Meeting Report

Pacific Malaria Drug Resistance Monitoring Network

Manila, Philippines
08–09 August 2011
Participants of the Pacific Malaria Drug Resistance Monitoring Network
08–09 August 2011, Manila, Philippines
REPORT

PACIFIC MALARIA DRUG RESISTANCE MONITORING NETWORK MEETING

Convened by:
WORLD HEALTH ORGANIZATION
Western Pacific Region

Manila, Philippines
8-9 August 2011
NOTE

The views expressed in this report are those of the participants in the Pacific Malaria Drug Resistance Monitoring Network Meeting and do not necessarily reflect the policies of the Organization.

This report has been printed by the World Health Organization Western Pacific Region for governments of Members States in the Region and for those who participated in the Pacific Malaria Drug Resistance Monitoring Network Meeting, held in Manila, Philippines from 8 to 9 August 2011.
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Keywords:
Malaria - prevention and control / Drug Resistance / Antimalarials - therapeutic use
The Pacific Malaria Drug Resistance Monitoring Network, aimed at strengthening antimalarial drug efficacy monitoring in the Pacific, was launched at an intercountry meeting held in Manila, Philippines from 8 to 9 August 2011. The meeting was attended by two temporary advisers, three observers, 16 WHO secretariat staff and 13 participants from six countries: Indonesia, Malaysia; Papua New Guinea, the Philippines, Solomon Islands and Vanuatu.

The objectives of the meeting were:

1. to review countries’ national malaria treatment policies and antimalarial drug efficacy, and data and monitoring systems and identify key issues and gaps;
2. to review and develop country plans for antimalarial drug efficacy monitoring for the next two years; and
3. to discuss terms of reference and partner cooperation within the proposed Pacific Malaria Drug Resistance Monitoring Network, including resource mobilization and linkages with other existing networks.

The meeting included country presentations, technical presentations by the participants and WHO staff, and group discussions. The participants noted that, while countries have performed well in reducing malaria cases, constraints still exist and there are several aspects which require attention. Some of these aspects are local capacity-building, standardization of therapeutic efficacy studies, improved information sharing, and harmonization of treatment policies across countries. After discussing the varying challenges and the gaps they would like to be addressed, all countries present concurred that there was a need for a regionwide monitoring network to support their efforts. A working group was formed to draft the terms of reference and recommendations for the proposed Pacific Malaria Drug Resistance Monitoring Network. These terms of reference and recommendations were then discussed in plenary session and modified.

The agreed terms of reference for the Pacific Malaria Drug Resistance Monitoring Network are:

1. to support countries (programmes and research institutions) to implement the WHO standard protocol for routine monitoring of antimalarial therapeutic efficacy of the first and second line treatments for *Plasmodium falciparum* and *Plasmodium vivax*;
2. to identify training needs and coordinate capacity-building for high quality drug resistance surveillance;
3. to coordinate laboratory support to countries and facilitate the use of WHO recommended standard procedures, and contribute to the development of new procedures where they are not available;
4. to coordinate independent monitoring and review of therapeutic efficacy study (TES) data;
5. to facilitate the timely reporting and sharing of TES results;
6. to coordinate network activities and facilitate collaboration through regional informal consultations, regional planning, resource mobilization and review of progress;
(7) to support countries in reviewing national malaria treatment policies (if requested); and

(8) to facilitate operational research and address knowledge gaps related to antimalarial drug resistance monitoring.

The following were the recommendations of the meeting:

(1) With antimalarial drug resistance being a major threat in the Region, antimalarial drug resistance monitoring efforts led by country programmes need to be strengthened, intensified and properly coordinated.

(2) The Pacific Malaria Drug Resistance Monitoring Network should be established and coordinated by WHO (with a full-time Secretariat).

(3) WHO and partners should immediately start mobilizing adequate resources for establishment of the Secretariat and its core activities.

(4) The draft for a two-year national drug efficacy monitoring plans should be finalized and endorsed by each country by the end of 2011.

(5) Countries should follow the latest WHO protocol for the antimalarial drug efficacy monitoring.

(6) Countries should identify their capacity-building and technical assistance needs and seek assistance from the network partners.

(7) Country data should be regularly reviewed (including for Day 3 positivity as an early warning sign for emerging artemisinin resistance) and shared within the network.

(8) The network should convene a TES workshop for all Pacific country focal points and principal investigators within one year of its inception, and hold a full network meeting every two years, to review progress and support high-quality TES implementation.
1. INTRODUCTION

Antimalarial drug resistance is a major public health problem hindering the control of malaria globally. The rapid spread of resistance to antimalarial drugs during the past few decades calls for intensified efficacy monitoring. The intensified action will ensure proper management of clinical cases and early detection of changing patterns of resistance in order to update and revise national malaria treatment policies. Surveillance of therapeutic efficacy over time is an essential component of a malaria programme. It is a key strategy to detect, monitor and prevent the spread of antimicrobial resistance.

All Pacific malaria-endemic countries are monitoring antimalarial drug efficacy, but there is a need to: (1) strengthen planning and implementation; (2) update country programmes on new monitoring procedures; and (3) ensure sharing of information and effective coordination of efforts, as it is being done in the Mekong malaria-endemic countries. The threat of emerging artemisinin resistance in neighbouring countries calls for immediate action to step up malaria drug resistance monitoring efforts in the Pacific.

The intercountry meeting in Manila, Philippines, aimed to strengthen antimalarial drug efficacy monitoring in the Pacific through the launch of the Pacific Malaria Drug Resistance Monitoring Network. The meeting brought together national malaria programme managers and focal persons on malaria treatment from six countries: Indonesia, Malaysia; Papua New Guinea, the Philippines, Solomon Islands and Vanuatu. It also brought together other stakeholders, partners and technical experts to explore collaboration and define the way forward. Timor Leste was invited but could not attend. The WHO Regional Office for the Western Pacific, in collaboration with the WHO Regional Office for South-East Asia, and its partners organized the meeting. The meeting took place from 8 to 9 August 2011 in Manila, Philippines (for programme and list of participants, see Annexes 1 and 2).

1.1 Objectives:

(1) to review national malaria treatment policies and antimalarial drug efficacy data, country monitoring systems and identify key issues and gaps;

(2) to review and develop country plans for antimalarial drug efficacy monitoring for the next two years; and

(3) to discuss terms of reference and partner cooperation within the proposed Pacific Malaria Drug Resistance Monitoring Network, including resource mobilization and linkages with other existing networks.

1.2 Welcome remarks

Dr Eva Maria Christophel, Team Leader, Malaria, other Vectorborne and Parasitic Diseases, WHO Regional Office for the Western Pacific, welcomed all attendants to the meeting and expressed her enthusiasm for the opportunity for the six countries from the Western Pacific and the South-East Asia Regions to come together and discuss the monitoring situations prevailing in each country and the possibility of establishing a Pacific drug resistance network.

1.3 Opening remarks

In his opening address, Dr Shin Young-soo, WHO Regional Director for the Western Pacific, remarked on the tremendous and sustained progress made in malaria control and elimination among the Western Pacific countries. Nine of the ten countries have pledged to eliminate malaria. Yet, the Western Pacific has been the epicentre of malaria drug resistance since the 1960s, and the emergence of artemisinin resistance could jeopardize the progress made.
A malaria monitoring network that builds on the example of the Mekong network is needed. The network would assist member countries in planning and implementing high-quality efficacy studies. The main focus would be on training and capacity-building for national staff. It would also provide assistance on data analysis and interpretation, and assist countries in reviewing and updating their national treatment policies. While WHO is strongly committed to establishing this network, this also requires strong political commitment from Member States, high-quality technical expertise from technical partners and adequate financial resources from donors. This network will have a positive impact on achieving the malaria-related targets in the Millennium Development Goals and those set in the Regional Action Plan for Malaria Control and Elimination in the Western Pacific (2010-2015).

1.4 Appointment of chairperson, vice-chairperson and rapporteur

Dr Shin Young-Soo called for the nomination of chairperson, vice-chairperson and rapporteur. Dr Mario Baquilod, Medical Officer, National Center for Disease Prevention and Control, Department of Health, Philippines, was nominated as chairperson. Dr Tenneth Dalipanda, Director of Public Health, Ministry of Health and Medical Services, Solomon Islands, was nominated as vice-chairperson, and Dr Christina Rundi, Senior Principal Assistant Director, Disease Control Division, Ministry of Health, Malaysia, was nominated as rapporteur.

2. PROCEEDINGS

2.1 Technical Session 1: Role of antimalarial drug efficacy monitoring

2.1.1 Resistance of *Plasmodium falciparum* and *Plasmodium vivax* malaria parasites to antimalarial medicines: a global overview (including the role of networks)

Ms Amy Barrette, Technical Officer, Global Malaria Programme, WHO, gave an overview of drug resistance and treatment failures and reviewed tools used for monitoring drug efficacy and resistance, including the 2009 WHO standardized protocol. Ms Barrette also discussed the evolution of the protocol and how its use in countries over the years has led to changes in malaria treatment policy. The types of support provided by WHO were also outlined. WHO provides technical support for data analysis, monitoring, report writing and publishing, and financial support for medicine procurement and quality control.

Ms Barrette also described the WHO database and gave examples of how data from the drug resistance database could be presented. The data in the database is compiled from three main sources: published journal articles; reports by ministries of health, national malaria control programmes and research institutions; and raw data from surveillance studies.

Ms Barrette summarized the benefits of regional and sub-regional networks in monitoring and controlling drug resistance. The networks can facilitate the implementation of the WHO protocol and standard operating procedures (SOPs), exchange of information and experiences, and help to inform treatment policy change.

2.1.2 Overview of malaria situation and drug resistance in the Western Pacific Region and meeting objectives

Dr Eva Maria Christophel, Team Leader, Malaria other Vectorborne and Parasitic Diseases, WHO Regional Office for the Western Pacific, presented an overview of antimicrobial drug resistance, why it is a major concern, and expressed the urgency of
implementing the six-point policy package to combat drug resistance in all member countries. The policy package urges the participating countries, partners and donors to:

(1) commit to a comprehensive, financed national plan with accountability and civil society engagement;

(2) strengthen surveillance and laboratory capacity;

(3) ensure uninterrupted access to quality essential medicines;

(4) regulate and promote national use of medicines, including in animal husbandry, and ensure proper patient care;

(5) enhance infection prevention and control; and

(6) foster innovations and research and development of new tools.

She then gave an overview on the malaria situation in the Western Pacific countries and remarked that, although malaria transmission and incidence rates are decreasing trend, they are still too high in several Pacific countries and represent a major health problem. She went on to review the drug resistance situation and national drug policy in the Region, and the emergence of artemisinin resistance in Cambodia.

2.1.3 Antimalarial drug resistance in the South-East Asian Region

Dr Md Mushfiqur Rahman, Malaria Unit, WHO Regional Office for South-East Asia, presented an overview of the situation of antimalarial drug resistance in the South-East Asia Region. He mentioned antimalarial drug resistance as a major public health problem as evidenced by Plasmodium falciparum (Pf) resistance to chloroquine and sulfadoxine-pyrimethamine (CQ and SP). Plasmodium vivax (Pv) also showed resistance to chloroquine in Indonesia. He discussed the serious issue of emerging resistance of Pf against artemisinin at the Thailand-Cambodia border and potential spread of the same and vulnerability in Myanmar, Bangladesh and some northeastern states of India. Dr Rahman presented in detail the country-specific drug resistance status and concluded his presentation with an overview of the current drug policy per country in the Region which has been updated/changed based on the results of the therapeutic efficacy studies (TES) in South-East Asian countries such as: Bangladesh, Bhutan, India, Indonesia, Nepal, Sri Lanka, Timor Leste, and the Democratic People’s Republic of Korea.

2.1.4 Lessons learnt from the Greater Mekong Subregion: antimalarial drug resistance, artemisinin resistance and containment, the role of the Mekong Malaria Programme network

Dr Charles Delacollette, Coordinator, WHO Mekong Malaria Programme, WHO Regional Office for South-East Asia, presented lessons learnt from the Greater Mekong Subregion. He focused on the need for programme managers and researchers to agree on the use of standardized study protocols across study sites and countries in order to compare outcomes, map results and take appropriate actions. There is still some disconnect among individual researchers and institutions, which may make results difficult to analyze and interpret. Dr Delacollette noted that having a good monitoring and surveillance system goes hand in hand with a response system, and there is a need to turn research into policy change by increasing connection between researchers and programme managers.

He emphasized that because malaria cases and artemisinin resistance are concentrated in border areas, the regional network plays an important role in the monitoring and surveillance of artemisinin resistance across countries. This enables a better coordinated effort
to elaborate common strategies to contain and combat artemisinin resistance. Finally, he summarized the role of the drug resistance monitoring network to contribute to the following activities: (a) agree on the use of standardized tools; (b) increase the capacity of investigators to perform quality studies; (c) exchange data and information; (d) strengthen good practices; and (e) provide incontrovertible evidence for action.

Successful networking models such as the Mekong in vivo TES model help to attract donors’ interest and additional funding to develop and support multipartners’ supranational interventions, for example the bi-country/bi-regional artemisinin resistance containment project along the Cambodia-Thailand border.

2.1.5 Containment of artemisinin resistance on the Cambodia-Thailand border

Dr Najibullah Habib, Technical Officer, Malaria, other Vectorborne and Parasitic Diseases, WHO Cambodia, made a presentation on the artemisinin resistance containment project on the Cambodia-Thailand border, of which he is the manager. The containment project is a multi-pronged emergency intervention to eliminate falciparum malaria in target areas. A map of the malaria containment zones was presented. Zone 1, where artemisinin resistance is confirmed, is targeted for malaria elimination, and Zone 2 is targeted for intense malaria control. Both zones are located mainly along the Cambodia-Thailand border. The targeted population in 10 provinces in Cambodia and seven provinces in Thailand consists of over five million people. Dr Habib described the seven pillars of the containment strategies:

1. to eliminate resistant parasites by detecting all malaria cases in target areas and effective treatment and gametocyte clearance;
2. to decrease drug pressure for selection of artemisinin-resistant malaria parasites;
3. to prevent transmission of resistant parasites by mosquito control and personal protection;
4. to limit the spread of resistant parasites by mobile/migrant populations;
5. to support containment/elimination of resistant parasites through behaviour change communication, and advocacy;
6. to undertake basic and operational research to fill knowledge gaps and ensure evidence-based strategies; and
7. to provide effective management and coordination for rapid and high quality implementation.

The containment project involves multiple avenues and approaches. It engages village malaria workers (VMW) who are able to diagnose malaria with the help of rapid diagnostic tests (RDTs) and treat with artemisinin-based combination therapy (ACT) malaria cases in the community; the anti-economic crime police, appointed to inspect drug outlets for artemisinin monotherapies and fake and substandard drugs; and taxi drivers who can reach out to migrant populations. Dr Habib also demonstrated Thailand’s malaria information system or BIOPHICS. This system consists of: real-time mapping, case tracking and follow-up, SMS reporting, monitoring situations and trends, and summary reporting, among others. Finally, a summary of the lessons learned from this project was presented. Overall, the containment project is having a positive impact; its flexibility and responsiveness are appreciated by partners, and good collaboration along with strong management helps in the effective implementation of containment efforts. The project demonstrated the important role of
monitoring resistance in detecting artemisinin resistance, and the experience is extremely useful for the countries in the WHO Western Pacific Region.

2.1.6 Wrap-up

Dr Qin Cheng of the Australian Army Malaria Institute commented on the speakers’ review of the situation of malaria drug resistance, and highlighted the importance of drug resistance monitoring as well as the effectiveness of a monitoring network. Overall, the malaria incidence rate is on a decreasing trend, yet malaria is still a major health problem in the Western Pacific countries. With drug resistance becoming widespread, ACTs were introduced to all countries over the past five years. As ACTs are the cornerstone of malaria programmes, resistance to ACT poses a threat to all recent gains. Therefore, countries must continue their drug resistance monitoring efforts, and a network will give the countries a greater chance of succeeding in the fight against drug resistance. The benefits and role of the network are summarized below.

Benefits of a regional drug resistance monitoring network:

- standardized study design, protocols, methods, SOPs;
- availability of comparable data;
- sharing and exchange of information and experiences;
- better control of border malaria;
- coordinated efforts and policy changes;
- better country support and capacity-building;
- sharing human resources, connecting research and operational teams; and
- liaising with donors and seeking funds with one voice.

Role of a regional drug resistance monitoring network:

- to identify problems and prioritize activities;
- to bridge different WHO Regions;
- to standardize study design, protocols, methods and SOPs;
- to share and exchange information, experience and human resources
- to coordinate efforts and policy changes;
- to connect research and operational teams;
- to liaise with donors and seek funds; and
- to document good practice and coordinate publications.
2.2 Technical Session 2: Country updates on the malaria situation, treatment policy, drug resistance situation and monitoring

2.2.1 Philippines

Dr Mario Baquilod, Medical Officer, National Center for Disease Prevention and Control, Department of Health, Philippines, presented drug resistance monitoring data from the Philippines. The Philippines has moved into micro-stratification of the endemic areas to better target control interventions (to village level). Dr Baquilod also presented graphs depicting the decrease of malaria morbidity and mortality over the past ten years. Therapeutic efficacy studies (TES) were regularly performed in the Philippines until 2009, showing more than 95% efficacy of artemether-lumefantrine (AL) and chloroquine (CQ).

2.2.2 Malaysia

Dr Christina Rundi, Senior Principal Assistant Director, Disease Control Division, Ministry of Health, Malaysia, described the national strategic plan for malaria elimination. The plan consists of seven elements:

(1) surveillance system;
(2) integrated vector management;
(3) early detection and prompt treatment;
(4) preparedness and outbreak response;
(5) communication and social mobilization;
(6) capacity-building; and
(7) operational research.

At present, Malaysia has moved into micro-stratification of the endemic areas. The national antibiotic guideline and the national guideline on the management of malaria were also discussed. Dr Rundi informed that the national guideline on the management of malaria is currently under revision.

The national antimalaria drug response surveillance programme began in 2003 in eighteen sentinel sites in the country. As of 2006, there was some evidence of treatment failure with chloroquine and sulphadoxine-pyrimethamine. However, the programme is also currently under review as the number of falciparum malaria cases is on the decline, and there is the need to include other antimalarial drugs.

2.2.3 Papua New Guinea

Dr Inoni Betuela, Head of Vectorborne Disease Unit, Papua New Guinea Institute of Medical Research (PNG-IMR), presented the data on the current situation in Papua New Guinea. Papua New Guinea is endemic to all four human malaria species and remains a high-burden country, with a higher prevalence in those older than 15 years old. The data show the *P. vivax* peaks in age groups less than four years. Although bed net/long-lasting insecticidal net (LLIN) coverage is more than 50% at household and village levels, surveys have shown less than 40% bed net use among the high-risk groups of pregnant women and children under five. There is less than 20% availability of diagnostic services and drugs in health facilities. Baseline TES of artemisinin-based combination therapies (ACTs) in 2005–2007 by PNG-IMR showed high efficacy: 90% of artesunate-sulphadoxine-pyrimethamine (ASU-SP), as well as dihydroartemisinin-piperaquine (DHA-PIP), and 95% of artemether-lumefantrine (AL). A concern for the country is the wide availability of antimalarial monotherapies (CQ, SP and artemisinins).
2.2.4 Solomon Islands

Dr Lyndes Wini, Medical Officer, Malaria and other Vectorborne Diseases Control Program, Ministry of Health, Solomon Islands, presented on the malaria situation in Solomon Islands, their current treatment policy and drug resistance situation. Over the past ten years, confirmed malaria cases have decreased. In the provinces, there have been decreased incidence rates from 2009–2011, and Isabel and Temotu provinces are now targeted for malaria elimination. Currently, all health facilities have ACT supplies and are provided with treatment guidelines. With CQ and SP still widely available, there is still a high proportion of presumptive treatments in the private sector, including among pregnant women.

TES has been performed since 1994 and continues to the present. In 2008–2009, an AL efficacy study was conducted in Malaita province, demonstrating 100% and 96% adequate clinical and parasitological response (ACPR) in \textit{P. falciparum} and \textit{P. vivax}, respectively.

There are still major challenges faced by Solomon Islands. Due to diverse malaria profiles, remoteness and scattered populations, malaria stratification has yet to be performed. Laboratory diagnosis is limited to only 58% of health facilities, and there is a low uptake of RDTs, which may be due to the historical use of microscopy as a way of diagnosis since people are not yet used to RDTs. Also, regular drug resistance monitoring has yet to be institutionalized.

2.2.5 Vanuatu

Dr Edward Tambisari, Malaria Case Management Officer, Malaria Unit, Department of Health, Vanuatu, presented on Vanuatu’s current malaria situation, treatment policy and drug resistance and monitoring. According to the World Malaria Report 2010, the annual parasite incidence (API) in Vanuatu ranges from 10–50 cases per 1000 population across its islands. Overall, confirmed cases within the past ten years have decreased and API among the six provinces have also decreased between 2005–2010. For treatment policy, the first line treatment for falciparum and vivax malaria has changed from CQ+ SP to AL. Also, since the introduction of RDTs from hospital to community level, diagnostic coverage has increased to greater than 90% as of May 2011. TES has been performed since 2001. Vanuatu is showing an increasing proportion of vivax cases in recent years. CQ+ SP was still effective (95% ACPR in 2005) when the country shifted to AL in 2007. There is an on-going \textit{P. falciparum} and \textit{P. vivax} therapeutic efficacy study in progress that started in March 2011, with four \textit{P. falciparum} and 34 \textit{P. vivax} cases enrolled so far.

2.2.6 Indonesia

Dr Worowijat, National Malaria Control Programme, Ministry of Health, Indonesia, discussed the malaria epidemiological profile of Indonesia. Malaria is the sixth leading causes of mortality by communicable diseases among all age groups (based on basic health research in 2007). There are a number of areas throughout Indonesia which have CQ or multidrug resistant malaria. A 2010 study showed that DHA-PIP was safe and effective for \textit{P. falciparum} and \textit{P. vivax}, with adequate clinical and parasitological responses (ACPR) of 100% and 97.6% respectively.

To combat malaria, Indonesia’s national malaria elimination strategy has four objectives:

1. to decrease villages with five or more per 1000 population malaria incidence rate by 50%;
2. to ensure all districts and cities are able to conduct confirmation of suspected malaria cases and treat 100% of these cases with ACT;
3. to ensure all endemic areas intensify and integrate malaria control; and
To begin step-wise elimination of malaria by islands.

To combat and eliminate malaria, Indonesia has adopted an approach to guarantee that diagnosis is confirmed by either microscopy or RDT; ACTs are prescribed; bednets and indoor residual spraying (IRS) are used for prevention; and intersectoral collaboration and community participation are recognized as necessary.

2.2.7 Wrap-up

Dr Dorina Bustos noted that most countries have moved to ACTs and are using parasite-based diagnosis, either microscopy or RDTs. It is noteworthy that Solomon Islands and Vanuatu have successfully rolled out ACTs and RDTs in the last two years with Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) support, and are now showing significant decreases in the morbidity and mortality rates. In general, country updates showed that there is a significant variation among countries that conduct TES: different protocols, different reporting systems, and different capacities. The disparity calls for harmonization.

2.3 Technical Session 3: Update on technical issues to strengthen drug resistance monitoring

2.3.1 Update on methods for antimalarial drug resistance monitoring and use of the WHO standard protocol

Dr Lasse Vestergaard, Medical Officer, Malaria, other Vectorborne and Parasitic Diseases, WHO Country Office in Vanuatu, made a presentation on the methods for drug resistance monitoring and the WHO standard protocol. Because many factors affect antimalarial treatment efficacy, standardization of methods and outcome classification are critical. Therapeutic efficacy studies are the most important to guide national treatment policy. In order to obtain high-quality results, quality assurance of procedures, continuous training and capacity-building are critical. The WHO protocol for assessment of therapeutic efficacy is the gold standard for treatment policy change. Dr Vestergaard then reviewed the definitions of different test outcomes based on clinical and parasitological criteria. He also mentioned parasite genotyping, mandatory with the 2009 protocol, to ensure correct interpretation of therapeutic efficacy results. Lastly, he acknowledged that in many countries, monitoring is already in place. The network would provide better coordination and standardization of work which are already in progress.

2.3.2 Practical issues of using the WHO standard protocol

Dr Dorina Bustos, Technical Officer, WHO Mekong Malaria Programme, WHO Regional Office for South-East Asia, examined the practical implications of adherence to the TES protocol. She discussed the WHO Ethics Review Committee (ERC) requirements in the submission of a protocol. A full protocol, signed by the principal investigator and endorsed by the Ministry of Health or director of the institute, an informed consent form in English and the local language, clearance from the national ethics committee, and annexes are required for submission of a protocol. She also spoke about the various sections of a study protocol, and considerations for each section, including challenges of selecting appropriate sentinel sites and achieving adequate sample size in low-transmission settings. Adherence to standard laboratory practices was also mentioned. Technical and administrative constraints such as data management, technical report writing, and re-training of TES field implementers and microscopists are required to ensure good clinical practices.

Dr Bustos also reviewed important lessons learnt from performing TES in Mekong countries and made seven recommendations:

(1) TES staff of the national programmes should be trained in quality control procedures in general.
(2) Mid-level management skills of the TES leader:

- a wide supervisory role
- the ability to take stock of project logistics, manpower needs; and
- familiarity with timelines, procedures and requirements of overall implementation

(3) Timely data analysis should be ensured.

(4) Coordination/meetings with border provinces/countries should be conducted regularly.

(5) Cross-country monitoring by principal investigators should include careful observation and learning of best practices.

(6) Countries should have a core of “qualified microscopists” (WHO certified) assigned to the sentinel sites who periodically undergo proficiency assessment and re-training to ensure quality assurance in malaria diagnosis and parasite counting.

(7) Study drugs that have undergone quality control in an external laboratory should be available for TES.

2.3.3 Use of laboratory methods to monitor antimalarial drug resistance

Dr Qin Cheng of the Australian Army Malaria Institute provided a comprehensive review of the tools used to monitor antimalarial drug resistance from the perspective of the laboratory including TES, in vitro susceptibility testing, molecular markers and measurement of blood drug concentrations. It was acknowledged that for all tools, the methods are often more developed for *P. falciparum* than *P. vivax*. Dr Cheng gave an update on the genotyping methods for both *P. falciparum* and *P. vivax* used to support TES, and also asked participants to consider how to classify patients who are found to be positive by PCR but negative by microscopy during TES. *In vitro* tools remain imperfect, due to the wide variation in use of methods, and the lack of standardized thresholds. Since many of the molecular markers are only available for a limited number of drugs (e.g. molecular markers for artemisinin resistance are still unknown), molecular makers are currently useful for monitoring the spread of resistance for only some companion drugs of ACTs. Importantly, samples should be saved for future analysis, when molecular markers become available.

2.3.4 Health research involving human subjects: ethical considerations and procedures to follow

Dr Jun Nakagawa, Technical Officer, Malaria, other Vectorborne and Parasitic Diseases, WHO Regional Office for the Western Pacific, presented an overview of the current research protocol and the ethical considerations when conducting research involving humans. Researchers conducting TES in the Pacific need to be cognizant of ethical considerations and procedures because therapeutic efficacy studies involve human subjects; hence, the need for an ethical review of protocols. Background information on why ethical reviews are conducted and guidelines and best practices concerning human subjects were reviewed. The function and structure of the ethics review committee (ERC) of the WHO Regional Office for the Western Pacific was also discussed. Dr Nakagawa explained the process of submitting a protocol and the required documents for submission to the ERC of the Regional Office. He concluded with proposals on how to improve protocols for submission and the submission process itself.
2.3.5 Wrap-up

Therapeutic efficacy studies remain the gold standard which guides national treatment policy change. Other tools (e.g. molecular markers, \textit{in vitro} and pharmacokinetic studies) exist to help detect and confirm drug resistance. Adherence to good clinical practices, standardized methods, and quality assurance of laboratory methods are critical for the early detection of antimalarial drug resistance.

2.4 Group work: development of Pacific malaria drug resistance monitoring plan

The tasks of the groups were to formulate a two-year national therapeutic efficacy study plan for each country, identify the role of partners and envisage the role of a proposed Pacific malaria drug resistance monitoring network.

Participants were divided into two groups:

- **Group 1**: Papua New Guinea, Solomon Islands and Vanuatu, facilitated by Dr Lasse Vestergaard
- **Group 2**: Indonesia, Malaysia, Philippines, and (on behalf of WHO Regional Office for South-East Asia), facilitated by Dr Dorina Bustos.

2.4.1 Presentation of group work

Each country presented its current and future TES plans, the required inputs for TES plans, such as human resources, technical assistance and capacity-building, and gaps that need to be filled in order to improve its programme along with WHO’s or other partners’ role in filling these gaps.

The results of the group work are presented in Annexes 3 to 5.

2.4.2 Wrap-up

Dr Inoni Betuela, Head of Vectorborne Disease Unit, Papua New Guinea Institute of Medical Research (PNG-IMR), summarized the TES that the countries have worked on. Dr Betuela noted that due to the different needs and stages of ACT, member countries need to take country-specific approaches, with the help of WHO. Also, funding for new clinical trials and the sustainability of the existing or established trials is a major issue as many countries are dependent on donor funding. Lastly, he commended WHO for the standardizing the TES protocol and expressed that it is now up to countries to follow and implement.

2.5 Consensus on the need for a Pacific malaria drug resistance monitoring network

Dr Eva Christophel led a discussion on the need for a malaria drug resistance monitoring network in the Pacific and the possible added value of such a network, in addition to what is already being performed at the country level. The discussion included therapeutic efficacy studies and training needs, as well as a possible extension of the network to include China, the Republic of Korea and the Democratic People’s Republic of Korea.

Dr Christophel emphasized that the focus for the Pacific is on producing high-quality and regular therapeutic efficacy studies. Possible and current partners for technical support were mentioned for different areas of need, such as training, clinical monitoring and laboratory support. The question of one designated network laboratory was broached since there are multiple partners supporting this need but with varying methodologies. Working together to harmonize and standardize protocols is therefore a necessary step.
A consensus was reached on the establishment of a Pacific malaria drug resistance monitoring network, comprising of seven countries: Indonesia, Malaysia, Papua New Guinea, the Philippines, Solomon Islands, Timor Leste and Vanuatu. It was also decided that the group would ask China, the Republic of Korea and the Democratic People’s Republic of Korea whether they would be willing to join the network. The representatives of the Member States present expressed their wish for WHO to lead the network and to establish a full-time Secretariat.

2.6 Technical Session 4: Establishment of the Pacific Malaria Drug Resistance Monitoring Network

2.6.1 Proposed terms of reference, members, partners, coordination and communication mechanisms

Dr Lasse Vestergaard presented a draft of the goals, objectives, functions and outputs of the proposed Pacific Malaria Drug Resistance Monitoring Network.

The proposed goals are:

(1) to provide the best evidence for treatment policy; and

(2) to allow early detection of any emerging artemisinin resistance in the countries.

The proposed objectives of the network are:

(1) to support member countries towards the implementation of routine monitoring of antimalarial therapeutic efficacy studies of first and second line treatments;

(2) to support countries in the collection and management of antimalarial drug efficacy data, review of data and reporting, maintenance of the national and Pacific network databases, and mapping of drug resistance;

(3) to support countries in reviewing and implementing national malaria treatment policies;

(4) to identify training needs for data collection, data analysis and reporting;

(5) to assist coordination of regional efforts in support of antimalarial drug efficacy monitoring in Pacific countries, such as: establishing linkages with other similar networks; convening meetings to review progress made; assisting in planning, budgeting and coordination of future antimalarial drug efficacy monitoring activities, including review of sentinel sites; establishing a network of reference laboratories; and

(6) to provide additional support as relevant regarding malaria treatment, including improving access to appropriate and good quality antimalarials (i.e. ACTs), improving parasite-based diagnosis, improving prescribing and rational use of antimalarials, and enforcing regulations and legislation (e.g. against the use of artemisinin monotherapies).
The functions of the network include:

1. setting up an office with a full-time or part-time coordinator (WHO staff member) to provide technical support and day-to-day running of network activities including reporting;

2. organizing network meetings every two years for network countries to present results and discuss any technical or operational issues, and facilitating intercountry communication and collaboration;

3. organizing relevant training seminars and technical workshops;

4. supporting countries in developing and updating their national TES plans and budgets;

5. supporting countries in TES protocol development and facilitation of ethics reviews;

6. facilitating coordination of country support from reference laboratories;

7. providing clinical monitoring visits and other technical support to ongoing studies, and assist in analysis and reporting of results to Ministries of Health and regional databases;

8. assisting countries in reviewing and updating national malaria treatment policies;

9. facilitating information sharing within the network, e.g. through a dedicated website;

10. assisting in resource mobilization, e.g. contributing to writing funding proposals;

11. assisting in advocacy, awareness raising, and political support; and

12. linking the Pacific region to other regions and networks, and ensuring rapid exchange of relevant news and lessons learned.

The outputs of the network would be:

1. availability of high-quality antimalarial drug efficacy data through harmonization of procedures between network countries;

2. relevant technical assistance for standardized TES implementation at country level and data management;

3. organization of reference laboratory support;

4. timely reviews of efficacy results to inform national treatment policies;

5. effective information sharing between countries to alert them of the need to revise TES plans in the case of signs of emerging artemisinin resistance;

6. effective QA systems in place at all levels;

7. continuous training and capacity-building of national staff; and
mobilized resources.

These proposed terms of reference were broad and many were interlinked. A plenary discussion followed on needs and priority actions. The finalization of the TOR and the recommendations were referred to a working group (see 2.7.2).

2.7 Training session and group work

2.7.1 Training on data entry and analysis

Dr Dorina Bustos presented during a training session an excel file which is currently being used for inputting malaria TES case data. This file can be adapted to each country in order to simplify and standardize data collection and analysis.

2.7.2 Group work: Refining terms of reference and recommendation for the Pacific Malaria Drug Resistance Monitoring Network

Dr Christina Rundi, Senior Principal Assistant Director, Disease Control Division, Ministry of Health, Malaysia, presented the outcome of the group work on defining the terms of reference for the Pacific Malaria Drug Resistance Monitoring Network, and a consensus was reached in the plenary session (Annex 6).

Goal: To support countries in the Pacific to generate and share up-to-date, high quality evidence on antimalarial drug efficacy to inform malaria policies.

Network objectives:

(1) to support countries (programmes and research institutions) to implement the WHO standard protocol for routine monitoring of antimalarial therapeutic efficacy of first and second line treatments for *P. falciparum* and *P. vivax*;

(2) to identify training needs and coordinate capacity-building for high-quality drug resistance surveillance;

(3) to coordinate laboratory support to countries and facilitate the use of WHO-recommended standard procedures, and contribute to the development of new procedures where they are not available;

(4) to coordinate independent monitoring and review of TES data;

(5) to facilitate the timely reporting and sharing of TES results;

(6) to coordinate network activities and facilitate collaboration through regional informal consultations, regional planning, resource mobilization and review of progress;

(7) to support countries in reviewing national malaria treatment policies (if requested); and

(8) to facilitate operational research to address knowledge gaps related to antimalarial drug resistance monitoring.
3. CONCLUSIONS AND RECOMMENDATIONS

In the plenary discussion, Dr Christophel presented the draft conclusions of the meeting and recommendations. These were discussed and refined by the participants.

3.1 Conclusions

The first half of the meeting focused on reviewing drug resistance data from each country and the issues with drug resistance monitoring. Artemisinin resistance is becoming a palpable threat in the Region. As the threat of resistance grows, there is a call for harmonization of protocols and quality assurance capacity-building across countries for therapeutic efficacy studies. The need for networking and improved coordination between countries, regional research institutions and WHO, was evident.

The overarching objective of the meeting focused on the need and added benefits of a malaria monitoring network for the Pacific. A consensus was reached to create a Pacific Malaria Drug Resistance Monitoring Network. This network will be comprised of five countries in the WHO Western Pacific Region (Malaysia; Papua New Guinea, the Philippines, Solomon Islands and Vanuatu) and two countries in the WHO South-East Asia Region (Indonesia and Timor Leste). Member States wanted WHO to lead this network and establish a full-time secretariat. Terms of reference of the network and recommendations for the network were agreed upon by the meeting participants.

3.2 Recommendations

1. With antimalarial drug resistance being a major threat in the Region, antimalarial drug resistance monitoring efforts led by country programmes should be strengthened, intensified and coordinated.

2. The Pacific Malaria Drug Resistance Monitoring Network should be established and coordinated by WHO (with a full-time Secretariat).

3. WHO and partners should immediately start mobilizing adequate resources for establishment of the Secretariat and core activities.

4. The draft two-year national drug efficacy monitoring plans should be finalized and endorsed by each country by the end of 2011.

5. Countries should follow the latest WHO protocol for the antimalarial drug efficacy monitoring.

6. Countries should identify their capacity-building and technical assistance needs and seek assistance from the network partners.

7. Country data should be regularly reviewed (including for Day 3 positivity as an early warning sign for emerging artemisinin resistance) and shared within the network.

8. The network should convene a TES workshop for all Pacific country focal points and principal investigators within one year, and hold a full network meeting every two years, to review progress and support high-quality TES implementation.
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<tr>
<th>Time</th>
<th>Day 1</th>
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<tr>
<td>8:00</td>
<td><strong>Registration</strong></td>
<td>8:30</td>
<td><strong>Summary of Day 1</strong> by Walter Kazadi-Mulombo, WHO Solomon Islands and Seyha Ros, WHO Vanuatu</td>
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<td>8:30</td>
<td><strong>Opening Ceremony</strong>&lt;br&gt;Opening remarks by the Regional Director WHO WPRO</td>
<td>8:45</td>
<td><strong>Presentation of Group work:</strong>&lt;br&gt;- country work plans for routine efficacy monitoring&lt;br&gt;- role of partners&lt;br&gt;- Pacific network</td>
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<td></td>
<td><strong>Self introduction of participants</strong></td>
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<td><strong>Discussion</strong>&lt;br&gt;Wrap-up &amp; recommendations - Dr Inoni Betuela, IMR/PNG</td>
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<td></td>
<td><strong>Nomination of Chair, Vice Chairs and Rapporteur</strong></td>
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<td><strong>Technical session 4:</strong>&lt;br&gt;Establishment of the Pacific Malaria Drug Resistance Monitoring Network&lt;br&gt;&lt;br&gt;10 minute presentations followed by 5 minutes discussion</td>
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<td></td>
<td><strong>Group photograph</strong></td>
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<td>Proposed Terms of Reference for the Pacific Network, members, partners, coordination and communication mechanisms – Lasse Vestergaard, WHO Vanuatu, Walter Kazadi – Mulombo, WHO Solomon Islands</td>
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<tr>
<td>9:15</td>
<td><strong>Coffee Break</strong></td>
<td>10:30</td>
<td><strong>TA and financial gaps, next steps – Dorina Bustos, WHO MMP</strong>&lt;br&gt;Wrap-up &amp; recommendations – Charles Delacollette, WHO MMP and Amy Barrette, WHO GMP</td>
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<tr>
<td>9:45</td>
<td><strong>Technical session 1:</strong> Role of antimalarial drug efficacy monitoring 10 minute presentations followed by 5 minutes discussion&lt;br&gt;&lt;br&gt;<em>P. falciparum</em> and <em>P. vivax</em> resistance to antimalarial medicines: a global overview (including the role of networks) – Amy Barrette/Pascal Ringwald, WHO GMP/HQ&lt;br&gt;&lt;br&gt;Overview of malaria situation and drug resistance in the Western Pacific Region, and meeting objectives – Eva Christophel, WPRO&lt;br&gt;&lt;br&gt;Antimalarial drug resistance in the SouthEast Asian Region – Mushfiqur Rahman, WHO SEARO&lt;br&gt;&lt;br&gt;Lessons learnt from the Greater Mekong Subregion: antimalarial drug resistance, artemisinin resistance and containment, the role of the Mekong Malaria Programme network – Charles Delacollette, WHO MMP&lt;br&gt;&lt;br&gt;Containment of artemisinin resistance on the Cambodia-Thailand border – Najibullah Habib</td>
<td>11:00</td>
<td><strong>Wrap-up &amp; recommendations – Charles Delacollette, WHO MMP and Amy Barrette, WHO GMP</strong></td>
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<td>10:00</td>
<td><strong>Technical session 4:</strong> Establishment of the Pacific Malaria Drug Resistance Monitoring Network&lt;br&gt;&lt;br&gt;10 minute presentations followed by 5 minutes discussion</td>
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<td>10:15</td>
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<td>Proposed Terms of Reference for the Pacific Network, members, partners, coordination and communication mechanisms – Lasse Vestergaard, WHO Vanuatu, Walter Kazadi – Mulombo, WHO Solomon Islands</td>
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<td><strong>TA and financial gaps, next steps – Dorina Bustos, WHO MMP</strong>&lt;br&gt;Wrap-up &amp; recommendations – Charles Delacollette, WHO MMP and Amy Barrette, WHO GMP</td>
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**Note:**<br>TA = Technical Assistance
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<td>10.4</td>
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<td>5</td>
<td>Discussion Wrap-up &amp; recommendations - Qin Cheng, AAMI</td>
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<td><strong>Technical session 2: Country updates:</strong> Malaria situation, treatment policy, drug resistance situation and monitoring</td>
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<td><em>10 minute presentations followed by 5 minutes discussion</em></td>
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<td>- Philippines, Malaysia</td>
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<td>- Papa New Guinea, Solomon Islands, Vanuatu</td>
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<td>12:30</td>
<td>Lunch</td>
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<td>1:30</td>
<td><strong>Technical session 2: continued</strong></td>
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<td>- East Timor, Indonesia</td>
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<td>2.15</td>
<td>Discussion Wrap-up &amp; recommendations - Dorina Bustos, WHO MMP</td>
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<td>2.30</td>
<td><strong>Technical session 3: Update on technical issues to strengthen drug resistance monitoring</strong></td>
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<td><em>10 minute presentations followed by 5 minutes discussion</em></td>
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<td>Update on methods for antimalarial drug resistance monitoring and use of the WHO standard protocol – Lasse Vestergaard, WHO Vanuatu</td>
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<td></td>
<td>Practical issues of using the WHO standard protocol, including sentinel site selection, frequency of studies, data analysis, monitoring; Challenges and ways forward for anti-malarial drug efficacy monitoring in settings with decreasing malaria transmission – Dorina Bustos, WHO MMP</td>
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<td>Use of laboratory methods to monitor antimalarial drug resistance</td>
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<td>1:30</td>
<td><strong>Training on data entry and analysis</strong> – Dorina Bustos</td>
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<td>3.00</td>
<td>(including molecular markers of resistance, <em>in vitro</em> testing) – Qin Cheng, Australian Army Malaria Institute</td>
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<td>3.15</td>
<td>Health research involving human subjects: ethical considerations and procedures to follow – Jun Nakagawa, WHO WPRO</td>
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<td>3:30</td>
<td>Discussion Wrapping up &amp; recommendations - Amy Barrette, GMP/HQ</td>
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<td>3:45</td>
<td>Afternoon Tea</td>
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<td>4:15</td>
<td><strong>Group work:</strong> Development of a 2-year Pacific Malaria Drug Resistance Monitoring Plan</td>
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<td>Introduction to group work</td>
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<td><strong>Tasks:</strong></td>
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<td>1. 2-year national plans (where, what, who)</td>
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<td>2. role of partners</td>
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<td>3. role of Pacific network</td>
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<td><strong>Groups</strong></td>
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<td>1: Papa New Guinea, Solomon Islands, Vanuatu + partners</td>
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<td>- <em>Facilitator:</em> Dr Lasse Vestergaard</td>
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<td>2. Philippines, Malaysia, Indonesia + partners</td>
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<td>- <em>Facilitator:</em> Dr Dorin Bustos</td>
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<td>4:00</td>
<td><strong>Plenary session:</strong></td>
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<td>Meeting conclusions and recommendations - Eva Christophel, WHO WPRO</td>
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<td>Closing</td>
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<td>5:00</td>
<td>Refreshments hosted by WHO</td>
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<td>5:30</td>
<td>Close for the Day</td>
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E-mail : ross@wpro.who.int
## CURRENT (2010-2011) AND FUTURE (2012-2013) COUNTRY TES PLANS

<table>
<thead>
<tr>
<th>Country</th>
<th>Parasite species</th>
<th>Current sentinel sites 2010-2011</th>
<th>Drugs tested 2010-2011</th>
<th>Current funding available 2010-2011</th>
<th>Proposed sentinel sites for 2012-2013</th>
<th>Drugs to be tested in 2012-2013</th>
<th>Anticipated funding available for 2012-2013</th>
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<tbody>
<tr>
<td>Timor Leste</td>
<td>Pf</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
<td>Suai Vila and Comoro Community Health Centres in Covalima and Dili districts</td>
<td>AL</td>
<td>Funding available from GF (amount not known)</td>
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<tr>
<td></td>
<td>Pv</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
<td>Aileu Vila and Formosa Community Health Centres in Aileu and Dili districts</td>
<td>CQ</td>
<td>Funding available from GF (amount not known)</td>
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<tr>
<td>Malaysia</td>
<td>Pf</td>
<td>Peninsular Malaysia: 8 sites: Gua Musang; Raub; Lipis; Jerantut; Muadzam; Tapah; Gerik; Kemaman Sabah: 4 sites: Telupid; Kota Marudu; Bangi; Pitas Sarawak: 2 sites: Seri Aman; Serian</td>
<td>CQ: Peninsular Malaysia and Sarawak SP: Sabah</td>
<td>Malaysian Government Peninsular Malaysia: 5 sites: Penang; Johor; Selangor; Kelantan; Kedah Sabah: 4 sites: Keningau; Tawau; Kudat; Ranau Sarawak: 2 sites: Sibu ; Miri</td>
<td>Artesunate – mefloquine or AL</td>
<td>Malaysian Government (except for assets)</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Parasite species</td>
<td>Current sentinel sites 2010-2011</td>
<td>Drugs tested 2010-2011</td>
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<tr>
<td>Philippines</td>
<td>Pf</td>
<td>Palawan</td>
<td>AL</td>
<td>GF/RBM project</td>
<td>Luzon (Zambales)</td>
<td>AL, quinine</td>
<td>GF</td>
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<tr>
<td></td>
<td>Pf</td>
<td>Palawan</td>
<td>AL</td>
<td>GF/RBM project</td>
<td>Palawan</td>
<td>AL (2012)</td>
<td>RBM project</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>Pf</td>
<td>2 sites</td>
<td>AL</td>
<td>Ongoing (under GF)</td>
<td>Same sites (ethical amendment to be in line with WHO current protocol)</td>
<td>AL (ongoing)</td>
<td>GF/WHO</td>
</tr>
<tr>
<td></td>
<td>Pf</td>
<td>2 sites</td>
<td>AL</td>
<td>Ongoing (under GF)</td>
<td>Same sites (ethical amendment to be in line with WHO current protocol)</td>
<td>AL (ongoing)</td>
<td>GF/WHO</td>
</tr>
<tr>
<td>Solomon Islands</td>
<td>Pf</td>
<td>2 sites: Tetere and Munda</td>
<td>AL (ongoing)</td>
<td>GF</td>
<td>2 sites: Malaita and Kira Kira</td>
<td>AL</td>
<td>GF</td>
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<tr>
<td>Country</td>
<td>Parasite species</td>
<td>Current sentinel sites 2010-2011</td>
<td>Drugs tested 2010-2011</td>
<td>Current funding available 2010-2011</td>
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<td>Drugs to be tested in 2012-2013</td>
<td>Anticipated funding available for 2012-2013</td>
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<tr>
<td>Vanuatu</td>
<td>Pv</td>
<td>2 sites: Tetere and Munda</td>
<td>AL (ongoing)</td>
<td>GF</td>
<td>2 sites: Malaita and Kira Kira</td>
<td>AL</td>
<td>GF</td>
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<tr>
<td></td>
<td>Pf</td>
<td>1 site</td>
<td>AL</td>
<td>GF/AusAID</td>
<td>1 site</td>
<td>AL</td>
<td>GF</td>
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<tr>
<td></td>
<td>Pv</td>
<td>1 site</td>
<td>AL</td>
<td>GF/AusAID</td>
<td>1 site</td>
<td>AL</td>
<td>GF</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Pf</td>
<td>1. Lampung province (Sumatera 2010), by Prof Inge; 2. Kalimantant and Sulawesi, by Dr Emiliana; 3. Timika (Papua), by Dr Jeane Rini; 4. East Nusa Tenggara (Dr. Syaffrudin from Eijkman and Dr Asep from Hospital); 5. North Maluku</td>
<td>DHA-PIP (sites 1&amp;3) ASU-AMO (site 2); DHA-PIP and ASU–AMO (sites 4 &amp; 5)</td>
<td>Malaria Transmission Consortium (1); GF R8 (2); AusAid and Wellcome Trust; GF: WHO (3); WHO (4&amp;5)</td>
<td>1 site in Lampung 2 sites in Kalimantant &amp; Sulawesi; 1 site in Papua; 3 sites in East Nusa Tenggara (West Sumba, Flores &amp; Atambua); 1 site in North Maluku</td>
<td>ASU-AMO &amp; DHA-PIP; - 1 site in Lampung - 2 sites in Kalimantant &amp; Sulawesi - 3 sites in East Nusa Tenggara (West Sumba, Flores &amp; Atambua) - 1 sentinel in North Maluku</td>
<td>WHO, GF, AusAid, Wellcome Trust</td>
</tr>
<tr>
<td>Country</td>
<td>Parasite species</td>
<td>Current sentinel sites 2010-2011</td>
<td>Drugs tested 2010-2011</td>
<td>Current funding available 2010-2011</td>
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<tr>
<td>Pv</td>
<td></td>
<td>1. Lampung Province (Sumatera 2010) by Prof Inge; 2. Kalimantan &amp; Sulawesi, by Dr Emiliana; 3. Timika (Papua) by Dr. Jeane Rini; 4. East Nusa Tenggara (Dr. Syaffrudin from Eijkman &amp; Dr Asep from Hospital); 5. North Maluku</td>
<td>Idem Pf</td>
<td>Malaria Transmission Consortium (1); GF R8 (2); AusAid &amp; Wellcome Trust; GF; WHO (3); WHO (4&amp;5)</td>
<td>Idem Pf</td>
<td>Idem Pf</td>
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</table>


## REQUIRED INPUTS FOR COUNTRY TES PLANS

<table>
<thead>
<tr>
<th>Country</th>
<th>Human resources</th>
<th>Transportation</th>
<th>Supplies</th>
<th>Technical assistance</th>
<th>Other components</th>
<th>QA system</th>
<th>Supervision</th>
<th>Capacity building</th>
<th>Laboratory support</th>
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</thead>
<tbody>
<tr>
<td>Timor Leste</td>
<td>Already trained</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Malaysia</td>
<td>MOH, State, district, Institute of Medical Research</td>
<td>Staff travel, transport means; transporta-tion of samples</td>
<td>Microscopes; filter papers; packaging materials for samples; motorbikes</td>
<td>Training (national; regional)</td>
<td>Progress meetings</td>
<td>Slide cross-checking (ongoing)</td>
<td>Site visits</td>
<td>Training at State level</td>
<td>Probes &amp; primers, reagents, consumables</td>
</tr>
<tr>
<td>Philippines</td>
<td>Fulltime: experienced nurse/study coordinator (1) and medical technologist (1); Part time: data manager/encoder; driver (travel to site); barangay health workers</td>
<td>Airfare, vehicle hire for travel to site; local travel - follow ups and home visits</td>
<td>Drug supplies (quality assessed), other drugs; laboratory supplies and consumables for malaria blood film, blood spot assays (genotyping); haemoglobin testing, pregnancy test; office supplies</td>
<td>Statistician, Molecular biology laboratory procedures</td>
<td>IRB review fee; patient costs; community incentives; communication; courier services; meetings with stakeholders; report writing; scientific presentations</td>
<td>Malaria microscopy QA; GCP site monitoring visits (by local independent group); site-specific and site monitoring visit SOPs</td>
<td>WHO; malaria program coordinator</td>
<td>Orientation and training; assessment and re-assessment of malaria microscopy proficiency; GCP training course</td>
<td>Molecular biology procedures; chloroquine metabolite assays</td>
</tr>
<tr>
<td>Country</td>
<td>Action Type</td>
<td>Items</td>
<td>Needs Improvements</td>
<td>Improve On Site</td>
<td>Clinical Trial Monitoring</td>
<td>Improve and Set Up In Sentinel Site</td>
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<tr>
<td>Papua New Guinea</td>
<td>Increase capacity</td>
<td>Add to fleet Increase and add microscopy Retraining of microscopy staff</td>
<td>Needs improvements</td>
<td>Improve on site</td>
<td>Clinical trial monitoring</td>
<td>Improve and set up in sentinel site</td>
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<tr>
<td>Vanuatu</td>
<td>NIHRD; Parasitology Department (University); Eijkman Institute; Hospital</td>
<td>self travel, public transport</td>
<td>Microscope, including supplies and reagents; stationery &amp; others supplies</td>
<td>Training for technical assistant national level, training for microscopist</td>
<td>Mapping, data management, meeting, hospital fee &amp; patient cost, publication</td>
<td>Training, networking'</td>
<td></td>
<td></td>
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<tr>
<td>Indonesia</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>NIHRD, Eijkman Institute, Parasitology Department (University), Hospital &amp; Regional Laboratory</td>
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<tr>
<td>S/ No.</td>
<td>Country</td>
<td>NMCP TES Focal Point</td>
<td>Principal Investigator &amp; Institution</td>
<td>Protocol used</td>
<td>Data management</td>
<td>Reporting &amp; Publications</td>
<td>Last Treatment Guidelines Review</td>
<td>Present source(s) of funding and amount available per year</td>
<td>What is needed to improve TES / DRM?</td>
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<tr>
<td>1</td>
<td>Timor Leste</td>
<td>WHO</td>
<td>WHO excel sheet</td>
<td>2007 (AL)</td>
<td>GF (amount not known)</td>
<td>Support needed for PCR, QA etc</td>
<td>To identify the lab and provide TA</td>
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<tr>
<td>2</td>
<td>Malaysia</td>
<td>Director of Disease Control, MOH and Institute for Medical Research</td>
<td>WHO 2003 but plan to use 2009 version</td>
<td>Technical report for MOH and WHO; Scientific publication</td>
<td>2011 (ongoing revision)</td>
<td>Government funding (USD100,000)</td>
<td>To identify the lab and provide TA</td>
<td></td>
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<tr>
<td>3</td>
<td>Philippines</td>
<td>Malari a control coordinator</td>
<td>Department of Parasitology, or Medical Department, Research Institute for Tropical Medicine</td>
<td>WHO, investigato r authored Depts. of Parasitology, and Epidemiology and Biostatistics</td>
<td>Peer review in Technical Working Group (TWG) meetings, feedback to stakeholders, technical reports to WHO (peer review) and sponsors, publications/draft</td>
<td>2009 (by TWG and professional medical societies)</td>
<td>GF (USD42,380 for AL for Pf); RBM project (USD40,000 for CQ for Pv)</td>
<td>Dedicated, well-trained team; technical supervision; referral system and support for SAEs; increase capacity of reference laboratory; training of sentinel site</td>
<td>Training, institutional collaborations, advocacy (national and sub-national), networking; incorporate in national and local (sentinel site) plans</td>
</tr>
<tr>
<td>Country</td>
<td>Name</td>
<td>Focal Person</td>
<td>Organization</td>
<td>System</td>
<td>Activities</td>
<td>Funding</td>
<td>TA</td>
<td>Support</td>
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<tr>
<td>PNG</td>
<td></td>
<td>Leo Makita</td>
<td>Dr Inoni Betuela, Dr Manuel Hetzel</td>
<td>PNGIMR internal database</td>
<td>Ongoing and biannual progress reports</td>
<td>AusAID and Global Fund, AUS 350,000</td>
<td>Financial support, TA</td>
<td>Funding and updating TES &amp; QA</td>
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<tr>
<td>Solomons Islands</td>
<td>Albino Bobogare</td>
<td>Dr Lyndes Wini</td>
<td>WHO</td>
<td>WHO Excel Spreadsheet</td>
<td>Requires capacity building</td>
<td>GF-RCC (USD 120,000 annually), AusAID (funds held with PacMISC)</td>
<td>Capacity building, External monitoring &amp; validation</td>
<td>Coordination, TA</td>
<td></td>
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<tr>
<td>Vanuatu</td>
<td>George Taleo</td>
<td>WHO TES Excel table</td>
<td>WHO TES protocol</td>
<td>NA</td>
<td>2007 (2009)</td>
<td>Global Fund RCC USD 60,000 2009-2011</td>
<td>Staff training (clinic staff, microscopist, data management), clinical monitoring and supervision</td>
<td>Training workshops, TA for study monitoring and data analysis, assist in review of efficacy results, revising treatment guidelines, provide training, assist in QA</td>
<td></td>
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<tr>
<td>Indonesia</td>
<td>Dr. Emiliana/NIHRD</td>
<td>WHO &amp; MoH</td>
<td>WHO &amp; MoH</td>
<td>ASU-AMO and DHA-PIP</td>
<td>USD</td>
<td>Molecular marker training, update to the protocol, networking</td>
<td>1. Network 2. Funding</td>
<td>1. Network 2. Funding WHO support</td>
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<tr>
<td>No.</td>
<td>Name</td>
<td>Organization</td>
<td>Affiliation</td>
<td>Funding</td>
<td>Training</td>
<td>Networking</td>
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<td>2.</td>
<td>Prof. Dr. Inge/PD</td>
<td>WHO</td>
<td>WHO &amp; MoH</td>
<td>WHO &amp; MoH</td>
<td>DHA-PIP</td>
<td>US $</td>
<td>Molecular marker training update, networking</td>
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<td>3.</td>
<td>Dr. Syaffrudin /Eijkman Institute</td>
<td>WHO</td>
<td>WHO &amp; MoH</td>
<td>WHO &amp; MoH</td>
<td>ASU-AMO, DHA-PIP</td>
<td>USD 95,000</td>
<td>Networking</td>
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<td>4.</td>
<td>Dr. Asep/Hospital NTT</td>
<td>WHO</td>
<td>WHO &amp; MoH</td>
<td>WHO &amp; MoH</td>
<td>ASU-AMO, DHA-PIP</td>
<td>USD 95,000</td>
<td>Networking</td>
<td></td>
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<td>5.</td>
<td>Dr. Jeane /Hospital</td>
<td>WHO</td>
<td>WHO &amp; MoH</td>
<td>WHO &amp; MoH</td>
<td>ASU-AMO, DHA-PIP</td>
<td>$ US 339,400 (in vivo 150,000 + in vitro 189,400) from AusAID $US 100,000</td>
<td>Networking</td>
<td></td>
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</tbody>
</table>

Key areas of need:
- Coordination of TES processes: Protocol; proposal dev, ethical review, funding, training, supervision, reporting/publication, etc
- Capacity building – programme level; research institution level
- Translating research results to policy and programming – communicating results for policy/programme use
- Advocacy and resource mobilisation – technical and financial including logistics
ANNEX 6

PACIFIC MALARIA DRUG RESISTANCE MONITORING NETWORK

TERMS OF REFERENCE

Goal
To support countries in the Pacific to generate and share up-to-date, high quality evidence on anti-malarial drug efficacy to inform malaria policies.

Terms of Reference
1. To support countries (programmes and research institutions) to implement the WHO standard protocol for routine monitoring of anti-malarial therapeutic efficacy of 1st and 2nd line treatments for *Plasmodium falciparum* and *Plasmodium vivax*

2. To identify training needs and coordinate capacity building for high quality drug resistance surveillance

3. To coordinate laboratory support to countries and facilitate the use of WHO recommended standard procedures, and contribute to the development of new procedures where not available

4. To coordinate independent monitoring and review of therapeutic efficacy study (TES) data

5. To facilitate the timely reporting and sharing of TES results

6. To coordinate Network activities and facilitate collaboration through regional informal consultations, regional planning, resource mobilization and review of progress

7. To support countries in reviewing national malaria treatment policies (if requested)

8. To facilitate operational research to address knowledge gaps related to anti-malarial drug resistance monitoring.
LIST OF DOCUMENTS DISTRIBUTED

- Methods for Surveillance of Antimalarial Drug Efficacy 2009 (hard and e-copy)
- TES template protocol + summary cover sheet (hard and e-copy)
- Methods and Techniques for Clinical Trials on Antimalarial Drug Efficacy: genotyping to identify parasite populations, 2007 (hard and e-copy)
- Field application of in vitro assays for the sensitivity of human malaria parasites to antimalarial drugs, 2007 (hard and e-copy)
- Global Plan for Artemisinin Resistance Containment, 2011 (hard and e-copy)
- Global Report on Antimalarial Drug Efficacy and Drug Resistance (hard and e-copy), 2010
- Monitoring Resistance of P. falciparum and P. vivax to Anti-Malarial Drugs in the Greater Mekong Sub-Region, Phuket/Thailand, 2007, Mekong Malaria Programme (hard and e-copy)
- Report of the workshop to review and plan therapeutic efficacy studies to monitor P. falciparum and P. vivax resistance to antimalarial drugs in the Greater Mekong Subregion, Mandalay/Myanmar, 2009, Mekong Malaria Programme (hard and e-copy)
- Responding to the challenge of antimalarial drug resistance by routine monitoring to update national malaria treatment policies. Vestergaard, Ringwald, 2007 (hard and e-copy)
- Report of the 14th South-West Pacific Malaria Meeting, Madang/Papua New Guinea, 2007 (e-copy)
- WPRO Ethics Review Committee Standard Operating Procedures, 2010 (e-copy)
- Containment Newsletters 1 + 2+3 (hard and e-copies)
LIST OF DOCUMENTS ON USB

- Timetable

- Presentations
  Technical Session 1
  1. Pacific Drug Resistance, Ms. Amy Barrette
  2. Overview of antimalarial drug resistance in the Western Pacific, Dr. Christophel
  3. Overview of TES on antimalarials in SEARO, Dr. Rahman
  4. Lessons learnt from the Greater Mekong Subregion, Dr. Delacollette
  5. Containment project on the Thai-Cambodia border, Dr. Habib

  Technical Session 2
  1. Drug resistance monitoring in the Philippines, Dr. Espino
  2. Drug resistance monitoring in Malaysia,
  3. Drug resistance monitoring in Papua New Guinea,
  4. Drug resistance monitoring in Solomon Islands,
  5. Drug resistance monitoring in Vanuatu,

  Technical Session 3
  1. Methods for anitmalarial drug resistance monitoring, Dr. Vestergaard
  2. Practical issues and operational challenges, Dr. Bustos
  3. Monitoring drug resistance, Dr. Cheng
  4. Health research involving human subjects, Dr. Nakagawa

  Summary of Day 1, Dr. Kazadi-Mulombo

  Group work outputs

  TES training, Dr. Bustos

  Do we need a network? Dr. Christophel

  Technical Session 4
  1. Pacific Malaria Drug Resistance Monitoring Network TORs, Dr. Vestergaard

  Pacific Malaria Drug Resistance Monitoring Network TORs-REVISED, Dr. Rundi

  Pacific Malaria Drug Resistance Monitoring Network- Recommendations, Dr. Christophel

- References
  1. Methods for surveillance of antimalarial drug efficacy 2009
  2a. TES dug efficacy protocol template
  2b. TES summary cover sheet
  2c. WHO Mekong TES template protocol
3. Methods and techniques for clinical trial on antimalarial drug efficacy
4. Field application of in vitro assays for malaria 2007
5. WHO Global Plan for Artemisinin resistance containment GPARC-DUP 2011
7. Monitoring resistance of Pf and Pv to antimalarial drugs in GMS 2007
8. Workshop report to review and plan TES, Myanmar 2009
9. Responding to the challenge of antimalarial drug resistance by routing monitoring
10. 14th SWPMM
11a. WPRO ERC SOP 2010
11b. WPRO ERC Annex, Application form
12. Containment project newsletters

- **Background documents**
  1. Handouts for the Pacific Malaria Drug Resistance Meeting
  2. Information Bulletin, general information
  3. Information Bulletin, list of attendees
LIST OF DOCUMENTS ON USB

- Timetable

- Presentations
  Technical Session 1
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  Do we need a network? Dr. Christophel

  Technical Session 4
  1. Pacific Malaria Drug Resistance Monitoring Network TORs, Dr. Vestergaard

  Pacific Malaria Drug Resistance Monitoring Network TORs-REVISED, Dr. Rundi

  Pacific Malaria Drug Resistance Monitoring Network- Recommendations, Dr. Christophel

- References
  1. Methods for surveillance of antimalarial drug efficacy 2009
  2a. TES drug efficacy protocol template
  2b. TES summary cover sheet
  2c. WHO Mekong TES template protocol
3. Methods and techniques for clinical trial on antimalarial drug efficacy
4. Field application of in vitro assays for malaria 2007
5. WHO Global Plan for Artemisinin resistance containment GPARC-DUP 2011
7. Monitoring resistance of Pf and Pv to antimalarial drugs in GMS 2007
8. Workshop report to review and plan TES, Myanmar 2009
9. Responding to the challenge of antimalarial drug resistance by routing monitoring
10. 14th SWPMM
11a. WPRO ERC SOP 2010
11b. WPRO ERC Annex, Application form
12. Containment project newsletters

- **Background documents**
  1. Handouts for the Pacific Malaria Drug Resistance Meeting
  2. Information Bulletin, general information
  3. Information Bulletin, list of attendees