廣州中醫藥大學
Guangzhou University of Chinese Medicine

South-South cooperation in science and technology to address climate change training courses

Mass Administration (MAD) With Artemisinin-Piperaquine Combination and Malaria Elimination

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Nov.2012

OUTLINE

- Background
- Artequick®
- Fast Eliminating Malaria by Sources Eradication(FEMSE)
- Experiences
- Next work

1. BACKGROUND

Malaria is a kind of serious infective diseases

- Malaria is caused by a parasite called Plasmodium, which is transmitted by the bites of infected mosquitoes. In the human body, the parasites multiply in the liver, and then infect red blood cells.

1. BACKGROUND

Malaria causes significant Economic losses in high-burden countries

- There were an estimated 655,000 malaria deaths in 2010, of which 91% were in Africa. Approximately 86% of malaria deaths globally were of children under 5 years old.
- Malaria can decrease the gross domestic product of some high-burden countries by over 1%.

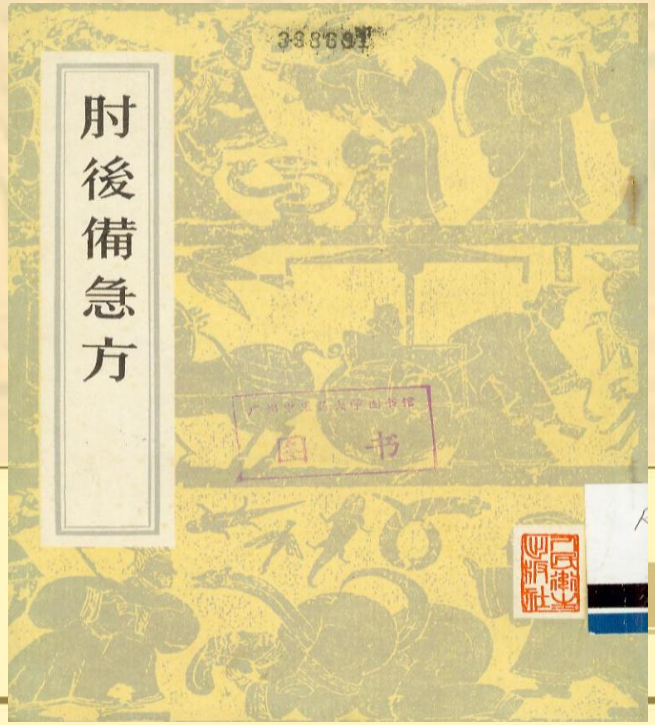
1. BACKGROUND

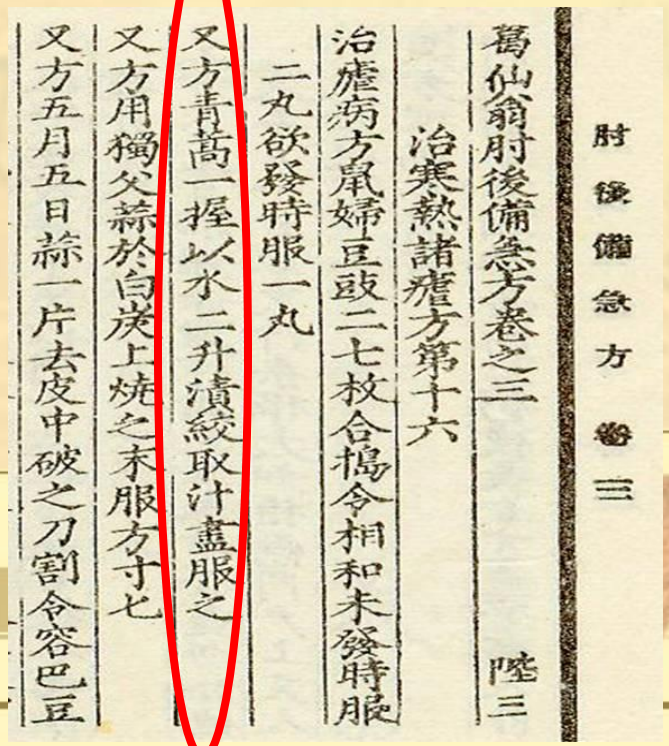
why global malaria is hard to eliminate?

- Serious spread of resistant Plasmodium falciparum
- The patients can not receive treatment of the ACTs in time
- Malaria elimination strategies
  - Mainly killing the mosquitoes
  - National anti-malarial systems were imperfect
  - The capacity of eliminating malaria wasn't enough, such as drug delivery system and education of locals.

2. Artequick®

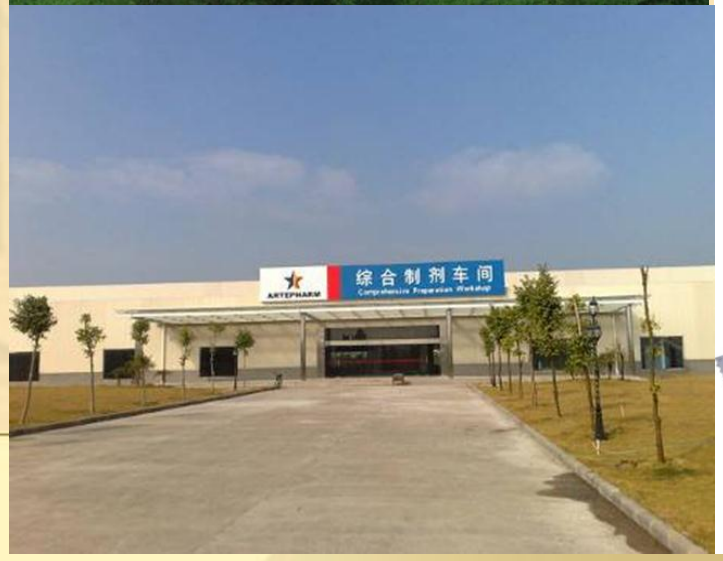
- Handbook of Precriptions for Emergency Treatments by Ge Hong (283-343):
- "Take one bunch of qinghao, Soak in two sheng(~0.4 L) of water, wring it out to obtain the juice and ingest it in its entirety"





2. Artequick®——High efficacy and Low toxicity of Artequick

- 1959 cases have been intensively observed at 13 clinical trial study sites in 6 countries.
- The 28-day cure rate in treatment with 1809 cases of uncomplicated Plasmodium falciparum malaria was 98.1%;that of 150 cases of vivax malaria was 97.8%.
- The mean fever clearing time was 28±24 hours.
- The mean parasite clearing time was 48±24hours.



Indus-triali-zation of Arte-quick®

3. FEMSE(Fast Eliminating Malaria by Sources Eradication)

- Mass administration of antimalarial drug-ATQ- was conducted in the highly malaria endemic area, by the way of combining malarial prevention with elimination, completely removing Plasmodium falciparum in the human body, and then the mosquito can not be infected ,thereby blocking the spread of malaria.
- FEMSE was proposed by Professor Li guoqiao, it was an effective approach using ACT for malaria elimination in malaria-endemic countries .
- The method made a good effect in Cambodia and Comoros, won the recognition of these countries and received the widespread concern from international community.

The Achievement Gained from the FEMSE in Cambodia （2004-2006）

- Mass administration of ATQ was conducted among 30,000 inhabitants from 27 natural villages, in the highly malaria endemic area of Kampong Speu Province in Cambodia. Three months after the mass administration, the parasites carriage rate declined from 52.3% to 5.2%,and there was no death cases of malaria.

The Achievement Gained from the FEMSE in Comoros (2007)

- FEMSE program was conducted in about 40,000 inhatbitants in the Moheli island of Comoros. Three months after the administration, the parasites carriage rate declined 98.6%, and there was no death cases of malaria.

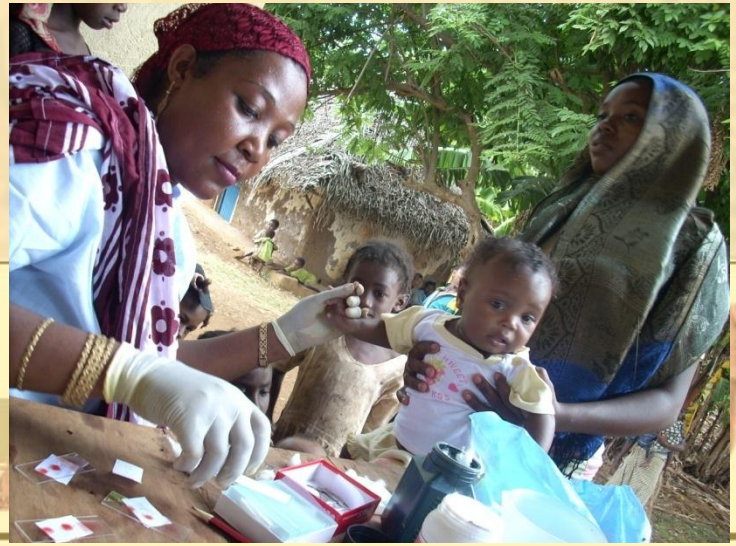
The photos about Mass administration scene in Comoros

The Achievement Gained from the FEMSE in Comoros（2007）

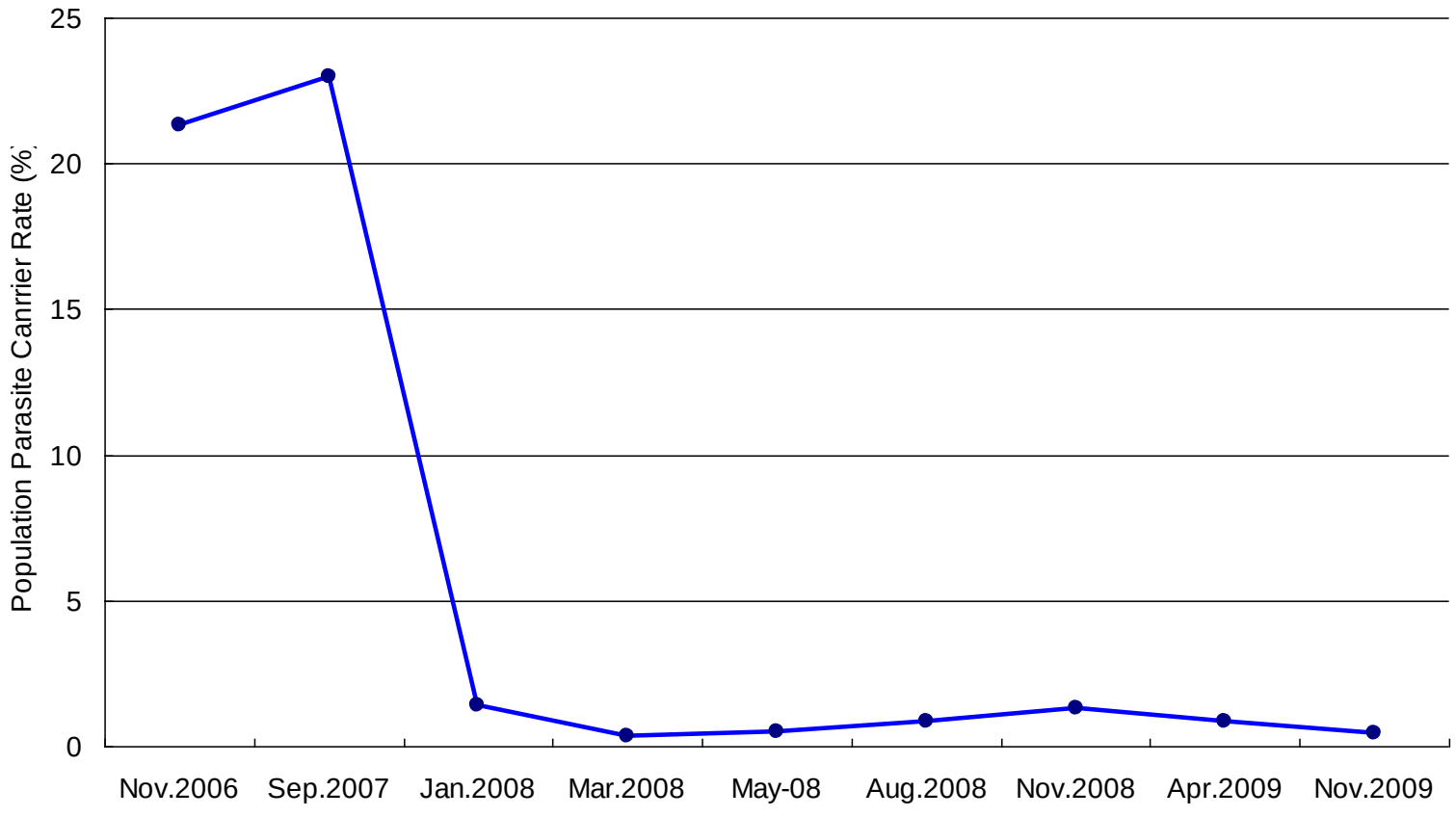
- Since the implementation of this program, Moheli island save 20 or more children's life every year , also there was a decrease of 6000 people suffering from malaria.
- This program promoted the friendship between the two countries, and president of Comoros and other officials visited China twice, to recommend the achievement of the FEMSE to the other African Heads of State.

The Achievement Gained from the FEMSE in Comoros（2007）

- This program also strengthened communication and exchanges with the WHO and other international organizations, WHO supported 20,000 nets for FEMSE, and WHO Director-General Margaret Chan, Assistant Director-General have coordinated the program.
- Reuters, Spanish news agency, Australia SBS, the BBC, Youtube website and other Asian/ African countries media have reported this program.

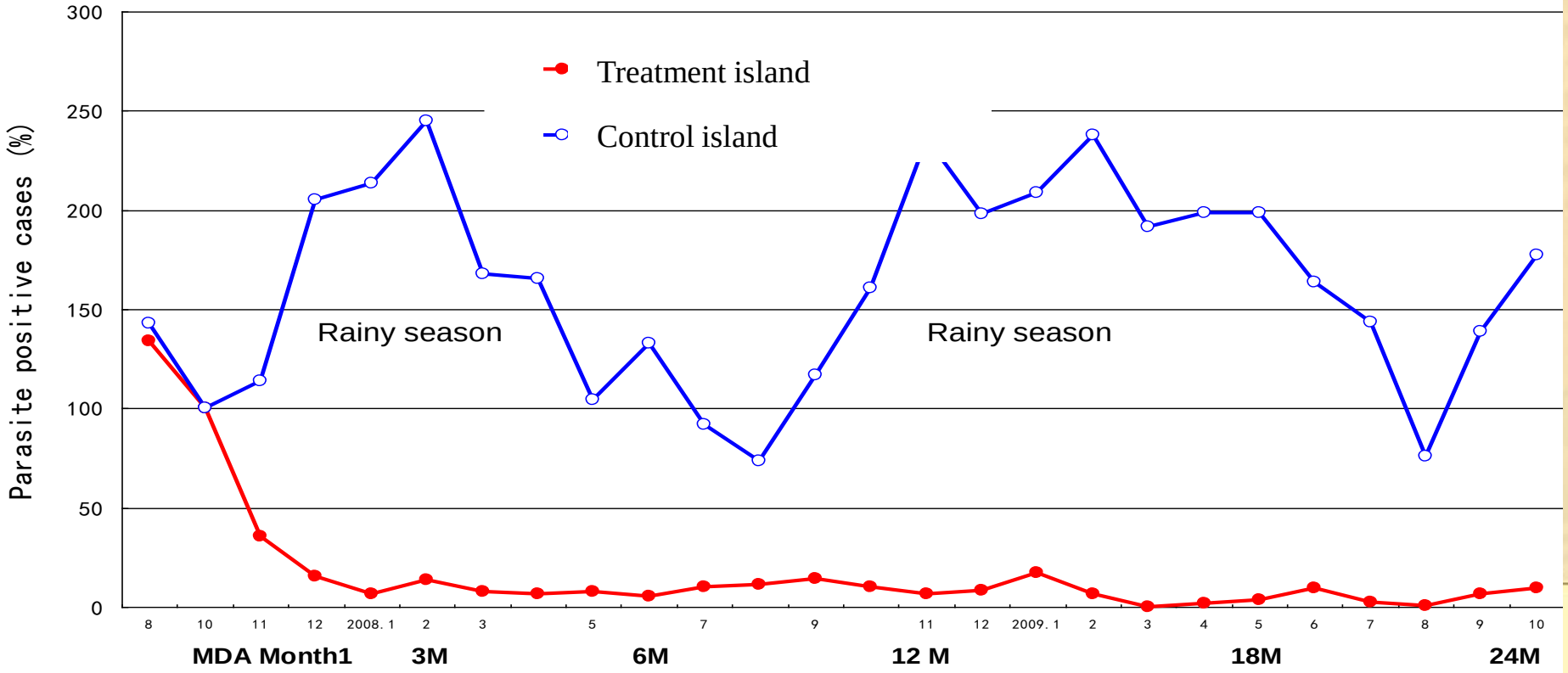


The parasite carriage rate after twice mass administration

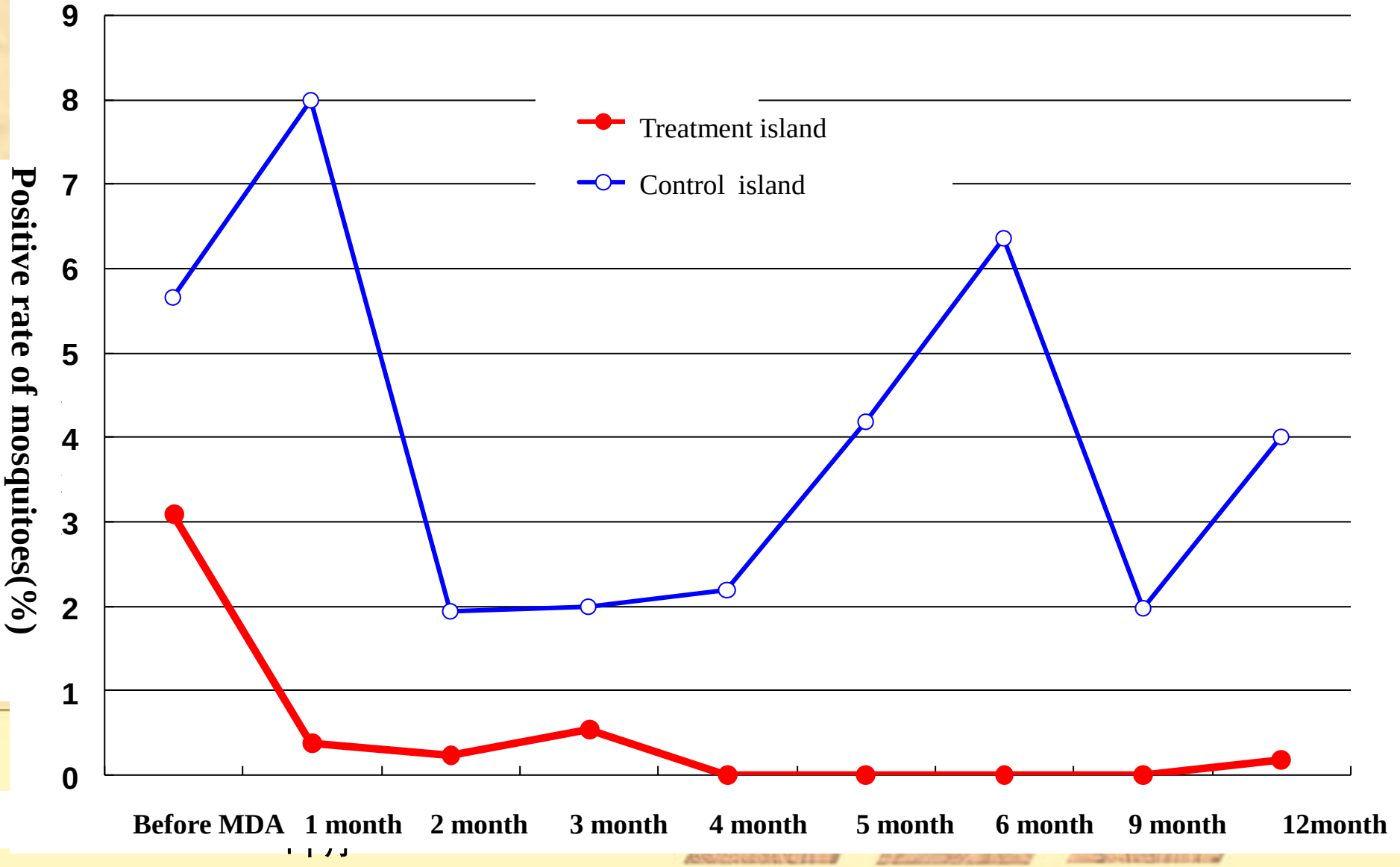


Journal of Guangzhou University of Traditional Chinese Medicine, 2010,27(1):90-98.

Comparing the positive parasite rate of patients of two islands in fixed-point hospital



The surveillance result of infection positive rate of mosquitoes



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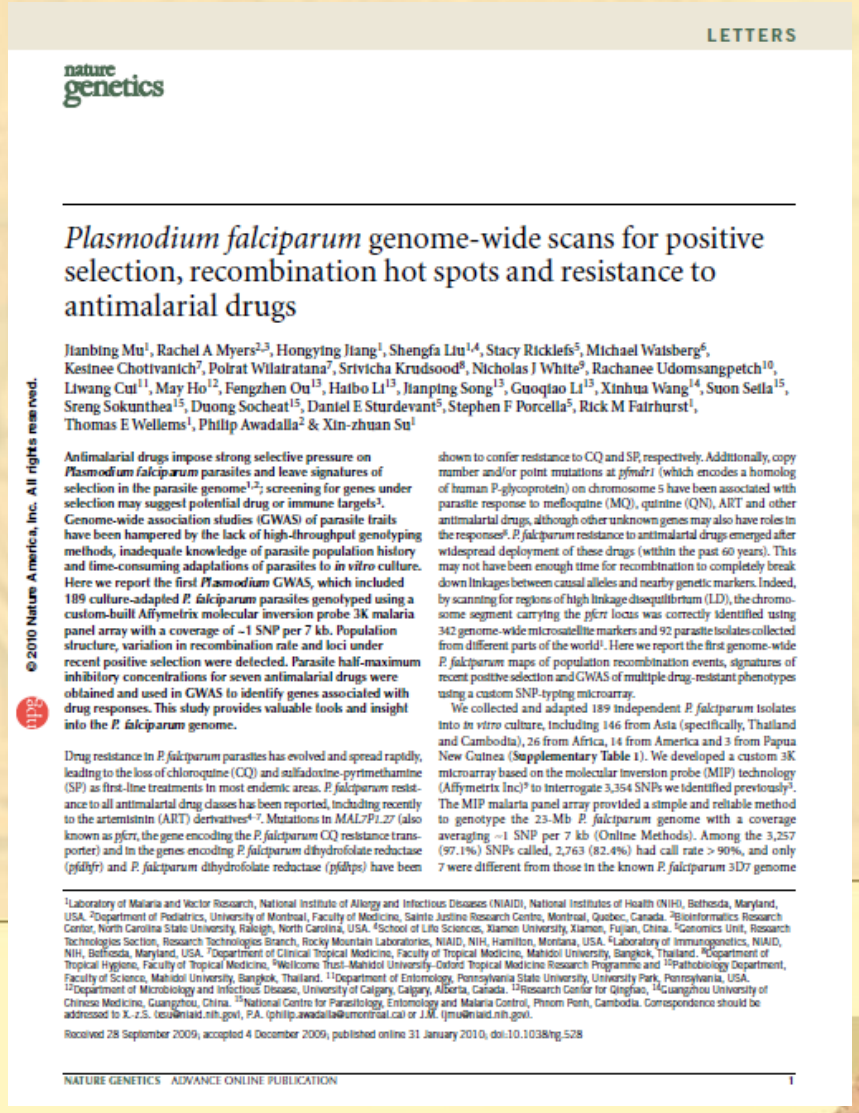

LETTERS

nature genetics

Plasmodium falciparum genome-wide scans for positive selection, recombination hot spots and resistance to antimalarial drugs

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Antimalarial drugs impose strong selective pressure on *Plasmodium falciparum* parasites and leave signatures of selection in the parasite genome[1,2]; screening for genes under selection may suggest potential drug or immune targets[3]. Genome-wide association studies (GWAS) of parasite traits have been hampered by the lack of high-throughput genotyping methods, inadequate knowledge of parasite population history and time-consuming adaptations of parasites to *in vitro* culture. Here we report the first *Plasmodium* GWAS, which included 189 culture-adapted *P. falciparum* parasites genotyped using a custom-built Affymetrix molecular inversion probe 3K malaria panel array with a coverage of ~1 SNP per 7 kb. Population structure, variation in recombination rate and loci under recent positive selection were detected. Parasite half-maximum inhibitory concentrations for seven antimalarial drugs were obtained and used in GWAS to identify genes associated with drug responses. This study provides valuable tools and insight into the *P. falciparum* genome.

Drug resistance in *P. falciparum* parasites has evolved and spread rapidly, leading to the loss of chloroquine (CQ) and sulfadoxine-pyrimethamine (SP) as first-line treatments in most endemic areas. *P. falciparum* resistance to all antimalarial drug classes has been reported, including recently to the artemisinin (ART) derivatives[4–7]. Mutations in *MAL7P1.27* (also known as *pfcrt*, the gene encoding the *P. falciparum* CQ resistance transporter) and in the genes encoding *P. falciparum* dihydrofolate reductase (*pfdhfr*) and *P. falciparum* dihydrofolate reductase (*pfdhps*) have been shown to confer resistance to CQ and SP, respectively. Additionally, copy number and/or point mutations at *pfmdr1* (which encodes a homolog of human P-glycoprotein) on chromosome 5 have been associated with parasite response to mefloquine (MQ), quinine (QN), ART and other antimalarial drugs, although other unknown genes may also have roles in the responses[8]. *P. falciparum* resistance to antimalarial drugs emerged after widespread deployment of these drugs (within the past 60 years). This may not have been enough time for recombination to completely break down linkages between causal alleles and nearby genetic markers. Indeed, by scanning for regions of high linkage disequilibrium (LD), the chromosome segment carrying the *pfcrt* locus was correctly identified using 342 genome-wide microsatellite markers and 92 parasite isolates collected from different parts of the world[1]. Here we report the first genome-wide *P. falciparum* maps of population recombination events, signatures of recent positive selection and GWAS of multiple drug-resistant phenotypes using a custom SNP-typing microarray.

We collected and adapted 189 independent *P. falciparum* isolates into *in vitro* culture, including 146 from Asia (specifically, Thailand and Cambodia), 26 from Africa, 14 from America and 3 from Papua New Guinea (**Supplementary Table 1**). We developed a custom 3K microarray based on the molecular inversion probe (MIP) technology (Affymetrix Inc)[9] to interrogate 3,354 SNPs we identified previously[3]. The MIP malaria panel array provided a simple and reliable method to genotype the 23-Mb *P. falciparum* genome with a coverage averaging ~1 SNP per 7 kb (Online Methods). Among the 3,257 (97.1%) SNPs called, 2,763 (82.4%) had call rate > 90%, and only 7 were different from those in the known *P. falciparum* 3D7 genome

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Received 28 September 2009; accepted 4 December 2009; published online 31 January 2010; doi:10.1038/ng.528

1. *Plasmodium falciparum genome-wide scans for positive selection, recombination hot spots and resistance to antimalarial drugs.*

Nature Genetics.

Published online 31 January 2010; doi:10.1038/ng.528

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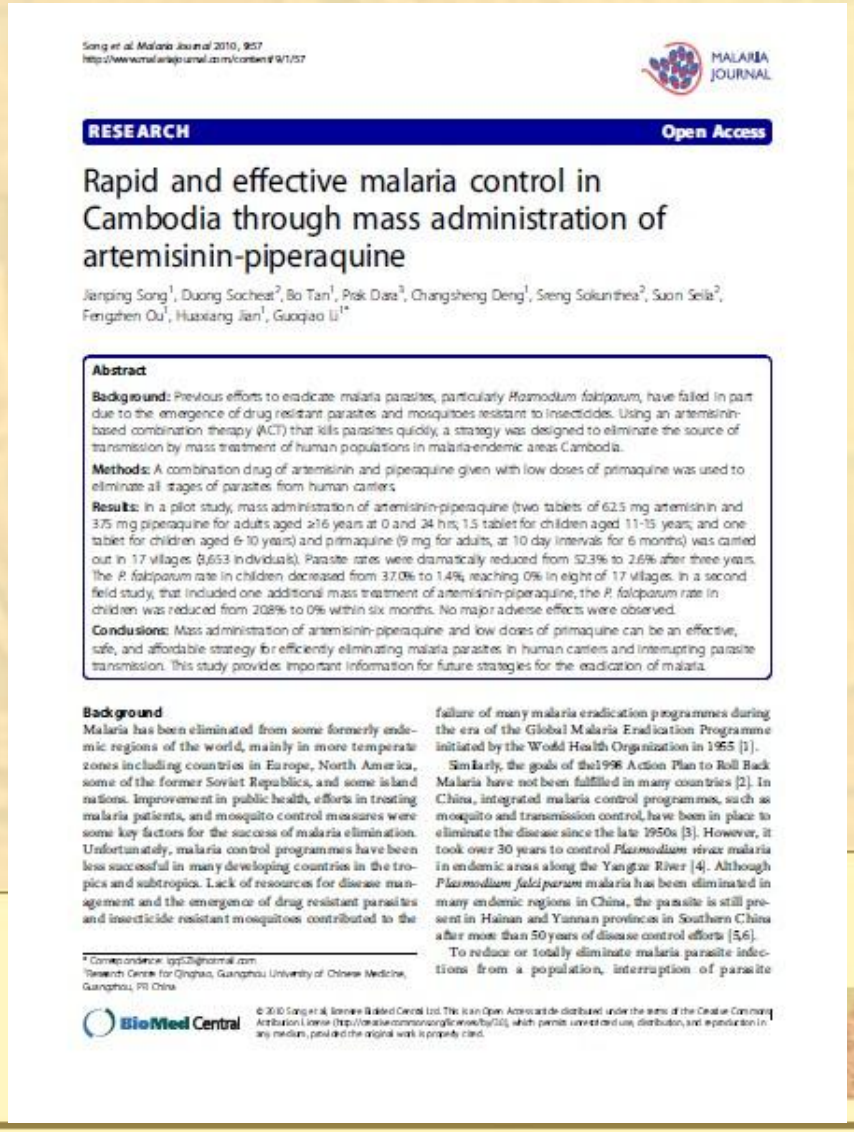

Song et al. Malaria Journal 2010, 9:57
http://www.malariajournal.com/content/9/1/57

MALARIA JOURNAL

RESEARCH Open Access

Rapid and effective malaria control in Cambodia through mass administration of artemisinin-piperaquine

Jianping Song[1], Duong Socheat[2], Bo Tan[1], Prak Dara[3], Changsheng Deng[1], Seng Sokunthea[2], Suon Seila[2], Fengzhen Ou[1], Huaxiang Jian[1], Guoqiao Li[1*]

Abstract

Background: Previous efforts to eradicate malaria parasites, particularly *Plasmodium falciparum*, have failed in part due to the emergence of drug resistant parasites and mosquitoes resistant to insecticides. Using an artemisinin-based combination therapy (ACT) that kills parasites quickly, a strategy was designed to eliminate the source of transmission by mass treatment of human populations in malaria-endemic areas Cambodia.

Methods: A combination drug of artemisinin and piperaquine given with low doses of primaquine was used to eliminate all stages of parasites from human carriers.

Results: In a pilot study, mass administration of artemisinin-piperaquine (two tablets of 62.5 mg artemisinin and 375 mg piperaquine for adults aged ≥16 years at 0 and 24 hrs; 1.5 tablet for children aged 11-15 years; and one tablet for children aged 6-10 years) and primaquine (9 mg for adults, at 10 day intervals for 6 months) was carried out in 17 villages (8,653 individuals). Parasite rates were dramatically reduced from 52.3% to 2.6% after three years. The *P. falciparum* rate in children decreased from 37.0% to 1.4%, reaching 0% in eight of 17 villages. In a second field study, that included one additional mass treatment of artemisinin-piperaquine, the *P. falciparum* rate in children was reduced from 20.8% to 0% within six months. No major adverse effects were observed.

Conclusions: Mass administration of artemisinin-piperaquine and low doses of primaquine can be an effective, safe, and affordable strategy for efficiently eliminating malaria parasites in human carriers and interrupting parasite transmission. This study provides important information for future strategies for the eradication of malaria.

Background

Malaria has been eliminated from some formerly endemic regions of the world, mainly in more temperate zones including countries in Europe, North America, some of the former Soviet Republics, and some island nations. Improvement in public health, efforts in treating malaria patients, and mosquito control measures were some key factors for the success of malaria elimination. Unfortunately, malaria control programmes have been less successful in many developing countries in the tropics and subtropics. Lack of resources for disease management and the emergence of drug resistant parasites and insecticide resistant mosquitoes contributed to the failure of many malaria eradication programmes during the era of the Global Malaria Eradication Programme initiated by the World Health Organization in 1955 [1].

Similarly, the goals of the1998 Action Plan to Roll Back Malaria have not been fulfilled in many countries [2]. In China, integrated malaria control programmes, such as mosquito and transmission control, have been in place to eliminate the disease since the late 1950s [3]. However, it took over 30 years to control *Plasmodium vivax* malaria in endemic areas along the Yangtze River [4]. Although *Plasmodium falciparum* malaria has been eliminated in many endemic regions in China, the parasite is still present in Hainan and Yunnan provinces in Southern China after more than 50 years of disease control efforts [5,6].

To reduce or totally eliminate malaria parasite infections from a population, interruption of parasite

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2.Rapid and effective malaria elimination in Cambodia through mass administration of artemisinin-piperaquine. ***Malaria Journal.*** *2010, 9:57*

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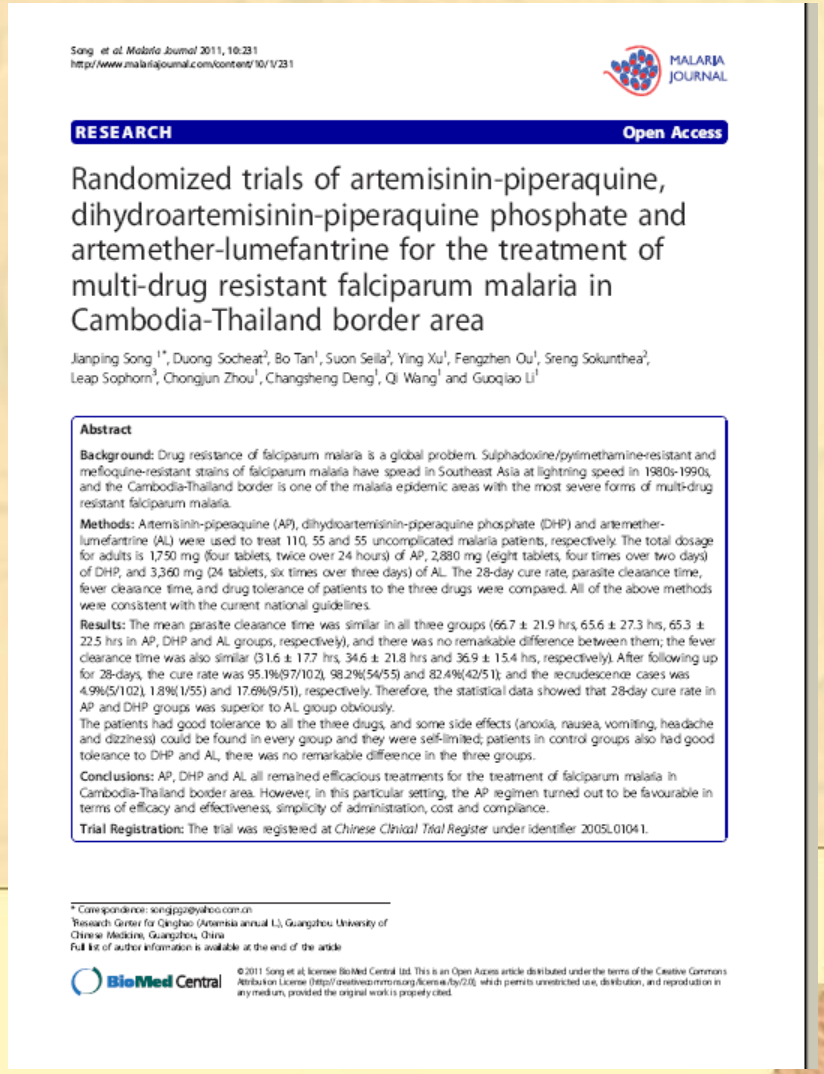

Song et al. Malaria Journal 2011, 10:231
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MALARIA JOURNAL

RESEARCH Open Access

Randomized trials of artemisinin-piperaquine, dihydroartemisinin-piperaquine phosphate and artemether-lumefantrine for the treatment of multi-drug resistant falciparum malaria in Cambodia-Thailand border area

Jianping Song[1*], Duong Socheat[2], Bo Tan[1], Suon Seila[2], Ying Xu[1], Fengzhen Ou[1], Sreng Sokunthea[2], Leap Sophorn[3], Chongjun Zhou[1], Changsheng Deng[1], Qi Wang[1] and Guoqiao Li[1]

Abstract

Background: Drug resistance of falciparum malaria is a global problem. Sulphadoxine/pyrimethamine-resistant and mefloquine-resistant strains of falciparum malaria have spread in Southeast Asia at lightning speed in 1980s-1990s, and the Cambodia-Thailand border is one of the malaria epidemic areas with the most severe forms of multi-drug resistant falciparum malaria.

Methods: Artemisinin-piperaquine (AP), dihydroartemisinin-piperaquine phosphate (DHP) and artemether-lumefantrine (AL) were used to treat 110, 55 and 55 uncomplicated malaria patients, respectively. The total dosage for adults is 1,750 mg (four tablets, twice over 24 hours) of AP, 2,880 mg (eight tablets, four times over two days) of DHP, and 3,360 mg (24 tablets, six times over three days) of AL. The 28-day cure rate, parasite clearance time, fever clearance time, and drug tolerance of patients to the three drugs were compared. All of the above methods were consistent with the current national guidelines.

Results: The mean parasite clearance time was similar in all three groups (66.7 ± 21.9 hrs, 65.6 ± 27.3 hrs, 65.3 ± 22.5 hrs in AP, DHP and AL groups, respectively), and there was no remarkable difference between them; the fever clearance time was also similar (31.6 ± 17.7 hrs, 34.6 ± 21.8 hrs and 36.9 ± 15.4 hrs, respectively). After following up for 28-days, the cure rate was 95.1%(97/102), 98.2%(54/55) and 82.4%(42/51); and the recrudescence cases was 4.9%(5/102), 1.8%(1/55) and 17.6%(9/51), respectively. Therefore, the statistical data showed that 28-day cure rate in AP and DHP groups was superior to AL group obviously.
The patients had good tolerance to all the three drugs, and some side effects (anoxia, nausea, vomiting, headache and dizziness) could be found in every group and they were self-limited; patients in control groups also had good tolerance to DHP and AL, there was no remarkable difference in the three groups.

Conclusions: AP, DHP and AL all remained efficacious treatments for the treatment of falciparum malaria in Cambodia-Thailand border area. However, in this particular setting, the AP regimen turned out to be favourable in terms of efficacy and effectiveness, simplicity of administration, cost and compliance.

Trial Registration: The trial was registered at *Chinese Clinical Trial Register* under identifier 2005L01041.

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3. Randomized trials of artemisinin-piperaquine, dihydroartemisinin-piperaquine phosphate and artemether-lumefantrine for the treatment of multi-drug resistant falciparum malaria in Cambodia-Thailand border area

- ***Malaria Journal.*** *2011, 10:231*

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PLoS one

Optimising Strategies for *Plasmodium falciparum* Malaria Elimination in Cambodia: Primaquine, Mass Drug Administration and Artemisinin Resistance

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Abstract

Background: Malaria elimination requires a variety of approaches individually optimized for different transmission settings. A recent field study in an area of low seasonal transmission in South West Cambodia demonstrated dramatic reductions in malaria parasite prevalence following both mass drug administration (MDA) and high treatment coverage of symptomatic patients with artemisinin-piperaquine plus primaquine. This study employed multiple combined strategies and it was unclear what contribution each made to the reductions in malaria.

Method and Findings: A mathematical model fitted to the trial results was used to assess the effects of the various components of these interventions, design optimal elimination strategies, and explore their interactions with artemisinin resistance, which has recently been discovered in Western Cambodia. The modelling indicated that most of the initial reduction of *P. falciparum* malaria resulted from MDA with artemisinin-piperaquine. The subsequent continued decline and near elimination resulted mainly from high coverage with artemisinin-piperaquine treatment. Both these strategies were more effective with the addition of primaquine. MDA with artemisinin combination therapy (ACT) increased the proportion of artemisinin resistant infections, although much less than treatment of symptomatic cases with ACT, and this increase was slowed by adding primaquine. Artemisinin resistance reduced the effectiveness of interventions using ACT when the prevalence of resistance was very high. The main results were robust to assumptions about primaquine action, and immunity.

Conclusions: The key messages of these modelling results for policy makers were: high coverage with ACT treatment can produce a long-term reduction in malaria whereas the impact of MDA is generally only short-term; primaquine enhances the effect of ACT in eliminating malaria and reduces the increase in proportion of artemisinin resistant infections; parasite prevalence is a better surveillance measure for elimination programmes than numbers of symptomatic cases; combinations of interventions are most effective and sustained efforts are crucial for successful elimination.

Citation: Maude RJ, Socheat D, Nguon C, Saroth P, Dara P, et al. (2012) Optimising Strategies for *Plasmodium falciparum* Malaria Elimination in Cambodia: Primaquine, Mass Drug Administration and Artemisinin Resistance. PLoS ONE 7(5): e37166. doi:10.1371/journal.pone.0037166

Editor: Steffen Borrmann, Kenya Medical Research Institute - Wellcome Trust Research Programme, Kenya

Received November 25, 2011; Accepted April 16, 2012; Published May 25, 2012

Funding: This study was funded by the Wellcome Trust of Great Britain (www.wellcome.ac.uk, grant number 077166/Z/05/Z). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

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Introduction

Elimination of malaria from much of the world is a declared aim of the World Health Organization [1] and is currently being attempted or planned in many countries [2]. As the epidemiology of malaria varies widely, malaria elimination requires a variety of approaches individually optimized for different transmission settings. It is expensive and slow, or often impossible, to develop these approaches by trial and error in the field [3]. Mathematical modelling is a rapid, low cost means of using limited available data to compare large numbers of strategies and optimize their impact. It has great potential to help guide the efforts to achieve elimination [3]. Very little mechanistic modelling of malaria elimination has been attempted thus far [3]. One exception is models developed for malaria elimination in the context of newly discovered artemisinin resistance in Western Cambodia [4] for which mathematical modelling is helping to guide planning.

4. Optimising Strategies for Plasmodium falciparum Malaria Elimination in Cambodia: Primaquine, Mass Drug Administration and Artemisinin Resistance

- ***PLoS ONE.*** *2012, 5（7）:1-10*

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90 广州中医药大学学报 Journal of Guangzhou University of Traditional Chinese Medicine 2010 年 1 月第 27 卷第 1 期 January 2010, Vol. 27, No. 1

·疟疾研究·

One-year Report on the Fast Elimination of Malaria by Source Eradication (FEMSE) Project in Moheli Island of Comoros

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(1. China Research Center for *Qinghao* [*Artemisia Annua* L.], Guangzhou University of TCM, Guangzhou 510405 Guangdong, China; 2. Comoros National Malaria Control Center, Ministry of Health, Comoros)

Abstract: **Objective** To investigate the therapeutic effect of the method of Fast Elimination of Malaria by Source Eradication (FEMSE) in Moheli island of Comoros. **Methods** Based on the FEMSE project, parasite positive cases were given a standard treatment course of ARTEQUICK (artemisinin plus piperaquine) plus primaquine; two tablets for adults at 0 hour and two tablets at 24 hours, a total of 4 tablets during one treatment course. One time of Mass Drug Administration (MDA) was for the children with parasite carrier rate less than 10%. Two times of MDA was for the children with parasite carrier rate more than 10%, and the interval between the two MDA was 42 days. Coverage rate for MDA and population carrier rate were observed. **Results** The number of people taking the first MDA of Artequick-Primaquine was 32,519 (the whole population registered at the same time being 37,243, 367 infants under 6 months old not involved), and the coverage rate for MDA was 88.2%. The population involved in the second MDA was 35,370 (the whole population registered at the same time being 37,112, 335 infants under 6 months old not involved), and the coverage rate for MDA was 96.2%. Parasite carrier rate was 22.95% (281/1,224) before MDA, 1.41% (28/1, 987) two months after MDA and 0.33% (8/2,458) four months after MDA, with a decrease of 98.56%. **Conclusion** The decrease of parasite carrier rate from 22.95% to 0.33% before and after MDA indicates that MDA of Artequick-Primaquine based on FEMSE can decrease the parasite carrier rate in a short time, without any obvious side effects. Further decrease of parasite carrier rate and incidence will be achieved if the measures for clearing malaria are fully implementated during the consolidation phase.

Key words: ARTEQUICK-PIPERAQUINE-PRIMAQUINE/therapeutic use; MALARIA/drug therapy; FAST ELIMINATION OF MALARIA BY SOURCE ERADICATION

CLC Number: R 531.3 **Document code**: A **Article ID**: 1007-3213 (2010) 01-0090-09

0 Introduction

From 1950s to 1980s, China got an important lesson from a large-scale malaria control program: "In malaria endemic areas where *Anopheles sinensis* is the main vector, indoor residual spraying has weak and slow effects on the elimination of mosquito for the vector is existing in wild." Therefore, "prevention and control measures should focus on the elimination of the transmission source. The failed experience of using a unified indoor residual spraying measure alone to combat malaria has been adopted in a lot of countries for a long period, which should be avoided"[1]. Since 1970s, China adopted comprehensive prevention measures based on Mass Drug Administration (MDA) thus to gradually reduce the morbidity in areas where

Received date: 2009-12-15

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5. *One-year Report on the Fast Elimination ofMalaria by Source Eradication (FEMSE) Project in Moheli Island of Comoros.* ***Journal of Guangzhou University of Traditional Chinese Medicine,*** *2010,27(1):90-98.*

Social Benefits Generated by FEMSE

- WHO officials made a special trip in March 2008, leading the delegation of the Ministry of Health for 5 countries of the Southern African Development Community (SADC). They visited FEMSE work team, and wanted to take advantage of the anti-malarial new technologies and new drugs for their countries .
- Comoros President, Vice President and Minister of Health also visited our Fengshun base to promote the implementation of FEMSE in Comoros.

Social Benefits Generated by FEMSE

- Artemisinin project has been listed as the key projects of Traditional Chinese Medicine powerful province and the National Science and Technology International cooperation project .
- In 2007, Guangzhou University of Chinese Medicine has also become a base of 38 foreign cooperation in the Ministry of Science and Technology .

The visit of Domestic and foreign leaders

Awards

The task of constructing Comoros anti-malaria center

- We completed the task of assistance on Comoros anti-malaria center, provided anti-malaria drug Artequick and medical equipments to the Ministry of Health of the Comoros.
- Our malaria prevention experts went to the Comoros, launched a 60-day work on assistance of construction anti-malaria center and training of malaria knowledge.

4. EXPERIENCE

I. **Combining anti-malaria center construction with the FEMSE program, can make the work done well.**

- Our country assisted 200,000 doses of the Artequick, 30 sets of microscope, and other medical supplies to anti-malaria center, trained anti-malarial staff of more than 250 people, established three anti-malarial system. All of the above guaranteed the implementation of the FEMSE program goes well.

4. EXPERIENCE

II. Mass administration and eradication of infective sources was a effective way to eliminate malaria.

- Ø According to the malaria epidemiological characteristics, we choose a relatively enclosed, and with few interference factors as the experimental unit.
- Ø Moheli island had a population of 36,000 in November 2007, through the active intervention of twice mass administration, [taking Artequick (artemisinin - piperaquine) + primaquine (primaquine 9mg)], the parasite carriage rate declined from 23% to 0.33%,and there was no dead case of malaria more. It's the fast malaria elimination in Moheli.

4. EXPERIENCE

III. Eliminating malaria was based on effective anti-malarial systems.

- Before the implementation of the program, there was no anti-malarial system in Moheli.
- After the implementation of the program, our team, together with the Comoros anti-malaria center set up the *Comoros - China Joint Anti-malarial Center*, and then set up the *Moheli Island Anti-malarial Aub-center*, which was responsible for the guidance and assistance of the program.
- After the foundation of Moheli sub-centers, they were responsible for the work of organization and management of malaria elimination, including the formation of anti-malarial team ,training of volunteers, and the establishment of a monthly reporting system for the local malaria situation.

4. EXPERIENCE

IV. Strengthening the training of local anti-malarial team guaranteed project implementation.

- We took advantage of the local technical strength to set up anti-malaria center. After personnel selection, training, finally a microscopic examination team with 14 locals was established.
- *Comoros - China Joint Anti-malarial Center*, organized the discussion about technical details of FEMSE among all of the senior technical staff in local. Which made them fully understand the implementation measures and significance of this program, to obtain their support.

4. EXPERIENCE

V. Obtaining the support of the local government and strengthening publicities to the public, was important to malaria prevention and treatment.

VI. Strengthening international cooperation and scientific research work can promote and consolidate the project.

5. NEXT WORK

- October 16, 2012, the launching ceremony of the FEMSE expanding project has been held in the *Anjouan* island . Comoros .
- Next we will plan to execute the FEMSE program in the other two islands of Comoros-*Grande Comore* and *Anjouan*.

Thanks !