ANTIMALARIAL MEDICINE POLICY

GHANA

DECEMBER 2022

MINISTRY OF HEALTH
PREFACE

As a country, we have made tremendous progress in our fight against malaria over the years. Malaria mortalities for instance have reduced significantly from 2,799 in 2012 to 275 in 2021. The role of antimalarial medicines in this achievement, backed by strong, responsive, practical and evidence-based antimalarial medicine policies, cannot be underestimated.

As we plan, work and inch towards zero malaria deaths, malaria pre-elimination in some districts and ultimately elimination in Ghana, it is vital to relook, revise and realign our medicines policy to facilitate the achievement of these goals; to bring it to speed with current global recommendations as well as regional/national research findings, bearing in mind experiences with the implementation of previous antimalarial medicine policies and the most recent antimalarial medicine policy (2020).

This revised edition of the antimalarial medicines policy is as a result of consultative meetings held with all relevant stakeholders involved in malaria case management across the country. The language is simple and precise, and the book concise to allow for easy reading and comprehension.

I implore all stakeholders and health personnel across the length and breath of the country, within the public and private sectors, to comply with the guidelines of this policy to ensure prompt, safe, effective and appropriate antimalarial treatment to the entire population, reduce malaria morbidity and mortality, and ultimately to achieve the Ministry’s vision of “a healthy population for national development”.

Kwaku Agyeman-Manu
HON. MINISTER FOR HEALTH
ACKNOWLEDGEMENT

This revised edition of the antimalarial medicine policy is a result of the hard work and dedication of members of the expert review committee. We acknowledge the effort and contribution of the committee members:

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GHS-NMEP
GHS-ICD
GHS-NMEP
WHO
WHO
IMPACT MALARIA
NHIA
TTH
HTH
MOH / PHARMACY
PHARMACY COUNCIL
GHS
UG-NMIMR
UG-NMIMR
KNUST
MOH- MPU
CPMR
FDA
FDA
We also acknowledge the efforts, support and oversight roles of the Director-General of the Ghana Health Service (Dr. Patrick Kuma-Aboagye) and the Director of Public Health of the Ghana Health Service (Dr. Franklin Asiedu Bekoe), as well as the financial support of the Global Fund in the revision and update of this document from the 2020 edition.
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACT</td>
<td>Artemisinin-based Combination Therapy</td>
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<tr>
<td>AL</td>
<td>Artemether-Lumefantrine</td>
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<tr>
<td>AP</td>
<td>Artesunate-Pyronaridine</td>
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<td>API</td>
<td>Annual Parasite Index</td>
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<td>AS-AQ</td>
<td>Artesunate-Amodiaquine</td>
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<tr>
<td>CCTH</td>
<td>Cape Coast Teaching Hospital</td>
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<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
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<td>CPMR</td>
<td>Centre for Plant Medicine Research</td>
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<td>DALYs</td>
<td>Disability Adjusted Life Years</td>
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<td>DHAP</td>
<td>Dihydroartemisinin-Piperaquine</td>
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<td>DOT</td>
<td>Directly Observed Therapy</td>
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<td>EML</td>
<td>Essential Medicine List</td>
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<td>EPI</td>
<td>Expanded Program on Immunisation</td>
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<td>FDA</td>
<td>Food and Drugs Authority</td>
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<td>G6PD</td>
<td>Glucose-6-phosphate dehydrogenase</td>
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<td>GCP</td>
<td>Ghana College of Pharmacists</td>
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<td>GCPS</td>
<td>Ghana College of Physicians and Surgeons</td>
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<td>GDHS</td>
<td>Ghana Demographic and Health Survey</td>
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<td>GHSC</td>
<td>Global Health Supply Chain</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GSA</td>
<td>Ghana Standards Authority</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>GHS</td>
<td>Ghana Health Service</td>
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<td>HTH</td>
<td>Ho Teaching Hospital</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IM</td>
<td>Intramuscular</td>
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<td>ITNs</td>
<td>Insecticide-Treated bed Nets</td>
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<td>IV</td>
<td>Intravenous</td>
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<tr>
<td>IPTp</td>
<td>Intermittent Preventive Treatment in Pregnancy</td>
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<tr>
<td>KBTH</td>
<td>Korle-bu Teaching Hospital</td>
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<tr>
<td>KNUST</td>
<td>Kwame Nkrumah University of Science and Technology</td>
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<td>MPU</td>
<td>Medicine Policy Unit</td>
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<td>MICS</td>
<td>Multiple Indicator Cluster Survey</td>
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<td>MIS</td>
<td>Malaria Indicator Survey</td>
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<td>MVIP</td>
<td>Malaria Vaccine Implementation Programme</td>
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<td>NHIML</td>
<td>National Health Insurance Medicines List</td>
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<td>NMEP</td>
<td>National Malaria Elimination Programme</td>
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<td>NMIMR</td>
<td>Noguchi Memorial Institute for Medical Research</td>
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<td>OPD</td>
<td>Outpatient Department</td>
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<tr>
<td>OTC</td>
<td>Over-the-Counter</td>
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<td>PCR</td>
<td>Polymerase chain reaction</td>
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<tbody>
<tr>
<td>Pf</td>
<td><em>Plasmodium falciparum</em></td>
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<td>Po</td>
<td><em>Plasmodium ovale</em></td>
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<tr>
<td>Pv</td>
<td><em>Plasmodium vivax</em></td>
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<tr>
<td>PSM</td>
<td>Procurement and Supply Management</td>
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<td>RDD</td>
<td>Research and Development Division</td>
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<td>SBCC</td>
<td>Social Behavioural Change Communication</td>
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<td>SMC</td>
<td>Seasonal Malaria Chemoprevention</td>
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<td>SPH</td>
<td>School of Public Health</td>
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<td>SPMDP</td>
<td>Society of Private Medical and Dental Practitioners</td>
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<td>STG</td>
<td>Standard Treatment Guidelines</td>
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<tr>
<td>SP-AQ</td>
<td>Sulphadoxine-pyrimethamine and Amodiaquine</td>
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<td>T3</td>
<td>Test, Treat and Track</td>
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<td>TTH</td>
<td>Tamale Teaching Hospital</td>
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<tr>
<td>UG</td>
<td>University of Ghana</td>
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<td>UHAS</td>
<td>University of Health and Allied Sciences</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Figure 2:
Site-specific PCR-uncorrected and PCR-corrected cure rates for AS-AQ, AL, and DHAP (2020 – 2021)
1.0 INTRODUCTION

Malaria is a major cause of illness and death in Ghana, particularly among children and pregnant women. In 2021, confirmed malaria accounted for 19.8% of all out-patient illnesses and 19.6% of all admissions. The average malaria parasite prevalence among children aged 6–59 months in the 2019 Malaria Indicator Survey (MIS) was 14.1% with regional variations from as low as 2.4% in the Greater Accra Region to as high as 27.0% in the Western Region (now Western and Western North Regions) (Figure 1).

Malaria during pregnancy causes maternal anaemia and placental parasitaemia, both of which are responsible for miscarriages and low birth weight babies among pregnant women. In 2021, pregnant women accounted for about 2.4% of confirmed outpatient department (OPD) malaria cases in the country.

Malaria is a major cause of under-development and inflicts serious socio-economic burden on the entire citizenry. In 2014, businesses lost about US$6.58 million to malaria in Ghana, 90% of which were direct costs. Malaria is estimated to cause the loss of about 10.6% Disability Adjusted Life Years (DALYs) costing an equivalent of up to 6% of GDP annually in economic burden.

The Ministry of Health in its Mid-Term Strategic Plan 2022–2025, considers malaria a priority disease which has to be tackled in order to achieve the SDG 3.3. (end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases by 2030).
Case Management has been and continues to be one of the main strategic interventions for the elimination of malaria in the country. The Ghana Health Service (GHS)/National Malaria Elimination Programme (NMEP) since 2009 has been promoting the World Health Organization's (WHO) recommendation of universal parasitological diagnosis of malaria. This brings a shift from presumptive clinical diagnosis to the test, treat and track (T3) policy.

The effectiveness of the T3 policy is highly dependent on antimalarials, which should be safe, effective, available, affordable and acceptable to the entire population. To achieve this objective, an up-to-date evidence-based Antimalarial Medicine Policy for the country is needed.

The policy will contribute to:

- Preventing progression of uncomplicated malaria to severe disease and death
- Reducing the number of clinical episodes of malaria
- Shortening the duration of clinical episodes of malaria and reducing the occurrence of malaria-associated complications such as anaemia
- Reducing consequences of placental malaria and maternal malaria-associated anaemia through intermittent preventive treatment during pregnancy
- Delaying the development and spread of resistance to antimalarials

This Antimalarial Medicine Policy is a fundamental and dynamic document that needs to be reviewed regularly to reflect changes in global trends and the country context.
1.1 Background

In the year 2000, WHO recommended the use of combination therapy for malaria treatment. Ghana, based on its drug efficacy findings, adopted Artemisinin-based Combination Therapy (ACT), specifically Artesunate-Amodiaquine (AS-AQ), as first-line treatment for malaria in 2004. The policy has been revised subsequently, and the latest revision was in 2020.

In the 2020 revision, Ghana adopted a multiple first-line approach in the treatment of uncomplicated malaria. AS-AQ and Artemether-Lumefantrine (AL) were the first-line treatment options whilst Dihydroartemisinin-Piperaquine (DHAP) was the second-line option reserved for treatment failures or for patients who were unable to tolerate the first-line options. ACTs have remained efficacious since their introduction in Ghana. Data obtained from sentinel sites during the 2018–2020 surveillance period showed PCR corrected cure rates of 99.1% for AS-AQ and 97.6% for AL. Recent data from the 2021–2022 surveillance period showed PCR corrected cure rates of 96.8% for AS-AQ, 97.7% for AL and 100% and 97.0% for DHAP for Days 28 and 42 respectively.

Parenteral Artesunate remained the medicine of choice in the initial management of severe malaria followed by a full course of ACT when the patient is able to take oral preparations.

Sulphadoxine-Pyrimethamine and Amodiaquine combination (SP-AQ) was maintained as medicine of choice for Seasonal Malaria Chemoprevention (SMC).
Figure 2: Site-specific PCR-uncorrected and PCR-corrected cure rates for AS-AQ, AL, and DHAP (2020 – 2021)

National averages:

**AS-AQ**
- PCR-uncorrected: 92.9%
- PCR-corrected: 96.8%

**AL**
- PCR-uncorrected: 96.2%
- PCR-corrected: 97.7%

**DHAP**
- PCR-uncorrected: 100% (for day 28) and 89.1% (for day 42)
- PCR-corrected: 100% (for day 28) and 97.0% (for day 42)
1.2 Rationale for Revising the Medicine Policy

The Ministry of Health constituted the Antimalarial Medicine Policy Expert Review Committee on 17th May 2022 to review the existing 2020 medicine policy. This was necessitated by the:

1. Beneficial evidence of multiple first-line therapy against parasite resistance
2. Revised WHO guidelines for malaria, November 2022
3. Changing parasite prevalence rates across the country
4. Current information on prevalence of Plasmodium species
5. Evidence on prescriber, dispenser and client ACT preferences
   [ACT preference study 2021]

1.3 Policy objective

To provide prompt, safe, effective and appropriate antimalarial treatment to the entire population.
2.0 MANAGEMENT OF UNCOMPLICATED MALARIA

Studies conducted on drug efficacy and safety have shown no marked difference between the efficacy and safety profiles of AS-AQ, AL, DHAP and Artesunate-Pyronaridine (AP) \textsuperscript{5-8,10}. Although national data on the efficacy of AP is limited, regional data suggests comparable cure rates with AS-AQ and AL\textsuperscript{9}. These ACTs are therefore the medicines of choice for managing uncomplicated malaria in Ghana as described in section 2.1 below.

2.1 Drug of Choice for Uncomplicated Malaria Treatment

The First-line Antimalarials:

Based on the comparable efficacies of the ACTs and the benefit of multiple first-line therapy in delaying the emergence and spread of drug resistance \textsuperscript{11-12}, Ghana is maintaining a multiple first-line approach in the treatment of uncomplicated malaria.

The first-line ACTs are therefore as follows;

I. Artesunate-Amodiaquine (AS-AQ)
II. Artemether-Lumefantrine (AL)
III. Artesunate-Pyronaridine (AP)

The choice of the first-line ACT shall be based on patient’s tolerance and acceptance.

The Second-line Antimalarial:

The second-line ACT for the treatment of uncomplicated malaria shall be the recommended strength and dosage forms of: Dihydroartemisinin-Piperaquine (DHAP)

2.2 Treatment of uncomplicated \textit{P. ovale} and \textit{P. vivax} malaria

In cases of confirmed \textit{P. ovale} or \textit{P. vivax} infections, Primaquine should be added to the ACT for the purpose of preventing relapse (radical cure). The G6PD status of the patient should be determined to guide the dosage and duration of primaquine administration.
NOTE: Adherence to testing before treatment, and using the appropriate dosing is essential to ensure prompt and effective treatment.

2.3 Management of Uncomplicated Malaria in Pregnancy

2.3.1 First Trimester
Artemether-Lumefantrine (AL) shall be the medicine of choice for the management of uncomplicated malaria in the first trimester of pregnancy. Where AL is not available or not recommended, other ACTs (ASAQ or DHAP, but not AP) may be considered for use. There is currently no documented record of the use of AP in the first trimester of pregnancy. A combination of oral Quinine and oral Clindamycin can be used as alternative if the above-recommended ACTs are not available. Pharmacovigilance and clinical research on the safety and efficacy of antimalarial medicines for treatment of malaria in pregnancy should continue and be supported.

2.3.2 Second and Third Trimesters
AS-AQ or AL shall be used as first-line for the management of malaria in the second and third trimesters of pregnancy. DHAP shall be used as a second-line. A combination of oral Quinine and oral Clindamycin can be used as alternatives if the recommended ACTs are not available.

Pregnant women with co-morbidities of HIV and sickle cell disease shall be treated as above for uncomplicated malaria. However, avoid the use of Amodiaquine-containing combination therapy for HIV patients on Co-trimoxazole, Zidovudine and Efavirenz.

2.4 Community Management of Uncomplicated Malaria
ACTs shall be the medicine of choice for treating uncomplicated malaria in the community.

All patients who deteriorate or do not improve within 24 hours of treatment of uncomplicated malaria shall be referred immediately to a nearby health facility.

2.5 Treatment Failure

2.5.1 Treatment Failure of Uncomplicated Malaria
For the management of treatment failures, the following options are recommended: An alternative ACT (AS-AQ, or AL or AP or DHAP) which has not been previously
The choice of the first-line ACT shall be based on patient’s tolerance and acceptance.

The Second-line Antimalarial: The second-line ACT for the treatment of uncomplicated malaria shall be the recommended strength and dosage forms of: 

- Dihydroartemisinin-Piperaquine (DHAP)

2.2 Treatment of uncomplicated *P. ovale* and *P. vivax* malaria

In cases of confirmed *P. ovale* or *P. vivax* infections, Primaquine should be added to the ACT for the purpose of preventing relapse (radical cure). The G6PD status of the patient should be determined to guide the dosage and duration of primaquine administration.

NOTE: Adherence to testing before treatment, and using the appropriate dosing is essential to ensure prompt and effective treatment.

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A combination of oral Quinine and oral Clindamycin can be used as alternative if the above-recommended ACTs are not available.

Pharmacovigilance and clinical research on the safety and efficacy of antimalarial medicines for treatment of malaria in pregnancy should continue and be supported.

2.3.2 Second and Third Trimesters

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2.4 Community Management of Uncomplicated Malaria

ACTs shall be the medicine of choice for treating uncomplicated malaria in the community.

All patients who deteriorate or do not improve within 24 hours of treatment of uncomplicated malaria shall be referred immediately to a nearby health facility.

2.5 Treatment Failure

2.5.1 Treatment Failure of Uncomplicated Malaria

For the management of treatment failures, the following options are recommended:

- An alternative ACT (AS-AQ, AL, or DHAP) which has not been previously administered. If for any reason, ACT cannot be administered, then a combination of oral Quinine and oral Clindamycin could be used.

Treatment Failure should be distinguished from Inadequate Treatment. Treatment failure is said to have occurred if fever and asexual parasitaemia fail to resolve or recur within 28 days of receiving the recommended treatment in the correct dosage and duration. Inadequate treatment, on the other hand, defined as failure to complete the initial course of treatment for whatever reason (e.g. vomiting, non-compliance, etc.).

In case of inadequate treatment, a full course of the initial antimalarial combination medicine used may be repeated.

2.5.2 Treatment Failure of Uncomplicated Malaria in Pregnant Women

2.5.2.1 First Trimester

If AL fails, any of the following ACTs (AS-AQ, or DHAP) is an alternative. Where alternate ACT is not available or contraindicated, a combination of oral Quinine and oral Clindamycin shall be given.

2.5.2.2 Second and Third Trimesters

An alternative ACT (AS-AQ, AL, or DHAP) should be given depending on which medicine was used previously. Where alternate ACT is not available, a combination of oral Quinine and oral Clindamycin shall be given.

2.6 Treatment of Uncomplicated malaria with Herbal Medicine

Herbal medications were introduced as an option for uncomplicated malaria treatment in 2020.

Treatment with herbal medicines shall be as stipulated in the Recommended Herbal Medicines Lists by the Ministry of Health (MoH RHML). Currently, these medications may contain the following medicinal plants alone or in combination:

1. *Cryptolepis sanguinolenta*
2. *Morinda lucida*
3. *Khaya senegalensis*
4. *Cassia occidentalis* and
5. *Azadirachta indica*.

These medications are not recommended for:
a. Pregnant women  
b. Lactating mothers  
c. Children below twelve (12) years of age  
d. Severe malaria cases  
e. *P. ovale* and *P. vivax* cases  

Little evidence exists regarding efficacy of herbal medicines against *P. ovale* and *P. vivax*. In view of this, herbal antimalarials are currently not recommended for treatment of *P. ovale* and *P. vivax* infections.

### 2.7 Malaria Vaccine

The RTS,S/AS01 vaccine is an injectable malaria vaccine. It acts against *Plasmodium falciparum*, the deadliest malaria parasite globally, and the most prevalent in Ghana and the rest of sub-Saharan Africa. Following positive results from the pilot implementation of the RTS,S/AS01 malaria vaccine in Ghana, Kenya and Malawi, WHO on 6th October 2021, recommended widespread use of the RTS,S malaria vaccine in children living in regions with moderate to high malaria transmission. The vaccine was found to be cost-effective, safe, efficacious, feasible to implement, increase access to malaria prevention interventions among others. It is given as an intramuscular injection. In Ghana, the dosing of RTS,S malaria Vaccine is scheduled at 6, 7, 9 and 24 months of age for doses 1, 2, 3 and 4 respectively. However, following the WHO position on the flexibility of the schedule for the dose 4, the schedule will be changed from 24 months of age to 18 months to align with the schedule for second year of life vaccines and interventions during the expansion/continuation phase of the Malaria Vaccine Implementation Programme (MVIP).
3.0 PRE-REFERRAL TREATMENT OF SEVERE MALARIA

The condition of the patient with severe malaria can deteriorate very rapidly. As such, patients with severe malaria should be managed in a hospital setting. In non-hospital settings, such patients should be referred immediately to a hospital after instituting pre-referral management as per the following guideline.

3.1 Pre-referral treatment in communities

All patients presenting with severe malaria at the community level (Over-the-counter-medicine shops, pharmacies, community-based agents/ volunteers) should be referred immediately to the nearby health facility. Children under 6 years shall be given an initial dose of suppository artesunate prior to referral to the health facility. Fever should be controlled with tepid sponging and Paracetamol.

3.2 Pre-referral treatment in healthcare facility

Health facilities (Community-based Health Planning and Services [CHPS] compounds, Maternity Homes, Health Centers, Clinics), when sending the severe malaria patient on referral to a Hospital, should start initial parenteral antimalarial treatment and supportive care immediately while arranging for the patient to be transferred.

The order of preferred pre-referral antimalarial are as follows for adults, children above 6 years and children under 6 years:

- IM Artesunate or
- Rectal Artesunate (for under 6 years only) or
- IM Artemether or
- IM Quinine
4.0 MANAGEMENT OF SEVERE MALARIA

Severe Malaria is a life-threatening disease caused mostly by *Plasmodium falciparum*. It is a medical emergency that needs immediate and urgent treatment.

Parenteral artesunate is the treatment of choice for all cases of severe malaria. Treat adults and children with severe malaria (including infants, pregnant women in all trimesters and lactating women) with intravenous or intramuscular artesunate for at least 24 hours (irrespective of the patient’s ability to tolerate oral medication earlier) before giving the oral follow-up treatment.

If injection artesunate is not available, use injection artemether in preference to injection quinine for parenteral treatment of children and adults with severe malaria until injection artesunate is obtained.

Once a patient has received at least 24 hours of parenteral therapy and can tolerate oral therapy, complete treatment with 3 days of ACT.

4.1 Management of Severe Malaria in Pregnancy

First, Second and Third Trimesters

Treat pregnant women in all trimesters with severe malaria with intravenous or intramuscular artesunate for at least 24 hours until they can tolerate oral medication.

If artesunate is not available, use intramuscular artemether in preference to intravenous/intramuscular quinine for parenteral treatment until artesunate is obtained.

Once a patient has received at least 24 hours of parenteral therapy and can tolerate oral therapy, complete treatment with recommended full course of ACT (AS-AQ, AL or DHAP).13
5.0 INTERMITTENT PREVENTIVE TREATMENT OF MALARIA DURING PREGNANCY

Currently, apart from Insecticide Treated Nets (ITNs), the most preferred intervention to prevent malaria in pregnancy is Intermittent Preventive Treatment using Sulphadoxine-Pyrimethamine (SP). This shall be administered at predefined intervals (every 4 weeks) starting at 16 weeks of gestation.

Intermittent Preventive Treatment in pregnancy (IPTp) is preferably provided as part of a comprehensive antenatal care package with other medicines like haematinics and anthelmintics. SP for IPTp shall be administered under the supervision of a qualified health worker as Directly Observed Therapy (DOT).

5.1 Drug of Choice for Intermittent Preventive Treatment in Pregnancy (IPTp)

Sulphadoxine-Pyrimethamine (Sulphadoxine 500mg + Pyrimethamine 25mg) shall be reserved for IPTp given as DOT.

5.1.1 Conditions for use of Sulphadoxine-Pyrimethamine (SP)

All pregnant women shall undergo screening before the commencement of IPTp in order to exclude those who are either G6PD deficient or allergic to sulphonamides. Folic acid at a low dose of 0.4mg (400mcg) can be given concomitantly with SP. Daily dose equal or above 5mg should not be given with SP as this counteracts SP efficacy as an antimalarial. Pregnant women should be cautioned on the use of multiple preparations that may all contain Folic Acid.

Note: In addition to IPTp, all pregnant women should be encouraged to sleep under ITNs.

5.2 Alternatives to SP For Preventing Malaria in Pregnancy

Currently there is no recommended alternative to SP for IPTp in Ghana. It must therefore be emphasized that, for women who cannot take SP, they need to consistently use ITNs and other protective measures. They must also be educated to report early to the nearest health facility when they have symptoms suggestive of malaria.

Pregnant women with HIV receiving a single daily dose of Co-trimoxazole do not need to take monthly doses of SP for IPTp. This is because Co-trimoxazole also serves as a form of malaria prophylaxis in these patients.
6.0 SPECIAL INTERVENTIONS

6.1 SEASONAL MALARIA CHEMOPREVENTION
Seasonal Malaria Chemoprevention (SMC) is defined as the intermittent administration of full treatment courses using the recommended antimalarial medicine during peak malaria transmission season to prevent malaria illness with the objective of maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malaria risk.

A complete treatment course of antimalarial is given to eligible children at high risk of severe malaria in some locations at monthly intervals during the peak malaria transmission season. The number of monthly cycles for SMC could vary based on available resources.

6.1.1 Drug of Choice for Seasonal Malaria Chemoprevention (SMC)
The recommended antimalarial for SMC is Sulphadoxine-Pyrimethamine plus Amodiaquine (SP-AQ).

6.1.2 Target Area for Seasonal Malaria Chemoprevention
Target area for SMC implementation is the Sahel sub-region and similar areas where malaria transmission is highly seasonal and the majority of clinical malaria cases occur during a short period of about 4 months. In Ghana, SMC is currently being implemented in the Upper West, Upper East, North East, Northern, Savannah, Bono East, and Oti regions.

6.2 REDUCING MALARIA PARASITE TRANSMISSIBILITY IN LOW TRANSMISSION AREAS
A low transmission setting is defined as an area with parasite prevalence less than 10% or Annual Parasite Index (API) less than 250 per 1000 population. In low transmission areas, a single low dose of primaquine (0.25 mg/kg bw) should be administered with ACT to patients with *P. falciparum* malaria (except pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months). G6PD testing is not required.

6.3 MALARIA CHEMOPROPHYLAXIS FOR NON-IMMUNE INDIVIDUALS/TRAVELERS
Medicines recommended for use as malaria chemoprophylaxis among non-immune persons/travelers in Ghana are:

a. Oral Atovaquone-proguanil or
b. Oral Doxycycline or
c. Oral Mefloquine

Dosing must be based on body weight. Non-immune persons/travelers are required to start any one of these medicines 1–21 days before arriving in endemic area, and continue 7–28 days after leaving the endemic area.
Government has the responsibility of ensuring access to and safety of medicines to forestall implementation challenges. It is critical that all antimalarials deployed are of good quality, safe and efficacious. To this end, the pharmaceutical regulatory activities of the Food and Drugs Authority (FDA) shall be intensified, and the national drug quality control laboratory further equipped and resourced. This is to ensure the quality, safety and efficacy of recommended antimalarials and increase public confidence in the implementation of this policy.

Improved patient acceptance of ACTs shall be promoted by appropriate agencies of the Ministry of Health to ensure compliance. This will entail extensive public education on the revised management of malaria using multiple approaches such as print media, mass media and other social behavioural change communication (SBCC) strategies.

7.1 Classifying Antimalarial Therapies

The recommended ACTs and herbal antimalarial medications shall remain as Over-the Counter (OTC) medicines permissible to be dispensed at all levels of care to ensure ready availability to the general public. All other antimalarial medications mentioned in this policy remain either as a programme and/or prescription-only medicines.

7.2 Supply of Antimalarials

The Government of Ghana shall support the local pharmaceutical manufacturing industry to build capacity to meet internationally accepted requirements of current Good Manufacturing Practices (cGMP) in the production of ACTs and other antimalarials. This will facilitate sustainability of this policy, especially the provision of facilities for conducting bioavailability and bioequivalence studies among others. This will also enhance the manufacture and supply of ACTs and other antimalarials to both the public and the private sectors. The FDA shall monitor the quality, efficacy and safety, including Adverse Drug Reactions (ADRs) resulting from the use of all antimalarials (locally produced or imported) in accordance with the provisions of the Public Health Act 851, 2012.

7.3 Access to medicines under this policy

To ensure smooth implementation of this policy, the Ministry of Health and its agencies shall ensure access and availability of the recommended antimalarials in all facilities.
7.4 Managing Drug Resistance

Emergence and spread of drug resistance remain a major threat to the utility and longevity of ACTs. Markers of Artemisinin-partial resistance have been confirmed in Africa and in Ghana. In view of this, the MoH, GHS, NMEP and all key collaborators are to take steps to ensure delay in drug resistance development. These steps may include:

a. Continuous drug efficacy monitoring and mitigation effect
b. Deployment of multiple first-line treatment strategies
c. Any other evidence-based strategy/intervention.

7.5 Operational Considerations

This revised policy shall be implemented through an immediate nationwide rollout.

7.5.1 Implementation strategy

For effective implementation of this policy, the procurement, revision of guideline documents and social behavioural change communication (SBCC) strategies shall be as follows:

7.5.1.1 Procurement

Existing mechanisms will be maintained to ensure minimal price disparities between products from the public and private sectors.

7.5.1.2 Revision of the STGs, EML and NHIML

Sections of the Standard Treatment Guidelines (STGs), Essential Medicines List (EML), National Health Insurance Medicines List (NHIML) and other guidelines for health workers, curricula or documents recommending treatment for malaria shall be revised in line with this policy.

7.5.1.3 Social Behavioural Change Communication (SBCC)

The revision of STGs, EML and NHIML shall be matched with SBCC interventions to ensure the same messages are communicated to health care workers and members of the public.
8.0 CAPACITY BUILDING

The Ministry of Health shall ensure appropriate activities are conducted to facilitate the smooth implementation of the policy.

8.1 Stakeholders
Health professionals, policy makers, manufacturers, other service providers, relevant training institutions (including medical schools, nurses’ training colleges and pharmacy schools etc.), health managers in the public and private sectors, as well as the general public, shall be well informed about the revised policy.

8.2 Training
Training needs shall be assessed and training manuals developed and updated to ensure every target group is catered for. The health industry shall be re-oriented to become responsive to local needs, and not compromise on quality and value for money. A comprehensive training programme shall be conducted for all relevant healthcare providers prior to the rollout of public education programmes.

8.3 Public Education
Public education shall be directed at all target groups including health professionals, community-based service providers and the general public using the appropriate tools and media.
9.0 MONITORING AND EVALUATION

A framework for monitoring this policy shall include the following:

a. Prescribing and Dispensing
b. Patient Acceptance and Compliance
c. Safety, Quality and Efficacy of Products
d. Safety Monitoring
e. Availability and Accessibility

9.1 Prescribing and Dispensing
Prescribing and dispensing practices at all service delivery points shall be monitored and evaluated to enhance rational use of the recommended antimalarials.

9.2 Patient Acceptance and Compliance
The Ministry of Health and its agencies shall conduct regular surveys to assess patient acceptance and compliance with the medicines under this policy to inform promotional needs for improvement of acceptability.

9.3 Safety, Quality and Efficacy of Products
Post-market surveillance and laboratory testing shall be conducted by the FDA to ensure that both imported and locally manufactured products meet the relevant pharmacopoeial and manufacturing standards of safety, quality and efficacy. cGMP audit inspections of manufacturing facilities, both local and overseas, shall be rigorously enforced by the FDA.

The FDA shall also be required to furnish the Ministry of Health with periodic updates of the safety, quality and efficacy of products on the market.

The NMEP shall monitor antimalarial drug efficacy throughout the country.

The safety, quality and efficacy of malaria diagnostic devices and reagents shall also be monitored by the FDA and Ghana Standards Authority (GSA).

9.4 Safety Monitoring
The FDA, health agencies and research institutions shall develop and outline procedures for efficient safety monitoring countrywide.

9.5 Availability and Accessibility
Relevant indicators shall be developed to measure and monitor the availability and accessibility of the products under this policy to the general public.
10.0 REGULATION

10.1 Registration of Products
Only antimalarials recommended by this policy and duly registered by the FDA shall be authorised for supply and use by the general public. The registration includes evaluation of information on safety, quality and efficacy by the FDA. New fixed-dose combinations and new pre-packaged products must be registered even if the individual components of the combination are already registered.

10.2 Use of other Antimalarial Agents

10.2.1 Artemisinin-based Derivatives
The use of Artemisinin-based derivatives as monotherapies for the treatment of any type of malaria outside the provisions of the new antimalarial medicine policy shall remain discontinued in all health institutions. However, Artesunate (injection and suppository) and Artemether injection will continue to be used as initial therapy for severe malaria. This should be followed by a full course of ACT treatment.

10.2.2 Quinine in First Trimester of Pregnancy
Oral Quinine in combination with oral Clindamycin shall be used for treatment of uncomplicated malaria in the first trimester of pregnancy only when AL or alternate ACTs (ASAQ or DHAP) are not available or are not recommended. Oral Quinine use as monotherapy for the treatment of uncomplicated malaria in the first trimester of pregnancy shall remain discontinued.

10.2.3 Sulphadoxine-Pyrimethamine (SP)
Sulphadoxine-Pyrimethamine (SP) shall be reserved only for use in the prevention of malaria during pregnancy as Directly Observed Therapy (DOT), and in combination with Amodiaquine for Seasonal Malaria Chemoprevention (SMC). The use of Sulphadoxine-Pyrimethamine (SP) as monotherapy for uncomplicated malaria shall remain discontinued.

10.2.4 Primaquine
1. Primaquine shall be reserved solely for use as follows; in confirmed P. ovale and P. vivax malaria cases in addition to the recommended ACTs (G6PD testing shall be a prerequisite).
2. as a single low dose gametocytocidal medicine in addition to the recommended ACT for reducing transmissibility of P. falciparum infections in low transmission areas (G6PD testing is not required)

10.2.5 Amodiaquine
Amodiaquine as monotherapy for uncomplicated malaria shall remain discontinued. Amodiaquine in combination with Sulphadoxine-Pyrimethamine (SP) shall be reserved only for Seasonal Malaria Chemoprevention (SMC).

10.2.5 Atovaquone-Proguanil, Doxycycline and Mefloquine
These medicines, with respect to malaria case management, shall be reserved solely for chemoprophylaxis among non-immune travelers.
11.0 PUBLIC – PRIVATE PARTNERSHIP

The current policy shall build on the earlier work of capacity building in the private sector and other providers of care. The emphasis would be to promote the adoption of standards, and regulation of the industry in collaboration with the Ministry of Trade and Industry, GSA, Association of Ghana Industries (AGI) and other relevant regulatory agencies.

The Ministry of Health shall encourage collaboration with all stakeholders in the industry to understand the components, structure, conduct, performance and contribution of such partnerships to the national economy.

The local industry shall be supported to develop and market products and services for the health care market, establish and strengthen intra-sectoral policy dialogue, coordination, planning and accountability.

The Ministry shall provide a framework of relevant incentives and sanctions that enhance performance, promote accountability and continuously refine the role of Government in the delivery of health.
REFERENCES


Ministry of Health (MOH). Ghana Health Service (GHS). National Malaria Elimination Programme (NMEP), Ghana