The AFB stain: 1% carbon fuchsin is prepared using ethanol, basic fuchsin powder, phenol crystals (colourless) and distilled water; the decolourising solution is 3% HCl in ethanol and is prepared by adding fuming hydrochloric acid (HCl) and 95% ethanol; and the counterstain is 0.1% methylene blue, prepared by adding methylene blue chloride to distilled water. Staff are to be commended on their storage of reagents and in the correct preparation of high quality staining reagents. All stored reagents are regularly filtered (and heated if need be) to prevent any sedimentation. The prepared stains are labelled with dates of preparation and expiry. The following recommendations are for this section:

- Create a material safety data sheet folder for all reagents.
- Incorporate the reagent preparation methodology to the SOP.
- Enquire with the pharmacy for calibration weights to check the accuracy for the electronic balance.
- Discard unused and expired reagents and consumable items identified during this visit.

Management of Infectious and Laboratory Waste

All biological wastes (applicator sticks, sputum samples after testing, contaminated glass slides, used gloves and used GeneXpert cartridges) are discarded in a discard bucket with a plastic liner which is then in turn discarded in a biological hazard auto-clavable bag. These discard bags are then incinerated by the hospital biological rubbish disposable unit. The biological hazard bags are in stock and is part of the stock taking list. A printed and electronic copy of the WHO Tuberculosis Laboratory Biosafety Manual was shared with the laboratory for reference use. There are no recommendations under this section.

EQA Principles, Blinded Smear Rechecking and Panel Testing

The EQA principles was explained to the staff and the importance of actively participating in the EQA programme was impressed upon to staff. The Kiribati NTP TB laboratory's reference laboratory is SA Pathology Main Laboratory, Adelaide, Australia. This arrangement covered by the long term agreement (LTA) with the Pacific TB Laboratory Initiative (PATLAB) participating laboratories which provide EQA and direct laboratory support to the national TB Laboratories as a part of the Global Fund HIV/TB grant implementation in Western Pacific Region, organised by UNDP.

SA Pathology will provide the relevant EQA services to NTP TB laboratory which includes blind smear rechecking, and panel tests. The current contract between Kiribati's NTP and SA Pathology has been extended till the end of 2017.

Blind smear testing was last carried out in Q2 2015 according to filed reports. The responsible NTP nurse had sent BSR slides for Q1 and Q2 2016 to SA pathology, however the contract had expired between the two parties, therefore participation in this BSR EQA was stopped. Discussions were had with the NTP Nurse Ms Salaamo Taing, who will be responsible for selecting the BSR's and for dispatching them each quarter to SA Pathology. The work plan incorporates the dates for BSR dispatches and this was shared with Ms Taing.

No panel test slides have been received by the NTP TB laboratory since its inception. The TCH medical laboratory has always received this panel tests and have participated on both laboratories behalf. It is important that the NTP TB laboratory is included in this EQA as well. Quarterly report templates were customised to include documentation ID to make it a "controlled document" for use by the laboratory.

The NTP manager, coordinator and the laboratory supervisor have all indicated that they would prefer an annual supervisory visit as part of the EQA programme, and were very appreciative of this timely visit. Post assessment feedback is inserted to this report as annex 9.

Recommendations for EQA include:

- Start participating in the BSR from Q1 this year.
- Contact SA Pathology for panel tests, and start participating in this EQA programme.
- The laboratory should consider enrolling in the EQA programme for GeneXpert by acquiring dried culture spot's (DSC) with known concentration of whole inactivated Mycobacterium tuberculosis (Rifampicin sensitive) bacilli.

Increasing Sample Numbers Tested in the Laboratory

Large number of specimens have been received by the laboratory for TB investigation in recent years – 4014 samples in 2015 (3786 for AFB smear and 228 samples for GeneXpert 2015) and 4347 samples in 2016 (3825 for AFB and 522 samples for GeneXpert).

As discussed with Ms Bereka Reiher (NTP coordinator), the general public are becoming more aware of the symptoms of TB via health promotion work carried out by the NTP team. There has been an increase in the NTP human resourcing, active TB case finding is taking place, DOT workers are carrying out more coordinated house to house visits. Rural health workers have been provided further training on when to refer cases for testing and treatment. Patients are presenting themselves to the clinic as well. Awareness on the symptoms of TB has been raised by radio announcements. TB disease has been stigmatised in the Kiribati society in past however community perception of it is changing with the change in local name for TB - ("Karinge" which translates to "skin and bones") is now referred to as tuberculosis so public are not uncomfortable in presenting to the clinic with symptoms and are accepting treatment. It is expected that more cases will be identified in 2017.

There are currently 13 clinics on Tarawa for the NTP to use and where specimens may be collected from. 17 outer island sites exist as well, for which samples are flown over to Bonriki airport for processing by the NTP laboratory. The NTP is to be commended on its excellent work in increasing the awareness for TB and strengthening the DOT's programme on island.

Advice and On-site Coaching on Gaps Identified

Currently there is no SOP manual available for the NTP TB laboratory, as this was never drafted for the lab since its inception. The staff have used the TB handbook and the GeneXpert manual to perform tests, and procedures outlined in these documents have been followed. Outtakes from these documents are stuck on walls for easy user reference.

Outline of a number of SOP documents have been shared with the laboratory supervisor and all documents drafted for the laboratory was given to the NTP manager and the laboratory supervisor on a USB drive. The documents

were created in accordance with the ISO 15189 medical laboratory international standards to eventually prepare the laboratory to seek accreditation. A table of contents was created for this SOP manual and for those documents which were not drafted, template examples were given electronically for adaptation into the laboratories own documents. Timeline was established for the completion of the SOP's and the PPTC will be able to guide the laboratory supervisor and provide remote assistance in its development. The action plan [Annex 7] outlines the timeframe allocated to SOP development.

Presentation was given to all staff from the NTP TB laboratory and two selected staff from the TCH medical laboratory. Presentation contents included background on TB disease, latent TB vs active TB cases, Global TB rates, TB diagnosis in laboratory – AFB smear's, sputum specimen quality, acceptance and rejection criteria's, method on performing AFB smear's, reading and reporting AFB smear results, GeneXpert technology, AFB smear's vs GeneXpert. A separate presentation was given on performing calibration using pert check cartridges.

A hand on preventative maintenance training was given to TCH laboratory staff on the GeneXpert installed in 2016. Unfortunately, the preventative maintenance tasks were neglected by the TCH laboratory staff. The maintenance log created for the NTP TB laboratory was shared with the medical laboratory team, and routine maintenance task has been encouraged. Xpert check was also run on this GeneXpert for calibration successfully. Cepheid has now emailed back the calibration report for this equipment as well, which has been scanned into the analyser by the laboratory staff.

Rifampicin resistance observed in recent years in Kiribati include the following.

- 2017 – 40-year-old male had first sputum sample collected on 6/01/2017 and tested positive for MTB an RIF on GeneXpert. Second (18/01/17) and third sample (24/01/17) were requested from him for repeat GeneXpert test, all tests were positive for MTB and resistant to RIF. A specimen has now been referred to SA Pathology for culture and DST. Treatment for MDR TB had been requested from WHO Manila at the time of this visit so that the patient could begin treatment. Contact tracing has begun for immediate family members – only 3 persons identified to be at risk.
- 2015 – 40-year-old male, presented with positive MTB and RIF result on GeneXpert, patient successfully treated – DST result indicated mono resistance. On repeat specimen in October 2016, the person tested negative for TB on GeneXpert and smear, and was negative on culture.
- 2014 – male, patient passed away before treatment could begin.

Recommendations include:

- Completion of the SOP's by March 2017.
- Regular preventative maintenance to be carried out on GeneXpert at the TCH medical laboratory.
- Once two results are positive on GeneXpert for MTB/ RIF resistance, specimen must be immediately sent to the reference laboratory and MDR treatment drugs must be requested immediately from WHO in order to being treatment.

GeneXpert

There are two GeneXpert 4 module analyser at the Tungaru Central Hospital. One was installed at the NTP TB Laboratory in 2015 and other in the main pathology laboratory at the hospital in 2016. Both are in good working condition. The maintenance, calibration has been discussed in this report earlier.

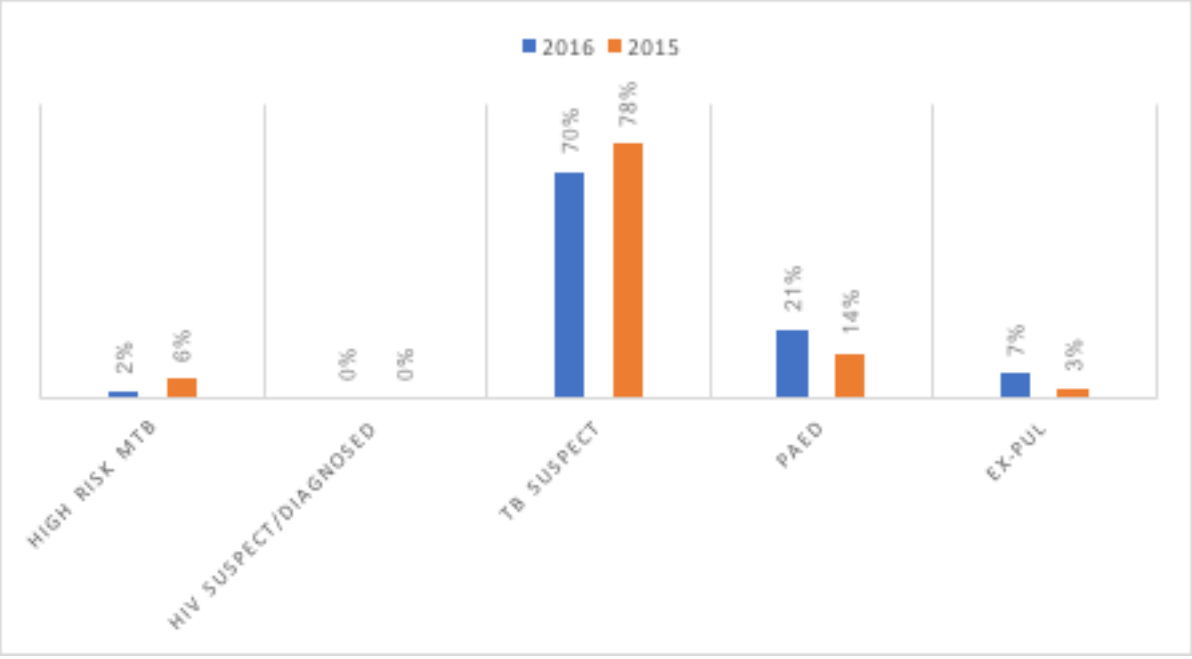
The discussions below are based on the GeneXpert testing carried out at the NTP TB laboratory. The testing algorithm used by the laboratory is as per WHO guidelines, and was set up by Dr Richard Lumb in 2015 during the installation and training of the machine. [Annex 11]. Majority of the specimens tested on the GeneXpert are from TB suspect cases and AFB smear test is performed on all samples as well. In 2016, out of the 522 specimens processed, 46 specimens were Xpert MTB positive, RIF negative and smear negative. 32 specimens were Xpert MTB positive and smear positive. 2 specimens were smear positive and Xpert negative.

The following tables and graph's summarise the GeneXpert workload for 2015 and 2016 for the NTP TB laboratory.

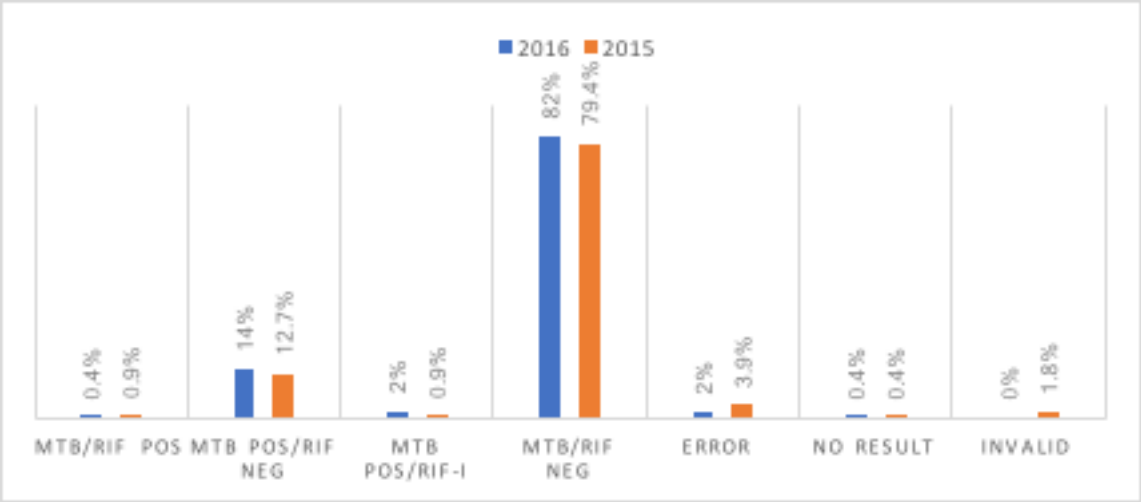
Table 1: Kiribati NTP TB Laboratory GeneXpert Test Result Statistics and Patient Type 2015 - 2016

GeneXpert Test Results	2016	2015
MTB/RIF POS	2	2
MTB POS/RIF NEG	75	29
MTB POS/RIF-I	9	2
MTB/RIF NEG	426	181
Error	8	9
No Result	2	1
Invalid	0	4
TOTAL	522	228
Patient Type	**2016**	**2015**
High Risk MTB	10	13
HIV Suspect/Diagnosed	0	0
TB suspect	363	178
PAED	110	31
Extra Pulmonary Specimens	39	7
TOTAL	522	228

Graph 1: Kiribati NTP TB Laboratory GeneXpert patient history: 2015-2016



Graph 2: Kiribati NTP TB Laboratory GeneXpert Test results: 2015-2016



There has been a general increase in the numbers of specimens being tested on the GeneXpert. The percentage number of negative test results between 2015 and 2016 are similar, as with the other results.

Challenges faced with Specimens

Common errors faced with sputum quality include not receiving request forms with the specimen and poor quality specimens. 2 – 3 days delay in receiving samples is experienced by the laboratory staff as hospital transportation services responsible for collection of specimens from these sentinel sites are inconsistent.

Salivary specimens are still processed by the laboratory and accepted by the NTP collection staff. In 2014, 1031 sputum samples collected were salivary – 33% of all samples collected. In 2015, 1148 samples were salivary – 30% of all 2015 sputum's collected. In 2016, 1310 samples were salivary – 34% of all 2016 sputum's collected. This large number of salivary specimens being collected and accepted for testing is of concern. False negative results could very well be reported from the laboratory. Specimen acceptance and rejection criteria has been created to strictly implement rejection of samples guidelines as per TB handbook.

Recommendations include:

- Educating collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Implementation of the specimen acceptance and rejection criteria, and making the collection staff aware of this policy. Clinical judgement is advised in scenarios where quality samples cannot be collected as per the developed policy.
- Incorporating this policy in the laboratory SOP.
- Explore implementation of a roster schedule which can be assigned to the MOH TCH transportation team so that specimen collection from the airport (for outer island samples) and the clinic's occur on a regular basis to avoid any delays in sputum delivery. The clinics or airport do not store specimens in the fridge which allows for over growth of commensal microflora which hinder preparation of good quality smear's and staining.

Summary

All EQA processes must be adhered to ensure the quality of results produced by the laboratory, as outlined in the action plan [Annex 7]. The summary of all recommendations is listed below. The laboratory supervisor together with the NTP manager must modify the current work plan to incorporate the recommendations listed in this report. The key recommendations include:

- A desktop computer be purchased and placed in the laboratory for electronic recording of results, and for drafting laboratory documents. The printer must be attached to this computer. Room 3 will be the ideal location for it.
- The BSC class II cabinet be arranged for certification and service – it was last tested and serviced on 22/7/2014 by Cleanroom Systems International LTD, Auckland, New Zealand.
- Implement the staff training and competency log for all staff (volunteers included) and use this log to training train staff from the TCH laboratory and review this training log every 6 months for all staff as per the agreed work plan.
- Completion of SOP's to coincide with the training workshop for TCH laboratory staff.
- Review the request forms to include collection of date of birth information– incident at the NTP clinic when samples were received on two different patients with similar first names and same surnames. One patient was positive and the other negative for AFB smear. The person who tested positive was rightly treated for TB, however the treatment notes were recorded under the incorrect patients' name.
- TB request forms to be made available in respective wards and hospital ward staff informed of the importance of using the appropriate request form for laboratory TB investigation.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant area's such as fire/ safety drills etc. [Annex 8].
- Stock take every month and place orders every 3 months as per work plan.
- Start participating in the BSR from Q1 this year and contact SA Pathology for panel tests, and start participating in this EQA programme.
- Regular preventative maintenance to be carried out on GeneXpert at the TCH medical laboratory.
- Once two results are positive on GeneXpert for MTB/ RIF resistance, specimen must be immediately sent to the reference laboratory and MDR treatment drugs must be requested immediately from WHO in order to being treatment.
- Educating collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received, and implementing the specimen acceptance and rejection criteria, and ensuring that the collection staff are aware of this policy.
- Explore the implementation of a roster schedule which can be assigned to the MOH TCH transportation team so that specimen collection from the airport (for outer island samples) and the clinic's occur on a regular basis to avoid any delays in sputum delivery.

Conclusion

The laboratory is well designed and organised and the staff are well trained and efficient in performing AFB staining and smear preparation, and carrying out GeneXpert tests. The stock supplies are ordered well in advance and there is adequate stock for all consumables. This laboratory is functioning well, despite the pressure put on human resources with the recent increase in specimen quantity.

I am confident that once the above recommendations have been actioned by the NTP team, the laboratory can confidently request for an external audit to gauge its pathway to accreditation in the near future.

Acknowledgments

My sincere thanks to the staff at the NTP TB laboratory and the TCH Hospital laboratory, the NTP team, and UNDP Fiji office support team for your valuable contributions and hospitality shown during this visit.

Nauru TB Laboratory Assessment and Evaluation Report

Background

The PPTC has worked with Nauru for a number of years in its capacity as a External Quality Assurance programme provider across 4 scientific disciplines, also on various visits to strengthen Medical Laboratory services towards accreditation standards and lastly assistance in providing specialised training and education in the scientific disciplines. This mission however, was specifically for TB technical support and assistance in line with the PacificTB initiative (PATLAB) supervisory network across the Pacific. Queensland Mycobacterium Reference Laboratory is the supervisory centre for specialist TB referred tests and were responsible for the last TB visit and assessment between 2012- 2014.

Nauru has a population of 10,600 with the incidence of TB estimated around 10 per 100,000* in 2016. In 2016, 10 cases were recorded. It is a low burden community with incidents of MDR-TB and HIV related risk at very low or extremely rare levels .The TB Laboratory is incorporated into the Microbiology facility and is predominantly manned by 1 senior Technologist. A further 5 technicians at different stages of training are on rotation through the various departments and help cover after hours call work. The entire hospital is about to relocate to new facilities within the next 6 weeks. Only TB microscopy was carried out in the Laboratory with positive cases being referred to the reference laboratory, Queensland Mycobacterium Reference Laboratory, for culture and antibiotic susceptibility testing. A new Cepheid GeneXpert PCR analyser is on order and expected to be installed in the department within 2 months.

Executive Summary

This onsite TB EQA evaluation visit was very successful in enhancing specific technical support and assistance to Nauru. It was very timely and well appreciated due to the recent addition of new staff to the laboratory services. It also coincided with the completion of and eventual relocation into new Laboratory facilities and also coincided with an unfortunate outbreak of Dengue fever where a rising number of cases put huge pressure on the Lab services. There was no record of any previous TB evaluation visits but the last visit was thought to have been carried out in 2012 by SPC or QMRL.

The Laboratory operates very well and has progressed rapidly over the last 5 years in essential quality principles and structured operational procedures. However, participation in the TB EQA programme has been neglected in the last 2 years and therefore Microbiology received a timely boost towards its accreditation goals in the form of the on-site assessment and evaluation audits providing quality reviews in the TB section.

Significant strengthening of the TB EQA programme occurred with coordinated activities being aligned with the Reference Laboratory QMRL. This included collating Quarterly Workload Statistics, referring positive samples that require specialist testing, referring quarterly slide dispatches for rechecking and the return sending out of panel tests from the reference laboratory to Nauru. An annual workplan of these activities was created as a guide.

The Microbiology section does have significant gaps in expertise and experience which was partially addressed with the valuable refresher training to the senior Technicians and coaching in technical skills and procedures for trainee staff, provided on this visit.

The week-long workshop was also an opportunity to liaise with the healthcare workers in the NTP team.
This enabled them to be informed of the Laboratory assessment outcome, communicate the impact of new

developments planned for the future like the GeneXpert and help emphasise the importance of sputa collection and the avoidance of poor quality samples.

Overall the visit was a great success, was well received and fulfilled all the requirements detailed in the terms of reference. The Laboratory passed the assessment very well but now has other issues to contend with around staff management and the eventual relocation to the new hospital.

Activities

Audit of TB Section

The audit of the TB Section was carried out using the WHO DOTS programme checklist and questionnaire including the 'On-site Evaluation Report' and 'Self- Assessment checklist'. These have been modified to include GeneXpert operational procedures although the analyser is yet to be introduced to Nauru. The TB section performed well with strengths being its good structure and order around the testing processes, having an organised and clear TB register, and a good communication network between NTP team members and Laboratory. The microscopy and stain preparation section was done very well and practicing at a good standard.

Summary:

- GeneXpert PCR is due to be installed within 2 months.
- New Laboratory facilities are near completion and relocation of the service will be within a month.
- TB EQA programme will be restored and re -instated as a result of this assessment.
- A calendar of expected EQA activity for 2017 has been developed to re-establish Blind slide EQA reviews and closer ties to the reference Laboratory.
- TB SOP's outlining operational steps needs upgrading and further development.
- Staff training records (TB and Micro) competency needs further upgrades.
- Equipment service records/ maintenance records need improvement.
- Written instructions could be developed for the patient specimen collection centres.
- The need to refer Positive samples through to the reference centre for AST and finger printing was emphasised.
- Overall the laboratory is in a good position prior to moving into new facilities within the month. New trainees have been added to the workforce recently and are in desperate need of training, education and experience as present TB expertise is very limited to 2 staff.

The findings are as follows:

- Facilities: The present Laboratory workplace area comprises of 4 shipping container buildings adequately modified to house Laboratory practices as a temporary measure from over 2 years ago. These makeshift buildings serve surprisingly well as Laboratory facilities with well laid out benches, good workspace organisation and essential air conditioning units. However, the new laboratory facility, adjacent to the Paediatric ward is now near completion and a relocation into those facilities is expected within the next 6 weeks. The new facilities unfortunately have some design flaws and space limitations that will need to be addressed before final relocation occurs. The audit checklist was carried out on the transient "Container Laboratory" which at this stage has some distinct advantages over the new facility.

  TB specimens are processed in the Microbiology section which is well ventilated, adequately lighted and has tight security access. It is kept clean and tidy, has good workbench areas and is adequately served with electricity, gas supply and water. A Biohazard Safety cabinet is conveniently located in the far end of the room. The 2 microscopes are in good order and operating well, one of which is an excellent Nikon recently donated and being used for the TB slide analysis.

  The new facilities in the RON Hospital building do not fare so well. It has very good lighting with hard durable benches, secured rooms and good ventilation but is cramped for space in Microbiology with insufficient room for equipment, placement of the Biological Safety Cabinet, storage facilities, cupboards

for records, stock items and incubators or fridges. The existing equipment in the old Laboratory cannot be accommodated in the new without removing benches, shelves, service junctions for power and water, and relocating cupboard units and draws from the old. Additional equipment like the imminent arrival of a GeneXpert PCR unit with PC monitor has no room for it to be accommodated in Microbiology. Regretfully this has come about because no Laboratory members were included in the original design committee.

- *A private contractor will need to be utilized to make necessary structural changes to the new facility and best accommodate Laboratory design requirements for workflow, office space and operational equipment before the services can be relocated.*

- Equipment: One Biohazard Safety Cabinet in the Microbiology department is well maintained and certified with the next annual certification check being due in September 2017. This is a good practise to continue as the laboratory is regarded as a Grade 1 level TB facility meaning that low hazard risk activities like smear preparation and GeneXpert analysis are carried out but where BSCabinets are not essential requirements although preferred protective equipment to have. A UPS power unit is also attached to the cabinet which is good practice. For BSC's to be used appropriately they need to be certified annually and checked for effective performance as was the case here.
- Two good quality Microscopes are in use, one of which is a recently donated Nikon model and is in an excellent condition to serve the TB section. Both microscopes were checked for alignment. Two further microscopes are apparently on order and awaiting delivery soon.
- *An Equipment Maintenance Record sheet should accompany every item of Microbiology equipment listing Model specifications, manufacturer contacts and preventative maintenance or service work carried out. The laboratory Balance, Microscope and Cabinet are included here.*

- TB Register: Recording specimens and reporting in the TB Register was clear, well organised and up to date. The register was neat and tidy and easy to follow. The frequency of QC slides was performed regularly but recorded on a separate worksheet additional to the register. Although this was different from other laboratories it is still very acceptable with evidence of regular QC testing being done. Positive specimens that were recorded in the register were reported by quantity as expected. The storage of slides after analysis has now been arranged in numerical order starting from Jan 1 2017 and a new Q1 dispatch of slides for EQA were selected from this listing for delivery to the reference laboratory.
- *It is recommended to clearly show Initials of the authorising Technician on every line where a result is recorded in the Register.*

- Technical Staff: The Nauru Laboratory underwent staff changes in 2016/2017 which brought some disruption and loss of expertise to the overall service provision particularly in TB EQA processes, reporting and analysis responsibilities within Microbiology. There is still no one officially appointed to the Laboratory Manager position leaving a big burden of management and leadership on Ms Yordana Goya who doubles as Microbiology HOD, Quality Officer , administrator and staff manager. With the help of one other qualified scientist and four recent trainee staff, Yordana is expected to cover all the scientific disciplines including the demanding Blood Transfusion services and fulfil the requirements of Microbiology in her spare time. The Lab is in an extremely vulnerable position with only 2 qualified staff out of 7 Assistants and trainees. Expertise in TB analysis and reporting is also restricted to these 2 staff, hence the timing of this workshop was very valuable. This vulnerable situation was highlighted even more when Yordana was forced to return back to work recently whilst overseas on leave. Most of the staff are in stages of basic training and do not have authority to report results in Yordana's absence.
- *The vacant position of Laboratory Manager needs to be urgently filled so that department workload and afterhours rosters can be better co-ordinated.*
- *Yordana should be recognised for the enormous responsibility she carries across the whole Laboratory service. In addition to the vacant laboratory Manager position that has defaulted to Yordana, she puts a huge number of extra hours into the Laboratory in order to sustain the service to which she is not acknowledged for.*

- Staff Training records: The Staff training and Competency record has now been upgraded to include more detailed TB related skills and has been signed off for the 5-staff participating in the TB workshop. The department training records will continue to be managed by Yordana as trainees continue to be rotated

through Microbiology. An additional section was also added for the GeneXpert PCR in anticipation of its arrival in a few months.

- An additional Workshop Training record, based on the Pacific Island TB Handbook information and GeneXpert information was added to supplement the existing Staff competency and Training records. This log requires supervisor review or sign off every 6 months and creates a stronger and more relevant systematic training programme for the TB section within Microbiology.
- *The Training and Competency record sheet specific for the TB section will need to be utilised regularly for the Microbiology rotating staff. A copy is attached in Annex 5.*
- Stain Reagents: These were well stocked and organised, are being bought commercially and were filtered appropriately. However, clearer labelling of working bench reagents is recommended with listed initials, date and QC approval needing to be made more obvious. The time between ordering of supplies and eventual delivery continues to be a problem with some delayed shipments up to 3 months.
- Labelling of slides was always clear on the superior frosted slides with the TB register number and sequence in dark pencil for easy recognition.
- *It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
- A year calendar has been developed for the department and included in the Quality Manual to outline the TB EQA schedule and activity workplan expected for 2017/2018. (Annex 4).
- *It is recommended the Laboratory follow this timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*

External Quality Assessment

Queensland Mycobacterium Reference Laboratory is the PTRL supervisory lab for Nauru and covers the 4 components of EQA namely Blinded slide Re-checking (BSR) since 2010. Regretfully in Nauru's case, TB EQA

has been neglected over the last few years with no activity recorded for 2015 and 2016. However Positive cultures have been referred to QMRL for TB culture and sensitivity testing throughout this time. Statistics indicate 10 positive patients were detected in 2016.

Blind slide re-checking has not been sent for 2 years as a result of staff shortages making it difficult to manage, unawareness of the TB EQA requirements, the time and cost involved to organise postage and a general sense that TB EQA was of low priority for the Microbiology section.

In a concerted effort to re-instate the programme the first quarter Q1 2017 slides were prepared and posted to QMRL along with copies of the Register book, Quarterly Reports and statistics, giving the Nauru Laboratory a flying start to 2017 EQA requirements with a scheduled calendar and instructions to keep the momentum going.

Included in the package was:

a. A copy of the TB Register pages for the period Q1 2017 (Jan-March 2017)
b. Technical Quarterly workload Reports or Statistic report for Q1 2017
c. Listed slides and reported results from Nauru to be checked in the Q1 2017 BSR dispatch.

As a result of this visit the TB laboratory should be fully compliant and up to date with its EQA requirements in BSR, QWR and in the supplying of copies of the TB Register.

Positive smear sputum samples are also expected to continue to be referred to QMRL for culture and DST.

UNDP will cover the cost of postage to Brisbane in these referred specimens as indicated in UNDP shipping arrangement SOP.

An unstained Panel test of slides is also expected from QMRL for staining and reporting on, later this year. Previous panels sent in 2015 did not have a good response rate from Nauru as they apparently were late arriving due to

custom restraints and consequently reported on later well past the cut-off date. No report was ever received from this EQA exercise.

Other forms of EQA such as the self-assessment questionnaire, on-site assessment and training sessions from a Technical advisor are relatively simple exercises to be performed and are now expected to be carried out annually.

An EQA operating procedure summarising all the EQA activities and purposes has been drafted and included in the SOP Manual during this visit.

Recommendations for EQA include:

- *Prepare for second Blind slide review dispatch at the end of June (Q2 Apr- May-June 2017).*
- *Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of June 2017.*
- *Contact QMRL, Brisbane for expected arrival dates for unstained panel tests.*
- *Discuss with Reference lab future provision of EQA/ Statistic reports for GeneXpert in preparation for its arrival.*

Technician Training

- A hands-on training session for smear preparation, staining technique and microscopy reporting was held with all available staff. QC slides of both Positive and negative examples were used. Overall the stain quality was very good, the microscopy interpretation was accurate and the scoring or quantifying of positives, good. All 5 participants showed they were very capable in the process preparation and on reporting TB microscopy slides.
- A TB workshop training record was created and established for the 5 Trainee staff. As previously mentioned this was to supplement the already modified "Training and Competency Log". It also required of the staff to read portions of the Pacific TB Handbook and complete a number of staining procedures and interpretations. All 5 participants were successfully signed off for this record by the end of the week.

Recommendations regarding Technician training.

- *Each staff member needs to be signed off on the TB Competency & Training record 6 monthly.*
- *Laboratory staff need to be diligent in continuing to maintaining their ZN staining and interpretation skills even after the GeneXpert arrives and becomes operational.*

Workplace Safety

i. The TB Laboratory is restricted to microscopy on sputum samples and body fluids, therefore is regarded as a low risk environment provided it is performed by trained staff using standard procedures. It has already been noted that the Biological Safety Cabinet is certified and compliant. A daily record of housekeeping requirements and service checks is all that is needed. Specimen smears were being prepared and dried in the cabinet as expected.

ii. Adequate Personnel Protective equipment (PPE) was available in the form of gloves, laboratory gowns, masks (although not always necessary), closed shoes worn. Other recommended safety practices were being followed such as using applicator sticks for slide preparation, strong Hypochlorite or 70% IsoPropyl Alcohol disinfectant in use, good Biohazard waste disposal containers and autoclave operation was carried out before material left the Laboratory. The occupational Health and Safety status for the staff is non-existent. Mantoux's are not available to the staff, nor Quantiferon Gold, leaving annual chest x-ray as one of the few staff health monitoring tools to consider.

- *It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Senior Technicians who supervise the TB work.*

TB SOP Manual and documentation

i. The Standard Operating procedures regarding the TB section were blended into the Microbiology SOP manual and so the decision was made to create a separate TB SOP folder to simplify the processes and bring better clarity to the EQA programme, referral Laboratory requirements and specific TB QC measures.

ii. A significant number of SOP documents were created specifically for TB covering all its specimen processing issues with associated worksheets included. Further work is required to complete the manual. SOP's were prepared on Biosafety, Spillage, EQA requirements, Equipment servicing, Referral Laboratory information, AFB staining, diagnostic Algorithms and Training record log.

iii. The SOP documents are referenced from various WHO/ PATLAB TB publications and some copied from the Microbiology procedure notes.

iv. Biosafety for the TB laboratory has been referenced from the WHO publication : Tuberculosis Laboratory Biosafety Manual 2012 and the Pacific Island TB Handbook.

v. The laboratory should be commended for the big improvements and very good records they had in place to monitor and control various operations. There were worksheets, spreadsheets and clipboard listings for specimen numbers, workload, daily maintenance task lists, rejected specimens and stocklists for consumable items. This was very impressive and reflected a well organised, structured and controlled management of the service.

- *Continue to complete and finalise TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*
- *Work towards preparing GeneXpert operational procedures so they can also be included.*

Summary

The TB EQA processes were given a strong emphasis on this mission due to the obvious lapses evident in this area over the last 2 years. The re-instating of BSR and Quarterly reporting has now been carefull detailed, documented in SOP's and impressed upon the staff for continued participation, therefore ensuring a higher awareness of the quality of results produced by the Microbiology department. Very little statistical information had been referred to the supervising Reference laboratory throughout 2016 which is something needing immediate correction. Consequently, this has been strongly addressed and we are happy to report that the Laboratory is up-to-date according to 2017 EQA requirements.

Continued recommendations for EQA include:

- *Prepare for second Blind slide review dispatch at the end of June (Q2 Apr- May-June 2017).*
- *Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of June 2017.*
- *Contact QMRL, Brisbane for expected arrival dates for unstained panel tests.*
- *Discuss with Reference lab future provision of EQA/ Statistic reports for GeneXpert in preparation for its arrival.*

A summary of all recommendations are listed below:

- *A private contractor will need to be utilized to make necessary structural changes to the new facility*
- *and best accommodate Laboratory design requirements for workflow, office space and operational equipment before the services can be relocated.*
- *An Equipment Maintenance Record sheet should accompany every item of Microbiology equipment listing Model specifications, manufacturer contacts and preventative maintenance or service work carried out. The laboratory Balance, Microscope and Cabinet are included here.*
- *It is recommended to clearly show Initials of the authorising Technician on every line where a result is recorded in the Register.*
- *The vacant position of Laboratory Manager needs to be urgently filled so that department workload and afterhours rosters can be better co-ordinated.*

- *The Training and Competency record sheet specific for the TB section will need to be utilised regularly for the Microbiology rotating staff.*
- *Each staff member needs to be signed off on the TB Competency & Training record 6 monthly.*
- *Laboratory staff need to be diligent in continuing to maintaining their ZN staining and interpretation skills even after the GeneXpert arrives and becomes operational.*
- *It is recommended the Laboratory follow the EQA timeline calendar to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*
- *It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Senior Technicians who supervise the TB work.*
- *Continue to complete and finalise TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*
- *Work towards preparing GeneXpert operational procedures so they can also be included in the TB QM.*

Conclusion

The Laboratory has rapidly improved over the last year in the areas of record keeping, documentation and quality management which is a huge credit to the interim Laboratory manager. It is in a good position overall with new staff members, new equipment expected soon and the imminent transfer into a new building facility. A positive and progressive momentum has developed within the Lab. The staff capacity and service expertise in the TB section has received a significant boost with this weeks workshop and evaluation. The training sessions and demonstrations were well received by the participants and have helped restore competence in skill as well as an overall understanding behind the necessity for TB EQA requirements. TB EQA has previously been neglected, but thankfully competence has been restored for 2017 and better communication links with the Reference lab, QMRL, Brisbane will be significantly better. The inclusion of a EQA calendar for the lab staff will be a trusty reminder for all. The NTP team are also now up to date with laboratory developments and have a better understanding of sample collection issues and their role in the labs EQA requirements.

Having a high portion of trainees amongst the Laboratory has put a big onus on the qualified staff both in covering the responsibilities of the service and also in providing technical leadership in directing the trainees. The Lab is still very vulnerable if senior staff choose to have leave or are absent. The Quality Manual documentation is in a very good state due to the enormous efforts of individual staff and is in the process of being updated with new additions. The development and completion of the TB Training record is an excellent step in the right direction to maintain skill levels, staff confidence and a solid training programme. The challenge now lies with the trained technicians to practice and refresh their ability regularly and make it long term.

Finally, a big thank you to the staff at RON Hospital Laboratory, Ms Yordana Goya, the NTP team, UNDP GF program management staff for your valuable contributions in making this successful and enjoyable assessment visit happen and to the friendly Laboratory staff who looked after me and gave me Nauru hospitality for the week.

Niue TB Supervisory Evaluation Visit Report – 2017

Executive Summary

The PPTC has worked with the Niue Hospital since the 1980's in the capacity of strengthening medical laboratory services and providing specialised training in the various disciplines of medical laboratory sciences, either in-country or at the PPTC centre in Wellington. Since 1990, the PPTC has and continues to provide an EQA programme for Microbiology, Serology, Transfusion Science, Haematology and Biochemistry to Niue Foou Hospital Medical Laboratory. Niue laboratory technicians have participated in the distance taught PPTC Diploma in Medical Laboratory Sciences programme in the past, with one diploma graduate.

This visit was specifically for TB technical support and assistance. The previous EQA TB assessment of the laboratory service was carried out in 2014 by Mr Koen Van Der Vaat - Microbiology consultant contracted by the PPTC due to its role as the blind slide reference centre for Niue (2010 – 2014). LabPLUS, Auckland is now the laboratory's reference centre for all direct antibiotic susceptibility testing (DST), blind smear rechecking, and panel tests. Niue Foou Hospital is covered under the long term agreement organised by UNDP global fund programme.

Niue's current population is estimated to be 1,600. There are no current TB cases in Niue at this stage. 2 cases were seen in 2002 and 2011 and both were from expatriate workers on island. The laboratory findings for AFB were reported negative for sputum smear test. Diagnosis was confirmed by the referral laboratory in both instances. Niue relies heavy on expatriate workers on island, and it is possible that future cases of tuberculosis infection can be introduced as such, while the country strengthens its immigration and border control medical screening. With one flight a week out of the country, diagnosis may be delayed if no AFM smears are performed on island. Therefore, it is imperative that the laboratory continues to offer AFM smear test for initial screening and diagnosis.

The laboratory is staffed by a qualified scientist who is responsible for performing all laboratory testing for Niue Foou Hospital which includes the sciences of Biochemistry, Haematology, Microbiology, Serology and Cross Matching. The TB EQA evaluation visit was timely as the last visit occurred in 2014. All the TOR's were met for this visit and these are discussed in detail in this report.

Activities

The week long TB EQA evaluation visit was carried out from Monday 27 Feb till Thursday 2 March due to flight schedules for Niue, and the 4 day working week policy. The subheadings below address each of the terms of reference outlined earlier. An audit was carried out using WHO DOTS programme "on-site evaluation report checklist" and the laboratory was requested to complete the self-assessment checklist.

Laboratory Facilities

The laboratory has been assigned a main room (6.6m Length, 4m wide, and 2.7m high) and an office space. There are no windows and the laboratory space does not share any outside walls of the Hospital building. All the equipment and analysers are accommodated in the main laboratory area, with no separate spacing assigned for Microbiology tests. There is no separate storage space for the laboratory consumables and reagents. Non-perishable laboratory consumables are stacked in boxes around the laboratory room, while some reagents are stored in cupboard under benches. Temperature sensitive consumable are stored in available fridges. The room is cluttered due to limited spacing available, as no separate store room is available for laboratory use. The office space

is adequate, and houses the phone, bookshelves and a desktop computer. All phlebotomy work is carried out in a separate room which is shared with nursing staff for triage work on patients.

There is a ventilation inlet installed on the ceiling of the laboratory area and in the office. This ventilation is not adequate for laboratory needs. The staining fumes for carbon fuchsin is also released into the room. Currently all sputum and faecal specimens are processed outside the hospital building away from the patients and staff. Staff take into account the wind direction when processing these samples. While this method protects the user, specimen is susceptible to contamination from the environment. If the laboratory was to be allocated a larger accommodation, it could purchase a class II biological safety cabinet for processing all suspect highly infectious laboratory samples.

General laboratory equipment's undergo annual electrical checks from a service engineer under an contractual agreement from the Counties Manukau Hospital, New Zealand. For general microscopy work and TB investigations the laboratory has two CX31 Olympus microscopes, both of which were purchased under the global fund TB project. One is being used for laboratory investigations, while the other is still brand new and kept in its original packaging (lacks 100x oil magnification lens and has a spare lamp). Microscope in use was not aligned when checked. This was cleaned and serviced during this visit, and the laboratory scientist was taken through kohler illumination and shown how to perform preventative maintenance tasks. Microscope maintenance log has been shared. A cleaning kit, including lens cleaning solution, lint free tissues and a brush has been left in the laboratory.

The microscope is placed on a high bench and the setup is not egronomical. Furthermore, it sits next to the sysmex FBC analyses and vibrations affect the focus during slide reading. The staff have propped the microscopes on books and currently read slides standing up. Laboratory also requires a timer to time staining times.

Only the laboratory fridges are on a backup power supply socket, connected to the backup generator during power outages. A power outage was experienced on Monday during this visit and the laboratory technician was not able to perform any testing in the laboratory.

Following recommendations are made under this section:

- Allocating a storage area for the laboratory supplies to avoid clutter in the analysis area and to allow for better work flow.
- Purchase of a high stool with adjustable height for Microscope slide reading for a better egronomical practice.
- In the near future, a lower bench should be setup for the microscope, next to the staining sink. This will require the staff to move the metal filling cabinet in the office or next to the fridges where laboratory supplies are being stored. A new desk and an office chair level can be installed here, and this can be a designated microscopy area.
- Increase ventilation in the analysis area as this is an biohazard risk for staff.
- Consider the purchase of a class II biological safety cabinet to process infectious specimens.
- Maintenance log's must be created for routine medical analysers and tasks followed through (templates have been shared).
- All equipment and facilities document to be filed in the department SOP as per the shared SOP outline setup.
- Purchase of a laboratory timer for staining use and for other laboratory procedures.
- Explore connecting all laboratory equipment's and lighting to the backup power supply, so that work can still be carried out by laboratory staff during emergency situations.

Laboratory Personnel

The laboratory has only one staff, Ms Angelica Hipa, a laboratory scientist who has qualified from the Fiji school of medicine with the bachelors in medical laboratory sciences in 2016, and started working at the hospital in February 2016. She is knowledgeable and has theory background on TB testing, however is yet to come across a sputum sample requested for AFB/ TB investigations. She performs all other laboratory tests on island and is also responsible for phlebotomy. Her predecessor was an expatriate employee who is now employed by the public health unit, and is able to provide leave cover when needed. Staff training and competency log for TB [Annex 6] was introduced, and

Ms Hipa was taken through all tasks for the TB investigation. This must be used for any future training of staff and to assess competency.

Given the low number of cases, it is critical that all sputum samples requiring AFB smear testing is also referred to LabPLUS under the LTA contract for Niue for GeneXpert testing and confirmation. The limited number of samples tested for AFB on island is not enough for staff to maintain competency.

The following recommendations are for this section:

- Ensure completion of SOP's for processing sputum samples using the templates provided.
- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training, and for refresher training.
- *Send all suspect TB sputum samples for laboratory investigations to the reference laboratory for testing, under the UNDP global fund LTA.*

Specimen Processing and Health and Safety

All samples received in the laboratory are registered in the log book, which captures the assigned laboratory number (this is recorded on the form by the laboratory when the specimen is received), date of receipt and collection, description of sputum, patient's full name, gender, age or DOB, treatment unit and location, and episode type: diagnosis or follow-up specimen type, allocation for smear test results and the date results are being reported including space for the technician to sign their names when the results have been entered. The register captures information as per WHO guidelines.

Adequate handwashing basin, with soap is available. There is only one laboratory coat, personally owned by the staff for use. The hospital laundry does not wash this laboratory coat. Only one size of laboratory gloves was available, and is not the correct size for staff. Health and safety audit was carried out for the laboratory using the WHO LQMS Handbook guide checklist [Annex 8]. 70% alcohol is used as disinfection. Bleach was also recommended for use and staff was advised on how to achieve a 1% concentration of chlorine solution to use as disinfection solution, which must be prepared fresh every second day.

Since September 2016, the hospital is using the hospital information system (HIS) – MedTech, as a patient management tool. All laboratory tests are ordered electronically and results are entered in the system by the laboratory staff. The request form are generated electronically and used to manage patient data. This is not a complete laboratory information systems as results are still recorded manually by staff.

Mantoux tuberculin skin test "tuberculin vial's" are now available at the hospital, supplied by the UNDP GF programme. Screening for latent TB will be offered to staff in the near future. The public health unit needs to develop a protocol for testing to be used by hospital staff, using the recommendations provided by UNDP and WHO. It also needs to have a procedure in place for any positive Mantoux tuberculin skin test which can guide the physician on latent TB evaluation.

Recommendations:

- Purchase correct personal protective equipment (PPE) for use lab coats, correct glove size.
- Wear closed footwear and gloves when performing diagnostic tests.
- The reusable PPEs must be washed at the hospital, and not taken home to be cleaned.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant areas such as fire/ safety drills etc. [Annex 8].
- Prepare 1% chlorine solution for disinfectant use with cleaning up specimen spills.
- Public health to establish protocols and procedures for Mantoux tuberculin test, including procedures for any positive test result.

Consumables and Reagents Inventory and Ordering/Receiving of Supplies

The laboratory still struggles with delayed delivery and stock outs for laboratory consumables and reagents. A more robust ordering system needs to be put in place, and must be worked on with the hospital administration office, who authorise payment for supplies. A good stock card system has been implemented to keep track of laboratory inventory, so orders can be placed in time.

For TB consumables, the laboratory will only use the following materials: Sterile containers for sputum collection, biohazard bags for specimens, microscope slides, applicator sticks or sterile loops, and shipper packs for biological substance. These items do not require separate procurement and are covered by overall laboratory procurement, expect for prepared ZN stains kits which are purchased from Thermofisher Scientific or Fort Richard - NZ. The current set of ZN stain for AFB smear needs to be replaced as these expired in 2014.

Recommendations include:

- Stock take to carried out every month as per work plan [Annex 7].
- Set up a robust procurement system to ensure there are no stock outs and review invoice payment process currently in place.
- Purchase prepared ZN stains to replace the expired stock.

Preparation and Storage of Reagents

The laboratory does not prepare any reagents and stains for AFB. The ZN staining kit for AFB has been purchased pre made, which have previously been purchased from Thermofisher Scientific (expired in 2014) and Fort Richard (expired in 2011). Storage is adequate, and all reagents are stored in the dark, in the cupboards under the sink.

Stain's which expired in 2014 were used to carry out staining on control slides. Technician was taken through the smear preparation and staining procedure. Carbon Fuchsin concentration is half of what has been recommended by the TB handbook so adjustments were made to the staining procedure. (5min to 10 min with CF, 3mins to 5mins for decolouriser, and counterstain from 30sec to 3min. There is no Bunsen burner available therefore cotton wool dumbed with ethanol was used. 11 unused control slides were provide to the laboratory for future use.

Recommendations include:

- Procure- slide holders, over sink slide rack, a spirit burner or Bunsen burner
- Purchase a new set of ZN stain kit.

Management of Infectious and Laboratory Waste

All biological wastes for the laboratory are discarded in a discard bucket with a biohazard bag liner . These bags are then incinerated by the hospital biological rubbish disposable unit. The biological hazard bags are in stock. A printed and electronic copy of the WHO Tuberculosis Laboratory Biosafety Manual was shared with the laboratory for reference use. There are no recommendations under this section.

EQA Principles, Blinded Smear Rechecking and Panel Testing

The EQA principles was explained to the Ms Hipa and the importance of actively participating in the EQA programme was impressed upon. Niue Foou Hospital's laboratory's reference laboratory is LabPLUS, Auckland Hospital, New Zealand. This arrangement covered by the long term agreement (LTA) with the Pacific TB Laboratory Initiative (PATLAB) participating laboratories which provide EQA and direct laboratory support to the national TB Laboratories as a part of the Global Fund HIV/TB grant implementation in Western Pacific Region, organised by UNDP.

LabPLUS provides the relevant EQA services to Niue Foou laboratory which includes blind smear rechecking, and panel tests. Due to the limited number of cases, no blind smear testing has been carried out in the past. The work

plan [Annex 7] incorporates the dates for BSR dispatches, and Ms Hipa has been encouraged to complete the exercise for record keeping purposes. Last panel test slides received by the laboratory was in 2014 from LabPLUS. LabPLUS has confirmed that a set of panel slides will be sent to Niue this year. Quarterly report templates were customised to include documentation ID to make it a "controlled document" for use by the laboratory.

The public health officers, hospital medical superintendent and the laboratory scientist have all indicated that they would prefer an annual supervisory visit as part of the EQA programme, and were very appreciative of this timely visit.

Recommendations for EQA include:

- Participate in BSR when applicable.
- Contact LabPLUS for panel tests, and start participating in this EQA programme.

Increasing Sample Numbers Tested in the Laboratory

Very few samples have been received by the laboratory for TB investigations in the past. A meeting was organised with the Public Health Unit and the charge nurse. The sputum collection procedures from the TB Handbook was shared, and it was advised that the placards of the "TB cough check – specimen collection" procedures (given to both the public health team and the laboratory during the 2016 TB meeting in Nadi, Fiji) must be placed in the isolation ward and in the general specimen collection areas.

Patient information section was highlighted in the TB handbook and these should be used by the charge nurse and the public health team to train other nursing staff on giving correct instructions to patients to ensure good quality specimens are collected. Electronic copies of these information was given to Ms Hipa, to be shared with the public health staff.

The laboratory has been advised to refer all sputum samples to LabPLUS for further testing, regardless of the ZN smear result. This will be accepted for testing, as confirmed by LabPLUS and a protocol was shared with staff for these procedures. The SOP provided by UNDP GF for sending samples to reference laboratory was shared, and the procedures were explained to staff.

Recommendations include:

- Provide training session to nursing staff and any other medical staff on collection of good quality specimens (a refresher to be included in the hospitals continuous medical education sessions on an annual basis due).
- Displaying collection placards in the relevant sections of the hospital (wards and phlebotomy area).
- Send all suspect TB sputum samples for laboratory investigations to the reference laboratory for testing, under the UNDP global fund LTA.

Advice and On-site Coaching on Gaps Identified

Currently there is no updated SOP manual available for the laboratory for all its procedures. All documentation in the laboratory were drafted in 2011. Staff use the TB handbook and staining outtakes to perform tests, and procedures outlined in these documents have been followed. Outtakes from these documents are stuck on walls for easy user reference, which was reviewed during this visit.

Outline of a number of TB SOP documents have been shared with the laboratory and all documents drafted for the laboratory was given to Ms Hipa on a USB drive. The documents were created in accordance with the ISO 15189 medical laboratory international standards to eventually prepare the laboratory to seek accreditation. A table of contents was created for this SOP manual and for those documents which were not drafted, template examples were given electronically for adaptation into the laboratories own documents. Timeline was established for the completion of the SOP's and the PPTC will be able to guide the laboratory and provide remote assistance in its development. The action plan [Annex 7] outlines the timeframe allocated to SOP development.

A presentation was given to both Ms Hipa and Ms Manu (previous laboratory technician) Presentation contents included background on TB disease, latent TB vs active TB cases, Global and regional TB rates, TB diagnosis in

laboratory – AFB smear's, sputum specimen quality, acceptance and rejection criteria's, method on performing AFB smear's, reading and reporting AFB smear results, GeneXpert technology, AFB smear's vs GeneXpert.

The Public health team and the laboratory had also requested for information on laboratory accreditation. The audit document which the PPTC uses for its ISO15189 accreditation assessment (based on the "WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region") was shared with the laboratory staff, and advise was offered on how to approach accreditation. The laboratory will need to conduct an internal assessment or request for an external party to carry out an external assessment to identify the gaps in service and any deficiencies under the international standards.

Key consideration must be given to facility and laboratory accommodation (highlighted in this report), documentation for all procedures including the completion of the laboratory quality manual - customised to Niue Foou Hospital setting, participation in the EQA programme for all tests, performing regular internal quality controls on all tests, maintaining regular stock supplies and reagents for testing, carrying out preventative maintenance and having a service contracts for laboratory analysers and equipment's etc. All of these are covered in the audit document shared with the staff.

While the laboratory is adequately staffed, if quality improvements are to be made to reach accreditation status, another staff should be contracted for a fixed period of time to assist in the compilation of documentations, and in the implementation of a quality management system.

Challenges faced with Specimens

There are no technical issues with specimens for TB investigation. The laboratory has only processed 19 sputum samples since 2012. The quality of samples have been reasonably good, with majority of samples being muco-purulent or blood stained. The nursing staff however need to be reminded on the specimen requirements, and on good quality collection protocols as mentioned earlier. Specimen acceptance and rejection criteria has been created to implement rejection of samples guidelines as per TB handbook.

Recommendations include:

- Educating collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Implementation of the specimen acceptance and rejection criteria, and making the nursing staff aware of this policy. – this criteria can be modified to incorporate all of the specimen types received for laboratory tests.

Summary

The summary of all recommendations are listed below. The laboratory staff together with the public health staff must modify the current work plan to incorporate the recommendations listed in this report. The key recommendations include:

- Allocating a storage area for the laboratory supplies to avoid clutter in the analysis area and to allow for better work flow.
- Purchase of a high stool with adjustable height for Microscope slide reading for a better egronomical practise.
- Increase ventilation in the analysis area as this is an biohazard risk for staff.
- Maintenance logs must be created for routine medical analysers and tasks followed through (templates have been shared).
- All equipment and facilities document to be filed in the department SOP as per the shared outline.
- Explore connecting all laboratory equipment's and lighting to the backup power supply, so that work can still be carried out by laboratory staff during power outages and emergency situations.
- Ensure completion of SOPs for processing sputum samples using the templates provided.

- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training.
- Purchase correct PPE for use lab coats, correct glove size, and wear closed footwear and gloves when performing diagnostic tests.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant areas such as fire/ safety drills etc. [Annex 8].
- Public health to establish protocols and procedures for Mantoux tuberculin test, including procedures for any positive test result.
- Set up a robust procurement system to ensure there are no stock outs and review invoice payment process currently in place.
- Purchase prepared ZN stains to replace the expired stock.
- Participate in BSR when applicable, and contact LabPlus for panel tests, and start participating in this EQA programme.
- Provide training session to nursing staff and any other medical staff on collection of good quality specimens (a refresher continuous medical education session to be provided on an annual basis due to limited cases).
- Displaying collection placards in the relevant sections of the hospital (wards and phlebotomy area).
- Send all suspect TB sputum samples for laboratory investigations to the reference laboratory for testing, under the UNDP global fund LTA.
- Implementation of the specimen acceptance and rejection criteria, and making the nursing staff aware of this policy.

Conclusion

The laboratory at Niue Foou Hospital is staffed appropriately given their workload. Very little TB suspect cases are identified on the island, with limited specimens tested for AFB, given the low incidence rates. It is imperative that staff competency is retained for any future cases, and this can be managed by panel test EQA. Control slides must be stained with any patient samples, and all suspected TB sputum samples for laboratory investigations must be referred to the reference laboratory for testing, under the UNDP global fund LTA.

The laboratory must continue to participate in the EQA programmes for its laboratory tests, and IQC procedures must be implemented for all tests performed. The PPTC can remotely guide the laboratory in fulfilling the above recommendations, where needed. Given the workload and the test menu of the laboratory, I am confident that it can make the necessary improvements and seek external audit for accreditation assessment in the near future.

Acknowledgments

My sincere thanks to the staff at Niue Foou Hospital, the Public Health Team, and UNDP GF Programme Management staff for your valuable contributions and hospitality shown during this visit.

Samoa TB Laboratory Assessment and Evaluation Report

Background

The PPTC has worked with Samoa for a number of years in its capacity as an External Quality Assurance programme provider across 4 scientific disciplines, also on various visits to strengthen Medical Laboratory services towards accreditation standards and lastly assistance in providing specialised training and education in the medical sciences. This mission however, was specifically for TB technical support and assistance in line with the Pacific TB initiative (PATLAB) supervisory network across the Pacific. LabPlus Auckland is the supervisory centre for specialist TB referred tests. The PPTC was responsible for the last TB visit and assessment in 2015, carried out on behalf of LabPlus Auckland and W.H.O.

Samoa has a population of 196,600 in 2016 with the incidence of TB estimated around 8.0 per 100,000*. In 2016 ,13 cases were recorded with 19 cases in 2015. It is a low burden country with incidents of MDR-TB and HIV related risk at very low or extremely rare levels . Statistics for 2017 upto mid-March show, 2 positives from 77 specimens processed through the GeneXpert . No Rifampicin resistance has been recorded to date.

The TB Laboratory is incorporated into the Microbiology facility although it is located in a separate purpose built room as seen in the photos at the end of this report. Up to 3 staff may be rostered in Microbiology and between them, one will be responsible for the TB section. There has been a change over the last 6 months where previously 1 senior TB Technician was permanently placed in the TB laboratory. Mr Pati Lale, retired in late 2016 with over 25 years experience. A further 6 technicians at different stages of training are on rotation through the Microbiology department and along with the Micro HOD participated in the training sessions in this workshop. Prior to October 2016, only TB microscopy was carried out in the Laboratory with positive cases being referred to LabPlus Auckland reference laboratory. A new Cepheid GeneXpert PCR analyser was introduced to the department and has been operational since March 2016.

Executive Summary

This onsite TB EQA evaluation visit was very successful in enhancing specific technical support and assistance to Samoa and raising the profile of TB analysis which regretfully appears to have lapsed over recent months. It was very timely and well appreciated due to the recent addition of new staff to the laboratory services and the retirement of the long serving TB Technician. The previous TB evaluation visit was carried out in March 2015 also by the PPTC so this assessment visit was good for continuity and follow-up of earlier recommendations.

The Laboratory operates very well and has progressed rapidly over the last 5 years in essential quality principles and structured operational procedures. Participation in the TB EQA programme however has had an obvious gap for last year and Microbiology therefore received a timely boost towards its accreditation goals in the form of on-site assessment and evaluation audits providing a complete quality revision for the TB section.

Significant strengthening of the TB EQA programme occurred with coordinated activities being aligned with the Reference Laboratory LabPlus Auckland. This included collating Quarterly Workload Statistics, referring positive samples that require specialist testing, referring quarterly slide dispatches for rechecking and the return sending out of panel tests from the reference laboratory to Samoa. An annual workplan of these activities was created as a guide.

The Microbiology section was found to be vulnerable when covering the department evenly in expertise and experience over shifts, weekends and after-hours. This was largely due to the demanding staff roster which saw senior Microbiology staff not on-site for a portion of the week and trainees responsible for the section. This issue

was partially addressed with a time of valuable refresher training to staff, coaching in technical skills and the explaining of TB procedures for trainees and qualified staff provided on this visit.

The week-long workshop was also an opportunity to liaise with the healthcare workers in the NTP team. This enabled them to be informed of the Laboratory assessment outcome, communicate the impact of new developments like the GeneXpert and help emphasise the importance of sputa collection and the avoidance of poor quality samples.

Overall the visit was a great success, was well received and fulfilled all the requirements detailed in the terms of reference. Continued liaison between Laboratory, Physicians and NTP members is still required to strengthen the testing algorithms and policies PCR technology has introduced and impacted upon Samoa .

Activities

Audit of TB Section

The audit of the TB Section was carried out using the WHO DOTS programme checklist and questionnaire including the 'On-site Evaluation Report' and 'Self- Assessment checklist'. These have been modified to include GeneXpert operational procedures introduced in 2016 to Samoa. The TB section performed well with strengths being its good, efficient order around the GeneXpert testing, specimen listing and clarity in the PC TB register, and a good communication network between NTP team members and Laboratory. The microscopy and stain preparation section was still done very well , although less frequently than previously practiced.

Summary of self – assessment checklist and evaluation points:

- Cooling and ventilation required in TB room, air conditioning unit recommended.
- Need to consider locking Laboratory after hours.
- Training log for TB training needs update and more consistent staff assessments .
- New TB SOP manual is about to be released.
- Book version of Lab register has been re-instated in addition to PC version.
- Equipment service records need to be established with maintenance records improved.
- Biosafety Cabinet is not working, needing replacement bulbs, HEPA filters and Microscope set up in TB room needs ergonomic improvements to enable proper seating position.
- The Leica microscope drifts in and out of focus. A Leica specialist may be required.
- EQA programme for TB has been badly neglected and needs attention in all 4 components. BSR, Quarterly reports, GeneXpert stats, Panel test dispatches from LabPlus
- Refreshed reagents and better labelling on bottles is required.
- Results of control slides need to be recorded in the register.
- Positive smear reports need to be confirmed by 2 people to verify the result.
- The need to refer Positive samples through to the Reference lab needs to be followed.
- Daily housekeeping/cleaning schedule needs implementing on the GeneXpert.

The findings are as follows:

- Facilities: The present TB Laboratory is a rectangular side room adjacent to Microbiology and opening into the larger laboratory work area. It is small and confined with a Biohazard cabinet occupying one end with a workbench, staining sink and microscope filling up the outside facing wall and window. Ideally it is suited for 2 people. It can naturally be very hot with direct sunlight streaming in and with no air conditioning unit or ventilation operating apart from a floor fan and the large windows having to be opened. The training session photos depicted in Annex 7 where taken in the TB room.

  The state of the TB room upon arriving, was unfortunately an appalling mess and not fit for a laboratory.

  The room was littered with insects, dirt and lizard droppings across the floor, bench and window sills, showing obvious signs it had been neglected since Pati's departure in Nov 2016, over 3 months earlier.

Also of impact in utilising this room was the total reliance on the GeneXpert placed in Microbiology, for TB diagnostic tests with, as expected, a dramatic drop in AFB smears occurring. This factor encouraged the TB room to be ignored unless it was absolutely necessary. Many specimen slides were not prepared during the time following Pati's departure.

A major clean-up was called for the whole room and a stop put to the ants nest erupting from a large crack in the wall. The floors were scrubbed, benches and the cabinet cleaned, microscopes cleaned and aligned correctly and the ant nest sealed over so that the room resembled its former glory.

- *Domestic cleaners are required in the Laboratory including the TB section to maintain the facility as a sterile, infectious - free working environment. Sections of the Laboratory are poorly cleaned and maintained.*

- Two Biohazard Safety Cabinets are present in Microbiology and TB department but regretfully have not been certified and serviced for some years. This laboratory is a Grade 1 level TB facility meaning that low hazard risk activities like smear preparation and GeneXpert analysis are practised and where Biosafety Cabinets are preferred but not essential requirements. However for BSC's to be used appropriately they need to be certified annually and checked for effective performance. The TB BSC needs bulb replacements, UV light, HEPA filters and performance checks to make it safe for operations.
- *Both BSC Cabinets in Microbiology and TB sections need annual certification and performance checks.*

- TB Register: Recording and reporting in the TB Register book had stopped and phased out in favour of the specimen register now provided on the GeneXpert PC. The problem with the PC listing however , was that there was no entry for AFB smear results, regardless if they were performed or not to confirm an Xpert result.

  It was decided to re-instate the TB register book in conjunction with the computer listing so that 2 points of reference could be used to track reported TB results. The TB book would have both AFB microscopy and GeneXpert results listed, whereas the PC listing was only for PCR analysis with no microscopy. The TB book could be mobile, regularly updated with incoming specimens but mostly located in the TB section therefore promoting the continuation of microscopy practices. Having the register in two forms means the book is always available if the PC is shutdown as only one PC is operating for the whole Microbiology section.

  The specimen lab sequence number would also now be generated from the TB register book before being transposed to the computer PC listing. This helps to avoid different sequential numbers from the two registers being in use and confusing specimen labelling.

  All non-pulmonary TB specimens are recorded in both the PCR Register and TB book register where the AFB smear result will now accompany it. The frequency of QC slides was also looked for and now re-added in the TB book. The storage of slides after analysis has also now been arranged for storage in numerical order and will be operational for the Q2 BSR finishing late June 2017.
- *It was recommended that the TB Register book be re-instated as a record of both AFB microscopy and GeneXpert results. It would supplement the computer PC register of specimen results, which does not include the microscopy , and is attached to the GeneXpert analyser.*

- Technical Staff: The Laboratory has been through staff changes in 2016 which resulted in some disruption and mis- communication through the transition time particularly in TB EQA processes, reporting and analysis responsibilities within Microbiology. The previous TB technician position has now been merged into the pool of Microbiology staff, most of whom are multi-skilled and rotate through Biochemistry, Haematology, Blood Transfusion along with TB / Microbiology. Three of the 4 General Microbiology staff were included in GeneXpert training when it was installed in 2016. However the staff were lacking confidence in TB microscopy and smear reporting prior to this visit as very few AFB stains had been performed over the previous 12 months. Demonstrations of the ZN staining method were carried out for the trainees using commercial QC positive slides. The trainees then followed with staining and interpretation scoring to compare results. The TB Laboratory Training record (Annex 5) was developed for the 7 participants so that we could work our way through each listed skill requirement to have it completed by the final day and hopefully restore confidence in the departments processes.
- *The reporting of any Positive AFB smear should be confirmed by a second staff member and signed accordingly.*
- *The TB Training record should be refreshed in 6 months time with the requirement that every staff member has their record signed off and reviewed by a second supervising staff member.*

- Staff Training records: The Lab Training and Competency record, a larger document than the TB Training sheet, has now been upgraded to include more detailed TB related skills and has been signed off for the 7 staff participating in the TB workshop. These department training records will continue to be supervised and signed off by Makerita as trainees are rotated through TB and Microbiology duties. An additional section was added for the GeneXpert PCR analyser in the Training and Competency Record. This is the full Laboratory competency log that covers the wider laboratory disciplines and has compulsory sections for staff working after-hours and weekends.

  The TB Workshop Training record, which was mentioned previously, is based on the Pacific Island TB Handbook and WHO GeneXpert information. It was introduced during the week as a TB training record to supplement the existing Staff competency and Training files. This log requires supervisor review or sign off every 6 months and creates a stronger and more relevant systematic training programme only for the TB section within Microbiology.
- *The Lab Training and Competency record now with specific amendments for the TB section, will need to be utilised regularly for the Microbiology rotating staff. This is different from the TB record just recently created from the workshop and mentioned above.*
- Stain Reagents: Stain stocks were adequate and available but need refreshing as they are near expiry dates and will eventually fail QC to force there replacement. The stock bottles will continue to require filtering and appropriate QC before use. Relabelling the reagents would be helpful. During the course of the week a number of stains were performed that were very acceptable and clear showing that the stain quality is still of a good standard. The time between ordering of supplies and eventual delivery doesn't appear to be a problem.
- *A commercial ZN staining kit should be ordered now in anticipation of a long delivery time.*
- *It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
- *A source of commercial QC slides is being looked into. This would enable more frequent QC usage.*
- EQA Calendar: A year calendar has been developed for the department and included in the Quality Manual to outline the TB EQA schedule and activity workplan expected for 2017/2018.
- *It is recommended the Laboratory follow this timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*

Labelling on the frosted slides was neat and clear with the TB register number/ sequence in dark pencil.

- Microscopes: Two available were of good quality. An Olympus BX41 and Leica DM 2000. Both were clean, aligned properly and in good order although the Leica had a tendency to drift off the fine focus setting. The fluorescent capability of the Leica was not required. However, no spare bulbs of the right wattage were available.

  The ergonomic seating position when at the Microscope is not ideal. Removing the cupboard door from the adjacent bench unit is recommended to allow better comfort whilst looking at smears.
- *Spare bulbs are required for the Olympus and Leica microscopes. Philips 6V 20 watt size.*
- *It is suggested removing the cupboard door by the Microscope will enable a more ergonomic sitting position when reading AFB smears.*

Positive specimens recorded in the register were graded for quantity in line with the scoring on Page 25 of Pacific Island TB Handbook. Staff were well aware of the grading score required when reporting a Positive AFB smear and its correlation to the GeneXpert result.

External Quality Assessment

LabPlus Auckland undertakes the Blinded slide Re-checking (BSR), EQA reports and has done since 2011, covering the role as Samoa's reference centre for 20 years. In previous years TTM Laboratory had built up a good EQA performance record with regular participation and submitting of BSR slides for checking. However since the arrival of the GeneXpert in March 2016 and the corresponding drop off in number of AFB smears analysed, the TB EQA programme appeared to disintegrate . No EQA reports or Quarterly stats were submitted for all of 2016, leaving a

large gap. The retirement of the long standing TB Technician in November 2016 made the situation worse as EQA information was not passed onto Microbiology staff regarding the continuing programme requirements. Up until November 2016, AFB smears were at least made and scored, whereas after November, no AFB stains were prepared from specimens but substituted totally by the GeneXpert result.

In an effort to restore microscopy skills back into the TB EQA programme and restore the necessity of EQA overall, the preparation of AFB smears was re-established on all samples prior to them being processed on the GeneXpert. This enabled the slides to be stained and reported on later, in batches, to follow after the Xpert result. The TB Register book also had to be brought back as the primary result record sheet for both AFB smear result and GeneXpert result, as this is the source of BSR slide dispatches and needs to correlate PCR and Microscopy.

No slides could be collected for the Q1 2017 BSR allocation because there were less than 5 available. The Q1 slides and reports are not due until the end of March.

The TB EQA (PATLAB) programme has a number of components that needed to be re-established.

a. A consultant visit for assessment and evaluation.
b. Technical Quarterly workload Reports for Microscopy (AFB smears) due March,June,Sept,Dec
c. Quarterly GeneXpert workload report to be sent to LabPlus.
d. Quarterly Blind Slide Review dispatches to be sent to LabPlus.
e. Copy of TB register to accompany BSR dispatches
f. Unstained Panel slides sent from LabPlus Auckland to Samoa for reporting on.(Yearly)

Positive smear sputum samples may need to be considered for referral to LabPlus for culture and DST, particularly if they are suspected MDR samples. Smear Positive specimens that are MTB/RIF negative on the GeneXpert however do not need to be sent off shore. To date, only a few of the 13 reported positives in 2016 had been referred as there was no Rifampicin resistance detected from the GeneXpert screen. The staff were uncertain about the notification of positives to the reference laboratory as well as the conditions indicated that referred specimens needed to fulfil. More frequent communication between TTM and LabPlus is needed to enforce this.

A Blind unstained Panel test of slides was due to arrive in Samoa in from LabPlus in April, for staining and reporting on. Previous panels sent in 2015 had a good response and accuracy rate reported from Samoa. Other forms of EQA such as the self assessment questionnaire, on-site assessment and training sessions from a Technical advisor are relatively simple exercises to be performed and are now expected to be carried out annually.

The PPTC is in a good position to follow-up the TB activities established from this visit at least twice before the end of 2017 and monitor the staff training records. An EQA operating procedure summarising all the EQA activities and purposes has been drafted and included in the SOP Manual during this visit.

Recommendations for EQA include:

- *Prepare for first Blind slide review dispatch at the end of March (Q1 Jan- Mar 2017).*
- *Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of March 2017.*
- *Report on and return the panel slides sent by LabPlus Auckland (April 2017)as a valuable EQA exercise.*
- *Discuss with Reference lab future provision of EQA for GeneXpert.*

Microscopy and GeneXpert correlation

i. A hands-on training session for smear preparation, staining technique and microscopy reporting was very helpful for the staff. QC slides of both Positive and negative examples were used. Overall the stain quality was very good, the microscopy interpretation was accurate and the scoring or quantifying of positives, good. All 6 participants showed they were very capable in the process preparation and on reporting TB microscopy slides although more experience with true specimens would be of continuing benefit.
ii. 4 staff were previously trained by Cepheid Inc in the GeneXpert operations when it was installed in March 2016. 3 staff now remained. It was recommended to prepare AFB slide smears prior to adding lysing buffer

to the GeneXpert specimen and in this way ensuring a slide was prepared for each specimen received. Xpert testing algorithm was based on WHO recommendations.

(Xpert MTB/RIF Implementation manual. WHO).*

iv. Some clarification around the algorithms was needed as staff were unsure how to best utilise the Xpert technology . The GeneXpert was used as the first line diagnostic test for all body fluids, sputum samples and aspirates, followed by the ZN stain later. Treatment follow up specimens only received an AFB smear. Samoa appeared to have abundant stock of cartridges, with good expiry, adequate enough to cover workload, so this approach was recommended.

v. A maintenance schedule created from Cepheid was re-introduced and expected to be signed off on daily .

- *Preventative maintenance schedule to be followed and signed on the GeneXpert daily.*
- *Medical Staff, NTP team and Laboratory representatives to clarify and establish what diagnostic algorithm is best suited for Samoa and the raised need to have corresponding AFB smears recorded alongside GeneXpert result.*

Workplace Safety

i. The TB Laboratory is restricted to reporting microscopy on sputum samples ,body fluids and GeneXpert PCR , therefore is regarded as a low risk environment provided it is performed by trained staff using standard procedures. It has already been noted that the Biological Safety Cabinet, the primary equipment to contain TB aerosols urgently requires certification and checks on performance. Specimen smears were being prepared in the cabinet and GeneXpert cartridges inoculated.

ii. Adequate Personnel Protective equipment (PPE) was available in the form of gloves, laboratory gowns, masks (although not always necessary), closed shoes worn. Other recommended safety practices were being followed such as using applicator sticks for slide preparation, strong Hypochlorite or Chlorohexidine disinfectant in use, good Biohazard waste disposal containers and autoclave operation . The spirit burner flame was being used to heat slides during the staining and initial fixing which was adequate and served to reduce the need for the gas cylinder having to be moved between rooms.

iii. The occupational Health and Safety status for the staff is minimal. Mantoux's are not available to the staff, nor Quantiferon Gold, leaving annual chest x-ray as one of the few staff health monitoring tools to consider.

- *It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Technicians who supervise the TB work.*

TB SOP Manual and documentation

i. The Standard Operating procedures for TB had been merged into general Microbiology SOP's so it was decided to re-establish a TB SOP manual with related worksheets, EQA templates, and methods. This was to help separate TB issues and raise the profile of TB operational processes away from general Microbiology. Rather than extract all the TB policies from the Microbiology folder, a second copy of relevant SOP's were integrated with new documents to compile the TB SOP 2017 version.

A significant number of SOP documents were created specifically for TB including Biosafety, Spillage, EQA requirements, Equipment servicing, Referral Laboratory information, AFB staining, diagnostic Algorithms and Training record log.

ii. The SOP documents are referenced from various WHO/ PATLAB TB publications and reviews of previous procedure notes.

iii. Biosafety for the TB laboratory has been addressed in a section of general laboratory hazards including waste disposal. Most of this information has been referenced from the WHO publication: Tuberculosis Laboratory Biosafety Manual 2012 and the Pacific Island TB Handbook.

- *Continue to complete GeneXpert operational SOP's, and finalise TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*

Summary

All EQA processes must be adhered to, to ensure the quality of results produced by the Microbiology Laboratory. Very little statistical information has been referred to the supervising Reference laboratory throughout 2016 and consequently this has been strongly addressed during this visit to restore the delivery of Quarterly reports review information. Currently the Laboratory is up-to-date according to 2017 EQA requirements.

Recommendations for EQA include:

- Prepare for first Blind slide review dispatch at the end of March (Q1 Jan- Mar 2017).
- Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of March 2017.
- Return panel test results to LabPlus Auckland.
- Discuss with Reference lab future provision of EQA for GeneXpert monitoring.

A summary of all the recommendations are listed below:

- *Domestic cleaners are required in the Laboratory including the TB section to maintain the facility as a sterile, infectious free working environment. Sections of the Laboratory are poorly cleaned and maintained.*
- *Both BSC Cabinets in Microbiology and TB sections need annual certification and performance checks.*
- *It was recommended that the TB Register book be re-instated as a record of both AFB microscopy and GeneXpert results. It would supplement the computer PC register of specimen results, which does not include the microscopy , and is attached to the GeneXpert analyser.*
- *The reporting of a Positive AFB smear should be confirmed by a 2nd staff member and signed .*
- *The TB Training record should be refreshed in 6 months time with the requirement that every staff member has their record signed off and reviewed by a second supervising staff member.*
- *The Lab Training and Competency record now with specific amendments for the TB section, will need to be utilised regularly for the Microbiology rotating staff. This is different from the TB record just recently created from the workshop and mentioned above.*
- *A commercial ZN staining kit should be ordered now in anticipation of a long delivery time.*
- *It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
- *A source of commercial QC slides is being looked into. This would enable more frequent QC usage.*
- *It is recommended the Laboratory follow the EQA Calendar timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*
- *Spare bulbs are required for the Olympus and Leica microscopes. Philips 6V 20 watt size.*
- *It is suggested removing the cupboard door by the Microscope will enable a more ergonomic sitting position when reading AFB smears.*
- *Preventative Maintenance schedule to be followed and signed on the GeneXpert daily.*
- *Medical Staff, NTP team and Laboratory representatives to clarify and establish what diagnostic algorithm is best suited for Samoa and the raised need to have corresponding AFB smears recorded alongside GeneXpert result.*
- *It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Technicians who supervise the TB work.*
- *Continue to complete GeneXpert operational SOP's, and finalise TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*
- *Medical Staff, NTP team and Laboratory representatives to clarify and establish what diagnostic algorithm is best suited for Samoa's population.*

Conclusion

The Laboratory is in a good position overall to continue improving its service expertise in the TB section. The training sessions and demonstrations were well received by the participants and have helped restore competence in skill as well as an overall understanding behind the necessity of TB EQA requirements. The department struggled with the technical impact of PCR in 2016 which led to areas of the TB EQA being neglected, thankfully competence has been restored for 2017 and better communication links with the Reference lab, LabPlus Auckland, will be significantly improved. The inclusion of a EQA calendar for the lab staff will be a trusty reminder for all. The NTP team are also now up to date with laboratory developments and have a good understanding of sample collection issues and their role in the labs EQA requirements.

The impact of the GeneXpert on workload is yet to be fully understood and still developing as a significant diagnostic tool. Any variation to the PATLAB testing algorithms is still to be discussed by the NTP team for approval. The low burden population of Samoa has some advantages regarding PCR technology, one being its utilisation to detect other diseases namely Chlamydia, HIV. The laboratory facilities are ideal to easily accommodate this.

The Q Manual documentation is well underway and in the process of being updated with new additions.

The development and completion of the TB Training record is an excellent step in the right direction to maintain skill levels, staff confidence and a solid training programme. The full laboratory Competency Log has now also been upgraded and includes the GeneXpert and TB operations. The challenge now lies with the trained technicians to practice and refresh their ability regularly and make it a well retained skill set.

The modern facilities, TB room and Biohazard Safety Cabinet need to be addressed in terms of certification of the BSC, air conditioning and general hygienic cleanliness especially the floor.

Finally, a big thank you to the staff at TTM Hospital Laboratory, the NTP team, UNDP Global Fund management unit staff for your valuable contributions in making this successful assessment visit be an enjoyable one and to the friendly administration and technical staff who hosted me for the week and looked after me.

Tonga TB Laboratory Assessment and Evaluation Report

Background

The PPTC has worked with Tonga since 1990 in the capacity of strengthening Medical Laboratory services and the specialised training and education of the technical workforce. This mission however, was specifically for TB technical support and assistance in line with the Pacific TB initiative (PATLAB) supervisory network across the Pacific. The last EQA-TB assessment of the laboratory service appears to have been in 2012 Mr Ross Vaughan (LabPlus Auckland), although no report was sited from this. The PPTC have also carried out less official audit activities over the TB laboratory since then in its role in promoting general laboratory accreditation standards.

Tonga has a current population of 106,000 with the incidence of TB estimated around 1.5 per 100,000*. It is a low burden community with rare incidents of MDR-TB and HIV related risk .The TB Laboratory is incorporated into 2 rooms making up the Microbiology facility and is manned by 2 senior Technologists and 2 trainee technicians. Until 2017, only TB microscopy was carried out in the Laboratory with positive cases being referred to the reference laboratory, LabPlus Auckland, for culture and further antibiotic susceptibility testing. A new Cepheid GeneXpert PCR analyser has been installed in December 2016 and as expected, is already impacting on the testing workload statistics and efficiencies within the service.

Executive Summary

This onsite Tb EQA evaluation visit was specifically for TB technical support and assistance. It was very timely and well appreciated due to the recent arrival of the GeneXpert PCR technology to the laboratory services and also the fact that a specific TB visit was last carried out in 2012.The Laboratory operates very well and has progressed rapidly over the last 5 years in essential quality principles,

personnel management training aspects and structured operational procedures. This has seen its advance towards international accreditation standards drawing closer to possible achievement by 2018. The Microbiology section therefore have received a timely boost from this visit towards its goal in the form of the on-site assessment and evaluation reviews being part of external quality assessment for TB laboratories.

Significant strengthening of the TB EQA programme occurred with coordinated activities being aligned with the Reference Laboratory LabPlus. This included collating Quarterly Workload Statistics, referring positive samples that require specialist testing, referring quarterly slide dispatches for rechecking and the return sending out of panel tests from the reference laboratory to Tonga. An annual workplan of these activities was created as a guide.

Considerable effort was also put into documentation improvements, the reviewing of standard operating procedures, TB Biosafety manuals and staff training competency records. Further work is required in this area as the operational impact of the GeneXpert is fully embraced by the department and covered in all the documented policies.

The Microbiology section experienced some staff turn over and disruptions in 2016 which left some gaps in expertise and experience, subsequently this visit provided valuable refresher training to the senior Technicians and coaching in technical skills and procedures for trainee staff.

The week long workshop was a successful opportunity to liaise with the healthcare workers in the NTP team ,to inform them of the Laboratory assessment outcome, communicate with them the impact of new developments like the GeneXpert and help emphasise the importance of sputa collection and the avoidance of poor quality samples.

Overall the visit was a great success, was well received and fulfilled all the requirements detailed in the terms of reference.

Activities

Audit of TB Section

The audit of the TB Section was carried out using the WHO DOTS programme checklist and questionnaire including the 'On-site Evaluation Report' and 'Self- Assessment checklist'. These have been modified to include GeneXpert operational procedures. Overall the section performed well with strength areas being good processes and systems in place, an adequate mix of expertise and experience amongst the staff and good communication links between the NTP team and Laboratory. The microscopy and stain preparation section was done very well and practicing at a good standard.

The findings are as follows:

- Facilities: The laboratory workplace area is well laid out ,clean and tidy, of a good size and adequate for the scope of testing and specimen workload. 2 rooms make up the Microbiology section with a second Safety cabinet secured in a small attached 3rd room compartment. The second room is a recent renovation with spacious bench space, storage shelves and houses most of the bulk equipment like incubators, autoclave, fridges and is suited for media preparation. Separate clean areas for paperwork and administration is limited by the necessity of 1x PC to be close to the main work bench area. The GeneXpert may be relocated into the 2nd room and alleviate space for a better defined office area here. The lighting also could be improved for the main culture plate reading area as no external windows are present. The microscope was in good order being cleaned and aligned correctly. It is fairly new and in good condition, Olympus BX41. The air conditioning units work well. The main problems are with the leaking air ventilation system dripping water at various pipping joints .The exposed pipping covering the ceiling has been a problem since the Laboratory moved into this facility a number of years ago. It poses a contamination risk and compromises the sterile clean environment required for Microbiology, particularly with new PCR DNA work, if suitable ceiling tiles are not inserted to isolate water damaged pipping from the laboratory environment.
- *Placement of ceiling tiles: It is recommended that all the ceiling water extraction pipes are repaired for Leakage and that ceiling tiles be inserted to separate these service pipes from the working environment creating a false ceiling.*
- Two Biohazard Safety Cabinets are in the department but regretfully have not been certified and serviced for some years. This laboratory is a Grade 1 level TB facility meaning that low hazard risk activities like smear preparation and GeneXpert analysis are practised and where BSCabinets are preferred but not essential requirements. However for BSC's to be used appropriately they need to be certified annually and checked for effective performance. A maintenance schedule has been developed to ensure regular testing and cleaning is practiced but rarely completed by staff.
- *It is strongly recommended that a BSC Air Certification company be arranged to fumigate and certify both the Microbiology and TB cabinets to be fit for service.*
- Recording and reporting in the TB Register is confusing and not always up to date, the problem being that 2 x registration books are in use with different sequential lab numbers being listed. All TB specimens are recorded in one Register with the final results and sputum per patient being recorded in a second book. GeneXpert results are now also recorded in the second "result notification book". The frequency of QC slides was evident and included in the register. The storage of slides after analysis has now been arranged in numerical order and a fresh system is in operation starting from Jan1, 2017.
- *Recording and Reporting in register book:*
  - *It is recommended that if 2 Register Books are to be used, the report book needs to carry over the exact same number as the original sequenced registration number.*
  - *The patient D.O.B. be included in the "Age" column as a better defined means of identification.*
- The Microbiology and TB section underwent staff changes in 2016/2017 which brought some disruption to the TB EQA processes, reporting and analysis responsibilities within Microbiology. Senisaleti has now

returned from study leave and has this year restored order and structure to the workflow. 2x Trainee Technicians, Atevalu Lino and Makamoeafi Vaai were present for the TB workshop but will now be rotating on to another section to be replaced by 2 x new faces. The Staff training and Competency record has now been upgraded to include TB related skills and brought up to date for the 4 staff participating in the TB workshop. The department training records will continue to be managed by Senisaleti with assistance from the Training officer Sitanilei and Senior Technician Filimone. Having sufficient staff with TB section capability will be under pressure for the next few months until the replacement Trainees come up to competency.

- *The Training and Competency record sheet specific for the TB section will need to be utilised regularly for the Microbiology rotating staff. A copy is attached in Annex 5.*
- Standard operating procedures and the TB documentation manual needs updating with additions to include the GeneXpert, EQA processes and modified Training log. These were identified in the checklist and have been expanded upon in more detail later in this report.
- Stain reagents were well stocked and organised, being made in-house and filtered appropriately. However, clear labelling of working bench regents is recommended with listed initials, date and QC approval needing to be made obvious. The time between ordering of supplies and eventual delivery continues to be a problem with some delayed shipments up to 3 months.
- Labelling was not always clear on the standard slides but much superior on frosted slides with the TB register number/ sequence in dark pencil.
- *It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
- Positive specimens recorded in the register need to be graded for quantity in line with the scoring on Pg 25 of Pacific Island TB Handbook. Recording a Positive is not adequate enough. This point was also expressed in the last Q3 BSR report.
- A year calendar has been developed for the department and included in the Quality Manual to outline the TB EQA schedule and activity workplan expected for 2017/2018. (Annex 5).
- *It is recommended the Laboratory follow this timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*

Summary of points from the On site Evaluation Audit

- Staff competency and training records for the TB section have been updated and now need to be practically implemented for all personnel.
- SOP's outlining operational steps for GeneXpert/ general Tb SOP's need further work and development.
- Ceiling Tiles are required for Microbiology section.
- Biohazard Safety Cabinet needs annual certification and performance check.
- Clear and consistent Registration book listings needed.
- Written specimen instructions could be provided to patients in sample collection clinic.
- Labelled slides for smears could include first four letters of surname plus registration number.
- 2017 Calendar for EQA should be followed as per schedule for reporting and slide dispatches.
- The requirement to refer positive samples through to the reference laboratory needs to continue.
- Stock and consumables are well supplied for the next 6 months.

External Quality Assessment

LabPlus Auckland undertakes the Blinded slide Re-checking (BSR) and has done so since 2011. The last shipment referred was Q3 in October 2016 where 3x Quarterly dispatches were sent in one dispatch, which is not a favourable situation for all parties concerned. It is understood from the Tonga NTP team that there was no funding for the postage shipment of these EQA slides so they were detained and batched together. This funding issue has been

resolved after a conversation with Dr Louse Fonua, Communicable Disease Medical Doctor ,and more diligence to send slides according to the expected calendar schedule will hopefully follow.

The Q4 2016 shipment along with copies of the Register book, Quarterly Reports and statistics was delivered in person to LabPlus Auckland on returning. The Q1 2017 slides and reports are not due until the end of March.

Included in the package was:

1. A copy of the TB Register pages for the period Q4 2016 (October – Dec 2016)
2. Technical Quarterly workload Reports or Statistic report for Q4 2016
3. Listed slides and reported results from Tonga to be checked in the Q4 2016 BSR dispatch.

Since late 2015/2016 there has been a distinct absence of Quarterly Workload Reports sent through to LabPlus along with no copy of the TB Register to verify those statistics. We can now report as a result of this visit that the TB laboratory is fully compliant and up to date with its EQA requirements in BSR, QWR and supplying Register copies.

Positive smear sputum samples are also expected to be referred to LabPlus for culture and DST. To date no specimens have been referred for 2016 although 4-5 positives have been recorded. This is partly due to staff not being aware of this requirement and the apparent lack of budget for postage cost as explained earlier.

A Blind unstained Panel test of slides is expected from LabPlus for staining and reporting on, later this year. Previous panels sent in 2015 did not have a good response rate from Tonga as they apparently were misplaced or never replied to by the previous TB Technician. Other forms of EQA such as the self assessment questionnaire, on-site assessment and training sessions from a Technical advisor are relatively simple exercises to be performed and are now expected to be carried out annually.

The PPTC is in a good position to follow-up the TB activities established from this visit at least twice before the end of 2017 and monitor the staff training records. An EQA operating procedure summarising all the EQA activities and purposes has been drafted and included in the SOP Manual during this visit.

Recommendations for EQA include:

- *Prepare for first Blind slide review dispatch at the end of March (Q1 Jan- Mar 2017).*
- *Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of March 2017.*
- *Contact LabPlus Auckland Reference Laboratory for expected arrival dates for unstained panel tests.*
- *Discuss with Reference lab future provision of EQA for GeneXpert.*

Technician Training

- A hands-on training session for smear preparation, staining technique and microscopy reporting was held with the staff. QC slides of both Positive and negative examples were used. Overall the stain quality was very good, the microscopy interpretation was accurate and the scoring or quantifying of positives, good. All 4 participants showed they were very capable in the process preparation and on reporting TB microscopy slides.
- 6 staff were previously trained by Cepheid Inc in the GeneXpert operations when it was installed in December 2016. 2 of those trainees have now moved out of the department leaving the other 4 members to resume testing duties. Four more samples were analysed during the workshop session with attention being made on machine maintenance, notification of the results to the requesting Physician, preparing slide smears prior to adding lysing buffer to the GeneXpert specimen and algorithms for diagnostic testing based on WHO recommendations. (* Xpert MTB/RIF Implimentation manual. WHO).
- Clarification around the algorithms was needed as staff were unsure how to best utilise the Xpert technology and the evidence suggesting it could be used as first line diagnostic test followed by the ZN stain later. Tonga was in the fortunate position of having abundant stock of cartridges, with good expiry, and adequate to cover workload, so this approach was recommended.
- A training record based on the Pacific Island TB Handbook information and GeneXpert information was added to the existing Staff competency and Training records. This log requires supervisor review or sign

off every 6 months and creates a stronger and more relevant systematic training programme for all the Microbiology staff.

Recommendations regarding Technician training.

- *Each staff member needs to be signed off on the TB Competency & Training record 6 monthly.*
- *Preventative Maintenance schedule to be followed and signed on the GeneXpert daily.*
- *Medical Staff, NTP team and Laboratory representatives to clarify and establish what diagnostic algorithm is best suited for Tonga's population.*

Workplace Safety

1. The TB Laboratory is restricted to microscopy on sputum samples ,body fluids and GeneXpert PCR, therefore is regarded as a low risk environment provided it is performed by trained staff using standard procedures. It has already been noted that the Biological Safety Cabinet, the primary equipment to contain TB aerosols urgently requires certification and checks on performance. Specimen smears were being prepared in the cabinet and GeneXpert cartridges inoculated.
2. Adequate Personnel Protective equipment (PPE) was available in the form of gloves, laboratory gowns, masks (although not always necessary), closed shoes worn. Other recommended safety practices were being followed such as using applicator sticks for slide preparation, strong Hypochlorite or Chlorohexidine disinfectant in use, good Biohazard waste disposal containers and autoclave operation . The Bunsen burner flame in the 2nd Cabinet needs to be replaced due to flame and gas problems. This is already being looked into for replacement.
3. The occupational Health and Safety status for the staff is non-existent. Mantoux's are not available to the staff, nor Quantiferon Gold, leaving annual chest x-ray as one of the few staff health monitoring tools to consider.

- *It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Senior Technicians who supervise the TB work.*

TB SOP Manual and documentation

- The Standard Operating procedures regarding the TB section appear to have been lost from previous years, so a fresh new approach was initiated to clarify processes, new technologies, staff records and requirements around EQA.
- A significant number of SOP documents were created specifically for the TB laboratory covering all its functions and associated worksheets included. Further work is required as most are in draft form. SOP's were prepared on Biosafety, Spillage, EQA requirements, Equipment servicing, Referral Laboratory information, AFB staining, diagnostic Algorithms and Training record log.
- The SOP documents are referenced from various WHO/ PATLAB TB publications and the review of previous procedure notes.
- Biosafety for the TB laboratory has been addressed in a section of the Quality Manual where procedures have been created to address general laboratory hazards including waste disposal Most of this information has been referenced from the WHO publication : Tuberculosis Laboratory Biosafety Manual 2012 and the Pacific Island TB Handbook.
- *Continue to complete GeneXpert operational SOP's, and finalise TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*

Summary

All EQA processes must be adhered to, to ensure the quality of results produced by the Microbiology Laboratory. Very little statistical information has been referred to the supervising Reference laboratory throughout 2016 and consequently this has been strongly addressed during this visit to the point of delivering Quarterly reports and slides for review, so that the Laboratory is up-to-date according to 2017 EQA requirements.

Recommendations for EQA include:

- Prepare for first Blind slide review dispatch at the end of March (Q1 Jan- Mar 2017).
- Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of March 2017.
- Contact LabPlus Auckland Reference Laboratory for expected arrival dates for unstained panel tests.
- Discuss with Reference lab future provision of EQA for GeneXpert monitoring.

A summary of all the recommendations are listed below

- Placement of ceiling tiles: It is recommended that all the ceiling water extraction pipes are repaired for Leakage and that ceiling tiles be inserted to separate these service pipes from the working environment creating a false ceiling.
- It is strongly recommended that a BSC Air Certification company be arranged to fumigate and certify both the Microbiology and TB cabinets to be fit for service.
- Recording and Reporting in register book:
  - It is recommended that if 2 Register Books are to be used, the report book needs to carry over the exact same number as the original sequenced registration number.
  - The patient D.O.B. be included in the "Age" column as a better defined means of identification.
- The Training and Competency record sheet specific for the TB section will need to be utilised regularly for the Microbiology rotating staff. A copy is attached in Annex 5.
- It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.
- It is recommended the Laboratory follow this timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.
- Each staff member needs to be signed off on the TB Competency & Training record 6 monthly.
- Preventative Maintenance schedule to be followed and signed on the GeneXpert daily.
- Medical Staff, NTP team and Laboratory representatives to clarify and establish what diagnostic algorithm is best suited for Tonga's population.
- It is recommended that some form of annual screening for TB exposure be adopted for the Microbiology Senior Technicians who supervise the TB work.
- Continue to complete GeneXpert operational SOP's, and finalise TB QM manual.
- Include Specimen acceptance and rejection criteria policy in TB QM for all staff to acknowledge.

Conclusion

The Laboratory is in a good position overall to continue improving its service expertise in the TB section. The training sessions and demonstrations were well received by the participants and have helped restore competence in skill as well as an overall understanding behind the necessity of TB EQA requirements. The department struggled with technical leadership in 2016 which led to areas of the TB EQA being neglected, thankfully competence has been restored for 2017 and better communication links with the Reference lab, LabPlus Auckland, will be significantly better. The inclusion of a EQA calendar for the lab staff will be a trusty reminder for all. The NTP team are also now up to date with laboratory developments and have a better understanding of sample collection issues and their role in the labs EQA requirements.

The impact of the GeneXpert on workload is yet to be fully understood and still developing as a significant diagnostic tool. Any variation to the PATLAB testing algorithms is still to be discussed by the NTP team for approval. The low burden population of Tonga has some advantages in the GeneXperts use, one being its utilisation to detect other diseases namely Chlamydia, HIV. The laboratory facilities are ideal to easily accommodate this. The Q Manual documentation is well underway and in the process of being updated with new additions.

The development and completion of the TB Training record is an excellent step in the right direction to maintain skill levels , staff confidence and a solid training programme. The challenge now lies with the trained technicians to practice and refresh their ability regularly and make it long term.

The refurbished facilities, TB room and Biohazard Safety Cabinet need to be addressed in terms of certification of the BSC, ventilation and repair of leaks from the overhead air piping, and minor equipment purchases like a burner for the cabinet to aid daily processes and practices. Many of these can be quickly addressed with minimal cost outlay.

Finally, a big thank you to the staff at Vaiola Hospital Laboratory, the NTP team, UNDP support team for your valuable contributions in making this successful assessment visit happen and to the friendly administration and technical staff who hosted me for the week and kept me well fed.

Tuvalu TB Laboratory Assessment and Evaluation Report

Background

The PPTC has worked with Tuvalu for a number of years in its capacity as an External Quality Assurance programme provider across 4 scientific disciplines, also on various visits to strengthen Medical Laboratory services towards accreditation standards and lastly assistance in providing specialised training and education in the scientific disciplines. This mission however, was specifically for TB technical support and assistance in line with the PacificTB initiative (PATLAB) supervisory network across the Pacific. LabPlus Auckland is the supervisory centre for specialist TB referred tests and have overseen the TB EQA activities since 2015. The last TB assessment visit however was carried out by the PPTC in March 2014, on behalf of the reference laboratory.

The nation of Tuvalu consists of 9 islands with a total population of around 10,100 (SPC 2016) of whom 4,500 reside on Funafuti Atoll. The NTP operates one DOTS centre on Funafuti based at the 50 bed Princess Margaret Hospital, the only hospital in the country. The hospital laboratory processes specimens for microscopy for acid-fast bacilli (AFB) and GeneXpert PCR analysis which has been operational since April 2016. No TB culture is performed but positive smears referred to LabPlus Auckland.

The incidence of TB estimated around 178 per 100,000*. In 2016, 17 positive specimens were recorded by either GeneXpert or microscopy equating to 10 patients .It is a low burden community with incidents of MDR-TB and HIV related risk at very low or extremely rare levels . The TB Laboratory is incorporated into the Microbiology facility and is predominantly manned by 1 Trainee Technician overseeing GeneXpert operations and AFB microscopy. A further 2 qualified Scientists and 1 trainee technician make up the full staff quota on rotation through the various departments and help cover after hours call work.

Executive Summary

This onsite TB EQA evaluation visit was very successful in enhancing specific technical support and assistance to Tuvalu. It was very timely and well appreciated due to previous staff changes in 2016 including the addition of 3 new staff to the laboratory services. Undoubtedly there has been a loss of expertise in Microbiology and TB areas since early 2016 but the current staff are rebuilding the skill base and determined to restore confidence and capacity. One senior staff member, Mr Felix Koakoa was the only remaining staff from the previous 2014 TB assessment.

The Laboratory operates from 2 separate buildings which presents a significant challenge across the service. The Microbiology section which was only recently repaired after flooding damage, has now been re-occupied and resumed testing for bacterial culture, staining and GeneXpert processing. However transiting from one building to another, staff supervision issues and general communication poise challenging problems to an otherwise efficiently working laboratory.

Participation in the TB EQA programme was also neglected in the last 18 months, making this visitation a very appropriate time for re-training and in the re-establishment of expected statistical reporting requirements. Microbiology received a timely boost towards long-term accreditation goals in the form of the on-site assessment and evaluation audits providing a frank and honest procedural review in the TB section.

Significant strengthening of the EQA programme occurred with coordinated activities being aligned with the Reference Laboratory LabPlus, Auckland. This included collating Quarterly Workload Statistics, referring positive samples from Tuvalu that require specialist testing, referring quarterly slide dispatches for rechecking and the return

sending out of panel tests from the reference laboratory to Tuvalu. An annual workplan calendar of these activities was created as a guide.

The Laboratory does have significant gaps in expertise and experience in TB processing particularly in microscopy. This has mostly developed since the arrival of the GeneXpert PCR technology and the tendency to rely solely on this machine. Microscopy was partially addressed with the valuable refresher training to senior Technicians and coaching in technical skills and procedures for trainees provided on this visit.

The week long workshop was also an opportunity to liaise with the NTP team but this did not eventuate as the TB Co-ordinator was on leave at the time. Laboratory staff were informed of the Laboratory assessment outcome, could observe first-hand the impact new developments like the GeneXpert were making on workflow and were

reminded to emphasise the importance of sputa collection and the avoidance of poor quality samples as a means to minimise Laboratory errors.

Overall the visit was a great success, was well received and fulfilled all the requirements detailed in the terms of reference. The Laboratory passed the assessment well but now needs regular strengthening and competency, personnel management and maintaining TB EQA performance.

Activities

Audit of TB Section

The audit of the TB Section was carried out using the WHO DOTS programme checklist and questionnaire including the 'On-site Evaluation Report' and 'Self- Assessment checklist'. These have been modified to include GeneXpert operational procedures introduced to Tuvalu in April 2016.The TB section performed well in the Audits mostly because of good structures and order previously established in 2014 carried over into 2017 and taught to the new staff members. The documentation around standard operating procedures needs significant updating and completion as does an organised and clear TB register that incorporates the GeneXpert results. Some strengths were the strong communication network existing between local NTP members and Laboratory along with the microscopy and stain preparation section which was re-activated, performed well during the course of the week and proved to be of a good standard to continue with.

Summary of Checklist Points:

- GeneXpert PCR is used as the primary diagnostic screen but AFB smears still need to be processed as a back up and as a means to maintain technical competence in Microscopy.
- UPS's are required for critical machines other than GeneXpert. Electrical supply is too unreliable.
- Tuvalu buys distilled water/deionised water because water is at a premium, filtration units are too expensive and distillation unit is too expedient on water consumption.
- Staff formal training on microscopy and establishing Training records will be addressed on this visit.
- EQA programme and workload reports did not occur for 2016, urgently need to be re-instated.
- Microscope manufacturers manual for CX31 Olympus would be helpful in the laboratory.
- TB Specimens being transported long distance need chilly bins or cold chain storage.
- The practice of 24 hour turn around time for TB microscopy should be enforced and monitored.
- Cleaning and disinfection schedule for equipment and GeneXpert needs to be signed off daily.
- A Standard Operating Procedures TB Manual needs attention and updating from 2014.
- Equipment maintenance records exist but need to be kept up to date.
- No written specimen rejection criteria SOP in lab.
- GeneXpert : Need to work on SOP manual apart from the manufacturers manual as a quick summary of Instructions.

The findings are as follows:

- Facilities: The Hospital Laboratory operates from 2 separate buildings divided by a vehicle driveway, which presents a significant challenge in providing a compact unified service in Tuvalu. The Microbiology section is housed in a relatively new facility which was only recently repaired after flooding damage, but has now been re-occupied and resumed testing for bacterial culture, staining and GeneXpert processing. However transiting from one building to another numerous times daily whilst carrying specimens or results can be a tedious exercise. Staff supervision issues, general communication issues across both sites and the unsupervised work of trainee staff poise challenging problems to an otherwise efficiently working laboratory.

  On arrival, the Laboratory in general was dirty, cluttered and untidy due to the fact the Microbiology room was yet to be re-instated as operational after undergoing flood damage repairs. A lot of storage items and consumables were compacted in the main lab in readiness for relocation. So over the following few days some extensive cleaning of equipment, scrubbing of floors, sinks and bench preparation work was carried out by the staff throughout both Laboratory rooms to re-instate them both as suitable working environments.

  The floor of both sites is still unacceptably dirty for a practicing Laboratory. A Cleaner needs to be brought in to mop and clean regularly the heavy traffic areas. The re-instated Microbiology section now has significant bench space, suitable lighting and storage cupboards to function well provided regular cleaning occurs and the roof remains water tight. The Biological safety cabinet, the GeneXpert machine, incubators and fridges are all well spaced with the microscope and staining sink in close proximity.
- *An efficient and regular cleaning roster is required to maintain sterile hygienic conditions in the Laboratory. Addressing the state of the floor should be a priority requiring urgent action.*

- Equipment: Three microscopes were present in the Laboratory, only one of which was in good order and operating well. A second Olympus CH model required immediate attention, cleaning and alignment to get it back up to scratch for AFB smears. The 3rd microscope was a non-functioning Nikon model that has now been removed and put into storage. The 2 Olympus models can now offer good service for Microbiology and Haematology needs.
- One Biohazard Safety Cabinet in the Microbiology department is maintained but is not certified for annual performance and efficiency checks. The local Biomedical staff however ,do carry out electrical safety and basic functionality at a low level but don't monitor bacterial fumigation and extraction steps. The Tuvalu Laboratory is a level 1 TB facility meaning that low hazard risk activities like smear preparation and GeneXpert analysis are carried out but where BS Cabinets are not essential requirements because culturing TB is not done. Nevertheless, BS Cabinets are preferred protective equipment to have. A UPS power unit should also be attached to the cabinet as a good practice. For BSC's to be used appropriately they need to be certified annually and checked for effective performance.
- *The Biohazard Safety Cabinet is in need of a performance efficiency check for annual certification.*
- *An Equipment Maintenance Record sheet should accompany every item of Microbiology equipment listing Model specifications, manufacturer contacts and preventative maintenance or service work carried out. The laboratory Balance, Microscope and Cabinet are included here. Records were available but were untouched for 2 years.*

- TB Register: The recording of specimens and reporting in the TB Register had diminished significantly since the time of the GeneXpert being introduced. It was obvious that the register had become redundant as had the practice of making AFB smears and was substituted by the PC spreadsheet used to record GeneXpert results. Two separate Lab numbers were also being generated on the one specimen in accordance to the Tb Register or GeneXpert Registration which was adding to the confusion. In light of this, it was decided to re-instate the original TB register book with an added column for Xpert results to be recorded. The primary registration number would then be the one used in the TB entry book and be traced through to the final result report. The specimen results were transcribed from the PC to bring the original TB registration book up-to-date.

  The frequency of QC slide usage had also suffered badly since the arrival of Xpert and so this was also re-instated , encouraged to be performed regularly and recorded in the summarised register. The records prior to April 2016 showed a very tidy and clear reporting process that unfortunately stopped quite abruptly. Positive specimens that were recorded in the register were reported by quantity as expected.

The storage of slides after analysis has now been arranged in numerical order starting from Jan 1 2017 and a new Q2 dispatch of slides for EQA are intended to be selected from this listing for delivery to the reference laboratory in July.

- *AFB smears are still required to be made prior to a sputum sample being processed on the geneXpert. These smears can be batched and screened at a later stage and used to confirm Xpert results. In this way, microscopy skills in AFB will not be lost and the EQA programme enabled to be maintained.*
- *It is recommended to clearly show Initials of the authorising Technician on every line where a result is recorded in the Register whether it be a AFB result or a GeneXpert result.*
- *A primary registration and specimen reception desk should be established in the main laboratory room where specimens are listed and laboratory registration numbers recorded. TB Register book included here. Request forms with associated Lab number and labelled specimen can be distributed from here to the designated work benches.*
- *Having an automated time stamp on the front specimen reception bench would greatly benefit the monitoring of turn-around times for all specimen types received.*
- *The primary TB Register number should be the one used to register the specimen on the Xpert PC list.*
- *Non-pulmonary specimens such as Pleural Fluids, CSF should also be recorded first in the Register Book, secondly in the PC.*

- Technical Staff: The Tuvalu Laboratory underwent staff changes in 2016/2017 which brought some disruption and loss of expertise to the overall service provision particularly in TB EQA processes, reporting and analysis responsibilities within Microbiology. 2 Qualified scientists and 2 Assistants in training make up the staff. They are multi-skilled and rotate through each department including TB and Microbiology. All the staff were included in GeneXpert training when it was installed in 2016. It would be fair to say however that all the staff were not confident in TB microscopy and smear reporting prior to this visit as very few AFB stains had been performed over the previous 12 months, consequently the ZN staining kit had expired and general Microbiology abandoned after water damaged the building some months ago. The TB Laboratory Training record was developed for the 4 participants so that we could work our way through each listed skill requirement to have it completed by the final day and hopefully restore confidence in the departments processes.
- *The reporting of any Positive AFB smear should be confirmed by a second staff member and signed accordingly.*
- *The TB Training record should be refreshed in 6 months' time with the requirement that every staff member has their record signed off and reviewed by a second supervising staff member.*

- Staff Training records: The Staff training and Competency record has now been upgraded to include more detailed TB related skills and has been signed off for the 4 staff participating in the TB workshop. The department training records will continue to be managed by Felix as trainees continue to be rotated through TB and Microbiology duties. An additional section was added for the GeneXpert PCR analyser in the Personnel Training and Competency Record. This is the full Laboratory competency log that covers the wider laboratory disciplines.
- An additional Workshop Training record, based on the Pacific Island TB Handbook information and GeneXpert information was added to supplement the existing Staff competency and Training records. This log requires supervisor review or sign off every 6 months and creates a stronger and more relevant systematic training programme for the TB section within Microbiology.
- *The Training and Competency record sheet specific for the TB section will need to be utilised regularly for the Microbiology rotating staff. This is different from the TB record mentioned above.*

- Stain Reagents: Commercial staining kits were well stocked and organised, but have reached expiry date and will eventually fail QC to force there replacement. The stock bottles will continue to require filtering and appropriate QC before use. During the course of the week a number of stains were performed that were very acceptable and clear showing that the stain quality is still of a good standard. The time between ordering of supplies and eventual delivery continues to be a problem with some delayed shipments up to 3 months.
- *A commercial ZN staining kit should be ordered now in anticipation of a long delivery time.*

- *It is recommended that the first four letters of the surname also be included on the slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
- EQA Calendar: A year calendar has been developed for the department and included in the Quality Manual to outline the TB EQA schedule and activity workplan expected for 2017/2018. (Annex 4).
- *It is recommended the Laboratory follow this timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.*

External Quality Assessment

LabPlus Auckland is the PTRL supervisory lab for Tuvalu and covers the 4 components of EQA namely Blinded slide Re-checking (BSR), Quarterly workload reports, Panel testing and now the Xpert quarterly statistics. The final component of EQA, the assessment visit was previously carried out in 2014 by the PPTC on behalf of LabPlus. Sadly in Tuvalu's case, TB EQA has been neglected over the last 18 months with no activity recorded since Q2 2015 . No BSR packages could be sent for 2017 because very few AFB smears were being processed or available to be sent.

Positive specimens detected in Tuvalu are also supposed to be referred to LabPlus Auckland for culture confirmation but of the 13 Positive cases detected in 2016 it is doubtful that any of them were received for culture in the Reference Laboratory. So far, 3 Positive cases have been detected but unlikely to have been referred to LabPlus, for 2017.

EQA activities have broken down over the last 18 months as a result of a key staff member resigning, new staff members being unawareness of the TB EQA requirements, the time and cost involved in organising referral postage to the reference lab, difficulties encountered in transporting Biological items to and from Fiji due to stringent border control, and a general sense that TB EQA was of low priority since the implementation of the GeneXpert.

In a concerted effort to re-instate the programme the first quarter 2017 Q1 Xpert statistics were prepared and posted to LabPlus, the TB Register book was brought up to date in preparation for Q2 reporting, Quarterly Report templates were provided, systematic storage of AFB smears for 2017 was started and a scheduled calendar of key dates for 2017 EQA requirements was created. All of these giving Tuvalu Laboratory a much needed boost to resurrect its TB EQA participation.

An EQA operating procedure summarising all the EQA activities and purposes has been drafted and included in the SOP Manual during this visit. Tuvalu TB Laboratory should be fully aware of its EQA requirements in BSR, QWR and in the supplying of copies of the TB Register.

An unstained Panel test of slides was also due to arrive from LabPlus, this week for staining and reporting on, Other forms of EQA such as the self assessment questionnaire, on-site assessment and training sessions from a Technical advisor are relatively simple exercises to be performed and are now expected to be carried out annually.

Recommendations for EQA include:

- *Prepare for second Blind slide review dispatch at the end of June (Q2 Apr- May-June 2017).*
- *Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics by end of June 2017.*
- *Stain and report on the unstained panel tests recently received from LabPlus Auckland.*
- *Discuss with Reference lab future provision of EQA developments for GeneXpert.*

Technician Training

- A hands-on training session for smear preparation, staining technique and microscopy reporting was held with all available staff. QC slides of both Positive and negative examples were used. Overall the stain quality was very good, the microscopy interpretation was accurate and the scoring or quantifying of positives, good. All 4 participants showed they were very capable in the process preparation and on reporting TB microscopy slides.
- A TB workshop training record was created and established for the 4 participating staff. As previously mentioned this was to supplement the already modified "Training and Competency Log". It also required

of the staff to read portions of the Pacific TB Handbook and complete a number of staining procedures and interpretations. All 4 participants were successfully signed off for this record by the end of the week.

Recommendation regarding Technician training.

- *Laboratory staff need to be diligent in continuing to maintaining their ZN staining and interpretation skills and interpret the AFB smear even after the GeneXpert result may have already been reported.*

Workplace Safety

- The TB Laboratory is restricted to Xpert and microscopy on sputum samples and body fluids, therefore is regarded as a low risk environment provided it is performed by trained staff using standard procedures. It has already been noted that the Biological Safety Cabinet needs a certified compliance and performance check. A daily record of housekeeping requirements and service check acknowledgements is also needed. Specimen smears were being prepared and dried in the cabinet as expected.
- Adequate Personnel Protective equipment (PPE) was available in the form of gloves, laboratory gowns, masks (although not always necessary), closed shoes worn. Other recommended safety practices were being followed such as using applicator sticks for slide preparation, strong Hypochlorite or 70% Iso Propyl Alcohol disinfectant in use, good Biohazard waste disposal containers and autoclave operation was carried out before material left the Laboratory.
- The occupational Health and Safety status for the staff is non-existent. Mantoux's are available to the staff, but no recorded evidence of annual staff testing nor the equivalent blood test Quantiferon Gold, leaving annual chest x-ray as one of the few staff health monitoring tools to consider.
- *It is recommended that some form of annual screening for TB exposure be adopted for all the Microbiology Technicians who may be exposed while performing the TB work.*

TB SOP Manual and documentation

- A separate and specific SOP Manual was developed for the TB section processes and related documentation policies. They had previously been included into the General Microbiology SOP manual and often over-looked, so the decision was made to simplify the requirements and bring better clarity to the EQA programme, referral Laboratory requirements and specific TB QC measures.
- A number of SOP documents were created (See Annex 5) covering all TB specimen processing issues with associated worksheets included. Further work is required to complete the manual. SOP's were prepared on Biosafety, Spillage, EQA requirements, Equipment servicing, Referral Laboratory information, AFB staining, GeneXpert instructions, diagnostic Algorithms and the Training record log.
- The SOP documents are referenced from various WHO/ PATLAB TB publications and some copied from the Microbiology procedure notes.
- Biosafety for the TB laboratory has been referenced from the WHO publication: Tuberculosis Laboratory Biosafety Manual 2012 and the Pacific Island TB Handbook.
- *Continue to complete and be familiarised with the TB QM manual.*
- *Include Specimen acceptance and rejection criteria policy for all staff to acknowledge.*
- *Work towards preparing and completing GeneXpert operational procedures so they can replace the existing draft policies.*

Summary

The TB EQA processes were given a strong emphasis on this mission due to the obvious lapses evident over the last 18 months. The re-instating of BSR and Quarterly reporting has now been carefully detailed, documented in SOP's

and impressed upon the staff for continued participation, therefore ensuring a higher awareness of the quality of results produced by the Microbiology department and a retaining of interpretive skill in AFB microscopy.

Very little statistical information had been referred to the supervising Reference laboratory throughout 2016 which is something needing immediate correction. Consequently, this has been strongly addressed and we are happy to report that the Laboratory is preparing statistical workload reports for the Q2 June period, according to 2017 EQA requirements. Regretfully very little communication has occurred between Tuvalu and LabPlus in recent months partially due to the limited internet available on the island and conflict in sending specimens through Fiji Customs control restricting transport through to Auckland.

A summary of all recommendations are listed below:

1	***Issues from Self assessment.*** *i. GeneXpert PCR is used as the primary diagnostic screen but AFB smears still need to be processed as a back up and as a means to maintain technical competence in Microscopy.* *ii. UPS's are required for critical machines other than GeneXpert. Electrical supply is too unreliable.* *iii. Tuvalu buys distilled water/deionised water because water is at a premium, filtration units are too expensive and distillation unit is too expedient on water consumption.* *iv. Staff formal training on microscopy & establishing Training records accomplished this visit.* *v. EQA programme and workload reports urgently need to be re-instated.* *vi. Microscope manufacturers manual for CX31 Olympus would be helpful in the laboratory.* *vii. TB Specimens being transported long distance need chilly bins or cold chain storage.* *viii. The practice of 24 hour turn around for TB microscopy should be enforced and monitored.* *ix. Cleaning and disinfection schedule for equipment & GeneXpert needs to be signed off daily.* *x. A Standard Operating Procedures TB Manual needs finalisation and updating from 2014.* *xi. Equipment maintenance and service records exist but need to be kept up to date.* *xii. No written specimen rejection criteria SOP available in lab.* *xiii. GeneXpert needs SOP manual apart from the manufacturers manual as a quick summary of Instructions.*
2	*An efficient and regular cleaning roster is required to maintain sterile hygienic conditions in the Laboratory. Addressing the state of the floor should be a priority requiring urgent action.*
3	*The Biohazard Safety Cabinet is in need of a performance efficiency check for annual certification.*
4	*An Equipment Maintenance Record sheet should be kept up to date to accompany every item of Microbiology equipment listing Model specifications, manufacturer contacts and preventative maintenance or service work carried out. The laboratory Balance, Microscope and Cabinet are included here. Records were available but were untouched for 2 years*
5	*AFB smears are still required to be made prior to a sputum sample being processed on the GeneXpert. These smears can be batched and screened at a later stage and used to confirm Xpert results. In this way, microscopy skills in AFB will not be lost and the EQA programme enabled to be maintained.*
6	*A primary registration and specimen reception desk should be established in the main laboratory room where specimens are listed and laboratory registration numbers recorded. TB Register book included here. Request forms with associated Lab number and labelled specimen can be distributed from here to the designated work benches.*
7	*It is recommended to clearly show Initials of the authorising Technician on every line where a result is recorded in the Register whether it be a AFB result or a GeneXpert result.*
8	*Having an automated time stamp on the front specimen reception bench would greatly benefit the monitoring of turn-around times for all specimen types received.*
9	*The primary TB Register number should be the one used to register the specimen on the Xpert PC list. Non-pulmonary specimens such as Pleural Fluids should also be recorded first in the Register. .*
10	*The reporting of any Positive AFB smear should be confirmed by a second staff member and signed accordingly before reporting.*
11	*The TB Training record should be refreshed in 6 months time with the requirement that every staff member has their record signed off and reviewed by a supervising staff member.*

12	*The Training and Competency record specific for Microbiology but including TB, will need to be utilised regularly for rotating staff. This is different from the TB workshop record mentioned above.*
13	*A commercial ZN staining kit should be ordered now in anticipation of a long delivery time.*
14	*It is recommended that the first four letters of the surname also be included on the AFB slide in block capitals to aid identification. The TB Register number should be big and bold on frosted labelled slides.*
15	***EQA** :* *i. Prepare for second Blind slide review dispatch at the end of June (Q2 Apr- May-June 2017).* *ii. Prepare for Quarterly Stat Reports on specimens and GeneXpert statistics end of June 2017.* *iii. Stain and report on the unstained panel tests recently received from LabPlus Auckland.* *iv. Discuss with Reference lab future provision of EQA developments for GeneXpert* *v. It is recommended the Laboratory follow the timeline to ensure a comprehensive and robust EQA programme is maintained particularly for workload statistics and microscopy reviews.ie BSR*
16	*It is recommended that some form of annual screening for TB exposure be adopted for all the Microbiology Technicians who may be exposed while performing the TB work.*
17	*Continue to complete and be familiarised with the TB QM manual.*
18	*Include Specimen acceptance and rejection criteria policy for all staff to acknowledge in QM.*
19	*Work towards preparing and completing GeneXpert operational procedures so they can replace the existing draft policies.*

Conclusion

The Laboratory is on the road to recovery and heading in a positive direction. The restoration of the Microbiology facility after water damage was a major achievement over the week and has boosted staff morale and capability. It is in a good position overall with the new staff members eager to learn and make a difference in restoring good standards of practice. A positive and progressive momentum has developed within the Lab.

Tuvalu's progress towards achieving accreditation standards has however slowed somewhat over the last 2 years. More time and effort has rightfully been put into vulnerable areas like staff retention, capacity building and training skills as opposed to management systems, operational documentation requirements and internal audit assessments. In a quick ISO 15189 assessment on the final day, Tuvalu came close to a 50% achievement score suggesting that many of the quality system essentials still need to be strengthened and fully implemented to continue the accreditation journey, hopefully by 2020.

The staff capacity and service expertise in the TB and Microbiology section has received a significant boost with this weeks workshop and evaluation. The training sessions and demonstrations were well received by the participants and have helped restore competence in skill as well as an overall understanding behind the necessity for TB EQA requirements. TB EQA has previously been neglected as had the maintenance of SOP's and documentation manuals, but thankfully competence has been restored for 2017 and better communication links with the Reference lab, LabPlus Auckland has already occurred. The inclusion of a EQA calendar for the lab staff will be a trusty reminder for all. The staff team are also now up to date with recent laboratory developments and have a better understanding of sample collection issues and the role of GeneXpert alongside EQA requirements.With Tuvalu being somewhat isolated and independent as well as receiving little support from Fiji Laboratories, it has difficulty in receiving supplies and maintaining network links with other South Pacific Medical services. This emphasises the need for good planning and management systems to be in place putting significant pressure on Felix and Taupesa to direct and encourage the trainees and provide technical leadership. The Lab is still very vulnerable if senior staff choose to have leave or are absent.

The Quality Manual documentation is in a good state and is in the process of being updated with new additions in an effort to keep it up-to-date and relevant. The development and completion of the TB Training record is an excellent step in the right direction to maintain skill levels , staff confidence and a solid training programme. The challenge now lies with the trained technicians to practice and refresh their ability regularly and make it long term.

Finally, a big thank you to the staff at Princess Margaret Hospital Laboratory, Felix Koakoa, the NTP team, UNDP Global Fund programme management team for your valuable contributions in making this a successful and enjoyable assessment visit and especially to the friendly Laboratory staff who looked after me with some good Tuvalu hospitality for the week.

Vanuatu TB Supervisory Evaluation Visit Report

Background

The PPTC has worked with the Vila Central Hospital since the 1980's in the capacity of strengthening medical laboratory services and providing specialised training in the various disciplines of medical laboratory sciences, either in-country or at the PPTC centre in Wellington. Since 1990, the PPTC has and continues to provide an EQA programme for Microbiology, Serology, Transfusion Science, Haematology and Biochemistry to Vila Central Hospital Medical Laboratory, and to the Northern Provincial Hospital in Luganville. Numerous laboratory technicians from Vanuatu's hospital laboratories have participated in the distance taught PPTC Diploma in Medical Laboratory Sciences programme in the past, with six diploma graduate to date. One technician is expected to graduate this year from the 2015-2016 diploma cycle. Furthermore, three laboratory technicians are enrolled in the 2017-2018 diploma programme. The PPTC currently is under contract with the NZ Ministry of Foreign Affairs and Trade to lead Vanuatu laboratory services to accreditation by 2020.

This visit was specifically for TB technical support and assistance to the national hospital laboratory – Vila Central hospital medical laboratory, TB section. The previous EQA TB assessment of the laboratory service was carried out in 2013 by Queensland Mycobacterium Reference laboratory (QMRL) staff. QMRL further assisted the National TB programme in Vanuatu to provide training to all TB microscopists based at all provincial hospitals/ centre's during their visit. QMRL is the laboratory's reference centre for all direct antibiotic susceptibility testing (DST), blind smear rechecking, and panel tests. Vanuatu's National TB programme is covered under the long term agreement with QMRL organised by UNDP global fund programme.

Vanuatu's current population is estimated to be 264,652, and Vanuatu reports approximately 110 cases of TB each year. Vila Central hospital (VCH) and Northern Provincial hospital (NPH) are both considered direct observation treatment centres (DOTS), based in Port Vila (Shefa province) and Luganville/ Santo (Sanma province) respectively. There are 4 sub DOT centre's (provincial hospitals) based in each of the following provinces Tafea (Lenakel hospital), Torba (Torba mini hospital), Malampa (Norsup hospital) and Penama (Lolowai hospital). TB case detection via laboratory diagnosis is based on smear microscopy (AFB smear's) in all sub DOT centres. Culture and direct sensitivity test is referred for testing at the QMRL in Brisbane, Australia. Vanuatu has had two GeneXpert installed in 2016 at both referral hospitals in the country (DOT centres). First machine was installed at the VCH in early 2016, funded by the global fund UNDP programme. Second equipment was installed at the NPH in October 2016, by the PPTC "Pacific Accreditation Programme", funded by the New Zealand Government Ministry of Foreign Affairs and Trade.

Slide and specimen referral system in place from the province to the VCH TB laboratory who then forward slides to QMRL. There is one national TB laboratory officer employed based at VCH and is assisted by a laboratory technician. All other DOT and sub DOT centres have a TB microscopist, who are employed as laboratory assistants. The TB laboratory staff are supervised and managed by their immediate laboratory managers in each hospital/ centre with overarching support provided by the national TB laboratory officer based at VCH. VCH acts as the reference laboratory for TB for the country and provides in-country technical support to peripheral level laboratories. They also prepare and provide all ZN AFB stains and TB consumables (slides, biohazard bags, shipping container's etc.) to DOT's and sub DOT centres.

This report outlines the visit carried out the PPTC for the Vila Central Hospital, medical laboratory department, TB section. This laboratory is the referral medical diagnostic laboratory for the country.

Executive Summary

This onsite TB EQA evaluation visit was successful in enhancing specific technical support and assistance to the Vila Central Hospital TB Laboratory. It was very timely and well appreciated by the national TB programme and the laboratory staff for an external perspective on their laboratory processes as the previous TB evaluation visit was carried out in 2013.

The Laboratory operates very well, however there has been slow progress over the last 5 years in essential quality principles and structured operational procedures. Participation in the TB EQA programme however has had an obvious gap for last year for quarter's 3 and 4. This visit has provided an excellent section overview and will enable the laboratory as a whole in achieving its accreditation goals.

Strengthening of the TB EQA programme was the main focus of this visit, and an annual work plan was created as a guide for when each EQA programme participation were due. The AFB staining procedures were reviewed and refresher training was provided to the staff. Importance on continuous monitoring of the quality of slides has been encouraged, and the need to filter the stains regularly as well. Work was also carried out on developing and outlining the standard operating procedures for this section, with a number of documents being drafted and printed. Outline of other documents which were not prepared was given to the section for further amendments. Apart from the usual laboratory duties of testing and reporting of results, the VCH TB section also plays a national role in coordinating all other DOTs and sub DOT centres, which puts additional burden on staffing and workload, therefore of concern was progression planning and staffing in this department. A few recommendations have been made in this report to avoid any interruption in the provision services.

The TB EQA evaluation visit was timely as the last visit occurred in 2013 from a supervising laboratory. All the TOR's were met for this visit and these are discussed in detail in this report.

Activities

The week long TB EQA evaluation visit was carried out from Monday 27 to Friday 31 March at the Vila Central Hospital, Medical Laboratory – TB section. The agenda for this visit is attached as annex 1. The subheadings below address each of the terms of reference outlined earlier. An audit was carried out using WHO DOTS programme "on-site evaluation report checklist" [annex 2] and the laboratory was requested to complete the self-assessment checklist. [annex 3].

Laboratory Facilities

The TB laboratory has been assigned a separate area within the central laboratory department and two rooms are allocated to the TB section. First room is assigned to smear slide reading, result entry and electronic data entry and report preparation. GeneXpert is also installed in this area with all MTB/RIF testing carried out in here. Second room is assigned to specimen storage, smear preparation, slide staining and specimen preparation for GeneXpert testing. Both rooms have good air-conditioning and are well ventilated.

An equipment inventory for the TB section was created and is attached as annex 4. All laboratory equipment's need to undergo annual electrical checks from a service engineers based at the hospitals maintenance unit. The section has an excellent microscope setup for TB microscopy, which has a teaching header arm attached to it. This Nikon double header Eclipse E200 microscope was donated by the JICA programme during the built of the hospital. The microscope is kept in a clean condition. A maintenance log for the microscope was created and shared with staff. The setup is ergonomical and a swivel adjustable stool is available for the user. The microscope was cleaned and serviced during this visit, and staff were shown how to carry out preventative maintenance on it. The microscope in the Microbiology laboratory was cleaned as well and staff were taken through the cleaning procedure. A maintenance log for this microscope was also shared.

The TB section needs a printer to be able to print their own reports etc. Currently they are sharing the main laboratory printer which is a small output printer used by all other sections and printing of electronic reports is not encouraged due to the demand on printer cartridges. It will be useful for the TB section to have their own to be able

to print and generate quarterly reports, and when required GeneXpert result reports. The section will also be able to print the required SOP's and documentation as recommended.

GeneXpert maintenance log is completed on a regular basis and is kept in good condition by staff. The filter was cleaned and replaced during this visit, and the staff have been encouraged to do this during their monthly maintenance. The biological safety cabinet class II (AirTech) is not operational and needs servicing. It has not been certified and fumigated since its installation in early 2015. This needs to be addressed immediately by the NTP and the laboratory management.

The sink level for staining is adequate and there is a slide rack available for staining procedures. A pipe tubing, acquired from the maintenance section of the hospital, was installed in the tap to allow for direct and gentle washing of the slides during this visit. Spirit burners were available in the laboratory however was not used as the methylated spirit was unavailable. A bottle of methylated spirit was purchased from a local store and left with the staff.

Following recommendations are made under this section:

- Maintenance log for the Microscope to be implemented and used.
- Biological Safety Cabinet to be serviced and certified for use.
- Electrical check to be organised at an annual interval for all equipment.
- Purchase of a printer for preparation of report and GeneXpert result printing.

Laboratory Personnel

The TB section of the medical laboratory has two personnel, Mr Raymond Seule' and Mr Stephen Abel. Raymond is the national TB laboratory officer and is the focal person for all laboratories (sub-DOTS and DOT) performing TB testing. Mr Stephen Abel works with Raymond, however is on rotation through other departments (currently working with the phlebotomy section) and is not fulltime in this section. Both staff perform all TB testing and are knowledgeable.

Raymond is required to carry out supervisory visits to all the sub DOT's and DOT centres in Vanuatu which can take him off the bench for a few weeks at a time. He also prepares and sends reagents and laboratory consumables, with the assistance of Stephen. Raymond, being in the service for over 20 years is also entitled to longer annual leave periods. For the continuous service provision and uninterrupted service, it is strongly recommended that a backup scientist is trained to perform Raymond's duties during his absence. It is also recommended that all new staff laboratory staff undergo rotation in the TB section, which is already in place for other sections.

Staff training and competency log [Annex 6] was introduced, and all tasks were taken through for the TB investigation. This must be used for any future training of staff and to assess competency. It will also be useful in the training of the rotation staff.

The laboratory has completed draft SOP's on using Xpert MTB and RIF assay and the Ziehl-Neelsen technique for TB microscopy. The complete guidelines on creating a TB procedures manual was shared with Raymond electronically and some new documents were printed and included in a newly created SOP folder. The draft copies of their own procedures were also printed for review by the staff, and these were incorporated in the new folder.

The following recommendations are for this section:

- Ensure completion of SOP's for processing sputum samples using the templates provided.
- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training.
- Training of new staff in the TB section, and including the TB section as a rotation option for new staff who have recently qualified from the Fiji National University.

Specimen Processing and Health and Safety

All samples received in the laboratory are registered in the log book, which captures the assigned laboratory registration number (this is recorded on the form by the laboratory when the specimen is received), date of receipt and collection, full name of patient, Age and Gender, Address/ location of patient, DOTS centre location, weather examination is for diagnosis or follow-up, HIV result of patient where applicable, Follow-up month (options from 2nd, 3rd, 5th, 6th, and 8th month), Sputum result (sputum sample 1, 2 and 3), GeneXpert Result (with options for test being valid, MTB result and RIF result), and a column for remarks. There is no space for recording the quality of specimen, the date results are being reported, and there is no space for the technician to sign their names when the results have been entered. The bulk of the register captures the required information as per WHO guidelines.

Majority of the specimens received for processing at the VCH laboratory is from the hospital, followed by samples from private clinics, and from smaller health centres and community aid posts in the Shefa province. Most results are reported within 24 hours, with some taking up to 48 hours which is acceptable given the workload of the section. All positive results are phoned through if the clinician's details are provided and the NTP is informed as well of the results for follow up on treatment.

Handwashing basin, and soap is available in this section. Adequate PPE's including face masks, correct size gloves and laboratory coats are available. Health and safety audit was carried out for the laboratory using the WHO LQMS Handbook guide checklist [Annex 8]. 70% alcohol is used as disinfection. Bleach is also used as a disinfectant, and staff were advised on how to achieve a 5% concentration of chlorine solution to use as disinfection solution, which must be prepared fresh every second day. The procedure was noted on the bleach dilution bottle.

Recommendations:

- Update the result workbook register to include additional information including sample description, date of reporting and technician signature space.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant area's such as vaccinations, fire/ safety drills etc. [Annex 8].
- Prepare 5% chlorine solution for disinfectant use with cleaning up specimen spills and for cleaning bench as per discussions.

Consumables and Reagents Inventory and Ordering/ Receiving of Supplies

The TB section, under Raymond's guidance preforms well with stock supply items. There is a central procurement system in place for all the government hospitals in Vanuatu, and all laboratory supplies and consumables are ordered through the VCH laboratory department. The VCH laboratory places their orders via the central medical stores who are then responsible for placing orders with suppliers, custom clearance and collection of deliveries and receiving and delivering of supplies to the laboratory stores. They also process payments for stock ordered as long the ordering criteria is met in terms of budget and quantity. A stock card system has been implemented to keep track of laboratory inventory, so orders can be placed in time as well.

For TB consumables, the laboratory uses the following materials which are ordered under the general laboratory supplies: Latex gloves, surgical masks, biological hazard discard bags, Biological specimen bags, Sterile 70ml

containers for sputum collection, shipper packs for biological substance and methanol (methyl alcohol). The following items are ordered specifically by the TB section: frosted end microscope slides, wooden applicator sticks, Whatman filter paper, Hydrochloric acid (reagent grade - local supplier), methylene blue powder, Phenol crystals, Carbon fuchsin powder, Microscope oil immersion oil, Kimtech lint free wipes. The 70% ethanol is acquired from the Pharmacy and methylated spirit (for spirit burner) can be purchased from a local shop. All items are in stock and exceed the minimum 3 monthly targets. GeneXpert cartridges are ordered via UNDP (including Xpert check kit).

A stock take and consumable list was created with Raymond, which incorporates the following information, and an initial stocktake was undertaken for all items.

i. Test Kit and manufacturer
ii. Product Code
iii. Pack Size
iv. Approx. 3 Monthly Targets
v. Stock Take count's for each month (x3) with expiry dates
vi. Monthly Usage (x3)
vii. New order amount and date

Recommendations include:

- Initiate the use of the stock take and consumables list.
- Include any stock supply items for sub DOT centres and modify the 3 monthly targets if needed.

Preparation and Storage of Reagents

All in-use reagents are stored in the media and reagent preparation room for the laboratory in under-sink cupboards, and this is where all stains are prepared. All additional stock is stored in the store room. The laboratory uses Ziehl-Neelsen (ZN) staining to perform its AFB smear staining, which are prepared in house. The TB handbook 's reagent preparation instructions are used to prepare the ZN reagents for which the laboratory has plenty on stock of. The AFB stain: 1% carbon fuchsin is prepared using ethanol, basic fuchsin powder, phenol crystals (colourless) and distilled water; the decolourising solution is 3% HCl in ethanol and is prepared by adding fuming hydrochloric acid (HCl) and 95% ethanol; and the counterstain is 0.1% methylene blue, prepared by adding methylene blue chloride to distilled water.

The laboratory prepares stains for all the other centres (DOT and sub-DOT), and these are shipped by the VCH when required (with an aim for 6monthly dispatches). Stain deposits were observed in some of the slides reviewed. Stephen was taken through the filtration process of stains. A new set of stains were prepared by Stephen as the current stock had expired in September 2016. The laboratory had kept using these stains as the controls were staining accurately. As there was no dark bottles available for the laboratory to use to store the prepared stains, we covered clear plastic bottles in brown paper to protect the stored stains from light. Staff were reminded to record the date of preparation, expiry dates, and the name of staff preparing the reagents. QC of newly made reagents was encouraged and carried out.

The working reagent squeeze bottles were replaced with spare reagent bottles from the Serology section, as the stain bottles being used had stain particles and old residue stuck inside of them which often breaks off and affects the quality of stains.

Internal quality control (IQC) results are being recorded inconsistently. Staff have been advised to run controls once monthly and when new reagents are being prepared. IQC results should be recorded in the logbook register. 25 positive control slides were prepared from a 3+ positive sample for IQC use, and approximately 12 commercially prepared positive slides left with the laboratory.

The following recommendations are for this section:

- Continuously monitor expiry date of the reagents – 12 months from the date of preparation.
- Monitor stain quality on a regular basis, and filter stain when required.

- Perform IQC once monthly and when new stains are prepared.
- Record IQC result in the laboratory register.
- Create a material safety data sheet folder for all reagents.
- Incorporate the reagent preparation methodology to the new SOP.

Management of Infectious and Laboratory Waste

All biological wastes (applicator sticks, sputum samples after testing, contaminated glass slides, used gloves) are discarded in a discard bucket with bleach solution which is then in turn discarded in a biological hazard auto-clavable bag. These discard bags are then incinerated by the hospital biological rubbish disposable unit. The biological hazard bags are in stock and is part of the general laboratory consumable list. The GeneXpert cartridges are discarded in a similar manner as the rest of the biological wastes produced by the laboratory. There are no recommendations under this section.

EQA Principles, Blinded Smear Rechecking and Panel Testing

The EQA principles was explained to the staff and the importance of actively participating in the EQA programme was impressed upon. Vanuatu's NTP reference laboratory is Queensland Mycology Reference Laboratory (QMRL) based in Brisbane, Australia. This arrangement covered by the long term agreement (LTA) with the Pacific TB Laboratory Initiative (PATLAB) participating laboratories which provide EQA and direct laboratory support to the national TB Laboratories as a part of the Global Fund HIV/TB grant implementation in Western Pacific Region, organised by UNDP.

QMRL provides relevant EQA services to VCH TB section which includes blind smear rechecking (BSR), and panel tests. The laboratory has modified the quarterly reporting form for its NTP, and it is an excellent way to record and report new data. Unfortunately due the lack of a printer in this section, these have not been printed and are stored in the PC which is not backed up. Quarterly reports were last prepared for quarter 1 and 2 in 2016. No reports were prepared for quarter 3 and 4 last year and no reports has been prepared for 2017 quarter 1.

The blind smear slides have not been sent to QMRL for the last two quarters in 2016. They are yet to send the 2017 quarter 1 slides as well for BSR. The laboratory staff including the NTP have been urged to participate in the BSR and dispatch the 2017 Q1 slides for evaluation by QMRL. Last panel test slides received by the laboratory was in 2016 October from QMRL, which is then shared with the rest of the DOT and Sub-DOT centres for an evaluation as well. Another dispatch is expected in October 2017. Quarterly report templates were customised to include documentation ID to make it a "controlled document" for use by the laboratory.

The National TB programme and the laboratory staff have all indicated that they would prefer an annual supervisory visit as part of the EQA programme, and were very appreciative of this timely visit. Post assessment feedback is inserted to this report as annex 9. It is understood that the NTP requires further assistance in re-training the sub-DOT staff in AFB and in strengthening the internal EQA procedures as part of the NTP. There is a supervisory visit planned for NPH for a follow-up on the GeneXpert testing.

Recommendations for EQA include:

- Participate in BSR, and send the blind slides to QMRL.
- Complete regular quarterly report for the NTP and QMRL as per the agreed work plan.

Increasing Sample Numbers Tested in the Laboratory

This was discussed with the National TB programme manager. This is a work in progress for Vanuatu, and the plan is to mobilise more trained staff in rural and remote areas, as a number of Vanuatu's population live in isolated, and remote areas with little access to health services. Active case finding is part of the NTP's plan, which they have been working on for a few years. There are variations in case detection rates among provinces. Four provinces, Tafea, Shefa and Torba/Sanma have a CDR in 2015 over 80% while 2 provinces Malampa and Penama have a CDR of 32% and 24% respectively as reported by the NTP.

The NTP was advised to disseminate the sputum collection placards to the rural clinics and sub DOT centres and raise awareness of the TB symptoms through local media (radio, TV etc.).

Advice and On-site Coaching on Gaps Identified

The staff have used the TB handbook and the GeneXpert manual to perform tests, and procedures outlined in these documents have been followed. Outtakes from these documents are stuck on walls for easy user reference. The ZN staining method SOP was printed in 2015 and other documents (GeneXpert testing and ZN staining procedure) were in draft format. These were all printed out and stuck in the newly created SOP folder for the department.

Furthermore, an outline of a number of SOP documents have been shared with Raymond and all documents drafted for the laboratory was given to the NTP manager and Raymond on a USB drive. The documents were created in accordance with the ISO 15189 medical laboratory international standards to eventually prepare the laboratory to seek accreditation. A table of contents was created for this SOP manual and for those documents which were not drafted, template examples were given electronically for adaptation into the laboratories own documents. Timeline was established for the completion of the SOP's and the PPTC will be able to guide the laboratory supervisor and provide remote assistance in its development. The action plan [Annex 7] outlines the timeframe allocated to SOP development.

A presentation was given to all medical laboratory staff including the TB staff members. Presentation contents included background on TB disease, latent TB vs active TB cases, Global TB rates, TB diagnosis in laboratory – AFB smear's, sputum specimen quality, acceptance and rejection criteria's, method on performing AFB smear's, reading and reporting AFB smear results, GeneXpert technology, AFB smear's vs GeneXpert.

Recommendations include:

- Completion of the SOP's by mid May 2017.
- Create a SOP for all internal laboratories (for sub-DOT and DOT centre's), which must include the protocol for stock order's, EQA' and smear testing procedures.
- Regular preventative maintenance to be carried out on Microscope.

Challenges faced with Specimens

The VCH TB laboratory may receive samples from rural health clinics which are delivered to the hospital by staff or patients friends travelling to Port Vila, leading to delays for up to 5 days after collection from rural or remote areas. Poor quality specimens are an issue at times, which is hard to judge as specimen quality is not recorded in a consistent manger. Incomplete forms can be an issue as well. The delay in receiving samples allows for over growth of commensal microflora which hinders preparation of good quality smear's and staining. Referred samples from Lenakel Hospital (Tafea Province - Tanna) are received for GeneXpert testing, which is delivered via an overnight flight.

All samples received from rural areas are processed regardless of sample quality due to the logistics involved in recollection. Usual rejection criteria are not applied to these specimens. Salivary specimens are still processed by the laboratory and accepted by the NTP collection staff. A specimen acceptance and rejection criteria has been created to strictly implement rejection of samples guidelines as per TB handbook, which will mostly be implemented for hospital samples and samples received from private clinics.

Other challenges include receiving forms which have missing patient details and information on whether sample is for follow-up or diagnosis. Laboratory has been advised to always inform the requestor if vital information is missing before processing a sample.

Recommendations include:

- Educating collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Dissemination of sample collection placards to rural clinics and all collection centres for sputum sample.

- Implementation of the specimen acceptance and rejection criteria, and making the collection staff aware of this policy with clinical input.
- Incorporating this policy in the laboratory SOP.

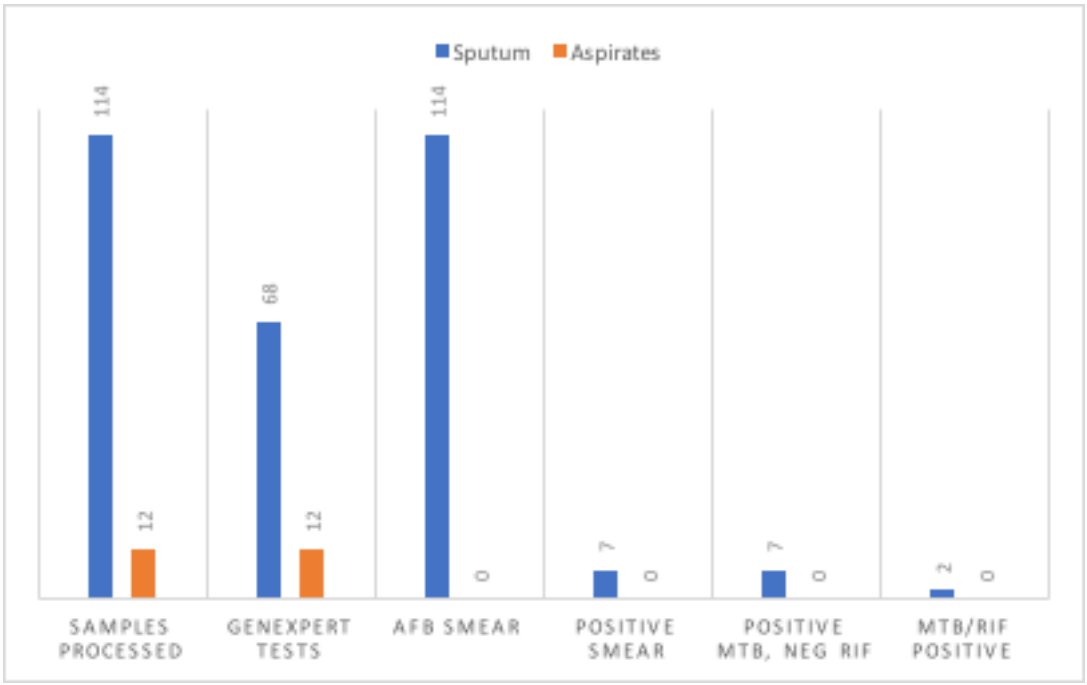
Workload Statistics and GeneXpert Use

The WHO and PATLAB recommended testing algorithm is available for GeneXpert MTB testing. The NTP and the laboratory are in contact with the WHO medical officer for tuberculosis regarding the testing criteria. Due to the low number of tests performed when the testing algorithm is followed, the laboratory has been advised to perform GeneXpert testing on all samples.

The tests carried out by the laboratory for the first quarter was reviewed during this visit. A total of 126 samples were tested from the 1st January to 28th March. 114 samples were sputum and 12 were aspirates (pleural fluids/ tap, ascites fluid, gastric aspirates). 80 samples were tested on the GeneXpert in total (68 sputum samples and all aspirates). During this period 7 samples tested positive on both ZN smear and GeneXpert according to the register.

Out of the 7 positives one samples, a 9-year-old male child has tested positive for MTB and RIF on the GeneXpert. A repeat sample was tested on this patient on the GeneXpert with the same result. This sample has been referred to QMRL for DST, before treatment is started and drugs received from Manila. Last year a patient had tested positive for MTB and RIF on the GeneXpert, however the DST results from the reference laboratory was negative for any drug resistance, and the patient was successfully treated on first line drugs, therefore the clinicians are awaiting results from the reference laboratory before starting treatment, as advised by TB experts.

Jan - March 2017 (2 Jan - 28 March) TB Tests Performed at VCH Laboratory TB Section



*MTB/RIF positive results – both are on the same patient.

Summary

All EQA processes must be adhered to ensure the quality of results produced by the laboratory, as outlined in the action plan [Annex 7]. The summary of all recommendations are listed below. The laboratory supervisor together

with the NTP manager must modify the current work plan to incorporate the recommendations listed in this report. The key recommendations include:

- Ensure completion of SOP's for processing sputum samples using the templates provided.
- Incorporation of the staff training and competency log for TB investigations for all future laboratory staff training.
- Training of new staff in the TB section, and including the TB section as a rotation option for new staff who have recently qualified from the Fiji National University.
- Update the result workbook register to include additional information including sample description, date of reporting and technician signature space.
- Review the laboratory health and safety audit results and implement the changes highlighted by the non-compliant area's such as vaccinations, fire/ safety drills etc. [Annex 8].
- Implement the use of the stock take and consumables list and include any stock supply items for sub DOT centres and modify the 3 monthly targets if needed.
- Continuously monitor expiry date of the reagents – 12 months from the date of preparation.
- Perform IQC once monthly and when new stains are prepared.
- Incorporate the reagent preparation methodology to the new SOP.
- Participate in all EQA programmes including BSR, and send the blind slides to QMRL.
- Complete regular quarterly report for the NTP and QMRL as per the agreed work plan.
- Completion of the SOP's by mid May 2017.
- Create a SOP for all internal laboratories (for sub-DOT and DOT centre's), which must include the protocol for stock order's, EQA' and smear testing procedures.
- Regular preventative maintenance to be carried out on Microscope.
- Educate collection staff about good quality specimens as the laboratory results will only be as good as the quality of specimen received.
- Dissemination of sample collection placards to rural clinics and all collection centres for sputum sample.
- Implementation of the specimen acceptance and rejection criteria, and make the collection staff aware of this policy.

Conclusion

The laboratory is well designed and organised with new facilities. The GeneXpert maintenance is performed on a regular basis. Staff are well trained and efficient in performing AFB staining and smear preparation, and carrying out GeneXpert tests. The stock supplies are ordered well in advance and there is adequate stock for all consumables. Some key recommendations need to be addressed. Of concern is the availability of adequately trained new staff. Staffing must be addressed for progression planning, and to avoid any interruptions in the provision of TB testing services which is critical in the diagnosis of TB for the people of Vanuatu. I am confident that once the above recommendations have been actioned by the TB section, the laboratory can confidently request for an external audit to gauge its pathway to accreditation in the near future.

Acknowledgments

My sincere thanks to the staff at the NTP TB laboratory and the VCH Hospital laboratory, the NTP team, and the UNDP GF Programme Management staff for your valuable contributions and hospitality shown during this visit.

UNDP TB Laboratory Training Symposium

A comprehensive training for the TB Laboratory technicians from the Pacific Island Countries (PIC) was held from 7 to 11 August 2017 at the Novotol International Hotel, Nadi, Fiji. The training addressed the important aspects of improving laboratory functions and quality assurance. Among the key topics covered was on- Site Evaluation, Gene Xpert Training and International Air Transport Association (IATA) certification and accreditations. This training of TB laboratory technicians from the PICs was conducted with the collaboration of Fiji Global Fund Grant, Fiji National TB program, SPC and the UNDP Multi Country Grant. A total of 25 participants from 9 countries (Cook Island, Fiji, FSM, Kiribati, Palau, Samoa, Tonga, Tuvalu and Vanuatu) were in attendance. The training was facilitated by Russel Cole, Navin Karan, Dr Subhash Yadav, Praneel Maharaj, Imran Khan and Salanieta Duituturaga.

This symposium proved to be an excellent opportunity to feedback to the users on the findings of the on-site TB EQA evaluation visits. As indicated above, discussions around the key subject areas enabled all participants to clarify doubts. The diagnostic algorithm was discussed in detail as well and participants are now clear on issues around testing and reporting of TB results.

Annex

Annex 1: BSC Maintenance Log

Biosafety Cabinet Maintenance Checklist – _____ Laboratory

INSTALLATION DATE	
SERIAL NUMBER	

Please write your initials in the boxes below

MONTH	
YEAR	

DAILY MAINTENANCE – END OF DAY	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Clean the cabinet after use (allow air to free flow for 3-5 mins)																															
Decontaminate all the surfaces using 70% ethanol. Lift and clean under equipment's, and clear the work area.																															
Discard gloves and remove all PPE's.																															
Turn off ventilator, florescent lamp, close the front opening and **TURN ON the UV lamp** to decontaminate the cabinet – for 15min.																															

WEEKLY MAINTENANCE	**WEEK 1**	**WEEK 2**	**WEEK 3**	**WEEK 4**	**WEEK 5**
Decontaminate work surface and interior surface with 70% Ethanol					
Clean front class door and surface of UV lamp using cleaning solution					
Verify the precision of the manometer reading. If any discrepancy, record in the logbook					

MONTHLY MAINTENANCE	
Clean the exterior surfaces – front and upper part to remove dust – use a damp cloth	
Disinfect the surface of the lower compartment with 70% Ethanol	
Perform the tasks listed under weekly maintenance	

YEARLY MAINTENANCE – ENGINEER	
Carry out certification process as per NSF 49 regulation	
Check the intensity of UV lamps with radiometer, change if necessary	
Check the state of the florescent lamp, change if necessary	

Annex 2: Pre-Maintenance Checklist for BSC Cabinets

Please use your hospital biomedical engineer for this assessment. Indicate if an assessment is not carried out.

Tasks	**BSC Cabinet 1**	**BSC Cabinet 2**
Location (Hospital name and section it is placed in, Island, Suburb)		
Manufacturer		
Model and Serial Number		
Hospital inventory code		
Cabinet Class		
User manual available?		
Is it being used daily?		
Date of installation		
Date of last certification		
Date of last fumigation		
Date of HEPA filter replacement		
Electrical Checks		
Does the motor function/ operate?		
Voltage measurement		
Amperage measurement		
Operation temperature of the motor		
Noise level and vibration of motor		
Fluorescent lamp – is it functional?		
UV lamp – does it turn on? Also measure light intensity (require a radiometer)		
Electrical outlet – is it intact? Comment on Quality of contact & available voltage.		
All switches – list the control state & integrity, & list switches which are not working)		
All cables and connectors – visual condition?		
Alarms – test the state of alarms – do they work?		
Physical Checks		
Internal and External condition of the cabinet – check and comment		
Visual filter check (if possible) – state condition		
Are the joints, seals, penetration and soldering free from leaks (Exterior)		
Sliding window/ external cover – comment on functionality		
Condition of the BSC area		
Temperature (approx. 20-22^{0}C)		
Humidity (approx.. 45-55%) – need to use a hygrometer if available		
Cleanliness – comment on the condition of the BSC		

Referenced from the WHO Maintenance Manual for Laboratory Equipment 2nd Edition, Chapter 6: Biological Safety Cabinets Pages 35-43.

Annex 3: Staff Training and Competency Log

Staff Name and Employee Number: _____

Date Completed	*Staff Member*	*Assessed by*	*Next Assessment date*

This Record is kept in your Staff Training Log, 6 monthly, with a copy held by the Tb Laboratory Supervisor.

	Date	**Assessor**	**Staff**	**Date**	**Assessor**	**Staff**
Describe Specimen collection factors when receiving specimen.						
Labelling on container & request form						
Rejection criteria for specimen						
TB Register recording – patient details			.			
Consequences of incorrect results						
Labelling slide and preparation of smears						
Describe details of ZN stain and method						
Stain, examine and report on 10 slides						
Reagent preparation for ZN stain						
Using QC slides – Neg and Pos. Includes making QC slides, frequency of testing (once monthly or when making new set of reagents, and recording of results.)						
Storage of slides in numerical and date order for blind smear EQA programme.						
Microscope setup						
Microscope maintenance.						
Scoring of Slides						
Stain artifact , troubleshooting						
TB Lab Safety -PPE, Disinfectant Use						
Preparing working bleach						
What to do in spillages of specimen						
Waste Disposal						
Reporting of results – entering information in test register, patient form, and dispatching results to the responsible nurse.						

Dispatch samples to Reference Lab-Sputum						
Operating BS cabinet						
Daily Equipment monitoring - Fridge						
EQA processes in the TB Lab – Blind slides, Panel test, Quarterly Report						
Processing Extra-pulmonary specimens						

*References to "Laboratory Diagnosis of Tuberculosis by Sputum Microscopy – The Handbook, Global Edition 2013"

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