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FDA approves Coartem tablets to treat malaria

The United States Food and Drug Administration has approved Coartem tablets (artemether and lumefantrine) for the treatment of acute, uncomplicated malaria infections in adults and children weighing at least 5kg (approximately 11lb).

Coartem is not approved for the treatment of severe malaria nor to prevent malaria. Severe malaria is different than acute, uncomplicated malaria in that patients with severe malaria have altered consciousness and other metabolic and end-organ complications. These patients are not candidates for oral drugs and should be given intravenous antimalarial therapy.

Malaria is a serious public health problem in many parts of the world. Persons from the United States who live in or travel to high-incidence areas are at risk of infection. Malaria is transmitted when a person is bitten by an infected mosquito. Coartem has been shown to be effective in geographical regions with reported resistance to chloroquine, a drug that prevents and treats malaria.

Symptoms of malaria include fever, chills, and flu-like illness. Left untreated, the disease can cause severe complications, including death. About 90% of deaths from malaria are in sub-Saharan Africa. Malaria is also prevalent in parts of Asia and Latin America.

Coartem should be taken with food, particularly food that contains fat, because this allows the body to absorb the drug well.

Nigerian children with their aunt, Bola Adetoro in Atlanta, Georgia. They are not at risk for malaria in the United States, but are when they travel back to Nigeria. Photos WAW.

The most common adverse reactions to Coartem shown in clinical trials in adults are headache, anorexia, dizziness, physical weakness (asthenia), joint pain (arthralgia) and muscle pain (myalgia). The most common adverse reactions reported in children are fever (pyrexia), cough, vomiting, loss of appetite, and headache.

Artemether, one of the active ingredients in Coartem tablets, is the first artemesinin class drug approved in the United States. The artemesinins are derived from the leaves of the *Artemisia annua* plant that are used to treat malaria.

In compliance with a provision of the Food and Drug Administration Amendments Act of 2007, the FDA awarded Novartis Pharmaceuticals Corporation, Basel, Switzerland, a single priority review voucher to use towards a future new drug application. The provision, designed to encourage development of drugs to treat tropical diseases, authorizes the granting of such vouchers to sponsors of treatments for certain tropical diseases. The voucher may be transferred to another manufacturer.

Source: United States Food and Drug Administration, Washington, DC, 08 April 2009.

Comprehensive map of global malaria endemicity - a key resource for malaria control and elimination

Using data from nearly 8,000 local surveys of malaria parasite infection rates, an international team of researchers has built a global map showing the proportion of the population infected with the parasite *Plasmodium falciparum* at locations throughout the globe. Published in this week's PLoS Medicine, the map shows that areas where a high proportion of residents are infected are common – but by no means uniform – in Africa, while lower prevalence levels are found in the Americas and Central and Southeast Asia, although pockets of intermediate and high transmission remain in some parts of Asia.

Malaria is an infectious disease; the *P falciparum* parasite causes about 500 million humans to sicken each year, and about 40% of the world's population lives in areas where malaria is transmitted.

The team of researchers, led by Simon Hay from the Department of Zoology at the University of Oxford, shows that global malaria endemicity is substantially lower than would be predicted from inspection of historical maps. Nevertheless, their map indicates that, in 2007, almost 60% of the 2.4 billion people at any risk of malaria were living in areas where malaria is constantly present – 0.69 billion people in Central and South East Asia, 0.66 billion in Africa,

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A World Malaria Map: Plasmodium falciparum Endemicity in 2007. Simon I Hay, Carlos A Guerra, Peter W Gething, Anand P Patil, Andrew J Tatem, Abdisalan M Noor, Caroline W Kabaria, Bui H Manh, Iqbal R F Elyazar, Simon Brooker, David L Smith, Rana A Moyeed, Robert W Snow.

Background. It is exactly 40 y since the last global map of malaria endemicity was published. This paper describes the generation of a new world map of Plasmodium falciparum malaria endemicity for the year 2007.

Methods and Findings. A total of 8,938 *P falciparum* parasite rate (PfPR) surveys were identified. Of these, 7,953 passed strict data fidelity tests for inclusion into a global database of PfPR data, age-standardized to 2 to 10 y for endemicity mapping. A modelbased geostatistical procedure was used to create a continuous surface of malaria endemicity within previously defined stable spatial limits of *P falciparum* transmission. The uncertainty was expressed as the probability of predicting correctly one of 3 endemicity classes; previously stratified to be an informative guide for malaria control. Population at risk estimates, adjusted for the transmission modifying effects of urbanization in Africa, were then derived with reference to human population surfaces in 2007.

Of the 1.38 billion at risk of stable *P falciparum* malaria, 0.69 billion were found in Central and South East Asia (CSE Asia), 0.66 billion in Africa, Yemen, and Saudi Arabia (Africaþ), and 0.04 billion in the Americas. All exposed to stable risk in the Americas were in the lowest endemicity class (PfPR210 5%). The vast majority (88%) of those living under stable risk in CSE Asia were also in this low endemicity class; a small remainder (11%) were in the intermediate endemicity class (PfPR210 . 5 to , 40%); and the remaining fraction (1%) in high endemicity (PfPR210 40%) areas. High endemicity was widespread in the Africaþ region, with 0.35 billion at this level of risk. Most others live at intermediate risk (0.20 billion), with a smaller number (0.11 billion) at low stable risk.

Conclusions. High levels of *P falciparum* malaria endemicity are common in Africa. Uniformly low endemic levels are found in the Americas. Low endemicity is also widespread in CSE Asia, but pockets of intermediate and very rarely high transmission remain. This 2007 global *P falciparum* malaria endemicity map is the first of a series with which it will be possible to monitor and evaluate the progress of this intervention process.

Abstract summarized from PLoS.

Faculty of Pharmacy student pharmacists at University of Lagos, Nigeria. Nigeria has the greatest burden of malaria in any country in the world. If they stay in Nigeria and work as pharmacists, a large part of their work will be dispensing anti-malarial medicines.

Yemen, and Saudi Arabia, and 0.04 billion in the Americas.

Part of the *Malaria Atlas Project*, the new map reflects the use of model-based geostatistics to incorporate data obtained across space and time. It provides an important new resource by indicating areas where malaria control can be improved, as well as areas where malaria elimination may be possible. Prior to this study, the most recent global map of *P falciparum* endemicity was published in 1968 and suffered from a number of limitations, such as incomplete description of the input data used and lack of estimates for the uncertainty in its predictions. Because of the statistical methods used to construct the new map published in PLoS Medicine, the uncertainty in the results can be quantified.

Citation: Hay SI, Guerra CA, Gething PW, Patil AP, Tatem AJ, Noor AM, Kabaria CW, Manh BH, Elyazar IRF, Brooker SJ, Smith DL, Moyeed RA, Snow RW (2009). A world malaria map: Plasmodium falciparum endemicity in 2007. PLoS Medicine 6: e1000048. doi:10.1371/journal.pmed.1000048

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Stream in forest in Prince George's County, Maryland, United States, in the Fall. All malaria-carrying mosquitoes were eliminated from the United States in the 1950s and 1960s through systematic spraying of DDT.

Source: PLoS Medicine, Oxford, England, 23 March 2009.

Drug resistance could set back malaria control success

USD22.5 MILLION GRANT FROM GATES FOUNDATION TO CONTAIN MALARIA PARASITES RESISTANT TO ARTEMISININ

WHO today said that the emergence of parasites resistant to artemisinin at the Thai-Cambodia border could seriously undermine the success of the global malaria control efforts.

Surveillance systems and research studies supported by WHO to monitor antimalarial drug efficacy in countries have produced new evidence that parasites resistant to artemisinin have emerged along the border between Cambodia and Thailand. Locals, who walk miles every day to clear forests, could be infected with drug-resistant malaria. This could set back recent successes to control the disease.

Huge strides have been made in the past 10 years to reduce the burden of malaria. Strong malaria control programmes have helped to lower infection rates in several countries. The recent shift from failing drugs to the highly effective artemisinin-based combination therapies (ACTs) has been a breakthrough. Appropriate treatment with ACTs succeeds in more than 90% of infected humans. But malaria drug resistance now emerging along the Thai-Cambodia border threatens these gains.

With a USD22.5 million grant from the Bill & Melinda Gates Foundation, WHO will endeavour to contain artemisinin-resistant malaria parasites before they spread. WHO will work in collaboration with several

http://www.rollbackmalaria.org/

GLOBAL MALARIA PARTNERSHIP

ROLL BACK MALARIA

$225 Million Partnership to Bring Effective Malaria Drugs to All Who Need Them

key partners including the National Center for Parasitology, Entomology and Malaria Control of the Cambodian Ministry of Health, Bureau of Vector-Borne Disease of the Thai Ministry of Public Health, Faculty of Tropical Medicine of Mahidol University Bangkok, Institut Pasteur Cambodia, Mahidol Oxford Tropical Medicine Research Unit, Bangkok and the Malaria Consortium.

Resistance along the Thai-Cambodia border started with chloroquine, followed by resistance to sulfadoxine-pyrimethamine and mefloquine, drugs used in malaria control several years ago.

Malaria poses a risk to half of the world's population and more than 1 million humans die of the disease each year. The malaria map, or the area where it is prevalent, has been reduced considerably over the past 50 years, but the disease has defied elimination in areas of intense transmission.

Obstacles to malaria control include drug resistance in the parasite that causes the disease, as well as resistance of the vector mosquito to insecticides, environmental factors and counterfeit medicines. The likelihood of drug resistance is increased with the use of single-drug therapies for malaria, especially monotherapies of artemisinin and its derivatives. The malaria parasite can more easily adapt to and eventually overcome the obstacles presented by a single drug than a combination of drugs delivered together. This makes it crucial for monotherapies to be removed from the market. WHO treats uncomplicated falciparum malaria with artemisinin combination therapy (ACTs).

Source: World Health Organization (WHO), Geneva, Switzerland, 25 February 2009.

USAID gives malaria assistance to Zimbabwe

The collapse of the health system has increased the threat of a malaria epidemic.

To help mitigate a malaria outbreak, the United States Agency for International Development (USAID) is supporting emergency indoor residual spraying to fill gaps in the country's peviously strong malaria control program.

In most years spraying was completed by December. But Zimbabwe's national malaria program lacks the financial resources to achieve 75% of its scheduled

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spraying, which would target 20 high-risk districts and protect more than 400,000 households.

USAID gave USD200,000 in emergency funding, matched with GBP200,000 from the UK Department for International Development (DFID). This accelerated program will apply the insecticide in February and March before the usual malaria peak in April and May. USAID and DFID coordinated the program with the World Health Organization and implementing partners John Snow International, Crown Agents, and PLAN International, which organized logistics, personnel, equipment, and management.

Indoor residual spraying applies a WHO-approved insecticide to the indoor walls, ceilings, and eaves of houses to kill or shorten the lifetime of mosquitoes that carry the malaria parasite. Decades of experience have shown that timely and properly conducted spraying can have an immediate and dramatic impact on malaria transmission. Combined with the increased deployment of long-lasting insecticide-treated bednets, diagnostics, and drugs, indoor residual spraying will play a major role in reducing the risk of a malaria epidemic in Zimbabwe.

Source: USAID, http://www.usaid.gov, Washington, DC, 11 February 2009.

World Bank launches Phase II of Malaria Booster Program

USD1.1 Billion to Fight Disease in Africa; Nigeria and Democratic Republic of Congo Are Key Countries

The World Bank launched Phase II of its Malaria Booster Program in Abuja, in a joint effort with Nigeria's Ministry of Health. The World Bank is committing USD1.1 billion to expand country programs to combat malaria.

Caribbean-American children in Brooklyn's Crown Heights on a Spring Sunday morning.

World Bank Group President, Robert B Zoellick, said the new financial commitment would help African countries over the next 3 years expand their malaria prevention, care, and treatment programs.

In response to requests from donors and other partners, the World Bank has taken on a substantial role in supporting National Malaria Control Programs in coordinating efforts to fight malaria in the Democratic Republic of Congo and Nigeria. These countries account for 30 to 40% of all malaria deaths worldwide. Phase II of the Malaria Booster Program will work to expand bed net distribution, provide treatment to the rural poor and improve health systems in the Democratic Republic of Congo, Nigeria, and other countries.

Source: the World Bank, http://www.worldbank.org, Abuja, Nigeria, 04 December 2008.

Malaria Foundation stresses education of students is critical to end malaria

The Malaria Foundation International (MFI) is stressing the importance of education in the fight against malaria, and rallying students together in partnership. The MFI is emphasizing the critical importance of health education as a component for any successful disease control strategy, and this is especially true for malaria, which is a preventable and treatable disease. The MFI has recognized that lack of knowledge about malaria is a common finding in malaria-endemic countries, and this can be traced to the frequent lack of education about malaria in schools.

MFI mission is to facilitate the development of solutions to the health, economic and social problems caused by malaria. MFI has been developing a glob-

Hillside in malaria-endemic Rift Valley, Kenya.

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al network of Student Leaders Against Malaria (SLAM). Students from countries at risk for malaria partner with students in malaria-free countries. This approach to help “end malaria” is also an empowering means to increase student’s awareness of global issues and teach important leadership and networking skills.

Today marks the launch of a Global Malaria Action Plan, drafted by members of the Roll Back Malaria Partnership, including MFI’s founder and president, Dr Mary Galinski. This launch comes one week after the release of the World Malaria Report 2008, prepared by the World Health Organization.

These documents lay out the enormous burden of malaria worldwide, with new estimates for several hundred million humans sickened annually and close to a million deaths, and they promote new strategic objectives to control, eliminate and ultimately eradicate the disease.

The Malaria Foundation launched SLAM in 2005 with the lead of MFI’s African Liaison Dr Cindy Korir from Kenya, who engaged students from Kericho, Kenya. These students interacted with Ms Lexi Fields and her students from an elective course on malaria taught at the Galloway School in Atlanta, Georgia, and with students in a malaria club organized by Mr Josh Gottlieb in Detroit, Michigan. Recently, along with the participation of the American Embassy, Mr Tommie Hamaluba and his students from the Gaborone Secondary School in Botswana have been partnering with Mr Bill Meyers and his students from the Alexander Dawson School in Denver, Colorado.

The global SLAM network currently includes young leaders and students of all ages being mobilized in the United States, India and the African countries Botswana, Cote d'Ivoire, Liberia, Malawi, Niger, Nigeria, Rwanda, Southern Sudan, Tanzania and Zambia. All humans are welcome to join the SLAM network as participants or financial supporters.

MFI is a 501(c)(3) non-profit organization.

Source: The Malaria Foundation International, http://www.malaria.org, Atlanta, Georgia, 26 September, 2008.

School students near Akoka, Nigeria.

First quick test for malaria

The first authorized rapid test for detecting malaria has been cleared for marketing in the United States by the Food and Drug Administration. The Binax NOW Malaria Test is intended for laboratory use.

Standard laboratory tests for malaria require identifying malaria parasites in a blood sample under a microscope, which requires training and experience.

The Binax NOW test results are available in 15 minutes after a few drops of blood are placed on a dipstick. The test can distinguish the most dangerous malaria parasite, *Plasmodium falciparum*, from less dangerous ones. Results still need to be confirmed using standard microscopic evaluation.

"Since malaria is uncommon in the United States, clinicians and lab personnel may not be accustomed to diagnosing this disease," says Daniel Schultz MD, Director of the FDA Center for Devices and Radiological Health. "When used in combination with other laboratory tests, the Binax NOW test provides an additional tool to help them diagnose this disease faster in the United States."

The Binax NOW test was 95% accurate compared with standard microscopic diagnosis in a study outside the United States in malaria endemic areas.

Although malaria has been eliminated from the United States since the 1950s, it can still affect residents who travel or work in other countries.

According to the Centers for Disease Control, over 1,500 humans were reported to have malaria in the United States in 2005, including 7 deaths, www.cdc.gov/malaria.

Source: United States Food and Drug Administration. Washington, DC, 27 June 2007.

Compiled and edited by Wanjiru Akinyi Waruingi BSc(Hons), PhD

Professor Waruingi has an enormous debt of gratitude to Professor David Ifudu, Dean of Pharmacy at the University of Lagos, his family, and his faculty. Professor Ifudu and the former Dean of Pharmacy, Professor HAB Coker, have been training pharmacists in Nigeria for over 3 decades.