Given the emergence of resistance to artemisinins, ACTs and other antimalarial drugs in the Asia-Pacific Region, monitoring drug resistance using standardized WHO therapeutic efficacy study (TES) protocols is an important activity of national malaria programmes (NMPs) to identify early deterioration in the efficacy of recommended treatment regimens.

A meeting of the BBINS Malaria Drug Resistance Monitoring Network was held virtually on 19−21 August 2020. Country representatives from NMPs and Principal Investigators from Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Timor-Leste, WHO country office focal points, representatives from the WHO Regional Office, experts and partners attended the meeting.

Countries presented the results of TES studies conducted in 2018–2019. Panel discussions were held on updating malaria treatment regimens based on evidence generated from TES studies, and the challenges to conducting the studies during the COVID-19 pandemic while ensuring safety of patients and health staff. This document is a report of the virtual meeting, and includes the salient discussions and conclusions and recommendations agreed upon.
Meeting of the Expanded Bangladesh, Bhutan, India, Nepal and Sri Lanka (BBINS) Malaria Drug Resistance Monitoring Network (including Indonesia, Maldives and Timor-Leste)

19–21 August 2020
Meeting of the Expanded Bangladesh, Bhutan, India, Nepal and Sri Lanka (BBINS) Malaria Drug Resistance Monitoring Network (including Indonesia, Maldives and Timor-Leste)

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Abbreviations

ACD active case detection
ACPR adequate clinical and parasitological response
ACT artemisinin-based combination therapy
AS artesunate
BBINS Bangladesh, Bhutan, India, Nepal, Sri Lanka
CDS Communicable Diseases Department (of the WHO Regional Office)
CQ chloroquine
DHA dihydroartemisinin
ECAMM External Competency Assessment for Malaria Microscopy
ETF early treatment failure
GMP Global Malaria Programme
GMS Greater Mekong Subregion
GTS Global Technical Strategy
iDES integrated drug efficacy surveillance
K13 Kelch 13
LCF late clinical failure
LPF late parasitological failure
MQ mefloquine
NMCP National Malaria Control Programme
NSP National Strategic Plan
NTG National Treatment Guidelines
PCD passive case detection
PIP piperaquine
PQ primaquine
QA quality assurance
RDT rapid diagnostic test
SEARO (WHO) Regional Office for South-East Asia
SP sulfadoxine-pyrimethamine
TES therapeutic efficacy studies
WHO World Health Organization
Summary

The virtual meeting of the BBINS Malaria Drug Resistance Monitoring Network was held on 19–21 August 2020. Country representatives from National Malaria Programmes and Principal Investigators from Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Timor-Leste, country office focal points, representatives from the WHO Regional Office for South-East Asia headquarters, and experts and partners attended the meeting.

The meeting provided an update on the recommendations of the 2019 meeting and provided presentations on global and regional updates. Countries shared results of the recent therapeutic efficacy studies (TES) or integrated drug efficacy surveillance (iDES) from their respective countries. Updates on molecular markers for tracking artemisinin resistance Kelch13 and other molecular markers for malaria drug resistance were also discussed.

The Member countries then developed workplans and budgets for TES monitoring in 2021–2022. Panel discussions were also held on updating malaria treatment regimens across countries based on evidence generated from TES studies, and the challenges and mitigation measures for conducting TES studies in the context of the COVID-19 pandemic while ensuring safety of patients as well as of health staff.

The salient points/conclusions which emerged from the discussions were:

1. Most countries in the WHO South-East Asia Region have shown a decline in malaria cases.
2. National treatment policies should be updated, if relevant, based on the results of TES and WHO treatment guidelines. Countries are encouraged to include another ACT as a second-line drug (and ensure availability of stocks).
3. Countries are advised to do further investigations on reports of Kelch 13 mutations in their respective areas.
4. Protocols should be based on the WHO standardized protocol (template) with relevant modifications as per national regulations/guidelines.
5. If failure to achieve the required sample size is a regular feature in high-burden countries, the selection of the study sites needs to be revisited during the planning stage. The national and WHO Ethics Review Committee must be informed of any site amendment.
6. Countries near elimination should strengthen case-based surveillance, including monitoring of response to antimalarials. Funding for this should be secured in a sustainable manner. Including these in their country Global Fund proposals is encouraged.
7. TES studies are totally reliant on quality microscopy. Capacity-building should continue even during the ongoing COVID-19 pandemic using innovative methods.
8. In the context of COVID-19, suspected cases should be tested as per national guidelines ensuring safety of the patients and of health staff.
9. Confirmed cases of malaria, if found to be positive for COVID-19, should not be included in TES but should be treated/referred as per national guidelines.
(10) If confirmed cases of malaria were found to be positive for COVID-19 during follow-up, such cases should be withdrawn from the study and referred to a health facility as per the respective national guidelines.

(11) WHO should continue to support quality assurance for microscopy, PCR and molecular markers in the network/Region, including financial support, where relevant.

(12) WHO should provide technical support and guidance to countries for quality implementation of TES in the light of the dynamic pandemic situation.

(13) WHO should support capacity-building of country programmes for surveillance, which includes integrated drug efficacy surveillance (iDES).
1. **Background**

The WHO Regional Office for South-East Asia organized the virtual meeting on malaria drug resistance monitoring. WHO has set up three drug resistance monitoring networks in the Asia-Pacific Region, and one network – the BBINS – covers Bangladesh, Bhutan, India, Nepal and Sri Lanka. The networks conduct yearly meetings to assess progress and share technical updates. Monitoring the efficacy of antimalaria drugs is routinely conducted in these countries with technical support from WHO. This year, the meeting extended its invitation to Indonesia, Maldives and Timor-Leste besides Bangladesh, Bhutan, India, Nepal and Sri Lanka.

This meeting contributes tangibly towards the Flagship Priority Programme of strengthening antimicrobial resistance surveillance initiated by the Regional Director of the WHO South-East Asia (SEA) Region. Countries are enabled to implement malaria strategic plans, with focus on improved diagnostic testing and treatment, antimalarial resistance monitoring surveillance, outbreak detection and response, especially in near-elimination areas, through capacity strengthening and updated treatment policy recommendations and guidelines in line with the Global Malaria Programme’s (GMP) strategic direction towards malaria elimination.

Due to the COVID-19 pandemic situation, the meeting was held virtually from 19—21 August 2020. It was hosted by the Malaria unit of the Department of Communicable Diseases of the WHO Regional Office.

The specific objectives were as follows:

1. Presentation of and discussions on the latest malaria drug efficacy monitoring data.
2. Updates on molecular markers and available tools.
3. Updating national plans for drug efficacy monitoring and support through the networks.

The participants included representatives from the national malaria programmes and the principal investigators for TES from the SEA Region countries of Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Timor-Leste; technical experts and partners; WHO country office focal points; and representatives from the WHO Regional Office and headquarters.

2. **Proceedings**

**Opening session**

The meeting began with a welcome address by Dr Tjandra Y. Aditama, Acting Director for Communicable Diseases, WHO SEARO.

This was followed by the address by the WHO Regional Director for South-East Asia, Dr Poonam Khetrapal Singh, which was read on her behalf by Dr Pem Namgyal, Director for Programme Management at the Regional Office. The Regional Director highlighted that malaria morbidity and mortality in the SEA Region had declined by 74% and 93%
respectively during period 2010–2018. She acknowledged the dedication of the leaders and malaria workers of the Member countries that led to this improvement in the malaria situation in the SEA Region. Member States were encouraged to continue obtaining quality data for malaria interventions. WHO will continue supporting Member States to maintain this rate of progress and accelerate the current efforts for malaria control, she reiterated.

The Director of the WHO Global Malaria Programme (GMP), Dr Pedro Alonso, delivered the remarks. The remarks provided key messages on the importance of maintaining continuity of malaria services during the COVID-19 pandemic. They highlighted the importance of addressing drug and insecticide resistance and emphasized the technical updates on therapeutic efficacy studies (TES) or integrated drug efficacy surveillance (iDES), and the way forward in the future. WHO and its collaborating centres will continue to provide technical assistance to Member States, he added.

Dr Neena Valecha, Regional Adviser for Malaria, WHO SEARO, articulated the objectives of the meeting. She introduced the country teams present and announced the names of unanimously agreed Chair, Vice-Chair and Rapporteurs for the three-day meeting.

The meeting began with technical updates from the global and regional levels, followed by country presentations on Days 1 and 2. The technical updates focused on the purpose of maintaining the malaria drug resistance monitoring system, TES protocols and quality assurance. A progress update on the recommendations of the 2019 meeting was presented. Countries shared results of their recent TES and iDES and other recent advances.

The status of molecular marker K13 for tracking artemisinin resistance and other molecular markers for malaria drug resistance were also shared. On Day 3, the countries presented their workplans and budgets for TES and/or iDES monitoring in 2021–2022. Panel discussions focused on challenges and mitigation measures for conducting TES studies in the context of COVID-19 and ensuring the safety of patients as well as of health staff.

3. **Session 1: Updates**

Ms Charlotte Rasmussen, Technical Officer, Global Malaria Programme, WHO/HQ, presented a summary of the global situation of antimalarial drug efficacy and artemisinin resistance. TES is considered the gold standard for monitoring drug resistance to inform treatment policy. In countries implementing elimination activities, drug efficacy can be monitored by integrated drug efficacy surveillance (iDES). To support implementation of iDES, a strong surveillance system is essential. Additional information can be gathered from molecular markers, in vitro and ex vivo studies. It is reported that the number of patients with Day 3 parasitemia is mainly associated with K13 mutation.

The WHO recommended ACTs are still highly efficacious to uncomplicated *Plasmodium falciparum* (*Pf*) malaria. Drug resistance in *Pf* has posed the greatest challenges, especially *Pf* resistance in the countries of the Greater Mekong Subregion. A compilation of TES results from 2010–2019 was presented. During this period, 1059 studies had been conducted in five WHO regions (Africa, the Americas, South-East Asia, Eastern Mediterranean and the Western Pacific). Among these regions, 54% of TES studies was conducted in the African Region. Six different types of WHO recommended ACTs constituted 99% of the TES study. Among the six different ACTs, 44% of TES studies tested efficacy of the Artemether–Lumefantrine combination. It was pointed out that artemisinin (partial) resistance is associated with K13 mutation.
Ms Rasmussen also made a presentation on the following (i) K13 genotyped samples (2010–2019) by regions and genotype; (ii) relation between drug efficacy and K13 mutations; and (iii) chloroquine resistance in *Plasmodium vivax*. Chloroquine remains efficacious for *P. vivax* in many countries. However, *P. vivax* chloroquine treatment failure on or before Day 28 or prophylactic failure has been observed in several countries. Confirmation of true chloroquine resistance requires additional studies of drug concentrations in blood.

Dr Neena Valecha presented on the malaria situation and therapeutic efficacy status in the South-East Asia Region. Approximately 228 million malaria cases were reported in 2018; 93% of these cases had occurred in the African Region. The number of countries which had less than 100 indigenous cases increased to 27 in 2018 compared with 17 countries in 2017. The SEA Region reported 7.9 million malaria cases in 2018, of which 58% were reported from India, 30% from Indonesia and 10% from Myanmar. About 53% of the global *vivax* burden is in the SEA Region, of which India reported 47% of the cases. Malaria cases and deaths declined by 69% and 70% respectively in 2018 compared with the number of cases and deaths reported in 2010. Maldives and Sri Lanka continued to be malaria-free while Timor-Leste reported zero cases since 2017.

Dr Valecha highlighted the impact of the COVID-19 pandemic on health systems including essential services for malaria. She added the information about different guidance documents for maintaining malaria services recommended to be used as a reference by Member States. With respect to TES studies, the BBINS network is one of the global TES networks. Different combinations of ACT are being tested for drug efficacy in the BBIN countries of Indonesia and Timor-Leste.

Preliminary findings on a review of various drug resistance research conducted by NMCP and partners during the period of 2010–2020 were presented. The review included more than 3300 abstracts, 180 studies and unpublished reports from NMCPs and research institutions. The results showed that the treatment failure is less than 10% for the first-line ACT for *Pf*. K13 mutation is present but not common and all treatment failures are not clearly linked with K13 mutation. Chloroquine remains highly efficacious for *P. vivax*.

Dr Maria Dorina Bustos, Technical Officer, SEARO, presented the recommendations from the 2019 TES meeting and quality assurance for TES. It was reiterated that TES implementors are encouraged: to share results with respective country programmes as soon as these are completed and to publish the findings; to further investigate K13 mutations when first reported; and update the treatment guidelines as per WHO guidelines and TES findings when necessary. Information sharing on imported cases with the relevant country of origin was also recommended. Countries should also strengthen capacities for microscopy and malaria microscopy QA ensured in TES implementation.

The External Competency Assessment in Malaria Microscopy (ECAMM) should include programme-based laboratory technicians engaged in TES. It is recommended for WHO to streamline the approval process of protocols and budget at country offices, the Regional Office and headquarters to avoid implementation delays; to continue to support quality assurance for PCR and molecular markers; and to establish links and information sharing between GMS and BBINS border countries.

For quality assurance in TES monitoring, use of the TES standardized protocol and ethical approval was reiterated. The national and WHO ERC approvals are usually valid for one year, but an extension can be requested if needed. The importance of informed consent (ICF), assent for minors and assent for pregnancy test were highlighted, as well as the need for clinical trial registration on the website prior to the start of patient enrolment.
It was also pointed out that TES is based on clinical and microscopy results, hence the importance of microscopy QA and ECAMM and onsite validation of TES results by two qualified microscopists.

WHO provides three quality control monitoring templates for TES: QC checklist pre-study; QC checklist interim (during study implementation) and QC checklist close-out. The QC checklist provides immediate documented feedback on gaps and challenges for improvement. The purpose of the checklist is to identify bottlenecks to resolve them and provide documentation, and all this is intended to improve onsite implementation.

Some issues and challenges encountered in QA monitoring: countries must adopt rescue treatment according to their NTGs, updated following the latest WHO treatment guidelines; procure WHO pre-qualified ACTs and PQ (recommended drug list [https://www.theglobalfund.org/media/4756/psm_products_malaria_list_en.pdf]); perform G6PD test for vivax studies as per NMCP policy; and send dried blood spot TES samples to a regional referral laboratory with material transfer agreement (MTA).

For countries implementing IDES, it was re-emphasized that ALL laboratory confirmed cases (from the private and public sector) are followed up as per national surveillance system guidelines.

In the Q&A, countries were informed that there is no need for ethical clearance for IDES nor patient consent form, as this is now programmatic routine surveillance. From Timor-Leste, a question was raised on primaquine resistance in relapsing *P. vivax* 2–3 times in a year in one patient. Dr Pascal Ringwald mentioned that recent studies have shown evidence of poor compliance or metabolism problems with primaquine in some patients, resulting in lower levels of the drug.

4. **Session 2. Country presentations on recent therapeutic efficacy studies/antimalarial drug efficacy surveillance**

4.1 **Bangladesh: Dr Afsana Alamgir Khan, Deputy Programme Manager, National Malaria Elimination & ATD Control Programme, Government of the People’s Republic of Bangladesh**

The Programme Manager, Dr Afsana Khan, presented data based on the overall country malaria situation. Malaria is not uniformly distributed in the country and has become focal over the past few years. A 57% case reduction was seen in 2019 compared with 2015. Even though there are 13 malaria endemic districts in Bangladesh, 95% of confirmed malaria cases are reported from three districts of the Chittagong Hill Tracts. The remaining eight districts have now set up case-based surveillance and are moving towards malaria elimination. In 2019, approximately 1.5 million people were tested for malaria and 1.14% suspected cases were positive.

LLINs covered 99.5% households in the three Chittagong Hill Tracts districts, with more than 700,000 LLINs having been distributed. It was supplemented with continuous distribution for *jhum* cultivators, forest goers, Army personnel and pregnant women. Six imported and 19 indigenous cases were classified in 2019. Artemether Lumefantrine (AL) remains the first-line drug against uncomplicated *Pf* and chloroquine with 14-day PQ for *P. vivax* malaria.

TES conducted in the last couple of years did not identify any ACT resistance in Bangladesh; yet, the country is at high risk of importation of drug-resistant malaria due to
the periodic large-scale movements of displaced refugees from Myanmar to endemic districts in the southeast. Dr Afsana added that TES needs to be continued routinely to have the evidence to take appropriate measures to either prevent or delay the emergence of drug resistance. There are currently some research collaborations looking into mapping of artemisinin resistance by molecular surveillance, and TRAC II studies on triple ACTs in uncomplicated *Pf* malaria and injectable AS + injectable quinine in cases of severe malaria.

Dr Ringwald raised the issue of the programme further investigating the C580Y mutation reported in a case from Cox’s Bazaar, hence the importance of TES in these areas.

### 4.2 India: Dr Neeraj Dhingra, Director, National Vector Borne Disease Control Programme, Government of India

The programme manager, Dr Neeraj Dhingra, presented an overview of progress towards malaria elimination in India and the categorization of states by malaria endemicity as per the National Framework for Malaria Elimination. Thirty six states are categorized into three groups according to the level of their annual parasite index (API). Fifteen low-endemic states which have API of less than 1 per 1000 population in Category 1, while 11 and 10 states are in Category 2 and 3 respectively. Category 2 states have less than 1 API per 1000 population, but some of the districts report API of more than 1 per 1000 population. The states which have API of 1 or more per 1000 population are in Category 3. In recent years, the malaria incidence in the country has significantly declined; WMR reported the number of endemic districts to have reduced from 143 in 2015 to 109 in 2019.

As per National Treatment Guidelines, AL is the first-line drug in north-eastern states and AS + SP is used nationwide against uncomplicated *Pf* malaria, while CQ + 14-day PQ is used against *Pv* malaria. In the last five years, India has conducted some 30 TES mainly in the central and the north-eastern states testing AL and AS + SP. There is an ongoing study in West Bengal (until 2021) that is looking at *Pf* parasite clearance phenotype by the slope of log parasite clearance curve and polymorphism in Kelch 13 gene. This study is essential to confirm initial reports of artemisinin resistance in West Bengal.

With respect to drug efficacy, he concluded that both AL, AS + SP and CQ are highly efficacious in their respective areas of use in India. No early treatment failure and no adverse event has been reported India for these. He also mentioned “no functional mutation in the K13 gene” and limited non-synonymous mutation at codon M579T.

### 4.3 Indonesia: Dr Pranti Sri Mulyani, Staff, National Malaria Control Programme, Republic of Indonesia and Professor Dr Din Syafruddin, Principal Investigator, Eijkman Institute, Jakarta

Malaria in Indonesia showed a downward trend in the last 10 years, especially in the western and central parts of the country, although it seems to have levelled off in the last five years. In 2019, 250 644 (0.93 cases per 1000 population) compared with 222085 cases in 2018 (0.84 case per 1000 population) were reported. *Pf* malaria is still the dominant *plasmodium* with over 50% prevalence compared with other species.

The latest updates on the national treatment protocol were from 2019 to revise the doses of primaquine for Day 1 for *Pf* from 0.75mg/Body Weight (BW) to 0.25 mg/BW. Other treatment regimens remain the same, with DHA-PIP and primaquine as the first-line drug for uncomplicated malaria for all *plasmodium* species. Pregnant women at all trimesters also receive DHP. Artesunate in injectable and oral form are recommended for severe malaria.
There were two TES sites for *Pf* and *Pv* in 2017–2018 conducted by Eijkman Institute, and 10 TES sites for *Pf* conducted by the regional technical health environmental and disease control teams in 2018–2019. The results from the TES of 2017–2018 in Keerom, Papua province, showed 100% PCR-corrected ACPR out of 114 enrolled *Pf* cases. Likewise, the *P. vivax* TES in Keerom and Merangin, Jambi province, revealed 100% ACPR of total analysed cases. Both *Pf* and *Pv* cases were followed till Day 42. Genotypic analyses of the parasite at Day 0 and the day of recurrences were conducted using three markers — msp1, msp2 and glurp. Of the six LTF, four cases were categorized as reinfection. The two other cases are either recurrence or re-infection. LTF was observed in six cases, 50% of which have increased the copy number of PI PM2 gene that is associated with resistance to piperaquine.

Of the 10 sites of TES for *P. falciparum* with 28 days follow-up conducted by B/BTKLPP in 2018–2019, only seven sites succeeded in enrolling cases, and two sites had a sample size <10. At each site, 100% ACPR at 28 days was observed, with one case in East Nusa Tenggara province and two cases in East Kalimantan recording Day 3 positive by microscopy. Slide validation with an independent WHO Level 1 certified microscopist is still ongoing, as well as genotyping assays by Eijkman Institute.

Challenges in drug procurement include the long process on registration of medicine at the government e-procurement catalogue, and limited raw materials for medicines in Indonesia, especially during the COVID-19 pandemic. Another challenge in implementing TES in Indonesia was the reduction in the number of cases. Indonesia needs to transition to iDES for the western and central part of the country with low cases, and TES for the eastern part.

Updates were provided on ongoing and upcoming operational research (OR). Indonesia participated in a completed multicentre study on improving radical cure for *P. vivax*. Other ORs with external collaborating institutions included: implementation research for high dose PQ in three sites of Indonesia; clinical trials on reducing *vivax* relapse by PQ administration in *Pf* infected individuals; serological screening and treatment of *Pv* to reduce relapses: triple ACT trial to combat artemisinin resistance; and looking into the role of plasma membrane calcium ATPase 4 (PMCA4) in modulating *Plasmodium* infection and malaria severity.

A clarification was raised on why 28-day follow-up was done on the DHA-PIP study, when this is an ACT with a longer half-life. Apparently, there were inherent issues on the protocol design and operational challenges with a longer follow-up period.

5. **Session 3. Updates on antimalarial resistance studies, iDES and molecular markers**

5.1 **Different drug efficacy surveillance systems: routine TES, integrated drug efficacy surveillance (iDES) in the context of elimination, and importation: Ms Charlotte Rasmussen, Technical Officer, Global Malaria Programme, WHO/HQ**

The difference between TES and iDES was explained. TES is the gold standard for monitoring drug efficacy to inform treatment policy. It is designed for efficacy monitoring for both *P. falciparum* and *P. vivax* recommended first- and second-line drugs that need to be monitored prior to possible introduction into the treatment policy.
TES is conducted in sentinel sites. Repeated TES in a limited number of sites is adequate to collect consistent longitudinal data and document trends. WHO recommends that TES should be conducted in sentinel sites at least once every two years to estimate the proportion of treatment failures among all malaria cases.

The required number of days for follow-up of cases, methods to differentiate recrudescence and reinfection, study template, ethical clearance, registration and material transfer agreement were presented. The adjustment and adaptation of TES protocol in different malaria endemicity settings was also presented. There are specific challenges in *P. vivax* TES as one looks at drug efficacy or resistance to the treatment of blood stage parasites. Concomitant treatment (with PQ) for the liver-stage parasite can increase efficacy of treatment drug (ACT) against resistant blood stage parasites.

For the TES, if locally acceptable, the radical treatment with PQ should be moved to Day 28. It is not possible to distinguish between vivax recrudescence, infection and relapse. Adequate drug blood concentration levels should prevent both recrudescence and relapse. If the drug given has long half-life (and has been absorbed as expected), recurrent parasitemia would not be expected before Day 28.

In areas with very low transmission of malaria, the required sample size is difficult to achieve. If elimination activities are implemented, data from the routine system may be used as the country shifts to case-based surveillance in malaria case management. In this scenario, iDES is performed as part of routine case-based surveillance. Only two data points (Day 0 and end-day) will be required. A second round of full follow-up will be required in case of treatment failure. Additional data can be collected depending on need and resources available (i.e. hospitalization during treatment, weekly time points for monitoring and follow-up until Day 42 or 56, one-year follow-up in *Pv* and PCR/genotyping assays for Day 0 and day of failure).

### 5.2 Updates on Kelch 13, P14 and other molecular markers for resistance:
Dr Benoit Wikowsky, Head of Unit, Malaria Molecular Epidemiology Unit, Pasteur Institute of Cambodia

Professor Din from Indonesia raised a question on what ACT to use next since they have begun to see treatment failures against DHA-PIP in certain foci in the country and also the increasing Plasmepsin2 markers observed in TES samples. Aside from more TES to be done to closely monitor the situation, Dr Witkowsky responded that given the experience in Cambodia, the ACT artesunate-mefloquine is shown to be very effective in piperaquine resistance parasites.

### 6. Session 4: Integrated drug efficacy surveillance (iDES) in near-elimination/elimination countries

#### 6.1 Bhutan: Mr Singye Dukpa, Senior Laboratory Technician, Vector Disease Control Programme, Gelephu

Bhutan presented its declining malaria trends from 2010 to July 2020. In 2010, the total cases were 436 compared with only 42 in 2019. From 2013 to 2019, the number of malaria deaths ranged from 0 to 1. The number of indigenous cases has decreased to 2 in 2019 as against 32 cases in 2015, and from 70 to 30 imported cases during the same period.

As Bhutan is going through the malaria elimination phase, monitoring of antimalarial drug efficacy is integrated into the routine surveillance system since 2017. The NTG has
been updated in 2020, with AL and single-dose PQ as first-line treatment against Pf and CQ + PQ14 against Pv malaria. DHA-PIP is the new second-line drug. AL and CQ show high cure rates against Pf and Pv. The iDES in the country is marked by its good case detection, reporting all laboratory-confirmed cases of malaria, ensuring that all patients receive supervised treatment with three-day hospitalization and follow-up of all patients to confirm complete cure. In 2019, 60% of the cases completed the 28-day follow-up, but they hope to improve this with a revised case follow-up form. The country is facing challenges of maintaining the competency of the microscopists, absence of genotyping facility, and unrestricted movements across the border.

6.2 Maldives: Ms Aishath Jaleela, Director, Pharmaceuticals, Food and Drug Authority, Ministry of Health

As Maldives is a malaria-free certified country since 2015, the presentation focused on the following best practices for malaria to prevent reintroduction of malaria. There are no indigenous cases since 1984, and one imported case was reported each year in 2017, 2018 and 2019. Maldives is also malaria vector-free since 1991.

Malaria surveillance is integrated with that of general communicable diseases. Malaria is a reportable disease and needs to be notified to the national programme within 24 hours. The imported cases are followed up as per the national guidelines. The programme updated its National Malaria Guidelines with a revised malaria investigation form with reference to WHO and CDC treatment guides.

Malaria drugs are available only from the national programme. The efficacy of ACTs, it’s WHO pre-qualified status and quality are monitored by the Maldives Food and Drug Administration (MFDA). An Integrated Vector Control Handbook has been developed and is circulated in the local language in all health facilities. The “MadhirHoHo” Campaign – a nationwide vector control campaign – has been initiated in collaboration with the President’s Office. The programme has created digitalized awareness products to be disseminated through national and different media channels, as well as in social media. There is currently strong collaboration with multi-stakeholders (government and private) involved in the COVID-19 response.

6.3 Nepal: Dr Basudev Pandey, Director, Epidemiology and Disease Control Division, Directorate of Health Services, Ministry of Health and Population

In Nepal, the majority of the malaria is caused by Plasmodium vivax. In 2019, from a total of 710 cases reported, 91% was P. vivax, while 9% was Plasmodium falciparum. A total of 131 cases were classified as indigenous (18%), while 579 cases were classified as imported (82%). Indigenous cases have been declining over the years paving the way for the interruption of local transmission. However, imported malaria contributes to the changes in epidemiological patterns and trends and continues to pose outbreaks when case detection and investigation is not optimal.

The National Malaria Programme (NMP) has been conducting case-based surveillance for all malaria cases and has a target of reaching zero indigenous cases by 2022. The majority of the investment from the Government of Nepal and the Global Fund is on strengthening surveillance and capacity-building activities in malaria case management, and key operational research activities. AL and CQ + PQ14 are first-line drugs for Pf and Pv, respectively, with DHA-PIP as second-line drug. The last TES conducted in 2014 for AL and
in 2017 for CQ (vivax) showed good responses to both the first-line anti-malarial drugs in the country.

The National Malaria Programme is planning to conduct TES in 2021–2022 and has allocated US$ 20 000 for this. However, the major challenges to conducting TES are the low case burden in Nepal and lack of trained human resources. Equally important for the conduct of a quality study is the availability of adequate funding as discussed in the budget plan. The NMP seeks support from WHO in developing TES proposal, training health workers on TES activity, and providing financial resources to conduct the TES study.

6.4 Sri Lanka: Dr Muzrif Munas, CCP, Anti-Malaria Campaign, Ministry of Health Care and Nutrition

Sri Lanka was certified as a malaria-free country in 2016. Currently, the country is in the phase of prevention of reintroduction of malaria (PoR). However, due to many reasons, receptivity and vulnerability for malaria remain high, causing malariogenic potential in the country.

Currently, around 50 imported malaria cases are detected annually. The reported number of imported cases has been fluctuating since 2011. From 2015 to 2020, 259 imported cases have been reported, and in the majority of these cases, the country of origin is either India or from the African continent. These imported cases reported in the post-elimination phase impose a high risk of re-introduction of malaria in the country.

When detected, each imported case is fully investigated and reviewed by an expert panel (i.e. Case Review Committee). All diagnosed cases are hospitalized and treated under close observation with quality assured drugs, until confirmed as negative by blood film. All cases are followed up after discharge as well. However, complete follow-up rate of these cases varies between 60%–80% per year, as some patients, especially the foreigners/tourists, are lost to follow-up when they leave the country.

The integrated drug efficacy surveillance (iDES) results from 2015 to date shows 3.3% failure of AL in uncomplicated Pf cases. Around 10% of Pv relapses (beyond 28 days) were also documented. Though the failures are less significant, the country has identified the following multifaceted challenges with iDES implementation, and urges global partners to respond to keep the country malaria-free:

➢ Reporting of imported malaria cases from endemic countries.
➢ Increased migration of labour and tourism.
➢ Challenges with the supply chain of antimalarial drugs (procurement of WHO prequalified drugs is in very small quantities, and there is wastage due to non-usage, etc.). Current plans are to address these challenges by increasing coverage of prophylaxis, screening inbound migrants, raising awareness, making uninterrupted supply of first- and second-line drugs, and continuing training on case management.
➢ There is a higher risk for re-introduction of malaria into the country and, therefore, strict monitoring and evaluation of all activities by the AMC is essential and this must continue.
➢ iDES has been already integrated into routine activities of AMC. Support from WHO is expected to strengthen iDES in Sri Lanka.

Currently the country has adopted several best practices which could be considered as strengthening the efforts to sustain the PoR:
➢ Availability of 24-hour national hotline services for reporting of cases and further action.
➢ Strict adherence to National Technical Support Group (TSG) decisions including hospitalization and in-ward management of all detected cases. Regular case review meetings with the TSG can be considered as a best practice related to malaria control in Sri Lanka.
➢ Initiation of parasitological survey within 24 hours and entomological survey within 48 hours from the point of case detection.
➢ Web-based disease surveillance and drug and risk group monitoring system.
➢ Availability of malaria drugs under the supervision of the Anti Malaria Campaign (AMC).

6.5 Timor-Leste: Ms Maria do Rosario de Fatima Mota, Programme Manager, National Malaria Programme, Ministry of Health

Timor-Leste has dramatically changed its malaria landscape in the past 12 years with the malaria burden decreasing steadily until the last reported indigenous case in June 2017. Nine imported malaria cases were reported in 2019, and there have been no malaria deaths since 2015.

Artemether-lumefantrine with PQ is the first-line treatment of uncomplicated Pf and Pv malaria since 2017. The combination of AL and PQ single-dose is used against Pf malaria, and AL + PQ 14 days for radical treatment of Pv in non-G6PD, or +PQ once weekly x 8 weeks for G6PD deficient Pv cases. Based on the recommendations of malaria experts, the NTG 2021–2023 for uncomplicated Pv and Pf malaria, including severe forms, were revised. The combination of dihydroartemisin-piperaquine (DHA-PIP) and primaquine (PQ) was added as a second-line drug, with artesunate IV followed by a full dose of AL when oral medication can be tolerated for severe form of Pf and Pf. However, PQ is not given to children below one year of age, Glucose 6 Phosphate Dehydrogenase and pregnant and lactating women.

iDES started in July 2017 after implementation of the National Malaria Elimination Strategy. Results of AL for treatment of Pf and Pv from 2017 to 2019 showed 100% ACPR in some 20 Pf and Pv cases that completed the iDES 28-day follow-up, and no Day 3 parasitemia. Four Pv cases reported in 2019 were imported from West Papua. However, two Pv cases out of four relapsed thrice or twice respectively, despite Directly Observed Treatment (DOTs) on a full course of PQ per week for eight weeks. The most likely reason could be inadequate metabolism of PQ in these patients. All mix infection cases recovered, and parasites cleared using AL+PQ.

The iDES team at the national and municipality levels are capacitated and maintained, with financial support from Global Fund secured for continuity of iDES. Moreover, collaboration with the Army Malaria Research Institute, Brisbane for PCR and external quality control is ongoing. Despite progress, there are challenges in implementation of iDES:, decreasing number of malaria cases with difficulty follow up in hard to reach areas; repeated relapses among the imported Pv cases from West Papua, hence another round of follow-up after retreatment; difficulties in procurement of small quantities of anti-malarial drugs through MoH, therefore requiring support to procure from GF-WOMBO system; and molecular assays need to be done at collaborative laboratories in Australia. Funds has been allocated to carry out iDES in the country since 2017 and ECAMM since 2009.
It was mentioned that in iDES, there is no need for ethical clearance as this is integrated in the routine programmatic surveillance of all cases, as defined in the NTG and Elimination Strategy.

7. **Session 5: Panel discussion led by Dr Kamini Mendis, Independent Consultant, Sri Lanka, and Dr Pedro Alonso, Director, Global Malaria Programme, WHO-HQ**

There was discussion on the updates provided by the countries as well as need to conduct quality studies.

8. **Session 6: Presentation of country plans**

The countries presented their TES plans for 2021. Some clarifications were raised by the panel and facilitators and these were appropriately responded to.

**Bangladesh**

The country plans to conduct TES for AL in three sites/districts in the Chittagong Hill Tracts in 2021, and another TES testing CQ + PQ in three sites in 2022, with a proposed budget of approximately US$ 60 000 per year. There are six WHO certified L1 microscopists at the central level, but they would need two batches of refresher microscopy training for laboratory medical technologists. Implementation will be by the programme in collaboration with BRAC. The programme plans three monthly monitoring and supervision visits by PI, Co-PI, CI and internal and external (WHO) Clinical Monitors during the implementation period.

**Bhutan**

Bhutan will continue its iDES and has plans for capacity strengthening for laboratory personnel, microscopy competency assessments, and supervision and monitoring. They plan to improve on the reporting system of all diagnosed cases of malaria with revised case report follow-up forms ensuring that all patients receive supervised treatment using DOTs and are followed up to complete cure till Day 28, including severe and imported cases whenever possible.

**India**

For the next two years, India’s NVBDCP and ICMR-NIMR/NIRTH planned to conduct TES to test AL in four sites in the northeast and four sites elsewhere in the country to test AS-SP, and one site to test CQ against vivax malaria, with a budget of US$ 50 000 per site. This proposed budget includes PPEs for the COVID-19 pandemic and capacity-building at each site. In the TES protocol design, provisions will be made to move the study to the adjacent district or state if sufficient number of patients are not enrolled to achieve the required sample size. There is need for more laboratory staff training for both TES and planned iDES activities in low-burden districts.

**Nepal**

The National Malaria Programme is planning to conduct the TES in 2021 to 2022 in five hospital sites mainly in the southern border areas and has allocated US$ 20 000 from the Global Fund. The major challenges to conducting TES are the low case burden in Nepal.
and lack of trained human resources. Equally important for the conduct of a quality study is the availability of adequate funding as discussed in the budget plan. The NMP seeks technical support from WHO in developing the TES proposal, training health workers on TES activity implementation including microscopy, and providing adequate financial sources to conduct the study.

An observation was raised that Nepal reported only about 131 indigenous cases, with 82% imported cases from neighbouring countries, in 2019; hence the need to improve and strengthen the elimination surveillance system. With very few indigenous cases, the country can set up iDES to follow up on the indigenous cases (or case-based surveillance), as this was also last year’s TES meeting recommendations to the programme.

Sri Lanka

In order to improve iDES, Sri Lanka proposes capacity-building of clinicians and laboratory technicians (PHLT); strengthening of laboratory facilities; establishing a laboratory for molecular monitoring (sequencing and genotyping), including the molecular monitoring of parasitic drug resistance genes. Currently, samples are tested in Singapore. The AMC also plans to procure WHO prequalified drugs either through the WHO Country Office or through pooled procurement mechanisms, and to use evidence-based estimation and strict monitoring of the supply chain.

Indonesia

For 2021—2022, Indonesia plans to conduct TES in high-burden border areas in the east (north and southern borders of Papua province), and in some provinces in the central part of the country, to be implemented by Eijkman Institute and the National programme, respectively. To pilot iDES in the low-burden areas of central and western Indonesia, they plan integration of malaria drug efficacy monitoring into the surveillance programme. Systematic surveillance is not (yet) in place and there is a need for local capacity-building for malaria management, to include capacity-building for laboratory personnel, competency assessment, monitoring and supervision.

Timor-Leste

TL will conduct iDES and has made plans for capacity-building for health and laboratory personnel, competency assessments and supervision. It has budgeted approximately US$10,500 per year for iDES activities, mainly to cover costs for HR training, supervision, microscopy strengthening/training in the national laboratory for confirmation of cases, supervision transport and fuel costs, supplies and documentation, costs for patient DOTs and follow-up by local staff, especially for *Plasmodium vivax* cases (one year), and slide validation and PCR confirmation.

9. Session 7: Conclusions and recommendations

9.1 Recommendations for the countries

- National treatment policies should be updated, if relevant, based on results of TES and WHO treatment guidelines. Countries are encouraged to include another ACT as a second line treatment of (and ensure availability of stock).
- Protocols should be based on WHO standardized protocols (template) with relevant modification as per national regulations/guidelines.
➢ If failure to achieve required sample size is a regular feature in high-burden countries, the selection of the study sites needs to be revisited during planning. National and WHO EC must be informed of any site amendment.

➢ Countries near elimination should strengthen case-based surveillance, including monitoring of response to antimalarials. Funding for this should be secured in a sustainable manner, and including these in country Global Fund proposals is encouraged.

➢ TES studies are totally reliant on quality microscopy. Capacity-building should continue even during the ongoing COVID-19 pandemic using innovative methods.

➢ In the context of COVID-19, suspected cases should be tested as per national guidelines ensuring safety of the patients and the staff.

➢ Confirmed cases of malaria, if found to be positive for COVID-19, should not be included in TES, but should be treated as per national guidelines.

➢ If confirmed cases of malaria were found to be positive for COVID-19 during follow-up, such cases should be withdrawn from the study and referred to the health facility as per the respective national guidelines.

9.2 Recommendations for WHO

➢ WHO should continue to support quality assurance for microscopy, PCR and molecular markers in the network/Region, including financial support, where relevant.

➢ WHO should provide technical support and guidance to countries for quality implementation of TES in the light of the dynamic pandemic situation.

➢ WHO should support capacity-building of country programmes for surveillance, which includes iIDES.
Annex 1

Agenda

Opening session
Welcome address by Dr Tjandra Yoga Aditama, Ag CDS, WHO South-East Asia
Message from Dr Poonam Khetrapal Singh, WHO Regional Director for South-East Asia
Remarks by Dr Pedro Alonso, WHO Global Malaria Programme, WHO Headquarters

Session 1: Updates
Updates on antimalarial drug resistance, including partial resistance to artemisinin and partner drug
Updates on drug efficacy surveillance systems: routine TES, integrated drug efficacy surveillance (iDES) in the context of malaria elimination and importation
Updates on progress and TES studies in the South-East Asia Region, and review of recommendations of previous TES network meeting and quality assurance

Session 2: Country presentations on recent therapeutic efficacy studies/antimalarial drug efficacy surveillance
Presentations by TES Principal Investigators of Bangladesh, India, Indonesia and Nepal

Session 3: Updates on antimalarial resistance studies, iDES and molecular markers
Different drug efficacy surveillance systems: routine TES, iDES in the context of elimination, and importation
Updates on Kelch 13, P14 and other molecular markers for resistance

Session 4: Integrated drug efficacy surveillance (iDES) in near elimination/elimination countries
Presentations by Malaria Programme Officers of Bhutan, Sri Lanka and Timor-Leste

Session 5: Panel Discussion

Session 6: Presentations of country plans
Plenary presentations and discussions of country plans/drug resistance surveillance and budget by Country TES Principal Investigators and/or Malaria Programme Officers of Bangladesh, India, Indonesia, Nepal, Bhutan, Timor-Leste, Maldives and Sri Lanka

Session 7: Next steps and closing
Conclusions and recommendations
Closing remarks by Dr Tjandra Yoga Aditama Director
## Annex 2

### List of participants

#### Government Nominees

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Given the emergence of resistance to artemisinins, ACTs and other antimalarial drugs in the Asia-Pacific Region, monitoring drug resistance using standardized WHO therapeutic efficacy study (TES) protocols is an important activity of national malaria programmes (NMPs) to identify early deterioration in the efficacy of recommended treatment regimens.

A meeting of the BBINS Malaria Drug Resistance Monitoring Network was held virtually on 19–21 August 2020. Country representatives from NMPs and Principal Investigators from Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Timor-Leste, WHO country office focal points, representatives from the WHO Regional Office, experts and partners attended the meeting.

Countries presented the results of TES studies conducted in 2018–2019. Panel discussions were held on updating malaria treatment regimens based on evidence generated from TES studies, and the challenges to conducting the studies during the COVID-19 pandemic while ensuring safety of patients and health staff. This document is a report of the virtual meeting, and includes the salient discussions and conclusions and recommendations agreed upon.