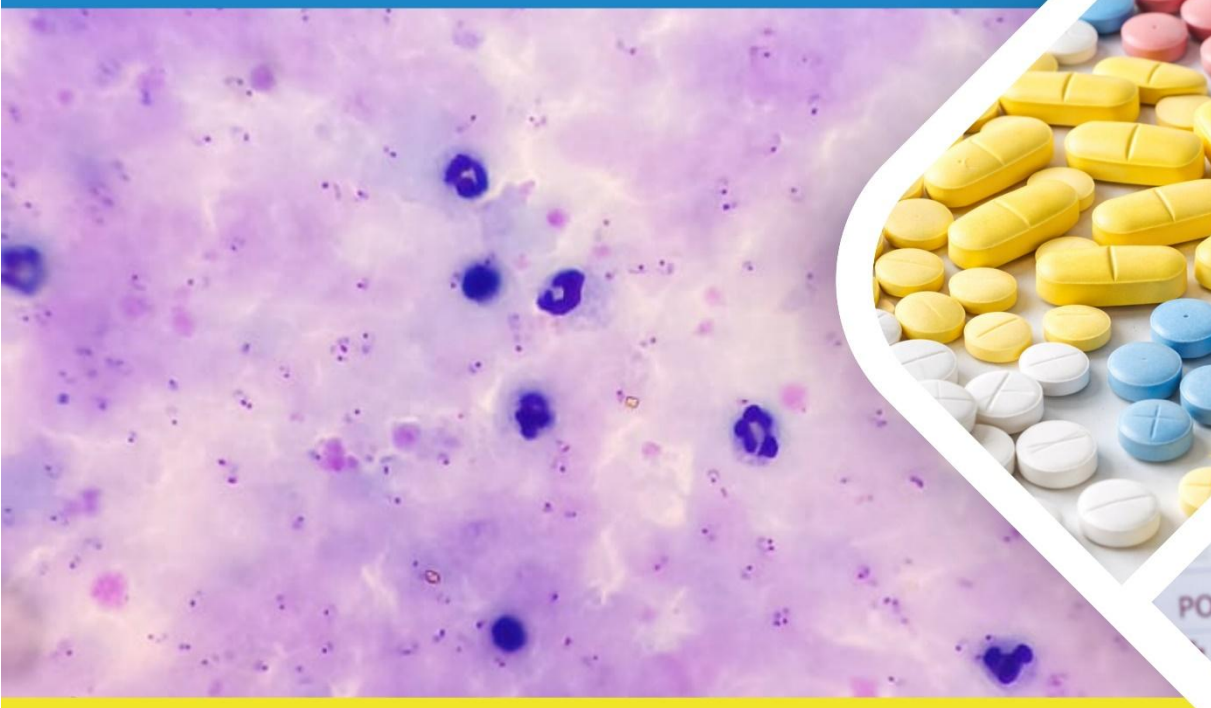
REPUBLIC OF KENYA

MINISTRY OF HEALTH

GUIDELINES FOR THE DIAGNOSIS & TREATMENT OF MALARIA IN KENYA









NATIONAL MALARIA CONTROL PROGRAM
MINISTRY OF HEALTH, KENYA

Komesha Malaria
Okoa Maisha

7TH EDITION, MARCH 2026

GUIDELINES FOR THE DIAGNOSIS, TREATMENT & PREVENTION OF MALARIA IN KENYA

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Guidelines for the diagnosis and treatment of malaria in Kenya

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FOREWORD

Malaria remains a leading public health challenge in Kenya, contributing significantly to morbidity and mortality and imposing a heavy burden on individuals, families, communities, and the health system. The Government of Kenya, through the Ministry of Health, remains firmly committed to accelerating progress toward malaria control and elimination. The ministry remains committed to our national targets to reduce malaria incidence by 80 percent and malaria-related deaths by 90 percent from 2023 levels by 2027/2028, and to interrupt local transmission in selected counties.

The Ministry of Health recognizes that achieving these targets requires a strong foundation in effective malaria case management. This means ensuring universal access to prompt and accurate parasitological diagnosis, followed by timely treatment with quality-assured antimalarial medicines in strict accordance with national policy. Standardized, evidence-based guidance is essential to delivering consistent, high-quality care across all levels of the health system and among all service providers.

It is with great pleasure that the Ministry of Health presents the Seventh Edition (2026) of the Kenya Malaria Diagnosis and Treatment Guidelines. This edition reflects the Ministry's commitment to providing health workers with updated, evidence-based guidance aligned with current global recommendations, including those of the World Health Organization. The guidelines have been developed through a rigorous technical review process, drawing on national surveillance data, operational experience, and the latest scientific evidence. They are designed to standardize malaria case management across public, private, and faith-based health facilities at all levels of care.

The Ministry of Health affirms its continued leadership in coordinating the national malaria response and calls upon all health workers, county governments, development partners, and stakeholders to adopt and consistently implement these guidelines. Their faithful application will be instrumental in improving quality of care, reducing the malaria burden, and advancing Kenya's journey toward malaria elimination.



Dr. Patrick Amoth, CBS
Director General for Health
Ministry of Health

PREFACE

The Kenya Malaria Diagnosis and Treatment Guidelines, Seventh Edition (2025) have been developed to provide up-to-date, practical, and evidence-based guidance for malaria case management across Kenya's diverse transmission settings. This revision incorporates the latest scientific evidence, reflects evolving malaria epidemiology, and aligns national practices with current World Health Organization recommendations, while remaining grounded in the operational realities of the Kenyan health system.

The guidelines reinforce universal parasitological confirmation of all suspected malaria cases and promote the use of quality-assured antimalarial medicines, with particular attention to the needs of vulnerable groups including young children and pregnant women. They are intended to standardize care across public, private, and faith-based facilities at all levels, and to support health workers in delivering consistent, high-quality malaria case management as a cornerstone of primary healthcare.

This edition was developed through a rigorous, consultative process led by the Ministry of Health, in collaboration with county health departments, research and academic institutions, and implementing partners. It draws on programme implementation experience, routine health data, and operational research to ensure its relevance to the Kenyan context.

All users are encouraged to apply these guidelines consistently in their respective settings and to provide feedback to inform future revisions.



Dr. Joel Gondi
Director, Primary Healthcare Services
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The National Malaria Control Programme (NMCP) wishes to express its sincere gratitude to all individuals, technical experts, and institutions whose knowledge, dedication, and time contributed to the development and review of the Kenya Malaria Diagnosis and Treatment Guidelines, Seventh Edition (2025). The breadth and quality of this work reflects a collective effort, and the NMCP is appreciative of every contribution made.

The NMCP extends special recognition to the members of the technical working groups and expert review panels who gave generously of their time and expertise to ensure that these guidelines are evidence-based, technically sound, and responsive to the Kenya malaria context. Your rigorous engagement in the review process has been invaluable.

The NMCP gratefully acknowledges the support of implementing partners, development agencies, and research institutions whose technical and financial contributions were instrumental in making the development of these guidelines possible. The Programme recognizes that sustained partnership and collaboration remain foundational to Kenya's malaria control and elimination agenda, and we look forward to continued joint efforts in translating these guidelines into improved health outcomes across the country.

Finally, and most importantly, the NMCP acknowledges the dedication of health workers at every level of the health system, in public, private, and faith-based facilities, whose frontline commitment to quality malaria care is the cornerstone of Kenya's progress in reducing the burden of this disease.



Dr. Kibor Keitany, OGW
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ABBREVIATIONS

ACT	Artemisinin-based combination treatment
ADR	Adverse drug reaction
AIDS	Acquired immune deficiency syndrome
AL	Artemether-lumefantrine
ANC	Antenatal care or clinic
AS+AQ	Artesunate-Amodiaquine
ASPY	Artesunate-Pyronaridine
BWT	Birth weight
CHMTs	County Health Management Teams
CQ	Chloroquine
CSF	Cerebro-spinal fluid
DHAP	Dihydroartemisinin-piperaquine
DHI	District Health Information System
DNA	Deoxyribonucleic acid
DOMC	Division of Malaria Control
DOT	Directly observed treatment
DOI	Directly observed ingestion
EIA	Enzyme Immuno-assay
ELISA	Enzyme Linked Immunosorbent Assay
ENSO	El-Nino Southern Oscillation
EPR	Epidemic preparedness and response
FIND	Foundation for Innovative New Diagnostics
G6PD	Glucose 6-phosphate dehydrogenase
GCS	Glasgow Coma Scale
GMP	Good Manufacturing Practices
GTS	Global Technical Strategy
Hb	Haemoglobin
HIV	Human immunodeficiency virus
HRP2	Histidine-Rich Protein 2
HRP3	Histidine-Rich Protein 3
IFA	Immunofluorescence Assay
IM	Intramuscular
IMNCI	Integrated management of neonatal and childhood illnesses
IPTp	Intermittent preventive treatment of malaria in pregnancy
IV	Intravenous
KEMSA	Kenya Medical Supplies Authority
kg	kilogram
KMIS	Kenya Malaria Indicator Survey
KNH	Kenyatta National Hospital
LFT	Liver function tests
LLIN	Long lasting insecticidal nets
M&E	Monitoring and Evaluation
MFT	Multiple First-Line Therapies
mg	milligram
ml	millilitre

NSAID	non-steroidal anti-inflammatory drug
PCR	Polymerase Chain Reaction
PCR	Polymerase chain reaction
PCV	Packed cell volume
pLDH	Parasite lactate dehydrogenase
PMI	President's Malaria Initiative
PPB	Pharmacy and poisons board
QA	Quality Assurance
QBC	Quantitative Buffy Coat
RDT	Rapid diagnostic test
SOP	Standard operating procedure.
SP	Sulphadoxine/ pyrimethamine
TSS	Tropical splenomegaly syndrome
WBC	White blood cell
WHO/GMP	World Health Organization/Global Malaria Program
µL	microlitre

GLOSSARY OF TERMS

Afebrile: Without fever.

Anaemia: A reduction in the quantity of oxygen-carrying pigment haemoglobin in the blood.

Antimalarial Drug Resistance: The ability of malaria parasites to survive and multiply despite adequate drug exposure at recommended or higher doses. It arises from genetic mutations or gene amplifications that reduce the parasite's susceptibility to antimalarial medicines.

Antipyretic: A drug such as paracetamol that relieves fever without affecting the causative agent (in this case the parasite).

Artemisinin-based combination therapy (ACT): A combination of artemisinin or one of its derivatives with antimalarial or antimalarials of a different class.

Asexual cycle: The life cycle of the malaria parasite in the host from merozoite invasion of red blood cells to schizont rupture (merozoite, ring stage, trophozoite, schizont, merozoites). Duration approximately 48hr in *Plasmodium falciparum*, *P. ovale* and *P. vivax*; 72 hours in *P. malariae.*

Asexual parasitaemia: The presence in host red blood cells of asexual parasites. The level of asexual parasitaemia can be expressed in several different ways: the percentage of infected red blood cells, the number of infected cells per unit volume of blood, the number of parasites seen in one microscopic field in a high-power examination of a thick blood film, or the number of parasites seen per 200–1000 white blood cells in a high- power examination of a thick blood film.

Base: The main active part of a drug (see also salt).

Cerebral malaria: Severe P. falciparum malaria with cerebral manifestations, usually including coma (Glasgow coma scale <11, Blantyre coma scale <3). Malaria with coma persisting for >30min after a seizure is considered to be cerebral malaria.

Cinchonism: Poisoning caused by an overdose of cinchona or the alkaloids quinine, quinidine, or cinchonine derived from it.

Combination treatment: A combination of two or more different classes of antimalarial medicines with unrelated mechanisms of action.
Co-formulation: two or more drug substances combined in a single dosage form.

Cure: Elimination of the symptoms and asexual blood stages of the malaria parasite that caused the patient or caregiver to seek treatment.

Endemic: Occurring frequently in a particular region or population.

Essential medicines: Are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.

Febrile: With an increase in temperature compared with the normal.

Fever: An increase in body temperature above the normal temperature i.e. above a normal temperature of 37.5°C.

Febrile convulsions: Convulsions occurring in children aged 6 months - 6yrs due to fever

caused by infection outside the central nervous system.

Gametocytes: Sexual stages of malaria parasites present in the host red blood cells.

Hyperpyrexia: Temperature over 39.5°C.

Hypersensitivity: An abnormal response to the presence of a particular antigen, which may cause a variety of tissue reactions ranging from serum sickness to an allergy.

Hypnozoites: Persistent liver stages of *P. vivax* and *P. ovale* that remain dormant in host hepatocytes for an interval (most often 3–45 weeks) before maturing to hepatic schizonts. These then burst and release merozoites, which infect red blood cells. Hypnozoites are the source of relapses.

Immunity: All those natural processes which prevent infection, re-infection, or super- infection, or which assist in destroying parasites or limiting their multiplication, or which reduce the clinical effects of infection.

Isotonic solution: Refers to two solutions having the same osmotic pressure across a semi-permeable membrane.

Low parasitemia: <200 parasites/μL or <5 parasites/200 WBC

Lumbar puncture: The insertion of a needle into the fluid-filled space of the spinal cord in the lumbar region and the removal of a sample of that fluid for examination.

Monotherapy: Antimalarial treatment with a single medicine (either a single active compound or a synergistic combination of two compounds with related mechanisms of action).

Multiple First-Line Therapies: The use of two or more effective ACTs for the treatment of uncomplicated malaria, either simultaneously or in rotation (Cycling).

Non-immune: Having no immunity at all to a particular organism or disease.

Parenteral: The provision of medication into the body by any means other than through the alimentary canal (oral route or rectal), such as by subcutaneous, intramuscular or intravenous injection.

Plasmodium: A genus of protozoan vertebrate blood parasites that includes the causal agents of malaria. *Plasmodium falciparum, P. malariae, P. ovale* and *P. vivax* cause malaria in humans. Human infections with the monkey malaria parasite, *P. knowlesi* have also been reported from forested regions of South-East Asia.

Pre-erythrocytic development: The lifecycle of the malaria parasite when it first enters the host. Following inoculation into a human by the female anopheles mosquito sporozoites invade parenchyma cells in the host liver and multiply within the hepatocytes for 5–12 days, forming hepatic schizonts. These then burst liberating merozoites into the bloodstream, which subsequently invade red blood cells.

Proficiency assessment: It is a process of exposing practicing microscopists to slides of known results with a view of assessing their ability to correctly read slides.

Pruritus: Itching caused by local irritation of the skin or at times nervous disorders.

Radical cure: In *P. vivax* and *P. ovale* infections only, this comprises a cure as defined

above plus prevention of relapses by killing hypnozoites.

Malaria Rapid diagnostic test (mRDT): Is an immunochromatographic test for malaria presented in the form of a dipstick, cassette or card in which the coloured line indicates that plasmodial antigens have been detected.

Recrudescence: The recurrence of asexual parasitaemia after treatment of the infection with the same infection that caused the original illness. This results from incomplete clearance of parasitaemia due to inadequate or ineffective treatment. It is therefore different to a relapse in *P. vivax* and *P. ovale* infections, and it differs from a new infection or re-infection (as identified by molecular genotyping in high to moderate transmission zones).

Recurrence: The recurrence of asexual parasitaemia following treatment. This can be caused by a recrudescence, a relapse (in *P. vivax* and *P. ovale* infections only) or a new infection.

Relapse: The recurrence of asexual parasitaemia in *P. vivax* and *P. ovale* malaria deriving from persisting liver stages. Relapse occurs when the blood stage infection has been eliminated but hypnozoites persist in the liver and mature to form hepatic schizonts. After variable intervals of weeks to months, the hepatic schizonts burst and liberate merozoites into the bloodstream.

Salt: Any compound of a base and an acid, e.g. quinine dihydrochloride or quinine sulphate.

Schizonts: Mature malaria parasites in host liver cells (hepatic schizonts) or red blood cells (erythrocytic schizonts) that are undergoing nuclear division. This process is called schizogony.

Sensitive: Possessing the ability to respond to a stimulus.

Severe anaemia: Haemoglobin concentration of <5g/100 ml (haematocrit <15%).

Severe falciparum malaria. Acute falciparum malaria with signs of severity and/or evidence of vital organ dysfunction.

Slide rechecking: It is a verification process where slides are re-examined by a second reader and a third reader where there is disagreement.

Sporozoites: Motile malaria parasites that are infective to humans, inoculated by a feeding female anopheles mosquito. The sporozoites invade hepatocytes.

Treatment failure: A failure to achieve the desired therapeutic response after the initiation of therapy. Treatment failure is not synonymous with drug resistance.

Trophozoites: A stage of development of the malaria parasites within host red blood cells. Mature trophozoites contain visible malaria pigment.

Uncomplicated malaria: Symptomatic infection with malaria parasitaemia without signs of severity and/or evidence of vital organ dysfunction.

MALARIA TREATMENT SNAPSHOT

Diagnosis of Malaria

- All people with suspected malaria should have a parasitological test to confirm the diagnosis.
- The diagnosis can be confirmed by use of a rapid diagnostic test (RDT) or microscopy.

Treatment of Uncomplicated *P. falciparum* Malaria

- Treat adults and children with uncomplicated *P. falciparum* malaria with an artemisinin-based combination therapy (ACT) drug.
- All treatments with ACTs should be for at least **three days**.

ACTs for Diversification under Multiple First-Line Therapies (MFT) Strategy

To align to WHO recommendations for reducing the risk of resistance and improving treatment outcomes, Kenya proposes to introduce Multiple First-Line Therapies (MFT) for the management of uncomplicated Plasmodium falciparum malaria. Under the MFT strategy, the first-line antimalarial therapy will be systematically substituted with an alternative ACT at predetermined intervals, typically every 24 to 36 months. This periodic rotation is intended to optimize treatment efficacy, delay the development of drug resistance, and sustain the long-term effectiveness of ACTs in malaria case management.

Recommended ACT options under MFT include:

ACT Option	Abbreviation
Artemether-Lumefantrine	AL
Dihydroartemisinin-Piperaquine	DHAP
Artesunate-Amodiaquine	AS + AQ
Artesunate-Pyronaridine	ASPY

The selection of a specific ACT may depend on factors such as deployment strategies, patient characteristics, drug availability, and resistance profiles.

Treatment of Uncomplicated P. *falciparum* Malaria in Special Risk Groups

Special Risk Group	Recommended Treatment
Pregnant women (all trimesters)	ACTs (AL only)
Infants <5 kg	ACT at same dose as for children of 5 kg
Patients with hyperparasitemia	ACT plus close monitoring due to increased risk of severe disease
Patients with Sickle Cell Disease	ACT plus supportive care (e.g., hydration); initiate chemoprevention where indicated

ACT choice should follow the MFT implementation framework while ensuring safety and suitability for each special group.

Treatment of Uncomplicated P. vivax, P. ovale, and P. malariae Malaria

All patients with uncomplicated P. vivax, P. ovale, or P. malariae malaria—including adults, children, and pregnant women in all trimesters—should be treated with a quality-assured artemisinin-based combination therapy (ACT).

- The choice of ACT should follow **national treatment policy** and align with the **Multiple First-Line Therapies (MFT)** strategy where applicable.

- ACT selection may be influenced by factors such as drug availability, patient suitability, and regional deployment plans.

Note: For *P. vivax* and *P. ovale* infections, a radical cure with primaquine should be considered to prevent relapses, in accordance with national guidelines and G6PD status

Preventing Relapse in P. vivax or P. ovale Malaria

Primaquine for Radical Cure

To prevent relapse caused by dormant liver stages (*hypnozoites*) of *P. vivax* and *P. ovale*, a 14-day course of primaquine is recommended in addition to ACT.

Eligibility for Radical Cure with Primaquine

Eligible Group	Recommended Regimen
Adults and children (non-pregnant, non-lactating, and G6PD-normal)	ACT plus primaquine 0.25 mg/kg per day for 14 days

Primaquine should NOT be given to:

- Pregnant women

- Breastfeeding women (if the infant is under 6 months or if G6PD status is unknown)

- Infants under 6 months

- Individuals with confirmed G6PD deficiency

G6PD testing is recommended before administering primaquine for radical cure, to avoid the risk of haemolysis.

Pre-Referral Treatment of Severe Malaria Pending Transfer to Higher-Level Facilities

Scenario	Treatment
Facility with injectable options available	Single IM dose of artesunate: Adults: 2.4 mg/kg Children ≤20 kg: 3.0 mg/kg
If artesunate is unavailable	Use artemether 3.2 mg/kg IM or quinine 20 mg/kg IM
Where IM injections are unavailable (children <6y)	Give rectal artesunate 10 mg/kg and refer immediately

Treatment of severe P. falciparum and P. vivax malaria

Severe malaria is a medical emergency, and all patients should be treated as in- patients and provided the highest level of care including intensive supportive care available.

For both severe *P. falciparum* and *P. vivax* malaria, treat all adults including pregnant women in all trimesters and children with intravenous or intramuscular artesunate, for a minimum of 3 doses/ or 24hrs.

Give children weighing less than 20 kg 3mg/kg per dose of artesunate. Heavier children and adults should receive 2.4mg/kg per dose of artesunate.

Once the patient has received at least 24hrs of parenteral therapy, AND is able to tolerate oral therapy, complete treatment with a three-day course of ACTs.

In addition, Patients with severe *P. falciparum mixed with either P. vivax or P. ovale, or Severe P. vivax* malaria should be treated with a 14- day course of 0.25 -0.5mg/kg per day of primaquine to prevent future relapse.

Prevention of malaria in pregnancy (IPT-p)

In very high to moderate malaria transmission zones, administer Intermittent Preventive Treatment with SP (IPTp-SP) to all eligible pregnant women with each scheduled antenatal visit starting from 13 weeks of pregnancy (the second trimester). Each SP dose should be given as Directly Observed Therapy (DOT) at least one month apart (4 weeks).

Community IPTp (Intermittent Preventive Treatment for Pregnant Women

This is a WHO-recommended strategy to prevent malaria during pregnancy which entails administration of quality-assured SP for IPTp to eligible pregnant women by trained community level health service providers, commonly referred to as Community Health Promoters (CHPs). c-IPTp complements the delivery of IPTp-SP at ANC facilities. The c-IPTp approach intends to bridge the gap between ANC attendance and IPTp coverage and allows CHPs to create awareness and sensitize pregnant women on the need to attend an

ANC clinic for comprehensive ANC services.

Chemoprevention of malaria in other populations

Perennial malaria chemoprevention (PMC)

Perennial malaria chemoprevention (formerly Intermittent preventive treatment for infants- IPTi) is the administration of a full treatment course of an antimalarial medicine at predefined intervals, regardless of whether the child is infected with malaria, in order to prevent illness in moderate to high perennial malaria transmission settings. The goal of PMC is to protect young children by establishing preventive antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the age of greatest risk of severe malaria.

Seasonal Malaria Chemoprevention (SMC)

Seasonal malaria chemoprevention is the intermittent administration of a curative dose of antimalarial medicine during the malaria season, regardless of whether the child is infected with malaria. The objective of SMC is to establish antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the period of greatest malaria risk. SMC is recommended in areas of seasonal malaria transmission i.e. where more than 60% of the annual malaria cases occur within 3 - 5months.

The antimalarial drug combination of choice for SMC is Sulfadoxine–pyrimethamine + Amoduaquine (SP+AQ). SP+AQ is available as dispersible tablets in two different blister packs for the following two age groups:

- **Infants 3 to <12 months of age:** a single dose of a tablet of 250/12.5 mg SP and three 75 mg tablets of AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are given on days 2 and 3, respectively.
- **Children aged 12–59 months:** a single dose of a tablet of 500/25 mg SP and three tablets of 150 mg AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are

given on days 2 and 3, respectively.

(As there are currently no specific blister packs for children >60 months of age, countries should ensure that the target dose of SP+AQ based on weight is delivered daily for 3 days: SP – 25/1.25 (25-70/1.25-3.5) mg/kg bw single dose and AQ – 10 (7.5-15)mg/kg bw daily for 3 days.)

Post discharge malaria chemoprevention (PDMC)

Post-discharge malaria chemoprevention is the administration of a full antimalarial treatment course at regular intervals to children admitted with severe anaemia. The purpose of PDMC is to prevent new malaria infections in children aged 10 years and below admitted with severe anaemia during the period after hospital discharge when they are at high risk of re-admission or death. The drug of choice for PDMC is Dihydroartemisinin - Piperaquine (DHAP) two weeks post discharge and subsequently every month up to a maximum of 4 doses i.e. 2 weeks, 6 weeks, 10 weeks and 14 weeks post discharge.

Intermittent preventive treatment in school-aged children (IPTsc)

Intermittent preventive treatment in school-aged children (IPTsc) is the administration of a full treatment course of an antimalarial medicine at regular intervals to treat and prevent malaria infections in children who are old enough to attend school.

Malaria Vaccine

This is the use of malaria vaccines for the prevention of P. falciparum malaria in children living in moderate to very high malaria transmission zones. Malaria vaccine is provided in a four-dose schedule in children from 5 months of age for the reduction of malaria disease and burden. RTS,S/AS01 malaria vaccine is administered at 6 months, 7 months, 9 months and 24 months of age. R21 malaria vaccine is administered at 5 months, 6 months, 7 months and 24 months of age.

Mass drug administration (MDA)

Mass drug administration for malaria is the administration of a full therapeutic course of an antimalarial medicine at approximately the same time, and often at repeated intervals, to all age groups of a population in a defined geographical area. Antimalarial medicines are administered without prior malaria testing and therefore regardless of the malaria infection status of individuals.

1.INTRODUCTION

1.1 Background

Malaria remains a significant public health concern in Kenya with one third of the population living in areas with high risk of malaria. *Plasmodium falciparum* is the commonest cause of malaria in Kenya. Other parasite species present include P. vivax, P. malariae, P. ovale. Interventions to manage malaria in Kenya have been integrated and include vector control, chemoprevention, case management, surveillance, social behaviour change and malaria elimination in targeted counties. The interventions are implemented based on malaria stratification.

Early detection, prompt and effective treatment are the cornerstones of malaria case management. ACTs are at present the best treatment for uncomplicated malaria and the efficacy of the treatments recommended in this guideline continue to be monitored regularly.

1.2 Objective

The objective of this prevention,diagnosis and treatment guidelines is to provide the target audience with evidence-based recommendations for the prevention, diagnosis, and treatment of malaria.

1.3 Target Audience

These guidelines are intended for: All healthcare providers, public health stakeholders and policy specialists working in health facilities, research institutions, health training institutions, non-governmental organizations and agencies working as partners in health or malaria programs.

1.4 Formulations

Only ACTs that are co-formulated should be used for the treatment of uncomplicated malaria in Kenya. In order for the ACT to provide its intended benefits of effective treatment and extended useful therapeutic life of both drugs, it is strongly recommended that ACTs should include **at least 3 days of treatment with an artemisinin derivative. In addition, it is recommended that *Plasmodium vivax, Plasmodium ovale* and all confirmed malaria cases in elimination settings should also be treated with low dose primaquine to achieve radical cure.** Paediatric formulations should be used for infants and children in order to ensure the correct dosing. Where available, child friendly formulations (flavoured / liquefiable by dose) should be used. All other previously used monotherapies including oral artemisinins should not be used for treatment of malaria and will not be licensed for this purpose anymore.

1.5 Malaria diagnosis

Diagnosis of malaria is based on detection of parasites and parasite products in the blood following clinical suspicion. It is currently recommended to confirm diagnosis of malaria in all age groups and in all epidemiological settings. The two methods used routinely for parasitological diagnosis of malaria are microscopy and mRDTs. This is done to ensure that patients with fever arising from other causes are managed accordingly and treatment is targeted to patients with confirmed malaria infection.

Diagnostic tests are available at all levels of the health care system.



Parasitological diagnosis of malaria is recommended for all patients with suspected malaria, appropriate **treatment should NEVER be delayed or denied** due to inability to test for malaria.

2.MALARIA IN KENYA

Malaria is caused by parasites of the genus Plasmodium. In Kenya, Plasmodium falciparum is the predominant species, responsible for 76% of infections, followed by Plasmodium malariae (4%) and Plasmodium ovale (1%) (KMIS, 2020). Mixed infections involving Plasmodium falciparum and Plasmodium malariae also occur and account for 19% of the reported cases (NMCP and ICF, 2021). Cases of Plasmodium vivax have been reported in Northern Kenya (Isiolo, Mandera, Turkana, Marsabit, and Wajir) through routine surveillance data.

Epidemiology of Malaria in Kenya

Kenya has seven malaria epidemiological zones, with diversity in risk determined largely by passive surveillance data, environmental data, and KDHS information on health seeking behaviour.

Table 1: Classification of counties based on malaria burden.

Classification of malaria burden	Adjusted incidence, median (interquartile range)	Counties
No transmission	-	Nairobi
Very low burden	2.0 (1.0—3.2)	Embu, Kirinyaga, Kitui, Laikipia, Lamu, Machakos, Makueni, Mandera, Murang'a, Nyandarua, Nyeri, Wajir
Low burden	11.0 (9.0—15.5)	Bomet,Garissa, Isiolo, Kajiado, Kiambu,Marsabit, Meru, Nakuru, Taita Taveta, Tharaka-Nithi
Moderate burden	54.0 (30.5—71.0)	Elgeyo-Marakwet, Mombasa, Narok, Nyamira, Samburu, Tana River, Uasin Gishu
Moderate to high burden	95.0 (82.0—117.0)	Baringo, Kericho, Kilifi, Kisii, Nandi, Trans Nzoia
High burden	474.0 (343.0—478.0)	Bungoma, Homa Bay, Kwale, Turkana, West Pokot
Very high burden	748.0 (649.0—850.0)	Busia, Kakamega, Kisumu, Migori, Siaya, Vihiga

Source: Kenya Malaria Strategy 2023 - 2027

The very high burden zones comprised of six counties (Busia, Kakamega, Kisumu, Migori, Siaya, and Vihiga) with an average adjusted incidence of 748 malaria cases per 1,000 people (Table 4). Nairobi was uniquely classified as a 'no transmission' area due to historical evidence of very low risk of local transmission.

3. CLINICAL FEATURES AND CLASSIFICATION OF MALARIA

Infection with malaria parasites may be asymptomatic or result in a wide variety of symptoms, ranging from very mild to severe disease and even death. Malaria is a curable disease if promptly diagnosed and effectively treated.

3.1. Asexual life cycle of malaria

The clinical symptoms associated with malaria are caused by asexual erythrocytic or blood stage parasites. When the parasite develops in the erythrocyte, numerous known and unknown waste substances such as hemozoin pigment and other toxic factors accumulate in the infected red blood cell. These waste products are released into the bloodstream when the infected cells lyse, simultaneously releasing invasive merozoites. The hemozoin and other toxic factors such as glucose phosphate isomerase (GPI) stimulate macrophages and other cells to produce cytokines and other soluble factors which act to produce fever and rigor and probably influence other severe pathophysiology associated with malaria.

Plasmodium falciparum-infected erythrocytes, with mature trophozoites, adhere to the vascular endothelium of venular micro-circulation leading to their sequestration in the vessels of the brain causing the severe disease syndrome known as cerebral malaria, which is associated with high mortality.

3.2. Suspected malaria

The signs and symptoms of malaria are non-specific. Malaria is suspected clinically primarily on the basis of fever or a history of fever. There is no combination of signs or symptoms that reliably distinguishes malaria from other causes of fever; diagnosis based only on clinical features has very low specificity and results in overtreatment. Other possible causes of fever and whether alternative or additional treatment is required must always be carefully considered. The focus of malaria diagnosis should be to identify patients who truly have malaria, to guide rational use of antimalarial medicines.

In high transmission zones, malaria should be suspected in any patient presenting with a history of fever or temperature ≥ 37.5 °C and no other obvious cause. In areas in which malaria transmission is stable (or during the high-transmission period of seasonal malaria), malaria should also be suspected in children with palmar pallor or a haemoglobin concentration of < 8 g/dL.

In low transmission zones, health workers should identify patients who may have been exposed to malaria (e.g. recent travel to high to moderate transmission zones without protective measures) and have fever or a history of fever with no other obvious cause.

3.3. Classification of malaria

Malaria can be classified as either uncomplicated or severe based on clinical presentation.

3.3.1. Uncomplicated Malaria

This is characterized by fever in the presence of peripheral parasitaemia. Other features may include chills, profuse sweating, muscle pains, joint pains, abdominal pain, diarrhoea, nausea, vomiting, irritability and refusal to feed. These features may occur singly or in combination.

3.3.2. Severe Malaria

3.3.2.1. Severe P. falciparum malaria

This is a life-threatening manifestation of malaria, and is defined as the detection of P. falciparum in the peripheral blood in the presence of any one or more of the clinical or laboratory features listed in Table 5,6 & 7.

3.3.2.2. Severe P. vivax malaria.

Although *P. vivax* malaria is considered to be benign, with a low case-fatality rate, it may cause a debilitating febrile illness with progressive anaemia and can also occasionally cause severe disease, as in *P. falciparum* malaria. Reported manifestations of severe *P. vivax* malaria include severe anaemia, thrombocytopenia, acute pulmonary oedema and, less commonly, cerebral malaria, pancytopenia, jaundice, splenic rupture, haemoglobinuria, acute renal failure and shock.

4.PARASITOLOGICAL DIAGNOSIS OF MALARIA

The recommended tests to detect the presence of malaria parasites and parasite products are microscopy or malaria rapid diagnostic tests (mRDTs). Quality Microscopy is the gold standard method for parasitological diagnosis of malaria. mRDTs are used where microscopy services are not available. Quality assurance of microscopy and mRDTs is vital for ensuring the reliability of test results.

4.1. Malaria Microscopy

This is performed by examining Giemsa stained thick and thin blood films for detecting the presence, Species and estimating the quantity of malaria parasites.

- Thick films are used for parasite detection and quantification and can be used to monitor response to treatment.
- Thin films are used for species identification and parasite quantification in high parasitemia.

4.1.1 Quality Assurance (QA) in Malaria microscopy

QA in malaria microscopy ensures accurate and reliable diagnosis. QA programs involve systematic processes to maintain and improve diagnostic accuracy, reducing errors in parasite detection, speciation, and quantification.

4.1.1.1. Internal Quality Control (IQC)

Internal quality control is conducted within laboratories to monitor day-to-day performance. It includes routine maintenance of microscopes, assessment of the stain quality, proper slide preparation, and the preparation of IQC slides (weak positive and negative controls). IQC ensures that individual microscopists maintain consistency and accuracy in malaria diagnosis.

4.1.1.2. External Quality Assessments (EQA)

External quality assessment is conducted by external bodies to evaluate and enhance laboratory performance. Available malaria EQA schemes include proficiency testing, slide rechecking, and on-site Technical Support Supervision & mentorship. These programs help identify gaps in microscopy and provide immediate corrective and preventive actions to improve malaria diagnosis.

4.2. Malaria Rapid Diagnostic Tests

Malaria Rapid diagnostic tests (mRDTs) are immunochromatographic tests based on detection of specific parasite antigens. Tests which detect histidine-rich protein 2 (HRP2) are specific for *P. falciparum* while those that detect parasite lactate dehydrogenase (pLDH) or aldolase known as combo or pan mRDTs have the ability to differentiate between *P. falciparum* and non-*P. falciparum* malaria (*P. vivax, P. malariae and P. ovale*). With appropriate training, mentorship, technical support supervision and competence appraisal, mRDTs are simple to use and sensitive in detecting low parasitemia.

The use of mRDTs is, however, not recommended for follow-up of previously confirmed cases as most of the tests remain positive for between 2 to 3 weeks following effective antimalarial treatment and clearance of parasites. mRDTs cannot be used to determine parasite density.

When using mRDTs, it is important to adhere strictly to the manufacturer's instructions, especially the time of reading, amount of blood, number of buffer drops and the interpretation of the test results. Remember to observe biosafety procedures at all times. Malaria program reviews specifications for mRDTs to be used taking into account among other things the latest WHO recommendations.



There is **no need** to confirm an initial mRDT Positive with microscopy. Microscopy should be used for all treatment follow up.

Quality assurance of microscopy

Table 2: Quality Assurance of Malaria Microscopy

Quality Assurance Process	Quality Assurance location
Product evaluation (Reagents,stains,equipment)	County/National
Proficiency Testing (Individual & facility Staff competence appraisal)	Scheme provider (Accredited under ISO 17043)
Slide rechecking	Facility/County/National
Technical supportive supervision	Facility/County/National
IQC	Facility
Internal audit (Individual & facility Staff competence appraisal)	ISO/IEC 19011
Malaria microscopy scope accreditation	ISO/IEC 15189:2022-International

Quality assurance of mRDTs

The following key steps are involved in quality assurance of mRDTs to ensure quality/ accurate results.

Table 3 : Quality Assurance of mRDTs

Quality Assurance process	Quality Assurance location
GMP in production	Manufacturer
Product evaluation	FIND/WHO
Lot testing (pre-shipment/ post-shipment)	In-country
Post Marketing Surveillance	In-country
IQC	At point of use
EQA	At national level

PfHRP2/3 gene deletion

Deletions in the pfHRP2 and pfHRP3 genes of the parasite render parasites undetectable by mRDTs based on histidine-rich protein 2 (HRP2).

Surveillance on the prevalence of suspected false-negative HRP2 mRDTs results among symptomatic patients attending public health facilities with *P. falciparum* infection detected by pf-pLDH mRDT was conducted in 2020 in 10 counties (2 counties per epidemiological zone). During periodic surveillance WHO recommends if the threshold of pfHRP2/3 gene deletions causing false negative *P. falciparum*

mRDTs is at or above 5%, it warrants a change in mRDT and informs the country policy on mRDT.

4.3. Other Parasite Detection Methods

Several advanced techniques exist for detecting malaria parasites, though they are not widely used in routine clinical management due to their complexity, cost, or resource requirements. These methods are primarily employed in research, epidemiological studies, or specialized diagnostic settings.

4.3.1 Serological Tests

Serological tests detect host antibodies against asexual blood-stage malaria parasites, indicating prior exposure rather than current infection. While useful for surveillance and epidemiological mapping, they are not suitable for diagnosing active infections.

Common serological methods include:

- Latex agglutination assays
- Immunofluorescence antibody testing (IFA)
- Enzyme-linked immunosorbent assay (ELISA)
- Enzyme immunoassay (EIA)

4.3.2 Detection of Parasite DNA

Molecular techniques detect parasite DNA and are highly sensitive and specific for identifying ongoing malaria infections. These methods are particularly effective in detecting low-level parasitemia that might be missed by microscopy or rapid diagnostic tests (RDTs).

Common DNA-based diagnostic methods include:

- Polymerase Chain Reaction (PCR)
- Loop-mediated Isothermal Amplification (LAMP)
- Quantitative PCR (qPCR)

Molecular Surveillance

Molecular surveillance uses these DNA-based techniques to monitor the genetic characteristics of malaria parasites across populations. It is an essential component of malaria control and elimination strategies, offering insights into:

- Drug resistance mutations (e.g., pfcrt, pfmdr1, kelch13)
- Species identification and detection of mixed infections
- Transmission dynamics and parasite population structure

Molecular surveillance informs public health policies, guides treatment protocols, and enables early detection of emerging threats such as antimalarial drug resistance.

Qualitative Buffy Coat (QBC) Technique

This method involves staining parasite DNA in microhematocrit tubes using fluorescent dyes (e.g., acridine orange), followed by detection using epi-fluorescent microscopy. While faster than conventional microscopy and more sensitive, it still requires specific equipment and expertise.

Molecular Techniques (Expanded)

Among the molecular techniques, **Polymerase Chain Reaction (PCR)** remains a cornerstone. It amplifies specific DNA sequences, allowing for highly sensitive and specific detection of malaria parasites.

However, PCR and other molecular approaches require:

- Sophisticated and costly laboratory equipment
- Trained personnel
- Stable electricity and controlled environments

These limitations currently restrict their routine use in many endemic settings, though they remain invaluable for reference laboratories and surveillance programs.

Parasite culture

It entails cultivation of live malaria parasites useful in research but not for the routine- clinical diagnosis of malaria.

4.3.3 Exploring New Innovations

Automated malaria analysers

Flow cytometry is a sensitive and automated method used for detecting, differentiating, and quantifying malaria parasites. It works by detecting fluorescent signals from markers taken up by the parasites. The technique offers high sample throughput, minimal manual handling, and a better detection limit compared to traditional methods.

Automated malaria analysers using AI

The system uses stored sample data to detect malaria parasites through extrapolation, with automated processing, high sample throughput, and enhanced detection sensitivity.

Automated malaria analysers using virtual microscopy

E-learning enables malaria parasite detection through 3D virtual microscopy for improved clarity, with built-in virtual tally counters for accurate quantification.

4.3.4 G6PD Detection

A quantitative spectrophotometric

This is the gold standard for G6PD diagnosis quantitatively and is confirmed through a blood test that measures the activity of the G6PD enzyme in red blood cells

A rapid fluorescent spot test

This is considered the standard method; a positive result indicates G6PD deficiency if the blood spot doesn't fluoresce under ultraviolet light.

4.3.5 Therapeutic efficacy studies

WHO recommends TES every two years to monitor the threat of emergence and spread of parasite resistance to antimalarial drugs.

Tests are done in high outpatient attendance of malaria patients. This includes microscopy and PCR to differentiate between recrudescence and reinfection.

4.4. Biosafety During Testing

Standard biosafety precautions must be followed during sample collection, testing and disposal of waste. Good laboratory practices through following standard operating procedures and provision of safety equipment must be in place during malaria testing.

5.MANAGEMENT OF UNCOMPLICATED MALARIA

5.1 Recommended ACTs for Treatment of Uncomplicated P. falciparum Malaria in All Age Groups

The following artemisinin-based combination therapies (ACTs) are recommended for the treatment of uncomplicated P. falciparum malaria in Kenya:

- Artemether-Lumefantrine (AL)
- Dihydroartemisinin-Piperaquine (DHAP)
- Artesunate-Amodiaquine (AS + AQ)
- Artesunate-Pyronaridine (ASPY)

Each ACT regimen should provide **at least three days** of treatment containing an artemisinin derivative.

The specific ACT selected should be administered according to the nationally approved dosing schedule and adjusted by age or weight category.

5.2 Introduction of Multiple First-Line Therapies (MFT) for Uncomplicated Malaria

To improve long-term treatment efficacy and reduce the risk of antimalarial resistance, Kenya's National Malaria Control Programme (NMCP) is planning to adopt **Multiple First-Line Therapies (MFT)** for the diversification of ACTs for management of uncomplicated malaria.

Under this approach, **more than one ACT will be deployed concurrently** as first-line treatment for uncomplicated malaria across different regions, age groups, or health facility levels.

Objectives of MFT Implementation:

- **Delay the emergence and spread of drug resistance** by minimizing selective pressure associated with reliance on a single ACT.
- **Preserve ACT efficacy** by distributing usage across multiple drugs with different partner components.
- **Increase operational flexibility** by aligning ACT deployment with geographic variations in malaria transmission, drug efficacy data, and supply dynamics.
- **Strengthen health system resilience** through improved supply chain adaptability, better forecasting, and the ability to manage localized shortages or outbreaks.

Key Considerations for MFT Deployment:

- **ACT allocation** may be guided by:
  - **Geographic area** (e.g., high vs. low transmission zones)
  - **Patient factors** (e.g., comorbidities, previous treatment history)
  - **Health system capacity** and availability of ACTs at each facility

- **Implementation** will require:
  - Ongoing surveillance of efficacy and safety
  - Robust supply chain and procurement systems
  - Training of health care workers in differentiated ACT use
  - Community engagement to promote understanding and adherence

Operational Note:

While **Artemether-Lumefantrine (AL)** remains highly effective and widely available in Kenya, the **introduction of MFT is a forward-looking strategy** that enhances the sustainability of national treatment efforts. Drug selection at the facility level should strictly adhere to national

guidelines, informed by:

- Drug availability
- Patient suitability
- Local transmission patterns
- Programmatic context

i) Artemether-Lumefantrine (AL).

It is currently available as a co-formulated tablet containing 20mg of Artemether and 120mg of Lumefantrine in varying strengths. Child-friendly dispersible tablets are also available. AL is administered as a 6-dose regimen given over three days (See Table 4 below).

Table 4: Dosing Schedule for Artemether-Lumefantrine

Weight	Age	Dose of AL to be administered at 0 hrs, 8 hrs, 24 hrs, 36 hrs, 48 hrs and 60 hrs
5 to <15kg	5 months to <3 years	20mg artemether and 120mg lumefantrine
15 to <25kg	3 to <8 years	40mg artemether and 240mg lumefantrine
25 to <35kg	8 to <12 years	60mg artemether and 360mg lumefantrine
≥35kg	≥12 years	80mg artemether and 480mg lumefantrine

- In children below 5 kg, if appropriate weight for age, evaluation of other causes of fever including malaria should be undertaken. Where malaria is confirmed, the current recommended treatment is one tablet of AL given according to the schedule in table 1 under close supervision2.
- For children < 25 kg, dispersible tablets should be administered where available. Place the tablet in a cup or spoon, add a little water to it, wait a few minutes for tablets to disperse and then administer the resulting suspension to the child.
- Administer the first dose as a Directly Observed Treatment (DOT) at the health facility or at the household.
- Absorption of lumefantrine is enhanced by co- administration with fat. Patients or caregivers should be informed that this ACT should be taken immediately after food or a fat-containing drink (e.g. milk), particularly on the second and third days of treatment.

ii) Dihydroartemisinin-Piperaquine (DHAP)

This is currently available as a fixed-dose combination administered once daily for three days as shown below

Therapeutic dose and range: A target dose (range) of 4 (2-10) mg/kg body weight/day of dihydroartemisinin and 18 (16-27) mg/kg body weight per day of piperaquine once a day for 3 days for adults and children weighing ≥ 25kg. The target dose and ranges for children weighing <25kg are 4 (2.5-10) mg/kg body weight/day dihydroartemisinin and 24 (20-32) mg/ kg body weight/day piperaquine once a day for 3 days.

Children weighing <25kg treated with dihydroartemisinin+piperaquine should receive a minimum of 2.5mg/kg body weight per day of dihydroartemisinin and 20mg/kg body weight per day of piperaquine daily for 3 days.

High-fat meals should be avoided, as they significantly accelerate the absorption of piperaquine, thereby increasing the risk for potentially arrhythmogenic delayed ventricular repolarization (prolongation of the corrected electrocardiogram QT interval). Normal meals do not alter the absorption of piperaquine. As malnourished children are at increased risk for treatment failure, their response to treatment should be monitored closely.

Table 5: Dosing Schedule for Dihydroartemisinin-Piperaquine

Body weight (kg)	Dihydroartemisinin + piperaquine dose (mg) given daily for 3 days
<8kg	20mg dihydroartemisinin + 160 mg piperaquine
8 to <11kg	30mg dihydroartemisinin + 240 mg piperaquine
11 to <17 kg	40mg dihydroartemisinin + 320 mg piperaquine
17 to <25kg	60mg dihydroartemisinin + 480mg piperaquine
25 to <36kg	80mg dihydroartemisinin + 640mg piperaquine
36 to <60kg	120mg dihydroartemisinin + 960 mg piperaquine
60 to <80kg	160mg dihydroartemisinin + 1280mg piperaquine
>80kg	200mg dihydroartemisinin + 1600 mg piperaquine

iii) Artesunate- Amodiaquine (AS-AQ)

- Formulations currently available: A fixed-dose combination in tablets containing 25 + 67.5 mg, 50 + 135 mg or 100 + 270 mg of artesunate and amodiaquine, respectively
  Target dose and range: The target dose (and range) are 4 (2–10) mg/kg bw per day artesunate and 10 (7.5–15) mg/kg bw per day amodiaquine once a day for 3 days. A total therapeutic dose range of 6–30 mg/kg bw per day artesunate and 22.5–45 mg/kg bw per dose amodiaquine is recommended.

Body Weight (Kg)	Artesunate + amodiaquine dose (mg) given daily for 3 days
<9	25mgrtesunate + 67.5mg amodiaquine
9 to < 18	50mg Artesunate + 135mg amodiaquine
18 to < 36	100mg Artesunate + 270mg amodiaquine
≥ 36	200mg Artesunate + 540mg amodiaquine

- **NOTE**: Artesunate + amodiaquine is associated with severe neutropenia, particularly in patients co-infected with HIV and especially in those on zidovudine and/or cotrimoxazole. Concomitant use of efavirenz increases exposure to amodiaquine and hepatotoxicity. Thus, concomitant use of artesunate + amodiaquine by patients taking zidovudine, efavirenz and cotrimoxazole should be avoided and alternative drugs considered unless this is the only ACT promptly available.

iv) Artesunate-pyronaridine (ASPY)

The target dose range is 7.2–13.8 mg/kg body weight of pyronaridine and 2.4–4.6 mg/kg body weight of artesunate. The tablets should be taken orally once daily for 3 days and according to body weight as follows: 24 to <45 kg (two tablets), 45 to <65 kg (three tablets), and ≥65 kg (four tablets). It can

be administered at any time, regardless of food consumption.

Body weight(kg)	ASPY (mg) given once daily for 3 days
≥5 to< 9	20mg Artesunate + 60mg Pyronaridine
9 to < 17	40mg Artesunate +120mg Pyronaridine
17 to < 24	60mg Artesunate +180mg Pyronaridine
24 to < 45	120mg Artesunate +360mg Pyronaridine
45 to < 65	180mg Artesunate +540mg Pyronaridine
≥65	240mg Artesunate +720mg Pyronaridine

5.3 Reporting of Uncomplicated malaria using ICD 11

Interpretation of parasitological test results (Malaria Species confirmed) and ICD 11 Classification

Depending on the test results (Microscopy, mRDT or any other approved test, the following ICD11 codes should be used to classify Uncomplicated Malaria.

1. **1F40.Z** - Malaria due to *Plasmodium falciparum*, unspecified (Uncomplicated *Plasmodium falciparum* Malaria)
2. **1F41.Z** - *Plasmodium vivax* malaria without complication (Uncomplicated *Plasmodium vivax* Malaria)
3. **1F42.Z** - *Plasmodium malariae* malaria without complication (Uncomplicated *Plasmodium malariae* Malaria)
4. **1F43** - Malaria due to *Plasmodium ovale* (Uncomplicated *Plasmodium ovale* Malaria)
5. **1F44** - Other parasitologically confirmed Malaria (Uncomplicated Malaria by other species including *Plasmodium knowlesi* Malaria)

5.4 Counselling at point of service and follow up

- Show all caregivers of young children how to prepare the dispersible tablet prior to administration. Ensure she/he understands how to administer the same to the child prior to leaving the facility.
- If vomiting occurs within 30 minutes after drug administration, the dose should be repeated and replaced by the facility. If vomiting persists, the patient should return to the facility for review
- Explain the dosing schedule, use probing questions to confirm the patient's understanding.
- Emphasize adherence to the dosing schedule even if the patient feels better after a few doses.
- Advise patients to return immediately to the nearest health facility if the condition deteriorates at any time or if symptoms have not resolved after 3 days.
- Explain to the patient potential side effects and that they should report to the healthcare provider immediately in case adverse reaction is experienced

5.5 Supportive treatment

- **Fever management:** Administer paracetamol (15mg/kg/bwt) after every 6-8 hours) as the recommended antipyretic for fever and exposure.
- **Encourage adequate fluids and food**: Caregivers should be encouraged to give extra fluids and where applicable continue breastfeeding. Food and fluid should be administered

in small quantities at frequent intervals especially when the child is still very sick.

5.6 Treatment Failure

Treatment failure can be defined as a failure to achieve the desired therapeutic response after the initiation of therapy in accordance with the recommended treatment regimen. Treatment failures should be suspected if a patient deteriorates clinically at any time or symptoms persist 3-14 days after initiation of therapy. Whenever possible, treatment failure must be confirmed parasitologically (by microscopy). **Use of RDTs is not recommended**[3].

Treatment failure may result from poor adherence to treatment, unusual pharmacokinetic properties in that individual or drug resistance. In evaluating a patient with treatment failure, it is important to determine from the patient's history whether he or she used the recommended antimalarial and dose, whether they vomited the previous dose or did not complete a full treatment course. Treatment failure is not synonymous with drug resistance.

Development of symptoms 14 days after initiation of therapy where there has been prior clearance of symptoms should be considered as a new infection, Repeat the malaria blood slide test (microscopy), if positive, treat with the first line drug.

The recommended second-line treatment is an alternative ACT known to be effective.

5.7 Treatment of Uncomplicated P.vivax Malaria

Uncomplicated P. vivax malaria should be treated with an ACT. It is vital to have confirmed lab diagnosis of P. vivax malaria before commencing treatment. Unlike P. falciparum, P. vivax has dormant liver stages which require treatment. In order to achieve a radical cure and prevent relapses, use Primaquine.

Primaquine

Primaquine is a critical component in the treatment of non-Plasmodium falciparum malaria, particularly Plasmodium vivax and Plasmodium ovale infections. These species are unique in their ability to form dormant liver stages (hypnozoites), which can cause relapses of malaria months or even years after the initial infection. The primary role of primaquine in the treatment regimen is to target these liver stages and prevent relapses, a process known as radical cure. Unlike the treatment for Plasmodium falciparum, which focuses mainly on the elimination of the blood-stage parasites, the inclusion of primaquine is essential for addressing the hypnozoites in Plasmodium vivax and Plasmodium ovale infections.

Therapeutic dose: Primaquine should be given at a high total dose (7mg/kg) at 0.5mg/ kg/ day once a day for 14 days or 1mg/kg/day for 7 days for prevention of relapses in patient with uncomplicated P. vivax except (In pregnant women, infants less than 1 month old and lactating women to children less than 1 month old).

Primaquine causes abdominal discomfort when taken on an empty stomach hence should always be taken with food. The G6PD status of patients should be used to guide administration of primaquine. This is because Primaquine may cause haemolysis in patients with glucose-6- phosphate dehydrogenase (G6PD) deficiency. In case of adverse reactions such as bleeding, stop treatment immediately and fill in the relevant ADR reporting form.

In mild-to-moderate G6PD deficiency, primaquine 0.75 mg base/kg body weight should be given once a week for 8 weeks.

In severe G6PD deficiency, **primaquine is contraindicated.** The decision to give or withhold primaquine should depend on the possibility of giving the treatment under close medical supervision, with ready access to health facilities with blood transfusion services.

When G6PD services are not available, a decision to prescribe or withhold primaquine should be based on the balance of the probability and benefit of preventing relapse against the risks of primaquine-induced haemolytic anaemia

6.MANAGEMENT OF SEVERE MALARIA

6.1. Introduction

Severe malaria is a **complication of malaria infection** characterized by the presence of **one or more life-threatening clinical or laboratory features**, typically associated with high levels of *Plasmodium falciparum* parasitaemia. It occurs when malaria parasites multiply rapidly in the blood, causing extensive red blood cell destruction and affecting vital organs.

The condition often progresses rapidly, particularly in young children, pregnant women, non-immune individuals, and those with delayed access to effective treatment. Severe malaria may present with symptoms such as impaired consciousness or coma, convulsions, respiratory distress, severe anaemia, hypoglycaemia, renal impairment, or shock.

Severe malaria is most commonly caused by ***P. falciparum***, the predominant malaria species in Kenya. However, ***P. vivax*** can occasionally cause severe disease, particularly in young children or immuno-compromised patients.

Without urgent and appropriate treatment, severe malaria has a **high risk of mortality**. Early diagnosis, prompt administration of **parenteral antimalarial therapy**, and supportive care in a facility with **inpatient capacity** are critical for survival.

Where referral is necessary, **pre-referral treatment** should be initiated immediately to prevent deterioration during transport. (Refer to Section 6.5 for guidance on pre-referral interventions.)

6.2. Diagnosis

The clinical manifestations of malaria severity depend on various factors including age and the levels of malarial immunity. In children the common presentations of severe malaria are severe anaemia, respiratory distress and cerebral malaria. Severe malaria can occur in the absence of fever. An outline of the presentations, their frequency of occurrence is summarized in Table 5 below.

6.2.1. Clinical features of severe falciparum malaria

The clinical features of severe malaria are outlined in Table 6

Table 6: Signs and Symptoms of Severe Malaria in adults and Children

Sign or symptom	Adults	Children
Duration of illness	5-7 days	Shorter (1-2 days)
Respiratory distress/deep breathing (acidosis)	Common	Common
Convulsions	Common (12%)	Very common (30%)
Posturing (decorticate/ decerebrate and opisthotonos rigidity	Uncommon	Common
Prostration/ obtundation	Common	Common
Resolution of coma	2-4 days	Faster (1-2 days)
Neurological sequelae after cerebral malaria	Uncommon (1%)	Common (5-30%)
Jaundice	Common	uncommon

Hypoglycemia*	Less common	Common
Metabolic acidosis*	Common	Common
Pulmonary oedema	uncommon	Rear
Renal failure*	common	Rear
CSF opening pressure*	Usually, normal	Usually raised
Bleeding/clotting disturbances*	Up to 10%	Rare
Invasive bacterial infection (co-infection) *	Uncommon (<5%)	Common (10%)

Laboratory confirmation required

For epidemiological purposes, severe malaria is defined as one or more of the following parameters, occurring in the absence of an identified alternative cause and in the presence of P. falciparum asexual parasitaemia.

Table 7: Clinical Parameters

Clinical state	Definition
Impaired Consciousness	Glasgow coma scale <11 (annex 4), Blantyre coma Scale <3 in children
Prostration	Generalized weakness so that the person is unable to sit, stand or walk without assistance
Multiple convulsions	More than 2 episodes within 24 hours
Pulmonary oedema	Radiologically confirmed oxygen saturation <92% on room air with respiratory rate >30/minute often with chest indrawing and crepitations on auscultation.
Significant bleeding	Including recurrent or prolonged bleeding from the nose, gums or venipuncture sites; haematemesis or malaena
Shock	Compensated shock is defined as capillary refill or temperature gradient on leg (mid to proximal limb), but no hypotension. Decompensated shock is defined as systolic blood pressure <70mmHg in children or 80mmHg in adults, with evidence of impaired perfusion (cool peripheries or prolonged capillary refill

Laboratory parameters

- In all patients with suspected severe malaria the use of parasitological diagnosis is recommended irrespective of whether the patient had fever or history of fever
- Do not withhold antimalarial treatment if parasitological diagnosis is not possible.
- Start presumptive treatment immediately while efforts to confirm diagnosis are ongoing.
- Frequent monitoring of parasitemia (every 12 hours) is important during the first three days of treatment in order to monitor parasite response to treatment with antimalarial medicine.
- A negative malaria blood slide result may be indicative of another cause of infection.
- Other investigations to determine severity and prognosis to be undertaken where feasible.
- There is also considerable clinical overlap between septicaemia, pneumonia and severe

malaria, and these conditions may coexist. When possible, blood should always be taken on admission for bacterial culture.

- In high to moderate malaria transmission zones, particularly where parasitaemia is common in young age groups, it is difficult to rule out septicaemia immediately in a shocked or severely ill obtunded child. In all such cases, empirical parenteral broad-spectrum antibiotics should be started immediately, together with antimalarial treatment

6.2.2. Clinical features of severe P. vivax malaria

Severe vivax malaria may present with some symptoms similar to those of severe **P. falciparum malaria and can be fatal.** Prompt and effective treatment and follow-up should be the same as for severe falciparum malaria.

6.2.3. Reporting of Severe malaria using ICD 11

Interpretation of parasitological test results (Malaria Species confirmed) and ICD 11 Classification for Severe Malaria

Depending on the test results (Microscopy, mRDT or any other approved test, the following ICD11 codes should be used to classify Severe Malaria.

1. **1F40.0** - *Plasmodium falciparum* malaria with cerebral complications (Severe *Plasmodium falciparum* Malaria)
2. **1F40.Y** - Other severe and complicated *Plasmodium falciparum* malaria (Severe *Plasmodium falciparum* Malaria)
3. **1F41.0** - *Plasmodium vivax* malaria with rupture of spleen (Severe *Plasmodium vivax* Malaria)
4. **1F41.Y** - Malaria due to *Plasmodium vivax* with other complications (Severe *Plasmodium vivax* Malaria)

6.3. Treatment of Severe Malaria

The recommended treatment for severe malaria is **parenteral artesunate**. The preferred route of administration is intravenous (IV). However, intramuscular (IM) can be used as an alternative where the intravenous route is not feasible. In the absence of artesunate IM artemether should be administered in preference to quinine.

6.3.1. Administration of Artesunate

Parenteral artesunate is the recommended first-line treatment for severe malaria. Treatment should be initiated as soon as severe malaria is suspected, even if laboratory confirmation is pending.

Artesunate may be administered by either:

- **Intravenous (IV) injection** – the **preferred route** where venous access is available because it provides rapid therapeutic drug levels.
- **Intramuscular (IM) injection** – used when **IV access cannot be established promptly**.

Injectable artesunate is available in two formulations:

1. Conventional two-step formulation, which requires:
    - Reconstitution with 5% sodium bicarbonate
    - Followed by dilution with normal saline (0.9% sodium chloride) or 5% dextrose
2. One-step (single dilution) arginine-based formulation, which requires:
    - Only one reconstitution step
    - No additional dilution

For the single dilution formulation, the final concentration of the prepared solution for both IV and IM administration is 20 mg/ml.

General Preparation Principles

1. **Weigh the patient accurately** to determine the correct dose (Ensure **accurate weight measurement** to prevent dosing errors)
2. **Calculate the required dose** according to **weight the patient**
3. **Determine the number of vials required**.
4. Prepare the solution **immediately before administration**.
5. The prepared solution should **be used within 1 hour**.
6. **Discard any unused solution** after 1 hour.
7. Ensure **aseptic technique** during preparation and administration.
8. Monitor patients closely for **clinical response and possible adverse reactions**.

Intravenous (IV) Administration

Intravenous administration is the **preferred route** for patients with severe malaria when venous access is available.

A. Conventional Two-Step Formulation (IV)

1. Determine the required dose and number of vials according to **weight the patient**
2. **Reconstitute the artesunate powder** by adding the **5% sodium bicarbonate solution supplied with the vial**.
3. **Gently swirl** until the powder dissolves completely and the solution becomes **clear**.
   - If the solution does not dissolve completely or remains cloudy, **discard the vial and prepare a new one**.
4. **Dilute the reconstituted solution** by adding **5 ml of normal saline (0.9% sodium chloride)**.
   - If normal saline is unavailable, **5% dextrose** may be used.
5. The final solution will have a **concentration of approximately 10 mg/ml**.
6. **Calculate the required volume** according to patient weight (see Annex 4 Table 21).
7. **Withdraw the calculated dose** using a sterile syringe.

Administration

- Administer by slow IV injection over 3–5 minutes.
- Observe the patient during administration for any adverse reactions.

B. One-Step (Single Dilution) Arginine-Based Formulation (IV)

The single-dilution formulation simplifies preparation and reduces the risk of dosing errors.

Preparation Steps

1. Determine the required dose and number of vials according to **weight the patient**
2. **Add the supplied solvent Ampoule (contains a sterile, clear, colorless liquid comprising sodium bicarbonate (8.4 mg/mL) and arginine (20 mg/mL) directly to the vial** containing the artesunate powder.
3. **Gently swirl the vial** until the powder dissolves completely and the solution becomes **clear**.
4. The prepared solution has a **final concentration of approximately 20 mg/ml**.
5. **Withdraw the calculated dose** according to patient weight.

Administration

- Administer by slow IV injection over 3–5 minutes.
- No additional dilution with normal saline or dextrose is required.

Intramuscular (IM) Administration

Intramuscular administration is recommended **when IV access cannot be obtained promptly**.

The injection should be administered **deep into the muscle**.

A. Conventional Two-Step Formulation (IM)

1. Determine the required dose and number of vials according to **weight the patient**
2. **Reconstitute the artesunate powder** with the **5% sodium bicarbonate solution supplied with the vial**.
3. **Gently swirl** until the solution becomes **clear**.
   - If the powder does not dissolve completely or the solution remains cloudy, **discard and prepare a new vial**.
4. **Dilute the solution** by adding **2 ml of normal saline (0.9% sodium chloride)**.
   - If saline is unavailable, **5% dextrose** may be used.
5. The final solution will have a **concentration of approximately 20 mg/ml**.
6. **Calculate the required injection volume** based on the patient's weight (see Annex 4 Table 21).
7. **Withdraw the calculated dose** using a sterile syringe.

Administration

- Administer by **deep intramuscular injection** into a large muscle.

Injection Volume Guidance

To minimize injection site discomfort and ensure adequate absorption:

- Infants and small children
  - Volumes greater than 2 ml should be divided between two injection sites.
- Adults
  - Volumes greater than 5 ml should be divided between multiple injection sites.

Alternate injection sites for subsequent doses where possible.

B. One-Step (Single Dilution) Arginine-Based Formulation (IM)

Preparation Steps

- Determine the required dose and number of vials according to **weight the patient**
- **Add the supplied solvent directly to the vial containing artesunate powder**.
- **Gently swirl** until the solution becomes **clear**.
- The prepared solution has a **final concentration of approximately 20 mg/ml** for **both IV and IM administration**.
- **Withdraw the calculated dose** according to patient weight.

Administration

- Administer by **deep intramuscular injection** into a large muscle.
- Apply the same **volume division recommendations** used for conventional IM administration.

Artesunate

Artesunate is dispensed as a powder of artesunic acid. **This must be dissolved in sodium bicarbonate (5%) to form sodium artesunate**. The solution is then diluted in approximately 5ml of normal saline and given by intravenous (IV) injection or by intramuscular (IM) maximum 5ml per site. The solution should be freshly prepared prior to administration and should be used within 1 hour. The solution should **NEVER** be stored.

Dosage and administration of artesunate:

- For children ≤ 20kg administer 3.0 mg/kg
- For other patients >20kg administer 2.4 mg/kg
- A dosing schedule for parenteral artesunate-based on body weights and dose (ml) is given in Annex 10.3, Table 21

Administration of Artesunate:

6.3.1.1. Intravenous

Intravenous routes are preferred.

Weigh the patient to determine the dosage needed and therefore the number of vials required.

Dissolve each vial of artesunic powder with all the 5% sodium bicarbonate solution provided with each vial. Shake gently until the resultant solution is clear. (If it doesn't dissolve and become clear, discard the vial and reconstitute a new one)

Dilute resultant solution in each vial with 5ml normal saline if normal saline is not available 5% dextrose* can be used.

The final solution has a strength of 10mg/ml.

Calculate the volume of solution containing the required amount to be given seed *skill in calculation of artesunate (refer to Annex 10.3, Table 21)*

Administer by slow IV over 3-5 minutes.

6.3.1.2. Intramuscular

Weigh the patient to determine the dosage needed and therefore the number of vials required.

Dissolve each vial of artesunic powder with all the 5% sodium bicarbonate solution provided with each vial. Shake gently until the resultant solution is clear. (If it doesn't dissolve and become clear, discard the vial and reconstitute a new one)

Dilute resultant solution with 2ml normal saline if normal saline is not available 5% dextrose* can be used.

The final solution has a strength of 20mg/ml.

Calculate the volume of solution containing the required amount to be given see *skill on calculation of artesunate (Annex 10.3, Table 21)*.

Administer by IM route.

Spread the doses of more than 2ml over different sites for babies and 5ml for adults.

- This refers to 60mg artesunate. For all other strengths refer to product insert for diluent volume.



Figure 1: 60mg artesunate

- Artesunate powder Saline solution Bicarbonate solution

Artemether is dispensed as a clear oily solution of differing concentrations. Artemether must only be given by intramuscular (IM) injection.

Administer artemether, as follows:

- Artemether is administered by the intramuscular route at a loading dose of 3.2mg/kg IM stat then 1.6mg/kg/kg IM once every 24 hrs until the patient is able to tolerate oral medications (Maximum of 7 days).
- Thereafter a complete course of *Artemether-lumefantrine* is given.
    - New generation artesunate (Annex the reconstitution)

Artemether

Administer a STAT dose of 3.2mg/kg of artemether solution by the intramuscular route to the anterior thigh. Maintenance dose is 1.6mg/kg bwt intramuscularly daily

Quinine

Quinine should only be given as an intravenous infusion and **NEVER** given as an intravenous (**bolus**) injection.

Loading dose should be omitted if the patient has received quinine in the last 24 hours or has received mefloquine in the last 7 days.

Quinine is **not** contraindicated in severe anaemia.

If there is no improvement in the patient's condition within 48 hours or in renal insufficiency, the dose of quinine should be reduced by a 1/3 to 10mg/kg every 12 hours.

In hepatic insufficiency, the dose of quinine should be reduced by 25%. Hypoglycaemia is a potential side effect of quinine administration particularly in pregnant women and should therefore be administered in a glucose-containing infusion (preferably 10% glucose).

6.3.1.3. Quinine administration in children

Administer quinine as follows:

- Put up IV quinine drip 20mg/kg body weight loading dose in 15mls/kg of 5% dextrose or normal saline to run over 4 hours to run at a rate not exceeding 5mg salt/kg body weight per hour.
- Calculate the number of drops per minute to deliver the quinine in 4 hours - see *skill on*

calculation of drops/min (annex 3, table 19 - quinine IV infusion).

- Give 10mg/kg in 10ml/ kg of isotonic solution (5% dextrose or normal saline) to run at the same rate as the previous one, 8 hours from commencement of the initial dose of quinine.
- Repeat 10mg/kg quinine infusion every 8 hours until the patient can take medication orally. Thereafter give a complete course of artemether-lumefantrine (AL).
- Alternatively, if AL is not available, treat with oral quinine given at 10mg/kg every 8 hours to complete a total of 7 days.

6.3.1.4. Quinine administration in adults

Administer quinine as follows:

- A loading dose of quinine 20mg/kg (maximum 1,200mg) diluted in maximum 500ml of isotonic solution (5% dextrose or normal saline) is given intravenously to run over 4 hours to run in a way not to exceed 5mg salt/kg body weight per hour.
- Calculate the number of drops per minute to deliver the quinine in 4 hours - see *skill on calculation of drops/min (Annex 3, Table 20)*
- Give 10mg/kg (maximum 600mg) diluted in 10ml/kg (maximum 500ml) of isotonic solution (5% dextrose or normal saline) 8 hours from commencement of the initial dose of quinine to run over 4 hours at the same rate as previous one.
- Repeat 10mg/kg quinine infusion every 8 hours until the patient can take medication orally.
- Thereafter a complete course of artemether-lumefantrine (AL) is given.
- If AL is not available, oral quinine is continued at 10mg/kg (maximum 600mg) every 8 hours to complete a total of 7 days treatment, in combination with clindamycin 150mg twice daily for 7 days or doxycycline 100mg twice daily for 7 days.



Give child quinine doses every 8 hours to standardized practice and comply with WHO guidelines.

Note: In the case of severe P. vivax malaria, once the patient has completed treatment, a full dose of primaquine should be administered to clear liver stages.

Severe malaria patients who may be able to tolerate oral treatment

Patients with the following features can be treated with AL, if not available, oral quinine can be used.

- Severe anaemia (haemoglobin level of <5g/dl or
- haematocrit of <15%, or
- Two or more convulsions within a 24hr period, or
- Hyperparasitaemia and who are stable but show none of the features of prostration, respiratory distress (acidotic breathing) or
- alteration in the level of consciousness.

They should, however, be treated as in-patients for close monitoring. Thus, any emerging complications of severe malaria should be managed promptly and appropriately

6.4. Supportive Treatment

Supportive treatment is crucial in reducing the high mortality associated with severe malaria. The table 6 below highlights specific management for manifestations or complications of severe malaria.

Table 8: Supportive Treatment for Manifestations of Severe Malaria

Manifestation/ Complication	Immediate Management
Coma (cerebral malaria)	Maintain airway, place patient on his or her side, exclude other treatable causes of coma (e.g. hypoglycaemia, bacterial meningitis); avoid harmful ancillary treatments, intubate if necessary.
Hyperpyrexia	Administer tepid sponging, fanning, a cooling blanket and paracetamol.
Convulsions	Maintain airways; treat promptly with intravenous or rectal diazepam, lorazepam, midazolam or intramuscular paraldehyde. Check blood glucose.
Hypoglycaemia	Check blood glucose, correct hypoglycaemia and maintain with glucose-containing infusion. Although hypoglycaemia is defined as glucose < 2.2 mmol/L, the threshold for intervention is < 3 mmol/L for children < 5 years and <2.2 mmol/L for older children and adults.
Severe anaemia	Transfuse with screened fresh whole blood.
Acute pulmonary Oedema	Prop patient up at an angleof 45°, give oxygen, give a diuretic, stop intravenous fluids, intubate and add positive end-expiratory pressure or continuous positive airway pressure in life-threatening hypoxaemia.
Acute kidney injury	Exclude pre-renal causes, check fluid balance and urinary sodium; if in established renal failure, add haemofiltration or haemodialysis, or, if not available, peritoneal dialysis.
Spontaneous bleeding and coagulopathy	Transfuse with screened fresh whole blood (cryoprecipitate, fresh frozen plasma and platelets, if available); give vitamin K injection.
Metabolic acidosis	Exclude or treat hypoglycaemia, hypovolaemia and septicaemia. If severe, add haemofiltration or haemodialysis.
Shock	Suspect septicaemia, take blood for culture and sensitivity

It is assumed that appropriate antimalarial treatment will have been started in all cases.

Prevent by avoiding excess hydration.

6.5. Pre-Referral Management of Severe Malaria

The risk for death from severe malaria is greatest in the first 24 h, yet, in most high to moderate malaria transmission zones countries, the transit time between referral and arrival at a health facility where intravenous treatment can be administered is usually long, thus delaying the start of appropriate antimalarial treatment. During this time, the patient may deteriorate or die. It is therefore recommended that patients, particularly young children, be treated with a first dose of one of the recommended treatments before referral (unless the referral time is <6 h).

The recommended pre-referral treatment options for children <6 years, in descending order of preference, are intramuscular artesunate; rectal artesunate; intramuscular artemether; and intramuscular quinine. For older children and adults, the recommended pre-referral treatment options, in descending order of preference, are intramuscular injections of artesunate; artemether; and quinine.

In rare cases where patients present with septicaemic shock, broad spectrum parenteral antibiotics should also be administered along with the antimalarial.

If for any reason referral is not possible or delayed, treatment for severe malaria with the use of IM artesunate should be continued. Health workers at such facilities should ensure that treatment continues until the patient **PHYSICALLY** moves to another facility.

It is not enough to give a referral note and assume that the patient has been referred. The referral note should be as comprehensive as possible, and a health worker should accompany the referred patient.

6.6. Administration of parenteral artemisinins

Artesunate is dispensed as a powder of artesunic acid. This must be dissolved in 5% sodium bicarbonate (diluent) to form sodium artesunate.

(Refer to 6.3.1.2 for administration instructions).

Administration of rectal artesunate

Artesunate for rectal administration is presented in suppositories of different strengths. The appropriate single dose of artesunate should be administered.

A single dose of 10mg/kg body weight should be given to children <6 years and only when intramuscular artesunate is not available.

In the event that a suppository is expelled from the rectum within 30 minutes of insertion, a second suppository should be inserted. In young children the buttocks should be held together for 10 minutes to ensure retention of the rectal dose of artesunate. Patients should be transported immediately to a higher-level facility where IM or IV treatment is possible. In the event that referral is not possible a single daily dose of artesunate should be administered until parenteral treatment or oral AL is instituted.

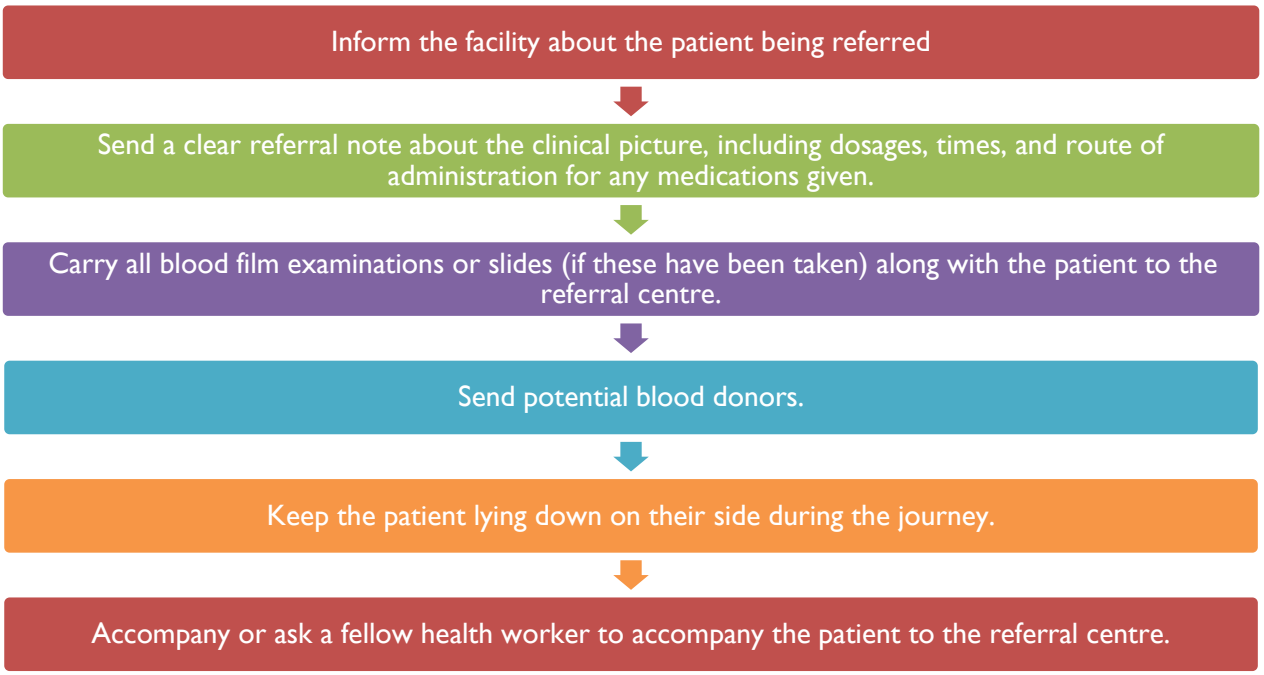
Administration of intramuscular quinine

Quinine **MUST** be diluted (maximum concentration is 100mg/ml for adults, and 50mg/ml for children) before intramuscular injection.

A loading dose of 20mg/kg of quinine (diluted to a maximum 100mg/ml for adults and 50mg/ml for children) is given by intramuscular injection (preferably into the anterior thigh). A maximum of 3ml should be injected into one site. If the amount to be injected exceeds 3ml, multiple sites should be used.

An example of body weights and doses (ml) of injection is given (*refer to Annex 10.3, Table 20*).

Referral of the patient



6.7. Follow-Up of All Patients with Severe Malaria

Monitor for possible complications and manage accordingly.

Monitor Hb levels and manage anaemia appropriately.

Monitor and rehabilitate patients with complication

Post discharge malaria chemoprevention (PDMC)

Background and rationale:

World Health Organization (WHO) recommends post-discharge malaria chemoprevention (PDMC) for children discharged from hospital in moderate to high malaria transmission settings after treatment for severe anaemia that is not due to blood loss following trauma, surgery, malignancy or a bleeding disorder to reduce the risk of death and hospital readmission.

In Kenya, PDMC is the administration of full therapeutic courses of antimalarial medicines at scheduled intervals for three months after hospital discharge to children hospitalised with either: **i) severe malaria, ii) severe anaemia due to malaria or, iii) all-cause severe anaemia**. Continued treatment with effective antimalarial medicines maintained at therapeutic levels post-discharge clears residual malaria parasites and prevents new infections through parasiticidal action. This significantly lowers the risk of recrudescent infections and/or re-infections during the **high-risk three-month post-discharge period**, while the children are recovering. Randomized controlled trials and pooled meta-analyses demonstrate that PDMC used in settings with moderate to high malaria transmission:

- Reduces **all-cause mortality by approximately 77%** during the intervention period.
- Reduces all-cause hospital readmissions by approximately 55%.

Eligibility for PDMC

PDMC should be prescribed at discharge to **ALL** children **aged <10 years** admitted to hospital with either:

i. severe malaria

ii. severe anaemia due to malaria (Hb ≤ 7mg/dl)

iii. all-cause severe anaemia (Hb ≤ 7mg/dl)

All children must be clinically stable at discharge, have completed standard inpatient management and be discharged on a **full course of oral antimalarial treatment** in accordance with the national treatment guidelines.

Exclusion criteria:
PDMC should not be given to:

i. Children with severe anaemia due to blood loss following trauma, surgery, malignancy or a bleeding disorder.

ii. Children receiving concurrent alternative malaria chemoprevention strategies.

PDMC Regimen
Dihydroartemisinin–Piperaquine (DHAP) is the drug of choice for PDMC. DHAP is a long-acting antimalarial making it effective for monthly dosing, it is well tolerated and optimal for adherence with a once-a-day dosing.

Full therapeutic courses of DHAP for PDMC should be prescribed at discharge per the dosing guidelines provided in section 5 above for administration as per the schedule below:

Full course of oral antimalarial medication at discharge (As per national guidelines)	PDMC Course 1 timing post discharge	PDMC Course 2 timing post discharge	PDMC Course 3 timing post discharge
At discharge	2 weeks	6 weeks	10 weeks

Alternative Regimens
Where DHA-PPQ is contraindicated or unavailable, **A**rtemether Lumefantrine (AL), Artesunate-Amodiaquine (AS-AQ) and Artesunate-pyronaridine (ASPY) may be considered in line with national treatment policy.

Note: A child who is unwell at the scheduled PDMC date should be advised to seek care at the closest facility and managed as per standard of care.

Delivery platforms

Kenya is currently conducting implementation studies to determine feasibility of the following delivery and adherence support strategies. The strategies under evaluation have been selected to optimise coverage and adherence to the full PDMC regimen:

Option A: PDMC delivery at Discharge

- All PDMC courses are dispensed to the caregiver at hospital discharge.
- Caregivers administer subsequent doses at home at scheduled intervals.
- Advantages:
    - Lower household and system costs
    - Reduced access barriers
- Disadvantages:
    - Requires strong hospital-to-community linkage and follow-up mechanisms to support community-based adherence.

Option B: Facility-Based Monthly Collection of PDMC

- The first PDMC course is dispensed at hospital discharge.
- Caregivers collect the second and third PDMC courses from the nearest health facility at scheduled intervals.
- Advantages:
    - Supports rational antimalarial use by linking dispensing to scheduled facility review.
- Disadvantages:
    - Higher household and system costs
    - Potential access barriers
    - Requires strong downward referral mechanisms to facilitate dispensing at follow-up facilities.

Adherence support strategies

- Adherence to PDMC should be supported through:
    - Clear counselling at discharge
    - Simple written dosing instructions
    - Recording PDMC schedule in child health records
    - Emphasis on safe drug storage and completion of all courses
- Community-based adherence support strategies may include:
    - Linkage to community health services for home-based follow-up and reminders by CHPs
    - SMS reminders to caregivers

7.MANAGEMENT OF MALARIA IN PREGNANCY, CHEMOPREVENTION AND IMMUNOPREVENTION

Pregnancy increases the risk of malaria infection in all women. Malaria during pregnancy causes febrile illness, anaemia and increases the risk of maternal illness and death, miscarriage, stillbirth, low birth weight and neonatal death. All pregnant women living in malaria risk areas should be advised on use of relevant malaria prevention measures and confirmed cases of malaria treated promptly with effective antimalarials as per malaria treatment guidelines. Women in their first and second pregnancies, and all HIV infected women are at greatest risk of the effects of malaria.

7.1 Management of Uncomplicated Malaria in Pregnancy

Diagnosis

Table 9: Symptoms and Signs of Uncomplicated Malaria in Pregnant Women

Type of malaria	Signs & Symptoms Usually Present	Signs & Symptoms Sometimes Present
Uncomplicated malaria	Fever shivering/ chills/ rigors Headache, muscle/joint pain nausea and vomiting, False labor pain (uterine contractions)	Enlarged spleen

In all pregnant women with fever or history of fever the use of parasitological diagnosis is recommended.

- At health facilities where malaria diagnostics (microscopy or RDT) are not available, patients suspected of having malaria should be treated for malaria.

Treatment

The recommended treatment for uncomplicated malaria in pregnancy in all trimesters is Artemether-Lumefantrine (AL).

Follow-up management

Counsel on Antenatal Care[6]

7.2 Management of Severe Malaria in Pregnancy

Severe malaria in pregnancy is a medical emergency that puts the lives of both the mother and unborn baby at high risk. Aggressive management is essential.

7.2.1 Diagnosis

Features of severe malaria in pregnant women are similar to those in non-pregnant women. These are detailed in Section 6.1.1. and table 9 below. Pregnant women have an increased risk of quinine induced hypoglycaemia and also complications from severe anaemia.

Table 10: Signs and Symptoms of Severe Malaria in Pregnant Women

SIGNS AND SYMPTOMS USUALLY PRESENT	SIGNS AND SYMPTOMS SOMETIMES PRESENT

Three or more signs and Symptoms of uncomplicated malaria plus one or more of the following • Convulsions • Severe jaundice • Signs of severe dehydration, especially if woman has been vomiting repeatedly. • Sudden weight loss • Sunken eyes • Reduced skin turgor • Dry mouth • Reduced amount of urine or no urine at all • Spontaneous bleeding from the gums, skin and vein puncture sites	Three or more signs and Symptoms of uncomplicated malaria plus one or more of the following: • Confusion, drowsiness, coma • Fast breathing/breathlessness/ difficulty in breathing • Vomiting at every feed or unable to feed • Pale conjunctivae, mucous membranes, tongue and palms • jaundice

7.2.2 Treatment

Parasitologically confirmed diagnosis should be done in ALL suspected cases of severe malaria in pregnancy. If such confirmation is missing or delayed, start treatment for severe malaria immediately

The recommended medicine for severe malaria in pregnancy is parenteral artesunate. In the absence of artesunate, artemether or quinine can be given. The preferred route of administration is intravenous for artesunate. However, the intramuscular route can be used as an alternative where the intravenous route is not feasible. Due to the increased risk of hypoglycaemia in pregnant women, a dextrose containing solution must be used for quinine administration.

NOTE: Pregnancy is not a contraindication for the use of a loading dose of quinine

7.2.3 Pre-referral treatment for severe malaria in pregnancy

Treatment of a patient with severe malaria should begin in the primary health facility (while waiting for referral) so that life-saving therapy is not delayed.

Management of severe malaria in pregnancy should follow the adult dosage for artesunate. Where artesunate is not available, artemether can be administered. A loading dose of artesunate at 2.4mg/kg body weight should be administered.

All efforts should be made to move the patient to a centre where expertise and infrastructure exist for the adequate management of severe malaria.

In patients with alteration in the levels of consciousness, a broad-spectrum parenteral antibiotic (preferably Ceftriaxone, if available) should also be administered along with the antimalarial.

It is not enough to give a referral note and assume that the patient has been referred.

A health worker should accompany the referred patient to the next level of health care.

7.2.4 Reporting of Malaria in Pregnancy using ICD 11 Classification

Interpretation of parasitological test results (Malaria Species confirmed) and ICD 11 Classification of Malaria in Pregnancy

Malaria in pregnancy should be coded carefully to reflect both the type of malaria and the pregnancy

status. Three ICD 11 codes commonly used

i) **JB63.60;** Malaria complicating pregnancy, childbirth, or the puerperium; refers to severe or complicated malaria cases during pregnancy and should NOT be used for uncomplicated malaria.
ii) **JB63.6Z;** generalized puerperal infection (Protozoal diseases complicating pregnancy, childbirth or the puerperium, unspecified)
iii) **B40.0**; Puerperal sepsis (Protozoal diseases complicating pregnancy, childbirth or the puerperium, unspecified)

NOTE: Since the Malaria species-specific codes do not specify pregnancy, a separate pregnancy code should be used alongside the malaria code to indicate the patient is pregnant as described in the table below.

Condition	Appropriate ICD-11 Code(s)
Severe or complicated malaria in pregnancy	JB63.60 + Specific code for Severe Malaria by Species
Uncomplicated *P. falciparum* malaria in pregnancy	Pregnancy code + 1F40
Uncomplicated *P. vivax* malaria in pregnancy	Pregnancy code + 1F41
Uncomplicated *P. malariae* malaria in pregnancy	Pregnancy code + 1F42
Uncomplicated *P. ovale* malaria in pregnancy	Pregnancy code + 1F43

Examples:

i) JB63.60/1F40.0 - *Plasmodium falciparum* malaria with cerebral complications (Severe Plasmodium falciparum Malaria) in Pregnancy.
ii) B40.0/1F41.Y - Puerperal sepsis due to *Plasmodium vivax* malaria

7.3 Prevention of Malaria in Pregnancy

The goal of prevention of malaria in pregnancy is to reduce maternal and perinatal morbidity and mortality associated with malaria. The strategies in prevention of malaria in pregnancy are integrated into the overall antenatal care (ANC) package for maternal health. They include the provision of:

- Intermittent Preventive Treatment of Malaria in pregnancy (IPTp).
- Long lasting Insecticidal Nets.
- Provision of prompt diagnosis and treatment of malaria.
- Health promotion.

Intermittent preventive treatment of malaria in pregnancy (IPTp)

IPTp is the presumptive (regardless of whether the woman is infected or not) provision of a full treatment course of the recommended antimalarial at specific intervals during pregnancy. IPTp has been shown to reduce the risk of placental infection and the associated risk of maternal anaemia, miscarriage, premature deliveries and low birthweight. The current recommended medicine for IPTp is sulfadoxine 500mg and pyrimethamine 25mg (SP).

- IPTp is recommended in moderate and high malaria transmission areas.

- Administer IPTp with each scheduled visit from 13 weeks of pregnancy to ensure women receive a minimum of 3 doses.
- IPTp should be given at an interval of at **least** 4 weeks apart according to the IPTp schedule (Annex 10.6).
- IPTp should be given under Directly Observed Treatment (DOT) in the antenatal clinic and can be given on an empty stomach.
- SP for IPTp is safe up to term *(40 weeks pregnancy)* and even one dose is beneficial for women presenting late in pregnancy.
- All pregnant women should receive an iron supplementation during ANC as part of the prevention of anaemia.
- Tp-SP should be prescribed in high transmission areas and LLINs given during the ANC visit to all pregnant women.
- Low dose Folic acid 0.4mg is recommended during pregnancy and can be given together with SP. If low dose folic acid is not available, high dose folic acid (5mg) tablets should NOT be administered with SP given for IPTp and if need be, may be taken 14 days following administration of IPTp-SP.

Always ask the mother if she is allergic to sulphur-based drugs or has experienced side effects to sulphur-based drugs before giving SP.

7.3.1 IPTp and HIV+ pregnant women

HIV infection during pregnancy increases the risk of complications of malaria in pregnancy while malaria infection during pregnancy particularly placental malaria increases the risk of mother to child transmission of HIV.

Pregnant women who are HIV positive and are on daily Cotrimoxazole chemoprophylaxis should **NOT** be given SP for IPTp.

7.3.2 Linkage to Community Delivery of Intermittent Preventive Treatment of Malaria in Pregnancy with Sulfadoxine-Pyrimethamine (C-IPTp)

To improve the uptake and coverage of IPTp, health service providers at the community level should help identify and encourage pregnant women to visit health facilities and begin antenatal care (ANC) early, ideally during the first trimester. Early initiation of ANC will facilitate proper scheduling for pregnant women to start IPTp at 13 weeks and continue receiving subsequent monthly doses up to IPTp 8. Additionally, the health service providers should assist in tracing defaulters—pregnant women who miss scheduled ANC visits—and, where applicable, administer subsequent IPTp doses at home under directly observed ingestion.

M&E Indicators for malaria diagnosis and treatment

1. Proportion of eligible pregnant women who receive 3 or more doses of IPTp for malaria during their last pregnancy in targeted counties.

2. Percentage of IPTp missed opportunities referred.

3. Proportion of suspected malaria cases presenting to public health facilities tested with mRDT or microscopy.

4. Proportion of suspected malaria cases presenting to public health facilities managed in accordance with the Kenya malaria treatment guidelines.

5. Severe malaria case fatality rate (proportion of severe malaria cases resulting in death)

Other Malaria Chemoprevention and Immunoprevention interventions

Perennial malaria chemoprevention (PMC)

Perennial malaria chemoprevention (formerly Intermittent preventive treatment for infants- IPTi) is the administration of a full treatment course of an antimalarial medicine at predefined intervals, regardless of whether the child is infected with malaria, in order to prevent illness in moderate to high perennial malaria transmission settings. The goal of PMC is to protect young children by establishing preventive antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the age of greatest risk of severe malaria.

Seasonal Malaria Chemoprevention (SMC)

SMC is the intermittent administration of a curative dose of antimalarial medicine during the malaria season to asymptomatic children, regardless of whether the child is infected with the malaria parasite – that is, asymptomatic children are not tested for malaria before SMC administration. The objective of SMC is to establish antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the period of greatest malaria risk. SMC is recommended in areas of highly seasonal P. falciparum malaria transmission. In Kenya, Seasonal malaria chemoprevention (SMC) has been successfully implemented among children under-five in Turkana County. In Kenya, SMC drugs are mainly distributed through trained Community Health Promoters through door-to-door visitation, in community distribution points like markets. SMC drugs can also be given to eligible children through integrated outreaches and in health facilities by health workers. SMC has also been successfully digitalized on eCHIS and can therefore easily administered and reported on eCHIS where CHPs have been trained on eCHIS and the SMC module therein.

Eligibility for SMC

Children in age groups at high risk of severe malaria are eligible. The National Malaria Control Program will rely on epidemiological data to determine suitable geographical areas and age groups are at high risk of severe malaria where SMC can be implemented. These include children below 5 years of age and in some areas children under 10 years of age. The priority target areas for SMC implementation are those where:

- P. falciparum malaria transmission is highly seasonal and the majority (>60%) of clinical malaria cases occur within 4 consecutive months – where data on malaria from the health management information system are unreliable, rainfall data could be used as a proxy for seasonality in incidence (at least 60% of annual rainfall in 4 consecutive months); and
- The clinical attack rate of malaria (without SMC) is at least 0.1 episodes per child during the transmission season in the target group.

Timing of SMC

SMC should be implemented during the peak malaria transmission period, when the incidence of malaria is highest. SMC courses are given at 28-day intervals, beginning at the start of the transmission season and continuing for 3–5 cycles, depending on the local context. In Turkana for example, SMC was implemented in 5 monthly cycles from June to October. SMC administration should be chosen to cover the period when children are at greatest risk for malaria infection. The seasonal distribution of malaria (number of confirmed malaria cases per month) should be described by each county and/or sub county to define the ideal timing to start and end SMC. Rainfall data can also be used to estimate peak transmission periods. Depending on the seasonal patterns of malaria transmission, the timing

and number of SMC cycles (3–5) may vary between counties.

Drugs used for SMC

WHO recommends that medicines used as first- or second-line malaria treatment in a country not be used for chemoprevention in that country. The combination of SP+AQ is currently recommended for SMC for the following reasons.

- In the clinical trials that provided the evidence base for WHO recommendations, SP+AQ conferred greater protection than other medicine combinations.
- There are no indications that the chemoprevention efficacy of SP+AQ is diminishing in Africa.
- The SP+AQ regimen is well tolerated and relatively inexpensive.
- The SP+AQ regimen confers protection for 28 days. 2.5.1

Dosing schedules for SP+AQ The combination SP+AQ is available as dispersible tablets in two different blister packs for the following two age groups:

- Infants 3 to <12 months of age: a single dose of a tablet of 250/12.5 mg SP and three 75 mg tablets of AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are given on days 2 and 3, respectively.
- Children aged 12–59 months: a single dose of a tablet of 500/25 mg SP and three tablets of 150 mg AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are given on days 2 and 3, respectively.

(As there are currently no specific blister packs for children >60 months of age, countries should ensure that the target dose of SP+AQ based on weight is delivered daily for 3 days: SP – 25/1.25 (25-70/1.25-3.5) mg/kg bw single dose and AQ – 10 (7.5-15) mg/kg bw daily for 3 days.)

The packaging clearly indicates that both SP and AQ tablets need to be given on day 1, and only AQ tablets on days 2 and 3. Different manufacturers' packaging may be slightly different, and this should be considered in the development of training materials. The single dose of SP on the first day is given at the same time as the first dose of AQ. All children eligible to be treated in the first SMC cycle remain eligible throughout the campaign (i.e. children do not "age out" of SMC during a campaign). However, the reverse is not true – children who become eligible in later cycles should receive SMC from that point on.

Contraindications

SMC should not be given to:

- a child with an acute febrile illness or a severe illness – these children need to be referred to the nearest health facility for appropriate care (or tested and, if positive for malaria, treated on the spot with an antimalarial in countries where rapid diagnostic tests and ACT are available in the community as part of the SMC campaign);
- a child taking co-trimoxazole (e.g. HIV-positive child receiving co-trimoxazole prophylaxis).
- a child who has received a dose of either SP or AQ during the previous 2 weeks; or
- a child who is allergic to either SP or AQ. Seasonal malaria chemoprevention with sulfadoxine–pyrimethamine plus amodiaquine in children

Community distributors (CDs) of malaria medicines need to be trained on the contraindications. They should ascertain for each child in each cycle that none of the contraindications apply before administering the medicines.

Malaria Vaccines

Introduction

Malaria vaccines represent a major advancement in the fight against *Plasmodium falciparum*, the most deadly malaria parasite and the most common species in Kenya. Vaccination offers an additional, evidence-based tool to complement existing malaria interventions such as vector control, chemoprevention, and prompt case management.

The RTS,S/AS01 (Mosquirix®) malaria vaccine is the first malaria vaccine recommended by WHO for broader use in areas with moderate to high *P. falciparum* transmission. Kenya is among the first countries globally to pilot and begin phased introduction of the malaria vaccine in selected high to moderate transmission zones.

Vaccine Objective and Target Population

The primary objective of the malaria vaccine is to reduce malaria illness and death among young children, who are most vulnerable to severe disease and death from *P. falciparum* infection.

- Target group: Children aged 6 months to 24 months
- Coverage area: High to moderate transmission counties, as identified by the National Malaria Control Programme (NMCP)
- Integration: Administered through the Expanded Programme on Immunization (EPI) alongside other routine childhood vaccines

Vaccine Schedule (RTS,S/AS01)

The RTS,S vaccine is administered in a four-dose schedule:

Dose	Recommended Age	Interval
1st dose	6 months	Baseline
2nd dose	7 months	1 month after Dose 1
3rd dose	9 months	2 months after Dose 2
4th dose (booster)	24 months (2 years)	15–18 months after Dose 3

The booster dose is critical to sustaining protection beyond the first year of life.

Efficacy and Impact

Clinical trials and real-world implementation have shown that the RTS,S/AS01 vaccine:

- Reduces clinical malaria cases by up to 40%.
- Reduces severe malaria cases by up to 30%.
- Has a favorable safety profile
- Provides additional protection when used alongside other core interventions, including:
    - Insecticide-treated nets (ITNs)
    - Indoor residual spraying (IRS)
    - Case management with ACTs
    - Malaria chemoprevention

In the Kenyan pilot, the vaccine has shown operational feasibility and high community acceptance and is now being considered for scale-up in targeted areas.

Post discharge malaria chemoprevention (PDMC)

Post-discharge malaria chemoprevention is the administration of a full antimalarial treatment course at regular intervals to children admitted with severe anaemia. The purpose of PDMC is to prevent new malaria infections in children aged 10 years and below admitted with severe anaemia during the period after hospital discharge when they are at high risk of re-admission or death. The drug of choice for PDMC is Dihydroartemisinin - Piperaquine (DHAP) two weeks post discharge and subsequently every month up to a maximum of 4 doses i.e. 2 weeks, 6 weeks, 10 weeks and 14 weeks post discharge.

Intermittent preventive treatment in school-aged children (IPTsc)

Intermittent preventive treatment in school-aged children (IPTsc) is the administration of a full treatment course of an antimalarial medicine at regular intervals to treat and prevent malaria infections in children who are old enough to attend school.

Mass drug administration (MDA)

Mass drug administration for malaria is the administration of a full therapeutic course of an antimalarial medicine at approximately the same time, and often at repeated intervals, to all age groups of a population in a defined geographical area. Antimalarial medicines are administered without prior malaria testing and therefore regardless of the malaria infection status of individuals.

8.BASIC PRINCIPLES IN MANAGEMENT OF MALARIA HEALTH PRODUCTS AND TECHNOLOGIES

8.1 Introduction

Health products and technologies required for the management of malaria include those for prevention, diagnosis and treatment. The commodities required are as follows:

- **Prevention:** sulfadoxine + pyrimethamine, proguanil, atovaquone, amodiaquine, mefloquine, doxycycline, long lasting
- insecticidal nets (LLINs), Malaria vaccine,
- **Diagnosis:** malaria rapid diagnostic tests (RDTs), microscopy reagents, Glucose 6 phosphate dehydrogenase rapid diagnostic tests
- **Treatment:** artemether + lumefantrine, artesunate amodiaquine, dihydroartemisinin piperaquine, artesunate pyronaridine

8.2Commodity management

Managing Access to health products and technologies

Commodity management is a set of practices aimed at ensuring timely availability

and appropriate use of safe, effective, quality products in any health-care setting.

The Commodity Management Cycle is a systematic approach to ensure that medicines at all levels of health care delivery are consistently available and appropriately used. It emphasizes the connections between four drug management activities - selection, procurement, distribution and use. The cycle is depicted below:

The cycle was developed by the Management Sciences for Health Centre for Pharmaceutical Management in collaboration with the World Health Organization's Action Program on Essential Drugs

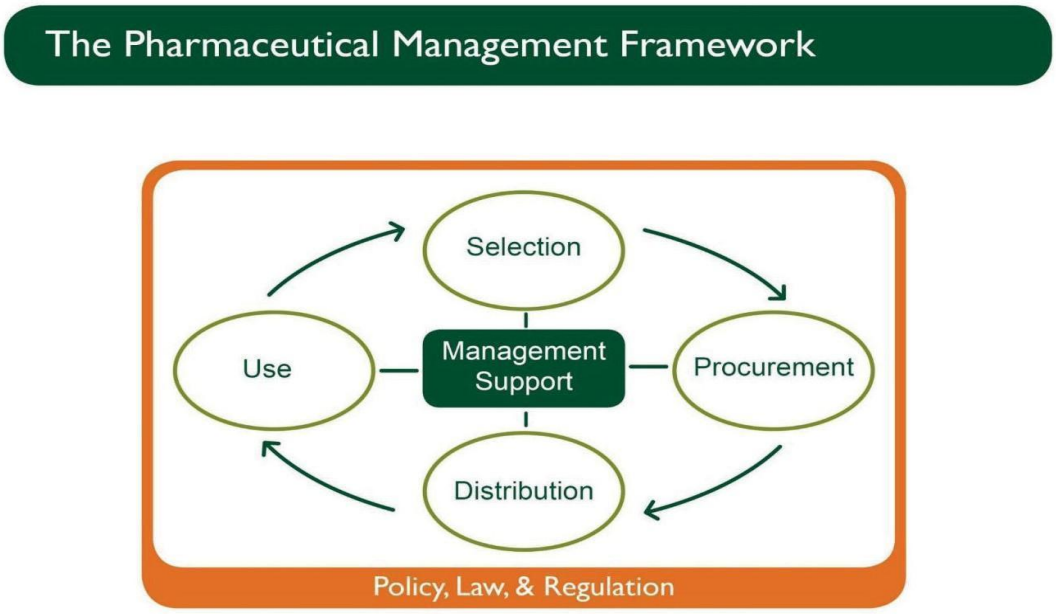


Figure 2: The Commodity Management Cycle

8.3 Selection

Selection of products for malaria prevention, control and elimination is based on the latest WHO guidelines (insert reference) and considers local considerations e.g. local resistance patterns and prevalence of malaria species. Malaria commodities recommended for use in the country are included in the latest Kenya Essential Medicines List (KEML) and the Kenya Essential Medical Laboratory Commodities List (KEMLCL).

8.4 Procurement

Procurement entails quantification (forecasting and supply planning), acquisition of the desired commodities and overall management of the acquisition process.

8.4.1 Quantification

Quantification is the process of estimating the quantities of health products and technologies needed for a specific period of time in order to ensure uninterrupted supply. Quantification is an important step in procurement and ordering for re-supply. Good quantification ensures the appropriate allocation of funds to enable purchase of the right commodity in the right quantity at the right time.

The rationale for quantification of malaria commodities:

- To ensure that there are sufficient quantities to meet clients' / patients' needs and avoid shortages/ stock-outs.
- To avoid surpluses that may lead to over-stocking, expiries and/or wastage of commodities.
- To make informed adjustments to procurement when faced with budgetary constraints.

Quantification methods

This guideline focuses attention on the two most commonly used methods— consumption and morbidity. The particular method used depends on the type of data available. The *Guidelines for Quantification and Pipeline Monitoring of Malaria Commodities of 2018 (reference)* provided detailed guidance on the processes to be followed for forecasting, supply planning and pipeline monitoring for malaria commodities. A brief description of the two main forecasting methods is provided below.

Consumption method

This is the currently recommended quantification method for malaria commodities. The consumption-based method uses historical data on the actual commodities to calculate the quantity of commodities that will be needed in the future. When using the consumption method for quantification, reporting rates and out of stock periods must be factored into the calculation. Additionally, for artemether + lumefantrine, substitution across the four AL presentations should be taken into account.

Morbidity method

The morbidity-based method uses data about diseases and the frequency of their occurrence in the population (incidence or prevalence) or the frequency of their presentation for treatment. It determines the quantity of commodities needed for the treatment of specific diseases, based on projections of the incidence of those diseases. The morbidity method is currently used to forecast requirements for long-lasting insecticidal nets for routine and mass distribution, indoor residual spraying supplies and sulfadoxine + pyrimethamine tablets for prevention of malaria in pregnancy.

8.4.2 Acquisition and management of the tender process

Acquisition of malaria commodities in Kenya is done by the Kenya Medical Supplies Authority (KEMSA), local agencies, as well as other international procurement agencies with guidance from the National Malaria Program. Local and International best procurement practices should be followed to ensure that appropriate and quality-assured health commodities are obtained at the lowest possible acquisition cost. The Procurement and Supply Management (PSM) unit of the Malaria Program is responsible for ensuring appropriate coordination of the various funding and procuring agencies to ensure a well-managed pipeline.

8.5 Distribution

WHO Good distribution practices

The goal of distribution is to maintain a steady supply of health commodities to facilities while ensuring that resources are used in the most effective way. The distribution cycle includes the following: customs clearance, transport and delivery, inventory management and storage.

8.5.1 Customs clearance, transport and delivery

These processes should be undertaken by the agency responsible for warehousing and distribution i.e. KEMSA in collaboration with the malaria program and any other procuring agencies.

8.5.2 Inventory management

An inventory management system is a cycle of activities comprising ordering, receiving, storage, issuing and reporting of commodities.

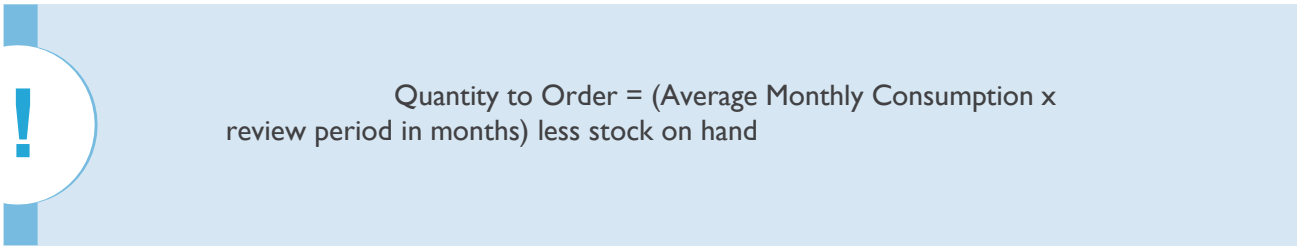
Definitions of terms in inventory management

- **Average monthly consumption (AMC)**: This refers to the average quantity of commodities consumed per month.
- Stock on Hand (SOH): The quantity of Malaria commodities available in the stores plus dispensing areas following a physical count.
- **Months of stock (MOS):** The quantity on hand expressed as the number of months that quantity should last. It is calculated based on the commodity's average monthly consumption.
- **Lead time:** The time interval between when a new stock is ordered and when it is received and available for use.
- **Review period:** The routine interval of time between assessments of stock levels to determine if an order should be placed. It is also known as order interval or resupply interval.
- **Maximum stock level:** The amount of stock above which a facility should not exceed under normal circumstances, a maximum of 6 months of stock.
- **Minimum stock level:** The amount of stock below which a facility should not fall under normal circumstances, a minimum of 3 months of stock.
- **Shelf life:** The length of time a product may be stored without compromising its usability, safety, purity or potency (expiry date).
- **Pipeline:** The entire chain of storage facilities and transportation links through which supplies are moved from manufacturers to clients
- **Stock out days:** The number of days that the commodity is not in stock.

Ordering

The facility should order commodities quarterly or as necessary in case of emergency, from KEMSA through the KEMSA logistics management information system (LMIS). The LMIS is linked to the

Kenya Health Information System (KHIS) and consumption data from the latter is used to derive reorder quantities using the formula below:



Quantity to Order = (Average Monthly Consumption x review period in months) less stock on hand

Receiving

Commodities should be received by a designated health facility staff who should counter-check commodities received against what was ordered and what is on the delivery note. Any discrepancies and tampering should be noted on the delivery note and all receipts should be accurately recorded in the stock card.

Storage (WHO Good storage practices)

Commodities should be stored under optimal conditions to ensure their safety and efficacy in accordance with good storage practices:

- Proper arrangement
- Quality maintenance (appropriate temperature, light and humidity).
- Assured security
- Good inventory control and stock rotation (First in First Out/ First Expiry First Out)
- Good record keeping
- Regular stock counts during which damaged, expired and obsolete items are identified and separated from the usable stock. Disposal of unusable stock should be carried out according to the guidelines for disposal of pharmaceuticals and biosafety guidelines for medical waste.

Issuing

The facility should issue commodities to various points of use, using an issue/ requisition voucher (S11/ S12) and must record the issue on the bin card.

Reporting

The facility should report on a monthly basis through KHIS. Primary data sources for this include the daily activity registers, stock/bin cards, S11s, S12s. The data is collated in the monthly summary tool by the facility staff and forwarded to the sub-county level by the 5th of the following month. The relevant sub-county official should upload all the reports within the sub-county by the 15th of the same month.

Malaria commodity data from the community health units (CHU) is captured using the electronic community health information system (eCHIS) and/or CHU DARs. Data from CHU DARs is reported in the CHU monthly summary form and submitted to the link health facility by the 3rd of the following month. The link health facility should submit the CHU reports alongside the facility health report to the sub-county. eCHIS is linked to the KHIS.

Types of inventory records

Various forms are used for requisitioning and issuing medicines, financial accounting, and preparing consumption and stock balance reports.

Table 11: Types of Inventory Records

Record type	Source document	Information
Stock keeping records	Bin cards, stock ledger card	Stock at hand; receipts, losses balances and adjustments
Transaction records	Issue and receipt voucher (S12, S11), KEMSA delivery notes, standard order form	Orders, issues and receipts
Consumption	Daily activity register, health	Consumption data; stock out
records	facility monthly summary	days; patient numbers

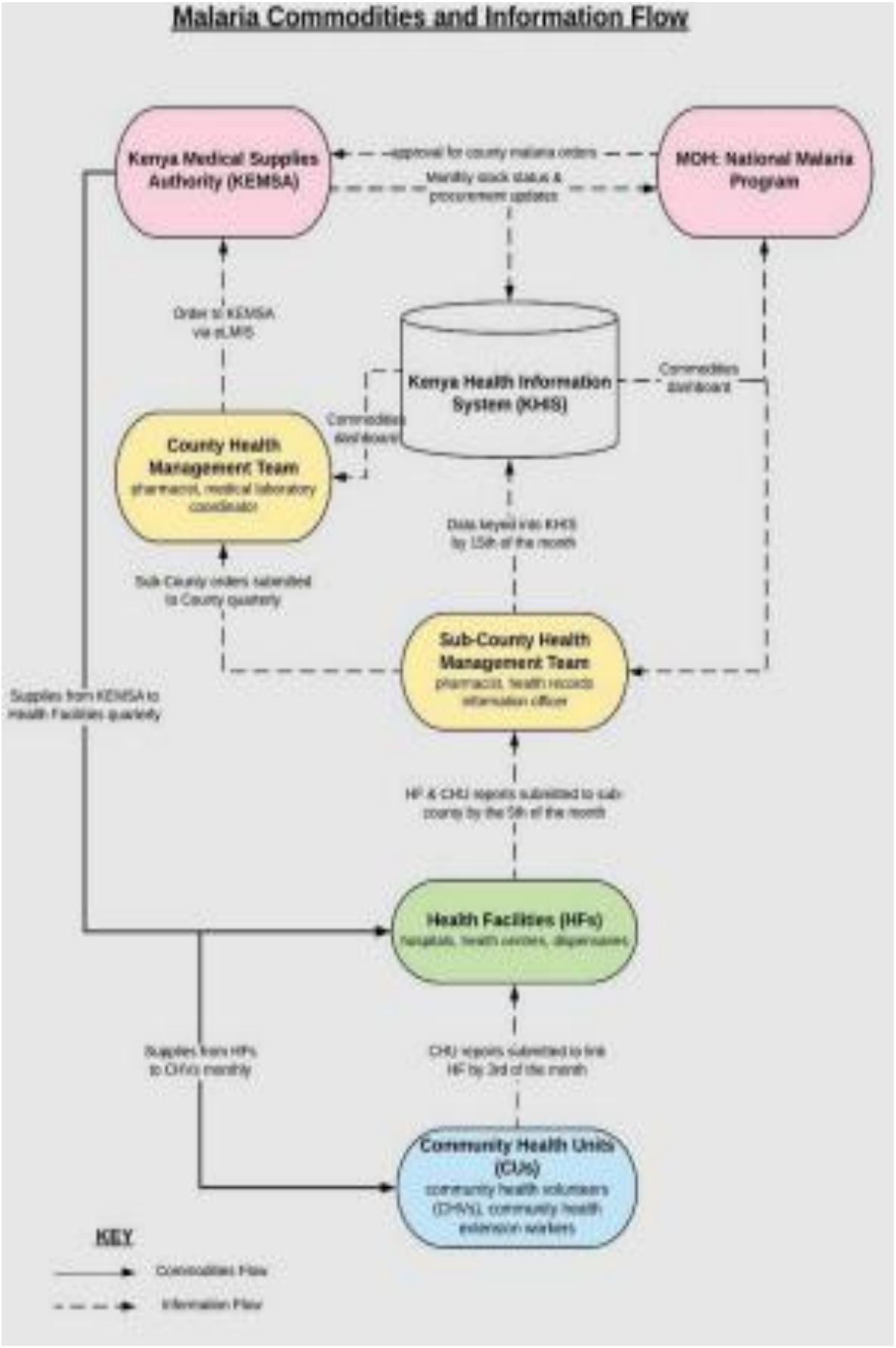


Figure 3: Flow of Logistics Management Information

8.5.3 Reverse Logistics

This is the process of moving malaria commodities from health facilities back to the supplier or KEMSA in order to recapture value or dispose properly. It may include planning, implementation, and control of the process flow in order to ensure efficiency and cost-effectiveness.

Reverse logistics may be applied for suspected poor-quality medicinal products and long-lasting insecticidal nets at the peripheral facilities. KEMSA has a well-defined process for this.

Expired commodities should be disposed of by the county authorities in accordance with the relevant laws and guidelines. In the event that funds are available at national level to support reverse logistics, KEMSA will liaise with the National Malaria Program and the various county pharmacists to implement this.

8.5.4 Redistribution

This is the process of moving malaria commodities between various entities e.g. inter and intra county, Sub County and between health facilities.

8.5.5 M&E Indicators

- National reporting rate
- Proportion of health facilities having no stock-out of all ACTs in a month
- Number of patients treated with ACTs.
- Proportion of health facilities having no stock-out of RDTs in a month

8.6 Rational Use of Medicines

8.6.1 Definition of rational use

The rational use of medicines requires that patients and clients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community.

8.6.2 Factors affecting rational use of medicines.

- **Diagnosis** – correct diagnosis based on parasitological confirmation.
- **Prescribing** – prescribing /administering the recommended medicine based on the correct diagnosis. For example, injectable artesunate should only be prescribed for severe malaria cases.
- **Dispensing –** correct dispensing (quantity, packaging and labelling) of the prescribed medicine.
- **Patient/Client compliance** - patients'/client's adherence to health worker instructions and label
- instructions

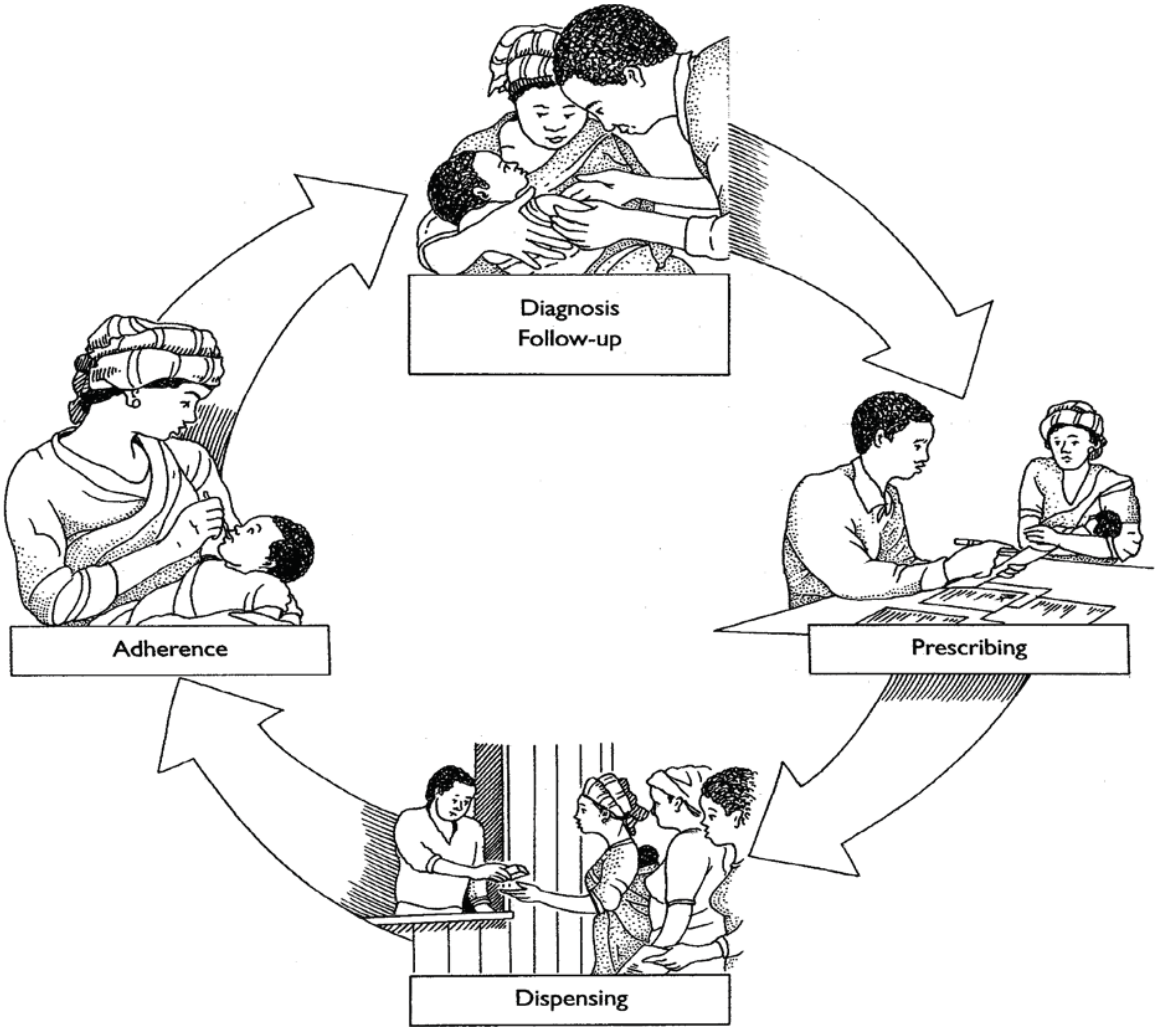


Figure 4: The Medicine Use Cycle (Who 1988)

8.6.3 *Implications of irrational use of medicines*

- This can destroy the benefits of a good pharmaceutical management system and also reduce the useful therapeutic life of an effective medicine.
- Resources spent on procurement are lost if the correct medicines are not prescribed and dispensed to the right patient.

8.6.4 *Minimum dispensing information*

- Directly observed treatment for SP and the first dose of AL .
- Instructions on how long to take the medicine.
- Instructions on what to do if the patient vomits within 30 minutes of taking the medication.
- The common adverse drug reactions (ADRs) and instructions to report any suspected ADRs.
- Clear label with appropriate patient and medicine information.

8.6.5 M&E Indicators

- Proportion of patients with fever presenting to health facilities who are managed in accordance with national malaria guidelines.
- Proportion of patients presenting to health facilities with fever and ACT prescribed, to whom counselling, and ACT dispensing tasks are performed according to national guidelines.

8.7 Quality Assurance

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas: development, quality control, production, distribution, and inspections.

Several activities are carried out to ensure that the quality of malaria commodities is maintained from the point of procurement through storage and distribution to the last point of use.

During procurement, all commodities should have documentation from the relevant regulatory authority e.g. Good Manufacturing Practices (GMP) from manufacturing sites, registration and retention certifications from PPB for medicines. At the point of delivery, inspection and testing is done at KEMSA to ensure that the commodities meet the specified quality criteria. At predetermined intervals, the commodities are sampled randomly during storage to ensure that they still meet the quality standards.

Once in a year, post marketing surveillance (PMS) is done jointly across the country in public health facilities as a collaborative exercise between PPB, KEMSA and the malaria program to sample malaria commodities for testing. Feedback is given by the PPB to health facilities thereafter and any findings used for improvement.

8.8 Pharmacovigilance

8.8.1 Definition of pharmacovigilance

Pharmacovigilance is defined as the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with a view to identifying new information about hazards, and preventing harm to patients.

Goals of pharmacovigilance are:

- To minimize medicines' harm to the patients
- To control economic impact of managing Adverse drug reactions (ADRs) e.g. cost of hospitalization, cost of more medications.

8.8.2 Adverse drug reactions (ADRs)

This is a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease.

Report ALL suspected ADRs which:

- Lead to death, disability (significant, persistent or permanent) or congenital
- anomalies
- Are life-threatening.
- Require hospitalization (initial or prolonged) or intervention to prevent permanent

impairment or damage.

Report suspected ADRs even if:

- You are not certain if the drug caused the ADR.
- You do not have all the details.

8.8.3 Poor quality medicinal products (PQMPs)

Substandard/ Spurious/ Falsely labelled/ Falsified and Counterfeits (SSFFCs) medicines are a global health problem. Any suspected poor-quality medicinal products should be reported to the Pharmacy and Poisons Board. Suspicion of poor quality may arise from physical examination of a product (e.g. discoloration, disintegration of tablets) or observation of lack of efficacy with a given batch of medicines.

8.8.4 Tools for reporting side effects, adverse drug reactions and poor-quality medicines

Reporting of ADRs is done using the forms below: (These forms are also available online at the Pharmacy and Poisons Board website www.pharmacyboardkenya.org)

- PV1: Yellow form-to capture all suspected adverse drug reactions.
- PV4: White alert card-to report life threatening drug reactions.
- PV6: Pink form-to report poor quality medicinal products

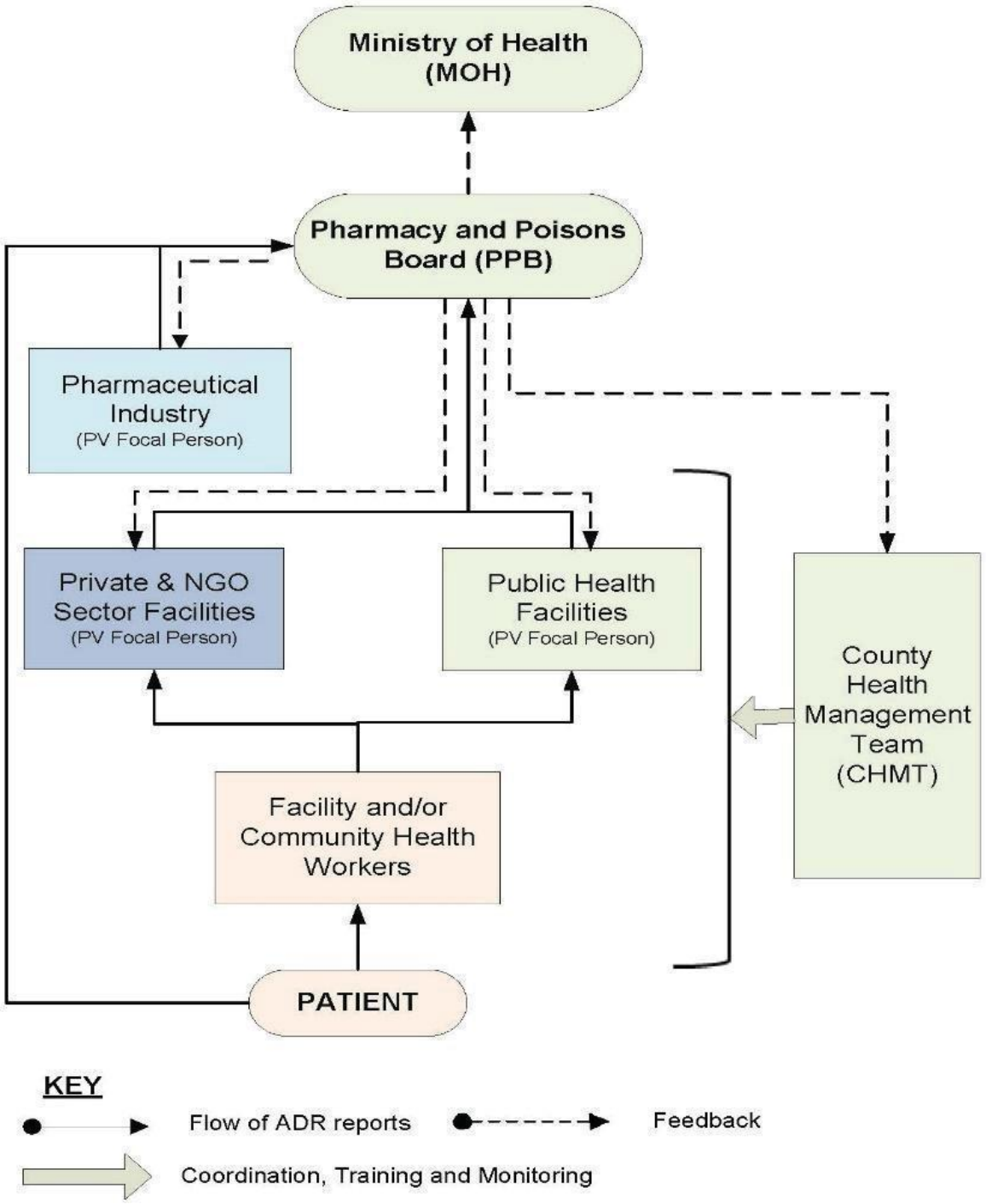


Figure 5: Flow of Information on Adverse Drug Reactions

- Feedback to all levels of the system is the responsibility of the Pharmacy and Poisons Board (PPB).
- ADR reports may be submitted to the PPB Pharmacovigilance Center as follows:
    - Manually: Hard copies may be sent by courier or hand delivered to PPB.
    - Electronically: *either* via the PV Electronic Reporting System on the PPB web-site-http://www.pv.pharmacyboardkenya.org/; *or* via the mobile phone applications that can be downloaded from the same link.

8.8.5 M&E Indicators

- Number of ADR reports submitted to PPB.
- Number of suspected poor-quality malaria medicines submitted to PPB

8.9 Malaria Elimination

8.9.1 Introduction

Malaria elimination is defined as the interruption of local transmission, resulting in zero incidence of indigenous malaria cases of a specified *Plasmodium* species in a defined geographical area, as a result of targeted, sustained interventions. Even after achieving elimination, continued measures are required to prevent re-establishment of transmission.

In Kenya, malaria transmission is heterogeneous, with very low transmission areas reporting a parasite prevalence of less than 1%. According to the Kenya Malaria Strategy 2023–2027 (KMS), the country will focus efforts on malaria elimination in selected low and very low burden counties.

The National Malaria Control Programme (NMCP) will coordinate and lead the elimination agenda, which includes:

- Establishing policy and technical structures to support implementation
- Strengthening surveillance and case investigation systems
- Ensuring access to high-quality diagnosis, treatment, and follow-up
- Promoting adherence to national treatment guidelines across all transmission settings

These activities are aligned with the WHO Global Technical Strategy for Malaria 2016–2030, which prioritizes elimination in very low and low-transmission settings as a pathway to a malaria-free world.

The selection of counties for elimination will be guided by malaria incidence, transmission intensity, health system readiness, and surveillance performance indicators.

8.9.2 Case Management in Elimination Settings

As transmission decreases, malaria elimination efforts must ensure early detection, prompt treatment, and complete follow-up of every malaria case—whether symptomatic or asymptomatic.

1. **Diagnosis of malaria cases**
   - All suspected malaria cases must be promptly diagnosed using malaria microscopy or mRDT.
   - Malaria microscopy remains the gold standard for malaria diagnosis.

2. **Management of Uncomplicated Malaria**
   - Antimalarial treatment should be limited to cases with positive test results.
   - All confirmed cases of uncomplicated malaria—regardless of symptoms—must be promptly treated with an ACT plus Single low dose of primaquine according to national treatment guidelines.
   - In counties implementing Multiple First-line Therapies (MFT), ACT selection should align with the designated ACT for that region and population group.
   - Treatment must be documented, notified, and followed by case investigation and classification (imported, indigenous, introduced, or relapsing).

3. **Management of Severe Malaria**
   - All cases of severe malaria must be urgently referred to a facility capable of providing inpatient care and parenteral antimalarial therapy, including:
     - Injectable artesunate as the first-line treatment
     - Supportive care based on presenting complications (e.g., hypoglycaemia, anaemia, renal impairment)
   - Pre-referral treatment with injectable or rectal artesunate should be administered at lower-level facilities as per national guidelines.

- All severe cases must be reported, followed up, and included in surveillance data.

4. **Management of Malaria in Pregnancy**
   - In elimination settings, malaria in pregnancy must be treated promptly due to increased risk of complications for both mother and fetus.
   - Confirmed uncomplicated malaria in pregnant women should be treated with an appropriate ACT, depending on trimester:
     - Artemether-lumefantrine, dihydroartemisinin-piperaquine, or artesunate-amodiaquine may be used in all trimesters, as per Kenyan guidelines.
   - Suspected or confirmed severe malaria in pregnancy requires urgent inpatient management with injectable artesunate.
   - Cases of malaria in pregnancy must be reported and investigated to determine source and prevent future transmission.

8.9.3 Use of Primaquine in Elimination Settings

In areas targeting elimination, efforts must go beyond treating symptomatic cases to include transmission-blocking strategies.

- All confirmed asymptomatic, sub-clinical, or sub-microscopic *P. falciparum* infections should be:
  - Detected through targeted screening using parasitological tests.
  - Treated with a full course of ACT.
  - Administered a single low dose of primaquine (0.25 mg/kg) to clear gametocytes and interrupt transmission

This single low dose of primaquine is for *transmission reduction only* and does not replace the 14-day primaquine regimen used for radical cure of *P. vivax* or *P. ovale*.

A low dose of primaquine may be given without G6PD testing, as the risk of haemolysis is minimal at this dose.

8.9.4 Monitoring and Evaluation Indicators

To track progress towards elimination, the following indicators should be routinely monitored:

- Proportion of confirmed malaria cases notified.
- Proportion of notified cases investigated within the recommended timeframe.
- Proportion of cases classified (indigenous, imported, introduced, or relapsing)
- Proportion of confirmed *P. falciparum* cases receiving a low dose of primaquine

8.10 Malaria and Sickle Cell Disease in Kenya

Background

Sickle Cell Disease (SCD) is a hereditary blood disorder characterized by the presence of abnormal hemoglobin (HbS), which leads to the distortion (sickling) of red blood cells. SCD is relatively prevalent in Kenya, particularly in high to moderate malaria transmission zones regions, due to the evolutionary advantage conferred by the sickle cell trait (heterozygous HbAS) against Plasmodium falciparum infection.

However, individuals with SCD (homozygous HbSS) are highly vulnerable to severe malaria, which

can trigger acute complications, exacerbate baseline anaemia, and significantly increase the risk of hospitalization and mortality.

8.11 Clinical Considerations

Malaria in individuals with SCD often presents more severely due to:

- Increased haemolysis, leading to profound anaemia.
- Higher risk of vaso-occlusive crises triggered by fever and dehydration.
- Increased susceptibility to infections, including bacterial sepsis.
- Delayed parasite clearance in some cases

Prompt diagnosis and aggressive management are essential to reduce morbidity and mortality in this population.

8.12 Case Management of Malaria in Sickle Cell Disease

Diagnosis

- All febrile episodes in individuals with SCD should be promptly investigated for malaria using parasitological confirmation (microscopy or mRDT).
- Given the increased risk of co-infection, consider bacterial sepsis and other febrile illnesses in the differential diagnosis.

Treatment of Uncomplicated Malaria in SCD

- Treat with a WHO-recommended ACT (e.g., Artemether-Lumefantrine, Dihydroartemisinin-Piperaquine, or Artesunate-Amodiaquine), as per national guidelines.
- Emphasize supportive care, including:
    - Adequate hydration
    - Antipyretics (e.g., paracetamol)
    - Monitoring for signs of anaemia and vaso-occlusive crises
    - Early referral if clinical deterioration is observed

Treatment of Severe Malaria in SCD

- Admit immediately to a facility with inpatient capacity.
- Initiate injectable artesunate as first-line treatment.
- Provide comprehensive supportive care, including:
    - Blood transfusion for severe anaemia (as indicated)
    - Pain management for vaso-occlusive crises
    - Broad-spectrum antibiotics if sepsis is suspected.
    - Close monitoring of oxygen saturation, hydration status, and renal function

Malaria Prevention in Individuals with SCD

Due to their increased vulnerability, all individuals with SCD—especially children—should be prioritized for malaria prevention, including:

- Routine use of insecticide-treated nets (ITNs)
- Indoor residual spraying (IRS) where applicable
- Chemoprevention:
    - Daily prophylaxis with Proguanil is recommended for children with SCD in high-transmission areas, in line with WHO and Kenyan clinical guidelines.
    - Other options may be considered based on regional resistance patterns and availability.

Surveillance and Reporting

- Malaria cases in individuals with SCD should be documented and reported as a special risk group in surveillance systems.
- Strengthen linkages between malaria and NCD programs to ensure integrated service delivery for affected populations.

Key Messages for Health Workers

- Always suspect malaria in febrile patients with SCD.
- Prioritize parasitological confirmation and early treatment.
- Provide supportive care to prevent complications.
- Reinforce malaria prevention in all individuals living with SCD.

8.13 Malaria Prevention Among Travellers to Malaria-Endemic Areas

Introduction

In Kenya, malaria transmission is not uniform, with endemic areas primarily concentrated in the lake region, coastal region, and parts of western Kenya. Travellers from low-risk or non-endemic areas — including urban centres such as Nairobi or highland regions — are often non-immune or semi-immune, placing them at increased risk of malaria when visiting endemic counties.

Malaria prevention among travellers is essential to reduce the risk of infection, severe illness, and possible onward transmission upon return.

Target Groups

- Residents of low or non-transmission areas (e.g. Nairobi, Central Kenya)
- Children and adults travelling for:
    - Family visits
    - Work or business.
    - School holidays
    - Pilgrimages or cultural events
- Non-Kenyan nationals visiting endemic areas for short or long stays.

Recommended Preventive Measures

1. Personal Protection Against Mosquito Bites

All travellers to malaria-endemic counties should be advised to strictly adhere to vector control measures, including:

- Consistent use of insecticide-treated nets (ITNs), especially while sleeping.
- Wearing long-sleeved clothing and trousers in the evenings
- Using WHO-approved insect repellents on exposed skin (e.g. DEET-based repellents)

2. Chemoprophylaxis (Malaria Preventive Medicine)

For non-immune individuals (especially children, pregnant women, and foreign nationals), chemoprophylaxis should be considered when visiting high-transmission counties.

Chemoprophylaxis is not routinely recommended for residents of endemic areas. However, for individuals from non-endemic regions travelling to high-transmission areas, it may be appropriate based on duration of stay, location, and individual risk factors.

Recommended options for short-term travellers (based on WHO guidance):

Drug	Start	Duration	Notes
Atovaquone-proguanil	1–2 days before travel	Daily during stay and for 7 days after leaving	Well-tolerated, convenient dosing
Doxycycline	1–2 days before travel	Daily during stay and for 4 weeks after	Not for children under 8 years or pregnant women
Mefloquine	≥2 weeks before travel	Weekly during stay and for 4 weeks after	Avoid in individuals with psychiatric history

☑ *Choice of prophylaxis should be guided by age, pregnancy status, drug tolerance, duration of travel, and availability of medicines.*

Special Considerations

- Pregnant travellers should avoid non-essential travel to high-transmission areas. If travel is unavoidable, use personal protection rigorously, and consult a healthcare provider for prophylaxis options (e.g., mefloquine).

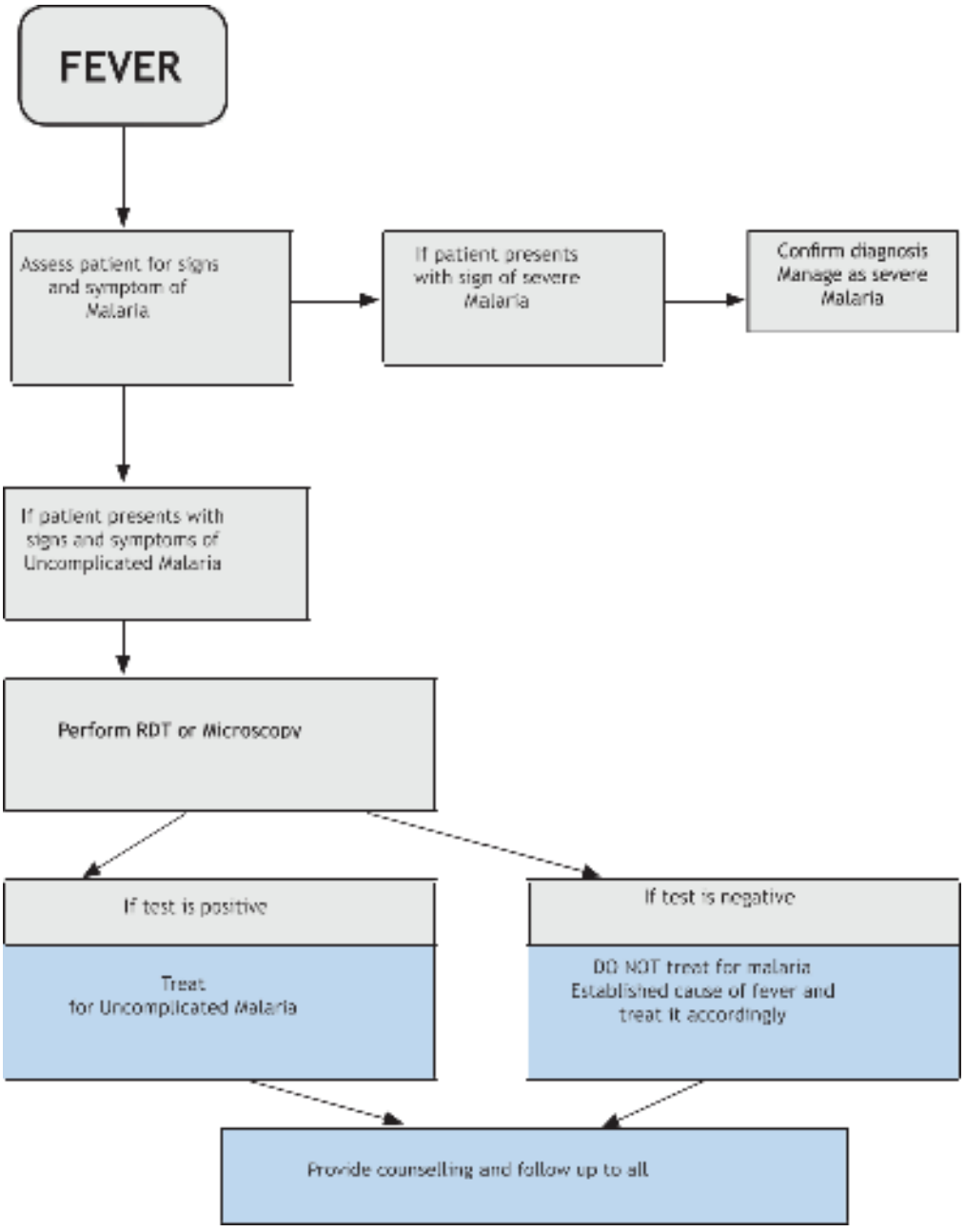
- Children are at higher risk of severe malaria. Ensure ITN use and consider chemoprophylaxis where appropriate.

- Travellers with chronic illnesses, such as HIV, diabetes, or Sickle Cell Disease, should be counselled on increased risk and preventive strategies.

- Returning travellers should be educated to seek medical care immediately if they develop fever or flu-like symptoms within one month after leaving a malaria area.

9.ANNEXES

ANNEX I: OUTPATIENT ALGORITHM FOR DIAGNOSIS AND MANAGEMENT OF MALARIA FOR CHILDREN AND ADULTS



ANNEX 2: THE PHARMACOLOGY OF ANTIMALARIALS

Antimalarials can be classified according to their chemical composition and mode of action. In this guideline, classification based on the mode of action is used.

Table 14: Classification of antimalarials

Class	Definition	Examples
Blood schizonticidal drugs	Act on (erythrocytic) stage of the parasite thereby terminating clinical illness	Quinine, artemisinins, amodiaquine, chloroquine, lumefantrine, tetracycline, atovaquone, sulphadoxine, clindamycin, proguanil
Tissue schizonticidal drugs	Act on primary tissue forms of plasmodia which initiate the erythrocytic stage. They block further development of the infection	Primaquine, pyrimethamine, proguanil, tetracycline
Gametocytocidal drugs	Destroy sexual forms of the parasite thereby preventing transmission of infection to mosquitoes	Primaquine, artemisinins, quinine
Hypnozoitocidal drugs	These act on persistent liver stages of *P.ovale* and *P.vivax* which cause recurrent illness	Primaquine, tafenoquine
Sporozontocidal drugs	These act by affecting further development of gametocytes into oocytes within the mosquito thus abating transmission	Primaquine, proguanil, chlorguanil

ANNEX 3: ADDITIONAL INFORMATION ON ANTIMALARIALS

Only fixed dose ACTs should be used for the treatment of uncomplicated malaria. Not

all the medicines in this reference section are recommended for use in Kenya.

1. Artemether-lumefantrine (AL)

For information on regular tablets and child friendly dispersible tablets, see Section 5.2.1. AL may also be presented as a powder for suspension. Once reconstituted, the suspension must be used as directed and discarded after 3 days.

Table 15: DOSING SCHEDULE FOR AL POWDER FOR RECONSTITUTION

Body weight in kg	Dosage (in ml) to be administered once a day for three days
3	4.5
4	6
5	7
6	8
7-8	10
9-10	13
11-12	15
13-14	18
15-17	22
18-20	25
21-23	29
24-26	33
27-29	37
30	40

Side effects

Dizziness and fatigue, lack of appetite, nausea, vomiting, abdominal pain, palpitations, muscle pain, joint pain, headache and rash.

Contraindications

- There is limited data on the safety of use in the first trimester pregnancy.
- Persons with known hypersensitivity to either of the components.

2. Dihydroartemisinin-piperaquine (DHA-PPQ)

This DHA-PPQ is available as both adult and paediatric tablets administered once a day for three days. See section 5.3.2 for dosing information.

Side effects
Nausea, diarrhoea, loss of appetite, rash, pruritus.

Contraindications
- Hypersensitivity to any of the components of the combination.
- There is limited data on the safety of use in the first trimester pregnancy.

3. Amodiaquine-artesunate (ASAQ)
It is available as fixed dose combination tablets containing amodiaquine and artesunate dose.

Dose
Amodiaquine 10mg/kg daily for three days plus artesunate 4mg/kg given daily for 3 days.

Side effects
Pruritus, rash, and with higher doses, syncope, spasticity, convulsions and involuntary movements.

Contraindications
- Hypersensitivity to any of the component medicines.
- Not recommended during the first trimester of pregnancy.

4. Primaquine

Dose
Primaquine is available as tablets containing 5.0, 7.5 or 15mg primaquine diphosphate. Dose 0.25-0.5mg/kg once daily for 14 days.

Side effects
The most important adverse effects are haemolytic anaemia in patients with G6PD deficiency. Therapeutic doses may also cause abdominal pain if administered on an empty stomach. Larger doses can cause nausea and vomiting. Methaemoglobinaemia may occur. Other uncommon effects include mild anaemia and leukocytosis. Overdosage may result in leukopaenia, agranulocytosis, gastrointestinal symptoms, haemolytic anaemia and methaemoglobinaemia with cyanosis.

5. Quinine

Quinine is presented as the following tablet strengths:

- 300 mg quinine dihydrochloride
- 300 mg quinine hydrochloride
- 300 mg quinine bisulphate
- 300 mg quinine sulphate
- 200 mg quinine sulphate

Table 16: QUININE TABLETS EQUIVALENCE TABLE

Quinine salt	Number of tablets
300 mg Quinine Dihydrochloride	1
300 mg Quinine Hydrochloride	1
300 mg Quinine Bisulphate	1.5
300 mg Quinine Sulphate	1.5

Dose

Quinine is administered in severe malaria as a seven-day dose of 10mg/kg salt three times a day every 8 hours.

Table 17: DOSING SCHEDULE FOR QUININE 200MG TABLETS

Weight in kg	No of 200mg tablets
4 – 7	¼
8 – 11	½
12 – 15	¾
16 – 23	1
24 – 31	1½
32 – 39	2

Table 18: DOSING SCHEDULE FOR QUININE 300MG TABLETS

Weight in kg	No. of 300mg tablets
6 – 11	¼
12 – 17	½
18 – 23	¾
24 – 35	1
36 – 47	1½
48+	2

For children below the lowest weight category, the dosage of quinine is 10mg/kg, and the tablets should thus be reconstituted into a suspension and given based on the weight of the patient. It is important to note that this is not an accurate method for quinine dosing, and the reconstitution must be done prior to each dose as the stability of quinine in the liquid used is not known.

Injectable quinine

- Quinine hydrochloride (82% quinine base).
- Quinine dihydrochloride (82% quinine base).
- Quinine sulphate (82.6% quinine base) respectively.

The ampoules contain 300mg/ml and come as 2 ml or 1 ml ampoules.

Quinine for intramuscular injection

The dosage of IM quinine injection for pre-referral treatment is a loading dose of 20mg/kg up to a maximum of 1,200mg.

How to give an intramuscular injection

- Weigh the patient (if he/she cannot be weighed the following formula can be used to estimate the weight of children under 5 years:
  (Age (in years) x 2) + 8 = wt in kg)
- Use a 10ml sterile syringe. Draw up 5ml of sterile water for injection. Then into the same syringe, draw up 300mg (1ml) from an ampoule of quinine. The syringe now contains 50mg quinine per ml. Mix the drug by shaking the syringe before injection.

*For the formulation of 600mg/2ml, only one ml is drawn out into the syringe. For the 300mg/ml the whole vial is drawn out while for the 150mg/ml, two vials will be required to make 300mg.

- In all situations a maximum of 3ml should be injected into one injection site. If the amount to be injected exceeds 3ml, half the amount should be injected into each injection site (refer to table below for number of sites).

Table 19: DOSING SCHEDULE FOR IM INJECTIONS OF QUININE

Dilute quinine to 50mg/ml – and give based on 10mg/kg doses.

Body weight	Volumes of diluted quinine injection (ml) to be administered	Number of injection sites
≤5 kg	1.0ml	1
5.1 - 7.5 kg	1.5ml	1
7.6 –10kg	2.0ml	1
10.1 - 12.5 kg	2.5ml	1
12.6 - 15 kg	3.0ml	1
15.1 - 17.5 kg	3.5ml	2
17.6 – 20 kg	4.0ml	2
20.1 - 22.5kg	4.5ml	2
22.6 – 25 kg	5.0ml	2
25.1 - 27.5 kg	5.5ml	2
27.6 –30 kg	6.0ml	2
30.1 - 32.5 kg	6.5ml	3
32.6 – 35 kg	7.0ml	3

Quinine intravenous infusion

Intravenous quinine is administered in isotonic fluid; either 5% dextrose or dextrose - saline as follows. See section on treatment of severe malaria.

Adults

- The first dose is 20mg/kg in 500mls of isotonic fluid given over 4 hours (maximum 1,200 mg).
- Use the formula to calculate number of drops per minute:

Drop factor (from infusion set) x vol. to be given time in mins (240)

- Then 8 hours after commencing the initial dose give 10mg/kg in 500mls of isotonic fluid over 4 hours (maximum 600mg).
  Repeat 10mg/kg 8 hourly until the patient can take it orally.
- Then preferably, give a full treatment course of artemether-lumefantrine or quinine may be continued orally at 10mg/kg three times a day to complete a total of 7 days treatment of quinine.

- Assessment of fluid status should be monitored regularly including urine output.
- If the patient cannot be weighed – IV quinine loading dose should be 900mg. Followed by 600 mg 8 hourly.

Children

- Put up IV quinine drip (20mg/kg body weight loading dose in 15ml/kg of isotonic fluid) to
- run over 4 hours.
- Fluid intake should be calculated according to weight, bolus 20ml/kg (minimum 10ml/ kg) and maintenance 4-6 ml/kg/hr.
- 8 hours after commencing the initial dose of quinine, give 10mg/Kg in 10mls/kg of
- isotonic fluid.
- Repeat 10mg/kg 8 hourly until the patient can take medication orally.
- Then preferably, give a full treatment course of artemether-lumefantrine or quinine may be continued orally at 10mg/kg three times a day to complete a total of 7 days treatment of quinine.

Side effects

The triads of quinine toxicities comprise cinchonism, hypoglycaemia and hypotension. Careful attention should be paid to these and adequate measures taken to correct them.

Cinchonism is characterized by tinnitus, high tone deafness, visual disturbances, headache, dysphoria, nausea and vomiting and postural hypotension all of which disappear on withdrawal of the drug. It is usually mild.

Hypotension is often associated with excessively rapid IV infusion or bolus injection. Hypoglycaemia is due to the stimulative effect of quinine on the cells of the pancreas which produce insulin. It is common in pregnancy and very prolonged and severe infection.

Other side effects include nausea, vomiting, diarrhoea, blurred vision, distorted colour perception, photophobia, diplopia and night blindness, cutaneous flushing, pruritus, rashes, fever and dyspnoea.

Black water fever is seen in patients with G6PD enzyme deficiency and malaria treated with quinine. It is characterized by haemolysis, Haemoglobinuria and in severe forms renal failure.

Artesunate injection

Description: Artesunate is a white crystalline powder. It is a rapidly acting blood schizonticide active against all *plasmodium* species. It is active against asexual parasites killing all stages from young rings to schizonts. In *P. falciparum* malaria, it also kills the gametocytes including stage 4 gametocytes.

Administration

Artesunate is administered intravenously (IV) or intramuscularly (IM) after reconstitution with sodium bicarbonate, followed by dilution with normal saline or 5% dextrose. Water for injection should not be used for dilution because it can cause hemolysis due to its hypotonic nature (it's too weak or "hypotonic

Intravenous

- An Intravenous route is preferred.
- Weigh the patient to determine the dosage needed and therefore the number of vials required.
- Dissolve each vial of artesunic powder with all the 5% sodium bicarbonate solution provided with each vial. Shake gently until the resultant solution is clear.
- Dilute resultant solution with 5 ml normal saline or 5% dextrose*.
- **NEVER use water for injection to dilute artesunate**
- The final solution has a strength of 10mg/ml.
- Calculate the volume containing the required amount of drug to be given (mg) required x vol in vials/amount in mg in vials = volume containing required drug.
- Administer by slow IV over 3-5 minutes.

Intramuscular

- Weigh the patient to determine the dosage needed and therefore the number of vials required.
- Dissolve each vial of artesunic powder with all the 5% sodium bicarbonate solution provided with each vial. Shake gently until the resultant solution is clear.
- Dilute resultant solution with 2ml normal saline or 5% dextrose*.
- The final solution has a strength of 20mg/ml.
- Calculate the volume containing the required amount of drug to be given: (mg) required x vol in vials/amount in mg in vials = volume containing required drug.
- Administer by IM route.
- Spread the doses of more than 2ml over different sites for babies and 5ml for adults.
- * This refers to 60mg artesunate. For all other strengths refer to product insert for diluent volume.

Precautions

- Inject immediately after reconstitution and discard if not used within 1 hour.
- Discard if the solution isn't clear.
- Do not use in an intravenous drip.
- Water for injection isn't suitable for dilution of artesunate injection.
- Sodium artesunate MUST be reconstituted with sodium bicarbonate solution to activate it.

Side effects

Dizziness, vomiting, headache, insomnia, cough, altered taste, abdominal pain, diarrhea, rash, pain at the injection site.

1. *Uncommon: Anaemia*

Contraindications

Oral artesunate should not be used during the 1st trimester of pregnancy.

Dosing schedule

Artesunate is administered at 0hrs, 12hrs, 24hrs then daily until the patient can take orally. A patient should receive a minimum of 3 doses of IV/IM artesunate before being transitioned to oral ACTs. If the patient cannot take orally, continue the artesunate injection for a maximum of 7 days then give a three-day course of ACT as appropriate.

All attempts should be made to allow patients who can take orally to take a full course of AL.

- Discard after 1 hour of reconstitution.

ANNEX 4: COMA MONITORING SCALES

The Glasgow Coma Scale

Table 20: THE GLASGOW COMA SCALE (for adults and children over 5 yrs)

Behaviour	Response	Score
Eye Opening Response	Spontaneous: open with blinking at baseline	4
	Opens to verbal command, speech, or shout	3
	Opens to pain, not applied to face	2
	None	1
	Oriented	5
	Confused conversation, but able to answer questions	4
Verbal Response	Inappropriate responses, words discernible	3
	Incomprehensible speech	2
	None	1
	Obeys commands for movement	6
Motor Response	Purposeful movement to painful stimulus	5
	Withdraws from pain	4
	Abnormal (spastic) flexion, decorticate posture	3
	Extensor (rigid) response, decerebrate posture	2
	None	1

It is recommended to use the simpler Blantyre coma score for children. However, if the GCS is used for children under 5, adjust the verbal response according to the Table 24 overleaf.

Table 21: RECONSTITUTION OF ARTESUNATE

	For Intravenous Route			For intramuscular Route		
	Concentration 10mg/ml			Concentration 20mg/ml		
	(3.0 mg x body weight) Concentration (10mg/ml)			(3.0 mg x body weight) Concentration (10mg/ml)		
	Example					
	Dose needed for 8kg child					
	(3.0x 8)/10= 2.4 ml rounded to 3 ml			(3.0x 8)/20= 1.2 ml rounded to 2 ml		
Less than 20 Kg	Weight	Dose				
	Kg	mg	ml	Kg	mg	ml
	6-7	20	2	6-7	20	1
	7-10	30	3	7-10	30	2
	11-13	40	4	11-13	40	2
	14-16	50	5	14-16	50	3
	17-20	60	6	17-20	60	3
	(2.4x 26)/10= 6.24 ml rounded to 7 ml			(2.4 x 26)/20 = 3.12 rounded to 4 ml		
More than 20kgs	26-29	60	6	26-29	60	3
	30-33	70	7	30-33	70	4
	34-37	80	8	34-37	80	4
	38-41	90	9	38-41	90	5
	42-45	100	10	42-45	100	5
	46-50	110	11	46-50	110	6
	51 54	120	12	51 54	120	6
	55-58	130	13	55-58	130	7
	59-62	140	14	59-62	140	7
	63-66	150	15	63-66	150	8
	67 70	160	16	67 70	160	8
	71-75	170	17	71-75	170	9
	76 79	180	18	76 79	180	9
	80-83	190	19	80-83	190	10
	84-87	200	20	84-87	200	10
	88-91	210	21	88-91	210	11
	92-95	220	22	92-95	220	11
	96-100	230	23	96-100	230	12
		240	24		240	12

To obtain the Glasgow Coma score obtain the score for each section and add the three figures to obtain a total out of 15.

Interpretation of symptoms: (Severe: 8 or less; Moderate: 9-12; Mild: 13 or more).

The Blantyre coma scale

The Blantyre coma scale[9] is a modification of the Glasgow coma scale suitable for use in children not yet able to speak. The scale uses motor and crying responses to pain and includes the ability to watch. It can be used to assess young children with cerebral malaria.

Table 22: THE BLANTYRE COMA SCALE FOR CHILDREN <5 YEARS

Behaviour	Response	Score
Eye Opening Response	Spontaneous: open with blinking at baseline	4
	Opens to verbal command, speech, or shout	3
	Opens to pain, not applied to face	2
	None	1
	Oriented	5
	Confused conversation, but able to answer questions	4
Verbal Response	Inappropriate responses, words discernible	3
	Incomprehensible speech	2
	None	1
	Obeys commands for movement	6
Motor Response	Purposeful movement to painful stimulus	5
	Withdraws from pain	4
	Abnormal (spastic) flexion, decorticate posture	3
	Extensor(rigid)response, decerebrate posture	2
	None	1

It is recommended to use the simpler Blantyre coma score for children. However, if the GCS is used for children under 5, adjust the verbal response according to Table 23 below.

Table 23: ADJUSTED VERBAL RESPONSE FOR CHILDREN <5YRS

Score	2 to 5 years	0 to 23 months
5	Appropriate words or phrases	Smiles or coos appropriately
4	Inappropriate words	Cries and consolable
3	Persistent cries and/ or screams	Persistent inappropriate crying and/ or screaming
2	Grunts	Grunts or is agitated or restless
1	No response	No response

To obtain the Glasgow Coma score obtain the score for each section and add the

three figures to obtain a total out of 15.

Interpretation of symptoms: (Severe: 8 or less; Moderate: 9-12; Mild: 13 or more).

The Blantyre coma scale

The Blantyre coma scale 9 is a modification of the Glasgow coma scale suitable for use in children not yet able to speak. The scale uses motor and crying responses to pain and includes the ability to watch. It can be used to assess young children with cerebral malaria.

Table 24: THE BLANTYRE COMA SCALE FOR CHILDREN <5 YEARS

Response	Findings	Score
Eye movement	Directed (e.g. towards mother's face)	1
	Not directed	0
Best verbal response	Appropriate cry	2
	Inappropriate cry	1
	None	0
Best motor response	Localizes painful stimuli	2
	Withdraws limb from pain	1
	Non-specific or absent response	0

Blantyre coma scale = (best motor response score) + (best verbal response score) + (eye movement score).

The score can range from 0-5. Any score < 4 is abnormal while 2 or less indicates unrousable coma. The score can be used repeatedly to assess improvement or deterioration.

Molyneux ME Taylor TE et al. Clinical features and prognostic indicators in paediatric cerebral malaria: A study of 131 comatose Malawian children. Q J Med. 1989; 71: 441-459

ANNEX 5: UPDATED IMNCI ALGORITHM

The integrated management of neonatal and childhood illnesses (IMNCI) algorithm has been updated to reflect their recommendation for confirmation of malaria diagnosis before treatment.

Table 25: IMNCI *ALGORITHM*

DOES THE CHILD HAVE FEVER?
(by history or feels hot or temperature 37.5°C* or above)

IF YES:
Has the child travelled to a high risk (Malaria endemic, seasonal transmission or epidemic prone) area in the last 1 month?
Decide Malaria Risk: high or low risk.

THEN ASK:
- For how long?
- If more than 7 days, has fever been present every day?
- Has the child had signs of measles within the last 3 months?

LOOK AND FEEL:
- Look or feel for stiff neck.
- Look for runny nose.

Look for signs of MEASLES:
- Generalized rash and one of these: cough, runny nose, or red eyes.
- Look for any other cause of fever***

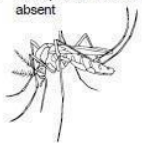
High Malaria risk:
Do a malaria test
- Endemic Zone
- Seasonal Transmission Zone
- Epidemic prone areas

Low malaria risk:
- Do a malaria test if no obvious cause of fever

NOTE: If you can't test, don't withhold treatment

TEST POSITIVE
- *P.falciparum* PRESENT
- *P.vivax* PRESENT

TEST NEGATIVE
- *P.falciparum* or *P.vivax* absent





Check for Complications of **MEASLES**

If the child has signs of measles now or within the last 3 months
- Look for mouth ulcers, are they deep or extensive?
- Look for pus draining from the eye
- Look for clouding of the cornea

CLASSIFY FEVER: HIGH OR LOW MALARIA RISK

CLASSIFY MEASLES

If MEASLES now or within the last 3 months, Classify

CLASSIFY		IDENTIFY TREATMENT
SIGNS	CLASSIFY AS	TREATMENT
• Any general danger sign or • Stiff neck. AND • Confirm malaria with a test.	VERY SEVERE FEBRILE DISEASE OR SEVERE MALARIA	• **Give first dose of Artesunate for severe malaria (see pg 16)** • **Give first dose of Ceftriaxone (see pg 16)** • **Treat the child to prevent low blood sugar (see pg 17)** • Give one dose of paracetamol in clinic for high fever (≥38.5 °C) (see pg 14) • **Admit or Refer URGENTLY to hospital** • **Screen for possible TB disease and check for HIV.**
• Malaria test POSITIVE**	UNCOMPLICATED MALARIA	• **Give Artemether + Lumefantrine (AL) (see pg 16)** • Give one dose of paracetamol in clinic for high fever (≥38.5 °C) (see pg 14) • **Give Vitamin A (see pg 14)** • Follow up in 3 days if fever persists *(see pg 23)* • If fever is present every day > 7 days assess further or refer • Screen for possible TB disease and check for HIV • Advise when to return immediately.
• Malaria test NEGATIVE	FEVER: NO MALARIA	• Give one dose of paracetamol in clinic for high fever (≥38.5 °C) • Assess for other possible causes of fever • Follow up in 3 days if fever persists (see pg 23) • If fever is present every day for more than 7 days assess further or refer (see pg 23) • Screen for possible TB disease and check for HIV • Advise mother when to return immediately.
Generalized rash of measles and • One of: cough, runny nose or red eyes	SUSPECTED MEASLES	• Give Vitamin A (See page 14) • Notify, take blood sample for confirmation • Screen for possible TB disease and check for HIV • Advise mother when to return immediately.
Any general danger sign or • Clouding of cornea or • Deep or extensive mouth ulcers.	SEVERE COMPLICATIONS OF MEASLES	• Give Vitamin A (see pg 14) • **Give first dose of Ceftriaxone Antibiotic (See page 16)** • **If clouding of the cornea or pus draining from the eye, apply tetracycline eye ointment. (See page 15)** • **Notify, take blood sample for confirmation OR refer** • **Admit or refer URGENTLY to hospital** • **Screen for possible TB disease and check for HIV.**
• Pus draining from the eye or • Mouth ulcers.	EYE OR MOUTH COMPLICATIONS OF MEASLES****	• Give Vitamin A (See page 14) • **If pus draining from the eye, treat eye infection with tetracycline eye ointment. (See page 15)** • **If mouth ulcers, treat with Gentian Violet (see pg 15)** • Follow-up in 2 days (see pg 23) • If child has no indication for referral, notify and draw blood sample for confirmation of measles • Screen for possible TB disease and check for HIV.
• No pus draining from the eye or mouth ulcers.	NO EYE OR MOUTH COMPLICATIONS OF MEASLES	• **Give Vitamin A if not received in the last 1 month (see pg 14)** • If child has no indication for referral, draw blood and send for confirmation • Screen for possible TB disease immediately after the measles infection and check for HIV.

TABLE : 3

ANNEX 6: SCHEDULE FOR IPTp PROVISION

Table 26: IPTp provision schedule

Timing of Contact	Dose #
1: Up to 12 weeks	
1a: 13–16 weeks	IPTp-SP dose 1
2: 20 weeks	IPTp-SP dose 2
3: 26 weeks	IPTp-SP dose 3
4: 30 weeks	IPTp-SP dose 4
5: 34 weeks	IPTp-SP dose 5
6: 36 weeks	No SP, if last dose received < 1 month ago
7: 38 weeks	IPTp-SP dose 6 (if no dose in past month)
8: 40 weeks	

ANNEX 7: 7th Edition Guideline Review Team

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