

GUIDELINES FOR CASE MANAGEMENT OF MALARIA IN GHANA

4TH EDITION March, 2020



Additional information may be obtained from the National Malaria Control Programme, Public Health Division, Ghana Health Service, P. O. Box KB 493, Korle-Bu, Accra, Ghana; Telephone: 233 - 302 - 66 - 1484/233 - 302 - 680 - 465; Email: nmcp@ghsmai.org.

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FOREWORD

The goal of the Ghana National Malaria Control Programme (NMCP) is to effectively control malaria so that malaria is no longer a public health problem in the country. The NMCP is implementing a number of interventions through which this goal can be achieved. Case management remains one of the key interventions for malaria control in the country.

Malaria case management consisting of early diagnosis and prompt effective treatment contributes to overall reduction in malaria morbidity and mortality.

These guidelines are the outcome of consultative meetings co-sponsored by the Ministry of Health, Ghana Health Service (GHS), Global Fund and IMPACT Malaria

These guidelines are the sole recommendations for the management of malaria in Ghana and all who are engaged in managing malaria in Ghana should abide by these guidelines to harmonize malaria management practices within the country.

This document replaces the 2014 Guidelines for Case Management of Malaria in Ghana. The broad objective of this document is to provide a set of recommendations and regulations for the care of patients with malaria, based on the revised Anti-Malaria Medicine Policy, March, 2020 (4th Edition).

It is our hope that this document will provide the necessary standardized guide required for effective case management of malaria and by following these guidelines, case management of malaria will be improved throughout the country.



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ABBREVIATIONS AND ACRONYMS

ACT	Artemisinin based Combination Therapy
AS-AQ	Artesunate-Amodiaquine
ADR	Adverse Drug Reaction
ADRs	Adverse Drug Reactions
AE	Adverse Event
Aes	Adverse Events
AIDS	Acquired Immune Deficiency Syndrome
AL	Artemether-Lumefantrine
ANC	Antenatal Care
AR	Adverse Reactions
ARI	Acute Respiratory Infections
CBA	Community Based Agent
CHO	Community Health Officer
CHPS	Community-based Health Planning and Services
C/S	Culture and Sensitivity
DHIMS	District Health Information Management System
DHMT	District Health Management Team
DHS	Demographic and Health Survey
DOT	Directly Observed Therapy
FANC	Focused Antenatal Care
FDA	Food and Drugs Authority
G6PD	Glucose-6-Phosphate Dehydrogenase
GHS	Ghana Health Service
Hb	Haemoglobin
Hct	Haematocrit
HIV	Human Immunodeficiency Virus
HMM	Home Management of Malaria
ICCM	Integrated Community Case Management
ICP	Institutional Contact Person



IM	Intramuscular
ITN	Insecticide Treated Net
IPTP	Intermittent Preventive Treatment in pregnancy
IV	Intravenous
LLIN	Long Lasting Insecticide Net
LP	Lumbar Puncture
M&E	Monitoring & Evaluation
MICS	Malaria Indicator Cluster Survey NMCP
NMCP	National Malaria Control Programme
ORS	Oral Rehydration Salt
RDT	Rapid Diagnostic Test
RHMT	Regional Health Management Team
SMC	Seasonal Malaria Chemoprevention
SP	Sulphadoxine Pyrimethamine
SPMDP	Society of Private Medical and Dental Practitiners

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CHAPTER ONE

1.0 INTRODUCTION


Malaria is a parasitic disease caused by a protozoon of the genus *Plasmodium*. It is transmitted through the bite of an infective female Anopheles mosquito. The main parasite species causing malaria in Ghana are *Plasmodium falciparum* (89-99.5%), *P. malariae* (0.1-8.9%), and *P. ovale* (0.2-1.9%). *P. vivax* has not yet been seen on blood films in Ghana. *P. knowlesi* has been identified in Asia as a malaria parasite in humans. Mixed infections of *P. falciparum* and *P. malariae* range from 0.1 to 2.4% whilst mixed infections of *P. falciparum* and *P. ovale* range from 0.2 to 3.0%. Crude parasite rates range from 5.3 to 40.3%.

Anopheles gambiae s.l. and Anopheles funestus have been identified as the major vectors of malaria in all the ecological zones of the Northern Sahel, Middle transitional and in the southern zone. They account for about 95% of all catches. Anopheles arabiensis has been found in the Sahel zone but in fewer numbers. Anopheles melas also exists but in small proportions in areas with brackish water along the south-western coast, typically, in mangrove swamps.

Malaria is a major cause of illness and death in Ghana, particularly among children and pregnant women. In 2018, malaria accounted for 34.5% of all out-patient illnesses and 21.8% of all admissions. Malaria infection during pregnancy causes maternal anaemia and placental parasitaemia both of which are responsible for miscarriages and low birth weight babies.

Malaria parasite prevalence among children aged 6-59 months in the MIS 2016 report indicated a regional variation from as low as 4.8% in the Greater Accra region to as high as 31.1% in the Eastern region.

Since Ghana adopted the Roll Back Malaria Initiative in 1998/1999, the country has been implementing a combination of preventive and curative interventions as outlined in the Strategic Plan for Malaria Control in Ghana, 2014 – 2020. The country continues to implement strategies that are designed to enhance the attainment of the set objectives. Additionally, Ghana subscribes to sub-regional and global initiatives such as the T3 (Test, Treat and Track) initiative which seeks to ensure that every suspected malaria case is tested, that every case tested positive is treated with the recommended quality-assured antimalarial medicine, and that the disease is tracked through timely and accurate reporting to guide policy and operational decisions. These processes if strictly adhered to, will enhance an accurate profiling of the malaria burden and also greatly contribute to appropriately managing other causes of febrile illnesses. It will additionally reduce the unnecessary exposure of patients to anti-malaria medicines, reduce consumption of ACTs and thus eliminate pressure on the medicines.



These revised guidelines demonstrate a shift from the past when fever was invariably equated with malaria to testing of every suspected case of malaria before treatment. Injection Artesunate replaces quinine as the drug of choice for treatment of severe malaria following evidence from clinical trials (Aquamat Studies). This document replaces the July 2014 Guidelines for Case Management of Malaria in Ghana. The aim of this document is to provide a set of recommendations and regulations for the care of patients with malaria based on the revised Anti-Malaria Medicine Policy, January 2019 (3rd Edition) and current evidence-based best practices in malaria case management

1.1 Objective

The primary objective of the Malaria Control Programme is to reduce disease and death due to malaria, especially in children under five years and pregnant women. One of the main interventions to achieve this objective is effective case management.

Accurate and prompt malaria case management requires that all who provide health care should be able to:


- Correctly recognize the signs and symptoms of malaria and make correct diagnosis
- Confirm the diagnosis by use of appropriate test (RDT or microscopy)
- Provide correct and prompt treatment in accordance with the National Guidelines
- Track all positive and negative cases
- Recognize the importance of full compliance with treatment schedules
- Recognize the danger signs of severe/complicated malaria and act promptly
- Ensure prompt referral of cases when necessary
- Provide appropriate pre-referral treatment

1.2 Target Levels of Utilisation

There are four levels of health-care delivery in the country at which malaria will be diagnosed and managed. This classification is based on the level of training and competence as well as the nature of the support services available for health delivery.

The levels are:

- (a) Community level: households, licensed chemical sellers, community-based agents and volunteers.
- (b) Primary health facility level: CHPS compounds, health centers, private clinics and pharmacies, polyclinics and similar institutions.
- (c) Secondary health facility level: district hospitals.
- (d) Tertiary health facility level; regional hospitals and teaching hospitals.



These guidelines cover the management of malaria at all levels. The majority of malaria cases are managed at the lower levels while certain cases will require referral of patients to a higher level of care.

CHAPTER TWO

2.0 CLINICAL FEATURES OF MALARIA

2.1 Preamble

Infection with malaria parasite may result in a wide variety of symptoms. Malaria is a disease which presents with signs and symptoms similar to other conditions and differential diagnosis is critical, therefore the need for confirmation of suspected malaria. Malaria characteristically presents as a fever. The incubation period of the *P. falciparum* parasites is from 7 to 21 days. The first attacks are usually more severe and may persist for weeks if untreated. The onset of falciparum malaria may be insidious and the fever may be remittent or irregular. If the acute attack is treated rapidly, the disease is usually mild and recovery is uneventful.

If left untreated, sequestration of infected red blood cells in the deep tissues can cause serious complications. Malaria due to *P. falciparum* during pregnancy is extremely dangerous to both mother and foetus due to sequestration of parasites in the placenta.

2.2 Classification

Uncomplicated malaria: the presence of fever or a recent history of fever, with confirmed parasitological investigation in the absence of any signs of severe disease (refer to Section 3.0).

Severe/complicated malaria: presence or history of fever, plus any life-threatening condition with confirmed parasitological investigation (refer to Section 4.0). Throughout the document severe/complicated malaria would be referred to as severe malaria.

CHAPTER THREE

3.0 UNCOMPLICATED MALARIA

3.1 Case Definition

A person presenting with a history of fever within the preceeding 2-3 days, or found to have fever on examination (peripheral temperature: axillary or infra-red (≥ 37.5 oC) or core temperature (e.g. rectal temperature $\geq 38.5^{\circ}\text{C}$), in the absence of any other cause will be considered a suspected case of malaria. In the absence of signs of severe disease, a case of suspected malaria confirmed by parasitological investigation is considered to be “uncomplicated” malaria.

3.2 Signs and Symptoms

There is no combination of signs and symptoms that reliably distinguishes malaria from other causes of fever. The patient suffering from suspected uncomplicated malaria commonly complains of:

- fever or a history of fever within the preceding 2-3 days
- chills (feeling unusually cold)
- rigors (shivering)
- headache

Other clinical features may include:

- generalised body and joint pain
- nausea and/or vomiting
- loss of appetite
- sweating
- abdominal pain (especially in children)
- irritability and refusal to drink or breastfeed (in infants)

These features may occur separately or in combination. The presentation of malaria varies and may resemble other locally important diseases such as pneumonia, meningitis, enteric fever or septicaemia.

3.3 Diagnosis

In Ghana the definitive diagnosis of malaria is made by parasitological confirmation through microscopy or Rapid Diagnostic Test (RDT) to determine the presence of malarial parasites or parasite-specific antigens in the blood. Microscopy is the gold standard diagnostic method. This is in compliance with global initiatives and recommendations such as the Test, Treat and Track (T3) which is an initiative to scale up parasite-based diagnosis to all age groups. This means that in patients with suspected malaria, a parasite-based diagnosis with microscopy or RDT is recommended before giving anti-malarial treatment. All suspected malaria cases including children under five (5) years of age must be tested either by microscopy or RDT prior to treatment.

3.3.1 Diagnosis in Pregnant Women

In all pregnant women with fever or history of fever, a confirmatory diagnostic test for malaria is recommended (microscopy or rapid diagnostic test). Due to the risk of adverse drug effects in the first trimester of pregnancy, it is especially preferable to confirm the presence of malaria parasites before treatment is initiated. Unavailability of laboratory testing should not be a reason for withholding anti-malaria treatment in pregnant women. However, all attempts should be made to confirm by testing since in some cases symptoms of early cyesis may be similar to some symptoms of malaria e.g. anorexia, nausea and vomiting.

Other conditions including urinary tract infection; pneumonia; enteric fever; intra uterine infections (chorioamnionitis) may present with fever during pregnancy. To rule out other non-malarious causes of fever, it is therefore essential to take a comprehensive history and conduct a thorough examination, followed by a request for other relevant laboratory investigations (such as urine analysis). In all pregnant women with fever or history of fever, a confirmatory diagnostic test for malaria should be done.

In rare situations where parasitological diagnosis (microscopy or RDT) is not possible, a decision to provide antimalarial treatment must be based on the probability that the illness is malaria and not other diseases. For children under 5 years, treatment could be given on the basis of proper assessment and classification using the Integrated Management of Childhood and Neonatal Illness (IMNCI) guidelines.

All other causes of fever must be excluded. If both the slide and the RDT are negative, the patient is extremely unlikely to have malaria.

A negative result from a properly performed test should greatly raise the suspicion of an illness other than malaria, and these patients should be investigated for other causes. Treatment of malaria should be withheld from a patient who has a negative result to laboratory test, and adequate follow up, including repeating the malaria test. Other causes of fever must be investigated and treatment given appropriately.

3.4 Use and Interpretation of Diagnostic Tests for Malaria

The following guidelines apply to the use and interpretation of diagnostic tests (microscopy or RDT). All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis. Both microscopy and RDTs should be supported by a quality assurance programme (Refer to National Malaria Microscopy and Rapid Diagnostic Test Quality Assurance Manual, First edition, 2016, Ghana Health Service/NMCP).

3.4.1 Children Under Five (5) Years of Age.

Children under 5 years of age should be tested either by microscopy or RDT prior to treatment.

- If test is positive, treat for malaria
- If test is negative, look for other causes of fever. Fever in this age group may also be caused by other infections including common cold, pneumonia, otitis media, pharyngitis, tonsillitis, Urinary Tract Infections, meningitis, measles among others. Children should be thoroughly assessed and treated for these conditions. Note that, malaria can co-exist with other infections.

3.4.2 Patients Aged Five (5) Years and above

- If test is positive, treat for malaria
- If test is negative, look for other causes of fever. These conditions should be treated, if present. Additional information on diagnostic tests is provided in Annex C, including summarised Standard Operating Procedures and a flow chart to aid in decision making. For detailed information of the subject, refer to the National Guidelines for Laboratory Diagnosis of Malaria (Ghana Health Service, 2014).

3.5 Treatment of Uncomplicated Malaria

The clinical objectives of treating uncomplicated malaria are to:

- cure the infection as rapidly as possible (Cure is defined as elimination of all parasites from the body)
- prevent progression to severe disease.

The public health objectives of treatment are to:

- prevent onward transmission of the infection to others
- prevent the emergence and spread of resistance to antimalarial drugs.

3.5.1 Artemisinin-Based Combination Therapy

Since 2004 the national antimalarial medicine policy adopted the use of Artemisinin-based Combination Therapy (ACTs) for the treatment of uncomplicated malaria. Artemisinin and its derivatives are the most rapidly acting and effective anti-malarials available. They are administered in combination with a second, long acting anti-malarial in order to enhance treatment and protect against the development of drug resistance.

As per the antimalarial medicine policy, three Artemisinin-based Combination Therapy (ACT) products have been selected for use nationally:

- Artesunate-Amodiaquine (AS-AQ)
- Artemether-Lumefantrine (A-L)
- Dihydroartemisinin-Piperaquine (DHAP)

The first line ACTs are either Artesunate-Amodiaquine (AS-AQ) or Artemether-Lumefantrine (A-L)

The second line is Dihydroartemisinin Piperaquine (DHAP)

All three drugs are safe for use in children. Treat infants weighing <5kg with uncomplicated *P. falciparum* malaria with ACT at the same mg/kg bw target dose as for children weighing 5kg. Currently, ACTs are not recommended for use in the first trimester of pregnancy, however, their use should not be withheld in cases where they are considered to be lifesaving. All the three ACTs can be used in the 2nd and 3rd trimesters of pregnancy.


3.5.1.1 General Guidelines for Treatment Using ACTs

(a) Drug Administration

The first oral dose of the ACT should preferably be given under supervision of a health worker, especially for children. It is preferable to administer these medicines after meals (for AS-AQ and AL).

(b) Management of Vomiting

If vomiting occurs within 30 minutes, following drug administration, the dosage of the ACT should be repeated. If vomiting stops, patient can be given the subsequent doses to take home if the health care provider is sure that the patient will follow the instructions. Ask the patient to return to the clinic if vomiting persists. Persistent vomiting may suggest severe malaria and should be managed appropriately.



Anti-emetics are potentially sedative and may have neuropsychiatric adverse effects, which could mask or confound the diagnosis of severe malaria. They should therefore be used with caution. Ensure adequate fluid intake. In children, continue to feed or breastfeed.

3.5.1.2 Dosing Guidelines for Artesunate-Amodiaquine

This is currently available as a fixed-dose formulation with tablets containing 25/67.5mg, 50/135 mg or 100/270 mg of Artesunate and Amodiaquine respectively.

Therapeutic dose: A dose of 4 mg/kg/body weight per day Artesunate and 10 mg/kg/body weight per day amodiaquine is given once a day for 3 days, with a therapeutic dose range between 2–10 mg/kg/body weight per day Artesunate and 7.5–15 mg/kg/body weight per day dose Amodiaquine. It is given orally. The dosing should be done according to body weight. Health facilities therefore need to have weighing scales. As much as possible, avoid breaking tablets beyond half.

Table 1: ARTESUNATE – AMODIAQUINE FIXED DOSING 100/270mg TABLET**12 - HOURLY DOSING**

WEIGHT (kg) AGE (Years)	DAY 1		DAY 2		DAY 3	
	Morning	Evening	Morning	Evening	Morning	Evening
18kg - 35kg 6 - 13years	½	½	½	½	½	½
≥ 36kg 14 years and above	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab

For ease of administration, avoid in patients <18kg (6 years) and use appropriate lower strength formulations

Table 2: ARTESUNATE - AMODIAQUINE FIXED DOSING 100/270mg TABLET**24 – HOURLY DOSING**

WEIGHT (kg) AGE (Years)	DAY 1		DAY 2		DAY 3	
	Morning	Evening	Morning	Evening	Morning	Evening
9kg - 17kg 1 - 6 years	½	½	½	½	½	½
18kg - 35kg 6-13 years	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab
≥ 36kg 14 years and above	2	2	2	2	2	2

For ease of administration, avoid in patients <9kg (<1 year) and use appropriate lower strength formulations

The dose in mg/kg body weight is: Amodiaquine 10mg/kg body weight (bw) + Artesunate 4mg/kg body weight, taken as a SINGLE DOSE daily for three (3) days, after meals.

Each tablet contains both Artesunate (AS) and Amodiaquine (AQ), at the dosages indicated. The product packaging clearly indicates which dosing strength applies to which age group. Use of the fixed dose combination product improves adherence and ease of administration.

3.5.1.3 Dosing Guidelines for Artemether-Lumefantrine

This is currently available as a fixed-dose formulation with dispersible or standard tablets containing 20 mg of artemether and 120 mg of lumefantrine and standard tablets containing 40mg artemether and 240mg lumefantrine in a fixed-dose combination formulation. The 80/480 artemether-lumefantrine fixed-dose formulation is recommended for use in patients with weight 35kg and above for ease of administration

Therapeutic dose: The recommended treatment is a 6-dose regimen Artemether + lumefantrine given twice a day for 3 days (total, six doses). The first two doses should be given 8 hours apart.

The dosing is based on the number of tablets per dose according to pre-defined weight bands for 3 days. This extrapolates to 1.7/12 mg/kg body weight of Artemether and lumefantrine, respectively, per dose with a therapeutic dose range of 1.4–4 mg/kg of Artemether and 10–16 mg/kg of Lumefantrine.

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),

A flavoured dispersible tablet paediatric formulation of Artemether plus Lumefantrine is available for use in young children.

Note: Artemether- Lumefantrine is SAFE for infants under 5 kg or under 6 months of age. *(Refer to Table 4 below)*

Table 3: Artemether + Lumefantrine (20/120mg) Recommended Dosing Regime

Note: Each tablet contains Artemether 20mg + Lumefantrine 120 mg.

Artemether + Lumefantrine*

WEIGHT (kg) AGE (Years)		DAY 1		DAY 2		DAY 3	
		1st Dose	After 8hours	Morning	Night	Morning	Night
<15kg	<3 years	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab
15-25kg	3-8 years	2	2	2	2	2	2
25-35kg	8-12 years	3	3	3	3	3	3
35kg and above	>12 years	4	4	4	4	4	4

Table 4: Artemether + Lumefantrine Recommended Dosing Regimen

Artemether – lumefantrine 40/240

WEIGHT (kg) AGE (Years)		DAY 1		DAY 2		DAY 3	
		1st Dose	After 8hours	Morning	Night	Morning	Night
Under 5kg	<6 months	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab
15kg	6 months - 3years	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab
15 - 25kg	3 - 8years	1 tab	1 tab	1 tab	1 tab	1 tab	1 tab
25 - 35kg	8 - 12years	1 ½ tab	1 ½ tab	1 ½ tab	1 ½ tab	1 ½ tab	1 ½ tab
35kg and above	>12 years	2	2	2	2	2	2

Table 5: Artemether + Lumefantrine Recommended Dosing Regimen (80mg Artemether + 480mg Lumefantrine)

WEIGHT (kg) AGE (Years)		DAY 1		DAY 2		DAY 3	
		1st Dose	After 8hours	Morning	Night	Morning	Night
Under 5kg	<3 years	1/4 tab	1/4 tab	1/4 tab	1/4 tab	1/4 tab	1/4 tab
5 - 15kg	<3 years	1/4 tab	1/4 tab	1/4 tab	1/4 tab	1/4 tab	1/4 tab
15 - 25kg	3 - 8 years	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab	1/2 tab
25 - 35kg	8 - 12 years	3/4 tab	3/4 tab	3/4 tab	3/4 tab	3/4 tab	3/4 tab
35kg and above	>12 years	1 ½ tab	1 ½ tab	1 ½ tab	1 tab	1 tab	1 tab

NB: Decreased exposure to Lumefantrine has been documented in young children (<3 years) as well as pregnant women, large adults, patients taking Mefloquine Rifampicin or Efavirenz and in smokers. As these target populations may be at increased risk for treatment failure, their responses to treatment should be monitored more closely and their full adherence ensured.

3.5.1.4 Dosing Guidelines for Dihydroartemisinin Piperavaquine

This is currently available as a fixed-dose combination with tablets containing 20/160mg, 40/320mg and 80/640 mg of dihydroartemisinin and piperavaquine respectively. The 20/160mg strength is a paediatric formulation. Avoid fatty meals with intake of DHAP as the risk of arrhythmias is increased as a result of accelerated absorption of piperavaquine. Normal meals do not substantially alter the absorption of piperavaquine.

Therapeutic dose: A dose of 4 mg/kg/day dihydroartemisinin and 18 mg/kg/day piperavaquine once a day for 3 days, with a therapeutic dose range between 2–10 mg/kg/day dihydroartemisinin and 16–26 mg/kg/day piperavaquine. Children weighing <25kg treated with dihydroartemisinin + piperavaquine should receive a minimum of 2.5 mg/kg bw per day of dihydroartemisinin and 20 mg/kg bw per day of piperavaquine daily for 3 days. (Refer to Table 5 below)

Table 6: Dihydroartemisinin Piperavaquine (DHAP) Dosing Regimen for the 40mg/320mg formulation

WEIGHT (Kg)	AGE (Years)	DAY 1	DAY 2	DAY 3
<11	<1	1/2 tab	1/2 tab	1/2 tab
11 - 24	1- 6	1 tab	1 tab	1 tab
24 -50	7 - 13	1 ½ tab	1 ½ tab	1 ½ tab
50 - 70	14 -18	2 tabs	2 tabs	2 tabs
≥70	18	3 tabs	3 tabs	3 tabs

NB: Avoid the use of parenteral anti-malarials as initial start doses in the treatment of uncomplicated malaria. THE TREATMENT FOR UNCOMPLICATED MALARIA IS ORAL ACTs

Supportive Treatment for Uncomplicated Malaria:

- If patient have an axillary temperature of $\geq 37.5^{\circ}\text{C}$ or feels warm to touch on examination, give an antipyretic, preferably paracetamol. Treatment of fever is especially important for children. In children, ibuprofen, aspirin and non steroidal antipyretics are not recommended because of the risks of gastrointestinal bleeding, renal impairment and Reye's syndrome. Aspirin should not be given to pregnant women, nor to breastfeeding mothers.
- Children with high fever should be tepid- sponged. Use lukewarm water from the feet toward the upper part of the body. Do not pour cold water on the child
- Advise mothers/caregivers to give extra fluids, such as breast milk, drinking water, fresh fruit juices, coconut water, Oral Rehydration Salt solution (ORS), etc.
- Feed the child during illness.
- In case of itching, give an antihistamine. Explain that itching is a possible adverse drug reaction. If itching is mild, patients should continue taking the drug.

For Pregnant Women

In addition to the above ensure that:

- client takes iron tablets as per protocol on Iron and Folic Acid (See Section in box)
- client is advised to eat well
- client is encouraged to use ITNs and other preventive measures
- client takes analgesics as prescribed, e.g. paracetamol one gram (2 tablets) every 6 hours if needed
- Advice clients to return if they get signs and symptoms of severe malaria (refer to section on severe malaria)

Dosing Guidelines for Paracetamol

Treatment of fever with paracetamol is a recommended part of supportive care for malaria, especially in children. Paracetamol in tablet, syrup or suppository forms may be given every 4-6 hours until the temperature is normal, (Refer to Tables 7 and 8).

Table 7: Dosage for Paracetamol Tablet – 500mg

Age	Weight(kg)	Dose(mg)	Number of Tablets
6 months	≤5kg	125mg	1/4 tab
6 months - 2 years	5-12kg	125mg	1/4 tab
2 - 5 years	12 - 16kg	250mg	½ tab
6 - 9 years	16 -25kg	500mg	1 tab
10 - 14 years	25 -35kg	750mg	1 ½ tab
>15 years	>35kg	1000mg	2 tabs

NB: Do not repeat 125mg for children <6months or <5kg after the first dose

Table 8: Dosage for Paracetamol Rectal

Age	Weight(kg)	Dose(mg)	Number of Pellets
6 months	≤5kg	125mg	1 of 125
6 months - 2 years	5-12kg	125mg	1 of 125
2 - 5 years	12 - 16kg	250mg	1 of 250 / 2 of 125
6 - 9 years	16 -25kg	500mg	1 of 500 / 2 of 250 4 of 125
10 - 14 years	25 -35kg	750mg	1 of 500 + 1 of 250 3 of 250 / 6 of 125
>15 years	>35kg	1000mg	1 of 1000 / 2 of 500

NB: Do not repeat 125mg for children <6months or <5kg after the first dose

Table 9: Dosage for Paracetamol Syrup (120mg/5ml)

Age	Weight(kg)	Dose(mg)	Number of Pellets
6 months	≤5kg	60mg	2.5
6 months - 2 years	5-12kg	120mg	5
2 - 4 years	12 - 14kg	180mg	7.5
4 - 8 years	15 -25kg	240mg	10
8 - 10 years	25 -32kg	360mg	15
10 - 12 years	33 - 40kg	480mg	20

Patient Counselling

Advise the patient or caregiver to return for medical attention immediately (within the same day) if symptoms get worse, and especially if signs of severe disease develop. The patient should also return for medical attention if fever has not resolved by the last day of treatment. Inform the patient of the importance of full compliance to treatment schedule.

3.6 Recurrent falciparum malaria

Recurrence of *P. falciparum* malaria can result from re-infection or recrudescence (treatment failure). Treatment failure may result from drug resistance or inadequate exposure to the drug due to sub-optimal dosing, poor adherence, vomiting, unusual pharmacokinetics in an individual or substandard medicines. It is important to determine from the patient's history whether he or she vomited the previous treatment or did not complete a full course of treatment. When possible, treatment failure must be confirmed parasitologically. This may require referring the patient to a facility with microscopy or LDH-based RDTs, as *P. falciparum* histidine-rich protein-2 (PfHRP2)-based tests may remain positive for weeks after the initial infection, even without recrudescence.

Referral may be necessary anyway to obtain second-line treatment. In individual patients, it may not be possible to distinguish recrudescence from re-infection, although lack of resolution of fever and parasitaemia or their recurrence within 4 weeks of treatment are considered failures of treatment with currently recommended ACTs. In many cases, treatment failures are missed because patients are not asked whether they received antimalarial treatment within the preceding 1–2 months. Patients who present with malaria should be asked this question routinely.

3.6.1 Failure Within 28 Days

The recommended treatment following treatment failure should be an alternative ACT. Recurrence of fever and parasitaemia > 4 weeks after treatment may be due to either recrudescence or a new infection. All presumed treatment failures after 4 weeks of initial treatment should, from an operational standpoint, be considered new infections and be treated with the first-line ACT.

3.6.1.1 Management of Treatment Failure in Pregnancy

Treatment failure is said to occur if fever and parasitaemia fail to resolve or recur within 28 days of receiving the above listed treatments. True treatment failure, however, is very rare. The following should be established before a diagnosis of treatment failure is made:

- The pregnant woman still presents with signs and symptoms of malaria.
- That she completed the full treatment course and did not vomit after taking medications.
- That the symptoms are not due to other common infections such as ear, nose, throat, urinary tract infection, chorioamnionitis, enteric fever (typhoid), etc.
- That the presence of malaria parasites is confirmed through microscopy. In the event of treatment failure, the alternative drug to be used depends on which medicine was given first. The options are shown in the Table 10. Note that ACTs are not recommended for use in the first trimester; however, their use shall not be withheld in cases where they are considered to be life-saving or where other anti-malarials are deemed to be unsuitable. In the second or third trimester, an ACT can be used (either Artesunate-Amodiaquine or Artemether-Lumefantrine).

Table 10: Drug Selection For Treatment Failure In Pregnancy

1st Trimester	Quinine	DAY 1
	Quinine + Clindamycin (for 7 days)	Artesunate + Amodiaquine or Artemether + Lumefantrine
2nd or 3rd Trimester	Artesunate + Amodiaquine	Artesunate + Amodiaquine or Artemether + Lumefantrine
2nd or 3rd Trimester	Artemether + Lumefantrine	Quinine + Clindamycin or Artesunate + Amodiaquine

Combination of Quinine and Clindamycin should be given for 7 days for treatment failure Referral

3.7 Management of Uncomplicated Malaria in Pregnant Women

Pregnant women constitute the main adult risk group for malaria mainly due to lower immunity and placental parasitaemia. Malaria infection during pregnancy causes maternal anaemia and placental parasitaemia both of which are responsible for miscarriages and low birth weight babies among pregnant women. Pregnancy places a woman at risk of increased frequency of malaria episodes, and increased severity of malaria illness.

3.7.1 Treatment in the First Trimester

Treat pregnant women with uncomplicated *P. falciparum* malaria during the first trimester with Oral Quinine (10mg/kg body weight) twice a day in combination with Clindamycin (5mg/kg body weight) twice daily for 7 days or use quinine only if clindamycin is not available. Clindamycin should be administered with food and copious amounts of water.

ACTs are not recommended for use in the first trimester. However, their use shall not be withheld in cases where they are considered to be life-saving, or where other anti-malarials are considered to be unsuitable. In case ACTs needs to be considered, the client should be referred to a facility with a medical officer / obstetrician and gynaecologist.

3.7.2 Treatment in the second, third trimesters and Puerperium

In the second and third trimesters and puerperium, ACTs are recommended for the treatment of uncomplicated malaria. The options are:

- Artesunate-Amodiaquine for 3 days
Dosage of Artesunate-Amodiaquine: (100mg/270mg) 2 tablets daily for 3 days.
- Artemether-Lumefantrine for 3 days
Dosage of Artemether-Lumefantrine (80/480mg) Artemether + lumefantrine is given twice a day for 3 days (total, six doses). The first two doses should be given 8 hrs. apart. Refer to Table 5 for details (Note: AL should be administered after a fatty meal). In cases where ACTs are not available, Quinine plus Clindamycin should be used (refer to treatment in first trimester).
- Oral Quinine (10 mg/kg body weight) 8 hourly daily in combination with Clindamycin (5 mg/kg body weight) 8 hourly daily for 7 days may be used. Clindamycin should be administered with food and copious amounts of water

Treatment of Uncomplicated Malaria Caused by P. ovale, P. Malariae

The use of surveillance has further established the presence of *Plasmodium ovale* though in very low prevalence of 0.6% nationally. However regional prevalences of *P. ovale* range from 0% to 3.1% as they keep being discovered in some specific areas of the country.

The objective of treating malaria caused by *P. ovale* is to cure both blood stage and liver-stage thereby preventing relapse.

Treat confirmed cases of *P. ovale* malaria with the standard regimen of ACT. In addition to the ACT, to prevent relapse, treat *P. ovale* malaria in children and adults (except pregnant women, infants aged < 6 months, women breastfeeding infants < 6 months, women breastfeeding older infants unless they are known not to be G6PD deficient and people with G6PD deficiency) with Primaquine.

P. malariae do not form hypnozoites and so do not require radical cure with Primaquine. Therefore treat infections of *P. malariae* with ACTs.

CHAPTER FOUR

4.0 SEVERE MALARIA

Severe Malaria is a Medical Emergency

- Severe malaria also referred to as complicated malaria is confirmed malaria with life threatening complication(s)
- The main objective of management is to prevent deaths from the direct effect of the disease or complications.
- Management of severe malaria comprises mainly clinical assessment of the patient, specific antimalarial treatment, additional treatment and supportive care.

4.1 Introduction

Severe malaria is defined by clinical or laboratory evidence of vital organ dysfunction. It affects all ages but with a higher risk in children under five (5) years of age, pregnant women and non-immune individuals. The delay in diagnosis and inappropriate treatment of uncomplicated malaria especially in infants and children can lead to the rapid development of severe malaria. The principles of diagnosis and treatment for adults are the same as in children.

Mortality from untreated severe malaria (particularly cerebral malaria) approaches 100%. With prompt, effective antimalarial treatment and supportive care, the rate falls to 10-20% overall. (Ref WHO Severe malaria 2015). The risk for death increases in the presence of multiple complications.

The most common complications of severe malaria responsible for most deaths are:

- Cerebral malaria
- Respiratory distress (acidotic breathing)
- Pulmonary oedema
- Hyperlactataemia
- Hypoglycaemia
- Severe dehydration /Shock

(Reference: 2014 WHO. Tropical Medicine and International Health Vol 19 Suppl. PP. 7-131)

All cases diagnosed as severe malaria require hospitalization for effective in-patient management. In the absence of in-patient management capacity, refer immediately after appropriate pre-referral treatment.

4.2 Diagnosis of Severe Malaria

As with uncomplicated malaria, the diagnosis of severe/complicated malaria is based on a comprehensive history taking, examination and confirmation with diagnostic (microscopy or RDT) testing.

In all patients, clinical diagnosis of severe malaria should be made in a patient with:

- fever (history of fever or axillary temperature $\geq 37.5^{\circ}\text{C}$) PLUS
- any sign of severe disease from the list under section 4.2.1.

In young children, a clinical diagnosis of severe malaria can be suspected if there is;

- fever (history of fever or axillary temperature $\geq 37.5^{\circ}\text{C}$) PLUS
- any “general danger sign in young children” from the list under section 4.2.2

Severe malaria is usually caused by *Plasmodium falciparum* infection, and is confirmed by the presence of the asexual parasite forms in the blood. While diagnostic tests should not delay the initiation of treatment, it is mandatory to test for malaria parasites (especially *Plasmodium falciparum*).

Parasitological confirmation should be established by microscopy (preferred) or RDT.

Note: *High parasitaemia is not always present in severe disease. The initial diagnostic test maybe negative. Where there is high clinical suspicion of malaria, the test should be repeated at 12 hourly intervals up to 3 times within 24 hours (ie 0hr, 12hr and 24hrs)) Remember to rule out other differential diagnoses.*

4.2.1 Features of Severe Malaria

Malaria is considered as severe if a patient has any one or combination of the following clinical manifestations and laboratory findings:

Clinical Features:

- Altered consciousness (change of behaviour confusion, delirium, unarousable coma).
- Repeated generalised convulsions (fits) – 2 or more episodes within 24 hours.
- Deep breathing and respiratory distress (Acidotic breathing)
- Difficulty in breathing due to acute pulmonary oedema.
- Unexplained abnormal bleeding (Disseminated Intravascular Coagulation)

- Recurrent or prolonged bleeding from the nose, gums or venipuncture site, haematemesis or melena.
- Jaundice (yellowish colouration of the eyes)
- Prostration i.e. generalised weakness, such that the patient cannot walk or sit without assistance
- Hyperpyrexia (axillary temperature $\geq 41.0^{\circ}\text{C}$).
- Inability to take fluids or anything orally.
- Repeated profuse vomiting
- Circulatory collapse or shock (cold limbs, weak rapid pulse) (systolic BP of less than 80mmHg in adults and less than 50mmHg in children)
- Signs of hypoglycemia (sweating, pupillary dilation, abnormal breathing,)
- Coldness – confirm with blood sugar check
- Severe Pallor – confirm anaemia with diagnostic test
- Signs of haemoglobinuria (dark or cola-colored urine).
- Renal Impairment -Signs of renal failure (passing very little urine)
 - Urine Output $<25 - 30\text{mls/hour}$ for over at least 6 hours for adults or
 - $< 0.5\text{ml/kg/hr}$ over at least 6 hours for children

Laboratory Findings:

- Severe anaemia (severe anaemia; haematocrit $<15\%$ or Hb $<5\text{g/dl}$ in children or haematocrit $<20\%$ or Hb $<7\text{g/dl}$ in adults).
- Hypoglycaemia - Blood sugar or plasma glucose $<40\text{mg/dL}$ or 2.2mmol/L .*
- Renal Impairment serum creatinine: $>265\mu\text{mol/L}$ or 1.5 fold increase from baseline within 7 days or an increase of $26.5\mu\text{mol/L}$ from baseline within 48hour. Serum Urea $>20\text{mmol/L}$
- Jaundice - Plasma or serum bilirubin $>50\mu\text{mol/L}$ (3mg/dL)
- Metabolic Acidosis- Plasma bicarbonate $<15\text{mmol/L}$. Severe acidosis manifests clinically as respiratory distress (rapid, deep, laboured breathing)
- Hyperlactataemia -Lactate $> 5\text{mmol/L}$
- Haemoglobinuria - Positive blood on urine dip stick plus no RBCs in urine deposit
- Hyperparasitaemia ($>500,000$ parasites/microlitre or $>10\%$ parasite RBC) But for non immunes use $100,000$ p/ul

- Pulmonary Oedema - (Diagnosed with Chest x-ray)
- Although hypoglycaemia is defined as blood glucose $<2.2\text{mmol/L}$, treat for hypoglycaemia if blood glucose is $<3\text{mmol/L}$

4.2.2 General Danger Signs in Young Children

The term “general danger sign” represents an important concept in Integrated Management of Neonatal and Childhood Illnesses (IMNCI) (Refer Annex F for details). These are non-specific clinical findings that suggest the presence of serious underlying illness. When assessing a young child for malaria or any other acute condition, look for these general danger signs:

- The child is unable to drink or breastfeed.
- The child is vomiting everything he/she drinks or eats.
- The child has history of convulsions during the current illness.
- The child is lethargic, unconscious, or convulsing during the examination

A child with fever and any general danger sign should be diagnosed and treated for suspected severe malaria. Parasitological confirmation with microscopy or RDT should be done concurrently. The child should also be examined and investigated for other causes of fever (e.g. acute respiratory infection, pneumonia, septicemia, otitis media, meningitis etc.) and appropriately managed in addition to the specific treatment for malaria.

4.3 Referral

The condition of the patient with severe malaria can deteriorate very rapidly and should be managed in a hospital setting. Such cases should therefore be referred immediately to a hospital after instituting pre-referral management as per the following guideline.

4.3.1 Criteria for Referral

These essentially include two elements namely;

- severe disease and
- failure to respond to recommended therapy.

The presence of any of the clinical or laboratory findings listed for severe disease is an indication for immediate referral if the facility is not a hospital.

If the patient is already being managed in a hospital, the persistence or worsening of features of severe disease may prompt referral to a higher level of care. The decision to refer from a lower level hospital to a higher level (e.g. district to regional) will depend on the capacity of the referring health facility, the patient’s clinical course, and the feasibility of referral options.

4.4 Management of Severe Malaria before Referral

When severe malaria is identified, parenteral treatment (IV/IM medication) or Rectal Artesunate should begin promptly. This section provides guidance on management of severe malaria prior to referral.

4.4.1 Steps to Take During a Referral

When sending the patient on referral, remember to:

- i. Start initial parenteral antimalarial treatment and supportive care immediately while waiting for the patient to be transferred.

The order of preferred pre referral antimalarial are as follows:

A. For Children under 6years

1. Intramuscular Artesunate (3mg/kg if weight <20kg and 2.4mg/kg for body weight ≥ 20kg)
2. Rectal Artesunate (10mg/kg Body Weight in children)
3. Intramuscular Artemether (3.2mg/kg body weight as a loading dose)
4. Intramuscular Quinine (20mg/kg body weight as a loading dose)

B. For Children above 6years and adults

1. Intramuscular Artesunate (3mg/kg if weight <20kg and 2.4mg/kg for body weight ≥ 20kg)
2. Intramuscular Artemether (3.2mg/kg body weight as a loading dose)
3. Intramuscular Quinine (20mg/kg body weight as a loading dose)
- ii. Have the patient lie down on his/her side during the journey to avoid aspiration in case of vomiting
- iii. Continue feeding if possible
- iv. Send a staff with the patient if possible
- v. Send a clear letter or referral form about the clinical picture, the type of treatment given, dosages, times and route of administration for any medications given
- vi. If referral is not feasible immediately, continue treatment until the referral becomes possible. For dosage regimens, see the sections below on
 - IM Artesunate, (Section 4.4.2)
 - Rectal Artesunate (Section 4.4.3)
 - IM Artemether (Section 4.4.4)
 - IM Quinine (Section 4.4.5)

4.4.2 Administration of Intramuscular Artesunate before Referral

Dosage for IM Artesunate

The dosage is 3mg/kg body weight for patient less than 20kg and 2.4mg/kg for body weight 20kg or more and must be given at time 0 hour, 12 hours and 24 hours, then once daily. In situations where the patient is still within the facility following referral, parenteral treatment should be continued while waiting until patient leaves.

Table 11: How to reconstitute Artesunate injection for IM use

30mg. Vial	60mg. Vial	120mg. Vial
Step 1 Add 0.5ml of the SODIUM BICARBONATE SOLUTION to the vial containing the powder	Step 1 Add 1ml of the SODIUM BICARBONATE to the vial containing the powder	Step 1 Add 2ml of SODIUM BICARBONATE to the vial containing the powder.
Step 2 Gently Shake for 2-3 minutes to ensure dissolution into a clear solution.	Step 2 Shake for 2-3 minutes to ensure dissolution into a clear solution.	Step 2 Shake for 2 -3 minutes to ensure dissolution into a clear solution.
Step 3 Add approximately 1ml of NORMAL SALINE to the clear solution obtained in step 2 to obtain a solution of 20mg Artesunate per ml (total vol. 1.5ml).	Step 3 Add approximately 2ml of NORMAL SALINE to the clear solution obtained in step 2 to obtain a solution of 20mg Artesunate per ml (total volume 3ml).	Step 3 Add approximately 4ml of NORMAL SALINE to the clear solution obtained in step 2 to obtain a solution of 20mg Artesunate per ml (total volume 6ml).
Step 4 Withdraw the required amount of solution and inject at the chosen site	Step 4 Withdraw the required amount of solution and inject at the chosen site	Step 4 Withdraw the required amount of solution and inject at the chosen site

Table 12 Calculating the dose of IV/IM Artesunate for children less than 20kg

Calculate and withdraw the required dose in **ml** according to route of administration

Weight (Kg)	Dose (mg)	IV concentration: 10mg/ml	IM concentration: 20mg/ml
		ml	ml
6 - 7	20	2	1
8 - 10	30	3	2
11 - 13	40	4	2
14 - 16	50	5	3
17 - 20	60	6	3

<p>for IV route: <u>3.0mg x body weight (kg)</u> IV artesunate solution Concentration 10mg/ml Round up to the next whole number</p> <p>Example: Dose (ml) needed for 8kg child: <u>3.0 x 8 = 2.4ml</u> 10 2.4ml rounded up to 3ml</p>	<p>for IM route: <u>3.0mg x body weight (kg)</u> IM artesunate solution Concentration 20mg/ml Round up to the next whole number</p> <p>Example: Dose (ml) needed for 8kg child: <u>3.0 x 8 = 1.2ml</u> 20 1.2ml rounded up to 2ml</p>
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Calculating the dose of IV/IM Artesunate for children more than 20kg

Calculate and withdraw the required dose in **ml** according to route of administration

Weight (Kg)	Dose (mg)	IV concentration: 10mg/ml	IM concentration: 20mg/ml
		ml	ml
20 – 25	60	6	3
26 – 29	70	7	4
30 – 33	80	8	4
34 – 37	90	9	5
38 – 41	100	10	5
42 – 45	110	11	6
46 – 50	120	12	6
51 – 54	130	13	7
55 – 58	140	14	7
59 – 62	150	15	8

Weight (Kg)	Dose (mg)	IV concentration: 10mg/ml	IM concentration: 20mg/ml
		ml	ml
63 – 66	160	16	8
67 – 70	170	17	9
71 – 75	180	18	9
76 – 79	190	19	10
80 – 83	200	20	10
84 – 87	210	21	11
88 – 91	220	22	11
92 – 95	230	23	12
96 – 100	240	24	12

<p>for IV route: <u>2.4mg x body weight (kg)</u> IV artesunate solution Concentration 10mg/ml Round up to the next whole number</p> <p>Example: Dose (ml) needed for 8kg child: <u>2.4 x 26 = 6.24ml</u> 10 6.24ml rounded up to 7ml</p>	<p>for IM route: <u>2.4mg x body weight (kg)</u> IM artesunate solution Concentration 20mg/ml Round up to the next whole number</p> <p>Example: Dose (ml) needed for 8kg child: <u>2.4 x 26 = 3.12ml</u> 20 3.12ml rounded up to 4ml</p>
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4.4.3 Administration of Rectal Artesunate

Rectal Artesunate should be used in children <6 years of age or <25kg body weight. It is to be used in the pre-referral setting. Give a single dose at the time the decision to refer is made.

The dosage is 10 mg/kg body weight to be administered as a single rectal dose (Table13)

In the event that Artesunate suppository is expelled from the rectum within 30 minutes of insertion, a second suppository should be used especially in young children. The buttocks should be held together for 10 min to ensure retention of the rectal dose of Artesunate.

Table 13: Rectal Artesunate (Pre-Referral Treatment in Children less than 6 years)

Weight (kg)	Age	Artesunate Dose	Regimen
4-6	2 -6 months	50	One 50mg suppository
7 – 14	7 - 35 months	100	One 100 mg Or two 50mg
15-25	36 -71 months	200	One 200mg or two 100mg four of 50mg suppository

4.4.4 Administration of Intramuscular Artemether

The dose of IM Artemether is 3.2mg per kg body weight as a loading dose, then 1.6mg/kg body weight daily till the patient can tolerate oral therapy or up to a maximum of seven days.

4.4.5 Administration of Intramuscular Quinine

4.4.6 Intramuscular Quinine in Young Children.

The dosage is 20mg/kg body weight as a loading dose then 10 mg (0.2ml) per kg body weight every 8 hours (WHO Case management Guideline, 2015). Calculate the volume to be given, based on body weight (Table 14).

- Weigh the child.
- Prepare Quinine dilution of 100mg/ml: use a 10ml sterile syringe and needle to draw up 5mls of sterile water for injection or normal saline (not dextrose-containing IV fluids). Then into the same syringe draw up 300mg (1ml) from an ampoule of Quinine. The syringe now contains 50mg Quinine per ml.
- Administer by intramuscular injection to the thigh. If the calculated volume exceeds 3ml, inject half the dose into each thigh

Table 14: Dosing Regimen for Quinine IM Injection in Young Children.

Body Weight (kg)	Volume of Loading dose	Volume of maintenace Quinine Dihydrochloride Inj. (50 mg/ml dilution)
< 5 -	2.0 ml	1.0ml
5.1 – 7.5	3.0 ml	1.5ml
7.6 – 10.0	4.0 ml – half to each thigh	2.0ml
10.1 – 12.5	5.0 ml – half to each	2.5ml
12.6 – 15.0	6.0 ml – half to each	3.0ml
15.1 – 17.5	7.0 ml – half to each	3.5ml - half to each thigh
17.6 – 20.0	8.0 ml – half to each	4.0ml - half to each thigh
20.1 – 22.5	9.0 ml – half to each	4.5ml - half to each thigh
22.6 – 25.0	10.0 ml – half to each	5.0ml - half to each thigh
25.1 – 27.5	11.0 ml – half to each	5.5ml - half to each thigh
27.6 – 30.0	12.0 ml – half to each	6.0ml - half to each thigh

Note: The prepatation dosage of quinine in children > 30kg should be treated as adults

4.4.7 Intramuscular Quinine In Adults.

The dosage is 20mg/kg body weight as a loading dose (maximum 1200mg) then 10 mg/Kg body weight of Quinine given 8 hourly by deep IM injection, to a maximum dose of 600 mg per dose.

- Use a Quinine dilution of 100 mg/ml. To prepare this, draw 2mls of Quinine 600mg and add 4mls of sterile water or saline (not dextrose-containing IV fluids).
- Adults weighing less than 60 kg should be given the correct calculated dose for weight. For adults weighing 60kg or more will simply receive the maximum dose
- If the required volume is more than 5ml, divide it into two and inject at separate sites.

4.4.8 Use of Antipyretics

In young children, high temperatures are associated with vomiting, often regurgitating their medication, and seizures. Treat with antipyretics and if necessary tepid sponge

(Use lukewarm water beginning from the feet towards the upper part of the body). Antipyretics should be used if axillary temperature is $>38^{\circ}\text{C}$) and the patient can tolerate oral medication. Paracetamol (acetaminophen) 10 - 15 mg/kg/bw every 4 - 6 hours is widely used up to 60mg/kg/bw within 24 hours; it is safe and well tolerated, given orally or as a suppository. (Refer Tables 7 and 8 for dosing)

4.4.9 Management of Convulsions

Generalised seizures are common in children with *P. falciparum* malaria. In case of convulsions the following should be done:

- Clear and maintain airway.
- Check blood sugar and correct hypoglycaemia if present (Refer to 4.6 Supportive therapy for severe malaria in the hospital)
- Treat convulsions with diazepam:
If IV line is in place or can easily be obtained, give a slow intravenous injection of diazepam [0.25mg/kg body weight, (maximum 10mg)] OR Diazepam can also be given rectally (0.5 mg/kg body weight) In adults, 10mg of Diazepam can also be given Intramuscularly
- If convulsions reoccur or persists (about 5 – 10 minutes), repeat the diazepam once.

If the convulsion persists after repeat of the diazepam treatment give phenobarbitone 15mg/kg body weight IM Injection (If IV line is in place or can easily be obtained, you may give IV phenobarbitone slowly over 15 – 20 minutes)

This may be topped up if convulsions persist (15 minutes after Phenobarbitone IV) to a maximum dose of 20mg/kg.

You may also use Phenytoin to replace or add on to Phenobarbitone where necessary. The dosage is the same with slow IV as the Phenobarbitone (NB. Monitor for arrhythmias)

CAUTION: Avoid the use of IV anti convulsants at Health centres and CHPs compound.

Nursing Care

- Provide good nursing care: For example, keep an unconscious patient on his or her side and monitor vital signs.
- Prevent or correct dehydration by encouraging to drink or breastfeed, and by giving ORS. Unconscious patients should receive ORS by nasogastric tube.

- Prevent and/or manage hypoglycaemia:
- Continue feeding the patient if possible.
- If a child is able to breastfeed, encourage the mother to breastfeed the child.
- If a child is not able to breastfeed but is able to swallow, give expressed breast milk, or if not available, give “sugar water.” A young child should be given 30 - 50 ml of milk or sugar water before departure
- If child is not able to swallow, give 50ml of milk (expressed breast milk) or sugar solution by nasogastric tube, if trained to do so.
- To make “sugar water”, dissolve 4 level teaspoons of sugar or 2 cubes (20 grams) in a 200 ml cup of clean water.

4.5 Management of Severe Malaria in Hospital

The objectives of the treatment of severe malaria are to

- prevent the patient from dying
- prevent disabilities
- prevent recrudescence infection.

Management of severe malaria comprises mainly:

- clinical assessment of the patient for urgent treatment of life threatening problems,
- specific antimalarial treatment,
- additional treatment and supportive care

4.5.1 Initial Patient Evaluation

(a) Initial Assessment using the ABCDE approach;

- Airway, - Secure the airway in an unconscious patient. Consider intubation.
- Breathing (Keep oxygen saturation above 94%)
- Circulation – assess for shock
- Disability – Coma score
- Exposure – assess patient temperature and ensure safety

(b) Assess the patient looking for clinical features of severe malaria

(c) Insert an IV cannula and draw blood for laboratory testing

(d) Do the following laboratory tests immediately:

- Microscopy for malaria parasites-thick and thin blood films and /or RDT.
- Blood glucose, hypoglycaemia-present if glucose is $<2.2\text{mmol/L}$ or $<40\text{mg/dl}$.
- Full blood count, Haemoglobin (Hb) and/or Haematocrit (Hct). If $\text{Hb} < 7\text{g/dl}$ and $\text{Hct} < 20\%$, do grouping and cross-matching for possible transfusion.
- Urea /creatinine, and electrolytes

Do the following if indicated

- Lumbar Puncture (LP) for cerebrospinal fluid examination in those with altered sensorium or repeated convulsions to exclude other causes. Rule out contraindications for LP before the procedure.
- Additional tests indicated: clotting studies, blood culture, blood gases/ bicarbonate, and lactate.

(d) Start treatment whilst waiting for results of laboratory investigations:

- Weigh the patient, or estimate the body weight (for calculation of medication and fluid regimens).
- Administer parenteral anti-malarial medications as necessary (see Section 4.5.2).
- Provide additional supportive therapy as necessary (see Section 4.6).

4.5.2 Anti-malarial Medication for Severe Malaria

Following rapid clinical assessment and parasitological confirmation of the diagnosis, full parenteral doses of an appropriate anti-malarial should be started without delay. Parenteral treatment provides adequate blood-serum concentrations as quickly as possible initially

The available options in order of preference are:

1. IV/IM Artesunate,
2. IM Artemether,
3. IV/IM Quinine.

Parenteral treatment should be given for at least 24 hours and continue until patient is well enough to swallow. Treatment should then be completed by giving a full 3-day course of any one of the recommended oral ACTs (Artesunate- Amodiaquine, Artemether-Lumefantrine as first line and Dihydroartemisinin-Piperaquine as second line). Oral ACTs should be started at least 4 hours after the last parenteral antimalarial.

4.5.2.1 Dosage for Parenteral Artesunate

- Parenteral Artesunate is the treatment of choice for the treatment of severe malaria and should be given for a minimum of 24 hours, once started (irrespective of the patient's ability to tolerate oral medication earlier).
- For patients $\geq 20\text{kg}$, Artesunate 2.4 mg/kg and patient $\leq 20\text{kg}$ it is 3mg/kg body weight given IV on admission (time =0), 12 hours and 24 hours then every 24 hours must be given. The total duration must be a maximum of seven days.
- Oral ACTs should be started at least 4 hours and not later than 12 hours after the last artesunate injection.

4.5.2.2 Reconstituting Parenteral Artesunate

Artesunate is dispensed as a powder of Artesunate acid in vials of 30mg, 60mg or 120mg and usually in packs containing sodium bicarbonate solution and normal saline. It should be freshly reconstituted and used within one hour.

Check the brand available at your facility and follow the general instructions provided below.

Table 15: How to Reconstitute Parenteral Artesunate for IV use

30mg	60mg	120mg
Step 1 Add 0.5ml of the SODIUM BICARBONATE solution to the vial containing the powder.	Step 1 Add 1ml of the SODIUM BICARBONATE solution to the vial containing the powder.	Step 1 Add 2ml of the SODIUM BICARBONATE solution to the vial containing the powder.
Step 2 Gently Shake for 2–3 minutes dissolution to ensure into a clear solution	Step 2 Gently Shake for 2–3 minutes dissolution to ensure into a clear solution	Step 2 Gently Shake for 2–3 minutes dissolution to ensure into a clear solution
Step 3 For IV use, ADD approximately 2.5ml of normal saline to the clear solution to produce 3ml of solution with concentration 10mg Artesunate /ml.	Step 3 For IV use, ADD approximately 5ml of normal saline to the clear solution to produce 6ml of solution with concentration 10mg Artesunate /ml.	Step 3 For IV use, ADD approximately 10ml of normal saline to the clear solution to produce 12ml of solution with concentration 10mg Artesunate /ml.
Step 4 Withdraw the required amount of the solution and inject slowly at a rate of 3-4ml per minute.	Step 4 Withdraw the required amount of the solution and inject slowly at a rate of 3-4ml per minute.	Step 4 Withdraw the required amount of the solution and inject slowly at a rate of 3-4ml per minute.

NB: 5% Dextrose can be used in the absence of normal saline in step 3.

AVOID the use of water for injection.

4.5.2.3 Quinine Administration

Quinine should be given either by IV in dextrose infusion or IM until patient can swallow, then treatment shall be continued with oral Quinine. It should always be given by slow rate-controlled infusion, never by bolus intravenous injection. For safety, the dosage of Quinine must strictly be adhered to.

(a) Intravenous (IV) Administration of Quinine

- Give Quinine as a slow rate controlled IV infusion. The dose is Quinine Hydrochloride salt at 20mg/kg body weight as a loading dose (maximum 1200mg) then 10mg per kg body weight as maintenance dose (maximum dose 600mg) 8 hourly in 5-10ml/kg of dextrose saline or in 5% dextrose over 4-8 hours. The infusion rate should not exceed 5 mg salt per kg body weight per hour.

NB: Quinine should never be given by IV bolus injection, due to the risk of severe hypotension.

(b) Intramuscular (IM) Administration of Quinine

- Give Quinine by deep IM injection at 20mg/kg body weight as a loading dose (maximum 1200mg) then 10 mg/kg body weight as maintenance dose (maximum dose 600 mg) 8 hourly. For IM injection, remember to use sterile water or saline, not dextrose solution. Use the appropriate Quinine dilution for adults or children, as described above in Section 4.4.4 and Table 14.

(c) Oral Administration of Quinine to be Included:

- The dose of oral Quinine is 10mg per kg body weight (maximum dose 600 mg) every 8 hours to complete 7 days of treatment.
- Oral Quinine should be given concurrently with Clindamycin.

The maintenance dose of quinine should be reduced by one third ie. 10mg/kg bw every 12 hours

- If injection quinine should be continued beyond 48hours
- Renal impairment

Common Averse Drug Reactions (ADR) of Quinine include cinchonism (ringing sounds in the ears – tinnitus), hearing loss, nausea, uneasiness/restlessness, tremors and blurring of vision. Cinchonism is mild when Quinine is used in the recommended doses and subsides spontaneously when administration of the drug ends. The most serious frequent adverse drug reaction for injectable Quinine is hypoglycaemia, particularly in the 2nd and 3rd trimesters of pregnancy. Serious cardio-vascular and neurological toxicity are rare.

4.5.2.4 Intramuscular Artemether

The dose of IM Artemether is 3.2mg per kg body weight as a loading dose, subsequently 1.6mg/kg body weight once daily up to seven days. However, administer a complete course of an ACT once the patient is able to tolerate oral medication or after at least 24 hours of intramuscular injection.

Artemether should not be given in the first trimester unless there are no suitable alternatives. In most other respects, however, the treatment of severe malaria in pregnancy shall be the same as the treatment of severe malaria for the general population.

4.6 Supportive Therapy for Severe Malaria in Hospital

Timely provision of supportive care is often crucial for the survival of patients with severe malaria. Supportive care includes the following:

- Blood Transfusion for severe anaemia.
- Ensuring strict fluid and electrolyte balance. (NB avoid fluid overload)
- Anti-convulsants for convulsions.
- Anti-pyretics for hyperpyrexia.
- Standard care for the unconscious patient

4.6.1 General guidelines for supportive care in the hospital setting are as follows:

a. Convulsions

- Clear and maintain airway.
- Check blood glucose and correct hypoglycaemia
- Give anticonvulsants

i. Treat with diazepam:

If IV line is in place or can easily be obtained, give a slow intravenous injection of diazepam [0.25mg/kg body weight, (maximum 10mg)] OR Diazepam can also be given rectally (0.5mg/kg body weight) OR

- In adults, 10mg of Diazepam can also be given Intramuscularly
- If convulsions reoccur or persists (about 5 – 10 minutes), repeat the diazepam once

ii. Treat with phenobarbitone,

- If the convulsion persists after repeat of the diazepam treatment give phenobarbitone 15mg/kg body weight IM injection. (If IV line is in place or can easily be obtained, you may give IV phenobarbitone slowly over 15 – 20 minutes)
- This may be topped up if convulsions persist (15 minutes after Phenobarbitone IV) to a maximum dose of 20mg/kg.

You may also use Phenytoin to replace or add on to Phenobarbitone where necessary. The dosage is the same with slow IV as the Phenobarbitone (NB. Monitor for arrhythmias)

b. Coma

- Clear and maintain the airway. Intubate if necessary. Place the patient on his or her side. Exclude other treatable causes of coma (such as hypoglycaemia or hyperglycaemia and meningitis, etc.)
- Maintain normal blood glucose (Random blood glucose 4 -10 mmol/L)
- Maintain normal oxygen saturation (above 92%)
- Turn the patient every 2 hours to prevent pressure sores

c. Treatment of Hypoglycemia

- Check blood glucose hypoglycaemia threshold for treatment is <3mmol/L.
- Give bolus dextrose
- For adults 50mls of 50% dextrose by IV bolus injection
- For children give 10% dextrose, use 4ml/kg body weight
- Follow with IV infusion containing 5-10% dextrose (Eg.5% Dextrose, 10% Dextrose and 5% Dextrose Saline, One-fifth (1/5th) Normal Saline in 4.3% dextrose).
- If administering injection dextrose is not feasible, give glucose solutions through nasogastric tube (glucose powder or sugar water) or rectal Dextrose (25%) in children with 2mls/kg.
- Recheck blood glucose within 5 to 10 minutes. If hypoglycaemia is not corrected, repeat treatment.

d. Prevention of Hypoglycaemia

- Start or continue with IV infusion containing 5-10% glucose (Eg. 5% Dextrose Saline).
- Continue feeding the patient if possible. Encourage the mother to breastfeed child.

- If the child is not able to breastfeed but is able to swallow, give expressed breast milk, or if not available, consider giving sugar water.
- If the child is not able to swallow, give 50ml of expressed breast milk or sugar solution by nasogastric tube. (To make “sugar water” in a limited resource setting, one may dissolve 4 level teaspoons of sugar or 2 cubes (20 grams) in a 200 ml cup of clean water.)

e. Hyperpyrexia

- Provide tepid sponging (Lukewarm water beginning from the feet towards the upper part of the body)
- Give Paracetamol at 10-15mg/kg body weight(Refer to table 7, 8, 9)

f. Severe Dehydration

- Provide isotonic fluid (0.9% saline or Ringers lactate) by IV infusion,
- Monitor serum electrolytes and correct any imbalance appropriately.
- Watch out for over-hydration when administering IV fluids.
- Prevent and/or correct some (mild to moderate) dehydration by encouraging to drink or breastfeed, and by giving ORS. Unconscious patients may receive ORS by nasogastric tube. In the absence of signs of intravascular depletion, give two-thirds of the required daily maintenance in all critically ill or unconscious patients.

Note: Fluid replacement should be tailored to the exact need of the patient. In children, the routine administration of bolus fluid infusion for resuscitation is contraindicated if patient is not in shock. Caution must be taken in malnourished patients.

g. Circulatory Collapse or Shock:

- Correct hypovolaemia
- Suspect septicaemia especially gram-negative bacteria, take blood for cultures and give broad spectrum parenteral anti-biotics.

h. Pulmonary Oedema:

- Stop all intravenous fluids
- Prop patient at 45°
- Give oxygen to maintain saturation above 92%

- Give diuretic (Eg. Frusemide: 1-2mg /kg of body weight by intravenous injection) Repeat dose as necessary.
- For life- threatening hypoxaemia, consider intubation with mechanical ventilation.
- Check for over-hydration or volume depletion

i. Severe Anaemia:

- Diagnosed in patients with Hb <5g/dl (in children) and Hb <7g/dl (in adults), or packed cell volume <15% (in children) and <20% (in adults); and/or in anaemic patient with signs of heart failure (dyspnoea, enlarged liver, gallop rhythm).
- Haemotransfuse
- For children, transfuse with 10-20ml per kg body weight packed cells or whole blood as appropriate and
- For adults, haemotransfuse 1-2 units of blood.
- Reassess the need for further haemotransfusion frequently and recheck Hb within 24 to 48 hours. (Frusemide is given first in cases of heart failure).

j. Acute Renal Failure:

- Exclude dehydration,
- maintain strict fluid balance,
- monitor fluid input and urine output (urine output: >0.5-1ml/kg/hour).
- Carry out Renal Replacement Therapy (peritoneal dialysis or haemodialysis) if indicated and refer if the capacity for renal replacement therapy is not available.

CAUTION:

- Avoid drugs that increase the risk of gastro-intestinal bleeding:
 - Corticosteroids (eg Hydrocortisone).
 - Other anti-inflammatory agents, NSAIDs (e.g. Ibuprofen, Diclofenac, Aspirin).
 - Heparin.
- Avoid agents like Urea and Mannitol given for cerebral oedema.

4.7 Monitoring of Severe Malaria

Monitor the following on routine basis:

- i. Level of consciousness (see Blantyre and Glasgow coma scale in the Annexe (A).
- ii. Vital Signs: blood pressure, body temperature, pulse, respiratory rate four (4) hourly.
- iii. Fluid intake/output, including the rate of infusion of fluids.
- iv. Urine volume (6 hourly, may do hourly under Intensive Care), colour and specific gravity. If necessary insert urethral catheter to monitor urine output closely.
- v. Blood glucose: check 4-hourly while patient is unconscious.
- vi. Parasitaemia: obtain on admission (mandatory). While patient is hospitalised it is recommended to repeat microscopy daily until 3 consecutive negative results if the patient is not clinically responding as expected
- vii. Haemoglobin (Hb): obtain if anaemia is suspected to be worsening.
- viii. Occurrence of convulsions.

Assessment of Recovery

- i. Check for neurological sequelae (deficit): Assess patient for possible neurological sequelae (deficit) of the disease or the treatment. This is important in children, since it is likely that 10% of them may develop neurological sequelae after they recover from cerebral malaria.
 - Assess vision and hearing daily. If deficits found, refer for further evaluation and management.
 - Assess neuro-motor functioning. If deficits found, refer for appropriate management.

ii. Perform follow-up laboratory tests on the 7th and 14th days:

- Thick and thin blood films for malaria parasites
- Haematocrit or Haemoglobin for patients recovering from severe anaemia:
- Give iron and folic acid for two months with regular follow-up
- If child has sickle cell disease, give folic acid only, unless laboratory findings indicate the need for iron supplementation.
- Give antihelminthics as may be appropriate.

CHAPTER FIVE

5.0 COMMUNITY MANAGEMENT OF UNCOMPLICATED MALARIA

Community case management promotes early recognition, access to prompt diagnosis and effective treatment of malaria episodes by trained community health workers living as close as possible to the patients. Community case management should be integrated into community management of childhood illnesses, which ensures coverage of priority childhood illnesses outside of health facilities.

5.1 Personnel to Implement Community Case Management of Malaria

In the community case management, malaria is diagnosed and treated by community health workers (community health nurses, midwives, community health officers, enrolled nurses) and community-based agents. Community Based Agents (CBA) include appropriately trained members of groups such as over-the-counter medicine sellers (OTCMS) and community pharmacists. Community-based volunteers support Community Health Workers (CHWs) in the prevention, early detection and referral of malaria cases in the community.

5.2 Diagnosis

At the community level, fever or a history of fever should be considered as suspected malaria. In all cases, diagnosis should be confirmed with RDT before treatment.


However in children under five years, every child should be assessed in accordance with IMNCI guidelines for

- cough/difficulty in breathing
- diarrhoea general danger signs and assessment should also be carried out for
- Ear problems and
- Malnutrition. Refer (Annexe F)

5.3 Treatment

The recommended drug for confirmed uncomplicated malaria is ACTs (Refer table) Supportive care should also be provided. These include tepid sponging (use lukewarm water starting from the feet towards the upper part of the body) and administration of paracetamol where indicated. In rare situations, where parasitological diagnosis by RDT is not possible, a decision to provide antimalarial treatment must be based on the probability that the illness is malaria.

For children under 5 years, treatment could be given on the basis of proper assessment and classification using the Integrated Management of Childhood and Neonatal Illness (IMNCI) guidelines.



ARI, diarrhoea and/or other infections should also be identified and treated, as indicated, in accordance with IMNCI guidelines. The patient must be re-evaluated after 24 hours. If improvement is not seen, referral to a health facility is indicated.

5.4 Criteria for Referral

Safe and effective community case management of malaria will require community health workers to adhere carefully to referral criteria. The following categories of patients should not be managed at the community, but referred urgently to the next higher level of care for evaluation and treatment.

In summary, the following apply for referral:

- Children below 6 months of age.
- Any child who has had a fever for 7 or more days.
- Child is unable to drink or breastfeed.
- Child is vomiting everything he/she drinks or eats.
- Child has history of convulsions during the current illness.
- Child is lethargic, unconscious, or convulsing during the examination.
- child not responding to treatment or deteriorating within 24 hours
- Women in first trimester of pregnancy

CHAPTER SIX

6.0 MALARIA CHEMOPREVENTION

6.1 Seasonal Malaria Chemoprevention

6.1.1 Introduction

Seasonal Malaria Chemoprevention (SMC) is the intermittent administration of full treatment courses using recommended anti-malarial medicine during peak malaria season to prevent malaria illness.

6.1.2 Objective:

The main objective of SMC is to maintain therapeutic anti-malarial drug concentrations in the blood throughout the period of greatest malaria risk.

6.1.3 Target areas for implementation is the Sahel sub-region where:

- malaria transmission is highly seasonal and the majority of clinical malaria cases occur during a short period of about four months
- the clinical attack rate of malaria is greater than 0.1 attack per transmission season in the target age group
- Amodiaquine plus S-P remain efficacious (>90% efficacy) for SMC

In areas where SMC is deployed:

- Pharmacovigilance should be strengthened where it exists, and where it does not, it should be instituted.
- Drug resistance monitoring and system evaluation should be supported or instituted, including systems to assess the number of breakthrough infections and their intervals from the last dose of SMC.
- The health system needs to record and monitor AQ+SP doses administered in order to evaluate the impact of the intervention. Existing systems to document severe malaria, malaria deaths, and record confirmed cases of malaria should be strengthened. The northern /savanna belt of Ghana falls within the sahel region of Sub-Saharan Africa and therefore SMC is carried out in these areas.

6.1.4 Target population

6.1.4.1 Inclusion criteria

- children aged between 3 to 59 months in the target regions for SMC
- ability to tolerate Amodiaquine plus Sulfadoxine-Pyrimethamine (AQ+SP)

6.1.4.2 Exclusion criteria

SMC medicines should not be given to:

- A child who is sick with uncomplicated or severe malaria at the time of SMC administration. These children must be referred to a health centre for care using the integrated management of childhood illness (IMCI) guidelines. Mothers of these children must however be advised to make the child available after 30 days for the next round of SMC treatment
- An HIV-positive child receiving co-trimoxazole
- A child with severe acute or chronic illness or unable to take oral medication
- A child who has received a dose of either SP, AS-AQ or AQ or other drugs containing sulfonamide in the last 30 days. These children should be given an appointment for the next round of treatment.
- A child who is allergic to either drug (SP or AQ).

6.1.5 Administration of SMC medicines

- i. On the first day, a single dose of SP is given followed immediately by the first dose of AQ. On day 2 and 3 only AQ is given.
- ii. Administration of at least the first dose (single dose of SP and the first dose of AQ as above) must be directly observed. The subsequent doses must be followed up.
- iii. Points (i) and (ii) are carried out each month to a maximum of four rounds during the transmission season
- iv. Loose tablets should be made available for replacement doses when a child vomits (within 30 minutes), spits out or regurgitates the drugs.
- v. Missing one round of treatment does not prevent a child from receiving the next round of SMC drugs if it is not contraindicated for the child to receive SMC.

Table 16: Dosing Regimen for SMC Amodiaquine (AQ) plus Sulfadoxine-Pyrimethamine (SP)

Amodiaquine (AQ) 75mg tablet and Sulfadoxine-Pyrimethamine (SP) 250/12.5mg tablet				
Age (months)	Dose	Number of tablets		
		Day 1	Day 2	Day 3
3 – 11	SP 250/12.5mg	1	-	-
	AQ 75mg	1	1	1
12 – 59	SP 500/25mg	2	-	-
	AQ 150mg	2	2	2

Amodiaquine (AQ) 150mg tablet and Sulfadoxine-Pyrimethamine (SP) 500/25mg tablet				
Age (months)	Dose	Number of tablets		
		Day 1	Day 2	Day 3
3 – 11	SP 250/12.5mg	1/2	-	-
	AQ 75mg	1/2	1/2	1/2
12 – 59	SP 500/25mg	1	-	-
	AQ 150mg	1	1	1

**Take half tablet of 150mg AQ and 500/25mg SP if strength/dose not available.*

6.1.6. Giving the full treatment course is vital.

- Aim to administer 3 doses per treatment round to each eligible child up to four rounds (1cycle) during the high malaria transmission period. Children who receive less than 3 rounds or fewer doses per course of treatment are less protected.
- Protection against clinical malaria is associated with administration of the second and third dose of AQ. Therefore it is important that a child receives full doses of each round of treatment.
- If a child totally misses one treatment round because of illness or absence, treatment should be given at the next round of SMC, if the child is present and well.

6.1.7 Rounds of Treatment

There shall be 4 treatment rounds making one cycle each year during the high malaria transmission.

6.1.8 Dosing

Each SMC round comprises of a 3-day dosing of SP+AQ. On the first day a single dose of SP is given and followed immediately by the first dose of AQ. On day 2 and 3 only AQ is given.

6.1.9 Break through Malaria

Any child aged 3–59 months who develops malaria within the period of SMC implementation and has received SMC medications must have parasitological diagnosis (preferably microscopy). Treat with an ACT not containing any component of drugs used for SMC.

6.1.10 Adverse Events

SMC drugs are well tolerated when given in standard doses most common mild adverse events caused by AQ are vomiting, abdominal pain, fever, diarrhoea, itching, headache and rash.

These generally last for a short time; if they become severe, refer appropriately.

6.2 Intermittent Preventive Treatment In Pregnancy (IPTp)

6.2.1 Introduction

In Ghana, Intermittent Preventive Treatment in Pregnancy (IPTp) consists of anti- malarial medication (Suphadoxine–Pyrimethamine) given in treatment doses at predefined intervals. The first dose of Suphadoxine–Pyrimethamine (SP) is given at 16 weeks of gestation. Subsequent doses are given at least 4 weeks intervals till delivery. A minimum of 3 doses should be given during pregnancy.

In addition to the above ensure that the client continues with a comprehensive ante-natal package with other services and routine medications including:

- Iron tablets 60mg daily as prescribed
- Folic acid 400mcg* daily as prescribed
- Anthelmintic as prescribed
- Continue to use ITNs and other preventive measures

**This dose of folic acid can be safely used concurrently with IPTp-SP dosing.*

6.2.2 Dosing of SulphadoxinePyrimethamine for Intermittent Preventive Treatment in Pregnancy (IPTp-SP)

- A dose of tablets of Sulphadoxine-Pyrimethamine (500/25mg) must be given.
- SP is to be administered to pregnant women during routine antenatal visits as directly observed therapy (DOT).
- SP should be given at intervals of at least 4 weeks until delivery.
- SP can be given either on an empty stomach or with food.

6.2.2 Contraindications of IPT-SP

Pregnant women with the following conditions shall be exempted from using SP:

- G6PD enzyme full/partial defect or history suggestive of G6PD enzyme defect.
- Severe anaemia.
- Blood dyscrasias e.g. neutrophilia (high neutrophil count), thrombocytopaenia (Low platelet count).
- History of epileptic or seizure disorders
- Severe liver disease or unexplained recurrent jaundice.
- Known allergy to any sulphur containing drugs or allergy to Pyrimethamine.
- History of previous severe adverse reaction to SP.
- Recent (within past 4 weeks) treatment with a sulphur containing drug such as Co-trimoxazole including HIV positive pregnant women

Note:

- SP is not for treatment. Suspected malaria cases should be confirmed and treated according to national guidelines.
- Folic acid should be given at a dose of 0.4 mg or 400 micrograms daily. This dose can be safely used concurrently with SP dosing.
- The 5mg tablet of folic acid should not be administered concurrently with Sulphadoxine Pyrimethamine. For additional information on IPTp and malaria in pregnancy, refer to the current "Guidelines for Malaria In Pregnancy".

CHAPTER SEVEN

7.0 MALARIA PROPHYLAXIS FOR NON- IMMUNE INDIVIDUALS

7.1 Introduction

Prophylactic medication for malaria is recommended for non-immune individuals, because of the risk for severe disease. It is not 100% protective. Those on prophylaxis who develop signs and symptoms suggestive of malaria should seek prompt medical attention to confirm or rule out malaria.

The following are considered non immune individuals:

- Travelers from non-endemic malaria countries to Ghana Residents of Ghana or other endemic areas who have stayed for 6 months continuously or more in non-endemic areas.
- Malaria prophylaxis is not necessary in persons who have been resident and continue to stay in malaria- endemic areas for more than 6 months.

7.2 Precautionary Measures for Visitors

Travelers from non-endemic areas should see their health care provider 4 to 6 weeks prior to departure. As recommended by WHO, travelers and their advisers should note the five principles (the ABCDE) of malaria protection:

- Be Aware of the risk, the incubation period, the possibility of delayed onset, and the main symptoms.
- Avoid being Bitten by mosquitoes, especially between dusk and dawn.
- Take antimalarial drugs (Chemoprophylaxis) when appropriate, at regular intervals to prevent acute malaria attacks.
- Immediately seek Diagnosis and treatment if a fever develops 1 week or more after entering an area where there is a malaria risk and up to 3 months (or, rarely, later) after departure from a risk area.
- Avoid outdoor activities in Environments that are mosquito breeding places, such as swamps or marshy areas, especially in late evenings and at night.

7.2.1 Protection Against Mosquito Bites

All non-immune individuals should be advised that individual protection from mosquito bites between dusk and dawn is their first line of defense against malaria. Practical measures for protection include;

- Sleeping under long lasting insecticidal nets every night
- Staying in rooms with screened windows and/or air conditioning where possible

- Reducing time spent outdoors after dark
- Using mosquito repellants and coils

7.2.2 Recommended Medicines for Chemoprophylaxis

No anti-malarial prophylactic regimen gives complete protection, but good chemoprophylaxis (adherence to the recommended drug regimen) does reduce the risk of fatal disease. The following should also be taken into account:

- Dosage for children should be based on body weight.
- Anti-malarials should be started 1-21 days before arriving in the malaria-endemic area, and continued for 1-4 weeks after leaving the area, depending on the drug selected.
- Pregnant women, breastfeeding mothers, young children, and people with chronic illnesses should seek individual medical advice.

MEDICINES USED FOR CHEMOPROPHYLAXIS

DRUG	DOSAGE	ADVERSE EFFECTS	CONTRA-INDICATION	COMMENTS
Atovaquone-Proguanil combination tablet	11–20 kg: 62.5 mg atovaquone plus 25mg proguanil 21 – 30kg: 125 mg atovaquone plus 50mg proguanil 31-40kg: 187.5 mg atovaquone plus 75mg proguanil >40kg: 250 mg	Common: Nausea, vomiting, abdominal pain, diarrhoea, increased liver enzyme level Rare: Rash, Mouth ulcers, Seizures	-Hypersensitivity -Severe renal insufficiency	Duration: Start 1 day before departure and continue for 7 days after return -Not recommended with Pregnancy and Lactating mothers -Not recommended in <11kg -Take with food or milky products -may interfere with Rifampicin, Rifabutin, Metoclopramide, Tetracycline, Live Typhoid vaccine

DRUG	atovaquone plus 100mg proguanil			
Doxycycline	Paediatrics: 1.5mg-salt/kg daily Adult: 100mg daily	Common: Abdominal discomfort, photosensitivity Rare: Worsening of renal function, blood dyscrasias, oesophageal ulceration	- Pregnant women and lactating mothers -Children < 8 years -Hypersensitivity to Tetracyclines, including Doxycycline -Liver dysfunction	Duration: Start 1-2 day before departure and continue for 4 weeks after return -increase susceptibility to sunburn (use protection) -increase risk of candida infection -Should be taken with plenty water
Mefloquine	Paediatric: 5mg/kg weekly Adults: 250mg once weekly	Common: nausea, vomiting, diarrhoea, dizziness, headache, sleep disorders,	-Hypersensitivity -Psychiatric Disorders (Depression, Seizure Disorder, Severe Neuropsychiatric disease) -Concomitant Halofantrine treatment	Duration: Start at least 1 week (preferably 2-3 weeks before departure and continue for 4 weeks after return

		nightmares, mood change Rare: seizures, abnormal coordination, forgetfulness, anxiety, aggression, depression, Panic Attacks, Psychotic and Paranoid reactions, Suicidal ideation, Suicide (STOP THE DRUG)	-Treatment with Mefloquine in previous 4 weeks	-Safe in Pregnancy and Lactating mothers -Not recommended for children <5kg -Not to be given within 12 hours of quinine treatment -Not to be given with Oral Typhoid vaccine
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Malaria chemoprophylaxis should not be considered 100% effective. Patients on chemoprophylaxis may still develop malaria, even when taking the medication as directed. If signs and symptoms suggestive of malaria occur while taking chemoprophylaxis, the patient should seek prompt medical attention. Malaria chemoprophylaxis should be suspended during treatment of malaria and resumed immediately after treatment as recommended.

CHAPTER EIGHT

8.0 COMMUNITY EDUCATION IN MALARIA PREVENTION AND CONTROL

Health care workers and Community-based Agents should take every opportunity to educate their patients and the general public on malaria prevention and control. The general population should be educated that malaria is both preventable and treatable.

In order to control malaria in Ghana, communities and individuals must be educated to:

- Protect themselves against the bites of malaria-transmitting mosquitoes.
- Get tested and treated for malaria promptly with effective medications.
- Take the recommended steps to prevent malaria especially in pregnant women and children.

8.1 Protection Against Malaria-Transmitting Mosquitoes

Individuals and households are to be educated on the following protective methods

- Sleep under long lasting insecticidal nets (LLINs) every night and throughout the night.
- Fix window and door screens in their houses and use mosquito repellents, and coils. Wear protective clothing e.g. trousers, long sleeved shirts during the night.
- Indoor residual spraying (IRS) is a critical component of the integrated vector control strategies. Residents of communities where IRS is being implemented should be encouraged to get their rooms sprayed by the spray operators.
- As part of environmental management approach, identified potential breeding grounds for mosquitoes such as pools of water, irrigation dams, dug pits in mining and road construction areas should be modified or covered.

8.2 The following simple messages should be reinforced to patients and caregivers:

- For all cases of fever report to the nearest health facility as soon as possible
- Get tested for all suspected malaria cases,
- Get tested and treated for malaria promptly with effective medications
- Use medications recommended by the Ministry of Health.
- Comply fully with treatment as prescribed by your health provider.

8.3 Take the recommended steps to prevent malaria especially in pregnant women and children 3-59 months.

8.3.1 The following simple messages should be reinforced to pregnant women

Attend antenatal clinics early in pregnancy.

- Attend antenatal clinic as scheduled
- Take the recommended anti-malaria for intermittent preventive treatment in pregnancy (IPTp)
- SP-IPTp should be taken as directly observed therapy
- SP can be given at least four weeks interval from 16 weeks until delivery from
- SP can be given either on an empty stomach or with food
- Sleep under LLIN every night
- Report promptly to the health facility when there is fever

8.3.2 The following simple messages should be reinforced to caregivers of children in SMC targeted areas

- Make your children aged 3 – 59 months available to receive SMC during the peak transmission season
- Ensure the children complete all three doses in a round and all four rounds in a cycle
- Do not mix the tablets between children
- Report all adverse reactions promptly to the health care provider
- Ensure children sleep under LLIN every night

CHAPTER NINE

9.0 MONITORING AND EVALUATION

9.1 Introduction

Monitoring and Evaluation (M&E) is key to the Malaria Control Programme at all levels to track and guide successful implementation of intervention. M&E also helps in assessing the degree to which planned activities have achieved intended results. Data sources for malaria M&E include routine surveillance, operational research and surveys. Routinely, data for malaria case management will be tracked mainly through the District Health Information Management System (DHIMS). Key surveys that will be used to evaluate outcomes and impact of malaria case management include; Malaria Indicator Survey (MIS), Demographic and Health Survey (DHS) and Multiple Indicator Cluster Survey (MICS). Indicators to be tracked by the programme for malaria case management are shown below.

9.2 Indicators and their definitions

Indicator	Definition/ rationale/ interpretation	Measure	Frequency/ source
Impact indicators			
Malaria test positivity rate	<p>To reflect trends in malaria morbidity and identify areas with most intense malaria transmission.</p> <p>The test positivity rate assesses the proportion of tests (microscopy and/or RDT) that are positive for malaria among the suspected cases tested</p>	<p>Numerator: Number of laboratory-confirmed malaria cases (tested positive)</p> <p>Denominator: Number of suspected malaria cases tested (microscopy and/or RDT).</p>	<p>Monthly</p> <p>Health Information Management System (HMIS)</p>

Indicator	Definition/ rationale/ interpretation	Measure	Frequency/ source
Malaria Para- site prevalence: percentage of children aged 6–59 months with malaria infection (by microscopy and RDT)	The prevalence of para- sitemia is a useful indi- cator of the burden of malaria within popula- tions and provides a guide to the level of malaria transmission	Numerator: Number of children aged 6-59 months with malaria. infection detected by microscopy and/or RDT. Denominator: Num- ber of children aged 6-59 months tested for malaria parasites by microscopy and/or RDT	Every 3–5 years Population-based surveys with diagnos- tics (such as MIS)
Inpatient malaria cases per 10,000 population per year	Inpatient cases are makers of severe disease and indicates failure of health system to either prevent or effectively treat malar- ia. This indicator may re- flect impact of treatment as treatment may change clinical progression from uncomplicated to compli- cated	Numerator: Number of malaria inpatient cases Denominator: Popula- tion at risk	Monthly HMIS
Inpatient malaria deaths per 100,000 population per year	To monitor the impact of programme on the number of malaria deaths. Inpatient deaths are markers of very severe dis- ease and indicator failure of the health system to ei- ther prevent or effectively treat malaria	Numerator: Number of inpatient malaria deaths per year x 100,000 Denominator: Number of people in the popu- lation	Yearly Routine surveillance system (Health Infor- mation Management System)

Indicator	Definition/ rationale/ interpretation	Measure	Frequency/ source
Under 5 Malaria Case Fatality Rate	Children under 5 years old are more vulnerable to malaria. Therefore, mortalities in under five could be high as compared to patients 5 years and above. This indicator expresses the proportion of children under five years with malaria who die from it (ratio of deaths to inpatient cases)	Numerator: Number of children under-five (5) years dying of malaria Denominator: Number of children under five years admitted with malaria	Monthly Routine surveillance system (Health Information Management System)
Malaria-specific deaths per 100,000 persons	Mortality is a major component of the burden caused by malaria. This indicator helps to monitor the impact of programme on the number of malaria deaths. Malaria deaths are markers of very severe disease and indicator failure of the health system to either prevent or effectively treat malaria.	Numerator: Number of malaria deaths per year x 100,000 Denominator: Number of people in the population	Monthly/Quarterly Demographic Surveillance System (DSS) Vital registration System

Indicator	Definition/ rationale/ interpretation	Measure	Frequency/ source
Output/outcome indicators			
Proportion of suspected malaria cases that receive a parasitological test (microscopy or RDT) in health facilities	Proportion of suspected malaria cases that receive a parasitological test (microscopy or RDT) in health facilities	<p>Numerator: Number of suspected malaria cases at OPD that received a parasitological test</p> <p>Denominator: Number of all suspected malaria cases at OPD</p>	<p>Monthly</p> <p>Routine surveillance system (Health Information Management System)</p>
Proportion of reported malaria cases confirmed	As we enforce test treat and track, it expected that all malaria cases are tested and only test positives are treated and none of presumed cases treated. Therefore, it is expected that all reported malaria cases are confirmed	<p>Numerator: Number of confirmed (positive) out-patient malaria cases</p> <p>Denominator: Total reported malaria cases (confirmed and presumed)</p>	<p>Monthly</p> <p>Routine surveillance system (Health Information Management System)</p>
Proportion of health facilities reporting no stock-out of key commodities during the reporting period	Ensuring adequate and continued supply of the recommended anti-malarial and diagnostic commodities is key to the success in preventing and controlling malaria	<p>Numerator: Number of health facilities reporting no stock-out of key commodities at any time during the previous reporting period.</p> <p>Denominator: Number of health facilities.</p>	<p>Monthly</p> <p>Logistics Management Information System (LMIS)</p>

Indicator	Definition/ rationale/ interpretation	Measure	Frequency/ source
Proportion of confirmed malaria cases that received first line anti-malarial treatment according to national policy	This indicator assesses appropriate treatment of tested positive malaria cases with ACTs according to national policy. Prompt treatment with an effective anti-malarial drug regimen is a key component of the technical strategy for controlling and preventing malaria. Currently, the recommended first line anti-malarials are ACT for uncomplicated malaria treatment	Numerator: Number of confirmed (positive) out-patient malaria cases who received first line antimalarial treatment according to national policy Denominator: Number of confirmed (positive) out-patient malaria cases outpatient cases include those seen at the outpatient department of health facilities as well as those seen by community health workers.	3-5 years Routine surveillance system (Health Information Management System)
Proportion of children 3-59 months treated under SMC	Measures the coverage of SMC at any particular level after implementation. This is useful for assessing how many children were to be captured and treated and how many were actually reached and treated. Knowledge of the gap will help to adopt strategies to reach out to more children in subsequent rounds.	Numerator: number of children 3-59 months treated under SMC Denominator: number of children 3-59 months eligible for SMC	Yearly Routine surveillance system (Health Information Management System)

PHARMACOVIGILANCE

Figure 1: FLOW CHART FOR REPORTING ADVERSE EVENTS PATIENT/CLIENT

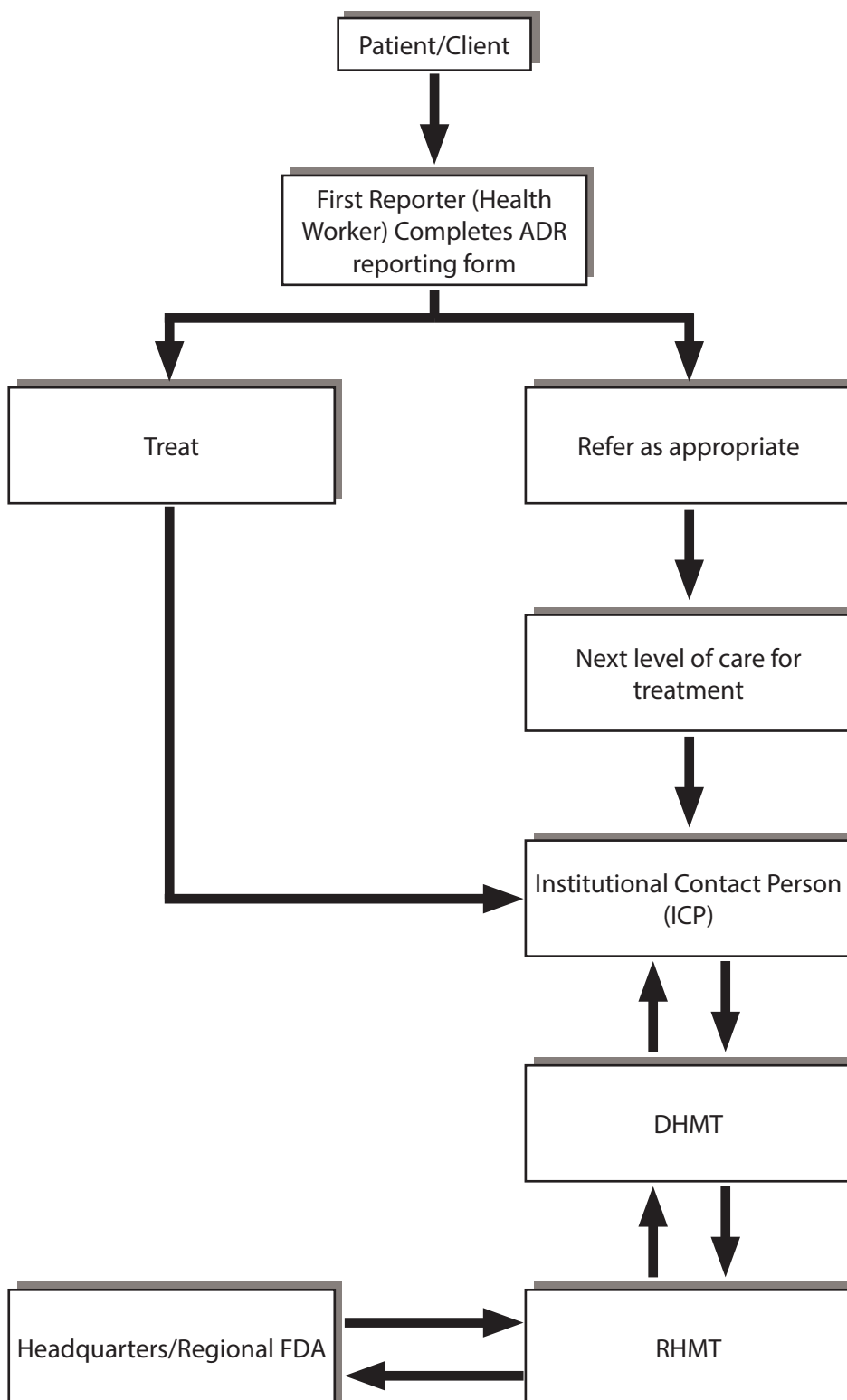


Fig. 2: Adverse Reaction Reporting Form

ADVERSE REACTION REPORTING FORM

(Please complete all sections as much as possible)

(A) PATIENT DETAILS

Age/Date of Birth (dd/mm/yyyy): / / Wt (kg):

Gender: M () F () If female, Pregnant Yes () No () Age of pregnancy.....

Name/Folder Number Telephone No:.....

Hospital/Treatment Centre.....

(B) DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN (Attach a separate sheet and all relevant laboratory tests/data when necessary)

Date reaction started (dd/mm/yyyy): / / Date reaction stopped (dd/mm/yyyy): / /

(C) OUTCOME OF ADVERSE REACTION:

Recovered () Not yet recovered () Unknown ()

Did the adverse reaction result in any untoward medical condition? Yes () No () If yes, Specify.....

SERIOUSNESS: Death () Life threatening () Disability () (specify)..... Hospitalization ()

Others (specify).....

(D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

Brand name	Generic name	Batch Number	Expiry date	Manufacturer
Reasons for use (Indication):		Dosage Regimen:	No. of days given:	Route of Administration:
Date started: (dd/mm/yyyy) / /		Date stopped: (dd/mm/yyyy) / /		
Did the adverse reaction subside when the drug was stopped (de-challenge)? Yes () No ()				
Was the product prescribed? Yes <input type="checkbox"/> No <input type="checkbox"/>		Source of Drug:		
Was product re-used after detection of adverse reaction (re-challenge)? Yes () No ()				
Did adverse reaction re-appear upon re-use? Yes () No ()				

(E) CONCOMITANT DRUGS: INCLUDING COMPLEMENTARY MEDICINES, CONSUMED AT THE SAME TIME AND/OR 3 MONTHS BEFORE

(Attach a separate sheet when necessary)

Name of Drug	Daily dose	Date started	Date stopped/ Ongoing	Reason(s) for use

(F) REPORTER DETAILS

Name of Reporter: Profession.....

Institution's Address:.....

Signature: Tel..... E-mail.....

Date (dd/mm/yyyy) : / /

***Confidentiality:** Identities of the reporter and the patient will remain strictly confidential*

Reporting

Primary reporter refers to any health professional

Institutional contact persons (ICP) are nominated by the hospitals and trained by the National Centre for Pharmacovigilance (NCPv) of the FDA. The ICP sends copies of the report to the DHMT to be forwarded to the RHMT and national level.

How to Report

To report a suspected ADR for drug products marketed in Ghana, health care professionals should complete a copy of the ADR Reporting Form (BlueForm).

All ADR reports should be sent to the nearest health centre; then sent through the DHMT to the RHMT to National Pharmacovigilance Centre, Food and Drugs Authority. Patients and health care professionals can also report directly to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the online BlueForm on the FDA website (www.fdaghana.gov.gh).

When to Report

Reporting of ADRs may be considered as expedited or non-expedited.

An expedited ADR report is an ADR report that falls under serious unexpected and serious expected adverse drug reactions. All expedited ADR reports received from spontaneous reporting should be reported **immediately** and not later than 15 calendar days from date of receipt.

All other reports of ADRs that do not qualify under expedited reporting do not need to be reported on an expedited basis, but should be reported on request or within a period of 28 days.

Reporting Timelines

Reporting of serious adverse events (death, life threatening and prolonged hospitalization) should be reported immediately and not later than 7 calendar days. For non-serious adverse effects, reports could be submitted within a period of 28 days.

All ADR reports should be sent to the nearest Health Centre; to be sent through the DHMT to the RHMT to National Centre for Pharmacovigilance, Food and Drugs Authority.

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ANNEXES

ANNEX A

COMA SCALES

1. THE GLASGOW COMA SCALE (FOR ADULTS AND CHILDREN >5 YEARS)

Type of Response	Response	Score
Eyes open:	Spontaneously	4
	To speech	3
	To pain	2
	Never	1
Best verbal response	Oriented	5
	Confused	4
	Inappropriate words	3
	Incomprehensible sounds	2
	None	1
Best motor response	Obeys command	6
	Localises pain	5
	Withdrawal	4
	Abnormal flexion to pain	3
	Abnormal extension to pain	2
	None	1
Total		3 - 15

To obtain the Glasgow coma score, obtain the score for each section, then add the three figures to obtain a total.

2. BLANTYRE COMA SCALE (FOR CHILDREN)

This score has been modified to be applicable to children, including those who have not learned to speak.

Type of Response	Response	Score
Eye movements	Directed (e.g., Follow mothers face)	1
	Not directed	0
Verbal response	Appropriate cry	2
	Moan or inappropriate cry	1
	None	0
Best motor response	Localizes pain stimulus	2
	Withdraws limb from pain	1
	None specific or absent response	0
Total		0 - 5

To elicit pain during coma evaluation:

- (a) Rub knuckles on patient's sternum.
- (b) Firm pressure on thumb nail with horizontal pencil.

A state of unrousable coma is reached at a score <3. Scoring can be repeated to assess improvement or deterioration.

ANNEX B

REFERRAL FORM

Date

DAY	MONTH	YEAR
-----	-------	------

REFERRING HEALTH FACILITY INFORMATION

NAME OF REFERRING CLINIC/HOSPITAL.....
ADDRESS OF REFERRING CLINIC(INCLUDE TELEPHONE NO).....
TEL. No OF REFFERRING CLINIC.....

PATIENT INFORMATION

SURNAME:.....		OTHER NAMES:.....	
M / F..... GENDER/...../..... DATE OF BIRTH	AGE	INSURANCE INSURED..... STATE ID No.:..... UNINSURED.....
ADDRESS OF CONTACT PERSON / RELATIVE			
TEL. No OF CONTACT PERSON.....			

REFERRAL DETAILS

CLINIC/HOSPITAL REFERRED TO: TIME:					
DIAGNOSIS					
PRESENTING COMPLAINT(S)					
EXAMINATION FINDINGS					
	HEIGHT	WEIGHT	TEMP.	BP	PULSE
RESULTS OF ANY INVESTIGATIONS CARRIED OUT				
TREATMENTS GIVEN				

COMMENTS
REFERRING OFFICER:	
NAME OF OFFICER REFERRING :
POSITION OF OFFICER REFERRING:
SIGNATURE:
RECEIVING CLINICIAN	
NAME OF OFFICER RECEIVING
POSITION OF OFFICER RECEIVING
COMMENTS (PLEASE WRITE SUMMARY OF FINAL DIAGNOSIS AND TREATMENT GIVEN)

<i>SIGNATURE</i>
	DATE...../...../.....

ANNEX C

DIAGNOSTIC PROCEDURES

C. 1 Microscopy

Microscopy is the established method for laboratory diagnosis of malaria. A drop of the patient's blood is collected by finger prick, or from a larger venous blood specimen. It is then spread on a glass slide ("blood smear"), dipped in a reagent that stains the malaria parasites (Giemsa stain), and examined under a microscope at a 1000-fold magnification. Malaria parasites are recognisable by their physical features and by the appearance of the red blood cells that they have infected. These characteristics often allow the laboratory technicians to identify the type (species) of parasite causing the infection, a finding that will guide the treatment. The laboratory technicians or Biomedical Scientist can also assess the percentage of red blood cells that are infected, a measure of severity of the infection.

Microscopy can only be performed by specially trained laboratory technicians and other specially trained health care workers. For microscopy guidelines and Standard Operating Procedures, refer to the Guidelines for Laboratory Diagnosis of Malaria (Ghana Health Service: 2014).

C2. Malaria Rapid Diagnostic Test (mRDT)

Microscopy remains the 'gold standard' for laboratory confirmation of malaria. Rapid Diagnostic Tests (RDTs) are tests based on the qualitative detection of parasite antigen. In the blood, malaria parasites produce chemicals (proteins) called antigens.

There are 3 types of antigens used for malaria diagnosis:

- Histidine-rich protein 2 (HRP2)- *P. falciparum* only
- Plasmodium lactate dehydrogenase (pLDH) - All species
- Aldolase – All species

RDT tests can detect either Pf alone or all species combined. Detection is by use of immunochromatography. RDTs are simple to use and can be carried out by non-laboratory health staff after formal training with supervisory follow up.

RDT test Kits packaging: single use buffer kit or multi use buffer RDT kit

C.2.1 Basic Principles of RDTs

Rapid diagnostic tests are immunochromatographic tests. In other words, they are a combination of (1) a test that uses antibodies with (2) a test that is based on protein migration on a wet film. RDTs are simple to use and can be carried out by non-laboratory health staff after formal training with supervisory follow-up.

RDTs detect specific parasite antigens in blood, mainly Histidine Rich Protein 2 (HRP2) or Plasmodium lactate dehydrogenase (pLDH). Most RDTs in routine use are HRP2-based, which means they detect only *P. falciparum* and cannot be used for follow-up of patients after treatment. RDTs cannot be used to determine parasite density. Some RDTs can achieve sensitivities similar to those commonly achieved by microscopy. It is recommended to use RDTs of sensitivity³ 95% at ³ 100 parasites/μL for *P. falciparum*. (More recent WHO quality control documents suggest ³200 parasites/μL.)

Target antigens

- **Histidine-rich protein 2 (PHRP- 2) of *P. falciparum***
 - A Plasmodium falciparum specific protein
 - Localized in the parasite cytoplasm and on Plasmodium RBC membrane
- **Plasmodium Lactase Dehydrogenase (pLDH) and Aldolase**
 - Are enzymes of the parasite glycolytic pathway
 - Are expressed by all stages of live malaria parasites
 - Are found in all the four human plasmodium species (Pf, Pm, Po, and Pv).
 - Different isomers (amino acid sequences) of pLDH exist for each species

C.2.2 Standard Operating Procedure for RDTs

Staff qualified to perform malaria rapid diagnostic tests (RDTs):

All medical laboratory technical staff and trained staff at all health facility levels are qualified to perform malaria rapid diagnostic tests.

Principle and Purpose:

The test utilises a device coated with monoclonal antibodies against malaria parasite antigens. Blood flows along the device and if malaria parasite antigens are present in the sample, the antigen antibody complex binds with a conjugate forming a coloured line (usually red). To ensure assay validity, a control band is incorporated into the test device.

The purpose of the test is to determine if a person has been recently exposed to malaria infection. Currently, available tests detect the following parasite products: histidine rich protein 2 (HRP2); Plasmodium lactate dehydrogenase (pLDH); aldolase. Tests may not distinguish current from recently treated infection. Some tests are able to distinguish *Plasmodium falciparum* from other malaria species. RDTs are now available as strips or cassettes. The HRP2 test detects trophozoites and young gametocytes, and for this reason can test positive even if the patient received effective treatment. The pLDH is only produced

by trophozoites, and normally will disappear after effective treatment. As a general rule, if treatment failure is suspected, use microscopy for (evaluation) not RDTs.

Contents of the RDT Kit

- Cassettes or Dipsticks
- Buffer (Single or Multi use)
- Inverted cup, loop, pipette or Capillary tube
- Blood Lancet
- Alcohol Swabs
- Instruction Leaflet or Package Insert
- Disposable Gloves (as per manufacturer)

Store in a cool place in the facility (1 - 40°C) or per manufacturer's instructions

Additional requirements are:

- Gauze or cotton wool.
- Sharps box or container.
- Disposal bucket.

Mechanism of RDT action

- Test cassette or dipstick contains a strip with antibodies against the malaria parasite antigen (in the human blood). Buffer lyses the red blood cells to release target antigens and transports it along the length of the strip when introduced. If malaria parasite antigens are present two bands are formed: a control band and a test band. In the absence of malaria parasite antigens, only the control band is formed
- Dye-labeled antibody (Ab), specific for malaria antigen (Ag), is present on the lower end of the nitrocellulose strip or in a well provided with the strip.

- Antibody, also specific for the malaria antigen, is also bound to the strip in a thin (test) line, and antibody specific for the control protein is bound at the control line.
- Blood and buffer, which have been placed in appropriate holes or wells on the cassette, are mixed with the labelled antibody and drawn along the strip across the lines of bound antibody
- If antigen is present, the labelled antibody will be trapped on the test line. Other labelled antibody is trapped on the control line. If sufficient labelled Ab accumulates, the dye label becomes visible to the naked eye as a narrow line.

Sample Required:

Whole blood obtained from a finger prick or anticoagulated venous blood.

mRDT Test Procedure

- Check the expiry date and ensure the test kit seal is not broken
- Assemble all logistics needed for the test
- Perform hand hygiene and put on new gloves
- Label the cassette with patient ID (name or number)
- Disinfect the 4th finger (3rd finger away from thumb) (ring finger) with 70% alcohol swab and **allow to air dry**
- Lance/prick the side of the disinfected finger and wipe off the first drop of blood with dry cotton
- Hold the inverted cup or capillary tube vertically to draw whole blood specimen. (DO NOT scoop blood with inverted cup!!)
- Transfer blood into the sample well marked (S) on the cassette
- Add drops of buffer solution **vertically** into the buffer well as recommended by manufacturer and **start timing**
- Wait and Read results per manufacturer's instructions
- Record and Document appropriately

Note

Customer care: Explain test procedure to client

- Demonstrate the site for pricking (upper later portion of finger. Do not use middle of the finger where bones are lined up. Avoid the thumb)
- Immediately write time after buffer is added

Procedural Note

Follow the storage instructions for each test kit. Some kits require storage in a refrigerator.

Note that kits may deteriorate at high temperatures and at high humidity.

Quality Control

- Ensure kits have not reached the expiry date.
- Ensure packaging and test strips and cassettes are not damaged.
- Ensure the control band appears for both positive and negative tests.

Interpretation

- Two or three RED lines, depending on the type of kit (patient and control windows) = a positive test. 3 lines may mean presence of *P. falciparum* OR mixed infection.
- One RED line (control window only) = a negative test
- No RED line in the control window = invalid test, repeat the test

Reporting Results

- Report as rapid diagnostic test for malaria Positive or Negative. Invalid results should be repeated with a new test kits.
- Indicate date and name of technical staff reporting.

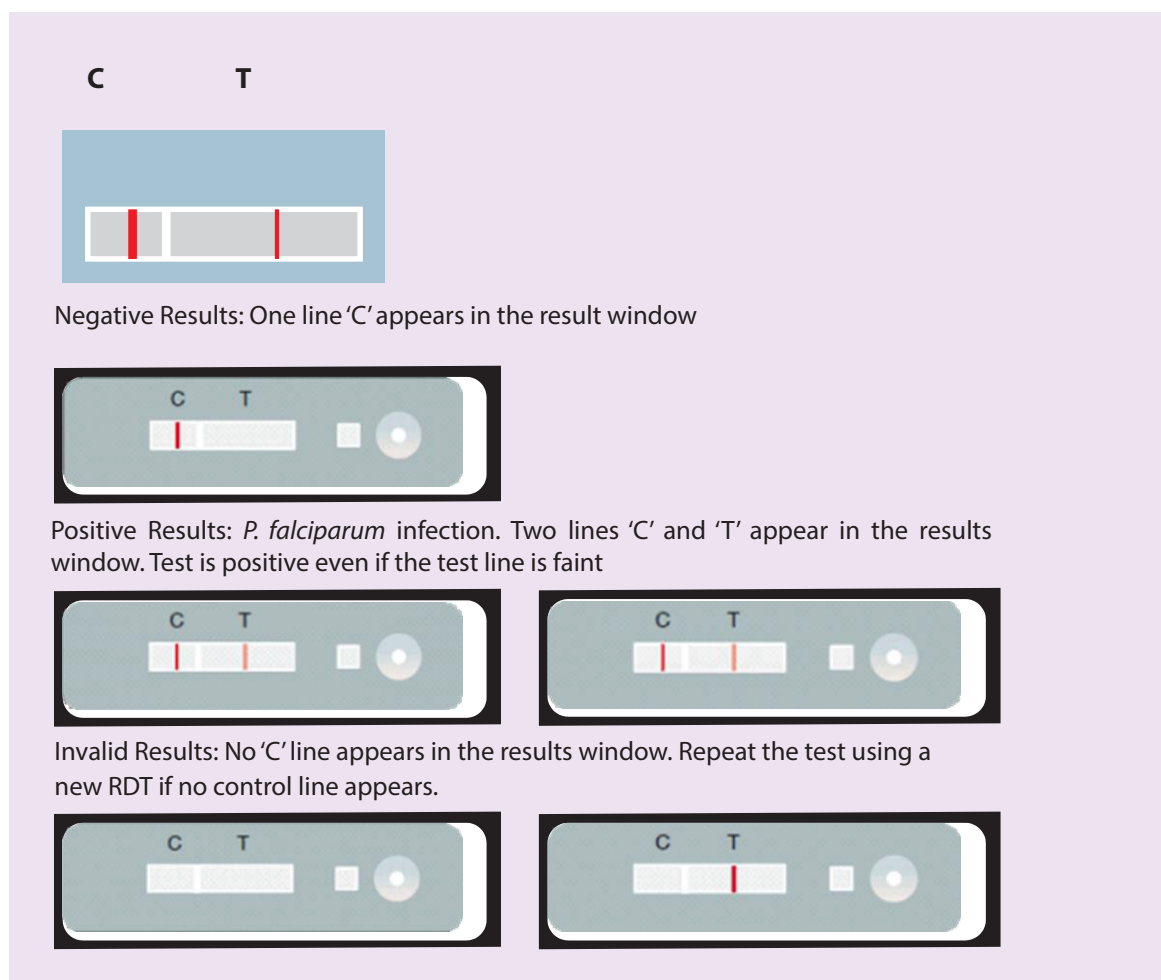
C.2.3 Points to remember when using RDTs

- Prior instruction in the use and interpretation of every product is vital.
- The manufacturer's instructions must be strictly followed.
- Always check the expiry date on the test packet, and discard expired tests.
- The RDT should be discarded if its envelope is punctured or badly damaged.
- The test envelope should be opened only when it has reached ambient temperature (if refrigerated), and the RDT must be used immediately after opening.
- If the procedure is delayed after opening the envelope, humidity can damage the RDT.
- The result should be read within the time specified by the manufacturer.
- Test lines may become "positive" several hours after preparation. Therefore, test results must be read only within the time specified by the manufacturer.
- An RDT cannot be re-used.
- A patient management plan for utilisation of results must be in place.

When used correctly, malaria RDTs can provide a useful guide to the presence of malaria disease caused by the species of parasite they are designed to detect. RDTs can help to guide case management, particularly when good quality microscope-based diagnoses are unavailable.

For a full set of technical guidelines, refer to the Guidelines for Laboratory Diagnosis of Malaria (Ghana Health Service: 2014)

FIGURE C.1

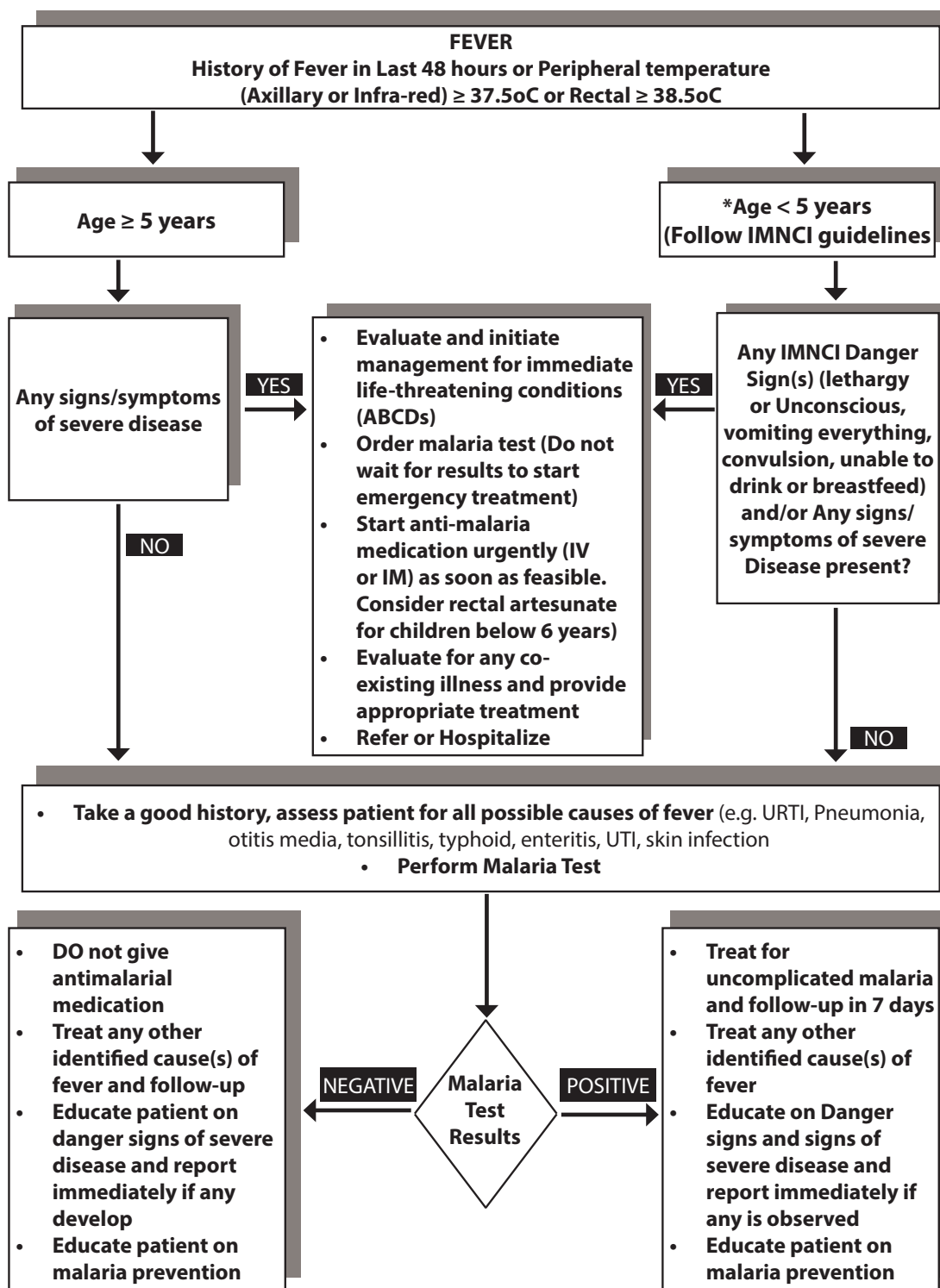


Use new package and lancet for each patient.

ANNEX D

Flow chart for the diagnosis and treatment of malaria

(To be used in all health facilities in Ghana, including private facilities)



ANNEX E

IMCI Case Management Guidelines – For Use In Children Below Five Years

VITAL SIGNS Malaria RDT	(1) Temperature (2) Respiratory Rate (3) Weight (4) MUAC (if >6months of age) Positive or Negative	If any danger sign(s) is(are) present, proceed to assess, classify and offer the recommended emergency treatment & refer to hospital.	
DANGER SIGNS	Not able to drink or breastfeed / vomits everything/history of convulsion or convulsing now/ lethargic or unconscious + other signs of severe/ complicated illness.		
ASSESSMENT (based on main IMCI symptoms)		CLASSIFICATION	TREATMENT
Fever (by history or feels hot or temperature >37.5C)	Any general danger sign or any of the following: (1) Stiff neck, (2) Severe pallor, (3) Deep and fast breathing, (4) Rapid pulse (cold extremities), (5) Dark urine (cola- coloured), (6) Jaundice, (7) Abnormal bleeding.	Severe malaria and/or other severe disease.	Give 1st dose of rectal artesunate or I/M Artesunate or IM Quinine. Give 1st dose of an appropriate antibiotic. Give diazepam if convulsing. Treat the child to prevent low blood sugar. Give one dose of paracetamol for high fever (>38.5°C). Refer URGENTLY to hospital. If referral or access to the nearest health facility is likely to be delayed continue rectal or parenteral artesunate or quinine.
	No general danger signs or above mentioned signs of severe malaria. MALARIA TEST POSITIVE	Uncomplicated malaria	Give oral Artesunate-Amodiaquine Or Artemether-Lumefantrine. Give one dose of paracetamol in clinic for high fever (38.5°C or above). Teach mother how to reduce fever at home. Advise mother when to return immediately. Follow-up in 3 days if fever persists. Give advice on malaria prevention and use of ITN. If on initial assessment fever has been present every day for more than 7 days start treatment for malaria and refer for further assessment.

ASSESSMENT (based on main IMCI symptoms)		CLASSIFICATION	TREATMENT
Fever (by history or feels hot or temperature >37.5C)	No general danger signs or above mentioned signs of severe malaria. MALARIA TEST NEGATIVE	Non malaria febrile illness	Do not give antimalarial drugs. Look for and treat other causes of fever according to IMCI classification and treatment guidelines. Give one dose of paracetamol in clinic for high fever (38.5°C or above). Advise mother when to return immediately. Follow-up in 2days if fever persists. If fever is present every day for >7days, refer for assessment.
	Has measles rash now or had measles within last 3 months and (1) Any general danger sign present or (2) Clouding of cornea or (3) Extensive mouth ulcers.	Severe complicated measles	Give vitamin A. Give first dose of an appropriate antibiotic. If clouding of the cornea or pus draining from the eye, apply tetracycline eye ointment. Refer urgently to hospital.
	Has measles rash now or had measles within last 3 months and has no signs of severe measles but has pus draining from the eye or mouth ulcers.	Measles with eye or mouth complications	Give vitamin A. If pus draining from the eye, treat eye infection with tetracycline eye ointment or chloramphenicol eye ointment. If mouth ulcers treat with gentian violet. Follow-up in 3 days.
	Has measles now or within past 3 months but no signs of severe measles or above mentioned complications	Uncomplicated measles	Give Vitamin A. Give mother one dose to give to the child at home the next day. Advise mother to return in one month for a 3rd dose.

ASSESSMENT (based on main IMCI symptoms)		CLASSIFICATION	TREATMENT
Cough or difficulty in breathing	Any danger sign or chest in-drawing or stridor in calm child.	Severe pneumonia or very severe disease.	Give first dose of an appropriate antibiotic. Refer URGENTLY to hospital**.
	Fast breathing(2-12mths RR>50b/min, 12-60mths RR`>40b/min).	Pneumonia.	Give appropriate antibiotics for 5 days***. If wheezing (that disappeared after rapidly acting bronchodilator) give an inhaled bronchodilator for 5 days****. If chest indrawing in HIV exposed/infect-ed child, give first dose of amoxicillin and refer. Soothe the throat and relieve the cough with a safe remedy. If coughing for more than 14 days or recurrent wheeze, refer for possible TB or asthma assessment. Advise mother when to return immediately. Follow-up in 3 days.
	No signs of very severe disease or pneumonia.	Cough or cold.	If wheezing (that disappeared after rapidly acting bronchodilator) give an inhaled bronchodilator for 5 days****. Soothe the throat and relieve the cough with a safe remedy. If coughing for > 14 days or recurrent wheezing, assess for TB or asthma. Advise mother when to return immediately. Follow-up in 5 days if not improving.
Diarrhoea	Has any two of the following signs: • Weak or unconscious. • Sunken eyes. • Unable to drink or drinking poorly. • Skin pinch goes back very slowly.	Severe dehydration.	If child has no other severe classification give fluid for severe dehydration (Plan C) OR If child also has another severe classification refer URGENTLY to hospital with mother giving frequent sips of ORS on the way. Advise the mother to continue breastfeeding. If child is 2 years or older and there is cholera in your area, give antibiotic for cholera.
	Two of the following signs: • Restless or irritable. • Sunken eyes. • Drinks eagerly, thirsty. • Skin pinch goes back slowly.	Some dehydration.	Give fluid, zinc supplements, and food for some dehydration (Plan B). If child also has a severe classification refer URGENTLY to hospital with mother giving frequent sips of ORS on the way. Advise the mother to continue breast-feeding. Advise mother when to return immediately. Follow-up in 5 days if not improving

ASSESSMENT (based on main IMCI symptoms)		CLASSIFICATION	TREATMENT
Diarrhoea	Signs inadequate to classify severe or some dehydration.	No dehydration.	Give fluid, zinc supplements, and food at home (Plan A). Advise mother when to return immediately. Follow-up in 5 days if not improving.
	Diarrhoea 14 days or more plus has signs of dehydration.	Severe persistent diarrhoea.	Treat dehydration before referring unless child has another severe classification. Refer to hospital
	Diarrhoea 14 days or more but has no signs of dehydration	Persistent diarrhoea.	Advise the mother on feeding a child who has PERSISTENT DIARRHOEA. Give multivitamins and minerals (including zinc) for 14 days. Follow-up in 5 days.
	Blood in the stool	Dysentery.	Give the appropriate antibiotic for 3 days. Follow-up in 3 days.
Malnutrition Look for pedal oedema Review WFH/L: Review MUAC:	Oedema of feet OR WFH/L less than -3 z-scores OR MUAC less than 115 mm AND any one of the following: (1) Medical complication present or (2) Not able to finish RUTF or (3) Breastfeeding	COMPLICATED SEVERE ACUTE MALNUTRITION.	Give first dose appropriate antibiotic. Treat the child to prevent low blood sugar. Keep the child warm. Refer URGENTLY to hospital.
	WFH/L less than -3 z-scores OR MUAC less than 115 mm AND able to finish RUTF.	UNCOMPLICATED SEVERE ACUTE MALNUTRITION.	Give oral antibiotics for 5 days. Give ready-to-use therapeutic food for a child aged 6 months or more. Counsel the mother on how to feed the child. Assess for possible TB infection. Advise mother when to return immediately. Follow up in 7 days.
	WFH/L between -3 and -2 z-scores OR MUAC 115 up to 125 mm.	MODERATE ACUTE MALNUTRITION.	Assess the child's feeding and counsel the mother on the feeding recommendations. If feeding problem, follow up in 7 days. Assess for possible TB infection. Advise mother when to return immediately. Follow-up in 30 days.
	WFH/L - 2 z-scores or more OR MUAC 125 mm or more.	NO ACUTE MALNUTRITION.	If child is less than 2 years old, assess the child's feeding and counsel the mother on feeding according to the feeding recommendations. If feeding problem, follow-up in 7 days.

ASSESSMENT (based on main IMCI symptoms)		CLASSIFICATION	TREATMENT
Anaemia Check palmar pallor. Is it: Severe palmar pallor*? Some palmar pallor	Severe palmar pallor.	SEVERE ANAEMIA.	Refer URGENTLY to hospital.
	Some pallor.	Anaemia	Give iron**. Give mebendazole if child is 1 year or older and has not had a dose in the previous 6 months. Advise mother when to return
	No pallor	NO ANAEMIA.	If child is less than 2 years old, assess the child's feeding and counsel the mother according to the feeding recommendations.

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