Regional workshop on the implementation of the “Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015)” in the Pacific Island Countries

14–17 September 2010
Suva, Fiji

World Health Organization
Western Pacific Region
REPORT

REGIONAL WORKSHOP ON IMPLEMENTATION OF THE
“ASIA PACIFIC STRATEGY FOR STRENGTHENING HEALTH LABORATORY SERVICES (2010-2015)” IN PACIFIC ISLAND COUNTRIES

Convened by

WORLD HEALTH ORGANIZATION
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The views expressed in this report are those of the participants at the Regional Workshop on the Implementation of the “Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015)” in Pacific Island Countries of the Western Pacific Region and do not necessarily reflect the policy of the World Health Organization.

**Keywords:** Laboratories – organization and administration; Pacific islands

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Regional Workshop on the Implementation of the “Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015)” in Pacific Island Countries, held in Suva, Fiji from 14 to 17 September 2010.
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SUMMARY

A Regional Workshop on Implementation of the “Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015)” in Pacific Island countries was held in Suva, Fiji from 14 to 17 September 2010.

The objectives of the workshop were:

(1) To identify major strategic elements of a national laboratory policy and plan;
(2) To develop a draft of the national laboratory policy and plan for their countries;
(3) To discuss and finalize indicators to monitor the progress of the national laboratory policy and plan; and
(4) To be introduced to the World Health Organization–Centers for Disease Control and Prevention (WHO–CDC) Laboratory quality management system training toolkit.

A total of 34 persons participated in this workshop including 14 nationals from 13 Pacific Island countries (PICs): Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Nauru, Palau, Papua New Guinea, Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu. There were also eight observers representing the Ministry of Health (MOH) Fiji, Mataika House, Secretariat of the Pacific Community (SPC), Pacific Island Health Officers Association (PIHOA), New Zealand Agency for International Development (NZAID), Pacific Paramedical Training Centre (PPTC), Centers for Disease Control and Prevention (CDC), Atlanta (Annex 2).

Participants exchanged experiences with regard to implementation of the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) and committed to adapt the Strategy to their national context. Two draft documents “Guidance to develop a national laboratory policy and plan” and “Regional Pacific laboratory standards” were discussed, finalized and endorsed by all participants. The Laboratory Quality Management System (LQMS) toolkit was introduced and disseminated to the participants.

The meeting noted that, from a public health perspective, it was critical to continue collaboration across disease control programmes to strengthen laboratory services in order to ensure that the principles of the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) are appropriately reflected in the national context.

Recommendations

Recommendations to Member States

1. Develop a national laboratory policy and plan encompassing the key elements of the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) through a process of national consultation.

2. Designate a national laboratory focal point and laboratory coordinating committee.
3. Provide adequate funding support to laboratories for the efficient implementation of the national policy and plan.
4. Adopt the Regional Pacific laboratory standards.
5. Recognize that quality laboratory services require an appropriately qualified and competent workforce.
6. Develop and monitor national indicators to assess laboratory services, document successes and identify gaps.
7. Explore the possibility of developing national EQA schemes.
8. Utilize the WHO/CDC/CLSI LQMS toolkit to improve the quality of laboratory results.
9. Explore the possibility of forming a regional association of laboratory professionals.

Recommendations to WHO

1. Finalize the guidance document for developing a national laboratory policy and plan and disseminate it to all Member States.
2. Finalize the regional Pacific laboratory standards and disseminate it to all Member States.
3. Develop a training schedule to implement the regional Pacific laboratory standards.
4. Make available the WHO laboratory assessment tool (LAT) to Member States.
5. Disseminate the WHO/CDC/CLSI LQMS toolkit through regional and national training, and provide post-training support.
6. Continue collaboration across disease control programmes to strengthen laboratory services.
7. Assist Member States in mobilizing resources from international developmental partners for sustainable health laboratory services.
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1. INTRODUCTION

1.1 Background information

Efficient and reliable health laboratory services are essential and fundamental components of any strong and effective health system, and are integral to both clinical and public health functions. In the Asia–Pacific region, considerable effort has gone into improving health laboratory services. However, much of the focus has been on specific disease-control programmes such as poliomyelitis, measles, HIV/AIDS, tuberculosis (TB) and malaria, where funding has been made available through global health initiatives. Frequently, however, the linkages between various laboratory initiatives, especially between public health and clinical services, have been weak, and the focus has been more on short-term results than on long-term capacity building. As a result, there is inefficiency in some areas, duplication in others and neglect of some aspects. Long-term sustainability has been put at risk, and health laboratory services have been further fragmented.

To address these issues, the World Health Organization (WHO) developed the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015), which was endorsed at the sixtieth session of the WHO Regional Committee for the Western Pacific in 2009. Resolution WPR/RC60.R6 urged Member States to use the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) as a strategic framework to guide the development of coherent national frameworks for laboratory services.

The way forward is to assist Member States in providing nationally coordinated and comprehensive laboratory services through the development of national laboratory policies and plans. In the context of the Pacific Island countries (PICs), it was decided that WHO would work with a few countries to impact, wherever possible, at the planning level. Six countries – Fiji, Kiribati, Nauru, Papua New Guinea, Solomon Islands and Tuvalu – were selected on the basis of population size and because they had recently revised or were about to revise their national health plans. WHO supported their ministries of health (MOHs) in developing, through a consultative process, their draft national laboratory policy and plans.

On-the-ground experiences of the six countries in identifying the major strategic elements of a national laboratory policy and plan, the process of developing the draft national laboratory policy and plan, and finalizing the indicators to monitor its progress will be used as a template for other similar countries.

The Laboratory Working Group of the WHO Regional Office for the Western Pacific (WPRO) provided technical support to the meeting on cross-cutting areas of work. This Working Group comprises several units – Expanded Programme on Immunization, HIV/AIDS and sexually transmitted infection (STI), Malaria, other vector-borne and parasitic diseases, Maternal and Child Health (MCH) and Nutrition, Noncommunicable diseases (NCDs) and mental health, and Stop TB and leprosy elimination. The WHO–Centers for Disease Control and Prevention (CDC) Laboratory quality management system (LQMS) training toolkit was also introduced to the participants.
1.2 Objectives

The objectives of the meeting were as follows:

(1) to identify major strategic elements of a national laboratory policy and plan;

(2) to develop a draft of the national laboratory policy and plan for their countries;

(3) to discuss and finalize the indicators to monitor the progress of the national laboratory policy and plan; and

(4) to be introduced to the WHO–CDC LQMS training toolkit.

1.3 Participants

Participants were invited from 21 PICs, but only 13 of these Member States sent nominations. Fourteen participants attended from the following 13 countries: Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Nauru, Palau, Papua New Guinea, Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu.

There were also two temporary advisers, eight observers from MOH Fiji, Mataika House, Secretariat of the Pacific Community (SPC), Pacific Island Health Officers Association (PIHOA), New Zealand Agency for International Development (NZAID), Pacific Paramedical Training Centre (PPTC), CDC, Atlanta and a WHO Secretariat team from Lyon (HQ), WHO South Pacific Office, Fiji and WPRO (Annex 1).

1.4 Organization and content

The programme for the meeting included sessions on (1) the development of a national laboratory policy and plan; (2) development of indicators to monitor the national laboratory plan; (3) development of regional Pacific laboratory standards and checklist; (4) laboratories in disease-control programmes; (5) regional and national external quality assurance schemes (EQAS); (6) laboratory courses by the Pacific Open Learning Health Network (POHLN).

Each session consisted of presentations, followed by questions, discussion, and exchange of views and experiences in the plenary sessions.

The workshop agenda and programme of work (time table) are given in Annex 2. The participants were provided with background materials related to the subjects including the WHO–CDC LQMS training toolkit.

1.5 Opening remarks

On behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific Region, Dr Chen Ken, WHO Representative for the South Pacific, welcomed the participants and read out the Regional Director’s message. He thanked Fiji for supporting WHO’s efforts in implementing the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015).

He reiterated in his speech that this meeting provided an opportunity for Member States to share experiences and develop future plans for strengthening health laboratory services. The way
forward in implementing the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) in PICs includes the development of national policies and plans. In 2010, WHO provided technical support to six pilot countries – Fiji, Kiribati, Papua New Guinea, Nauru, Solomon Islands and Tuvalu – in developing their draft national laboratory policy and plan through a consultative process. The formation of the Laboratory Working Group in WPRO will facilitate support to the meeting on cross-cutting areas of work. He reiterated that WHO would continue to provide technical support for strengthening health laboratory services.

The meeting was inaugurated by the Permanent Secretary of Health, Fiji MOH. She welcomed the participants and thanked WHO for organizing this meeting in Suva, Fiji with the support of MOH, Fiji. She acknowledged the need for quality laboratory services and said that over the past 18 months the Ministry had embarked on a vigorous health reform, which includes laboratory services. The review of current laboratory services and strengthening of laboratory services has been made possible through support to Fiji by the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund) and technical support provided by WHO.

She said that the MOH in Fiji had looked into the current structure, budget, systems and processes to identify weaknesses and gaps, and had tried to introduce and implement necessary solutions for improvements, for example, in the areas of procurement and supply of reagents and consumables. They also plan to review the current system of laboratory charges.

The Permanent Secretary Health highlighted the importance of strengthening health laboratory services and fully supported the implementation of the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) through the development of a national laboratory policy and plan. She emphasized the importance of regional cooperation in this emerging and important area, and acknowledged the technical assistance from WHO which has helped Fiji in drafting its national pathology laboratory policy with a strategic plan for the next five years. She reiterated that Fiji will remain committed and open to regional initiatives and support.

1.6 Appointment of Chair and Co-Chair

The workshop elected Dr Eka Buadromo, Consultant Pathologist, Colonial War Memorial Hospital, Suva, Fiji as the Chairperson and Dr Evelyn Lavu, Director, Central Public Health Laboratory, Port Moresby General Hospital, Papua New Guinea as the Co-Chairperson.

2. PROCEEDINGS

The meeting included:

- presentations of the country reports from the six countries that had worked with WHO to develop their draft national laboratory policy and plan;
- presentations and discussions on the two draft documents "Guidance to develop a national laboratory policy and plan" and "Regional Pacific laboratory standards”;
- introduction of the LQMS toolkit;

Dr Zamberi Sekawi, WHO Representative office in the South Pacific (WPR/SP), Fiji gave a presentation on implementation of the strategy in Fiji. Fiji is the recipient of a grant from the Global Fund, Round 9, which provided much-needed financial support to strengthen its health laboratories. Under this grant, the Fiji MOH started working with technical support from WHO in April 2010. The planned activities include development of the national laboratory policy and plan; laboratory situational analysis; laboratory workforce assessment and development of a national laboratory strategic plan 2011–2015.

The aim is to eventually comply with ISO 15189 standards, which is the global standard for medical laboratories. The draft national laboratory policy and plan has been developed, and is in the final stages of approval. The key points include establishment of a national laboratory coordinating committee, creation of a national advisor of pathology services and policies designed to set directions for quality-driven practices.

A countrywide analysis on the laboratory situation and assessment of the workforce were done and a number of recommendations made. These included establishing an LQMS; improving inventory and supply, and equipment procurement; improving human resources and organizational structure; improving working conditions and introducing core laboratories; establishing inter-laboratory supervision; improving staff training; rationalizing standardization of tests; improving communications to shorten the turnaround time of tests; improving infrastructure and utilities, and laboratory safety and waste management.

The design of the national laboratory strategic plan is based on these recommendations. It will be aligned with the MOH Strategic Plan in order to gain full support, commitment and funding. The following four objectives were identified for inclusion in the national laboratory workforce; ensuring good laboratory infrastructure and good financing practices.

2.2 Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015)

Dr Gayatri Ghadiok, from WPRO, Manila, provided an overview of the WHO WPR Regional Committee Resolution (annexe 3), in which all Member States had endorsed the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015). Resolution WPR/RC60.R6 recognized that strong health systems are the foundation that underpin the ability of all health programmes to deliver better results and that laboratory services are a critical component of health systems; that the strengthening of laboratory services is an important component of both the Asia Pacific Strategy for Emerging Diseases (APSED) and the International Health Regulations (IHR), 2005; that there is a need to strengthen the local and national capacity of each country in the areas of quality, safety and bench techniques, whether in public health or clinical services; and that there is a need to further enhance intercountry, interregional and global collaboration in strengthening health laboratory networks.

The intention is not to duplicate the strategic components of laboratory policies and plans developed by specific disease-control programmes, but to enhance nationally coordinated
laboratory services. The key stages in this process are government commitment and leadership; planning; developing key goals, objectives and measurable indicators; implementing the national laboratory policy and plan; monitoring and evaluation; and financing.

In 2010, WHO provided technical assistance to six countries at the planning stage. These six countries – Fiji, Kiribati, Nauru, Papua New Guinea, Solomon Islands and Tuvalu – were selected on the basis of their population size and because they had recently revised or were about to revise their national health plans. WHO supported the ministries of health in developing, through a consultative process, their draft national laboratory policy and plan. These six countries would share their on-the-ground experience in identifying the major strategic elements of a national laboratory policy and plan, the process of developing their draft national laboratory policy and plan, and of finalizing indicators to monitor its progress. These experiences would then be used as a template for other similar countries.

A WPRO Laboratory Working Group has been formed in WPRO, Manila and comprises the following units: Expanded Programme on Immunization (EPI); HIV/AIDS and STI; malaria, other vector-borne and parasitic diseases; MCH; NCD and Stop TB (STB).

2.3 Status of the national laboratory policy and plan in Pacific Island countries

2.3.1 Fiji Dr Eka Buadromo

The draft of the national laboratory policy and plan is ready and is now awaiting approval. There is a designated focal point and a national network of laboratories that participate in regional and national EQAS in all disciplines. There is currently no national advisory committee on laboratories and no national quality manager.

The key issues in the health laboratory services in Fiji include: the low priority accorded to the laboratory service; a scarcity of pathologists to lead the service; lack of national/international laboratory standards; and lack of commitment to the LQMS.

In order to implement the national laboratory policy and plan, support must be obtained from policy-makers and funding from partners in health; the plan must be aligned with the MOH strategic plan; commitment must be obtained from top management in laboratory administration; legislation of standards pursued; training conducted, continuing professional education and supervision provided, and the importance of laboratory services reinforced to clinicians.

2.3.2 Tuvalu Ms Silvia Rasovo

The national laboratory policy and plan is currently being drafted. There is a focal point and a national laboratory human resource plan. The laboratories participate in regional and national EQAS. There is currently no national advisory committee on laboratories and no national quality manager.

The key issues are limited microbiology testing, especially a lack of availability of blood culture services, improper collection of TB samples and preparation of smears; staff not trained in the LQMS and problems with waste disposal.

The MOH continues to support the laboratory services by allocating a budget and securing funds for the TB and HIV/STI programmes. Standard operating procedures (SOPs) are being developed and participation in EQAS will be increased. Laboratory technicians are undergoing online courses and scholarships have been secured for further training. The MOH is committed to the development of the national laboratory policy and plan.
2.3.3 **Solomon Islands** Mr Alfred Dofai

The MOH is actively developing the national laboratory policy and plan. Activities include visits to conduct situational analysis and workshops, and core group meetings on the strategic plan and policy. The Director of Pathology Service will be the focal point for laboratory services in the MOH. Laboratory services will be implemented at three levels of care – national referral level, provincial level and area health centres. The national laboratory policy and plan includes the following key components: legal and regulatory requirements, human resources, tests, techniques and equipment, quality management system, reagents and supplies, equipment care and maintenance, information management system, physical infrastructure, safety and waste management, and laboratory financing.

The national laboratory policy and plan is still in draft form and it is hoped that by the end of 2010, it will be finalized and adopted. Funding for its development and implementation is provided by the Global Fund Round 8.

2.3.4 **Nauru** Dr Alani Tangitau

The national laboratory policy and plan is currently in draft form. A national laboratory focal point has been designated but there is currently no national advisory committee on laboratories and no national quality manager. The laboratory participates in regional EQAS.

The key issues are inadequate funding and planning, poor infrastructure, lack of training and capacity building for human resources, lack of an LQMS, poor waste management and poor equipment maintenance.

The MOH is in the process of finalizing the national laboratory policy and plan. This will include the five-year strategic plan with budget allocation.

2.3.5 **Papua New Guinea** Dr Evelyn Lavu

The draft of the national laboratory policy and plan is in its final stage, together with national biosafety and biosecurity guidelines, which will be ready soon. The National Department of Health (NDOH) has designated a national laboratory focal point and there is a national network of laboratories which participates in regional and national EQAS. A national advisory committee on laboratories will be formed soon. A national laboratory human resource plan is available.

The national laboratory policy and plan was discussed with various stakeholders such as clinicians, hospital superintendents, executive managers and others. WHO is providing technical assistance. It is important to get a good focal point (person or committee) to get it working. The NDOH is committed to approving and implementing the national laboratory policy and plan. During a recent consensus workshop, many indicators for monitoring were set up.

2.3.6 **Kiribati** Ms Tiero Tetabea

Drafting of the national laboratory policy and plan is ongoing. There is a designated national laboratory focal point and a national network of laboratories which participate in regional EQAS. There is currently no national advisory committee and no national quality manager.

The key issues are an inadequate number of qualified staff, poor laboratory information system, inadequate budget, ineffective procurement and supply management, weak laboratory
networking, inadequate monitoring of laboratory services to ensure strict adherence to the LQMS and lack of national laboratory standards.

The MOH is committed to developing the national laboratory policy and plan with the formation of the planning committee. Some of the plans are included in the laboratory strategic plan developed in 2008, with strategic activities to improve the diagnostic capabilities of laboratories, and formulate and implement the national blood service strategy.

2.4 Plenary sessions

2.4.1 Guidelines for the development and implementation of a national laboratory policy and plan - Dr Jane Carter

A national policy and plan is a prerequisite for establishing an efficient, cost-effective and sustainable quality health laboratory service. It defines the components of a system that will ensure the safety and reliability of health laboratories, provides the framework for coordinated delivery of quality and accessible laboratory services countrywide, systematically outlines the major issues that need to be addressed, and is a measure of the commitment of a government to provide quality health services to its people.

Dr Carter brought out the challenges due to the different definitions of “policy” (a plan or course of action intended to influence and determine decisions), “plan” (a scheme, programme or method worked out to accomplish an objective), “strategy” (a plan of action designed to achieve a particular goal), and “strategic plan” (a tactical plan with interim objectives leading to strategic goals).

The objectives of a national laboratory policy and plan are

- to affirm government commitment and support for the organization and management of efficient, cost-effective and sustainable health laboratory services;
- to strengthen laboratory services to support diagnosis, treatment, prevention, surveillance and control of diseases;
- to ensure that the quality of provision of laboratory services meets established and accepted national standards;
- to empower the establishment and implementation of the national laboratory plan including allocation of adequate resources and funds;
- to ensure adequate and competent human resources to meet the requirements of the medical laboratory services including clinical, public health and national blood transfusion services;
- to commit to ethical values in laboratory practice including patient confidentiality, adherence to professional codes of conduct and ethical research practices; and
- to encourage research and collaboration to inform and improve the quality of laboratory services.
The formation of regional laboratory quality standards may be relevant for PICs as it may be difficult for individual countries to achieve international standards in a short period of time. Accreditation is expensive and most countries may not be able to afford it.

2.4.2 Targets and indicators

Dr Jane Carter

It is important to set targets and indicators to monitor the progress of the national laboratory plan, and define realistic time frames for reaching these targets. Indicators are data that provide information used to measure and monitor processes, progress and impact. Indicators established at the national level should be well defined: objective, reliable, sensitive, acceptable and measurable. Indicators can be used to support decision-making such as guiding activities, assessing national and donor funding, and helping to ensure transparency and accountability. A baseline assessment and indicators should be established before implementing the national laboratory strategic plan.

Examples of laboratory indicators

1. Testing statistics - number of each test performed per month or total tests performed per month
2. Specimen rejection - number of specimens rejected per month and reason for rejection
3. Turnaround time - average time from specimen receipt or log-in to release of results for different types of tests over a period of a month
4. Service interruption due to staff issues - number of days per month staff is out for meetings (M), leave (L), or illness (I).

Examples of country indicators

1. Existence of a national laboratory policy and strategic plan
2. Proportion of laboratories meeting national standards at each level of the health-care system
3. Proportion of laboratory equipment that meet specifications
4. Proportion of laboratories experiencing shortage of essential reagents
5. Existence of a biosafety management plan; proportion of facilities complying with standards
6. Proportion of laboratories with functioning manual or electronic laboratory information systems.
Proposed regional indicators

1. Number of countries with a national health laboratory policy and strategic plan based on a situational analysis
2. Number of countries with an identified, active national laboratory focal point
3. Number of countries with a biosafety management plan, and percentage of facilities complying with the standard plan
4. Number of countries and proportion of facilities in each country participating in comprehensive EQAS addressing commonly used tests
5. Proportion of laboratories participating in laboratory-based surveillance
6. Proportion of events of public health importance reported with laboratory participation.

2.4.3 Laboratories in disease control programmes

2.4.3.1 Expanded Programme on Immunization

Dr Raul Bonifacio (WR/SP) and Dr Youngmee Jee (WPRO)

The laboratory network in the WPR includes laboratories for diagnosing measles/rubella, poliomyelitis, Japanese encephalitis, hepatitis B and others. There are a few challenges in confirming the diagnosis in time in cases of acute flaccid paralysis because of delays in transporting specimens to the Victorian Infectious Diseases Reference Laboratory (VIDRL), Australia, the WHO polio regional reference laboratory in Australia. This highlights the importance of making contingency plans to ensure that specimens from contacts of an index case are referred in a timely manner. There are four WHO designated national laboratories in the Western Pacific Region which are involved in the measles/rubella laboratory network – Fiji, New Caledonia, Guam and French Polynesia; the Fiji laboratory in Mataika House is the only one accredited by WHO. Fiji, French Polynesia and Guam participated in the WHO proficiency test programme and all three laboratories received a 100% score. The laboratory in Mataika House, Fiji also sends measles/rubella samples to the VIDRL for confirmatory testing. Mataika House laboratory staff participated in the regional hands-on training in Hong Kong in November 2009. Recent measles genotype data are not available from Fiji and other PICs since the H1 outbreak in 2005–06 in Fiji.

Hospital-based active surveillance (HBAS) for measles and polio was established in 1997. The focus is on hospital inpatients. In the 20 PICs, there were 61 reporting sites involving more than 200 key clinicians. The target is children less than 15 years of age. Despite the National Measles Laboratory in Mataika House, Fiji, which was accredited in 2009, no samples from patients with acute fever and rash (AFR) have been received from PICs. There was one AFR case from Guam with a confirmed laboratory diagnosis and four AFR cases from the Federated States of Micronesia in 2010, but the samples were not referred for testing.

The requirements for virological surveillance to verify measles elimination are that testing should be performed in an accredited laboratory, and specimens (throat swab, nasal wash or aspirate, oral fluid) must be taken at first contact with suspected case. Viral RNA can be detected at lower frequencies in dried blood spots, IgM-positive serum.

Plans to improve virological surveillance in PICs in 2010–2011 include (i) encouraging all PICs to send AFR samples (suspected measles cases) to the WHO-accredited measles laboratory.
in Mataika House, Fiji and (ii) collecting virus isolation samples to obtain genotype information from all chains of measles transmission.

To verify measles elimination in PICs, obtaining genotype information for circulating measles virus strains and proving that there is no endemic transmission of measles virus would be required.

2.4.3.2 Sexually transmitted infections/HIV

Dr Brigitte De Hulsters (WR/SP)

In all PICs, there is a very high prevalence of chlamydial infection, gonorrhoea and syphilis, as seen from second generation surveillance (SGS) data from 2004 to 2008. The prevalence of chlamydial infection in this area is the highest in the world in low-risk groups such as pregnant women, with infection rates of up to 30%. She brought out the importance of laboratories for diagnosing and monitoring infection rates to allow documentation of the impact of interventions, and for a review of policies and interventions so that they could be changed according to the evolution of the “epidemic”. In 2008–2009, interventions for asymptomatic STI focused on screening and treating women presenting to antenatal clinics. This resulted in work overload of the laboratories, but unfortunately had no impact. In 2010, there was a regional recommendation for a change of policy. The new policy “Breaking the silence” will roll out this year.

Technical support to laboratories has been provided by the WHO South Pacific office in collaboration with PPTC. It includes an intervention which has recently started through a Response Fund grant: “Strengthening of laboratory capacity in STI/HIV for all Pacific Island countries; through hybrid training of the POLHN course and in-country workshops and training”. In 2008, for the diagnosis of chlamydial infection and gonorrhoea, BD Probe machines (and supplies) for nucleic acid assay testing were provided to eight countries – Cook Islands, Niue, Samoa, Tonga, Federated States of Micronesia, Palau, Marshall Islands and Vanuatu (Kiribati, Nauru and Tuvalu were given support to refer samples for testing) through Round 7 of the Global Fund. While there are certain benefits of having a confirmed diagnosis of chlamydial infection in-country, the cost of operations in terms of human resources, consumables, and the cessation of Gram stain, culture and antimicrobial resistance (AMR) testing for gonorrhoea were perceived as distinct disadvantages. The future policy and training will reintroduce these techniques and allow the BD Probe tec to test only for Chlamydia.

HIV testing in this region has been successfully harmonized. Data were shared from research on rapid testing strategies obtained from the national reference laboratory (NRL). Phase 1 has been completed, resulting in the use of Determine HIV1/2 as the screening test of choice in all PICs. Phases 2 and 3 to validate the algorithm using only three rapid tests are ongoing in Kiribati, Solomon Islands and Vanuatu; thus, countries would not have to refer samples overseas in future. All samples that are positive with Determine and some that are negative are still being sent to the NRL for further validation of the results. However, the results obtained by laboratories conducting these rapid tests can be delivered to clinicians and need not be confirmed by the NRL. The main challenge in the Pacific is the high cost of shipping samples to the NRL, leading to a delay in conveying test results to clinicians, and resulting in some cases of parent-to-child transmission (PTCT) and neonatal HIV. A possible solution is to either ship door-to-door or for the NRL to arrange a courier service to pick up and deliver samples. Currently, confirmatory testing remains a big problem.

It is equally important to harmonize testing protocols to improve efficiency. Dr Hulsters gave some examples of countries that use different test methods and protocols for testing for syphilis. The Determine TP rapid test is easy to perform and has been available for several years. It can be used in isolated places where there is no laboratory.
It is recognized that a strengthened laboratory service and linkages with clinical services will scale up the health sector response to STI. Strengthening laboratories through laboratory planning and strategizing, training and support of laboratory staff, ensuring funding, equipment and supplies improves STI control and health systems functioning. WHO will continue to provide laboratory support to countries to strengthen laboratory capacity in diagnosing STI/HIV.

2.4.3.3 **Tuberculosis (TB)** Dr Katsunori Osuga

In WPR, TB accounts for 21% of global TB burden. In addition, there are the challenges of multidrug-resistant (MDR) and HIV-associated TB. Some of the South Pacific countries have access to a full range of TB testing, including culture and drug-susceptibility testing. Other South Pacific countries have limited capacity to detect MDR-TB cases, although a diagnostic system has been established in collaboration with laboratories in Australia and New Zealand. Occasional cases of MDR-TB are seen in several PICs. There was an MDR-TB outbreak in Chuuk in the Federated States of Micronesia through importation and local transmission.

Regional plans for TB control include the 2000–2015 Plan. Dr Osuga also explained the evolution of drug-resistant TB to MDR-TB, and to extensively drug-resistant TB (XDR-TB). The challenge is that the diagnosis and treatment of MDR-TB are poor. Till 2009, no PIC had reported a case of XDR-TB.

However, there are several challenges to scaling up laboratory services, which include weak health systems, inadequate human resources, insufficient programmatic and managerial capacity, inadequate infrastructure especially for biosafety, problems of availability and access to diagnosis, slow technology transfer, low priority of the laboratory in TB control, and poor communication between national TB programmes and laboratory services.

Dr Osuga gave a historical overview of WHO policies, with current emphasis on early diagnosis and care, smear-negative TB, rapid detection of MDR/XDR-TB with the current technology, turnaround time and the improvement in sensitivity with progress in technology. There was mention of the Global Laboratory Initiative (GLI), which is dedicated to accelerating and expanding access to quality-assured laboratory services in response to the diagnostic challenges of TB, especially HIV-associated and drug-resistant TB.

The TB Supranational Reference Laboratory Network (SRLN) has five centres in WPR. For PICs, the Pacific TB Laboratory (PATLAB) Initiative was launched in mid-2007, with partner agencies such as CDC, SPC and WHO. Under the PATLAB Initiative, the Pacific TB Reference Laboratory Network was established with four laboratories (Brisbane, Honolulu, Adelaide and Wellington), and these provide referral services to Pacific TB laboratories in 22 PICs. The Pacific TB Reference Laboratory Network was set up and the activities include on-site evaluations, training, panel testing, blinded slide rechecking, drug resistance testing/surveillance and EQA. However, this network faces several challenges, which include local human resource/administrative issues in some PICs (low critical mass of trained medical technicians; inadequate skill levels of technicians in most PICs; low numbers of TB-proficient technicians); logistic difficulties in obtaining reagent supplies; lack of facilities for culture of *Mycobacterium tuberculosis*; difficulty/unreliability of e-mail to/from some PICs; small pool of available TB laboratory consultants; high workload of Pacific TB reference laboratories; and high cost of travel/shipping in the PICs.

The availability of new diagnostics, for example, Xpert™ MTB/RIF, generated a great deal of interest among participants. With this technique, MDR-TB can be detected with a sensitivity and specificity of >96%. This exciting new technology can be used for shared
platforms such as malaria, HIV, hepatitis B and C, and other emerging infectious diseases, resulting in increased cost-effectiveness.

2.4.3.4 Communicable diseases surveillance and response (CSR) Jennie Musto (WR/SP)

Ms Musto gave an overview of the Pacific Syndromic Surveillance, which includes acute fever and rash, diarrhoea, influenza-like illness and prolonged fever. The Pacific Public Health Surveillance Network (PPHSN) lists the following as target diseases: dengue, leptospirosis, measles/rubella, influenza, typhoid fever and cholera. The challenge in diagnosing primary dengue infection was highlighted as an example of when and which type of specific diagnostic tests should be ordered.

The issues highlighted in the area of laboratory diagnosis include the selection of appropriate rapid tests, for example, initial reliance on rapid tests that have low sensitivity especially for influenza outbreaks; underutilization of the polymerase chain reaction (PCR) laboratory in Fiji; International Air Transport Association (IATA) and its licensing and transportation requirements; high shipping costs; confusing roles of clinical and public health services resulting in an ineffective response to outbreaks; lack of human resources; lack of training; poor procurement and inventory management with frequent stock-outs; and lack of availability of personal protective equipment.

In addition, there are very little regional data. Due to transmission across borders, there is a need to improve reporting and the regional system for laboratory supplies.

2.4.3.5 Malaria Dr Lasse Vestergaard, CLO (VAN)

Dr Vestergaard gave an update on malarial diagnostics and cross-cutting issues. He provided an overview of the malaria control strategies, which include, among others, the availability of malaria diagnostics and effective treatment. Rapid malaria diagnosis and treatment is essential for early disease recognition, diagnosis, effective treatment and referral for severe disease, as well as surveillance, particularly in the context of elimination. Currently, malaria control and elimination efforts in the Solomon Islands and Vanuatu have been intensified.

The malaria laboratory services documented the evolution of chloroquin resistance from 1960 to 2000. An increasing number of countries now have chloroquin resistance. As a result, countries have shifted their treatment policies from the use of chloroquin to the use of artemisinin-based combination therapies (ACT). The WHO policy for parasite-based diagnosis states that in all suspected malaria cases, a confirmatory test should be performed, using either microscopy or rapid diagnostic tests (RDTs). Light microscopy remains the gold standard; RDTs should be used in peripheral health facilities/those health facilities without reliable capacity for microscopy; PCR should be used for species characterization where feasible, especially for testing the therapeutic efficacy of drugs, as well as in settings poised for elimination, as these setting may experience very low parasite densities which may be difficult to pick up using conventional microscopy. Other methods such as in vitro tests could also be used where indicated to study drug sensitivity.

Microscopy is recognized as the gold standard for diagnosis. It is relatively cheap, allows quantification of parasites, and therefore allows assessment of the response to treatment. However, several drawbacks are associated with this diagnostic modality. It is a time-consuming process and results are often not immediately available, it requires good training and regular refresher training of microscopists, the microscopes require regular servicing and maintenance, and it is only available in selected health facilities and not at the community level. Quality assurance guidelines and supervisory visits need to be in place for ongoing evaluation of
individual microscopists by senior malaria supervisors. Sending blinded test slides from reference laboratories should be encouraged.

On the other hand, RDTs, though expensive, provide immediate results. Their sensitivity as compared to light microscopy is variable, and countries need to refer to the WHO Malaria Diagnostics Evaluation Programme Foundation for Innovative New Diagnostics (FIND) evaluation scheme/report for selection of the appropriate RDTs in relation to the prevailing disease epidemiology. Existing RDTs have generally low sensitivity to *P. vivax* compared with *P. falciparum* and, as such, the prevalence of these species in the country should be considered when selecting RDTs. The other advantage with RDTs is that not much training is required and Aid Post workers can use it in the community. However, ongoing supervision of health workers is important, combined with case management workshops. The shelf-life of RDTs is a problem, with expiry dates being between one-and-a-half and two years. The cold chain needs to be maintained and test kits transported and stored under cold and dry conditions; stock management is an issue, so procurement and supplies need to be managed effectively. For quality assurance purposes, there should be pre-selection of commercial products, independent performance evaluation (WHO-FIND Diagnostics) and post-arrival batch testing before distribution in-country (sent to reference laboratories in Cambodia and the Philippines), as well as monitoring test performance in the field (at least once every three months under normal conditions of use).

Improved diagnosis of malaria should indirectly lead to better care for other illnesses. With laid-down norms, standards and SOPs, malaria microscopists can be trained to diagnose other microorganisms (diagnosis of TB and STIs). A shared distribution system can be put in place for RDTs and drug supplies; joint supervisory visits can be conducted to health facilities; laboratories and health centres can be refurbished, e.g. by providing cheaper electricity through solar panels. RDTs introduced at the peripheral level may lead the way for other point-of-care use tests.

2.4.3.6 Noncommunicable diseases (NCD)_Dr Li Dan (WRSP/DPS)

The presentation was entitled “Labs in NCD prevention and control in Pacific Island countries”. From the published STEPwise approach to Surveillance (STEPS) reports, Dr Dan presented the scientific, national, updated and comparable NCD STEPS data across the Pacific, e.g. the prevalence of overweight, obesity and diabetes mellitus among the age groups of 25–64 years in eight PICs. Overweight and obesity is a major problem in Tokelau, American Samoa and Nauru, which are the three countries in the world with the highest prevalence of overweight. Diabetes is a major problem in American Samoa, Tokelau and Federated States of Micronesia (Pohnpei). The prevalence of diabetes in American Samoa is the highest in the world. The Madang Commitment by WHO and SPC, endorsed by the health ministers of the all PICs, recommends scaling up surveillance and interventions for NCDs.

STEPS was initiated by WHO in 2001. It is an approach to NCD surveillance adopted by 119 WHO Member States and territories including the PICs to define core variables for surveys and achieve data comparability between countries and over time. Subsequently, eight PICs, i.e. Fiji, Nauru, American Samoa, Tokelau, Federated States of Micronesia, Marshall Islands, Kiribati and Solomon Islands have published the STEPS reports.

According to the Madang Commitment, the three common NCDs prevalent in the PICs are diabetes mellitus, cardiovascular disease and cancer. In the case of diabetes, less than 50% of cases have been diagnosed. In most countries, blood glucose (capillary or venous) is the common test performed. In some PICs such as Palau, a DCA 2000 machine is placed in community health centres as the expanded laboratory in the community. The challenge is to always have reagents in
stock and prevent stock-outs to ensure improved quality of care and timely intervention to avoid development of the complications of diabetes.

In the area of cancer prevention and control, laboratories play an important part in diagnosing hepatitis B infection; and screening for and early detection of cancers of the cervix, breast and colon. One of the challenges in cancer diagnosis is the accuracy of morphological diagnosis by laboratory staff. Pathological (histopathological or cytological) diagnosis needs to be strengthened. In Papua New Guinea, oral and cervical cancer are common in young patients, whereas in Kiribati, cancer of the cervix is the most common, but there is no organized screening for these. Dr Li also shared the strategic approach and action areas in the Western Pacific Regional Action Plan for NCD in which the role of laboratories in clinical intervention is highlighted.

2.4.4 Laboratory quality management system (LQMS) Dr Sébastien Cognat, WHO-HQ (Lyon Office)

The laboratory is a complex system and all aspects must function properly to achieve quality. Quality is defined as “the ability of a product or service to satisfy the stated or implied needs of a specific customer”. “Laboratory quality” often refers to accuracy, reliability and timeliness of the reported test results. Laboratory errors are expensive with regard to time, personnel effort and patient outcomes.

The International Organization for Standardization (ISO) and Clinical Laboratory and Standards Institute (CLSI) have defined a quality management system (QMS) as coordinated activities undertaken to direct and control an organization with regard to quality. Thus, all activities that contribute to the quality of tests, directly or indirectly, constitute a QMS. Dr Cognat also described the quality model and outlined the various activities performed in quality control (QC), quality assurance (QA), QMS, quality cost management (QCM) and total quality management (TQM), and their interdependent relationships.

From the laboratory point of view, the complexity of the laboratory system requires quality to be controlled at all stages of examination: pre-examination stage (patient preparation and sample collection, sample transport, receipt and preparation); examination stage, which includes personnel competencies and QC testing; post-examination stage, which includes reporting and record-keeping. Laboratory tests can be influenced by the laboratory environment, knowledge of staff, reagents and equipment, QC, communications, process management, occurrence/event management and record-keeping.

The 12 quality system essentials defined by the CLSI are a set of coordinated activities that function as building blocks for quality management and include organization, personnel, equipment, purchasing inventory, process control, information management, documents and records, occurrence management, assessment, process improvement, customer service, and facilities and safety. Approaches to implementation will vary with the local situation, starting with the easiest to the most difficult in a step-wise process. Ultimately, all elements of the QMS must be addressed.

Implementing quality management does not guarantee an error-free laboratory but detects errors that may occur and prevents them from recurring. Laboratories not implementing a QMS are likely to have undetected errors.

ISO documents pertaining to the laboratory are: ISO 9001:2000 Quality Management System Requirements – a model for QA in design, development, production, installation, and

Dr Cognat introduced the LQMS training toolkit developed by WHO (Lyon Office), US CDC and CLSI. It provides comprehensive materials to design and organize training workshops for all stakeholders in the health laboratory services. It is based on previous training sessions and modules provided by CDC and WHO to more than 25 countries, and on guidelines developed by the CLSI for implementing a QMS in health laboratories. The toolkit is organized into Modules, Structure and materials, Training techniques, Group discussions, Case studies, Exercises, Simulations and Interactive presentations. A small introductory printed booklet and all materials in electronic format are provided on a CD-ROM.

2.4.5 Regional Laboratory Quality Standards _John Elliot, Director Pacific Paramedical Training Centre (PPTC), New Zealand

This presentation was on Guidelines for developing and implementing laboratory quality standards for the Pacific region. The need to develop these standards was felt at the WHO Regional meeting held in Nadi, Fiji in 2009. The formation of regional standards as opposed to international standards may be relevant for PICs as it may be difficult to achieve the latter in a short period of time. Accreditation is expensive and most countries may not be able to afford it. The objective is to assist PICs in establishing minimum standards for medical laboratories at different levels of the health-care system, and a methodology to implement and monitor these. The standards outlined in this document are based on the ISO 15189 (2007) “Medical laboratories – particular requirements for quality and competence” and ISO 17025 (2005) “General requirements for the competence of testing and calibration laboratories”.

The standards are based on the following essential elements:

1. Organization and management
2. Quality management system
3. Human resources (personnel)
4. Accommodation and environmental conditions
5. Laboratory safety
6. Laboratory equipment
7. Laboratory commodity management
8. Information management
9. Managing laboratory specimens
10. Customer service and resolution of complaints
11. Outbreak alert and laboratory network.

The standards have a checklist that will be used to monitor them and analyse data. Each question in the checklist has a mark allocated to it (1/2/3) depending on its importance and/or complexity. After the audit is completed, the score is tallied and the “star” level determined.
Suggestions on how to implement the standards

1. Obtain consensus for these standards by peer review.
2. Obtain approval for these standards by the appropriate national authorities.
3. Draw up an implementation plan with short-term, medium-term and long-term objectives, activities and timelines, and indicative annual budgets.
4. Identify appropriate implementing agencies including the government, nongovernmental agencies and other implementing partners such as the private sector, and sensitize them to the plan and their possible contributions.
5. Sensitize participating institutions and health facilities to the new laboratory standards and plan.
6. Use existing guidelines, checklists, SOPs, laboratory record forms and recording formats, appraisal forms, audit checklists, etc.; or develop country-specific documents.
7. Establish national procedures for laboratory networking and referral of samples.
8. Draw up detailed annual operational plans with budgets.
9. Use a step-wise approach. Start with existing documents and processes. The laboratory decides which “elements” it will implement and, when it feels it is ready for assessment, it is audited against that element of the standard only.

A regional accreditation process is also proposed. The countries in the Pacific region should establish a step-wise regional laboratory accreditation scheme, with sharing of agreed standards across the region. Implementation of the regional accreditation scheme may involve each individual country establishing a national accreditation scheme appropriate for laboratories at different levels of the health service. The accreditation scheme would use internationally accepted standards adapted to the local environment. It is suggested that the scheme use an incremental, step-wise approach that is objectively measurable over time. This allows individual laboratories to identify specific weaknesses and address them to reach the next accreditation level. The scheme therefore uses a positive, reinforcing approach to continuous quality improvement, which is empowering for individual laboratories. The stepping-stone approach means that laboratories which have reached the highest level of standards can then apply for international accreditation status. This scheme is practical and affordable. The scheme should include development of training modules and approaches to strengthen various areas of the laboratory services. These modules should employ task-based and output-orientated training tools.

In the discussion following the presentation, several suggestions were made regarding the wording, and these will be taken into account in the revised standards. One of these was related to the naming of the final section and it was agreed that this should be: “Public health and laboratory network.” It was also agreed that “Error resolution” needs to be included.
2.4.6 Regional external quality assurance programme (REQAP)  
John Elliot, Director  
Pacific Paramedical Training Centre (PPTC), New Zealand

EQA refers to a system by which the performance of a laboratory is assessed periodically and retrospectively by an independent outside agency to indicate to the laboratory staff where there may be shortcomings and hence a need for improving and/or changing internal quality control procedures. The purpose of EQA is:

1. to provide assurance to consumers, both doctors and patients, that the laboratory results are of a good standard;
2. to assess and compare the quality of laboratory performance on a national and/or international scale;
3. to identify common errors and recommend corrective procedures;
4. to encourage the use of standardized procedures and good-quality reagents;
5. to encourage and continue the application of internal quality control processes; and
6. to act as an educational tool for the laboratories involved in the programme.

With support from WHO and NZAID, PPTC provides samples to laboratories for biochemistry, microbiology, haematology, blood transfusion and infectious diseases serology in the following PICs:

Federated States of Micronesia (Yap, Chuuk, Pohnpei Kosrae); Palau; Marshall Islands; Solomon Islands; Niue; Vanuatu; Kiribati; Tuvalu; Tonga; Samoa; Cook Islands; Fiji (Colonial War Memorial Hospital, Suva Lautoka and Labasa, and three private laboratories); Papua New Guinea (Port Moresby, Lae); Nauru.

The average participation rate (for all markers) ranges from 60% to 80% but, in some laboratories, participation in biochemistry is as low as 50%. The aim is to achieve 100% participation from countries. Countries should communicate with PPTC if they encounter any problems and they would not be penalized if there is a valid reason for not participating. Some staff in certain countries are afraid of performing proficiency testing in case they get it wrong. It is advised that the test specimen should be treated as a routine daily specimen. It should not be used as a punitive tool but as an educational tool.

2.4.7 Developing a regional external quality assessment scheme (REQAS)  
Dr Jane Carter

A regional EQAS was developed in East Africa. The whole process from “idea to concept to proposal” took from 1996 to 1998. The pilot phase began in 2006 and is now in the process of scaling up. Ownership belongs to the MOHs of participating countries. The scheme involves reference laboratories in the countries for production of quality materials, and is coordinated by the African Medical and Research Foundation (AMREF).

The objectives of the East African REQAS are:

1. to establish an EQAS that addresses the performance of essential diagnostic services in peripheral health facilities;
2. to establish minimum standards for clinical and laboratory diagnostic services;
3. to develop mechanisms for monitoring and maintaining the quality of essential diagnostic services;
4. to use evidence to influence policy and practice.

The scheme is integrated, and samples are sent for haematology, bacteriology, parasitology and serology. Prior to implementing the surveys, visits were made to all the reference laboratories, SOPs were drawn up for preparing materials, technical capacity was reviewed, budgets were prepared and memoranda of understanding (MOUs) signed. Reference laboratories prepare materials for stool helminths and parasites (ova of hookworm, *Ascaris lumbricoides*, *Trichuris trichiura*, *Schistosoma mansoni*; cysts of *Entamoeba histolytica*, *Giardia lamblia*); blood films for parasites (malaria, *Borrelia*, trypanosomes, *Wuchereria bancrofti*); syphilis serology; HIV serology; smears for Gram stain; peripheral blood films for blood cell morphology; haemoglobin lysate and haemoglobicyanide standard; and sputum smears for acid-fast bacilli (AFB). Packaging and transportation conform to IATA standards.

Results are analysed for response rate, turnaround time, overall country performance, performance by facility level and question type, and methods used for analysis, e.g. haemoglobin by the colorimetric or visual comparator methods. Major laboratory errors are identified and potential reasons for these explored, e.g. laboratories with qualified or unqualified laboratory staff, lack of electricity, etc. Feedback is given in the form of feedback reports, advice, guidance, training sheets, supportive supervision, composite reports, comprehensive analysis and policy advice. The breakdown of costing showed that the cost per laboratory per year for two surveys was US$ 289.

The advantages of a REQAS include:

1. standard laboratory procedures
2. standard quality of scheme materials – comparison of performance possible across countries
3. wider range of specimens
4. sharing resources for preparation of materials resulting in economy of scale
5. more national resources available for remedial action
6. lessons learnt from regional experience
7. increased regional cooperation.

EA-EQAS has several achievements. There is now an integrated scheme for public health laboratories. Laboratory standards are agreed upon and shared across four MOHs. The comprehensive analysis and reporting format identifies potential sources of error. It also influences policy and some laboratories have implemented changes. It was reported that a number of laboratories have improved their performance.

However, EA-REQAS also faces many challenges. Production of materials by reference laboratories is sometimes slow and of poor quality. There are difficulties in transportation and communication. Some supplies are difficult to get locally. The turnaround times can be long. Laboratories sometimes do not follow instructions and provide an incomplete response. More
importantly, now the pilot (introductory) phase is complete, the scheme needs to secure financial contributions from individual health facility laboratories.

2.4.8 Pacific Open Health Learning Net (POHLN) courses

Programme Coordinator

The POHLN has a distance learning programme which is provided by the PPTC and is one of the ways in which PPTC delivers core education to health laboratory technicians in PICs. The Diploma course, developed for POLHN by the PPTC, is divided into five modules and covers the basic medicine laboratory sciences as practised in all health laboratories: biochemistry, haematology, transfusion science, microbiology and immunology. All the modules are written by PPTC lecturers who are senior scientists and experts in their own particular discipline. The content of each module has been based on the current curriculum used by the New Zealand Institute of Medical Laboratory Sciences for the attainment for their qualified technician’s certificate. Each module is divided into six sections to cover the basic principles and theory of that laboratory science. At the end of each section, there are a series of multiple-choice questions that have to be completed and returned to the PPTC for marking. There is also a final assignment with each module which the student must complete. Each module consists of up to six weeks of study and each week requires up to two hours of student contact time.

Once registered with the PPTC, each candidate is forwarded the learning materials and instructions corresponding to the discipline or disciplines they have chosen to study. Instructions are given to each candidate as to how the programme is to be conducted in order to be awarded the Certificate (or Certificates) in Medical Laboratory Technology in the discipline (or disciplines) studied. All six sections of the module must be studied, and the six sets of related twenty questions plus the answers to the assignment questions must be completed, and the answers returned to the PPTC for marking. On successful completion of each module, the student is given a certificate of achievement by the PPTC. Students who have successfully completed all five modules are awarded a Diploma in Medical Laboratory Technology by the PPTC.

The programme is designed to qualify medical laboratory technicians in the medical laboratory sciences. The modules, however, are not only for new laboratory staff who wish to be trained as technicians, but also for qualified staff who wish to refresh or enhance their knowledge in the medical laboratory sciences. Its purpose is to extend or enhance knowledge and skills. It is an extramural programme designed for individual student participation. However, there are a few limitations. Because the course is operated outside of the classroom environment, it relies totally on student honesty in answering the questions and completing the assignments.

It is anticipated that, in 2011, this PPTC course will be reviewed both for its content and format, and appropriate changes will be made. These could include the following:

1. Introduction of log books for each discipline. (The practical element of the course as it currently exists is now considered by the PPTC to be too brief and therefore log books to assess practical competence will be introduced for each of the disciplines.)
2. Incorporation of the immunology module into the microbiology and transfusion modules with the creation of a new laboratory technology module
3. Conversion of the transfusion module from a printed version to a CD-ROM
4. Expansion of selected topics within the theoretical content with the introduction of new technologies
5. The increase in expected study time for each module.

The feedback from participants has indicated that the courses offered by the PPTC through POLHN are of excellent quality and of enormous value in terms of technician training and ongoing professional development. The PPTC is working towards having its diploma recognized and accepted by the Pacific Island MOHs as a most suitable qualification for all medical laboratory technicians employed in medical laboratories throughout the entire Pacific region. The PPTC is also currently negotiating with the Auckland University of Technology (New Zealand), Fiji School of Medicine and University of Otago (New Zealand) to gain recognition for the PPTC Diploma in Medical Laboratory Technology, with a view to some degree of cross-crediting with the BMLSc degree programme offered by these institutions.

3.2 Group discussions

3.2.1 Review and finalization of draft “Guidance for developing a national laboratory policy and plan”

The draft Guidance document was critically reviewed and discussed. Participants suggested that other components of health systems should be taken into account. Some requested for a template but it was agreed that a generic template may not be helpful as the policies and requirements may vary among countries.

The moderator reiterated that development of the national laboratory policy and plan is a long-term activity. Details of how to operationalize this plan are included in the national laboratory strategic plan, which indicates timelines, budgets, and roles and responsibilities. It was agreed that the preamble should be more detailed and clear to explain the intent of the document. Minor adjustments would be needed to make it more user-friendly. It would be an official government (MOH) document.

3.2.2 Development of the draft national laboratory policy and plan

Countries other than the six that have already worked on developing their draft national laboratory policy and plan were called upon to give their feedback and delineate the process of how they would go about doing the same exercise in their own countries. These seven countries are as follows.

Republic of the Marshall Islands

There is a need to get feedback from stakeholders. The challenge is to bring the laboratories to an acceptable and expected level. The MOH is now giving more support to increase the standard of service. At the moment, there are two laboratories providing service and technicians are now available. There is one final-year technician in-training course at the Fiji School of Medicine.
Tonga

Tonga’s strategy is to ensure top-level commitment. However, there is a need to get assistance from Member countries and WHO to help with the situational analysis and then draft the national laboratory policy and plan.

Palau

Palau has one national laboratory and two private laboratories. It needs assistance with situational analysis and is consulting stakeholders for the policy draft.

Cook Islands

A national health strategic plan has been set up for the next five years and includes a laboratory strategic plan. The laboratory is recognized as an important component with regard to STI and MCH programmes. It would be a challenge to have a national laboratory policy. Detailed analysis would need to be done. Training and continuing professional development are through staff participation in the POHLN course.

Federated States of Micronesia

There are four government laboratories and one private laboratory. Community laboratories provide point-of-care testing. There are two levels of government – Federal and State Governments. The challenge is that policies issued by the Federal Government may not be taken up by the State Governments. Three documents were prepared and will be presented soon: national laboratory strategic plan, licensing draft and laboratory standards. The stakeholders in the preparation of these documents include the Director of Health Services, Public Health Chief, laboratory managers, Red Cross Society, SPC and the private sector.

Samoa

There is one central laboratory, one medium-size laboratory and one private laboratory. The laboratory component is not under the administration of the MOH. However, the MOH acts as a regulatory body to the laboratories. Samoa appreciates the assistance of the PPTC and NZAID in creating awareness of the LQMS. The national laboratory strategic plan will be aligned with the MOH Strategic Plan. The current government is open to reform. They need assistance with situational analysis.

Vanuatu

The Honourable Minister had instructed the laboratory to come up with a national laboratory policy and plan. The last situational analysis done was in 2004 and there is a need to update this before drawing up the draft policy.
4. CONCLUSIONS AND RECOMMENDATIONS

4.1 Conclusions

The participants committed to implement the Asia Pacific Strategy for Strengthening Health Laboratory Services in their national context. They also endorsed the two draft documents that were critically reviewed:

1. Guidance for developing a national laboratory policy and plan
2. Regional Laboratory Quality Standards

4.2 Recommendations

4.2.1 Recommendations to Member States

1) Develop a national laboratory policy and plan encompassing the key elements of the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015) through a process of national consultation.
2) Designate a national laboratory focal point and laboratory coordinating committee.
3) Provide adequate funding support to laboratories for the efficient implementation of the national policy and plan.
4) Adopt the Regional Pacific laboratory standards.
5) Recognize that quality laboratory services require an appropriately qualified and competent workforce.
6) Develop and monitor national indicators to assess laboratory services, document successes and identify gaps.
7) Explore the possibility of developing national EQA schemes.
8) Utilize the WHO/CDC/CLSI LQMS toolkit to improve the quality of laboratory results.
9) Explore the possibility of forming a regional association of laboratory professionals.

4.2.2 Recommendations to WHO

1) Finalize the guidance document for developing a national laboratory policy and plan and disseminate it to all Member States.
2) Finalize the regional Pacific laboratory standards and disseminate it to all Member States.
3) Develop a training schedule to implement the regional Pacific laboratory standards.
4) Make available the WHO laboratory assessment tool (LAT) to Member States.
5) Disseminate the WHO/CDC/CLSI LQMS toolkit through regional and national training, and provide post-training support.
6) Continue collaboration across disease control programmes to strengthen laboratory services.
7) Assist Member States in mobilizing resources from international developmental partners for sustainable health laboratory services.

5. CLOSING SESSION

Dr Gayatri Ghadiok, Technical Officer, Essential Health Technologies Adviser, WHO WPRO, Manila thanked all the participants for their active interest.
INFORMATION BULLETIN NO. 2

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### Regional Workshop on the Implementation of the 'Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015)' in the Pacific Island Countries

14 to 17 September 2010, Suva, Fiji

### DRAFT PROGRAMME OF WORK

#### Day 1: 14 September 2010

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<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker/Representative</th>
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<tbody>
<tr>
<td>08:00 - 08:30</td>
<td>Registration</td>
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<tr>
<td>08:30 - 09:00</td>
<td>Welcome and opening ceremony</td>
<td>WHO South Pacific Representative</td>
</tr>
<tr>
<td>09:00 - 09:30</td>
<td>Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015)</td>
<td>Dr. Gayatri Ghadiok</td>
</tr>
<tr>
<td>09:30 - 10:00</td>
<td>Implementation of APS Labs – Fiji experience</td>
<td>Dr. Zamberi Sekawi</td>
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<tr>
<td>10:00 - 10:30</td>
<td>Group photograph and Coffee break</td>
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**Session I: Development of National Laboratory Policy and Plan**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Location/Experience</th>
<th>Speaker/Representative</th>
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<tbody>
<tr>
<td>10:30 – 12:00</td>
<td>Country experience: Development of National Laboratory Policy and Plan</td>
<td>Fiji, Kiribati, Tuvalu</td>
<td></td>
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<tr>
<td>12:00 – 13:00</td>
<td>Lunch break</td>
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<tr>
<td>13:00 - 14:30</td>
<td>Country experience: Development of National Laboratory Policy and Plan</td>
<td>Solomon Islands, Nauru, PNG</td>
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<tr>
<td>14:30 - 15:30</td>
<td>Discussion</td>
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<tr>
<td>15:30 - 15:45</td>
<td>Coffee break</td>
<td></td>
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<tr>
<td>15:45 - 16:15</td>
<td>Regional Laboratory Strategy: AFRO experience</td>
<td>WHO-AFRO</td>
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<tr>
<td>16:15 - 17:00</td>
<td>Guidelines: &quot;Development and Implementation of a National Laboratory Policy and Plan&quot;</td>
<td>Dr. Jane Carter</td>
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**End of Day 1**

#### Day 2: 15 September 2010

**Session II: Targets and Indicators**

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<tr>
<td>08:00 - 08:30</td>
<td>Targets and Indicators</td>
<td>Dr. Jane Carter</td>
</tr>
<tr>
<td>08:30 – 10:30</td>
<td>Group Work I: Review and Finalization of Guidelines</td>
<td>Participants from countries</td>
</tr>
<tr>
<td>10:30 - 10:45</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>10:45 - 12:00</td>
<td>Presentation and discussion of Group Work</td>
<td>Moderator: Dr. Jane Carter</td>
</tr>
<tr>
<td>12:00 - 13:00</td>
<td>Lunch</td>
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**Session III: Development of Draft National Laboratory Policy and Plan**

<table>
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<th>Time</th>
<th>Activity</th>
<th>Location/Experience</th>
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<tbody>
<tr>
<td>13:00 – 15:00</td>
<td>Group Work II: Development of Draft National Laboratory Policy and Plan</td>
<td>Participants from countries (other than the 6 PICs)</td>
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<tr>
<td>15:00 - 15:15</td>
<td>Coffee break</td>
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<tr>
<td>15:15 - 17:00</td>
<td>Presentation and discussion of Group Work</td>
<td>Moderator: Dr. Jane Carter</td>
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**End of Day 2**
### Day 3: 16 September 2010

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<td>08:00 – 08:30</td>
<td>LQMS: definitions and 12 modules WHO-HQ/ Dr. Sebastien Cognat</td>
</tr>
<tr>
<td>08:30 - 10:00</td>
<td>Group work III: Participants from countries</td>
</tr>
<tr>
<td>10:00 – 10:30</td>
<td>Discussion Moderator: Dr. Sebastien Cognat</td>
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<tr>
<td>10:30- 10:45</td>
<td>Coffee break</td>
</tr>
<tr>
<td>10:45 - 11:45</td>
<td>Regional Pacific Standards for Labs Mr. John Elliot</td>
</tr>
<tr>
<td>11:45 - 12:30</td>
<td>Discussion</td>
</tr>
<tr>
<td>12:30 - 13:30</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:30 – 15:00</td>
<td>Group work IV: Review and Finalization of Standards Participants from countries</td>
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<tr>
<td>15:00 – 15:15</td>
<td>Coffee break</td>
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<tr>
<td>15:15 – 16:00</td>
<td>Group work IV continued</td>
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<tr>
<td>16:00 – 17:00</td>
<td>Presentation and discussion of Group work Moderator: Mr. John Elliot</td>
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</table>

**End of Day 3**

### Day 4: 17 September 2010

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<thead>
<tr>
<th>Time</th>
<th>Session V: Labs in Disease Control Programs</th>
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<td>EPI WHO</td>
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<tr>
<td>08:30 - 09:00</td>
<td>STI/HIV WHO</td>
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<tr>
<td>09:00 – 09:30</td>
<td>TB WHO</td>
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<tr>
<td>09:30 – 10:00</td>
<td>CSR WHO</td>
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<tr>
<td>10:00 – 10:30</td>
<td>Malaria WHO</td>
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<td>10:30- 10:45</td>
<td>Coffee break</td>
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<tr>
<td>10:45- 11:15</td>
<td>NCD WHO</td>
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<tr>
<td>11:15 – 12:30</td>
<td>Panel Discussion WHO</td>
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<tr>
<td>12:30 - 13:30</td>
<td>Lunch</td>
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<tr>
<td>13:30 – 14:15</td>
<td>Overview of the Regional EQAS Mr. John Elliot</td>
</tr>
<tr>
<td>14:15 - 15:00</td>
<td>Developing a NEQAS Dr. Jane Carter</td>
</tr>
<tr>
<td>15:00 – 15:15</td>
<td>Coffee break</td>
</tr>
<tr>
<td>15:15 – 15:45</td>
<td>POHLN courses Mr. John Elliot, WHO</td>
</tr>
<tr>
<td>15:45 – 17:00</td>
<td>Recommendations, Way Forward, Closing WHO</td>
</tr>
</tbody>
</table>

**End of Day 4**
HONOURABLE DR. SALANIETA T. SAKETA, PERMANENT SECRETARY FOR HEALTH;

DISTINGUISHED GUESTS, LADIES AND GENTLEMEN.

On behalf of WHO and our Regional Director for the Western Pacific, Dr Shin Young-soo, I am pleased to welcome you to the Regional Workshop on the Implementation of the "Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015)" in the Pacific Island Countries.

Let me start by expressing my sincere thanks to the Government of Fiji for hosting this important workshop. Fiji has always supported WHO's efforts to introduce and implement quality management programmes in the Western Pacific Region, and we are delighted to be joined today by Member States from the South Pacific.

The last meeting of national managers of clinical and diagnostic laboratories took place in Nadi, Fiji in May 2009. At that meeting, country representatives reviewed the Asia Pacific Laboratory Strategy, which was subsequently endorsed at the Sixtieth Session of the Regional Committee of the Western Pacific in 2009. Resolution WPR/RC60.6 urged Member States to guide the development of coherent national frameworks for laboratory services.

The way forward includes the development of national laboratory policies and plans. In the context of the Pacific island countries, WHO has worked with six pilot countries: Fiji, Kiribati, Nauru, Papua New Guinea, Solomon Islands and Tuvalu, where the Ministries of
Health were supported in developing the draft national laboratory policy and plan through a consultative process.

This on-the-ground experience of identifying the major elements of a national laboratory policy and plan and the process of developing and finalizing the indicators to monitor its progress will be used as a template for other similar countries.

I am happy to note that two important documents, the "Regional Pacific Laboratory Standards" and the "Guidelines for Developing a National Laboratory Policy and Plan", will be reviewed and finalized in this workshop. The WHO-CDC Laboratory Quality Management Training toolkit will also be introduced to the participants.

The Laboratory Working Group in the Western Pacific Regional Office, comprising of several technical units: Communicable Disease Surveillance and Response (CSR), Expanded Programme on Immunization (EPI), HIV/AIDS and STI (HSI), Stop TB and Leprosy Elimination (STB), Malaria, other Vectorborne and Parasitic Diseases (MVP), Maternal and Child Health and Nutrition (MCN), and Noncommunicable Diseases and Health Promotion (NHP) will provide technical support to the meeting on cross-cutting areas of work.

In closing, I reiterate that WHO will continue to provide technical support to efforts in strengthening health laboratory services. I wish you an enjoyable stay in Suva and success in your deliberations. We look forward to working with you and hearing your conclusions and recommendations.
Bula and good morning to you all.

I take this opportunity to thank the organizers of the workshop in inviting me to provide some introductory remarks as the representative of the Ministry of Health and the Government of Fiji this morning.

It also gives me much pleasure to welcome you all our visitors to our beautiful country and hope that your stay here will be an enjoyable one.

This meeting in my view is timely as it sustains the momentum that is critically needed to progress the improvements necessary for all our laboratory systems.

The challenges that we face with the burden of NCDs, emerging and re-emerging infectious diseases such as SARS and the H1N1 pandemic together with the meeting of the requirements of the International Health Regulations (2005) have
really emphasised the need for quality laboratory services for all our countries to ensure a timely and accurate response.

As health care providers and policy makers for our individual countries the ball is in our court now so to say, to bring about this necessary change.

I have noted that the key building blocks for a quality laboratory service in any country are the following:

- A clear organizational structure with clear role delineation of each level of health care delivery
- A well trained human resources
- Proper legal and regulatory framework
- Physical infrastructure
- Equipment care and maintenance
- Reagents and supplies
- Tests, techniques and equipment
- Quality Management Systems
- Adequate funding and resourcing
- Safety and waste management
- Laboratory Information System

I wish to share with you some of the work that is being undertaken in Fiji to strengthen laboratory services and also in assuring a quality laboratory service that is accessible and affordable.

Over the last 18 months the Fiji Ministry of Health has embarked on a vigorous health reform including that for laboratory services.
The review of current laboratory services and laboratory services strengthening has been made possible through the Global Fund support to Fiji and with technical support provided by WHO.

Internally we had looked at our current structure, budget and systems and processes to see where the weaknesses and gaps are and to implement the necessary solutions for improvements.

Firstly we had to look at the area of reagents and consumables and its procurement system as a matter of priority given the fact that this has been an area of continuing over-expenditure for government that runs into millions of dollars.

The solution was to centralize procurement into our national procurement office at the Fiji Pharmaceutical & Biomedical Services Centre and to re-look at current supply chain system in view of costs and efficiencies.

This was followed by a review of current laboratory charges with the aim of cost-recovery for those that are able to pay or for services purchased by the private sector and paying patients.

Through the technical assistance from WHO Fiji began a draft of its national pathology laboratory policy with a strategic plan for the next 5 years to follow. This activity is intended to be completed by the end of this year.

Additionally we looked at the recommendation of a review made in 2006 as part of the Fiji Health Sector Improvement Program supported by AusAID for possible options for a laboratory information system for Fiji.
I am pleased to share that AusAID has now approved the funding of this new system for Fiji and this is to start operational at the Colonial War Memorial Hospital hopefully before the year ends as well.

Following the recent work of Dr Peter Flett the Ministry will now implement the establishment of the positions for a National Quality Manager and 3 divisional Quality Assurance officers. This will be followed by the establishment of a National Laboratory Services Advisor.

As alluded to earlier the momentum is on and I urge you all to make the best of these opportunities now to improve your laboratory systems as we owe it to our people to have the best quality laboratory service.

The Fiji Ministry of Health is cognizant of some of the regional role of some of its lab particularly for Mataika House and currently we are looking at its clear role delineation and resourcing.

As countries with limited resources we have to be realistic to our capabilities and what is affordable and so regional and laboratory networks must be harnessed and supported.

Recently we have worked on revitalizing linkages with laboratory networks in New Zealand and Australia for short-term training attachments of our human resources and also in ensuring a robust quality assurance system.

On behalf of our government we want to assure you as fellow Pacific Island nations that we will remain committed and open to regional initiatives and support.
I am sure that there are many good lessons and initiatives that you have made in your individual countries which you will share during this workshop so that we can learn from each other and grow.

There is no need to re-invent the wheel and we will be happy to share more of the lessons we have learnt with you.

I wish to conclude by wishing you all a productive and successful workshop.

Vinaka vakalevu and May God Bless You All.
ASIA PACIFIC STRATEGY FOR STRENGTHENING HEALTH LABORATORY SERVICES (2010–2015)

The Regional Committee,

Recognizing that strong health systems are the foundation that underpins the ability of all health programmes to deliver better results and that laboratory services are a critical component of health systems;

Reaffirming that primary health care, including the values of equity and universal access, forms the guiding principle for efforts to strengthen health systems;

Recalling resolution WPR/RC59.R4 on Health Systems Strengthening and Primary Health Care which noted the Strategic Plan for Strengthening Health Systems in the Western Pacific Region as an appropriate and useful framework to guide work in the Region on health systems strengthening, including work in laboratories;

Recognizing that the strengthening of laboratory services is an important component of both the Asia Pacific Strategy for Emerging Diseases (APSED) and the International Health Regulations (2005);

Acknowledging the need to enhance access and strengthen the local and national capacity of each country in the areas of quality, safety and bench techniques, and to provide accurate, timely and reliable services for diagnosis, treatment and monitoring, whether in public health or clinical services;
Recognizing also the need to further strengthen intercountry, interregional and global collaboration in strengthening health laboratory networks,

1. **ENDORSES** the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015);

2. **URGES** Member States:
   
   (1) to use the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) as a strategic framework to guide the development of coherent national frameworks for health laboratory services;

   (2) to provide adequate human, material and financial resources to strengthen local and national capacities for the implementation of national plans or equivalents;

   (3) to provide adequate and rational funding support to laboratories and to ensure that the financing plan for laboratory services is part of the country’s overall health budget;

   (4) to establish country-specific minimum standards for health laboratories at different levels and, where appropriate, a national body for accreditation of laboratories;

   (5) to develop appropriate infrastructure for biosafety and biosecurity;

   (6) to further strengthen and contribute to intercountry, interregional and multisectoral collaboration by actively participating in regional and subregional networks;

3. **REQUESTS** the Regional Director:

   (1) to use the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) as a strategic framework to guide support from WHO to Member States in the Region;

   …/
(2) to develop a regional workplan to further implement the Strategy, building on needs and priorities identified by capacity assessments and providing appropriate linkages with the laboratory components of related strategies and programmes;

(3) to provide coordinated technical assistance to Member States in strengthening health laboratory services based on primary health care principles;

(4) to assist Member States to develop minimum standards at different levels of health laboratories for undertaking essential tests, which should include human resources, infrastructure, equipment, reagents, technology, quality systems and referral mechanisms;

(5) to assist Member States in mobilizing resources from international developmental partners for strengthening of sustainable health laboratory services, where appropriate;

(6) to strengthen intercountry, interregional and multisectoral networks and to establish effective collaboration mechanisms;

(7) to develop tools and indicators for monitoring and evaluating implementation of the Strategy.