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REVISED POLICY AND GUIDELINES ON THE DIAGNOSIS AND TREATMENT FOR MALARIA

DOH ADMINISTRATIVE ORDER NO. 2009-0001, January 13, 2009

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I. Rationale

Malaria remains an important public health problem in the Philippines. It ranks ninth among the leading causes of morbidity[i] and is endemic in 59 of the 81 provinces.[ii] In 2007, the Department of Health-Malaria Control Program (DOH-MCP) reported a total of 36,235 malaria cases, giving an overall incidence of 41 per 100,000 population.

Treatment failure is one of the major problems hampering current efforts in the control of malaria. In 2002, the DOH issued Administrative Order (AO) No. 129-A s. 2002 changing the anti-malaria drug policy from the use of Chloroquine (CQ) and Sulfadoxneyrimethamine (SP) monotherapy to CQ+SP combination as the interim first line treatment. This change was based on the evidences resulting from therapeutic efficacy studies conducted in sentinel sites nationwide showing high treatment failures of CQ (>60%) and SP (>45%) which exceeded the 25% 2000 benchmark set by the World Health Organization (WHO) for clinical failures. In the said AO, the DOH prescribed the use of artemether-lumefantrine (AL) combination as the second line drug, limiting its use only in the treatment of confirmed Plasmodium falciparum, until further study on its efficacy is done before making it as the first line treatment.

Consequently, the DOH in the past 6 years (2002-2007) adopted the use of artemisinin-based combination therapy (ACT), particularly AL in the highly endemic areas of the country and conducted parallel efficacy studies (in the 3 sentinel sites: Kalinga, Isabela and Palawan and in several Mindanao provinces). Studies showed that the AL combination treatment in these areas is efficacious at 97-100%, consistent with results of studies done in other countries like Cambodia, Thailand, Tanzania, and Lao People's Democratic Republic.[iii]

These results indicate that AL combination which is a f ixed dose formulation is a better choice as the first line treatment of falciparum malaria than CQ+SP combination in terms of efficacy, safety and tolerance profile, and compliance.[iv] Moreover, there is also an increasing evidence in the efficacy of other ACTs and artemisinin-based suppositories.[v]

The existing health infrastructure in many endemic areas now has better capacity to confirm diagnosis and to supervise first-line treatment using ACTs. It is expected that with this, the Millennium Development Goal (MDG) of reversing the trend in malaria incidence in the Philippines by 2015 will be attained.

II. Declaration of Policy

In line with the goal of better health outcomes (AO No. 2005-0023), the Malaria Control Program aims for the reduction of malaria morbidity by at least 70%, and mortality by 50% in the 26 category A provinces, declaring more malaria-free provinces, and preventing the recurrence of malaria in malaria-free provinces towards reversing malaria incidence trend by 2015. Given the consistent results of efficacy studies undertaken not only worldwide but also in several parts of the country, the existing policy and guidelines on the diagnosis and treatment of

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malaria is revised and updated such that the first-line drug treatment of falciparum malaria is shifted from CQ + SP combination to AL combination. This issuance is made in response to the requirement contained in AO No. 129-A s. 2002 for further study to be undertaken by DOH on the use of AL combination therapy before it can be adopted nationwide as the first-line treatment.

III. Guiding Principles

The implementation of the updated policy and guideline on diagnosis and treatment of malaria shall be guided by the following principles:

A. Provision of Effective Diagnosis and Treatment - The revised anti-malarial drug policy and guidelines as prescribed and its implementation shall be subject to continuous review and evaluation by technical experts. Efficacy studies must be regularly undertaken and effective diagnosis and treatment approaches in other countries will be reviewed for possible adoption;

B. Primary Health Care Approach - The diagnosis and treatment of malaria must be implemented within the primary health care perspective. This includes, among others, the recognition as essential of the participation of the community in all aspects of diagnosis and treatment, the mobilization of barangay health workers and other community volunteers and groups for service delivery and other activities, and adapting the diagnostic and treatment approaches according to varying conditions across localities and communities;

C. Universal Access - Malaria diagnostic and treatment services in accordance with the revised policy and guideline must be made available and accessible to all, especially to the vulnerable groups like pregnant women, infants, indigenous peoples, soldiers, etc.

D. Integrated Service Delivery - The provision of diagnostic and treatment services based on the revised policy and guideline shall be integrated with the delivery of other health services at the different levels of health care. It is important therefore that the revised policy and guide be made part of the protocols of other relevant programs particularly in malaria-endemic areas (e.g. prenatal care, integrated management of childhood illnesses, immunization, micronutrient supplementation, etc.) in order to facilitate service delivery integration at the local level;

E. Health System Support - The implementation of the revised policy and guide to be effective must be accompanied and supported with appropriate information campaign, adequate and timely arrival of drugs and supplies, training of health providers and establishment of quality assurance.

F. Multi-Sectoral Collaboration - The adoption of the revised diagnostic and treatment policy and guidelines for malaria requires the full support of the different sectors at all levels of operations. Efforts of concerned DOH offices and its attached agencies (e.g. PhilHealth), other national government agencies (e.g. Department of Interior and Local Government, Department of Education, DepEd, National and Anti-Poverty Commission, Armed Forces of the Philippines, etc.) and the local government units (LGUs) cannot be overemphasized. The contributions of the private sector (e.g. NGOs, academe, technical experts, private practitioners, etc.) including the development partners and the donor community are equally important. Efforts will be exerted to enjoin the participation and involvement of these different stakeholders.

IV. Objectives

In general, this policy aims to ensure early and correct diagnosis and effective treatment of all malaria cases in the country. Specifically, it aims to:

1) guide health workers and medical practitioners in implementing the updated diagnosis and treatment of

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malaria;

2) promote the compliance and adherence of the DOH offices, the LGUs and private sector to the revised diagnosis and treatment guide;

3) generate the support of other stakeholders in facilitating the implementation of the revised diagnosis and treatment guidelines in all localities nationwide.

V. Scope of Application

This order shall apply to all national, regional and local government offices, public and private health facilities, NGOs, development partners and other stakeholders whose functions and activities contribute to the prevention and control of malaria nationwide.

VI. Definition of Terms

Combination Therapy: the combination of two schizontocidal drugs with independent modes of action and unrelated biochemical targets in the parasite (WHO, 2006), i.e.:

a. Artemisinin-based combination therapy (ACT): artemisinin derivatives in combination with another schizontocidal drug;

b. Quinine + AL or QN +doxycycline/tetracycline/clindamycin

Confirmed Malaria: malaria diagnosis in a patient confirmed by either

a. Microscopy: The gold standard for malaria diagnosis demonstrating the presence of parasites in a Giemsastained blood film, or

b. Rapid Diagnostic Test (RDT): rapid dipstick test that has passed quality control which detects parasite antigens in the human blood, that can be deployed in remote areas

Direct Observed Therapy (DOT): daily intake of the prescribed antimalarial drugs supervised and observed by health worker or treatment partner for the complete duration of treatment.

Health Worker/Practitioner: refers to physicians, nurses, midwives, barangay health workers and malaria microscopists trained in the diagnosis and treatment of malaria.

Malaria Microscopists: Medical Technologists or barangay microscopists trained by DOH-MCP-RITM accredited malaria microscopy training programs or other WHO accredited centers;

Malaria Treatment Failure: A patient with or without any symptoms of malaria who has taken the correct dosage of anti-malarial treatment and presents with clinical deterioration or recurrence of symptoms together with asexual parasitaemia within 28 days post-treatment.

Severe Malaria: This condition is due to the dysfunction of organ systems secondary to the combined effects of parasitemia (usually very high parasite load) with untreated infection, sequestration of infected red blood cells and anaemia. The clinical syndromes of coma (cerebral malaria), respiratory distress, severe anaemia, renal failure, disseminated intravascular coagulation, hypoglycemia and metabolic acidosis are present, which may also be observed in other local infectious diseases.

Uncomplicated Malaria: This is a febrile condition with any species of malaria parasites detected in a peripheral blood film and absence of severe disease and signs of multi-drug-resistant P. falciparum. Uncomplicated malaria may be accompanied by severe headaches and chills followed by a drenching sweat.

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VII. General Guidelines

1. The diagnosis of malaria will be done as follows:

1.1 Microscopy will continue to be the “gold standard” for diagnosing malaria. All areas with a functional laboratory will at all times employ this standard. Microscopy standards will be maintained by a quality assurance system.[vi]

1.2 Diagnosis Through Rapid Diagnostic Test kits that have passed quality control tests will be used in the following situations: (i) there is no microscopy center; (ii) requires client more than 2-hours travel to the nearest microscopy centers as in inaccessible coastal or island areas; (iii) areas where there are outbreaks; and (iv) selected hospitals without a trained microscopist in emergency situation;

2. Treatment of malaria shall follow the recommended therapeutic regimen:

2.1 The Artemether- Lumefantrine (AL) combination will be the first line medicine in the treatment of confirmed uncomplicated and severe Plasmodium falciparum malaria, replacing CQ + SP combination;

2.2 If AL is not available, whether the patient is conscious or unconscious, and in case of treatment failure, quinine (QN) in combination with either tetracycline or doxycycline or clindamycin (QN +T/D/C x 7 days), will be the second-line treatment.

2.3 In severe malaria cases wherein the patient is unconscious, and the facility has no capacity to adequately manage the patient (e.g. naso-gastric tube or intravenous therapy). Artesunate (AS) suppository can be introduced pending transfer of patient to the next level of care.[vii]

2.4 ACT can be used for all Plasmodium species and mixed infections;

2.5 All anti-malarial drugs will be selected based on pre-qualifications by WHO or Good Manufacturing Procedures (GMP) certifications

3. Direct Observed Treatment (DOT) will be adopted as the mode of treatment of all patients, with the first 3-day doses of AL treatment supervised by a trained health worker, BHW or treatment partner;

4. Immediate referral of patients will be done as deemed necessary with pre-referral treatment of appropriate anti-malarials administered by trained health workers especially of cases with severe malaria and in patients who are pregnant and children below 5 years old;

5. Competent health care providers will carry out diagnosis and treatment of malaria. Re-orientation and re-training will be conducted especially in endemic areas;

6. Diagnosis and treatment of malaria will be supported with adequate and quality drugs and other logistics required. The DOH shall provide for the national requirements of anti-malarial medicines while the provision of laboratory supplies shall be a shared responsibility between the DOH-Centers for Health Development (CHDs) and the LGUs. Anti-malarial drugs will be made available to all public and private health facilities. Upon effectively of this issuance, remaining unexpired stocks of sulfadoxine-pyrimethamine (SP) must be used before shifting to AL.

7. Malaria cases must be appropriately recorded and reported using the Philippine Malaria Information System (PhilMIS). In areas where PhilMIS has not been introduced or not yet functional, the regular Field Health Service Information System (FHSIS) will be used. PHILMIS and FHSIS will be mainstreamed under the Philippine Integrated Disease Surveillance and Response (PIDSR).

8. The compliance and adherence of all concerned entities to the revised policy and guide will be monitored on a

regular basis.

VIII. Roles and Responsibilities

The DOH-National Center for Disease Prevention and Control (NCDPC) with the support of the other national DOH offices will take the lead in the management and execution of this revised Policy and Guidelines on the Diagnosis and Treatment of Malaria. The Centers for Health and Development (CHD) will take on the primary task of cascading and adapting the policies and the general guidelines in their respective catchment provinces, cities and municipalities. Support from professional societies, NGOs and other private sectors will be mobilized and their participation will be institutionalized through the formation of national, regional and local coalitions with the primary mission of ensuring the prevention and control of malaria in the country as a whole and specifically in their respective areas of assignment. The following are the roles and functions of the different entities in the management and execution of this AO.

A. Department of Health at the National Level

1. National Center for Disease Prevention and Control (NCDPC)

The DOH-NCDPC will be primarily responsible for the overall execution of the revised policy and guidelines on the diagnosis and treatment of malaria. It will undertake the following tasks:

1.1 Lead in the dissemination of the revised Policy and Guidelines on the Diagnosis and Treatment of malaria and advocate for its adoption and implementation among concerned stakeholders;

1.2 Coordinate the design, implementation and/or advocacy pertinent to the installation of essential management system s (e.g. staff development program, logistics management, reporting system, quality assurance, surveillance system, etc.) to ensure the efficient implementation of this policy;

1.3 Conduct orientation and/or training of concerned CHD officials and staff on the revised diagnostic and treatment policy and guidelines when necessary;

1.4 Coordinate the timely procurement and distribution of quality anti-malarial drugs to different regions in the country based on the allocation list prepared by the Centers for Health Development;

1.5 Ensure quality assurance of diagnosis (microscopy and RDTs) and treatment in collaboration with the Bureau of Food and Drugs (BFAD), Research Institute for Tropical Medicine (RITM) and WHO;

1.6 Identify and select sentinel sites for therapeutic efficacy surveillance, in collaboration with Centers for Health Development and the LGUs;

1.7 Lobby and advocate for additional resources to strengthen the diagnosis and treatment of malaria based on the comprehensive financing strategy designed by the Health Policy Development and Planning Bureau.

1.8 Review the updated diagnostic and treatment guidelines as needed;

1.9 Monitor the performance of the CHDs in ensuring compliance and adherence of LGU providers (public and private) to the revised diagnosis and treatment policy and guidelines.

2. Procurement Division/Material Management Division

2.1 Undertake the timely procurement of all anti-malaria commodities;

2.2. Ensure the proper storage, timely distribution and delivery of commodities to the end-users

3. National Epidemiology Center (NEC)

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3.1 Provide accurate, timely and complete data as basis for policy decisions, strategic actions and prioritization of resources and efforts;

3.2 Enhance/mainstream FHSIS and PHILMIS as source for tracking malaria cases into PIDSR.

4. PhilHealth

4.1 Review as necessary benefit package for malaria diagnosis and treatment for both in-patient and out-patient care based on actuarial feasibility.

B. Centers for Health Development (CHD)

1. Ensure the dissemination, orientation and/or training of the CHD staff on the revised Policy and Guidelines on the Diagnosis and Treatment of Malaria and advocate for its adoption and implementation in the different localities within their respective regions;

2. Maintain quality assurance and internal control teams to ensure compliance to the set of standards for confirmed malaria diagnosis;

3. Ensure availability of anti-malarial drugs in coordination with the DOH-NCDPC and LGUs by: (i) facilitating the distribution of commodities according to the allocation list; (ii) augmenting laboratory supplies; (iii) quarterly monitoring of drugs and laboratory supplies utilization; (iv) maintaining stock level of medicines and other commodities for outbreak or emergency situations; and (v) maintaining the Geimsa-stained preparation/ production center in strategically located areas;

4. Mobilize additional resources to strengthen the implementation of the revised policy and guidelines.

5. Formulate and implement advocacy plans to generate stakeholders' support, particularly the local officials.

6. Ensure timely reporting and surveillance;

7. Investigate adverse reaction to medicines and prepare/submit appropriate report to the National Office;

8. Monitor the implementation of the revised policy and guide by both public and private providers in different localities in their respective regions;

C. Local Government Units

1. Provincial/City Health Office (P/CHO)

1.1 Conduct orientation/training of private and public health workers on the revised policy and guidelines on diagnosis and treatment of malaria;

1.2 Advocate with municipalities/cities and other concerned agencies and stakeholders to adopt and implement the revised policy and guidelines;

1.3 Provide counterpart funding for training, medicines and laboratory supplies;

1.4 Allocate anti-malarial drugs and laboratory supplies to service providers within the province and monitor utilization thereof;

1.5 Ensure proper storage and availability of anti-malarial medicines at dispensing facilities (i.e. accredited hospital pharmacies open 24/7), and require regular inventory of stocks;

1.6 Ensure effectiveness of the systems on health human resource development, logistics management, and reporting and surveillance and other systems towards the efficient implementation of the policy;

1.7 Ensure that quality assurance and control system are in place for diagnosis and treatment of malaria;

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1.8 Ensure that follow-up smears of positive cases are undertaken weekly in provincial and district hospitals, and where feasible for one month post-treatment or for a longer period if necessary;

1.9 Mobilize additional resources for the implementation of the revised diagnostic and treatment guide;

1.10 Ensure timely reporting and surveillance towards the efficient implementation of the policy;

1.11 Investigate adverse reactions to medicines and report the same to CHD and the regional B FAD;

1.12 Monitor the implementation of the revised diagnostic and treatment policy and guidelines in the public and private facilities especially hospitals;

2. Rural Health Units

2.1 Implement the revised diagnosis and treatment policy and guide;

2.2 Provide medicines for adverse drug reactions (ADRS) and report said cases to PHO accordingly;

2.3 Provide laboratory confirmation of diagnosis;

2.4 Do follow-up smears of positive cases weekly for one month post-treatment or for a longer period if necessary;

2.5 Ensure proper storage of anti-malarial drugs/other commodities, and make a regular inventory of stocks;

2.6 Conduct training for midwives, BHWs and volunteers on the revised diagnosis and treatment of malaria and provide counterpart support for trainees;

2.7 Collect, analyze and submit reports (PhilMIS in some provinces) as required;

2.8 Implement information and education campaign on the revised diagnostic and treatment guide;

2.9 Conduct and analyze client compliance survey.

3. Barangay Health Workers (BHWs)/Barangay Microscopists and Other Volunteers

3.1 Conduct case finding and supervise treatment;

3.2 Direct observation of intake of 1st-line anti-malarial medicines of positive cases;

3.3 Mobilize communities to use personal protection measures and to seek early diagnosis for provision of effective treatment;

3.4 Report/refer adverse reactions immediately;

3.5 Do follow-up smears of positive cases weekly for one month post-treatment or for a longer period if necessary;

3.6 Submit updated reports regularly;

D. Regional, Provincial and District Hospitals

1. Provide services according to quality assurance protocol and guidelines; and

2. Make available anti-malarial drugs to private practitioners.

E. Philippine Movement Against Malaria (PhilMAM) and other Non-Government Organizations collaborating with the Malaria Control Program.

As an implementing partner, may undertake the following responsibilities:

1. Support the implementation of the revised diagnostic and treatment policy and guide for malaria;

2. Provide support in health service delivery, provided that appropriate training was obtained i.e. Diagnosis and treatment of malaria, in partnership with local government units or community;

3. Provide relevant experiences in community based malaria control, development of IEC messages and promotion of enabling environment that will link health system with communities and can increase political support;

4. Undertake social marketing strategies to increase participation of communities and local government units in the prevention and control of malaria;

5. Assist in mobilizing resources for additional medicines and laboratory supplies.

IX. Repealing Clause

Administrative Order 19, s. 1996, AO 129 s. 2002 and all other orders and related issuances inconsistent with the provisions of this issuance are hereby rescinded.

X. Effectivity

This Order takes effect immediately.

Adopted: 13 Jan. 2009

(SGD.) FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

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[i] Field Health Service Information System, Department of Health, 2006

[ii] Program Accomplishment Report, Malaria Control Program, Department of Health, 2008

[iii]2006 WHO Guidelines for the Treatment of Malaria.

[iv] 2006 WHO Guidelines for the Treatment of Malaria.

[v] Artemisinin-based suppositories. Report of a WHO Informal Consultation, 27-28 March 2006, Geneva. WHO/HTM/MAL/2006. 1118

[vi] Quality Assurance Guide and Standards will be developed as part of the Integrated Malaria Control Operations Guide.

[vii]Clinical Review, Evidence Behind the WHO Guidelines : Hospital Care for Children: Efficacy and Safety of Artemisinin Derivatives in Children with Malaria, Journal of Tropical Pediatrics 2006; 52 (2): 78-82

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