WHO-EM/MAL/372/E

Report on the

Intercountry meeting of national malaria programme managers from HANMAT and PIAM-net countries

Sharm El Sheikh, Egypt
21–22 February 2013

World Health Organization
Regional Office for the Eastern Mediterranean

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1. INTRODUCTION

The third intercountry meeting of national malaria programme managers from HANMAT and PIAM-NET countries was organized by the World Health Organization Regional Office for the Eastern Mediterranean in Sharm El Sheikh, Egypt, from 21 to 22 February 2013. The objectives of the meeting were to:

- update the participants about the monitoring efficacy of antimalarial medicines and status of artemisinin resistance.
- present new therapeutic efficacy data from sentinel sites.
- plan for the next round of therapeutic efficacy studies (TES).

National malaria programme managers and focal points for case management attended from: Afghanistan, Djibouti, Islamic Republic of Iran, Pakistan, Saudi Arabia, Somalia, South Sudan, Sudan, Yemen, Ethiopia and Eritrea. WHO staff from headquarters and field staff from Afghanistan, Djibouti, Islamic Republic of Iran, Pakistan, Somalia, Sudan and Yemen also attended the meeting.

The Chair was shared on a rotating basis. The programme and list of participants are included as Annex 1 and 2, respectively.

2. TECHNICAL PRESENTATIONS

2.1 Therapeutic efficacy monitoring and the WHO protocol

M. Warsame /HQ

Treatment failure is not always due to drug resistance, it can be caused by many other factors, including: inadequate dosage, drugs of poor quality, pharmacokinetic factors, patient immunity and compliance. Further, PCR analysis must be conducted on treatment failures to determine whether treatment failure during follow-up was due to a true recrudescence (the same parasite), or a re-infection (caused by a new parasite). There are several tools available for monitoring drug efficacy and resistance, including the in vivo study using the WHO protocol (2009), pharmacokinetic studies, in vitro studies, and studies of molecular markers. However, the in vivo study results are the gold standard which is used to determine whether a change in treatment policy is required.

The methods for conducting a TES were reviewed in detail. The WHO template protocol is designed for studies of *P. falciparum;* however, it can be adapted for studies of *P. vivax.* Study follow-up is recommended over 28 days, but study follow-up can extend to 63 days for medicines which have longer half-lives. The protocol has been pre-approved by the WHO Ethical Review Committee. The ethical committee determined that it would be unethical to include women of childbearing age for whom pregnancy status is unknown, given the unknown safety profile of administration of artemisinin during pregnancy.

The 2009 protocol addresses the changing epidemiology of malaria and the challenges of adequate patient recruitment in low transmission areas, by expanding the baseline parasitemia range. Specifically, in low transmission areas, the lower limit of baseline parasitemia can be reduced to 500 parasites/uL. In very low transmission areas, the baseline parasitemia was reduced to 250 parasites/ul. However, such a low threshold demands highly skilled microscopists. Sample size can also be increased by increasing the age band. For example, patients of up to 10 years could be included in moderate transmission areas, and patients of all ages could be recruited in low transmission areas.

WHO Global Malaria Programme, in coordination with WHO Regional Office, is available to review the TES protocol, facilitate training and monitoring at study sites, provide financial and technical support, provide medicines and filter papers, and assist with quality control, report writing and publications. All countries are encouraged to publish their findings, in order to contribute to the scientific literature of therapeutic efficacy, and ultimately contribute to the creation of evidence and subsequent policy-setting. Journal fees exist for some journals, however articles can be submitted free of charge to the WHO Bulletin and the Eastern Mediterranean Health Journal.

2.2 Update on artemisinin resistance

Dr M. Warsame, WHO headquarters

The emergence of artemisinin resistance in four countries in the Mekong subregion presents a major threat to global malaria control and elimination efforts. Drug resistance monitoring plays a critical role in the global fight against artemisinin resistance. As researchers have yet to identify a molecular marker, currently the best available indicator for artemisinin resistance is the increase in day 3 parasite rate. If this proportion increases to more than 10%, artemisinin resistance is suspected, and must be subsequently confirmed with a study of artesunate monotherapy over 7 days.

An algorithm to help interpret results of TES findings has been developed. An increase in the day 3 positivity rate is indicative of reduced sensitivity to the artemisinin component, while an increase in treatment failure ($\geq$10%) afterwards up to day 28 is indicative of reduced sensitivity to the partner drug. Due to the different mechanisms of action in each drug in the combination, “ACT resistance” is inaccurate and should be avoided. Testing the partner drug alone would be unethical, as it would mean treating a patient with monotherapy. Testing the ACT as recommended, using a TES is the most effective way to determine the efficacy of the partner drug. Countries should have second- and third-line treatments ready, in case a change in treatment policy is needed. If the partner drug is failing, a new ACT could be selected. However, if artemisinin resistance emerges, it will be more problematic to find an alternative.

Maps showing the rates of treatment failure and day 3 positivity for study sites have recently been created. The maps can be customized by treatment, outcome indicator, geographic site, and year. The maps are dynamic, and allow the user to see changes in the study results over time, and to compare selected sites. Following selection, data from can be exported to Excel. Maps will also be available on the web site in the coming months.

2.3 Microscopy for TES

Professor A. Adeel, WHO Temporary Adviser, King Saud University

Microscopy is one of the most important elements for conducting a high quality TES. For the purposes of screening and enrolment, three blood slides are needed per patient, two thick and one thin. Blood slides are used for initial screening (first thick smear), to calculate parasite density and test for mixed infections (second thick smear), and to confirm mixed infection if the thick smear was inconclusive (thin smear). Blood slides are taken throughout the study, on days 2, 3, 7, 14, 21, 28, and subsequently every seven days until study completion. Special rules apply for dealing with low and high parasitic counts. To ensure quality assurance, two qualified microscopists should read the slides independently, and parasite densities should be calculated as an average of the two counts. Discordant results are to be examined by a third, independent microscopist. An excellent reference CD for malaria microscopy is available from the CDC, with examples of over 300 slides. Participants were advised to adhere to the guidelines for microscopy in the TES protocol.

2.4 TES challenges and implementation shortcomings

Dr M. Warsame, WHO headquarters

The following TES challenges were identified by programme managers:

- Poor security in areas of conflict
- Scarcity of good microscopists
- Recruitment of patients in areas of low transmission
  - It has been suggested that studies could be conducted in sentinel sites over a full year, rather than only during the transmission season. This would require a protocol specific to this approach.
  - If caseload is still too low, results could be pooled across sites. However, it is still useful to keep the same sentinel sites, in order to track changes over time.
- Follow-up
  - Selecting incentives for maintaining follow-up must be considered carefully. Study investigators should strive for a balance between giving incentives and coercion.
- Staffing
  - Staff should be hired to work specifically on the TES: health facility staff should not be expected to be responsible for the TES in addition to their regular workload. Staff costs must be part of the TES budget.

Common errors observed during clinical monitoring of TES have included:

- inadequate preparation time resulting in missing the malaria transmission season
- failure to adhere to the study protocol
- failure to recruit patients who live in close proximity to the hospital
- technical problems with parasitological assessment
- quality control and validation
- data entry problems.

The Excel spread sheet used for data collection could be improved to make it more user-friendly, particularly for staff working at the peripheral level. In addition, the Excel sheet could be expanded to include molecular marker data and side-effects. Data from the sentinel sites be incorporated into the national surveillance system with standardized functions for data collection, analysis and exporting.

2.5 Technical monitoring

N. Abdulrab, Ministry of Public Health and Population of Yemen

Variations in study methods and completeness of case report forms have been observed in all sites. A one-page case report form will be developed to enhance feasibility and ease of data collection. External monitoring is not routinely conducted in all countries, but it should be considered an essential aspect of conducting a TES, as it improves the quality of the study and the data, and ultimately protects the researchers.

2.6 Genotyping to differentiate recrudescence from re-infection: methods, techniques and interpretation of data

Dr Hanan El Mohammady Ismail, NAMRU 3

Multiplex PCR allows for detection of multiple genes in the same primer. Three genetic markers include *msp1, msp2* and *glurp*. The nested PCR increases specificity of the PCR. Recrudescence is identified when there is at least one allele in common between day 0 and the day of failure. A new infection is indicated when all alleles are different. PCR can be used for the detection of antimalarial drug resistance genes: for example the detection of mutations in *dhfr* and *dhps* genes.

Over the last year NAMRU-3 has provided analysis of filter papers from Pakistan, Somalia and Sudan. Parasites observed on day 3 will definitely be caused by the same parasite, and therefore PCR analysis is not required. In Somalia, quadruple and quintuple mutations were detected. In Sudan, with the exception of Gadaref, analysis showed that most of the treatment failures were due to reinfections. In Gadaref, 9 of the 13 treatment failures were confirmed recrudescence. Programmes are encouraged to avoid delays in PCR correction of samples, as delays consequently postpone the interpretation of study findings, prompt changes to treatment policy, and extend the time at which patients are at risk of receiving ineffective treatment.

2.7 Review of treatment policies

G. Zamani, WHO Regional Office for the Eastern Mediterranean Region

Updated available information on treatment policies is shown in Table 1.

Table 1. Updated information on treatment policies in HANMAT/PIAM-NET countries

Country/area	Uncomplicated unconfirmed	*P. falciparum*			Prevention during pregnancy	*P.vivax* treatment	Last drug policy update
		Uncomplicated	Treatment failure (second line)	Severe			
Afghanistan	CQ	AS+SP	QN+D or CL	AM;QN+Doxycycline or Clindamycin	–	CQ+PQ(14d 8 weeks)	2010
Djibouti	AS+SP	AS+SP	ATM-LUM	QN	–	–	2006
Iran (Islamic Republic of)	–	AS+SP (+ PQ in areas with local transmission)	ATM-LUM (+ PQ in areas with local transmission)	AS;QN+D	–	CQ+PQ(14d)	2010
Pakistan	CQ	AS+SP	QN or ATM-LUM	AS;QN	–	CQ+PQ(14d)	2010
Saudi Arabia	–	AS+SP	ATM-LUM	AS,AM;QN	-–	CQ+PQ(14d)	2008
Somalia	AS+SP	AS+SP	AL	AS, QN	SP (IPT)	–	2010
South Sudan	AS+AQ	AS+AQ, DHP (can be an option in private sector)	ATM-LUM	AS,AM;QN	SP(IPT)	AS+AQ (+PQ although not implemented	2006
Sudan	AS+SP	AS+SP	ATM-LUM	QNAM;	–	ATM-LUM +pq (14)	2011
Yemen	AS+SP	AS+SP	ATM-LUM	AM;QN	-–	CQ+PQ(14d)	2009

3. COUNTRY PRESENTATIONS

Participants provided an update of current national treatment policies and the latest therapeutic efficacy results. The TES study results are summarized in Tables 2 and 3. All malaria control programmes are encouraged to continue to share their results promptly after validation and finalization.

Table 2. TES summary resultsfor PIAM-net countries

Country	Site name	Year	Drug	ACPR D28	PCR corrected
Afghanistan	Kunar	2012	AS+SP	100	*
Afghanistan	4 provinces	2007-10	DHA+PPQ	100	*
Afghanistan	4 provinces	2007-10	AS+SP	100	*
Islamic Republic of Iran	Chabahar	2012	AS+SP	100	*
Islamic Republic of Iran	Saravan	2012	AS+SP	100	*
Islamic Republic of Iran	Sarbaz	2012	AS+SP	100	*
Pakistan		2011-12	AS+SP	98-100	*
Pakistan		2011-12	AS+SP	98-100	*
Somalia	Jamame	2011	AS+SP	77.3	*
Somalia	Jowhar	2011	AS+SP	99	*
Somalia	Janaale	2011	AS+SP	95.6	*
South Sudan		2004	AS+SP	91.2	
South Sudan		2004	AS+AQ	92.7	

Table 3. TES summary results for HANMET countries

Country	Site Name	Year	Drug	ACPR D28	PCR corrected
Sudan	Kassala	2011	AS+SP	95.9	
Sudan	W. Nile	2011	AS+SP	94.4	
Sudan	Gadarif	2011	AS+SP	87	
Sudan	Sinnar	2011	AS+SP	86.2	
Sudan	B Nile	2010	AL	98.5	
Sudan	Kassala	2010	AL	100	
Yemen	Sharas	2010	AS+SP	100	*
Yemen	Al Odein	2010	AS+SP	100	*
Yemen	Tor Bin Qais	2010	AS+SP	100	*
Yemen	Al Gafla Amran	2010	AS+SP	100	*
Yemen	Bajul	2010	AL	100	*
Yemen	Jabal Al Sharq	2010	AL	100	*

3.1 Afghanistan

Trials are currently ongoing with the support of Mahidol Oxford Tropical Research Unit. Recent studies have been conducted on DHA-PPQ for the treatment of *P.vivax*, as well as a prevalence study of G6PD deficiency (results not yet published). In Afghanistan, molecular analysis has detected the presence of double *dhfr* and triple *dhps* mutations in Jalalabad. This evidence indicated that resistance to SP was emerging; however, clinical failures were not yet being detected due to the effectiveness of the artemisinin component. Studies of AS+SP for treatment of *P.falciparum* in 2012 have shown high efficacy in four sites.

Chloroquine remains Afghanistan's choice of treatment for *P. vivax*. Programme staff felt that the high number of *P. vivax* cases should continue to be treated with chloroquine, rather than introducing an ACT, since this treatment is still effective, and also alleviates unnecessary drug pressure on artemisinin.

3.2 Islamic Republic of Iran

The Islamic Republic of Iran conducts surveillance monitoring and follow-up of all falciparum cases, regardless of patient origin. Treatment of patients in two areas were found to have 100% ACPR following treatment with AS+SP. TES conducted in the Islamic Republic Iran often have many cases lost to follow-up, largely due to the high number of imported cases.

Islamic Republic of Iran is currently preparing a *P. falciparum* slide bank, in order that new physicians can have access to microscopy slides for their future reference.

3.3 Pakistan

Studies were conducted on AS+SP in two sites in 2011 and 2012. In 2011 the ACPR was reported as 100%. The results of studies conducted in 2012 indicated an ACPR of 98-100%, however the results are currently being finalized. Previous studies conducted in 2008/09 were discontinued due to problems of quality assurance.

3.4 Somalia

In contrast to the seven sentinel sites established in 2002, there are currently three active sentinel sites in Somalia: Jamaame, Jannale and Jowhar. Studies of AS+SP conducted in 2011 show an ACPR (PCR corrected) of 77.3% in Jamame, 99% in Jowhar and 95.6% in Jannale. Day 3 positivity in all three sites was 0%. The high treatment failure rate (S/P in Jammame) indicates that a change in treatment policy should be considered. No data are available on the efficacy of AL in Somalia: TES on AL will begin in the fall of 2013. TES on a new potential drug is planned to be conducted in 2014.

3.5 South Sudan

The most recent therapeutic efficacy studies of ACTs in South Sudan were conducted in 2004. At that time, AS+SP had a PCR-corrected ACPR of 92.7%. This year, studies of AS+AQ and AL will be conducted in three sites starting with Rajaf site; enrolment will begin in March 2013.

3.6 Sudan

TES have been conducted in six sites since 2004. The most recent studies were conducted on AS+SP in 2011, in Kassala, White Nile, Gadarif and Sinnar. The treatment failure from the latter two sites was 13% and 13.8%, respectively. However, these results have yet to be PCR corrected. Study sites were established in Gadarif following communications from physicians who cautioned that the treatment was not working. Studies of artemether-lumefantrine in 2010 found treatment failure rates of 0% in Kassala and 1.5% in the Blue Nile sites.

The national malaria control programme in Sudan is also engaging in post-marketing stability studies, with a focus on AS+SP in four sentinel sites. A study of treatment adherence found that 23% of uncomplicated malaria cases at health facilities were being treated with artemether injections. At the community level, 13% of cases were being treated with SP alone.

The national malaria control programme in Sudan and all participating countries were encouraged to send filter papers for PCR correction as soon as possible. Filter papers from the 2011 study were received only last month. Further, all studies must be validated through clinical monitoring by an external expert.

3.7 Yemen

Studies of first- and second-line treatment have been conducted in Yemen consistently over the last 10 years. There are currently six sentinel sites in the country. Each site has a team of staff which are dedicated to the TES. Supervision is active at the beginning, middle and the end of each study. Currently there are four sites monitoring AS+SP and two sites monitoring AL. The ACPR (PCR corrected) was 100% in all sites.

Innovative solutions helped to overcome challenging field settings. For example, a mobile team set up a clinic in a school which is accessible to all study patients. In order to monitor both treatment doses of AL, patients are visited at home in the early morning and early evening. The Yemen team will monitor AS+SP in all sites in 2013.

4. RECOMMENDATIONS

1. Plan for review and update the antimalarial drug policy taking into consideration:
   - the new recommendations of MPAC related to inclusion of primaquine as gametocytocidal drug
   - the emergence of artemisinin resistance in certain areas in South East Asia
   - the high proportion of failure to SP+ AST in some sites in Somalia and Sudan.
2. Continue to strengthen monitoring invivo efficacy of first- and second-line drugs and other potential drugs. Molecular analysis of all cases on day zero will be valuable.
3. Follow up to 28 days using protocol of invivo monitoring, as part of the strategy of malaria elimination, all cases of falciparum, particularly local cases, with filter paper sampling, as part of routine surveillance, to ensure clinical and parasitological cure. The experience of the Islamic Republic of Iran in following up all cases as part of malaria surveillance is successful and could serve as an example for other similar settings.
4. Consider inclusion of all annual PF cases, having the inclusion criteria, in view of reduction of number of cases in several sites in countries controlling malaria, if feasible, and in case the site is of particular epidemiological value. The experience should be properly documented to contribute to the global guidance on protocol update.
5. Somalia should plan to organize a meeting with all stakeholders for urgent (interim) update of the drug policy considering the high failure rate to AST + SP from Jamame and data from molecular study showing high proportion of quintuple mutations to SP in Johawr and Jamame. In the meantime, repeat monitoring of AST and SP in Jamame. All sites should monitor ART+ LUM.

Annex 1

PROGRAMME

Thursday, 21 February 2013

08:00–08:30	Registration	
08:30–09:00	Opening session • Welcome Speech • Nomination of Officers • Objectives of the meeting and methods of work	*Dr H. Atta*
09:00–09:30	Update on artemisinin resistance and monitoring efficacy, plan for its containment, generic format of the WHO protocol for adaptation of countries	*Dr M. Warsame*
09:30–10:00	Data processing, Excel sheet entry analysis and interpretation of results	*Dr A. Barrette*
10:00–11:00	Discussion	
11:00 – 11:30	Standard procedures for the microscopy of therapeutic efficacy studies and quality control	*Dr A. Adeel*
11:30–12:30	TES implementation shortcomings: experience from countries and discussion – Technical monitoring	*Dr M. Warsame* *Dr N. Abdulrab*
12:30–14:00	Review of current drug policies	*Dr H. Atta* *Dr G. Zamani*
14:00–17:00	Country presentations on the results of therapeutic efficacy studies: – Afghanistan – Islamic Republic of Iran – Pakistan – Somalia – South Sudan – Sudan – Yemen	*Country Representatives*

Friday, 22 February 2013

08:30–09:00	Genotyping to differentiate recrudescence from re-infection: methods, techniques and interpretation of data	*Dr H. El Mohammady Dr M. Warsame*
09:00–09:30	Discussion	
09:30–11:00	Planning of the therapeutic efficacy studies for 2013–2014	*Group work*
11:00–14:00	Presentation of plans of the therapeutic efficacy studies for 2013–2014	
14:00–15:00	Conclusions and recommendations	
15:00	Closing session	

Annex 2

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